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**NOTE**

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Subject:	Proposal for a Regulation of the European Parliament and of the Council on <b><i>in vitro</i> diagnostic medical devices</b>

Delegations will find the text of the draft Regulation on *in vitro* diagnostic medical devices in the Annex to this Note. The text set out in the Annex reflects the preliminary agreement between the Institutions reached on 15 June 2016 and is presented with a view to reaching a political agreement in the Council.

Proposal for a  
**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**on *in vitro* diagnostic medical devices**  
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,  
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,  
Having regard to the proposal from the European Commission,  
After transmission of the draft legislative act to the national Parliaments,  
Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,  
After consulting the Committee of the Regions<sup>2</sup>,  
Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices<sup>3</sup> constitutes the Union regulatory framework for *in vitro* diagnostic medical devices. However, a fundamental revision of that Directive is needed to establish a robust, transparent, predictable and sustainable regulatory framework for devices which ensures a high level of safety and health whilst supporting innovation.

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<sup>1</sup> OJ C [...], [...], p. [...].

<sup>2</sup> The Committee of the Regions decided not to give its opinion.

<sup>3</sup> OJ L 331, 7.12.1998, p.1

- (2) This Regulation aims to ensure the smooth functioning of the internal market as regards *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users and taking into account the small and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for devices to meet common safety concerns as regards those products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of *in vitro* diagnostic medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for those devices by ensuring, among other things, that data generated in clinical performance studies is reliable and robust and that the safety of subjects participating in clinical performance studies is protected.
- (2a) This Regulation does not seek to harmonise rules relating to the further making available on the market of devices after they have already been put into service. e.g. in the context of second-hand sales.
- (3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, risk classification, conformity assessment procedures, performance evaluation and performance studies, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding *in vitro* diagnostic medical devices should be introduced to improve health and safety.

- (4) To the extent possible, guidance developed for *in vitro* diagnostic medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative the International Medical Devices Regulators Forum, should be taken into account to promote the global convergence of regulations which contributes to a high level of safety worldwide and to facilitate trade, in particular in the provisions on Unique Device Identification (UDI), general safety and performance requirements, technical documentation, classification criteria, conformity assessment procedures and clinical evidence.
- (5) There are specific features of *in vitro* diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the *in vitro* diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned.
- (7) The scope of application of this Regulation should be clearly delimited from other legislation concerning products such as medical devices, general laboratory products and products for research use only.
- (8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. In order to ensure consistent qualification across all Member States, particularly with regard to borderline cases, the Commission may, on its own initiative or at a duly substantiated request of a Member State, having consulted the MDCG, decide on a case-by-case basis whether or not a product or groups of products fall within the scope of this Regulation. When deliberating the regulatory status of products in borderline cases involving medicinal products, human tissues and cells, biocidal products or food products, the Commission should ensure an appropriate level of consultation of the EMA, the ECHA and the EFSA, as relevant.

- (8a) It appears that divergent national rules regarding the provision of information and counselling in relation to genetic testing may only have an impact on the smooth functioning of the internal market to a limited extent. Therefore it is appropriate to lay down only limited requirements in this regard in the present regulation, having regard to the need to ensure constant respect of the principles of proportionality and subsidiarity.
- (9) To ensure the highest level of health protection, the rules governing *in vitro* diagnostic medical devices manufactured and used, including measurement and delivery of results, only within a single health institution should be clarified and strengthened.
- (9a) Health institutions should have the possibility of manufacturing, modifying and using *in vitro* diagnostic medical devices in-house, not on an industrial scale, and thereby addressing target patient group specific needs which cannot be met at the appropriate level of performance by an equivalent device available on the market.
- (9b) It is appropriate to provide that certain rules of this Regulation as regards *in vitro* diagnostic medical devices manufactured and used only within health institutions, including hospitals as well as institutions, such as laboratories and public health institutes that support the health care system and/or address patient needs, but may not treat or care for patients directly, should not apply since the aims of this Regulation would still be met in a proportionate manner. It should be noted that the notion of health institution does not cover establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres. As a result, the exemption applicable to health institutions does not apply to those establishments.
- (10) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of an *in vitro* diagnostic medical device, is qualified as an *in vitro* diagnostic medical device, while software for general purposes, even when used in a healthcare setting, or software intended for well-being applications is not qualified as an *in vitro* diagnostic medical device. The qualification of software, either as device or accessory, is independent of its location or type of interconnection between the software and a device.

- (11) It should be made clear that all tests that provide information on the predisposition to a medical condition or a disease (e.g. genetic tests) and tests that provide information to predict treatment response or reactions, such as companion diagnostics, are *in vitro* diagnostic medical devices.
- (11a) Companion diagnostics are essential to define patients' eligibility to specific treatment with a medicinal product through the quantitative or qualitative determination of specific markers identifying subjects at higher risk of developing adverse reaction to the specific medicinal product or identifying patients in the population for whom the therapeutic product has been adequately studied, and found safe and effective. Such biomarker(s) may be present in healthy subjects and/or in patients.
- (11b) Devices that are used with a view to monitoring a treatment with a medicinal product in order to ensure that the concentration of relevant substances in the human body is within the therapeutic window are not considered companion diagnostics.
- (11c) The requirement to reduce risks as far as possible should be fulfilled taking into account the generally acknowledged state of the art.
- (12) Aspects addressed by Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC<sup>4</sup> are an integral part of the general safety and performance requirements for *in vitro* diagnostic medical devices. Consequently, this Regulation should be considered a *lex specialis* in relation to that Directive.

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<sup>4</sup> OJ L 390, 31.12.2004, p. 24

- (13) This Regulation should include requirements regarding the design and manufacture of *in vitro* diagnostic medical devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom<sup>5</sup> which pursues other objectives.
- (13a) This Regulation includes requirements regarding the safety and performance characteristics of in-vitro diagnostic medical devices intended to prevent occupational injuries, including protection from radiation.
- (15) It should be made clear that *in vitro* diagnostic medical devices offered to persons in the Union by means of information society services within the meaning of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations<sup>6</sup> as well as devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union must comply with the requirements of this Regulation when the product is placed on the market or the service is provided in the Union.
- (16) To recognise the important role of standardisation in the field of *in vitro* diagnostic medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 on European standardisation<sup>7</sup> should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.

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<sup>5</sup> OJ L 13, 17.1.2014, p. 1.

<sup>6</sup> OJ L 204, 21.7.1998, p. 37, as amended by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998, OJ L 217, 5.8.1998, p. 18.

<sup>7</sup> OJ L 316, 14.11.2012, p. 12.

- (16a) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices allows the Commission to adopt common technical specifications for specific categories of *in vitro* diagnostic medical devices. In areas where no harmonised standards exist or where they are not sufficient, the Commission should be empowered to lay down specifications which provide a means to comply with general safety and performance requirements and requirements for performance studies and performance evaluation and/or post-market follow-up.
- (16b) Common specifications should be developed after consulting the relevant stakeholders and taking account of the European and international standards.
- (17) The definitions in the field of *in vitro* diagnostic medical devices regarding the device itself, the making available of devices, economic operators, users and specific processes, the conformity assessment, clinical evidence, vigilance and market surveillance, standards and other technical specifications, should be aligned with well-established practice at Union and international level in order to enhance legal certainty.
- (18) The rules applicable to *in vitro* diagnostic medical devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93<sup>8</sup> and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.<sup>9</sup>
- (19) The rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to *in vitro* diagnostic medical devices and their accessories covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.

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<sup>8</sup> OJ L 218, 13.8.2008, p.30.

<sup>9</sup> OJ L 218, 13.8.2008, p. 82.



- (20) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, building on the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the different parts of this Regulation, to enhance understanding of the legal requirements and thus to improve regulatory compliance by the relevant operators.
- (20a) For the purpose of this Regulation, the activities of distributors include acquisition, holding and supply of *in vitro* diagnostic medical devices.
- (20b) Several of the obligations on manufacturers, such as performance evaluation or vigilance reporting, that were set out only in the annexes of Directive 98/79/EC should be incorporated into the enacting provisions of this Regulation to facilitate its application.
- (21) To ensure that *in vitro* diagnostic medical devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of their *in vitro* diagnostic medical devices is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance system in place which should be proportionate to the risk class and the type of the *in vitro* diagnostic medical device. In addition, in order to mitigate risks or prevent incidents related to *in vitro* diagnostic medical devices manufacturers should establish a system for risk management and a system for reporting incidents and field safety corrective actions.
- (21a) The risk management system should be carefully aligned with and reflected in the performance evaluation process for the *in vitro* diagnostic medical device, including the clinical risks to be addressed as part of performance studies, performance evaluation, and post-market performance follow up. Both the risk management and performance evaluation processes should be inter-dependent and should be regularly updated.
- (22) It should be ensured that supervision and control of the manufacture as well as post-market and vigilance activities of *in vitro* diagnostic medical devices is carried out within the manufacturer's organisation by a person responsible for regulatory compliance who fulfils minimum conditions of qualification.

- (23) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the *in-vitro* diagnostic medical devices produced by those manufacturers and in serving as their contact person established in the Union. Given that pivotal role, for the purposes of enforcement it is appropriate to make the authorised representative legally liable for defective *in vitro* diagnostic medical devices in case a manufacturer established outside the Union has not complied with its general obligations. The liability of the authorised representative provided for in this Regulation is without prejudice to the provisions of Council Directive 85/374/EEC [on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products]<sup>10</sup>, and accordingly the authorised representative is jointly and severally liable with the importer and the manufacturer.

The tasks of an authorised representative should be defined in a written mandate. Considering the role of authorised representatives, the minimum requirements to be met by them should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's person responsible for regulatory compliance.

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<sup>10</sup> OJ L 210, 7.8.1985, p. 29.

- (24) To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of an *in vitro* diagnostic medical device.
- (25) Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 of the Treaty on the Functioning of the European Union subject to the limitations set by the protection of health and safety and by the protection of intellectual property rights provided by Article 36 of the Treaty on the Functioning of the European Union. Application of this principle is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging should therefore be specified in this Regulation, taking into account the case-law of the European Court of Justice<sup>11</sup> in other relevant sectors and existing good practices in the field of *in vitro* diagnostic medical devices.
- (25a) In view of the fact that natural or legal persons may claim compensation for damage caused by a defective *in vitro* diagnostic medical device in accordance with applicable Union and national law, it is appropriate to require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC. Those measures should be proportionate to the risk class, type of device and the size of the enterprise.
- In this context it is also appropriate to lay down rules concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

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<sup>11</sup> Judgment of the Court of 28 July 2011 in joined cases C-400/09 and C-207/10.

- (26) *In vitro* diagnostic medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation. However Member States should be allowed to decide whether to restrict the use of any specific type of *in vitro* diagnostic medical device in relation to aspects that are not covered by this Regulation.
- (27) The traceability of *in vitro* diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of *in vitro* diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against falsified devices. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.
- (27a) The UDI system should apply to all *in vitro* diagnostic medical devices placed on the market except devices for performance studies and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the European Unique Device Identification System to become functional in time for the application of this regulation detailed rules should be laid down in this Regulation and in Regulation [reference to the future Regulation on medical devices].
- (28) Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

- (28a) To facilitate the functioning of the European Databank on medical devices (Eudamed), an internationally recognised medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons obliged to use that nomenclature under this Regulation. Furthermore this nomenclature should be provided, where reasonably practicable free of charge, also to other stakeholders.
- (29) One key aspect is the creation of a central database that should integrate different electronic systems to collate and process information regarding *in vitro* diagnostic medical devices on the market and the relevant economic operators, certain aspects of conformity assessment, notified bodies, certificates, performance studies, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) by further developing the databank set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.<sup>12</sup>
- (30) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on performance studies should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and to report serious adverse events, device deficiencies and related updates. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

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<sup>12</sup> OJ L 102, 23.4.2010, p. 45.

- (31) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC<sup>13</sup> of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>14</sup> applies to the processing of personal data carried out in the Member States, under the supervision of the Member States competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001<sup>15</sup> of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data<sup>16</sup>, applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In accordance with Article 2(d) of Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.
- (32) For class C and D *in vitro* diagnostic medical devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the performance evaluation in a document that should be publicly available.
- (32a) The sponsor should submit a summary of results of the performance study, easily understandable to the intended user together with the performance study report, where applicable, within the timelines. Where it is not possible to submit the summary of the results within the defined timelines for scientific reasons, the sponsor should justify this and specify when the results are going to be submitted.

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<sup>13</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

<sup>14</sup> OJ L 281, 23.11.1995, p. 31.

<sup>15</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

<sup>16</sup> OJ L 8, 12.1.2001, p. 1.

- (33) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.
- (33a) The outcome of the notified body assessment of manufacturers' technical documentation, in particular their documentation of performance evaluation and risk management, should be critically evaluated by the national authorities responsible for notified bodies. This evaluation, which is part of the risk based approach to the oversight and monitoring of notified body activities could be based on sampling of the relevant documentation.
- (34) The position of notified bodies vis-à-vis manufacturers should be strengthened, including their right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on *in vitro* diagnostic medical devices to ensure continuous compliance by manufacturers after receipt of the original certification.
- (34a) To increase transparency on the oversight of notified bodies by national authorities, the responsible authorities should publish information on their provisions for designation and monitoring of notified bodies for *in vitro* diagnostic medical devices. In accordance with good administrative practice this information should be kept up to date by the national authority in particular to reflect relevant, significant or substantive changes to the procedures.
- (34aa) The Member State in which a notified body is located should be responsible for enforcing the requirements of this regulation with regard to that notified body.
- (34b) In particular in view of the responsibility of Member States for the organisation and delivery of health services and medical care, Member States may lay down additional requirements on notified bodies designated for conformity assessment of devices based on their territory as concerns issues that are not regulated in this Regulation. That possibility is without prejudice to more specific horizontal EU legislation on notified bodies and equal treatment of notified bodies.

- (35) For class D *in vitro* diagnostic medical devices, competent authorities should be informed about certificates granted by notified bodies and be given the right to scrutinise the assessment conducted by notified bodies.
- (35a) For class D *in-vitro* diagnostic medical devices for which no common specifications exist it is appropriate to provide that in case it is the first certification for that specific type of device for which there is no similar device on the market having the same intended purpose and based on similar technology, expert panels should, in addition to the laboratory testing of the claimed performance and the compliance of the device by reference laboratories, be requested to provide their views on the preliminary assessment conducted by notified bodies on the performance evaluation. Competent authorities should be informed about devices which have been granted a certificate following this conformity assessment procedure. This performance evaluation consultation should lead to a harmonised evaluation of high risk *in vitro* diagnostic medical devices by sharing expertise on performance aspects and elaborating common specifications on categories of devices that have undergone this consultation process.
- (36) To enhance patient safety and to take due account of technological progress, the current classification system for *in vitro* diagnostic medical devices set out in Directive 98/79/EC should be fundamentally changed, in line with international practice, and the corresponding conformity assessment procedures should be accordingly adapted.
- (37) It is necessary, in particular for the purpose of the conformity assessment procedures, to classify *in vitro* diagnostic medical devices into four risk classes and to establish a set of robust risk-based classification rules, in line with international practice.
- (38) The conformity assessment procedure for class A *in vitro* diagnostic medical devices should be carried out, as a general rule, under the sole responsibility of the manufacturers, since such devices pose a low risk to patients. For *in vitro* diagnostic medical devices in classes B, C and D, the involvement of a notified body should be compulsory to the appropriate degree.



- (39) The conformity assessment procedures should be further strengthened and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.
- (39a) It is appropriate that certificates of free sale contain information that makes it possible to use the European databank on medical devices (Eudamed) in order to obtain information on the *in vitro* diagnostic medical device and in particular whether it is on the market, withdrawn from the market or recalled and on any certificate on its conformity.
- (40) It is necessary to clarify the requirements regarding batch release verification for the highest risk *in vitro* diagnostic medical devices.
- (41) European Union reference laboratories should be enabled to verify by laboratory testing the claimed performance and the compliance of such *in vitro* diagnostic medical devices with the applicable common specifications, when such common specifications are available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.
- (42) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements should be based on clinical evidence. It is necessary to clarify the requirements for the demonstration of the clinical evidence, that is based on data on scientific validity, and the analytical performance and clinical performance of the device. To allow for a structured and transparent process, generating reliable and robust data, sourcing and assessment of available scientific information and data generated in performance studies should be based on a performance evaluation plan.
- (42a) As a general rule, clinical evidence should be sourced from performance studies to be carried out under the responsibility of a sponsor who can be the manufacturer or another legal or natural person taking responsibility for the performance study.

- (42c) It is necessary to ensure that the clinical evidence of *in vitro* diagnostic medical devices is updated throughout their lifecycle, this entails the planned monitoring of scientific developments and changes in medical practice by the manufacturer. Relevant new information should then trigger a reassessment of the clinical evidence of the *in vitro* diagnostic medical device thus ensuring safety and performance through a continuous process of performance evaluation.
- (42d) It should be recognized that the concept of clinical benefit for *in vitro* diagnostic medical devices is fundamentally different from that of pharmaceuticals or of therapeutic medical devices as the benefit of *in vitro* diagnostic medical devices lies in providing accurate medical information on patients, where appropriate assessed against medical information obtained through the use of other diagnostic options and technologies, whereas the final clinical outcome for the patient is dependent on further diagnostic and/or therapeutic options which may be available.
- (42e) Where specific *in vitro* diagnostic medical devices have no analytical or clinical performance or specific performance requirements are not applicable, it is appropriate to justify in the performance evaluation plan, and related reports, omissions related to these requirements.
- (43) The rules on performance studies should be in line with major international guidance, such as the international standard on good clinical practice for clinical investigations of medical devices for human subjects to facilitate that the results of performance studies conducted in the Union could be accepted as documentation elsewhere and to facilitate that results of performance studies conducted outside the Union in accordance with international guidelines can be accepted within the Union. In addition the rules should be in line with the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

- (43a) It should be left to the Member State concerned to determine the appropriate body or bodies to be involved in the assessment of the application to conduct a performance study and to organise the involvement of ethics committees within the timelines for the authorisation of that performance study as set out in this Regulation. Such decisions are a matter of internal organisation for each Member State. When determining the appropriate body or bodies, Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available.
- (44) An electronic system should be set up at Union level to ensure that every interventional clinical performance study and other performance study involving risks for the subjects of the studies is recorded and reported in a publicly accessible database. To protect the right to protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union, no personal data of subjects participating in a performance study should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on performance studies on *in vitro* diagnostic medical devices should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

- (45) Where an interventional clinical performance study or another performance study involving risks for the subjects is to be conducted in more than one Member State, Member States should have the possibility to allow the sponsor to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the device for performance study and of the scientific design of the performance study to be conducted in several Member States, such single application should facilitate the voluntary coordination between the Member States under the direction of a coordinating Member State. The coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical performance study, including informed consent.

The Commission, collecting experiences of this voluntary coordination between Member States, should draw up a report and propose a review of the relevant provisions on a coordinated assessment procedure. After seven years the procedure should apply to all Member States concerned by the submission of a single application by the sponsor. In case the findings of the review are negative, the Commission should submit a review to extend the time period.

- (46) Sponsors should report certain adverse events and device deficiencies occurring during interventional clinical performance studies and other performance studies involving risks for the subjects to the Member States concerned. Member States should have the possibility to terminate or suspend these studies if considered necessary to ensure a high level of protection of the subjects enrolled in such studies. Such information should be communicated to the other Member States.
- (47) With exemption of some general requirements, the provisions of this Regulation should only cover performance studies intended to gather scientific data and which pursue regulatory purposes laid down in this Regulation.

- (47aa) It is necessary to clarify that performance studies using left-over specimens need not be authorised. Nevertheless, the general requirements and other additional requirements with regard to data protection and the requirements applicable to procedures that are performed in accordance with national law such as the ethical review should continue to apply to all performance studies, including when using left-over specimens.
- (47b) Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their *in vitro* diagnostic medical devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activities. To this end manufacturers should establish a comprehensive post-market surveillance (PMS) system, set up under the quality management system and based on a PMS plan. Relevant data and information gathered within PMS activities, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentation, such as risk assessment, performance evaluation and should serve the purposes of transparency.
- (47m) The principles of replacement, reduction and refinement in the area of animal experimentation laid down in the Directive 2010/63/EU of the European Parliament and the Council on the protection of animals used for scientific purposes should be observed<sup>17</sup>. In particular, the unnecessary duplication of tests and studies on vertebrates should be avoided.
- (48) In order to better protect health and safety regarding devices on the market, the electronic system on vigilance for *in vitro* diagnostic medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

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<sup>17</sup> OJ L 276, 20.10.2010. p. 33.

- (49) Member States should take appropriate measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents. Healthcare professionals, users and patients should be empowered and enabled to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers and share the information with their peers when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.
- (50) The evaluation of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State with the objective of sharing resources and ensuring consistency regarding the corrective action.
- (50a) The competent authorities should take into account, where appropriate, the information provided by and views of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.
- (51) The reporting of serious adverse events or device deficiencies during interventional clinical performance studies and other performance studies involving risks for the subjects, and the reporting of serious incidents occurring after an *in vitro* diagnostic medical device has been placed on the market should be clearly distinguished to avoid double reporting.
- (52) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.
- (52a) Any statistically significant increase in the number or severity of incidents that are not serious or expected erroneous results that could have a significant impact on the risk-benefit determination and which may lead to unacceptable risks should be reported to the competent authorities in order to permit their assessment and the adoption of appropriate measures.

- (53a) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement.
- (54) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the level and structure of the fees to ensure transparency. In order to ensure transparency the structure and level of fees should be publicly available on request.
- (55) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and *in vitro* diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices<sup>18</sup> to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. The MDCG should be able to establish subgroups in order to provide necessary in-depth technical expertise in the field of medical devices and *in vitro* diagnostic medical devices. When establishing subgroups, appropriate consideration should be given to the possibility to involve existing groups at EU level in the field of medical devices.

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<sup>18</sup> OJ L [...], [...], p. [...].

- (56) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is fundamental for ensuring a uniform high level of health and safety within the internal market, in particular in the areas of performance studies and vigilance. The principle of coordinated exchange and assessment should also apply across other authority activities described in this Regulation, such as notified body designation and should be encouraged in the area of market surveillance of *in vitro* diagnostic medical devices. Joint working, coordination and communication of activities should also lead to more efficient use of resources and expertise at national level.
- (57) The Commission should provide scientific, technical and corresponding logistic support to the coordinating national authority and ensure that the regulatory system for *in vitro* diagnostic medical devices is effectively and uniformly implemented at Union level based on sound scientific evidence.
- (58) The Union and, where appropriate, the Member States should actively participate in international regulatory cooperation in the field of *in vitro* diagnostic medical devices to facilitate the exchange of safety-related information regarding *in vitro* diagnostic medical devices and foster the further development of international regulatory guidelines promoting the adoption of regulations in other jurisdictions with a level of health and safety protection equivalent to that set by this Regulation.
- (59) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.



- (60) It is appropriate to empower the Commission to adopt delegated acts in order to supplement or amend certain non-essential provisions of this Regulation pursuant to Article 290 of the Treaty on the Functioning of the European Union. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016<sup>19</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with preparation of delegated acts.
- (61) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.<sup>20</sup>
- (62) The advisory procedure should be used for the adoption of the form and presentation of the data elements of the manufacturers' summary of safety and performance and of the model for certificates of free sale, given that those acts have a procedural character and do not directly have an impact on health and safety at Union level.
- (63) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures, imperative grounds of urgency so require.

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<sup>19</sup> OJ C [...], [...], p. [...].

<sup>20</sup> OJ L 55, 28.2.2011, p. 13.

- (64) To allow economic operators, especially SMEs, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation and to ensure its proper application, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements to be taken. However, parts of the Regulation that affect directly Member States and the Commission should be implemented as soon as possible. It is particularly important that by the date of application, a sufficient number of notified bodies are designated in accordance with the new requirements to avoid any shortage of *in vitro* diagnostic medical devices on the market.
- (65) In order to ensure a smooth transition to the registration of *in vitro* diagnostic medical devices, of relevant economic operators and of certificates, the obligation to submit the relevant information to the electronic systems put in place by this Regulation at Union level should, in case the corresponding IT systems are developed according to plan, become fully effective only 18 months after the date of application of this Regulation. During this transitional period certain provisions of Directive 98/79/EC should remain in force. However, economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered to be in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directive to avoid multiple registrations.
- (65b) In order to provide for a smooth introduction of the UDI system, the date on which the obligation to place the UDI carrier on the label of an *in vitro* diagnostic medical device should start to apply should moreover vary from one year to five years after the date of application of this Regulation depending upon the class of the *in vitro* diagnostic medical device concerned.
- (66) Directive 98/79/EC should be repealed to ensure that only one set of rules applies to the placing of *in vitro* diagnostic medical devices on the market and the related aspects covered by this Regulation. Also Commission Decision 2010/227/EU adopted in implementation of that Directive and Directives 90/385/EEC and 93/42/EEC should be repealed as from the date when the European databank on medical devices set up pursuant to Regulation (EU) No [future Regulation on Medical Devices] and this Regulation is fully functional.

(66a) The European Data Protection Supervisor has given an opinion<sup>21</sup> pursuant to Article 28(2) of Regulation (EC) No 45/2001.

(67) Since the objective of this Regulation, namely to ensure high standards of quality and safety for *in vitro* diagnostic medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, cannot sufficiently be achieved by the Member States and can, by reason of the scale of the measure, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

HAVE ADOPTED THIS REGULATION:

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<sup>21</sup> OJ L XX, X.Y.20ZZ, p.X.

# Chapter I

## Scope and definitions

### *Article 1*

#### *Scope*

1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices for human use in the Union. This regulation also applies to performance studies on *in vitro* diagnostic medical devices conducted in the Union.
- 1a. For the purposes of this Regulation, *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices shall hereinafter be referred to as 'devices'.
2. This Regulation shall not apply to:
  - (a) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;
  - (b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;
  - (c) internationally certified reference materials;
  - (d) materials used for external quality assessment schemes.

3. Any device which, when placed on the market or put into service incorporates as an integral part a medical device as defined in Article 2 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices shall be governed by that Regulation. The requirements of this regulation shall apply to the *in vitro* diagnostic medical device part.
4. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC.
  - 4a. Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery<sup>22</sup> shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in chapter II of Annex I of this Regulation.
5. This Regulation shall not affect the application of Council Directive 2013/59/Euratom.
  - 5a. This Regulation shall not affect the right of a Member State to restrict the use of any specific type of device in relation to aspects not covered by this Regulation.
6. This Regulation shall not affect national law concerning the organisation, delivery or financing of health services and medical care, such as the requirement that certain *in vitro* diagnostics medical devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or apply certain devices or that their application must be accompanied by specific professional counselling.
  - 6a. Nothing in this Regulation shall restrict the freedom of press or the freedom of expression in the media in so far as those freedoms are guaranteed in the Union and in the Member States, in particular under Article 11 of the Charter.

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<sup>22</sup> OJ L 157, 9.6.2006, p. 24.

## Article 2

### Definitions

For the purposes of this Regulation, the following definitions shall apply:

Definitions related to devices:

- (1) 'medical device' means 'medical device' as defined in Regulation (EU) No [Reference to the future Regulation on medical devices].
- (2) '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:
  - concerning a physiological or pathological process or state;
  - concerning congenital physical or mental impairments;
  - concerning the predisposition to a medical condition or a disease;
  - to determine the safety and compatibility with potential recipients;
  - to predict treatment response or reactions;
  - to define or monitor therapeutic measures.Specimen receptacles are considered to be *in vitro* diagnostic medical devices. For the purposes of this Regulation, 'specimen receptacle' means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.
- (3) 'accessory to an *in vitro* diagnostic medical device' means an article which, whilst not being an *in vitro* diagnostic medical device, is intended by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically enable the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the *in vitro* diagnostic medical device(s) in view of its/their intended purpose(s);

- (4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services;
- (5) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional;
- (6) 'companion diagnostic' means a device which is essential for the safe and effective use of a corresponding medicinal product to:
- identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
  - identify, before and/or during treatment, patients likely to be at increased risk for serious adverse reactions as a result of treatment with the corresponding medicinal product;
- (7) 'generic device group' means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;
- (8) 'single-use device' means a device that is intended to be used during a single procedure;
- (8a) 'falsified device' means any device with a false presentation of its identity, and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights.
- (8aa) 'kit' means a set of components that are packaged together and intended to be used to perform a specific *in vitro* diagnostic examination, or a part thereof;

- (9) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements or as specified by the manufacturer in the performance evaluation;
- (10) 'label' means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;
- (11) 'instructions for use' means the information provided by the manufacturer to inform the user of the device's intended purpose and proper use and of any precautions to be taken;
- (12) 'Unique Device Identification' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

Definitions related to the making available of devices:

- (13) 'making available on the market' means any supply of a device, other than a device for performance study, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (14) 'placing on the market' means the first making available of a device, other than a device for performance study, on the Union market;
- (15) 'putting into service' means the stage at which a device, other than a device for performance study, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;
- (15aa) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;



- (15b) ‘benefit-risk determination’ means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose;
- (15c) ‘compatibility’ is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:
- perform without losing or compromising the ability to perform as intended, and/or
  - integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or
  - be used together without conflict/interference or adverse reaction.
- (15d) ‘interoperability’ is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to
- exchange information and use the information that has been exchanged for correct execution of specified function without changing the content of the data, and/or
  - communicate with each other, and/or
  - work together as intended.

Definitions related to economic operators, users and specific processes:

- (16) ‘manufacturer’ means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark.
- (16a) ‘fully refurbishing’, for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

- (17) ‘authorised representative’ means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the European Union, to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;
- (18) ‘importer’ means any natural or legal person established within the Union who places a device from a third country on the Union market;
- (19) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market, up until the point of putting into service;
- (20) ‘economic operators’ means the manufacturer, the authorised representative, the importer, and the distributor;
- (21) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;
- (22) ‘user’ means any healthcare professional or lay person who uses a device;
- (23) ‘lay person’ means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

Definitions related to conformity assessment:

- (24) ‘conformity assessment’ means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;
- (25) ‘conformity assessment body’ means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

- (26) 'notified body' means a conformity assessment body designated in accordance with this Regulation;
- (27) 'CE marking of conformity' or 'CE marking' means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

Definitions related to clinical evidence:

- (28) 'clinical evidence' means the clinical data and performance evaluation results, pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer;
- (28a) 'clinical benefit of an *in vitro* diagnostic medical device' means the positive impact of a device related to its function (e.g. screening, monitoring, diagnosis or aid to diagnosis of patients) or a positive impact on patient management or public health;
- (29) 'scientific validity of an analyte' means the association of an analyte to a clinical condition or a physiological state;
- (30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting the intended purpose of the device;
- (31) 'analytical performance' means the ability of a device to correctly detect or measure a particular analyte;
- (32) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user;

- (33) 'performance study' means a study undertaken to establish or confirm the analytical or clinical performance of a device;
- (34) 'performance study plan' means a document that describes the rationale, objectives, design methodology, monitoring, statistical considerations, organisation and conduct of the performance study;
- (35) 'performance evaluation' means the assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device;
- (36) 'device for performance study' means a device intended by the manufacturer to be used in a performance study.

A device intended to be used for research purposes, without any medical objective, is not regarded as a device for performance study;

- (37) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;
- (37a) 'subject' means an individual who participates in a performance study whose specimen(s) undergo *in vitro* examination by a device for performance study and/or by a device used for control purposes;
- (37h) 'investigator' means an individual responsible for the conduct of a performance study at a performance study site;
- (38) 'diagnostic specificity' means the ability of a device to recognize the absence of a target marker associated with a particular disease or condition;
- (39) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;

- (40) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;
- (41) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;
- (42) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;
- (43) 'likelihood ratio' means the likelihood that a given result would be expected in an individual with the target clinical condition or physiological state compared to the likelihood that the same result would be expected in an individual without that clinical condition or physiological state;
- (43a) 'calibrator' means a measurement reference used in the calibration of a device;
- (44) 'control material' means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device;
- (45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the performance study;
- (45a) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular performance study after having been informed of all aspects of the performance study that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the performance study;

- (45b) 'Ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;
- (46) 'adverse event' means any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons in the context of a performance study, whether or not related to the device for performance study;
- (47) 'serious adverse event' means any adverse event that led to any of the following:
- a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or in the death of the individual's offspring,
  - death,
  - serious deterioration in the health of the individual being tested or the recipient of tested donations or materials, that resulted in any of the following:
    - (i) life-threatening illness or injury,
    - (ii) permanent impairment of a body structure or a body function,
    - (iii) hospitalisation or prolongation of patient hospitalisation,
    - (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
    - (v) chronic disease,
  - foetal distress, foetal death or a congenital physical or mental impairment or birth defect.
- (48) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of a device for performance study, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;

Definitions related to post-market surveillance, vigilance and market surveillance:

- (48a) ‘post market surveillance’ means all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;
- (48b) ‘market surveillance’ means the activities carried out and measures taken by public authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;
- (49) ‘recall’ means any measure aimed at achieving the return of a device that has already been made available to the end user;
- (50) ‘withdrawal’ means any measure aimed at preventing a device in the supply chain from further being made available on the market;
- (51) ‘incident’ means any malfunction or deterioration in the characteristics or performance of a device made available on the market including use-error due to ergonomic features, any inadequacy in the information supplied by the manufacturer and any harm as a consequence of the medical decision, action taken or not taken on the basis of information or result(s) provided by the device;
- (52) ‘serious incident’ means any incident that directly or indirectly led, might have led or might lead to any of the following:
- death of a patient, user or other person,
  - temporary or permanent serious deterioration of the patient's, user's or other person's state of health,
  - serious public health threat;

- (52a) 'serious public health threat' means any event , which could result in imminent risk of death, serious deterioration in state of health, or serious illness that may require prompt remedial action, and that may cause significant morbidity or mortality in humans or that is unusual or unexpected for the given place and time;
- (53) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation;
- (54) 'field safety corrective action' means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;
- (55) 'field safety notice' means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;

Definitions related to standards and other technical specifications:

- (57) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;
- (58) 'common specifications' (CS) means a document other than a standard that prescribes technical and/or clinical requirements that provide a means to comply with the legal obligations applicable to a device, process or system.



### *Article 3*

#### *Regulatory status of products*

1. At a duly substantiated request of a Member State, the Commission shall, after consulting the MDCG, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of an *in vitro* diagnostic medical device or of an accessory to an *in vitro* diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).
  - 1a. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1.
2. The Commission shall ensure the sharing of expertise between Member States, in the fields of *in vitro* diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.
  - 2a. When deliberating the regulatory status of products involving medicinal products, human tissues and cells, biocides or food products, the Commission shall ensure an appropriate level of consultation of the EMA, the ECHA and the EFSA, as relevant.

## Chapter II

### **Making available and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement**

#### *Article 4*

##### *Placing on the market and putting into service*

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.
2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.
3. Demonstration of conformity with the general safety and performance requirements shall include a performance evaluation in accordance with Article 47.
4. Devices that are manufactured and used within health institutions shall be considered as being put into service.
5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that the following conditions are met:
  - (aa) the device is not transferred to another legal entity,
  - (a) manufacture and use of the device occur under appropriate quality management systems,
  - (b) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation.

- (c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met or cannot be met at the appropriate level of performance by an equivalent device available on the market,
- (d) the health institution provides information upon request on the use of such devices to their competent authority, which shall include a justification of their manufacturing, modification and use;
- (e) the health institution draws up a declaration, that it shall make publicly available, including:
  - the name and address of the manufacturing health institution;
  - the details necessary to identify the devices;
  - a declaration that the devices meet the general safety and performance requirements set out in Annex I of this Regulation and, where applicable, information on which requirements are not fully met with reasoned justification,
- (f) as regards devices classified as class D in accordance with the rules set out in Annex VII, the health institution draws up documentation, allowing an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I of this Regulation are met. Member States may apply this provision also to devices classified as class A, B and C in accordance with the rules set out in Annex VII;
- (g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and
- (h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Member States may require that the health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

These provisions do not apply to devices which are manufactured on an industrial scale.

6. The Commission may adopt implementing acts to ensure the uniform application of Annex I, to the extent necessary to resolve issues of divergent interpretation and practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

#### *Article 4a*

##### *Genetic information, counselling and informed consent*

1. Member States shall ensure that where a genetic test is used on individuals, in the context of healthcare as defined in Article 3(a) of Directive 2011/24/EU<sup>23</sup> and for the medical purpose of diagnostics, improvement of treatments, predictive or prenatal testing, the individual being tested or, where applicable, his or her legally designated representative is provided with relevant information on the nature, the significance and the implications of the genetic test, as appropriate.
2. In the context of the obligations referred to in paragraph 1, Member States shall in particular ensure that there is appropriate access to counselling in the case of the use of genetic tests that provide information on the genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable according to the state of science and technology.
3. Paragraph 2 is not applicable in cases where a diagnosis of a medical condition and/or a disease which the individual being tested is already known to have is confirmed by a genetic test or in cases where a companion diagnostic is used.
4. Nothing in this article shall prevent Member States from adopting or maintaining measures at national level which are more protective of the patient, more specific or which deal with informed consent.

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<sup>23</sup> OJ L 88, 4.4.2011, p. 45.

## *Article 5*

### *Distance sales*

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation.
2. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication, directly or through intermediaries, to a natural or legal person established in the Union shall comply with this Regulation.
3. Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.
4. A Member State may, on grounds of protection of public health, require a provider of information society services as defined in Article 1(2) of Directive 98/34/EC to cease its activity.

## *Article 5a*

### *Claims*

In the labelling, instructions for use, making available, putting into service and advertising of devices, it is prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

- (a) ascribing functions and properties to the product which the product does not have;
- (b) creating a false impression regarding treatment or diagnosis, functions or properties which the product does not have;
- (c) failing to inform of a likely risk associated with the use of the product in line with its intended purpose;
- (d) suggesting uses of the product other than those declared in the intended purpose when the conformity assessment was carried out.

## *Article 6*

### *Use of harmonised standards*

1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

The first subparagraph shall also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance system, performance studies, clinical evidence or post-market performance follow-up.

References in the present regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the Official Journal of the European Union.

2. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, provided references have been published in the Official Journal of the European Union.

## *Article 7*

### *Common specifications*

1. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II, the performance evaluation and post-market performance follow-up set out in Annex XII or the requirements regarding clinical performance studies set out in Annex XIII. The CS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).
2. Devices which are in conformity with the CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CS or parts thereof.
3. Manufacturers shall comply with the CS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.

## *Article 8*

### *General obligations of the manufacturer*

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

- 1a. Manufacturers shall establish, execute, maintain and document a system for risk management as described in Section 1a in Annex I.
- 1c. Manufacturers shall conduct a performance evaluation in accordance with the requirements set out in Article 47 and Annex XII, including post-market performance follow-up.
2. Manufacturers shall draw up and keep up to date the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II and Annex IIa.

3. Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance study, shall draw up an EU declaration of conformity in accordance with Article 15, and affix the CE marking of conformity in accordance with Article 16.
- 3a. Manufacturers shall comply with the obligations related to the UDI system referred to in Article 22 and with the registration obligations referred to in Article 22b and 23a.
4. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any amendments and supplements, issued in accordance with Article 43, available to the competent authorities for a period of at least ten years after the last device covered by the declaration of conformity has been placed on the market.

Upon request by a competent authority, the manufacturer shall provide the full technical documentation or a summary thereof as indicated in the request.



A manufacturer with registered place of business outside the Union shall, in order to allow the authorised representative to fulfil the tasks mentioned in Article 9, paragraph 3 ensure that the authorised representative has the necessary documentation permanently available.

5. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or CS by reference to which conformity of a product is declared shall be adequately taken into account in a timely manner. Proportionate to the risk class and the type of device, manufacturers of devices, other than devices for performance study, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this regulation in the most effective manner.

The quality management system consists of all parts and components of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It is managing the structure, responsibilities, procedures, processes and management resources to implement the needed principles and actions to achieve compliance with the provisions of this regulation.

The quality management system shall address at least the following aspects:

- (aa) a strategy for regulatory compliance, including compliance with conformity assessment procedures and management of modifications to the devices covered by the system;
- (ab) identification of applicable general safety and performance requirements and exploration of options to address these;
  - (a) the responsibility of the management;
  - (b) resource management, including selection and control of suppliers and sub-contractors;
- (ba) risk management according to Section 1a of Annex I;
- (bc) performance evaluation, according to Article 47 and Annex XIII, including post-market performance follow-up;
- (c) product realisation, including planning, design, development, production and service provision;

- (ca) control of the UDI-Code assignments to all relevant devices and ensuring consistency and validity of information provided according to Article 22a and 22b;
- (cb) setting-up, implementation and maintenance of a systematic post-market surveillance system, according to Article 58a;
- (cc) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;
- (cd) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;
- (ce) management of corrective and preventive actions and verification of their effectiveness;
- (d) processes for monitoring and measurement of output, data analysis and product improvement.

6. Proportionate to the risk class and the type of device, manufacturers of devices shall implement and keep up to date the post-market surveillance system referred to in Article 58a.
7. Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 17 of Annex I in (an) official Union language(s) determined by the Member State where the device is made available to the user. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be easily understandable and provided in the official Union language(s) determined by the Member State where the device is made available to the user or patient.

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors and, where applicable, the authorised representative and the importers accordingly.

Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 43, in particular, of the non-compliance and of any corrective action taken.

- 8a. Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Article 59 and 59a.
9. Manufacturers shall, upon request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority where the manufacturer has his registered place of business may require that the manufacturer provide samples of the device free of charge or, where impracticable, grant access to the device. Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may, in order to ensure the protection of public health and patient safety, take all appropriate measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it until he cooperates or provides complete and correct information.

If a competent authority considers or has reason to believe that a device has caused damage, it shall, upon request, facilitate the provision, of the information and documentation referred to in the first sub-paragraph to the potentially injured patient or user and, as appropriate, the patient's or user's successor in title, the patient's or user's health insurance company or other third parties affected by the damage caused to the patient or user, without prejudice to the data protection rules and, unless there is an overriding public interest in disclosure, without prejudice to the protection of intellectual property rights. The competent authority need not comply with this obligation where disclosure of the information referred to in the first sub-paragraph is ordinarily dealt with in the context of legal proceedings.

10. Where manufacturers have their devices designed and manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 23.
11. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.

Proportionate to the risk class, type of device and the size of the enterprise, manufacturers shall have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

#### *Article 9*

##### *Authorised representative*

1. Where the manufacturer of a device is not established in any Member State, the device may only be placed on the Union market if the manufacturer designates a single authorised representative.
2. The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.
3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative. The authorised representative shall provide a copy of the mandate to the competent authority, upon request.

The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:

- (aa) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

- (a) keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);
- (ab) comply with the registration obligations laid down in Article 23a and verify that the manufacturer has complied with the registration obligations laid down in Article 22b;
- (b) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device in an official Union language determined by the Member State concerned;
- (ba) forward to the manufacturer any request by a competent authority where he has his registered place of business for samples, or access to a device and verify that the competent authority receives the samples or gets access to the device;
- (c) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
- (d) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
- (e) terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.

4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (1a), (1b), (2), (3), (3a), (5), (6), (7) and (8).

4a. Without prejudice to paragraph 4, where the manufacturer is not established in any Member State, and has not complied with the obligations laid down in Article 8, the authorised representative shall be legally liable for defective devices on the same basis as, jointly and severally, with the manufacturer.

5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefore.
6. Any reference in this Regulation to the competent authority of the Member State where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.

### *Article 10*

#### *Change of authorised representative*

The modalities of a change of authorised representative shall be clearly defined in an agreement between the manufacturer, where practicable the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects:

- (a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;
- (b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;
- (c) the transfer of documents, including confidentiality aspects and property rights;
- (d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as authorised representative.

## *Article 11*

### *General obligations of importers*

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.
2. In order to place a device on the market importers shall verify the following:
  - (a) that the device has been CE marked and that the declaration of conformity of the device has been drawn up;
  - (b) that a manufacturer is identified and that an authorised representative in accordance with Article 9 has been designated by the manufacturer;
  - (e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;
  - (f) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 22;

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and his authorised representative. Where the importer considers or has reason to believe that the device presents a serious risk or is falsified, he shall also inform the competent authority of the Member State in which he is established.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or on its packaging or in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.
4. Importers shall verify that the device is registered in the electronic system in accordance with Article 22b. Importers shall add their details to the registration according to Article 23a.

5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I and shall comply with the conditions set by the manufacturer, where available.
6. Importers shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.
7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative. Importers shall co-operate with the manufacturer, his authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, withdraw or recall it is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.
8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and his authorised representative.
9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any amendments and supplements, issued in accordance with Article 43.



10. Importers shall cooperate with competent authorities, at their request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request of a competent authority where the importer has his registered place of business, shall provide samples of the device free of charge or, where impracticable, grant access to the device.

## *Article 12*

### *General obligations of distributors*

1. In the context of their activities, when making a device available on the market, distributors shall act with due care in relation to the requirements applicable.
2. Before making a device available on the market distributors shall verify that the following requirements are met:
  - (a) the device has been CE marked and the declaration of conformity of the device has been drawn up;
  - (b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);
  - (c) for imported devices, the importer has complied with the requirements set out in Article 11(3);
  - (d) that, where applicable, a Unique Device Identification has been assigned by the manufacturer.

In order to meet the requirements referred to in subparagraphs (a), (b) and (d) the distributor may apply a sampling method representative of products supplied by that distributor.

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not make the device available on the market until it has been brought into conformity and inform the manufacturer and, where applicable, his authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is falsified, he shall also inform the competent authority of the Member State in which he is established.

3. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.
4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer.  
Distributors shall co-operate with the manufacturer and, where applicable his authorised representative and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, he shall also immediately inform the competent authorities of the Member States in which he made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.
5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, his authorised representative and the importer. They shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.
6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation that is at its disposal and is necessary to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the authorised representative for the device in question, where applicable, provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request of a competent authority, shall provide free samples of the device or, where impracticable, grant access to the device.

## Article 13

### *Person responsible for regulatory compliance*

1. Manufacturers shall have available within their organisation, at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of *in vitro* diagnostic medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:
  - (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices;
  - (b) four years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.
- 1a. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC are not required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.
2. The person responsible for regulatory compliance shall at least be responsible for ensuring the following matters:
  - (a) that the conformity of the devices is appropriately checked in accordance with the quality management system under which these devices are manufactured before a product is released;
  - (b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
  - (ca) that the post-market surveillance obligations in accordance with Article 8(6) are complied with;
  - (c) that the reporting obligations in accordance with Articles 59 to 64 are fulfilled;

(d) in the case of devices for performance studies intended to be used in the context of interventional clinical performance studies or other performance studies involving risks for the subjects, that the statement referred to in point 4.1 of Annex XIII is issued;  
If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1 and 2, their respective areas of responsibility shall be stipulated in writing.

3. The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties, regardless of whether or not he is an employee of the organisation.
4. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for *in vitro* diagnostic medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:
  - (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices;
  - (b) four years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices;

## *Article 14*

### *Cases in which obligations of manufacturers apply to importers, distributors or other persons*

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if he does any of the following:
  - (a) makes available on the market a device under his name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;
  - (b) changes the intended purpose of a device already placed on the market or put into service;
  - (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient.

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:
  - (a) provision, including translation, of the information supplied by the manufacturer in accordance with Section 17 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State;
  - (b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where impracticable, on its packaging or in a document accompanying the device.

He shall ensure that he has in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.

4. At least 28 calendar days prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 calendar days, he shall submit to the competent authority a certificate, issued by a notified body referred to in Article 27, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

## *Article 15*

### *EU declaration of conformity*

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.
2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.
3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.

## *Article 16*

### *CE marking of conformity*

1. Devices, other than devices for performance studies, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex IV.
2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided.
4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.
5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 40. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.
6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.

#### *Article 17*

##### *Devices for special purposes*

1. Member States shall not create any obstacle to devices for performance studies which are supplied for that purpose to laboratories or other institutions, if they meet the conditions laid down in Articles 48 to 58.
2. Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 52.
3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided that a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.



## *Article 19*

### *Parts and components*

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without changing its performance or safety characteristics or its intended purpose, shall ensure that the article does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available to the competent authorities of the Member States.
2. An article that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered as a device and shall meet the requirements laid down in this Regulation.

## *Article 20*

### *Free movement*

Except where otherwise provided in this regulation, Member States shall not refuse, prohibit or restrict the making available or putting into service within their territory of devices which comply with the requirements of this Regulation.

## **Chapter III**

### **Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices**

#### *Article 21*

##### *Identification within the supply chain*

1. Distributors and importers shall co-operate with the manufacturer or authorized representative to achieve an appropriate level of traceability of devices.
2. Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 8(4):
  - (a) any economic operator to whom they have directly supplied a device;
  - (b) any economic operator who has directly supplied them with a device;
  - (c) any health institution or healthcare professional to whom they have directly supplied a device.

#### *Article 21a*

##### *Medical devices nomenclature*

To facilitate the functioning of the European Databank on medical devices (Eudamed) established pursuant to Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices], the Commission shall ensure that an internationally recognised medical devices nomenclature shall be available free of charge to manufacturers and other natural or legal persons required to use that nomenclature for the purpose of this regulation. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

## Article 22

### *Unique Device Identification system*

1. The Unique Device Identification ('UDI') system described in Annex V Part C shall allow the identification and facilitate the traceability of devices, other than devices for performance studies, and shall consist of the following:
  - (a) production of a UDI that comprises the following:
    - (i) a device identifier ('DI') specific to a manufacturer and a device, providing access to the information laid down in Part B of Annex V;
    - (ii) a production identifier ('PI') that identifies the produced device's unit and if applicable the packaged devices as specified in Annex V Part C;
  - (b) application of the UDI on the label of the device or on its package;
  - (c) storage of the UDI by the economic operators, the health institutions and the healthcare professionals, according to the conditions established in paragraphs 5, 5aa and 5a respectively;
  - (d) establishment of an electronic system on UDI (UDI database) according to Article 24a of Regulation (EU) [Ref. of future Regulation on medical devices].
2. The Commission shall designate one or several entities that operate a system for assignment of UDIs pursuant to this Regulation and that satisfy all of the following criteria:
  - (a) the entity is an organisation with legal personality;
  - (b) its system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of this Regulation;
  - (c) its system for the assignment of UDIs conforms to the relevant international standards;
  - (d) the entity gives access to its system for the assignment of UDIs to all interested users according to a set of predetermined and transparent terms and conditions;

- (e) the entity undertakes the following:
  - (i) to operate its system for the assignment of UDIs at least ten years after its designation;
  - (ii) to make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs;
  - (iii) to remain in compliance with the criteria for designation and the terms of designation.

When designating entities, the Commission shall endeavour to ensure that UDI carriers are universally readable regardless of the system used by the assigning entity, with a view to minimising financial and administrative burdens for economic operators and health institutions.

- 3. Before placing a device, other than a custom made device, on the market, the manufacturer shall assign to the device and – if applicable – to all higher levels of packaging a UDI created in compliance with the rules of an entity designated by the Commission in accordance with paragraph 2.
- 4. The UDI carrier shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.
- 4a. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 59.

- 4b. The Basic UDI device identifier ('Basic UDI-DI' as defined in Annex V Part C) of the device shall appear on the EU declaration of conformity referred to in Article 15.
- 4c. The manufacturer shall keep up-to-date a list of all applied UDI as part of the technical documentation referred to in Annex II.
5. Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or they have been supplied with, if they belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.
- 5aa. Member States shall encourage, and may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices which they have been supplied with.
- 5a. Member States shall encourage, and may require, health care professionals to store and keep, preferably by electronic means, the UDI of the devices which they have been supplied with.
7. The Commission may by means of implementing acts specify the modalities and the procedural aspects with a view to ensuring harmonised application of the Unique Device Identification System for any of the following aspects:
- (a) the determination of the devices, categories or groups of devices to which the obligation laid down in paragraph 5 shall apply;
  - (b) the specification of the data to be included in the UDI production identifier ('UDI-PI') of specific devices or device groups;
- Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

- 7a. The Commission shall be empowered to adopt delegated acts in accordance with Article 85:
- (a) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress; and
  - (b) amending or supplementing Annex V in the light of international development and technical progress in the field of unique device identification.
8. When adopting the measures referred to in paragraph 7, the Commission shall take into account the following:
- (a) confidentiality and data protection as referred to in Articles 80 and 81;
  - (c) the risk-based approach;
  - (d) the cost-effectiveness of the measures;
  - (e) the convergence of UDI systems developed at international level;
  - (f) the need to avoid duplications in the UDI system;
  - (g) the needs of the health care systems of the Member States, and where possible, the compatibility with other medical devices' identification systems that are used by stakeholders.

#### *Article 22a*

##### *Electronic system on UDI ('UDI database')*

1. The Commission, after consulting the MDCG shall set up and manage an electronic system on UDI ('UDI database') in accordance with the conditions and modalities established by Article 24a of Regulation (EU) [Ref. of future Regulation on medical devices].
2. Before a device, other than a device for performance study, is placed on the market the manufacturer must ensure that the information referred to in Part B of Annex V of the device in question are correctly submitted and transferred to the UDI database.

## *Article 22b*

### *Process for registration of devices*

1. Before placing a device on the market, the manufacturer shall assign a Basic UDI-DI as defined in Annex V Part C to the device, in compliance with the rules of the designated issuing entities.
2. Where a manufacturer of a device, other than a device for performance study, applies a conformity assessment procedure according to Article 40(3), 40(4) or 40(5), the manufacturer shall submit to the UDI database the Basic UDI-DI and the linked information referred to in Part B of Annex V before placing the device on the market.
3. Where a manufacturer of a device, other than a device for performance study, applies a conformity assessment procedure according to Article 40(2) or 40(3), second sentence, (EU technical documentation assessment and EU type-examination) the manufacturer shall assign the Basic UDI-DI (Annex V Part C) to the device before applying for a conformity assessment procedure by a notified body.

The Notified Body shall reference the Basic UDI-DI on the certificate issued (Annex XI, Chapter I, section 4, point a)) and enter the information referred to in section 2.5 of Part A of Annex V. After the issuing of the relevant certificate and before placing the device on the market the manufacturer shall submit to the UDI database the linked information referred to in Part B of Annex V.

- 3a. Before placing a device on the market, the manufacturer shall submit to the Eudamed database the information referred to in section 2 of part A of annex V, with the exception of its section 2.5, and keep the information updated.

## *Article 23*

### *Electronic system on registration of economic operators*

1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 23a and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.
- 1b. Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available in their territory.
3. Within two weeks after placing a device, on the market, importers shall verify that the manufacturer or authorised representative has uploaded to the electronic system the information referred to in paragraph 1.

Where applicable, importers shall inform the relevant authorised representative or manufacturer if the information is not included or is incorrect. The importer shall add their details to the relevant entry/entries.



### *Article 23a*

#### *Process for registration of manufacturers, authorised representatives and importers, single registration number*

1. Manufacturers, authorised representatives and importers, who have not been registered before according to this article shall submit to the electronic system the information referred to in Annex V, Part A, Section 1, before placing a device on the market. In cases where the conformity assessment procedure requires the involvement of a notified body the information referred to in Annex V, Part A, Section 1 shall be submitted to the electronic system before applying to a notified body.
2. After having verified the data entered pursuant to paragraph 1, the competent authority shall procure from the electronic system referred to in Article 23 a single registration number ('SRN') and issue it to the manufacturer, the authorised representative or the importer.
3. The manufacturer shall use the single registration number when applying to a notified body for certification according to Article 41 and for entering the electronic system on UDI (in order to fulfil their obligations according to Article 22a(2) and Article 22b(2), (3) and (3a).
4. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.
5. Not later than one year after submission of the information in accordance with paragraph 1, and then every second year thereafter, the relevant economic operator shall confirm the accuracy of the data. Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in Section 1 of Part A of Annex V. In the event of failure to confirm within six months of the due date, any Member State may take appropriate corrective measures within its territory until the obligation referred to in this paragraph is complied with.
6. The data contained in the electronic system shall be accessible to the public.

- 7a. The competent authority may use the data to administer a fee to the manufacturer, the authorised representative or the importer pursuant to Article 82.

#### *Article 24*

##### *Summary of safety and performance*

1. In the case of devices classified as class C and D, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance.

It shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.

The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 40 and shall be validated by that body. After validation the notified body shall upload this summary report to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary report is available.

- 1a. The summary of safety and clinical performance shall include at least the following aspects:
- (a) the identification of the device and the manufacturer, including the basic UDI-DI and the single registration number;
  - (b) the intended purpose of the device, including indications, contra-indications and target populations;
  - (c) a description of the device, including a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other *in vitro* diagnostic medical devices and other products that are not *in vitro* diagnostic medical devices, which are intended to be used in combination with the device;
  - (d) reference to harmonised standards and common specifications;
  - (e) the summary of performance evaluation report as referred to in annex XII, and relevant information on the post-market performance follow-up (PMPF);
  - (f) the metrological traceability of assigned values;

- (g) suggested profile and training for users;
- (h) information on any residual risks and any undesirable effects, warnings and precautions.

2. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

### *Article 25*

#### *European databank on medical devices*

The Commission, after consulting the MDCG, shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Articles 27 and 27a of Regulation (EU) [Ref. of future Regulation on medical devices].

Eudamed shall include the following:

- (aa) the electronic system on registration of devices referred to in Article 22b;
- (a) the electronic system on UDI referred to in Article 22a;
- (b) the electronic system on registration of economic operators referred to in Article 23;
- (ba) the electronic system on notified bodies and on certificates referred to in Article 43a;
- (d) the electronic system on performance studies set up in Article 51,
- (e) the electronic system on vigilance and post-market surveillance referred to in Article 64a;
- (f) the electronic system on market surveillance referred to in Article 73b.

## **Chapter IV**

### **Notified Bodies**

#### *Article 26*

##### *National authorities responsible for notified bodies for in vitro diagnostic medical devices*

1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation shall nominate an authority, which may consist of separate constituent entities under national law, that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies, hereinafter referred to as the ‘national authority responsible for notified bodies’.
2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.
3. The national authority responsible for notified bodies shall be organised so that each decision relating to designation or notification is taken by personnel different from those who carried out the assessment.
4. The national authority responsible for notified bodies shall not perform any activities that notified bodies perform on a commercial or competitive basis.
5. The national authority responsible for notified bodies shall safeguard the confidential aspects of the information it obtains. However, it shall exchange information on a notified body with other Member States, the Commission and, when required, with other regulatory authorities.

6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel permanently available for the proper performance of its tasks.

Where the national authority responsible for notified bodies is a different authority than the national competent authority for *in vitro* diagnostic medical devices, it shall ensure that the authority responsible for *in vitro* diagnostic medical devices is consulted on relevant aspects.

7. Member States shall make publicly available general information on their provisions on the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and on changes which have a significant impact on these tasks.
8. The national authority responsible for notified bodies shall participate in peer-review activities laid down in Article 36.

## *Article 27*

### *Requirements relating to notified bodies*

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary so they are qualified to fulfil their tasks for which they are designated in accordance with this Regulation. The requirements to be met by notified bodies are set out in Annex VI.

In order to meet these requirements, notified bodies shall have permanent availability of sufficient administrative, technical and scientific personnel in accordance with Annex VI, Section 3.1.1 and personnel with relevant clinical expertise in accordance with Annex VI, Section 3.2.4, where possible employed by the notified body itself.

The personnel referred to in Annex VI, Sections 3.2.3 and 3.2.7 shall be employed by the notified body itself and shall not be external experts or be subcontractors.

- 1a. Notified bodies shall make available and submit upon request, all relevant documentation, including the manufacturer's documentation to the national authority responsible for notified bodies to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined within this Chapter.
2. In order to ensure the uniform application of the requirements set out in Annex VI, to the extent necessary to resolve issues of divergent interpretation and practical application, the Commission may adopt implementing acts in accordance with Article 84(3).

## *Article 28*

### *Subsidiaries and subcontracting*

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the applicable requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.
2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.
- 2a. The notified body shall make publicly available a list of its subsidiaries.
3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only provided that the legal or natural person that applied for conformity assessment has been informed of this.
4. Notified bodies shall keep at the disposal of the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

## *Article 29*

### *Application by a conformity assessment body for designation*

1. A conformity assessment body shall submit an application for designation to the national authority responsible for notified bodies of the Member State in which it is established.
2. The application shall specify the conformity assessment activities as defined in this Regulation, and the types of devices for which the body applies to be designated, supported by documentation proving compliance with all the requirements set out in Annex VI.

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 may be submitted in support of these requirements and shall be taken into consideration during the assessment described in Article 30. However, the applicant shall make available the full documentation to demonstrate conformity with these requirements upon request.

3. After being designated, the notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.

## *Article 30*

### *Assessment of the application*

1. The national authority responsible for notified bodies shall within 30 days check that the application referred to in Article 29 is complete and shall request the applicant to provide any missing information. Once the application is complete the national authority shall send it to the Commission.

The national authority shall review the application and supporting documentation in accordance with its own procedures and shall draw up a preliminary assessment report.

2. The national authority responsible for notified bodies shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the Medical Device Coordination Group established by Article 78 of Regulation [Ref. of future Regulation on medical devices] ('MDCG').
3. Within 14 days of the submission referred to in paragraph 2, the Commission, in conjunction with the MDCG, shall assign a joint assessment team made up of three experts, unless the specific circumstances require another number of experts, chosen from the list referred to in Article 30a. One of these experts shall be a representative of the Commission who shall coordinate the activities of the joint assessment team. The other two experts shall come from different Member States other than the one in which the applicant conformity assessment body is established.
- 3a. The joint assessment team shall be comprised of competent experts which reflect the conformity assessment activities and the types of devices which are subject to the application or, in particular when this procedure is initiated in accordance with Article 35 to ensure that the specific concern can be appropriately assessed.
4. Within 90 days after assignment of the joint assessment team, shall review the documentation submitted with the application in accordance with Article 29. The joint assessment team may provide feedback to or require clarification from the national authority responsible for notified bodies on the application and on the planned on-site assessment.

The national authority responsible for notified bodies together with the joint assessment team shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process.

The on-site assessment of the applicant body shall be led by the national authority responsible for notified bodies.



- 4a. Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team with a view to finding common agreement and resolution of any diverging opinions, with respect to the assessment of the application.

A list of non-compliances resulting from the assessment shall be presented by the national authority responsible for notified bodies to the applicant body at the end of the on-site assessment including a summary of the assessment delivered by the joint assessment team.

Within a specified timeframe, the applicant body shall submit to the national authority a corrective and preventive action plan to address the non-compliances.

- 4aa. The joint assessment team shall document any remaining diverging opinions with respect to the assessment within 30 days of completion of the on-site assessment and send these to the national authority responsible for notified bodies.
- 4b. The national authority responsible for notified bodies shall, following receipt of a corrective and preventive action plan from the applicant body, assess whether non-compliances identified during the assessment have been appropriately addressed. This plan shall include an indication of the root cause of the finding and a timeframe for implementation of the actions therein.

The national authority shall, having confirmed the corrective and preventive action plan, forward this plan and its opinion on this plan to the joint assessment team. The joint assessment team may request further clarification and modifications from the national authority responsible for notified bodies.

The national authority responsible for notified bodies shall draw up its final assessment report which shall include:

- the result of the assessment,
- confirmation that the corrective and preventive actions have been appropriately addressed and, where required, implemented,
- any remaining diverging opinion with the joint assessment team, and, where applicable,
- the recommended scope of designation.

5. The national authority responsible for notified bodies shall submit its final assessment report and, if applicable, the draft designation to the Commission, the MDCG and the joint assessment team.
6. The joint assessment team shall provide a final opinion regarding the assessment report prepared by the national authority responsible for notified bodies and, if applicable, the draft designation within 21 days of receipt of those documents to the Commission, which shall immediately submit this opinion to the MDCG. Within 42 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft designation which the national authority responsible for notified bodies shall duly take into consideration for its decision on the designation of the notified body.
7. The Commission may, by means of implementing acts, adopt measures setting out the modalities specifying procedures and reports for the application for designation referred to in Article 29 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

### *Article 30a*

#### *Nomination of experts for joint assessment of applications for notification*

1. The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of *in vitro* diagnostic medical devices to participate in the activities outlined in Article 30 and Article 36.
2. The Commission shall maintain a list of the experts nominated pursuant to paragraph 1, together with information on their specific competence and expertise. This list shall be made available to Member States competent authorities through the electronic system referred to in Article 43a.

### *Article 30b*

#### *Language requirements*

All documents required pursuant to Articles 29 and 30 shall be drawn up in a language or languages which shall be determined by the Member State concerned.

Member States, in applying the first sub-paragraph, shall consider accepting and using a commonly understood language in the medical field, for all or part of the documents concerned.

The Commission shall provide necessary translations of the documentation pursuant to Article 29 and 30, or parts thereof into an official Union language such that the documents can be readily understood by the joint assessment team assigned in accordance with Article 30(3).

## Article 31

### *Designation and notification procedure*

0. Member States may only designate conformity assessment bodies for which the assessment pursuant to Article 30 was completed and which satisfy the requirements set out in Annex VI.
1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the database of notified bodies developed and managed by the Commission.
4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities as defined in this Regulation, and the type of devices which the notified body is authorised to assess and, without prejudice to Article 33, any conditions associated with the designation.
- 4a. The Commission shall within six months of the entry into force of this Regulation, by means of implementing acts, draw up a list of codes and corresponding types of devices to describe the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). The Commission, after consulting the MDCG, may update this list *inter alia* based on information arising from the coordination activities described in Article 36.
5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the final opinion of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.
6. The notifying Member State shall, without prejudice to Article 33, inform the Commission and the other Member States of any conditions associated with the designation and provide documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI.

7. Within 28 days of a notification, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.
8. When a Member State or the Commission raises objections in accordance with paragraph 7, the Commission shall bring the matter before the MDCG within 10 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 40 days after the matter has been brought before it.
- 8a. Where the MDCG, after having been consulted in accordance with paragraph 8, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.
9. Where no objection is raised in accordance with paragraph 7 or where the MDCG, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted, or where the notifying Member State, having given its reasons for doing so in accordance with paragraph 8a, decides to notify the designation of the conformity assessment body, the Commission shall publish the notification within 14 days of receipt.

When publishing the notification in the database of notified bodies developed and managed by the Commission, the Commission shall add the information relating to the notification of the notified body to the electronic system referred to in Article 43a along with the documents mentioned in paragraph 5 and the opinion and response referred to in paragraphs 8 and 8a of this Article.

10. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.

11. The conformity assessment body concerned may perform the activities of a notified body only after the notification has become valid in accordance with paragraph 10.

### *Article 32*

#### *Identification number and list of notified bodies*

1. The Commission shall assign an identification number to each notified body for which the notification becomes valid in accordance with Article 31(10). It shall assign a single identification number even when the body is notified under several Union acts. If they are successfully designated in accordance with this regulation, bodies notified pursuant to Directive 98/79/EC shall retain the identification number assigned to them pursuant to that directive.
2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the conformity assessment activities as defined in this Regulation and the types of devices for which they have been notified, accessible to the public in the database of notified bodies developed and managed by the Commission. It shall also make this list available on the electronic system referred to in Article 43a. The Commission shall ensure that the list is kept up to date.

### *Article 33*

#### *Monitoring and assessment of notified bodies*

0. Notified bodies shall, without delay, and at the latest within 15 days, inform the national authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.

1. The national authority responsible for notified bodies shall monitor the notified bodies based on its territory and of their subsidiaries and subcontractors to ensure ongoing compliance with the requirements and the fulfilment of its obligations set out in this Regulation. The notified bodies shall, on request from the national authority responsible for notified bodies, supply all relevant information and documents, required to enable the authority, the Commission and other Member States to verify compliance with this Regulation.
2. The national authority responsible for notified bodies shall receive a copy of all requests submitted by the Commission or by another Member State authority to notified bodies on its territory relating to conformity assessments such notified bodies have carried out. Notified bodies shall respond without delay and within 15 days at the latest, to such requests. The national authority responsible for notified bodies of the Member State in which the body is established shall ensure that requests submitted by authorities of any other Member State or by the Commission are resolved unless there is a legitimate reason for not doing so in which case the matter may be referred to the MDCG.
3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body and, when appropriate, the subsidiaries and subcontractors under its responsibility still satisfy the requirements and fulfil their obligations set out in Annex VI. This review shall include an on-site audit of to each notified body and, when necessary, of its subsidiaries and subcontractors.

The national authority responsible for notified bodies shall conduct its monitoring and assessment activities according to an annual assessment plan to ensure that it can effectively monitor the continued compliance of the notified body with the requirements of this Regulation. This plan shall provide a reasoned schedule for the frequency of assessment of the notified body and associated subsidiaries and subcontractors. The authority shall submit its annual plan for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission.

- 3a. The monitoring of notified bodies by the national authority responsible for notified bodies shall include witnessed audits of the notified body personnel, including when necessary the personnel from subsidiaries and subcontractors, when conducting quality system assessments at a manufacturer's facility.
- 3b. The monitoring of notified bodies conducted by national authorities responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance systems to help guide its activities.

The national authority responsible for notified bodies shall provide for a systematic follow-up of complaints and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice.

- 3ca. The national authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or 'for-cause' reviews if needed to address a particular issue or to verify compliance.
- 3c. The national authority responsible for notified bodies shall assess the notified body assessments of manufacturers' technical and clinical documentation as further outlined in Article 33a.
- 3d. The national authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VI and shall monitor the timely implementation of corrective and preventive actions.
- 4. Three years after notification of a notified body, and again every fourth year thereafter, a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 29 and 30.



- 4a. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in order to modify the frequency of complete re-assessment referred to in paragraph 4.
5. The Member States shall report to the Commission and to the MDCG, at least once a year, on their monitoring activities regarding their notified bodies and, where applicable, subsidiaries and subcontractors. This report shall provide details of the outcome of the monitoring and surveillance activities, including activities pursuant to paragraph 3ca. This report shall be treated as confidential by the MDCG and the Commission however it shall contain a summary which shall be made publicly available.

The summary of the report shall be uploaded to the European databank referred to in Article 43a.

#### *Article 33a*

##### *Review of notified body assessment of technical documentation and performance evaluation documentation*

1. The national authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies shall assess an appropriate number of notified body assessments of manufacturers' technical documentation and performance evaluations to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. These assessments shall be conducted both off-site and during on-site assessments.
2. The sample of files assessed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified body and in particular high risk devices, appropriately justified and documented in a sampling plan, which shall be available from the national authority responsible for notified bodies upon request of the MDCG.

3. The national authority responsible for notified bodies shall assess whether the assessment by the notified body was conducted appropriately and verify the procedures used, associated documentation and conclusions drawn by the notified body. This shall include the manufacturer's technical documentation and performance evaluation upon which the notified body has based its assessment. These assessments shall be conducted utilising common specifications provided for in Article 7 in the conduct of the assessment.
4. The assessments shall also form part of the re-assessment of notified bodies in accordance with Article 33(4) and the joint assessment activities referred to in Article 35(2a). These assessment shall be conducted utilising appropriate expertise.
5. The MDCG may, based on the reports of these assessments by the national authority responsible for notified bodies or joint assessment teams, and inputs from the market surveillance, vigilance and post-market surveillance activities described in Chapter VII, or on the continuous monitoring of the technical progress, the identification of concerns and emerging issues on the safety and performance of devices, recommend that the sampling, either by the national authority responsible for notified bodies or as part of a joint assessment activity, shall cover a greater or lesser proportion of the performance evaluations and technical documentation assessed by a notified body.
6. The Commission may, by means of implementing acts, adopt measures setting out the modalities, associated documents for and coordination of the technical and clinical assessments referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

## *Article 34*

### *Changes to designations and notifications*

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the designation by the national authority responsible for notified bodies. The procedures described in Article 30(2) to (6) and in Article 31 shall apply to changes where they entail an extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the database of notified bodies referred to in Article 31(10).
- 1a. Where a notified body decides to cease its conformity assessment activities it shall inform the national authority responsible for notified bodies and the manufacturers concerned as soon as possible and in case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of activities on condition that another notified body has confirmed in writing that it will assume responsibilities for these products. The new notified body shall complete a full assessment of the devices affected by the end of that time period before issuing new certificates for those devices.
2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations or has not implemented the necessary corrective measures, the authority shall suspend, restrict, or fully or partially withdraw the designation, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the designation.

The national authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a designation.

- 2a. Where the designation of a notified body has been suspended, restricted, or fully or partially withdrawn, it shall inform the manufacturers concerned at the latest within 10 days.
3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are kept available for the national authorities responsible for notified bodies and national authorities responsible for market surveillance at their request.
4. The national authority responsible for notified bodies shall:
- assess the impact on the certificates issued by the notified body where there is a change to the designation;
  - submit a report on its findings to the Commission and the other Member States within three months after having notified the changes to the designation;
  - require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued to ensure the safety of devices on the market;
  - enter into the electronic system mentioned in Article 43(4) all certificates for which it has required suspension or withdrawal;
  - inform the competent authority for *in vitro* diagnostic medical devices of the Member State where the manufacturer or his authorised representative has his registered place of business through the electronic system referred to in Article 43a of the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others.

5. With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in the following circumstances:

- (a) the national authority responsible for notified bodies has confirmed, within one month of the suspension or restriction, that there is no safety issue for certificates affected by the suspension or restriction and the national authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction.

or:

- (b) The national authority responsible for notified bodies has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension/restriction, and indicates whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In case the national authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the manufacturer shall provide to the competent authority for devices within three months of the suspension or restriction the written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.

- 5a. With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:
- Where the competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer or the authorised representative of the device covered by the certificate is established has confirmed that there is no safety issue associated with the devices in question, and
  - another notified body has confirmed in writing that it will assume immediate responsibilities for these products and will have completed assessment of the devices within twelve months from the withdrawal of the designation.

Under those circumstances, the national competent authority of the member state where the manufacturer or the authorised representative is established may extend the provisional validity of the certificates for further periods of three months, which altogether may not exceed twelve months.

The authority or the notified body assuming the functions of the notified body affected by the change of designation shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

The Commission shall immediately enter information on the changes to the designation of the notified body into the electronic system referred to in the second subparagraph of Article 43a.

### *Article 35*

#### *Challenge to the competence of notified bodies*

1. The Commission, in conjunction with the MDCG, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in Annex VI or the obligations to which it is subject. It shall ensure that the concerned national authority responsible for notified bodies is informed and is given opportunity to investigate these concerns.

2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.
- 2a. The Commission, in conjunction with the MDCG, may initiate, as applicable, the assessment process described in Article 30(3) and (4) when there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VI and the investigation of the national authority is not deemed to have fully addressed the concerns or upon request of the national authority. The reporting and outcome of this assessment process shall follow the principles of Article 30. Alternatively, depending on the severity of the issue, the Commission in conjunction with the MDCG may request that the national authority responsible for notified bodies allow for participation of up to two experts from the list established pursuant to Article 30a in an on-site assessment as part of the planned monitoring and surveillance activities in accordance with Article 33 and as outlined in the annual plan described in paragraph 3 therein.
3. Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the designation if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.

- 3a. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

## *Article 36*

### *Peer review and exchange of experience between national authorities responsible for notified bodies*

1. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation. This shall address elements including:
  - (a) Development of best practice documents relating to the activities of the national authority responsible for notified bodies;
  - (b) Development of guidance documents for notified bodies in relation to the implementation of this Regulation;
  - (c) Training and qualification of the experts referred to in Article 30a.
  - (d) Monitoring of trends relating to changes to notified body designations and notifications and trends in certificate withdrawals and transfers between notified bodies;
  - (e) Monitoring of the application and applicability of scope codes referred to in Article 31(4a);
  - (f) Development of a mechanism for peer review between authorities and the Commission;
  - (g) Methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies for in vitro diagnostic medical devices.
2. The national authorities responsible for notified bodies shall participate in a peer review every third year through the mechanism developed pursuant to Article 36(1). These reviews shall normally be conducted during on-site joint assessments described in Article 30 but alternatively on a voluntary basis may take place as part of the national authority's monitoring activities in Article 33.
3. The Commission shall participate in the organisation and provide support to the implementation of the peer review mechanism.
- 3a. The Commission shall compile an annual summary report of the peer review activities which shall be made publicly available.



4. The Commission may, by means of implementing acts, adopt measures setting out the modalities and associated documents for the peer review, training and qualification mechanisms referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

#### *Article 37*

##### *Coordination of notified bodies*

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices].

The bodies notified under this Regulation shall participate in the work of that group.

#### *Article 38a*

##### *List of standard fees*

Notified bodies shall make the lists of standard fees for the conformity assessment activities publicly available.

# **Chapter V**

## **Classification and conformity assessment**

### **Section 1 – Classification**

#### *Article 39*

##### *Classification of in vitro diagnostic medical devices*

1. Devices shall be divided into classes A, B, C and D, taking into account the purpose intended by the manufacturer and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.
2. Any dispute between the manufacturer and the notified body concerned, arising from the application of the classification criteria, shall be referred for a decision to the competent authority of the Member State where the manufacturer has his registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State where the authorised representative referred to in the last indent of point (b) of Section 3.2. of Annex VIII has his registered place of business. Where the notified body concerned is located in a different Member State than the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

The competent authority of the manufacturer shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

3. At a request of a Member State the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:
  - (a) application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification;
  - (b) that a device, or category or group of devices shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities by way of derogation from the classification criteria set out in Annex VII, be reclassified.
- 3a. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 3, points (a) and (b).
- 3b. The implementing acts referred to in paragraphs 3 and 3a shall be adopted in accordance with the examination procedure referred to in Article 84(3).
4. In order to ensure the uniform application of the classification criteria set out in Annex VII, and taking account of the relevant scientific opinions of the relevant scientific committees, the Commission may adopt implementing acts in accordance with Article 84(3), to the extent necessary to resolve issues of divergent interpretation and practical application.

## **Section 2 – Conformity assessment**

### *Article 40*

#### *Conformity assessment procedures*

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to X.

- 1a. Prior to putting into service devices that are not placed on the market, with the exception of in-house devices manufactured pursuant to Article 4(5), manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to X.
2. Manufacturers of devices classified as class D, other than devices for performance study, shall be subject to a conformity assessment based on quality management system, and assessment of the technical documentation and batch verification as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on production quality assurance including batch verification as specified in Annex X.

In addition, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for technical documentation assessment set out in Section 6.1 of Annex VIII or in Annex IX.

In addition, where one or more reference laboratories are designated in accordance with Article 78, the notified body performing the conformity assessment shall request one of these reference laboratories to verify by laboratory testing the claimed performance and the compliance of the device with the applicable CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX. Laboratory tests performed by a reference laboratory shall in particular focus on analytical and diagnostic sensitivity using the best available reference materials.

For companion diagnostics the notified body shall consult the concerned competent authority designated in accordance with Directive 2001/83/EC<sup>24</sup> or the European Medicines Agency (EMA), as applicable, in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.

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<sup>24</sup> OJ L 311, 28.11.2001, p. 67.

- 2a. In addition, where no Common Specifications are available for a device in Class D and it is the first certification for that type of device, the notified body shall consult the relevant experts referred to in Article 81a of Regulation (EU) [Ref. of future Regulation on medical devices] on the performance evaluation report of the manufacturer. To this end, the notified body shall provide the performance evaluation report of the manufacturer to the expert panel within five days of receiving it from the manufacturer. The relevant experts shall, under the supervision of the Commission, provide their views to the notified body within the deadline for delivery of the scientific opinion by the reference laboratory as specified in section 5.4 of Annex VIII and in Section 3.5 of Annex IX.
3. Manufacturers of devices classified as class C, other than devices for performance study shall be subject to a conformity assessment based on quality management system as specified in Annex VIII, except for its Chapter II, with assessment of the technical documentation of at least one representative device per generic device group. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on production quality assurance, as specified in Annex X.

In addition, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for technical documentation assessment set out in Section 6.1 of Annex VIII or in Annex IX.

In addition, for all companion diagnostics the notified body shall follow the procedure for technical documentation assessment and shall consult the concerned competent authority designated by the Member States in accordance with Directive 2001/83/EC or the European Medicines Agency (EMA), as applicable, in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.

4. Manufacturers of devices classified as class B, other than devices for performance study, shall be subject to a conformity assessment based on quality management system, as specified in Annex VIII, except for its Chapter II, with assessment of the technical documentation of at least one representative device per generic device group.

In addition, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for assessment of the technical documentation set out in Section 6.1 of Annex VIII.

5. Manufacturers of devices classified as class A, other than devices for performance study, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 15, after drawing up the technical documentation set out in Annex II.

However, if the devices are placed on the market in sterile condition, the manufacturer shall apply the procedures set out in Annex VIII or in Annex X. Involvement of the notified body shall be limited to the aspects concerned with establishing, securing and maintaining sterile conditions.

7. Devices for performance studies shall be subject to the requirements set out in Articles 48 to 58.
8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language(s) determined by the Member State concerned. Otherwise they shall be available in an official Union language acceptable to the notified body.

9. The Commission may, by means of implementing acts, specify or modify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies, for any of the following aspects:
- the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in Sections 3.3.(c) and 4.5 of Annex VIII, in the case of devices classified as class C;
  - the minimum frequency of unannounced on-site audits and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device;
  - the frequency of samples of the manufactured devices or batches of devices classified as class D to be sent to a reference laboratory designated under Article 78 in accordance with Section 5.7 of Annex VIII and Section 5.1 of Annex X, or
  - the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, assessment of technical documentation and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII and Sections 3.2 and 3.3 of Annex IX.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

#### *Article 41*

##### *Involvement of notified bodies in conformity assessment procedures*

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application may not be lodged in parallel with another notified body for the same conformity assessment procedure.
2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment, by means of the electronic system referred to in Article 43a.

- 2a. Manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body and/or provide information about any previous application for the same conformity assessment that has been refused by another notified body.
3. The notified body may require any information or data from the manufacturer necessary in order to properly conduct the chosen conformity assessment procedure.
4. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

#### *Article 42*

##### *Mechanism for scrutiny of conformity assessments of class D devices*

1. A notified body shall notify the competent authority of certificates it has granted for devices classified as class D, with the exception of applications to supplement or renew existing certificates. Such notification shall take place through the electronic system referred to in Article 43a and shall be accompanied by the instructions for use referred to in Section 17.3 of Annex I, the summary of safety and performance referred to in Article 24, the assessment report by the notified body, and, where applicable, the laboratory tests and the scientific opinion by the reference laboratory according to Article 40(2) second subparagraph, and where applicable the views expressed by the experts in accordance with Article 40(2a), including, in case of divergent views between the notified body and the experts consulted, a full justification.
- 1aa. A competent authority and, where applicable, the Commission may, based on reasonable concerns apply further procedures according to Articles 33, 33a, 34, 35, 67 and, when deemed necessary, take appropriate measures according to Articles 68 and 71.



- 1a. The MDCG and, where applicable, the Commission, may, based on reasonable concerns, request scientific advice from the expert panels in relation to the safety and performance of any device(s).

### *Article 43*

#### *Certificates*

1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XI.
2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.
- 2a. Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or users or require manufacturers to undertake specific post-market performance follow-up studies pursuant to Part B of Annex XII.
3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

4. The notified body shall enter into the electronic system referred to in Article 43a information regarding certificates issued, including amendments and supplements, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.
5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the certificates set out in Annex XI.

#### *Article 43a*

##### *Electronic system on notified bodies and on certificates*

For the purposes of this Regulation the following information shall be collated and processed pursuant to Article 45a of Regulation [Ref of future Regulation on Medical devices] in the electronic system set up pursuant to that article:

- (a) the list of subsidiaries referred to in Article 28(2);
- (b) the list of experts referred to in Article 30a(2);
- (c) the information relating to the notification referred to in Article 31(9);
- (d) the list of notified bodies referred to in Article 32(2);
- (e) the summary report referred to in Article 33(5);
- (f) the notifications and certificates referred to in Article 42(1);
- (g) withdrawal of applications for the certificates referred to in Article 41(2);
- (ga) information regarding certificates referred to in article 43(4);
- (h) the summary of safety and performance referred to in Article 24.

## *Article 44*

### *Voluntary change of notified body*

1. In cases where a manufacturer terminates his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the incoming notified body and, where practicable the outgoing notified body. This agreement shall address at least the following aspects:
  - (a) the date of invalidity of certificates issued by the outgoing notified body;
  - (b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;
  - (c) the transfer of documents, including confidentiality aspects and property rights;
  - (e) the date after which the conformity assessment tasks of the outgoing Notified Body is assigned to the incoming notified body;
  - (f) the last serial number or batch code/lot number for which the outgoing notified body is responsible.
2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.

## *Article 45*

### *Derogation from the conformity assessment procedures*

1. By way of derogation from Article 40, any competent authority may authorise, on duly justified request, the placing on the market or putting into service, within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 40 have not been carried out and use of which is in the interest of public health or patient safety or health.
2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

3. Following a notification pursuant to paragraph 2, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).

#### *Article 46*

##### *Certificate of free sale*

1. For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, is established and that the device in question bearing the CE-marking in accordance with this Regulation may be marketed in the Union. The certificate of free sale shall set out the identification of the device in the electronic system set up under Article 22b. Where a notified body has issued a certificate referred to in Article 43, the certificate of free sale shall set out the unique number identifying that certificate, pursuant to section 3, Chapter II of Annex XI.
2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

## Chapter VI

### Clinical evidence, performance evaluation and performance studies

#### *Article 47*

##### *Performance evaluation and clinical evidence*

1. Confirmation of conformity with the general safety and performance requirements, in particular those concerning the performance characteristics referred to in Section I and Section II.6 of Annex I and where applicable relevant requirements of Annex IIa under the normal conditions of the intended use of the device, and the evaluation of the interference(s) and cross-reaction(s) and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on scientific validity, analytical and clinical performance data providing sufficient clinical evidence.

The manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate compliance with the relevant essential requirements on safety and performance which shall be appropriate to the characteristics of the device and its intended purpose.

To that end, manufacturers shall plan, conduct and document a performance evaluation in accordance with this Article and with Part A of Annex XII.

2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer and be based on a continuous process of performance evaluation, following a performance evaluation plan.

3. A performance evaluation shall follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with this Article and with part A of Annex XII:
  - (a) scientific validity;
  - (b) analytical performance;
  - (c) clinical performance.

The data and conclusions drawn from the assessment of these elements shall constitute the clinical evidence for the device. The clinical evidence shall scientifically demonstrate that the intended clinical benefit(s) and safety will be achieved according to the state of the art in medicine. The clinical evidence derived from the performance evaluation shall provide scientifically valid assurance, that the relevant general safety and performance requirements set out in Annex I, under normal conditions of use, are fulfilled.

4. Clinical performance studies in accordance with Annex XII, Part A Section 2 shall be carried out unless it is duly justified to rely on other sources of clinical performance data.
5. The scientific validity data, the analytical performance data and the clinical performance data, their assessment and the clinical evidence derived therefrom, shall be documented in the performance evaluation report referred to in Section 1.4 of Part A of Annex XII. The performance evaluation report shall be part of the technical documentation referred to in Annex II relating to the device concerned.
6. The performance evaluation and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's post-market performance follow-up plan in accordance with Annex XII part B, as part of the post-market surveillance plan referred to in Article 58b.

The performance evaluation report for devices classified as class C and D shall be updated when necessary, but at least annually with these data. The summary of safety and performance referred to in Article 24(1) shall be updated as soon as possible, where necessary.

8. Where necessary to ensure the uniform application of Annex XII, to the extent necessary to resolve issues of divergent interpretation and practical application, the Commission may, having due regard to technical and scientific progress, adopt implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

#### *Article 48*

##### *General requirements regarding performance studies*

0. The manufacturer shall ensure that a device for performance study complies with the general requirements of this Regulation apart from the aspects covered by the performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.
2. Where appropriate, performance studies shall be performed in circumstances similar to the normal conditions of use of the device.
- 2a. Performance studies shall be designed and conducted in a way that the rights, safety, dignity and well-being of the subjects participating in such performance studies are protected and prevail over all other interests and the data generated are going to be scientifically valid, reliable and robust.

Performance studies including performance studies using left-over samples shall be conducted in accordance with applicable law on data protection.

*Article 48aa*

*Additional requirements for certain studies*

1. Any performance study
  - (a) in which surgically invasive sample taking is done only for the purpose of the performance study;
  - (b) that is an interventional clinical performance study as defined in Article 2(37); or
  - (c) where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studiesshall, in addition to meeting the requirements set out in Article 48 and Annex XII, be designed, authorised, conducted, recorded and reported in accordance with Articles 48aa to 58 and Annex XIII.
- 1aaa. Performance studies involving companion diagnostics shall be subject to the same requirements as the studies listed in paragraph 1. This does not apply to studies involving companion diagnostics using only left-over samples - such studies shall however be notified to the competent authority.
- 1b. Performance studies shall be subject to scientific and ethical review. The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. Member States shall ensure that the procedures for the review by the ethics committees are compatible with the procedures set out in this Regulation for the assessment of the application for authorisation of a performance study. At least one lay person shall participate in the ethical review.



2. Where the sponsor of a performance study is not established in the Union, that sponsor shall ensure that a natural or legal person is established in the Union as its legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that legal representative shall be deemed to be a communication to the sponsor.

Member States may choose not to apply the subparagraph above as regards performance studies to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that performance study who shall be the addressee for all communications with the sponsor provided for in this Regulation.

- 6a. A performance study according to paragraph 1 may be conducted only where all of the following conditions are met:
- (a) the performance study was subject to an authorisation by a Member State(s) concerned, in accordance with this Regulation, unless otherwise stated;
  - (b) an independent ethics committee, set up according to national law, has not issued a negative opinion on the planned performance study valid for that entire Member State in accordance with its national law;
  - (c) the sponsor or its legal representative or a contact person pursuant to paragraph 2 is established in the Union;
  - (ca) vulnerable populations and subjects are appropriately protected in accordance with Article 48b to 48be;
  - (d) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;
  - (e) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent, in accordance with Article 48b;
  - (ea) the subject or, where the subject is not able to give informed consent, his or her legally designated representative, has been provided with the contact details of an entity where further information can be received in case of need;

- (f) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC are safeguarded;
- the performance study has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects and both the risk threshold and the degree of distress are specifically defined in the performance study plan and constantly monitored;
  - the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, any other person entitled by national law to the relevant patient care under performance study conditions;
  - no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate in the performance study;
- (h) where appropriate, biological safety testing reflecting the latest scientific knowledge or any other test deemed necessary in the light of the device's intended purpose has been conducted;
- (i) in case of clinical performance studies, the analytical performance has been demonstrated, taking into consideration the state of the art;
- (ia) in case of interventional clinical performance studies, the analytical performance and scientific validity has been demonstrated, taking into consideration the state of the art. Where for companion diagnostics the scientific validity is not established, the scientific rationale for the use of the biomarker shall be provided;
- (j) the technical safety of the device with regard to its use has been proven, taking into consideration the state of the art as well as provisions in the field of occupational safety and accident prevention;
- (k) the requirements of Annex XIII are fulfilled.
7. Any subject may, or, where the subject is not able to give informed consent, his or her legally designated representative, without any resulting detriment, withdraw from the performance study at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before the withdrawal.

8. The investigator shall be a person following a profession which is recognised in the Member State concerned, as qualifying for an investigator because of the necessary scientific knowledge and experience in patient care or laboratory medicine. Other individuals involved in conducting a performance study shall be suitably qualified by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.
9. Where appropriate, the facilities where the performance study involving subjects is to be conducted shall be similar to the facilities of the intended use and suitable for the performance study.

#### *Article 48b*

##### *Informed consent*

1. Informed consent shall be written, dated and signed by the person performing the interview referred to in point (c) of paragraph 2, and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 2. Where the subject is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. In that case, the witness shall sign and date the informed consent document. The subject or, where the subject is not able to give informed consent, his or her legally designated representative shall be provided with a copy of the document (or the record) by which informed consent has been given. The informed consent shall be documented. Adequate time shall be given for the subject or his or her legally designated representative to consider his or her decision to participate in the performance study.

2. Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent shall:
  - (a) enable the subject or his or her legally designated representative to understand
    - (i) the nature, objectives, benefits, implications, risks and inconveniences of the performance study;
    - (ii) the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the performance study at any time without any resulting detriment and without having to provide any justification;
    - (iii) the conditions under which the performance study is to be conducted, including the expected duration of the subject's participation in the performance study; and
    - (iv) the possible treatment alternatives, including the follow-up measures if the participation of the subject in the performance study is discontinued;
  - (b) be kept comprehensive, concise, clear, relevant, and understandable to the intended user;
  - (c) be provided in a prior interview with a member of the investigating team who is appropriately qualified according to the law of the Member State concerned; and
  - (d) include information about the applicable damage compensation system referred to in Article 48c;
  - (e) include the single identification number for this performance study and information about the availability of the performance study results in accordance with paragraph 6.
3. The information referred to in paragraph 2 shall be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, his or her legally designated representative.
4. In the interview referred to in point (c) of paragraph 2, special attention shall be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information.

5. In the interview referred to in point (c) of paragraph 2, it shall be verified that the subject has understood the information.
6. The subject shall be informed that the summary of the results of the performance study and a summary presented in terms understandable to the intended user will be made available in the EU database, referred to in Article 25 pursuant to Article 55(3), irrespective of the outcome of the performance study, and, to the extent possible, when the summaries become available.
8. This Regulation is without prejudice to national law requiring that, in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a performance study.

#### *Article 48ba*

##### *Performance studies on incapacitated subjects*

1. In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a performance study may be conducted only where, in addition to the conditions set out in Article 48aa(6a) all of the following conditions are met:
  - (a) the informed consent of their legally designated representative has been obtained;
  - (b) the incapacitated subjects have received the information referred to Article 48b in a way that is adequate in view of their capacity to understand it;
  - (c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to Article 48b to refuse participation in, or to withdraw from, the performance study at any time, is respected by the investigator;
  - (d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the performance study;

- (e) the performance study is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in performance studies on persons able to give informed consent, or by other research methods;
- (f) the performance study relates directly to a medical condition from which the subject suffers;
- (g) there are scientific grounds for expecting that participation in the performance study will produce:
  - (i) a direct benefit to the incapacitated subject outweighing the risks and burdens involved; or
  - (ii) some benefit for the population represented by the incapacitated subject concerned when the performance study will pose only minimal risk to, and will impose minimal burden on, the incapacitated subject concerned in comparison with the standard treatment of the incapacitated subject's condition.

2. The subject shall as far as possible take part in the informed consent procedure.

3. Point (g)(ii) of paragraph 1 shall be without prejudice to more stringent national rules prohibiting the conduct of those performance studies on incapacitated subjects, where there are no scientific grounds to expect that participation in the performance study will produce a direct benefit to the subject outweighing the risks and burdens involved.

#### *Article 48bb*

##### *Performance studies on minors*

1. A performance study on minors may be conducted only where, in addition to the conditions set out in Article 48aa(6a), all of the following conditions are met:
  - (a) the informed consent of their legally designated representative has been obtained;
  - (b) the minors have received the information referred to in Article 48b in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;

- (c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 48b to refuse participation in, or to withdraw from, the performance study at any time, is respected by the investigator;
- (e) the performance study is intended to investigate treatments for a medical condition that only occurs in minors or the performance study is essential with respect to minors to validate data obtained in performance studies on persons able to give informed consent or by other research methods;
- (d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the performance study;
- (f) the performance study either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;
- (g) there are scientific grounds for expecting that participation in the performance study will produce:
  - (i) a direct benefit to the minor subject outweighing the risks and burdens involved; or
  - (ii) some benefit for the population represented by the minor concerned when the performance study will pose only minimal risk to, and will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition.
- (h) The minor shall take part in the informed consent procedure in a way adapted to his or her age and mental maturity;
- (i) If during a performance study the minor reaches the age of legal competence to give informed consent as defined in the law of the Member State concerned, his or her express informed consent shall be obtained before that subject can continue to participate in the performance study.

2. Point (g)(ii) of paragraph 1 shall be without prejudice to more stringent national rules prohibiting the conduct of those performance studies on minors, where there are no scientific grounds to expect that participation in the performance study will produce a direct benefit to the subject outweighing the risks and burdens involved.

#### *Article 48bc*

##### *Performance studies on pregnant or breastfeeding women*

A performance study on pregnant or breastfeeding women may be conducted only where, in addition to the conditions set out in Article 48aa(6a) the following conditions are met:

- (a) the performance study has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;
- (b) if such a performance study has no direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, it can be conducted only if:
  - (i) a performance study of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;
  - (ii) the performance study contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction or other embryos, foetuses or children; and
  - (iii) the performance study poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth;
- (c) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child.
- (d) no incentives or financial inducements are given to subjects, except for compensation for expenses and loss of earnings directly related to the participation in the performance study;

#### *Article 48bd*

##### *Additional national measures*

Member States may maintain additional measures regarding persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in performance studies, or persons in residential care institutions.



*Article 48be*

*Performance studies in emergency situations*

1. By way of derogation from point (e) of Article 48aa(6a), from points (a) and (b) of Article 48ba(1) and from points (a) and (b) of Article 48bb(1), informed consent to participate in a performance study may be obtained, and information on the performance studies may be given, after the decision to include the subject in the performance study, provided that this decision is taken at the time of the first intervention on the subject, in accordance with the clinical performance study plan for that performance study and that all of the following conditions are fulfilled:
  - (a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the performance study;
  - (b) there are scientific grounds to expect that participation of the subject in the performance study will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;
  - (c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative;
  - (d) the investigator certifies that he or she is not aware of any objections to participate in the performance study previously expressed by the subject;
  - (e) the performance study relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the performance study is of such a nature that it may be conducted exclusively in emergency situations;
  - (f) the performance study poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of a subject condition.

2. Following an intervention pursuant to paragraph 1, informed consent in accordance with Article 48b shall be sought to continue the participation of the subject in the performance study, and information on the performance study shall be given, in accordance with the following requirements:
  - (a) regarding incapacitated subjects and minors, the informed consent shall be sought by the investigator from his or her legally designated representative without undue delay and the information referred to in Article 48b shall be given as soon as possible to the subject and to his or her legally designated representative;
  - (b) regarding other subjects, the informed consent shall be sought by the investigator without undue delay from the subject or his or her legally designated representative, whichever is sooner and the information referred to in Article 48b shall be given as soon as possible to the subject or his or her legally designated representative, whichever is sooner.

For the purposes of point (b) where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the performance study shall be obtained from the subject as soon as he or she is capable of giving informed consent.

3. If the subject or, where applicable, his or her legally designated representative does not give consent, he or she shall be informed of the right to object to the use of data obtained from the performance study.

#### *Article 48c*

##### *Damage compensation*

1. Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a performance study conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.

2. The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State concerned where the performance study is conducted.

#### *Article 49*

##### *Application for performance studies*

2. The sponsor of a performance study referred to in Article 48aa paragraphs 1 and 1aaa shall enter and submit by means of the electronic system referred to in Article 51 an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in Part A, Section 2 of Annex XII and in Annex XIII. The electronic system referred to in Article 51 shall generate a union wide unique single identification number for this performance study which shall be used for all relevant communication in relation to the performance study concerned. Within ten days after receipt of the application, the Member State concerned shall notify the sponsor whether the performance study falls within the scope of this Regulation and whether the application is complete.
  - 2a. Within one week of any change occurring in relation to the documentation referred to in Part A, Section 2 of Annex XII and in Annex XIII, the sponsor shall update the relevant data in the electronic system referred to in Article 51. The Member State concerned shall be notified of the update and the changes to the documents shall be clearly identifiable.
3. Where the Member State finds that the performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of ten days for the sponsor to comment or to complete the application. Member States may extend this period with a maximum of 20 days where appropriate.

Where the sponsor has not provided comments nor completed the application within the time-period referred to in the first subparagraph, the application shall be deemed to have lapsed. Where the sponsor considers that the application falls under the scope of the regulation and/or is complete but the competent authority does not agree, the application shall be considered as rejected. That Member States shall provide for an appeal procedure in respect of such refusal.

The Member State shall notify the sponsor within five days following receipt of the comments or of the requested additional information, whether the performance study is considered as falling within the scope of this Regulation and the application is completed.

- 3a. The concerned Member State may also extend the period referred to in paragraph 2 and 3 each by a further 5 days.
4. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 2 or 3 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the time periods referred to in paragraphs 2, 3 and 3a.
- 4a. In the period during which the application is being assessed the Member State may request, additional information from the sponsor. The expiry of the deadline pursuant to the second indent of paragraph 5(b) shall be suspended from the date of the first request until such time as the additional information has been received.
5. The sponsor may start the performance study in the following circumstances:
  - (a) in the case of performance studies according to Article 48aa(1)(a) and where the specimen collection does not represent a major clinical risk to the subject of the study, unless otherwise stated by national provisions, immediately after the validation date of application described in paragraph 4, provided that the competent ethics committee in the Member State concerned has not issued a negative opinion valid for that entire Member State in accordance with its national law;

(b) in case of performance studies according to Article 48aa(1)(b), (c) and 48aa(1aaa) or performance studies other than those referred to in subparagraph (a), as soon as the Member State concerned has notified the sponsor of its authorisation and provided that the competent ethics committee in the Member State concerned has not issued a negative opinion valid for that entire Member State in accordance with its national law. The Member State shall notify the sponsor of the authorisation within 45 days after the validation date referred to in paragraph 4. The Member State may extend this period by a further 20 days for the purpose of consulting with experts.

7. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress and global regulatory developments the requirements for the documentation to be submitted with the application for the performance study that is laid down in Chapter I of Annex XIII.
- 7a. The Commission may adopt implementing acts in accordance with Article 84(3), in order to assure the uniform application of the requirements for the documentation to be submitted with the application for the performance study that is laid down in Chapter I of Annex XIII, to the extent necessary to resolve issues of divergent interpretation and practical application.

#### *Article 49a*

##### *Assessment by Member States*

1. Member States shall ensure that the persons validating and assessing the application, or deciding on it, do not have conflicts of interest, are independent of the sponsor, the investigators involved and of persons or legal persons financing the performance study, as well as free of any other undue influence.
2. Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience.

3. Member States shall assess whether the performance study is designed in such a way that potential remaining risks to subjects or third person, after risk minimization, are justified, when weighed against the clinical benefits to be expected. They shall examine, under consideration of applicable Common Specifications or harmonized standards, in particular:
- (a) the demonstration of compliance of the device(s) for performance study with the applicable general safety and performance requirements, apart from the aspects covered by the performance study and whether, with regard to these aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, in case of performance studies, the evaluation of the analytical performance, and in case of interventional clinical performance studies, the evaluation of the analytical performance, clinical performance and scientific validity, taking into consideration the state of the art;
  - (b) whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, the equivalence of the level of protection to harmonised standards;
  - (c) the plausibility of the measures planned for the safe installation, putting into service and maintenance of the device for performance study;
  - (d) the reliability and robustness of the data generated in the performance study, taking account of statistical approaches, design of the performance study and methodological aspects (including sample size and comparator);
  - (da) the requirements of Annex XIII are met.
4. Member States shall refuse the authorisation of the performance study if:
- (b) the application submitted according to Article 49 paragraph 3 remains incomplete;
  - (ca) the device or the submitted documents, especially the performance study plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the performance study, in particular, is not suitable to provide evidence for the safety, performance characteristics or benefit of the device on subjects, or
  - (d) the requirements of Article 48aa are not met, or
  - (e) any assessment according to paragraph 3 is negative.

Member States shall provide for an appeal procedure in respect of such refusal.

*Article 49b*

*Conduct of a performance study*

1. The sponsor and the investigator shall ensure that the performance study is conducted in accordance with the approved performance study plan.
2. In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the performance study is in compliance with the requirements of this Regulation, the sponsor shall adequately monitor the conduct of a performance study. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the performance study including the following characteristics:
  - (a) the objective and methodology of the performance study and
  - (b) the degree of deviation of the intervention from normal clinical practice.
3. All performance study information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.
4. Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves the transmission over a network.
- 4a. Member States shall inspect on an appropriate level performance study site(s) to check that performance studies are conducted according to the requirements of this Regulation and to the approved investigation plan.
5. The sponsor shall establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the study.

## *Article 51*

### *Electronic system on performance studies*

1. The Commission shall, in collaboration with the Member States, set up, manage and maintain an electronic system on performance studies:
  - (aa) to create the single identification numbers for such performance studies;
  - (ab) to be used as an entry point for the submission of all applications or notifications for performance studies referred to in Article 49(2), 52, 53, 56 and for all other submission of data, or processing of data in this context;
  - (b) for the exchange of information relating to performance studies in accordance with this Regulation between the Member States and between them and the Commission including those according to Article 49a and 54;
  - (ca) for information by the sponsor according to Article 55, including the performance study report and its summary as required in its paragraph 3;
  - (d) for reporting on serious adverse events and device deficiencies and related updates referred to in Article 57.
2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article 81 of Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC<sup>25</sup> as concerns performance evaluation studies of companion diagnostics.
4. The information referred to in paragraph 1, except the information referred to in point b, which shall only be accessible to the Member States and the Commission, shall be accessible to the public, through the electronic system referred to in Article 51, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:
  - (a) protection of personal data in accordance with Regulation (EC) No 45/2001,

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<sup>25</sup> OJ L 158, 27.5.2014, p. 1.



- (b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure,
- (c) effective supervision of the conduct of the performance study by the Member State(s) concerned.

- 4a. No personal data of subjects participating in performance studies shall be publicly available.
- 4b. The user interface of the electronic system referred to in this Article shall be available in all official languages of the Union.

## *Article 52*

### *Performance studies with devices authorised to bear the CE marking*

1. Where a performance study is to be conducted to further assess devices which are authorised in accordance with Article 40 to bear the CE marking and within its intended purpose referred to in the relevant conformity assessment procedure, hereinafter referred to as ‘post-market performance follow-up study’, the sponsor shall notify the Member States concerned at least 30 days prior to their commencement if the study would submit subjects to additionally invasive or burdensome procedures. The notification shall be made by means of the electronic system referred to in Article 51. It shall be accompanied by the documentation referred to in Section 2 of Part A of Annex XII and in Annex XIII. Article 48aa paragraph 6a points (b) to (h) and (k), Articles 53, 54 and 55 Article 57(6) and the relevant provisions of Annexes XII and XIII shall apply.
2. If the aim of the performance study regarding a device which is authorised in accordance with Article 40 to bear the CE marking is to assess such device for a purpose other than that referred to in the information supplied by the manufacturer in accordance with Section 17 of Annex I and in the relevant conformity assessment procedure, Articles 48aa to 58 shall apply.

## *Article 53*

### *Substantial modifications to performance studies*

1. If the sponsor intends to introduce modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the data generated by the study, he shall notify, within one week, by means of the electronic system referred to in Article 51 the Member State(s) concerned of the reasons for and the content of those modifications. The notification shall be accompanied by an updated version of the relevant documentation referred to in Annex XIII in which changes shall be clearly identifiable.
  - 1a. The Member State shall assess the substantial modification to the performance study in accordance with the procedure laid down in Article 49a.
2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 38 days after notification, unless the Member State concerned has notified the sponsor of its refusal based on Article 49a paragraph 4 or on considerations of public health, of subject and user safety or health, or of public policy or the ethics committee concerned has issued a negative opinion which is valid for that entire Member State in accordance with its national law.
3. The Member State(s) concerned may extend the period referred to in paragraph 2 by a further 7 days, for the purpose of consulting with experts.

## *Article 54*

### *Corrective measures to be taken by Member States and information exchange between Member States on performance studies*

- 0a. Where a Member State concerned has grounds for considering that the requirements set out in this Regulation are no longer met, it may at least take the following measures on its territory:
  - (a) withdraw or revoke the authorisation of a performance study;
  - (b) suspend, temporary halt or terminate a performance study;
  - (c) require the sponsor to modify any aspect of a performance study.

- 0b. Before the Member State concerned takes any of the measures referred to in paragraph 0a it shall, except where immediate action is required, ask the sponsor and/or the investigator for their opinion. That opinion shall be delivered within seven days.
1. Where a Member State has taken a measure referred to in paragraph 0a, or has refused a performance study, or has been notified by the sponsor of the early termination of a performance study on safety grounds, that Member State shall communicate this decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 51.
2. Where an application is withdrawn by the sponsor prior to a decision by a Member State, that information shall be made available through the electronic system referred to in Article 51 to all Member States and the Commission.

#### *Article 55*

##### *Information by the sponsor at the end of a performance study or in the event of temporary halt or early termination*

1. If the sponsor has temporarily halted a performance study or has early terminated a performance study, he shall inform the Member States concerned within 15 days, through the electronic system in article 51, of the temporary halt or early termination, providing a justification. In case the sponsor has temporary halted or early terminated the performance study on safety grounds, he shall inform the Member states concerned thereof within 24 hours.
2. The sponsor shall notify each Member State concerned of the end of a performance study in relation to that Member State. That notification shall be made within 15 days from the end of the performance study in relation to that Member State.
- 2a. If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the performance study. That notification shall be made within 15 days from the overall end of the performance study.

3. Irrespective of the outcome of the performance study, within one year from the end of the performance study or within three months from the early termination or halt, the sponsor shall submit to the Member States concerned through the electronic system referred to in Article 51 a performance study report referred to in Section 2.3.3. of Part A of Annex XII.

It shall be accompanied by a summary presented in terms that are easily understandable to the intended user. Both the report and summary shall be submitted by the sponsor by means of the electronic system referred to in Article 51.

Where, for scientific reasons, it is not possible to submit the performance study report within one year after the completion of the study, it shall be submitted as soon as it is available. In this case, the clinical performance study plan referred to in Section 2.3.2. of Part A of Annex XII shall specify when the results of the performance study are going to be submitted, together with a justification.

- 3a. The Commission shall issue guidelines regarding the content and structure of the summary of the performance study report.

In addition, the Commission may issue guidelines for the formatting and sharing of raw data, for cases where the sponsor decides to share raw data on a voluntary basis. Those guidelines may take as a basis and adapt, where possible, existing guidelines for sharing of raw data in the field of performance studies.

5. The summary and the report according to paragraph 3 shall become publicly accessible through the electronic system, at the latest when the device is registered according to Article 22b and before it is placed on the market. In cases of early termination or halt the summary and the report shall become publicly accessible immediately after submission.

If the device is not registered according to Article 22b within one year after the summary and the report has been entered into the electronic system according to paragraph 3, they shall become publicly accessible at that point in time.

## *Article 56*

### *Performance studies conducted in more than one Member State*

1. By means of the electronic system referred to in Article 51, the sponsor of the performance study to be conducted in more than one Member State may submit, for the purpose of Article 49, a single application that, upon receipt, is transmitted electronically to the Member States concerned.
2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. The concerned Member States shall, within six days of submission of the application, agree on one of them taking the role of the coordinating Member State. If they do not agree on a coordinating Member State, the one proposed by the sponsor shall take that role. The deadlines referred to in Article 49 shall start on the day following the notification of the coordinating Member State to the sponsor (notification date).
3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation submitted in accordance with Chapter I of Annex XIII, except for Sections 1.1 1a., 4.2., 4.3. and 4.4. and Section 2.3.2.(c) of Part A of Annex XII thereof which shall be assessed separately by each Member State concerned.

The coordinating Member State shall:

- (aa) within 6 days of receipt of the single application notify the sponsor that it is the coordinating Member State (notification date);

- (a) within 10 days of the notification date, notify the sponsor whether the performance study falls within the scope of this Regulation and whether the application is complete, except for the documentation submitted in accordance with Sections 1.11a., 4.2., 4.3. and 4.4. of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII for which each Member State shall verify the completeness. Article 49(2) to (4) shall apply to the coordinating Member State in relation to the verification that the performance study falls within the scope of this Regulation and that the application is complete, having taken into account considerations expressed by the other Member States concerned, except for the documentation submitted in accordance with Sections 1.11a., 4.2., 4.3. and 4.4. of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII. Concerned Member States may communicate to the coordinating Member State any considerations relevant to the validation of the application within seven days from the notification date. Article 49(2) to (4) shall apply to each Member State in relation to the verification that the documentation submitted in accordance with Sections 1.11a., 4.2., 4.3. and 4.4. of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII is complete;
- (c) establish the results of its assessment in a draft assessment report to be transmitted within 26 days after the validation date to the concerned Member States. Until day 38 after the validation date the other concerned Member States shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State, which shall take due account of it in the finalization of the final assessment report, to be transmitted within 45 days following the validation date to the sponsor and the concerned Member States. The final assessment report shall be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 49(5), except for Sections 1.11a., 4.2., 4.3. and 4.4. of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII, which shall be assessed separately by each Member State concerned.

As concerns the assessment of the documentation related to Sections 1.11a., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII, done separately by each Member State, the Member State may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within the period set by the Member State concerned which shall not exceed 12 days from the receipt of the request. The expiry of the deadline pursuant to paragraph 2 shall be suspended from the date of the request until such time as the additional information has been received.

- 3a. For devices classified as class C and D, the coordinating Member State may also extend the periods referred to in paragraph 3 by a further 50 days, for the purpose of consulting with experts. In such case, the periods referred to in paragraphs 3 of this Article shall apply *mutatis mutandis*.
- 3aa. The Commission may, by means of implementing acts, set out the procedures and timescales for a coordinated assessment led by the coordinating Member State, that shall be taken into account by concerned Member States when deciding on the sponsor's application notification. Such implementing acts may also cover the procedures for coordinated assessment in the case of substantial modifications pursuant to paragraph 4 and in the case of reporting of events pursuant to Article 57(4) or in the case of performance studies involving companion diagnostics, where the medicinal products are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) No 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

- 3b. Where the conclusion of the coordinating Member State is that the conduct of the performance study is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State(s) concerned.

Notwithstanding the previous subparagraph, a Member State concerned may disagree with the conclusion of the coordinating Member State concerning the area of joint assessment only on the following grounds:

- (a) when it considers that participation in the performance study would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;
- (b) infringement of national law;
- (c) considerations as regards subject safety and data reliability and robustness submitted under paragraph 3 point (c).

Where a Member State concerned disagrees with the conclusion, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 51 to the Commission, to all Member States concerned, and to the sponsor.

- 3c. A Member State concerned shall refuse to authorise a performance study if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 3b, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.11a., 4.2., 4.3. and 4.4. of Chapter I of Annex XIII are not complied with, or where an Ethics committee has issued a negative opinion which in accordance with the law of the Member State concerned is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.



- 3ca. Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 51 as to whether the performance study is authorised, whether it is authorised subject to conditions, or whether authorisation is refused. Notification shall be done by way of one single decision within five days from the transmission, pursuant to paragraph 3, point (c), by the coordinating Member State of the final assessment report. An authorisation of a performance study subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.
- 3d. Where the conclusion of the coordinating Member State report is that the performance study is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.
4. The substantial modifications as referred to in Article 53 shall be notified to the Member States concerned by means of the electronic system referred to in Article 51. Any assessment as to whether there are grounds for refusal as referred to in paragraph 3b shall be carried out under the direction of the coordinating Member State, except for substantial modifications concerning sections 1.11a., 4.2., 4.3. and 4.4. of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII, which shall be assessed by each concerned Member State on its own.
6. The Commission shall provide administrative support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.

#### *Article 56a*

##### *Review of the coordinated procedure*

At the latest six years after the date referred to in Article 90(2), the Commission shall submit a report on experience gained from the application of Article 56 to the European Parliament and the Council and, if necessary, propose a review of Article 90(3)(e).

## Article 57

### *Recording and reporting of adverse events occurring during performance studies*

1. The sponsor shall fully record any of the following:
  - (a) an adverse event identified in the performance study as critical to the evaluation of the results of the performance study according to the clinical performance study plan;
  - (b) a serious adverse event;
  - (c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
  - (d) new findings in relation to any event referred to in points (a) to (c).
2. The sponsor shall report to all Member States where a performance study is conducted without delay any of the following by means of the electronic system referred to in Article 51:
  - (a) a serious adverse event that has a causal relationship with the device, the comparator or the study procedure or where such causal relationship is reasonably possible;
  - (b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
  - (c) new findings in relation to any event referred to in points (a) to (b).

The time period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial incomplete report followed up by a complete report.

Upon request by the Member State concerned, the sponsor shall provide all information referred to in paragraph 1.

3. The sponsor shall also report to the Member States concerned any event referred to in paragraph 2 occurring in third countries in which a performance study is performed under the same clinical performance study plan as the one applying to a performance study covered by this Regulation by means of the electronic system referred to in Article 51.

4. In the case of a performance study for which the sponsor has used the single application referred to in Article 56, the sponsor shall report any event as referred to in paragraph 2 by means of the electronic system referred to in Article 51. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Under the direction of the coordinating Member State referred to in Article 56(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a performance study needs to be terminated, suspended, temporarily halted or modified.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of post-market performance follow-up studies referred to in Article 52(1), the provisions on vigilance contained in Articles 59 to 64 shall apply instead of this Article.
6. Notwithstanding paragraph 5, this Article shall apply where a causal relationship between the serious adverse event and the preceding performance study has been established.

## *Article 58*

### *Implementing acts*

The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this Chapter, as regards the following:

- (a) harmonised electronic forms for the application for performance studies and their assessment as referred to in Articles 49 and 56, taking into account specific categories or groups of devices;
- (b) the functioning of the electronic system referred to in Article 51;
- (c) harmonised electronic forms for the notification of post-market performance follow-up studies as referred to in Article 52(1), and of substantial modifications as referred to in Article 53;
- (d) the exchange of information between Member States as referred to in Article 54;
- (e) harmonised electronic forms for the reporting of serious adverse events and device deficiencies as referred to in Article 57;
- (f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 57;
- (g) uniform application of the requirements regarding the clinical evidence/data needed to demonstrate compliance with the general safety and performance requirements specified in Annex I.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

## Chapter VII

### Post-market surveillance, vigilance and market surveillance

#### Section 0 – Post-market surveillance

##### *Article 58a*

##### *Post-market surveillance system of the manufacturer*

2. For any device, proportionate to the risk class and appropriate for the type of device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system which shall be an integral part of the manufacturer's quality management system according to Article 8(6).
3. The post-market surveillance system shall be suitable to actively and systematically gather, record and analyse relevant data on the quality, performance and safety of a device throughout its entire lifetime, to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions.
4. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:
  - (a) to update the benefit risk determination and risk management, the design and manufacturing information, the instructions for use and the labelling;
  - (b) to update the performance evaluation;
  - (c) to update the summary of safety and performance as referred to in Article 24;
  - (d) for the identification of needs for preventive, corrective or field safety corrective action;
  - (e) for the identification of possibilities to improve the usability, performance and safety of the device;
  - (f) when relevant, to contribute to the post-market surveillance of other devices;
  - (g) to detect and report trends in accordance with Article 59a.

The technical documentation shall be updated accordingly.

6. If in the course of the post-market surveillance a need for preventive and/or corrective action is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. When a serious incident is identified or a field safety corrective action is implemented, this shall be reported in accordance with Article 59.

#### *Article 58b*

##### *Post-market surveillance plan*

The post-market surveillance system as referred to in Article 58a shall be based on a post-market surveillance plan, the requirements of which are set out in Section 1.1. of Annex IIa. The post-market surveillance plan shall be part of the technical documentation as specified in Annex II.

#### *Article 58ba*

##### *Post-market surveillance report*

Manufacturers of class A and B devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex IIa together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the notified body and the competent authority upon request.

#### *Article 58c*

##### *Periodic safety update report*

1. Per device and where relevant per category or group of devices, the manufacturer of devices in class C and D shall prepare a periodic safety update report summarising the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex IIa together with a rationale and description of any preventive and corrective actions taken.

Throughout the lifetime of the device concerned this report shall set out:

- (a) the conclusion of the benefit risk determination;
- (b) the main findings of the Post Market Performance Follow-up Report and
- (c) the volume of sales of devices and an estimate of the population that use the device involved and, where practicable, the usage frequency of the device.

Manufacturers of class C and D devices shall update the report at least annually and it shall be part of the technical documentation as specified in Annexes II and IIa.

2. Manufacturers of devices in class D shall submit reports by means of the electronic system referred to in Article 64a to the notified body involved in the conformity assessment in accordance with Article 40. The notified body shall review the report and add its evaluation to the database with details of any action taken. Such reports and the notified body evaluation shall be available to competent authorities through the electronic system.
3. Manufacturers of devices other than those referred to in paragraph 2, shall make reports available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

## Section 1 – Vigilance

### *Article 59*

#### *Reporting of serious incidents and field safety corrective actions*

1. Manufacturers of devices, made available on the Union market, other than devices for performance study, shall report, through the electronic system referred to in Article 64a, the following:
  - (a) any serious incident involving devices made available on the Union market, except expected erroneous results which are clearly documented and quantified in the product information and in the technical documentation and are subject to trend reporting pursuant to Article 59a;
  - (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.
- 1a. As a general rule, the time period for reporting shall take account of the severity of the serious incident.
- 1b. Manufacturers shall report any serious incident as referred to in point (a) immediately after the manufacturer has established the causal relationship with their device or that such causal relationship is reasonably possible, and not later than 15 days after they have become aware of the serious incident.
- 1c. Notwithstanding paragraph 1b, in case of a serious public health threat the report shall be provided immediately, and not later than 2 days after awareness by the manufacturer of this threat.



- 1d. Notwithstanding paragraph 1b, in case of death or unanticipated serious deterioration in state of health the report shall be provided immediately after the manufacturer established or suspected a causal relationship between the device and the serious incident but not later than 10 elapsed days following the date of awareness of the serious incident.
- 1e. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.
- 1f. If after becoming aware of a potentially reportable incident there is still uncertainty about whether the incident is reportable, the manufacturer shall submit a report within the timeframe required for that type of incident.
- 1g. Except in cases of urgency where the manufacturer need to undertake the field safety corrective action immediately, without undue delay, the manufacturer shall report the field safety corrective action referred to in paragraph 1, point (b) in advance of the field safety corrective action being undertaken.
- 2. For similar serious incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 61(5), in consultation with the competent authorities referred to in points (a), and (b) of Article 64a(7), has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. Where a single competent authority is referred to in points (a) and (b) of Article 64a(7), the manufacturer may provide periodic summary reports on agreement with that competent authority.

3. The Member States shall take appropriate measures such as targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1.

They shall record reports that they receive centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

The manufacturer of the device concerned shall provide to the competent authority of the Member State where the serious incident occurred a report on the serious incident in accordance with paragraph 1 and ensure the appropriate follow-up. If the manufacturer considers that the incident is not a serious incident or an increase in expected erroneous results which will be covered by trend reporting according to Article 59(1a), it shall provide an explanatory statement.

If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with this article and to take or require the manufacturer to take the appropriate corrective action.

*Article 59a*

*Trend reporting*

1. Manufacturers shall report by means of the electronic system referred to in Article 64a any statistically significant increase in the frequency or severity of incidents that are not serious incidents that could have a significant impact on the risk-benefit analysis referred to in Sections 1. and 5. of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons or of any significant increase in expected erroneous results established in comparison to the stated performance of the device according to Annex I Section 6.1. points (a) and (b) and specified in the technical documentation and product information.

The manufacturer shall define how to manage these incidents and the methodology used for determining any statistically significant increase in the frequency or severity of these events or change in performance, as well as the observation period, in the post-market surveillance plan pursuant to Article 58b.

- 1a. The competent authorities may conduct their own assessments on the trend reports referred to in paragraph 1 and require the manufacturer to adopt appropriate measures in accordance with the present regulation in order to ensure the protection of public health and patient safety. The competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such evaluation and of the adoption of such measures.

## *Article 61*

### *Analysis of serious incidents and field safety corrective actions*

0. Following the reporting of a serious incident pursuant to Article 59(1), the manufacturer shall without delay perform the necessary investigations of the serious incident and the concerned devices. This shall include risk assessment of the incident and field safety corrective action taking into account criteria outlined in paragraph 2 as appropriate.

The manufacturer shall co-operate with the competent authorities and where relevant with the concerned notified body during these investigations and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident prior to informing the competent authorities of such action.

1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer, and, where relevant, with the notified body concerned.
2. In the context of the evaluation referred to in paragraph 0, the national competent authority shall evaluate the risks arising from the reported serious incidents and field safety corrective actions, taking into account the protection of public health and criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of direct or indirect harm and severity of that harm, clinical benefit of the device, intended and potential users, and population affected. It shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action, in particular taking into account the principle of inherent safety laid down in Annex I.

Upon request by the national competent authority, the manufacturer shall provide for all documents necessary for the risk assessment.

- 2a. The competent authority shall monitor the manufacturer's investigation of a serious incident. Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.
- 2b. The manufacturer shall provide a final report to the competent authority setting out its findings by means of the electronic system referred to in Article 64a. The report shall set out conclusions and where relevant indicate corrective actions to be taken.
- 2c. In the case of companion diagnostic, the evaluating competent authority or the coordinating competent authority referred to in paragraph 5 shall, depending on whether a national competent authority for medicinal products, or the European Medicines Agency (EMA), was consulted by the notified body in accordance with the procedures set out in Section 6.2. of Annex VIII and Section 3.6. of Annex IX, inform that competent authority or the EMA.
3. After carrying out the evaluation, the evaluating competent authority shall, through the electronic system referred to in Article 64a , inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence of a serious incident, including information on the underlying serious incidents and the outcome of its assessment.
4. The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. The field safety notice shall be edited in an official Union language or languages determined by the Member State where the field safety corrective action is taken. Except in case of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in cases referred to in paragraph 5 of this Article, the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

The field safety notice shall allow the correct identification of the device or devices involved, including the UDI, and of the manufacturer, including the SRN, that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without playing down the level of risk, the reasons for field safety corrective action with reference to the device deficiency or malfunction and associated risks for patient, user or other person and shall clearly indicate all the actions to be taken by users.

The manufacturer shall enter the field safety notice in the electronic system referred to in Article 64a through which that notice shall be accessible to the public.

5. The competent authorities shall nominate a coordinating competent authority to coordinate their assessments referred to in paragraph 2 in the following cases:
  - (a) where there is concern regarding a particular serious incident or cluster of serious incidents related to the same device or type of device of the same manufacturer in more than one Member State;
  - (b) where the appropriateness of a field safety corrective action that is proposed by a manufacturer in more than one Member State is in question.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the one of the Member State where the manufacturer or the authorised representative has his registered place of business.

The competent authorities shall actively participate in a coordination procedure. This procedure shall include the following:

- designation of a coordinating authority on a case by case basis, when required;
- a definition of the coordinated assessment process;
- tasks and responsibilities of the coordinating authority and the involvement of other competent authorities.

The coordinating competent authority shall, through the electronic system referred to in Article 64a, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

6. The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.
7. The Commission shall provide administrative support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

#### *Article 63a*

##### *Analysis of vigilance data*

The Commission shall, in collaboration with the Member States, put in place systems and processes to proactively monitor the data available in the database referred to in Article 64a, in order to identify trends, patterns or signals in the data that may identify new risks or safety concerns.

When a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the risk-benefit ratio, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, who shall take the necessary corrective actions.

#### *Article 64*

##### *Implementing acts*

The Commission may, by means of implementing acts, and after consultation of the MDCG, adopt the modalities and procedural aspects necessary for the implementation of Articles 58ba to 63a and 64a as regards the following:

- (a) typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

- (b) the reporting of serious incidents and field safety corrective actions, field safety notices, periodic summary reports, post-market surveillance reports, periodic safety update reports and trend reports by manufacturers as referred to in Articles 58ba, 58c, 59, 59a and 61;
- (ba) standard structured forms for electronic and non-electronic reporting, including a minimum data set for reporting of suspected serious incidents by healthcare professionals, users and patients;
- (c) timelines for the reporting of field safety corrective actions, periodic summary reports, and trend reports by manufacturers, taking into account the severity of the incident to be reported as referred to in Article 59;
- (d) harmonised forms for the exchange of information between competent authorities as referred to in Article 61;
- (e) procedures for designation of a coordinating competent authority; the coordinated assessment process; tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

#### *Article 64a*

##### *Electronic system on vigilance and post-market surveillance*

1. The Commission shall, in collaboration with the Member States, collate and process the following information by means of the electronic system set up pursuant to Article 25 including a link to the product information in accordance with Article 22a:
  - (a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 59(1) and Article 61(2b);
  - (b) the periodic summary reports by manufacturers referred to in Article 59(2);
  - (d) the reports by manufacturers on trends referred to in Article 59a;
  - (da) the periodic safety update reports referred to in Article 58c;
  - (e) the field safety notices by manufacturers referred to in Article 61(4);
  - (f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(3) and (5).



2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies that issued a certificate for the device in question in accordance with Article 41.
3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.
4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.
5. The reports on serious incidents referred to in point (a) of Article 59(1), shall be automatically transmitted, upon receipt, via the electronic system, to the competent authority of the Member State where the incident occurred.
- 5a. Trend reports referred to in Article 59a(1) shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the Member States where the incidents occurred.
6. The reports on field safety corrective actions referred to in point (b) of Article 59(1) shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:
  - (a) the Member State where the field safety corrective action is being or is to be undertaken;
  - (b) the Member State where the manufacturer or his authorised representative has his registered place of business.

7. The periodic summary reports referred to in Article 59(2) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States:
  - (a) the Member State(s) participating in the coordination procedure according to Article 61(5) and that agreed on the periodic summary report;
  - (b) the Member State where the manufacturer or his authorised representative has his registered place of business.
8. The information referred to in paragraphs 5 to 7 shall be automatically transmitted, upon receipt, through the electronic system, to the notified body that issued the certificate for the device in question in accordance with Article 43.

## **Section 2 – Market surveillance**

### *Article 65*

#### *Market surveillance activities*

1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.
  - 1a. The competent authorities shall draw up annual surveillance activities plans and allocate a sufficient number of competent human and material resources needed to carry out those activities taking into account the European market surveillance program developed by the MDCG according to Article 77 and local circumstances.

- 1b. For the purpose referred to in paragraph 1, the competent authorities:
- (a) may, *inter alia*, require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, where justified, provide the necessary samples of devices or access to the device free of charge; and
  - (b) shall carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.
- 1c. The competent authorities shall prepare an annual summary of the results of the surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 73b.
- 1d. The competent authorities may confiscate, destroy or otherwise render inoperable devices presenting an unacceptable risk or falsified devices where they deem it necessary in the interest of the protection of public health.
- 1e. Following each inspection carried out under paragraph 1b, the competent authority shall draw up a report the findings of the inspection in accordance with the legal and technical requirements applicable under this Regulation and any corrective actions needed.
- 1f. The competent authority which carried out the inspection shall communicate the content of this report to the inspected economic operator. Before adopting the report, the competent authority shall give the inspected economic operator the opportunity to submit comments. The final inspection report as referred to in paragraph 1b shall be entered into the electronic system provided for in Article 73b.
2. The Member States shall review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. The Member State concerned shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 73b.

3. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonized high level of market surveillance in all Member States.

Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation.

4. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.
5. Where appropriate, the competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

#### *Article 67*

##### *Evaluation regarding devices suspected of presenting an unacceptable risk or other non-compliance*

Where the competent authorities of a Member State, based on data obtained by vigilance or market surveillance activities or other information, have reason to believe that a device may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, or otherwise does not comply with the requirements laid down in this Regulation, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by or other non-compliance of the device. The relevant economic operators shall cooperate with the competent authorities.

## Article 68

### *Procedure for dealing with devices presenting an unacceptable risk to health and safety*

1. Where, having performed an evaluation pursuant to Article 67, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the devices concerned, his authorised representatives and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period that is clearly defined and communicated to the relevant economic operator, proportionate to the nature of the risk.
2. The competent authorities shall, without delay, notify the Commission, the other Member States and the notified body that issued a certificate in accordance with Article 43 for the device concerned of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 73b.
3. The economic operators shall without delay ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.
4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it.

They shall notify the Commission, the other Member States and the notified body that issued a certificate in accordance with Article 43 for the device concerned, without delay, of those measures, by means of the electronic system referred to in Article 73b.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification and tracing of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.
6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 73b, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 73b.
7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified.
8. Where paragraph 7 applies, all Member States shall ensure that appropriate restrictive or prohibitive measures, withdrawing, recalling or limiting the availability of the device on their national market are taken without delay in respect of the device concerned.

## *Article 69*

### *Procedure for evaluating national measures at Union level*

1. Where, within two months of receipt of the notification referred to in Article 68(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall, after consulting the concerned competent authorities and, where necessary, the concerned economic operators, evaluate the national measure. On the basis of the results of that evaluation, the Commission may decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).
2. If the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

If the Commission has not adopted a decision pursuant to paragraph 1 within eight months of receipt of the notification referred to in Article 68(4), the national measures shall be considered to be justified.

- 2a. Where a Member State or the Commission consider that the risk to health and safety emanating from a device cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

## *Article 71*

### *Other non-compliance*

1. Where, having performed an evaluation pursuant to Article 67, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.
2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall without delay take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article 73b.
3. The Commission may, by means of implementing acts, elaborate details on the nature of non-compliances and appropriate measures to be taken by competent authorities to ensure the uniform application of this article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

## *Article 72*

### *Preventive health protection measures*

1. Where a Member State, after having performed an evaluation, which indicates a potential unacceptable risk related to a device or a specific category or group of devices considers that, in order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, it may take any necessary and justified measures.



2. The Member State shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 73b.
3. The Commission, in consultation with the MDCG and, where necessary, the concerned economic operators, shall assess the national measures taken. The Commission may decide, by means of implementing acts, whether the national measures are justified or not. In the absence of a Commission decision within six months from their notification, the national measures shall be considered to be justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).
4. Where the assessment referred to in paragraph 3 demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 84(3) to take the necessary and duly justified measures.

### *Article 73*

#### *Good administrative practice*

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 68 to 72 shall state the exact grounds on which it is based. Where it is addressed to a specific economic operator, it shall be notified without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to him under the law or the administrative practice of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general scope, it shall be appropriately published.

2. Except in cases where immediate action is necessary for reasons of unacceptable risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time that is clearly defined before any measure is adopted. If action has been taken without the economic operator being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.
3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action and that the device is in compliance with the requirements of this Regulation.
4. Where a measure adopted pursuant to Articles 68 to 72 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall by means of the electronic system referred to in Article 73b inform the relevant notified body and the authority responsible for the notified body of the measure taken.

#### *Article 73b*

##### *Electronic system on market surveillance*

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:
  - (aa) summaries of the results of the surveillance activities referred to in Article 65(1c);
  - (ab) the final inspection report as referred to in Article 65(1f);
  - (a) information in relation to devices presenting an unacceptable risk to health and safety referred to in Article 68(2), (4) and (6);
  - (c) information in relation to formal non-compliance of products referred to in Article 71(2);
  - (d) information in relation to preventive health protection measures referred to in Article 72(2);
  - (e) summaries of the results of the reviews and assessments of the surveillance activities of the Member States referred to in Article 65(2).

2. The information mentioned in paragraph 1, points (a), (c) and (d) shall be immediately transmitted through the electronic system to all competent authorities concerned and, where applicable, to the notified body that issued a certificate in accordance with Article 43 for the device concerned and be accessible to the Member States and to the Commission.
3. Information exchanged between Member States shall not be made public when this may impair market surveillance activities and co-operation between Member States.

## **Chapter VIII**

### **Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers**

#### *Article 74*

##### *Competent authorities*

1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.

#### *Article 75*

##### *Cooperation*

1. The competent authorities of the Member States shall cooperate with each other and with the Commission which shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.
2. Member States shall with the support of the Commission participate, where appropriate, in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

## Article 76

### *Medical Device Coordination Group*

The Medical Device Coordination Group (MDCG) established in accordance with the conditions and modalities defined in Article 78 and 82 of Regulation (EU) [Ref. of future Regulation on medical devices] shall carry out, with the support of the Commission as provided in Article 79 of that Regulation, the tasks assigned to it by this Regulation.

## Article 77

### *Tasks of the MDCG*

The MDCG shall have the following tasks:

- (a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;
- (ac) to advise the Commission, at its request, in matters concerning the coordination group of Notified Bodies as established pursuant to Article 37;
- (c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the performance evaluation by manufacturers, the assessment by notified bodies and the vigilance activities;
- (ca) to contribute to the continuous monitoring of the technical progress and assessment whether the general safety and performance requirements in this Regulation and Regulation (EU) No [.../...] [on medical devices] are appropriate to ensure safety and performance of *in vitro* diagnostic medical devices and identify the need to amend Annex I;
- (cb) to contribute to the development of *in vitro* diagnostic medical devices standards and of Common Specifications;
- (d) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and regulatory status of *in vitro* diagnostic medical devices, clinical performance studies, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance program with the objective of efficiency and harmonisation of market surveillance in the European Union, in accordance with Article 65;

- (e) to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;
- (f) to contribute to harmonised administrative practice with regard to *in vitro* diagnostic medical devices in the Member States.

## *Article 78*

### *European Union reference laboratories*

1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.
2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:
  - (a) to verify the claimed performance and the compliance of class D devices with the applicable CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the second subparagraph of Article 40(2);
  - (b) to carry out appropriate tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 5.7. of Annex VIII and in Section 5.1. of Annex X;
  - (c) to provide scientific and technical assistance to the Commission, the MDCG, the Member States and notified bodies in relation to the implementation of this Regulation;
  - (d) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;
  - (e) to set up and manage a network of national reference laboratories after consulting with the national authorities and publish a list of the participating national reference laboratories and their respective tasks;

- (f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and market surveillance;
- (g) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;
- (h) to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;
- (i) to contribute to the development of common specifications and of international standards;
- (j) to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation and publish them by electronic means after consideration of national provisions on the respect of confidentiality.

2a. At the request of a Member State, the Commission may also designate EU reference laboratories where that Member State wishes to have recourse to such a laboratory to ensure the verification of the claimed performance and the compliance of Class C devices with the applicable CS when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.

3. EU reference laboratories shall satisfy the following criteria:

- (a) to have adequate and appropriately qualified staff with adequate knowledge and experience in the field of the *in vitro* diagnostic medical devices for which they are designated;
- (b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;
- (c) to have the necessary knowledge of international standards and best practices;
- (d) to have an appropriate administrative organisation and structure;
- (e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks;
- (f) to act in the public interest and in an independent manner;

- (g) to ensure that their staff do not have financial or other interests in the *in vitro* diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the *in vitro* diagnostic medical device industry and update this declaration whenever a relevant change occurs.

3a. The network of European Union reference laboratories shall satisfy the following criteria and the reference laboratories in the network shall coordinate and harmonise their working methods as regards testing and assessment. This involves:

- (a) applying coordinated methods, procedures and processes;
- (b) agreeing on the use of same reference materials and common test samples and seroconversion panels;
- (c) establishing common assessment and interpretation criteria;
- (d) using common testing protocols and assessing the test results using standardised and coordinated evaluation methods;
- (e) using standardised and coordinated test reports;
- (f) developing, applying and maintaining a peer review system;
- (g) organizing regular quality assessment tests (including mutual checks on the quality and comparability of test results);
- (h) agreeing on joint guidelines, instructions, procedural instructions or standard operational procedures (SOPs);
- (i) coordinating the introduction of testing methods for new technologies and according to new or amended CS;
- (j) reassessing the state of the art on the basis of comparative test results or by further studies, as requested by the Commission or a Member State;

4. EU reference laboratories may be granted a Union financial contribution.

The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).



5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.
6. The Commission shall specify by means of implementing acts in accordance with Article 84:
  - (a) detailed rules to facilitate the application of paragraph 2 and detailed rules to ensure compliance with the criteria referred to in paragraph 3.
  - (b) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU Reference Laboratory for providing scientific opinions in response to consultations by notified bodies and Member States in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.
7. EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts, shall take appropriate measures, including the restriction, suspension or withdrawal of the designation.
8. The provisions in Article 82(1) of Regulation (EU) No [...] [on medical devices] shall apply to the staff of EU reference laboratories.

#### *Article 79*

##### *Device registers and data banks*

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers and data banks for specific types of devices setting common principles to collect comparable information. Such registers and data banks shall contribute to the independent evaluation of the long-term safety and performance of devices.

## **Chapter IX**

### **Confidentiality, data protection, funding, penalties**

#### *Article 80*

##### *Confidentiality*

1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:
  - (a) personal data in compliance with Article 81;
  - (b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights unless disclosure is in the public interest;
  - (c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.
2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall not be disclosed without prior agreement with the originating authority.
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.
4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

## *Article 81*

### *Data protection*

1. Member States shall apply Directive 95/46/EC<sup>26</sup> to the processing of personal data carried out in the Member States pursuant to this Regulation.
2. Regulation (EC) No 45/2001<sup>27</sup> shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

## *Article 82*

### *Levy of fees*

1. This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles.
2. Member States shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted. The structure and level of fees shall be publicly available on request.

## *Article 82a*

### *Funding of notified body designation and monitoring activities*

- 1a. The cost associated with the joint assessment activities shall be covered by the Commission. The Commission shall lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

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<sup>26</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

<sup>27</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

## *Article 83*

### *Penalties*

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [*3 months prior to the date of application of the Regulation*] and shall notify it without delay of any subsequent amendment affecting them.

## **Chapter X**

### **Final provisions**

#### *Article 84*

##### *Committee procedure*

1. The Commission shall be assisted by the Committee on Medical Devices set up by Article 88 of Regulation (EU) [*Ref. of future Regulation on medical devices*].
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or Article 5, as appropriate, shall apply.

#### *Article 85*

##### *Exercise of the delegation*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 4(6), 8(2), 15(4), 22(7a), 43(5) and 49(7) shall be conferred on the Commission for a period of five years from the date of entry into force of this Regulation. The Commission shall draw up a report in respect of the delegated powers not later than nine months before the end of the five year period. The delegation of powers shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7a), 43(5) and 49(7) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
- 3a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 4(6), 8(2), 15(4), 22(7a), 43(5) and 49(7) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

## *Article 86a*

### *Separate delegated acts for different delegated powers*

The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.

## *Article 87*

### *Transitional provisions*

1. From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC shall become void.
2. Certificates issued by notified bodies in accordance with Directive 98/79/EC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex VI of Directive 98/79/EC which shall become void at the latest two years after the date of application of this Regulation.

Certificates issued by notified bodies in accordance with Directive 98/79/EC after the entry into force of this Regulation shall become void at the latest two years after the date of application of this Regulation.

3. By way of derogation from Directive 98/79/EC, devices which comply with this Regulation may be placed on the market before its date of application.
- 3a. Devices which were lawfully placed on the market pursuant to Directive 98/79/EC prior to the date referred to in Article 90(2) may continue to be made available on the market or put into service until three years after that date.
4. By way of derogation from Directive 98/79/EC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.

- 4a. As regards the devices subject to the procedures laid down in Article 40, paragraphs 2 and 2a, paragraph 4 applies provided that the necessary appointments to the MDCG and expert panels and of reference laboratories have been made.
5. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies who, during the period from the later of the two dates referred to in Article 90(2) and 90(3)(d) until 18 months after the later of the two dates referred to in Article 90(2) and 90(3)(d), comply with Article 23(3) and Article 23a(1) and Article 43(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Commission Decision 2010/227/EU.
6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(12) of Directive 98/79/EC shall keep the validity indicated in the authorisation.
7. Until the Commission in line with Article 24(2) has designated the UDI assigning entities, GS1 AISBL, HIBCC and ICCBBA shall be considered as designated UDI assigning entities.

#### *Article 88*

#### *Evaluation*

No later than five years after the date of application, the Commission shall assess the application of this Regulation and establish an evaluation report on the progress towards achievement of the objectives of the Regulation including an assessment of resources required to implement this Regulation. Special attention shall be given to the traceability of devices through the storage, pursuant to Article 22, of UDI by economic operators, health institutions and health professionals. The evaluation shall also include a review on the functioning of Article 4a.



## *Article 89*

### *Repeal*

Directive 98/79/EC of the European Parliament and of the Council is repealed with effect from [date of application of this Regulation] with the exception of

- Article 11, point (c) of Article 12(1) and Article 12(2) and 12(3) which are repealed with effect from the later of the two dates referred to in Article 90(2) and 90(3)(d) and
- Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC which are repealed with effect from 18 months after the later of the two dates referred to in Article 90(2) and 90(3)(d).

Commission Decision 2010/227/EU adopted in implementation of Directives 90/385/EEC, 93/42/EEC and 98/79/EC shall be repealed with effect from the later of the two dates referred to in Article 90(2) and 90(3)(d).

References to the repealed Directive shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XIV.

## *Article 90*

### *Entry into force and date of application*

1. This Regulation shall enter into force on the twentieth day after its publication in the *Official Journal of the European Union*.
2. It shall apply from [five years after entry into force].
3. By way of derogation from paragraph 2 the following shall apply:
  - (a) Article 23(3) and Article 43(4) shall apply from [18 months after date of application referred to in paragraph 2];

- (b) Articles 26 to 38 and Article 74 shall apply from [*six months after entry into force*]. Article 75 shall apply from [*twelve months after entry into force*]. Article 78 shall apply from [*six months prior to the date of application as referred to in paragraph 2*]. However, prior to [*date of application as referred to in paragraph 2*], the obligations on notified bodies emanating from the provisions in Articles 26 to 38 shall apply only to those bodies which submit an application for designation in accordance with Article 29 of this Regulation.
- (c) For class D devices Article 22(4) shall apply from one year after the date of application of this regulation. For class B and class C devices Article 22(4) shall apply from three years after the date of application of this regulation. For class A devices Article 22(4) shall apply from five years after the date of application of this regulation.
- (d) Without prejudice to the obligations for the Commission in accordance with Article 27a of Regulation [future Regulation on Medical devices] Article 22a(2), Article 22b(2), (3, second subparagraph) and (3a), Article 23a and 24, Article 30a(2, second sentence), Article 31(9, second subparagraph), Article 32(2), Article 33(5), Article 34(4, fourth and fifth indent), Articles 58c(2), 59 and 59a, Article 61(2b), (3) and (4, third subparagraph), Article 63a, Article 65(1c), (1f) and (2), Article 68(2) and (4), Article 71(2, last sentence), Article 73(4) and Chapter VI except Articles 47, 48, 48aa, 48b, 48ba, 48bb, 48bc, 50c, 48bd, 48be and 48c of this Regulation shall apply from [*five years after entry into force*], unless due to circumstances that could not reasonably have been foreseen when drafting the plan referred to in Article 27a(1) of Regulation [future Regulation on Medical devices] the European database referred to in Article 27 of that Regulation and the Electronic system on UDI referred to in Article 24a of that Regulation are not fully functional on [*five years after entry into force*] in which case they shall apply from six months after the publication of the notice referred to in Article 27a(3) of Regulation [future regulation on Medical devices].
- (e) The procedure set out in Article 56 shall, during a period of seven years following the date referred to in Article 90(2), apply only to the Member States concerned which have agreed to it. After this period, this procedure shall apply to all Member States concerned by the submission of a single application by the sponsor.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ,

*For the European Parliament*

*For the Council*

*The President*

*The President*

## ANNEXES

- I General safety and performance requirements
- II Technical documentation
- IIa Technical documentation on post-market surveillance
- III EU Declaration of conformity
- IV CE marking of conformity
- V Information to be submitted with the registration of devices and economic operators in accordance with Article 23a and core data elements to be provided to the UDI data base together with the device identifier in accordance with Article 22a and the European Unique Device Identification System
- VI Requirements to be met by Notified Bodies
- VII Classification criteria
- VIII Conformity assessment based on a quality management system and on assessment of technical documentation
- IX Conformity assessment based on type examination
- X Conformity assessment based on production quality assurance
- XI Certificates issued by a notified body
- XII Performance evaluation and post-market follow-up
- XIII Interventional clinical performance studies and other performance studies involving risks for the subjects of the studies
- XIV Correlation table

## GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

### I. GENERAL REQUIREMENTS

1. Devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.
- 1aa. The requirements in this annex to reduce risks as far as possible mean reduce risks as far as possible without adversely affecting the risk benefit ratio.
- 1a. The manufacturer shall establish, implement, document and maintain a risk management system.

Risk management is a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic update. It requires a manufacturer to:

- (a) establish and document a risk management plan for each device;
- (b) identify and analyse the known and foreseeable hazards associated with each device;
- (c) estimate and evaluate the associated risks occurring during the intended use and during reasonably foreseeable misuse;
- (d) eliminate or control these risks according to the requirements of Section 2;
- (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system on hazards and their frequency of occurrence, estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability.

(f) based on the evaluation of the impact of information from the production phase or the post market surveillance system if necessary amend control measures in line with the requirements of Section 2.

2. The risk control measures adopted by the manufacturer for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, the manufacturer shall apply the following principles in the priority order listed:
- (b) eliminate or reduce risks as far as possible through safe design and manufacture;
  - (c) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and
  - (d) provide information for safety (warnings/precautions/contraindications) and, where appropriate, training to users.

The manufacturer shall inform users of any residual risks.

- 2b. In eliminating or reducing risks related to use error the manufacturer shall apply the following principles:
- reducing as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
  - consideration of the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).
3. The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

4. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use will not be adversely affected during transport and storage (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.
5. All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients and/or user of the intended performance of the device during normal conditions of use.

## **II. REQUIREMENTS REGARDING PERFORMANCE, DESIGN AND MANUFACTURING**

### **6. Performance characteristics**

- 6.1. Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 2(2), as specified by the manufacturer, and suitable with regard to the performance taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable:
  - (a) the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions; and
  - (b) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.
- 6.2. The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.

- 6.3. Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.
- 6.4. Characteristics and performances of the device shall be specifically checked when they may be affected when the device is used for the intended use under normal conditions:
- for devices for self-testing, performances obtained by laypersons;
  - for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).

## **7. Chemical, physical and biological properties**

- 7.1. Devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Chapter I 'General Requirements'.

Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.

- 7.2. Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices.



7.3. Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products, processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006<sup>28</sup>, and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)<sup>29</sup>.

7.4. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.

## **8. Infection and microbial contamination**

8.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons.

The design shall:

- (a) allow easy and safe handling;
- (b) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use;

and, where necessary

- (c) prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.

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<sup>28</sup> OJ L 353, 31.12.2008, p. 1.

<sup>29</sup> OJ L 136, 29.5.2007, p.3.

- 8.2. Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market, and remain so under the transport and storage conditions specified by the manufacturer, until the protective packaging is damaged or opened.
- 8.3. Devices labelled as sterile shall have been processed, manufactured, packaged and, sterilised by appropriate validated methods.
- 8.4. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.
- 8.5. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.
- 8.6. The labelling of the device shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition additional to the symbol used to indicate that a product is sterile.

## **9. Devices incorporating materials of biological origin**

Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person.

In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.

## **10. Construction of devices and interaction with their environment**

- 10.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.
- 10.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:
- (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;
  - (c) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;
  - (d) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;
  - (e) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;
  - (f) the risks of accidental ingress of substances into the device;
  - (g) the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended;
  - (h) the risks of any foreseeable interference with other devices.
- 10.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices whose intended use includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.

- 10.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.
- 10.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.
- 10.6. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or related waste substances by the user, or other person. To that end, manufacturers shall investigate and test procedures and measures by which their devices can be safely disposed after use. These procedures shall be described in the instructions for use.
- 10.7 The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.

## **11. Devices with a measuring function**

- 11.1. Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with Annex I, II 6.1 first indent, taking into account the intended purpose of the device.
- 11.2. The measurements made by devices with a measuring function and expressed in legal units shall conform to the provisions of Council Directive 80/181/EEC<sup>30</sup>.

## **12. Protection against radiation**

- 12.1. Devices shall be designed, manufactured and packaged in such a way that exposure of users, or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.

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<sup>30</sup> OJ L 39, 15.2.1980, p.40.

12.2. When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as far as possible be:

- (a) designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and
- (b) fitted with visual displays and/or audible warnings of such emissions

12.3. The operating instructions for devices emitting hazardous or potentially hazardous radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance testing, the performance testing and the acceptance criteria shall also be specified, as well as the maintenance procedure.

### **13. Electronic programmable systems - Devices that incorporate electronic programmable systems and software that are devices in themselves**

13.1. Devices that incorporate an electronic programmable system, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance according to their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

13.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

13.3. Software referred to in this Section that are intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise).

- 13.3a. The manufacturer shall describe minimum requirements on hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

#### **14. Devices connected to or equipped with an energy source**

- 14.1. For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.
- 14.2. **Devices** where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply *and an appropriate warning or indication if, or if necessary before, the capacity of the power supply becomes critical.*
- 14.3. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.
- 14.4. Devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.
- 14.5. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the user, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

#### **15. Protection against mechanical and thermal risks**

- 15.1. Devices shall be designed and manufactured in such a way as to protect the user, or other person against mechanical risks.

15.2. Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.

15.3. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.

Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.

15.4. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

15.5. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

15.6. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle shall be designed and constructed in such a way as to minimise all possible risks.

15.7. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

15.8. Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.

## **16. Protection against the risks posed by devices intended for self-testing or near-patient testing**

16.1. Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient testing the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.

16.2. Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to

- ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information; and
- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.



16.3. Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user can:

- verify that, at the time of use, the device will perform as intended by the manufacturer; and
- be warned if the device has failed to provide a valid result.

### **III. REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE**

#### **17. Label and instructions for use**

##### **17.1. General requirements regarding the information supplied by the manufacturer**

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

- (i) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.
- (ii) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices.

Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.

- (iii) In duly justified and exceptional cases instructions for use may not be needed or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.
- (iv) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification (RFID) or bar codes.
- (v) When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing.
- (vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, precautions or warnings in the information supplied by the manufacturer.
- (vii) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.
- (viii) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by that Regulation shall be given in the instructions for use.

- (ix) The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.

## 17.2. Information on the label

The label shall bear the following particulars:

- (i) The name or trade name of the device.
- (ii) The details strictly necessary for the user to identify the device and, where it is not obvious for the user, the intended purpose of the device;
- (iii) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business;
- (iv) If the manufacturer has his registered place of business outside the Union, the name and address of the authorised representative;
- (v) An indication that the device is an *in vitro* diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;
- (vi) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate.
- (vii) the unique device identification (UDI) carrier according to Article 22 and Annex V Part C;
- (viii) An unambiguous indication of the date until when the device may be used safely, without degradation of performance, expressed at least as the year, the month and, where relevant, the day, in that order;
- (ix) Where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable.
- (x) Where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these, or other terms which accurately reflect the contents of the package;
- (xi) An indication of any special storage and/or handling condition that applies.
- (xii) Where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness;

- (xiii) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;
- (xiiia) If the instructions for use are not provided in paper form in accordance with Section 17.1(v), a reference to their accessibility (or availability), and where applicable the website address where they can be consulted;
- (xiv) Where applicable, any particular operating instructions;
- (xv) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;
- (xvi) If the device is intended for self-testing or near-patient testing, an indication of that fact;
- (xvia) Where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;
- (xviii) Where device kits include individual reagents and articles that are made available as separate devices, each of these devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation;
- (xix) The devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. As far as practicable and appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging.
- (xixa) The label for devices for self-testing shall bear the following particulars:
  - (a) The type of specimen(s) required to perform the test (e.g. blood, urine or saliva);
  - (c) The need for additional materials for the test to function properly;
  - (d) Contact details for further advice and assistance.The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.

### **17.2a. On the sterile packaging:**

The following particulars shall appear on the sterile packaging:

- (a) an indication permitting the sterile packaging to be recognized as such,
- (b) a declaration that the device is in a sterile condition,
- (c) the method of sterilization,
- (d) the name and address of the manufacturer,
- (e) a description of the device,
- (f) the month and year of manufacture,
- (g) an indication of the time limit for using the device safely,
- (h) an instruction to check the Instructions For Use for what to do if the sterile packaging is damaged etc.

### **17.3. Information in the instructions for use**

17.3.1. The instructions for use shall contain the following particulars:

- (i) The name or trade name of the device;
- (ia) The details strictly necessary for the user to uniquely identify the device;
- (ii) The device's intended purpose:
  - what is detected and/or measured;
  - its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);
  - the specific information that is intended to be provided in the context of:
    - = a physiological or pathological state;
    - = congenital physical or mental impairments;
    - = the predisposition to a medical condition or a disease;
    - = the determination of the safety and compatibility with potential recipients;
    - = the prediction of treatment response or reactions;
    - = the definition or monitoring of therapeutic measures;
  - whether it is automated or not;
  - whether it is qualitative, semi-quantitative or quantitative;
  - the type of specimen(s) required; and
  - where applicable, the testing population.

- for companion diagnostics, the INN (International Non-proprietary Name) of the associated medicinal product for which it is a companion test.
- (iii) An indication that the device is an *in vitro* diagnostic medical device, or if the device is a 'device for performance study' an indication of that fact;
- (iv) The intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);
- (v) The test principle;
- (vi) A description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);
- (via) A description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;
- (vii) A list of materials provided and a list of special materials required but not provided;
- (viii) For devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment:
  - information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or
  - information on any known restrictions to combinations of devices and equipment.
- (ix) An indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;
- (x) In-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;
- (xi) If the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;

- (xii) Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information shall cover, where appropriate:
- warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance;
  - warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
  - warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures (*e.g.* electromagnetic interference emitted by the device affecting other equipment);
  - precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user;
  - if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;
  - if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilization. Information shall be provided to identify when the device should no longer be reused, *e.g.* signs of material degradation or the maximum number of allowable reuses.
- (xiii) Any warnings and/or precautions related to potentially infectious material that is included in the device;
- (xiv) Where relevant, requirements for special facilities (*e.g.* clean room environment) or special training (*e.g.* radiation safety), or particular qualifications of the device intended user;

- (xv) Conditions for collection, handling, and preparation of the specimen;
- (xvi) Details of any preparatory treatment or handling of the device before it is ready for use (*e.g.* sterilisation, final assembly, calibration, etc.) for the device to be used as intended by the manufacturer;
- (xvii) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:
  - details of the nature, and frequency, of preventative and regular maintenance, including cleaning and disinfection;
  - identification of any consumable components and how to replace them;
  - information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;
  - methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.
- (xviii) Where applicable, recommendations for quality control procedures;
- (xix) The metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials and/or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure;
- (xx) Assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to batch variation provided with relevant figures and units of measure;
- (xxi) Analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;



- (xxia) Clinical performance characteristics as defined in Chapter II Section 6.1. of this Annex;
- (xxib) The mathematical approach upon which the calculation of the analytical result is made;
- (xxii) Where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;
- (xxiii) Where relevant, reference intervals in normal and affected populations;
- (xxiv) Information on interfering substances or limitations (*e.g.* visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;
- (xxv) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:
  - infection or microbial hazards (*e.g.* consumables contaminated with potentially infectious substances of human origin);
  - environmental hazards (*e.g.* batteries or materials that emit potentially hazardous levels of radiation);
  - physical hazards (*e.g.* explosion).
- (xxvi) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;
- (xxvii) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;
- (xxviii) A notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State where the user and/or the patient is established;

- (xxix) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation.

17.3.1a. In the case of the following devices, other than devices for performance studies:

- (i) companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product;
- (ii) devices intended to be used in screening for or in the diagnosis of cancer;
- (iii) devices intended for human genetic testing of class C;

the instructions for use shall also contain a link to website where the summary of safety and performance is made available to the public via Eudamed, according to Article 24.

17.3.2 In addition, the instructions for use for devices intended for self-testing shall comply with the following principles:

- (i) Details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results;
- (ia) Specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;
- (ib) The device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;
- (ii) The results shall be expressed and presented in a way that is readily understood by the intended user;
- (iii) Information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result (*e.g.* age, gender, menstruation, infection, exercise, fasting, diet or medication);

- (iv) the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information specific to the Member State(s) where the device is placed on the market on where a user can obtain further advice (*e.g.* national helplines, websites, *etc.*);
- (v) for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.

## TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unequivocal way and shall include in particular the elements described in this Annex.

### 1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

#### 1.1. Device description and specification

- (a) product or trade name and a general description of the device including its intended purpose and intended user;
- (b) the Basic UDI device identifier as referred to in item (i) of point (a) of Article 24(1) and in Part C of Annex V attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;
- (c) the intended purpose of the device which may include:
  - (i) what is detected and/or measured;
  - (ii) its function (*e.g.* screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);
  - (iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
  - (iv) whether it is automated or not;
  - (v) whether it is qualitative, semi-quantitative or quantitative;
  - (vi) the type of specimen(s) required;
  - (vii) where applicable, the testing population;
  - (viii) the intended user.
  - (viii a) in addition, for companion diagnostics, the relevant target population and the associated medicinal product(s).

- (d) the description of the principle of the assay method or the principles of operation of the instrument;
- (da) the rationale for the qualification of the product as a device;
- (e) the risk class of the device and the justification of the classification rule(s) applied according to Annex VII;
- (f) the description of the components and where appropriate, the description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers); and where applicable:
- (g) the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use;
- (h) for instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays;
- (i) for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation;
- (j) a description of any software to be used with the device;
- (k) a description or complete list of the various configurations/variants of the device that will be made available;
- (l) a description of the accessories, other *in vitro* diagnostic medical devices and other products, which are intended to be used in combination with the device.

## **1.2. Reference to previous and similar generations of the device**

- (a) an overview of the manufacturer's previous generation(s) of the device, if such exist;
- (b) an overview of identified similar devices available on the EU or international markets, if such exist.

## **2. INFORMATION SUPPLIED BY THE MANUFACTURER**

- (a) a complete set of
  - the label(s) on the device and on its packaging (single unit packaging, sales packaging, transport packaging in case of specific management conditions), in the languages accepted in the Member States where the device is envisaged to be sold;

- the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold;

### **3. DESIGN AND MANUFACTURING INFORMATION**

#### **3.1. Design information**

Information to allow the understanding of the design stages applied to the device.

This shall include:

- (a) the description of the critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the device;
- (b) for instruments, the description of major subsystems, analytical technology (*e.g.* operating principles, control mechanisms), dedicated computer hardware and software;
- (c) for instruments and software, the overview of the entire system;
- (d) for software, the description of the data interpretation methodology (*i.e.* algorithm);
- (e) for devices intended for self-testing or near-patient testing devices the description of the design aspects that make them suitable for self-testing or near-patient testing.

#### **3.2. Manufacturing information**

- (a) Information to allow the understanding of the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information shall be provided for the audit of the quality management system or other applicable conformity assessment procedures;
- (b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.

#### **4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS**

The documentation shall contain demonstration of conformity with the general safety and performance requirements laid down in Annex I, applicable to the device and taking into account its intended purpose, including the justification, validation and verification of the solutions adopted to meet those requirements. This demonstration shall include:

- (a) the general safety and performance requirements that apply to the device and why others do not apply;
- (b) the method(s) used to demonstrate conformity with each applicable general safety and performance requirement;
- (c) the harmonised standards or CS applied or other solutions employed;
- (d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method employed to demonstrate conformity with the general safety and performance requirements. This information shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

#### **5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT**

The documentation shall contain

- (a) the risk/benefit analysis referred to in Sections 1 and 5 of Annex I, and
- (b) the solutions adopted and the results of the risk management referred to in Section 1a of Annex I.

#### **6. PRODUCT VERIFICATION AND VALIDATION**

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

This includes:

## **6.1. Information on analytical performance**

### **6.1.1. Specimen type**

This section shall describe the different specimen types that can be used, including their stability (*e.g.* storage, where applicable transport conditions and, with a view to time-critical analysis methods, information on the timeframe between taking the specimen and its analysis) and storage conditions (*e.g.* duration, temperature limits and freeze/thaw cycles).

### **6.1.2. Analytical performance characteristics**

#### **6.1.2.1. Accuracy of measurement**

##### **(a) Trueness of measurement**

This section shall provide information on the trueness of the measurement procedure and summarise the data in sufficient detail to allow assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available.

##### **(b) Precision of measurement**

This section shall describe repeatability and reproducibility studies.

#### **6.1.2.2. Analytical sensitivity**

This section shall include information about the study design and results. It shall provide a description of specimen type and preparation including matrix, analyte levels, and how levels were established. The number of replicates tested at each concentration shall also be provided as well as a description of the calculation used to determine assay sensitivity.



#### 6.1.2.3. Analytical specificity

This section shall describe interference and cross reactivity studies to determine the analytical specificity in the presence of other substances/agents in the specimen.

Information shall be provided on the evaluation of potentially interfering and cross reacting substances/agents on the assay, on the substance/agent type and concentration tested, specimen type, analyte test concentration, and results.

Interferents and cross reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:

- (a) substances used for patient treatment (*e.g.* medicinal products);
- (b) substances ingested by the patient (*e.g.* alcohol, foods);
- (c) substances added during specimen preparation (*e.g.* preservatives, stabilisers);
- (d) substances encountered in specific specimens types (*e.g.* haemoglobin, lipids, bilirubin, proteins);
- (e) analytes of similar structure (*e.g.* precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition.

#### 6.1.2.4. Metrological traceability of calibrator and control material values

#### 6.1.2.5. Measuring range of the assay

This section shall include information on the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established.

This information shall include a description of specimen type, number of specimen, number of replicates, and preparation including information on matrix, analyte levels and how levels were established. If applicable, a description of high dose hook effect and the data supporting the mitigation (*e.g.* dilution) steps shall be added.

#### 6.1.2.6. Definition of assay cut-off

This section shall provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including:

- (a) the population(s) studied (demographics / selection / inclusion and exclusion criteria / number of individuals included);
- (b) method or mode of characterisation of specimens; and
- (c) statistical methods e.g. Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.

#### 6.1.3. The Analytical Performance Report according to Annex XII.

### 6.2. **Information on clinical performance and clinical evidence. Performance Evaluation Report**

The documentation shall contain the performance evaluation report, which includes the reports on the scientific validity, the analytical and the clinical performance, according to Annex XII, together with an assessment of these reports.

The clinical performance study documents referred to in Part A, Section 2 of Annex XII shall be included and/or fully referenced in the technical documentation.

### 6.3. **Stability (excluding specimen stability)**

This section shall describe claimed shelf life, in use stability and shipping stability studies.

#### 6.3.1. Claimed shelf-life

This section shall provide information on stability testing studies to support the claimed shelf life. Testing shall be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but shall be followed up with real time stability studies.

Such detailed information shall describe:

- (a) the study report (including the protocol, number of lots, acceptance criteria and testing intervals);
- (b) when accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies;
- (c) the conclusions and claimed shelf life.

#### 6.3.2. In-use stability

This section shall provide information on in-use stability studies for one lot reflecting actual routine use of the device (real or simulated). This may include open vial stability and/or, for automated instruments, on board stability.

In the case of automated instrumentation if calibration stability is claimed, supporting data shall be included.

Such detailed information shall describe:

- (a) the study report (including the protocol, acceptance criteria and testing intervals);
- (b) the conclusions and claimed in-use stability.

### 6.3.3. Shipping stability

This section shall provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions.

Shipping studies can be done under real and/or simulated conditions and shall include variable shipping conditions such as extreme heat and/or cold.

Such information shall describe:

- (a) the study report (including the protocol, acceptance criteria);
- (b) the method used for simulated conditions;
- (c) the conclusion and recommended shipping conditions.

### 6.4. Software verification and validation

The documentation shall contain evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed in-house and as applicable in an actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

### 6.5. Additional information in specific cases

- (a) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.
- (b) In the case of devices containing tissues, cells and substances of animal, human or microbial origin, information on the origin of such material and on the conditions in which it was collected.

- (c) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.
- (d) If the device is to be connected to other equipment in order to operate as intended, a description of this combination including proof that it conforms to the general safety and performance requirements when connected to any such equipment having regard to the characteristics specified by the manufacturer.

## TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Section 0 of Chapter VII shall be presented in a clear, organized, readily searchable and unequivocal way and shall include in particular:

1.1. The post-market surveillance plan in accordance with Article 58b.

The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 58a.

- (a) The post-market surveillance plan shall address the collection and utilization of available information, in particular:
- information concerning serious incidents, including information from periodic safety update reports, and field safety corrective actions,
  - records referring to non-serious incidents and data on any undesirable side effects,
  - information from trend reporting,
  - relevant specialist or technical literature, databases and/or registers,
  - information, including feedbacks and complaints, provided by users, distributors and importers,
  - publicly available information about similar medical devices.
- (b) The post-market surveillance plan shall include at least:
- a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterization of the performance of the devices also comparing the device with the similar products available on the market;
  - effective and appropriate methods and processes to assess the collected data;
  - suitable indicators and threshold values that shall be used in the continuous reassessment of the risk benefit analysis and of the risk management as referred to in Section 1a of Annex I;

- effective and appropriate methods and tools to investigate complaints or market experiences collected in the field;
- methods and protocols to manage the events subject to trend report as provided in Article 59a, including those to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;
- methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;
- reference to procedures to fulfil the manufacturers obligations laid down in Articles 58a, 58b and 58c;
- systematic procedures to identify and initiate appropriate measures including corrective actions;
- effective tools to trace and identify devices for which corrective actions might be necessary;
- a post-market performance follow-up plan according to Part B of Annex XII, or a justification why a post-market performance follow-up is not applicable.

1.3 The periodic safety update report referred to in article 58c and the post-market surveillance report referred to in Article 58ba.

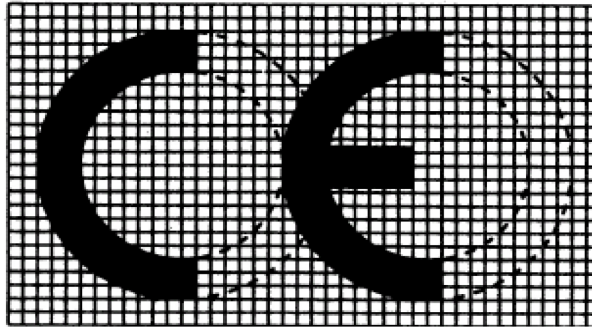
## EU DECLARATION OF CONFORMITY

1. Name, registered trade name or registered trade mark and single registration number referred to in Article 23a of the manufacturer, and, if applicable, his authorised representative, and the address of their registered place of business where they can be contacted and their location be established;
2. A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;
3. The basic UDI-DI as referred to in item (i) of point (a) of Article 22(1) and in Part C of Annex V as soon as identification of the device that is covered by the declaration shall be based on a UDI system;
4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered by the declaration (it may include a photograph, where appropriate), including its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the device identifier referred to in point 3;
5. Risk class of the device in accordance with the rules set out in Annex VII;
6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;
7. References to CS used in relation to which conformity is declared;
8. Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued;
9. Where applicable, additional information;
10. Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.



## CE MARKING OF CONFORMITY

1. The CE marking shall consist of the initials 'CE' taking the following form:



2. If the CE marking is reduced or enlarged the proportions given in the above graduated drawing shall be respected.
3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

**INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF  
DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH  
ARTICLE 23a  
AND  
CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATA BASE  
TOGETHER WITH THE DEVICE IDENTIFIER IN ACCORDANCE WITH  
ARTICLE 22a  
AND  
THE EUROPEAN UNIQUE DEVICE IDENTIFICATION SYSTEM**

**Part A**

**Information to be submitted with the registration of devices and economic operators in  
accordance with Article 23a**

Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the information referred to in Section 1 and shall ensure that the information on their devices referred to in Section 2 is complete, correct and updated by the relevant party.

**1. Information related to the economic operator**

- 1.1. economic operator's role (manufacturer, authorised representative, or importer),
- 1.2. name, address and contact details of the economic operator,
- 1.3. where submission of information is completed by another person on behalf of any of the economic operators mentioned under point 1, the name, address and contact details of this person,
- 1.3a. name address and contact details of the person(s) responsible for regulatory compliance according to article 13,

## **2. Information related to the devices**

- 2.4. UDI device identifier, or where identification of the device is not yet based on a UDI system, the data elements laid down in points 5 to 18 of Part B of this Annex,
- 2.5. type, number and expiry date of certificate and name or identification number of the notified body that has issued the certificate (and link to the information on the certificate entered by the notified body in the electronic system on certificates),
- 2.6. Member State where the device shall or has been placed on the market in the Union,
- 2.7. in case of devices classified as classes B, C or D: Member States where the device is or shall be made available,
- 2.9. presence of tissues, cells or substances of human origin (y/n),
- 2.10. presence of tissues, cells or substances of animal origin (y/n),
- 2.11. presence of cells or substances of microbial origin (y/n),
- 2.12. risk class of the device according to the rules set out in Annex VII,
- 2.13. where applicable, single identification number of the performance study,
- 2.14. in case of devices designed and manufactured by another legal or natural person as referred in Article 8(10), the name, address and contact details of that legal or natural person,
- 2.15. in case of devices classified as class C or D, the summary of safety and performance,
- 2.16. status of the device (on the market, no longer placed on the market, recalled, Field Safety Corrective Action initiated),
- 2.17. indication when the device is a 'new' device.  
A device shall be considered as 'new' if:
  - (a) there has been no such device continuously available on the Union market during the previous three years for the relevant analyte or other parameter;
  - (b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Union market during the previous three years.
- 2.18. Indication if the device is intended for self-testing or near-patient testing.

**PART B**

**CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER  
WITH THE UDI DEVICE IDENTIFIER IN ACCORDANCE WITH ARTICLE 22a**

The manufacturer shall provide to the UDI data base the UDI device identifier (UDI-DI) and to the following information related to the manufacturer and the device:

1. quantity per package configuration,
2. if applicable, the Basic UDI-DI according to Article 22(4b) and additional identifier(s),
3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number),
4. if applicable, the 'unit of use' device identifier (when a UDI is not assigned to the device at the level of its 'unit of use', a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient),
5. name and address of the manufacturer (as indicated on the label),
- 5a. the single registration number according to Article 23a(2),
6. if applicable, name and address of the authorised representative (as indicated on the label),
7. Medical Device Nomenclature code according to Article 21a,
- 7a. risk class of the device,
8. if applicable, trade/brand name,
9. if applicable, device model, reference, or catalogue number,
10. additional product description (optional),
11. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),
12. if applicable, additional trade names of the device,
13. labelled as single use device (y/n),
14. if applicable, restricted number of reuses,
15. device packaged sterile (y/n),
16. need for sterilisation before use (y/n),
17. URL for additional information, *e.g.* electronic instructions for use (optional),
18. if applicable, critical warnings or contraindications,
19. status of the device on the market (choice box, no longer placed on the market, recalled, Field Safety Action initiated).

## **PART C**

### **The European Unique Device Identification System**

#### **1. Definitions**

Automatic Identification and Data Capture (hereinafter AIDC)

AIDC is a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and shall be referenced in relevant certificates and declarations of conformity.

Unit of Use DI

The Unit of Use DI serves to associate the use of a device to/on a patient to data related to that patient in instances when a UDI is not labelled at the level of the device unit of use (*e.g.* several units contained in a plastic bag).

Configurable device

A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves.

Configuration

Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together to provide an intended use or purpose as a device. The combination of items may be modified, adjusted or customized to meet a customer need.

Device Identifier (hereinafter UDI-DI)

The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the "access key" to information stored in a UDI database.

### Human Readable Interpretation (hereinafter HRI)

Human Readable Interpretation is a legible interpretation of the data characters encoded in the UDI Carrier.

### Packaging levels

Packaging levels means the various levels of device packages that contain a fixed quantity of devices, *e.g.* each carton or case.

### Production Identifier (hereinafter UDI-PI)

The Production Identifier is a numeric or alphanumeric code that identifies the unit of device production.

The different types of Production Identifier(s) include serial number, lot/batch number, Software identification and/or manufacturing and/or expiration date.

### Radio Frequency Identification (hereinafter RFID)

RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.

### Shipping containers

Shipping container is a container where the traceability is controlled by a process specific to logistics systems.

### Unique Device Identification

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI and the UDI-PI.

Note: The word "Unique" does not imply serialization of individual production units.

### UDI Carrier

The UDI Carrier is the means to convey the UDI by using AIDC and, if applicable, its HRI.

Note: Carriers include, *inter alia*, ID/linear bar code, 2D/Matrix bar code, RFID.

## **2. UDI system - General requirements**

- 2.1. The marking of the UDI is an additional requirement – it does not replace any other marking or labelling requirements described in Annex I of this regulation.
- 2.2. The manufacturer shall create and maintain unique UDIs on his devices.
- 2.3. Only the manufacturer may establish the UDI on the device or its packaging.
- 2.4. Only coding standards offered by assigning entities designated by the European Commission according to article 22(2) may be used by the manufacturers.

## **3. The UDI**

- 3.1. A UDI shall be assigned to the device itself or its package. Higher levels of packaging shall have their own UDI.
- 3.2. Shipping containers shall be exempted. As an example, UDI is not required on a logistics unit; when a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places these devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) is not subject to UDI requirements.
- 3.3. The UDI shall contain two parts: an UDI-DI and an UDI-PI.
- 3.4. The UDI-DI shall be unique at all levels of device packaging.
- 3.5. If a lot number, serial number, software identification or expiration date appears on the label, they shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does NOT need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.
- 3.7. Each component that is considered a device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.
- 3.8. Kits shall be assigned and bear their own UDI.
- 3.9. The manufacturer shall assign the UDI to a device following the relevant coding standard.

- 3.10. A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability, in particular any change of one of the following UDI database data elements require a new UDI-DI:
- (a) Brand Name or Trade name,
  - (b) Device version or model,
  - (d) Labelled as single use,
  - (e) Packaged sterile,
  - (f) Need for sterilization before use,
  - (g) Quantity of devices provided in a package,
  - (h) Critical warnings or contraindications.
- 3.12. Manufacturers who repackage or relabel devices with their own label shall retain record of the Original Equipment Manufacturer's (OEM) UDI.

#### **4. UDI Carrier**

- 4.1. The UDI Carrier (AIDC and HRI representation of the UDI) shall be placed on the label and on all higher levels of device packaging. Higher levels do not include shipping containers.
- 4.2. In case of significant space constraints on the unit of use package the UDI carrier may be placed on the next higher package level.
- 4.3. For single use devices of class A and B packaged and labelled individually the UDI Carrier shall not be required to appear on the package but it shall appear on a higher level of packaging *e.g.* a carton containing several packages. However when the healthcare provider is not expected to have access (home healthcare settings) to the higher level of device packaging, the UDI shall be placed on the package.
- 4.4. For devices exclusively intended for retail Point of Sale (POS) the Production Identifiers in AIDC shall not be required to appear on the point of sale package.
- 4.5. When AIDC carriers other than the UDI Carrier are part of the product labelling, the UDI Carrier shall be readily identifiable.
- 4.6. If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.



- 4.7. If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label. For devices intended to be used outside of healthcare facilities such as devices for home care, the HRI shall however appear on the label even if this means that there is no space for the AIDC.
- 4.8. The HRI format shall follow the rules of the UDI code issuing organization.
- 4.9. If the manufacturer is using RFID technology, a linear or 2D bar code according to the standard provided by the assigning entities shall also be provided on the label.
- 4.10. Devices that are reusable shall bear a UDI Carrier on the device itself. The UDI Carrier of reusable devices that require disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the next use for the intended lifetime of the device.
- 4.11. The UDI Carrier shall be readable during normal use and throughout the intended life of the device.
- 4.12. If the UDI Carrier is readily readable or scanable through the device's package, then the placing of the UDI Carrier on the package shall not be required.
- 4.13. A single finished device made up of multiple parts that must be assembled before first use may bear the UDI Carrier on only one part.
- 4.14. The UDI Carrier shall be placed so that the AIDC can be accessed during normal operation or storage.
- 4.15. The bar code carrier(s) that include(s) UDI data identifiers "UDI-DI" and "UDI-PI" may also include essential data for the device to operate or other data.

## **5. The UDI database - General principles of the UDI database**

- 5.1. The UDI database shall support the use of all core UDI database data elements.
- 5.3. The manufacturer shall be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.
- 5.4. Appropriate methods/procedures for validation of the provided data shall be implemented.
- 5.5. The manufacturer shall periodically reconfirm all the data relevant to devices he has placed on the market, except for devices that are no more available on the market.
- 5.7. The presence of the device UDI-DI in the UDI database does not mean that the device is in conformity with this Regulation.
- 5.8. The database shall allow for the linking of all the packaging levels of the device.

- 5.9. The data for new UDI-DI shall be available at the time device is placed on the market.
- 5.10. Manufacturers shall update the relevant UDI database record within 30 days when a change is made to an element that does NOT require a new UDI-DI.
- 5.11. Internationally accepted standards for data submission and updates shall, wherever possible, be used by the UDI Database.
- 5.12. The core elements are the minimum elements needed to identify a device throughout its distribution and use.
- 5.13. The user interface of the UDI Database shall be available in all official languages of the Union in accordance with article 51(4b). The use of free-text fields shall, however, be minimized in order to reduce translations.
- 5.14. Data relating to devices that are no more available on the market shall be retained in the UDI database.

## **6. Rules for specific device types**

- 6.2. Reusable medical devices that are part of kits and that require cleaning, disinfection, sterilisation or refurbishing between uses
  - 6.2.1. The UDI of such devices shall be placed on the device and be readable after each procedure to make the device ready for the next use;
  - 6.2.2. The PI characteristics (*e.g.* lot or serial number) shall be defined by the manufacturer.
- 6.5. *In vitro* diagnostic medical device software
  - 6.5.1. UDI Assignment Criteria

The UDI shall be assigned at the system level of the software. Only software which are commercially available on their own and software which are medical devices in themselves, shall be subject to this requirement.

The software identification shall be considered the manufacturing control mechanism and shall be displayed in the UDI-PI.

6.5.1a. A new UDI-DI shall be required whenever there is a modification that changes:

- (a) the original performance and effectiveness,
- (b) the safety or the intended use of the Software.
- (c) interpretation of data.

These changes may include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

6.5.1b. The following changes of a Software shall require only a new UDI-PI (not a new UDI-DI):

Minor software revisions shall be identified with a new UDI-PI;

Minor software revisions are generally associated with bug fixes, usability enhancements (not for safety purpose), security patches or operating efficiency.

Minor revisions shall be identified by manufacturer-specific identification.

6.5.2. UDI Placement Criteria for Software

- (a) When the Software is delivered on a physical medium, *e.g.* CD or DVD, each package level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the software and its packaging must be identical to the UDI assigned to the system level software.
- (b) The UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format (*e.g.* an “about” file or included on the start-up screen).
- (c) Software lacking a user interface (*e.g.* middleware for image conversion) shall be capable of transmitting the UDI through an Application Programming Interface (API).
- (d) Only the human readable portion of the UDI shall be required in electronic displays of the software. The UDI AIDC marking shall not be required in the electronic displays, *e.g.* about menu, splash screen, etc.
- (e) The human readable format of the UDI for the software shall include the Application Identifiers (AI) of the used standard of the assigning entities, to assist the user in identifying the UDI and determining which standard is being used to create the UDI.

**REQUIREMENTS TO BE MET BY NOTIFIED BODIES****1. ORGANISATIONAL AND GENERAL REQUIREMENTS****1.1. Legal status and organisational structure**

- 1.1.1. A notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect, and shall have full documentation of its legal personality and status. This shall include information about ownership and the legal or natural persons exercising control over the notified body.
- 1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of this organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In this instance, the requirements of Section 1.2 of this Annex are applicable to both the notified body and the organisation to which it belongs.
- 1.1.3. If the notified body wholly or partly owns legal entities established in a Member State or in a third country or is owned by another legal entity, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented. Personnel of those entities performing conformity assessment activities according to this Regulation are subject to the applicable requirements of this Regulation.
- 1.1.4. The organisational structure, allocation of responsibilities, reporting lines and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.

- 1.1.5. The notified body shall clearly document its organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel who may have an influence upon the performance and results of the conformity assessment activities.
- 1.1.6. The notified body shall identify the top-level management that have overall authority and responsibility for each of the following:
- the provision of adequate resources for conformity assessment activities;
  - the development of procedures and policies for the operation of the notified body;
  - the supervision of implementation of the procedures, policies and quality management systems;
  - the supervision of the notified body's finances;
  - the activities and decisions taken by the notified body, including contractual agreements;
  - the delegation of authority to personnel and/or committees, where necessary, for the performance of defined activities; and
  - the interaction with the national authority responsible for notified bodies and the obligations regarding communications with other competent authorities, the Commission and other notified bodies.

## **1.2. Independence and impartiality**

- 1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitors of the manufacturer.

This does not preclude conformity assessment activities for competing manufacturers.

- 1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall document and implement a structure and procedures for safeguarding impartiality and for promoting and applying the principles of impartiality throughout its organisation, personnel and assessment activities. These procedures shall allow for the identification, investigation and resolution of any case in which a conflict of interests may arise including involvement in consultancy services in the field of *in vitro* diagnostic medical devices prior to taking up employment with the notified body. The investigation, outcome and its resolution shall be documented.
- 1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not
- be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of the products which they assess, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body, the conduct of the conformity assessment or the use of such products for personal purposes;
  - be involved in the design, manufacture or construction, the marketing, installation and use or maintenance of those products for which they are designated, nor represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated;
  - offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment.
  - be linked to any organisation which itself provides consultancy services as referred to in the previous indent. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

- 1.2.3a. Involvement in consultancy services in the field of *in vitro* diagnostic medical devices prior to taking up employment with a notified body shall be fully documented at the time of employment and potential conflicts of interests shall be monitored and resolved according to criteria set out in this Annex. Personnel who were former employees or provided consultancy services in the field of *in vitro* diagnostic medical devices for a specific client, prior to taking up employment with a notified body shall not be assigned for conformity assessment activities for that specific client or companies belonging to the same group for a period of 3 years.
- 1.2.4. The impartiality of the notified bodies, of their top level management and of the assessment personnel shall be guaranteed. The level of the remuneration for the top level management and assessment personnel of a notified body and subcontractors involved in assessment activities shall not depend on the results of the assessments. The notified body shall make publicly available the declarations of interest of its top-level management.
- 1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.
- 1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors or of any associated body, including the activities of its owners do not affect its independence, impartiality or objectivity of its conformity assessment activities.
- 1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC in relation to fees.
- 1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.

### **1.3. Confidentiality**

- 1.3.1. The notified body shall have documented procedures in place ensuring that confidentiality of the information which comes into its possession during the performance of the conformity assessment activities is observed by its personnel, committees, subsidiaries, subcontractors, any associated body or personnel of external bodies, except when disclosure is required by law.
- 1.3.2. The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation or any provision of national law giving effect to it, except in relation to the national authorities responsible for notified bodies, competent authorities for *in vitro* diagnostic medical devices in the Member States or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

### **1.4. Liability**

- 1.4.1. The notified body shall take out appropriate liability insurance , unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
- 1.4.2. The scope and overall financial value of the liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk profile of the devices certified by the notified body. The liability insurance shall cover cases where the notified body may be obliged to withdraw, restrict or suspend certificates.

### **1.5. Financial requirements**

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities within its scope of designation and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking in to account specific circumstances during an initial start-up phase.



## **1.6. Participation in coordination activities**

1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

1.6.1a. The notified body shall take into consideration guidance and best practice documents.

## **2. QUALITY MANAGEMENT REQUIREMENTS**

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and capable of supporting and demonstrating the consistent achievement of the requirements of this Regulation.

2.2. The quality management system of the notified body shall at least address the following:

- management system structure and documentation, including policies and objectives for its activities;
- policies for assignment of personnel to activities and their responsibilities;
- assessment and decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other notified body personnel;
- planning, conducting, evaluating and, if necessary, adapting its conformity assessment procedures;
- control of documents;
- control of records;
- management review;
- internal audits;
- corrective and preventive actions;
- complaints and appeals;
- continuous training.

If documents are used in various languages the notified body shall ensure and control that they have the same content.

- 2.3. The notified body top management shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation including subsidiaries and subcontractors being involved in conformity assessment activities according to this Regulation.
- 2.4. The notified body shall require all personnel to formally commit themselves by a signature or equivalent to comply with the procedures defined by the notified body. The commitment shall consider aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with clients. The personnel shall be required to complete written statements indicating their compliance to confidentiality, independence and impartiality principles.

### **3. RESOURCE REQUIREMENTS**

#### **3.1. General**

- 3.1.1. A notified body shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

In particular, it shall have the necessary personnel and possess or have access to all equipment, facilities and competence needed to perform properly the technical, scientific and administrative tasks entailed in the conformity assessment activities in relation to which it has been designated.

This presupposes at all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been designated, that the notified body has permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant devices and the corresponding technologies. These shall be sufficient to ensure that the notified body can perform the conformity assessment tasks including the assessment of the medical functionality, performance evaluations and the performance and safety of devices, for which it has been designated, having regard to the requirements of this Regulation, in particular those set out in Annex I.

A specific notified body's cumulative competence must enable it to assess the specific devices for which it is designated. The notified body must have sufficient internal competence to critically evaluate assessments conducted by external expertise. Specific tasks which a notified body cannot subcontract are outlined in Section 4.2 of this Annex.

Personnel involved in the management of the operation of the notified body's conformity assessment activities for devices shall have appropriate knowledge to set up and operate a system for the selection of the assessment and verification staff, verification of their competence, authorisation for and allocation of their tasks, their initial and ongoing training, their instruction and monitoring to ensure that personnel who administer and perform assessment and verification operations are competent to fulfil the tasks required of them.

The notified body shall identify at least one individual within its top-level management having overall responsibility for all conformity assessment activities in relation to *in vitro* diagnostic medical devices.

- 3.1.2a. The notified body shall ensure that personnel involved in conformity assessment activities maintain their qualification and expertise by implementing a system for exchange of experience and a continuous training and education programme.

- 3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation to the personnel, including any subcontractors and external experts involved in conformity assessment activities and inform these personnel accordingly.

### **3.2. Qualification criteria in relation to personnel**

- 3.2.1. The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (*e.g.* auditing, product evaluation/testing, technical documentation review, decision-making, batch release) as well as the devices, technologies and areas (*e.g.* biocompatibility, sterilisation, self and near patient-testing, companion diagnostics, performance evaluation) covered by the scope of designation.
- 3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 31, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined at least for the assessment of biological safety, performance evaluation, devices for self and near patient testing, companion diagnostics, functional safety, software, packaging and the different types of sterilisation processes.

- 3.2.3. The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall be employed by the notified body itself and shall not be an external expert or subcontracted. They shall have proven knowledge and experience in the following:
- Union *in vitro* diagnostic medical devices legislation and relevant guidance documents;
  - the conformity assessment procedures in accordance with this Regulation;

- a broad base of *in vitro* diagnostic medical device technologies, and the design and manufacture of *in vitro* diagnostic medical devices;
- the notified body's quality management system, related procedures and the required qualification criteria;
- training relevant to personnel involved in conformity assessment activities in relation to *in vitro* diagnostic medical devices;
- adequate experience in conformity assessments under this Regulation or previously applicable law within a notified body.

3.2.4. The notified body shall have permanent availability of personnel with relevant clinical expertise where possible employed by the notified body itself. These personnel shall be integrated throughout the notified body's assessment and decision-making process in order to:

- identify when specialist input is required for the assessment of the performance evaluation conducted by the manufacturer and identify appropriately qualified experts;
- appropriately train external clinical experts in the relevant requirements of this regulation, CS, guidance and harmonised standards and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;
- be able to review and scientifically challenge the clinical data contained within the performance evaluation, and any associated performance study, and appropriately guide external clinical experts in the assessment of the performance evaluation presented by the manufacturer;
- be able to scientifically evaluate and, if necessary, challenge the performance evaluation presented, and the results of the external clinical experts' assessment of the manufacturers performance evaluation;
- be able to ascertain the comparability and consistency of the assessments of performance evaluation conducted by clinical experts;
- be able to make an assessment of the manufacturer's performance evaluation and a clinical judgement of the opinion provided by any external expert and make a recommendation to the notified body's decision maker;

- be able to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.5. The personnel (Product Reviewers) responsible for carrying out product related review (e.g. technical documentation review or type examination including aspects such as performance evaluation, biological safety, sterilisation, software validation) shall have the following proven qualifications:

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, pharmacy, engineering or other relevant sciences;
- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of devices or technology to be assessed or related to the scientific aspects to be assessed;
- knowledge of the *in vitro* diagnostic medical device legislation, including the general safety and performance requirements laid down in Annex I;
- appropriate knowledge and experience of relevant harmonised standards, CS and guidance documents;
- appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;
- appropriate knowledge and experience of performance evaluation;
- appropriate knowledge of the devices which they are assessing;
- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out those assessments;
- the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.6. The personnel (Site Auditors) responsible for carrying out audits of the manufacturer's quality management system shall have the following proven qualifications:

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, *e.g.* medicine, pharmacy, engineering or other relevant sciences;
- four years professional experience in the field of healthcare products or related sectors (*e.g.* industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management;
- appropriate knowledge of the *in vitro* diagnostic medical devices legislation as well as related harmonised standards, CS and guidance documents;
- appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;
- appropriate knowledge of quality management systems and related *in vitro* diagnostic medical devices standards and guidance documents;
- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out those audits;
- training in auditing techniques enabling them to challenge quality management systems;
- the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.7. The personnel with overall responsibility for final review and decision-making on certification shall be employed by the notified body itself and shall not be external expert or be subcontracted. These personnel, together, shall have proven knowledge and comprehensive experience of the following:

- the *in vitro* diagnostic medical devices legislation and relevant guidance documents;
- the *in vitro* diagnostic medical device conformity assessments relevant to this Regulation;
- the types of qualifications, experience and expertise relevant to medical device conformity assessment;
- a broad base of *in vitro* diagnostic medical device technologies, including sufficient experience of the conformity assessment of the devices being reviewed for final certification, the *in vitro* diagnostic medical device industry and the design and manufacture of devices;
- the notified body's quality system, related procedures and the required qualification criteria;
- the ability to draw up records and reports demonstrating that the conformity assessment activities have been appropriately carried out.

### **3.3. Documentation of qualification, training and authorisation of personnel**

3.3.1. The notified body shall have a process in place to fully document the qualification of each personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2. Where in exceptional circumstances the fulfilment of the qualification criteria set out in Section 3.2 cannot be fully demonstrated, the notified body shall justify to the national authority responsible for notified bodies the authorisation of these personnel to carry out specific conformity assessment activities.



3.3.2. For all of its personnel referred to in Sections 3.2.3. to 3.2.7., the notified body shall establish and maintain up to date:

- a matrix detailing the authorisations and responsibilities of the personnel in respect of the conformity assessment activities;
- records demonstrating the required knowledge and experience for the conformity assessment activity for which they are authorised. The records shall contain a rationale for defining the scope of the responsibilities for each of the assessment personnel and records of the conformity assessment activities carried out by each of them.

### **3.4. Subcontractors and external experts**

3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract certain clearly defined component parts of a conformity assessment activity.

The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed, but nevertheless parts of these activities can be conducted by subcontractors and external auditors and experts working on behalf of the notified body. The notified body retains the full responsibility for being able to produce appropriate evidence of the competence of subcontractors and experts to fulfil their specific tasks, retains full responsibility for making a decision based on a subcontractor's assessment and full responsibility for the work conducted by subcontractors and experts on its behalf.

The following activities may not be subcontracted by the notified body:

- review of the qualification and the monitoring of the performance of external experts;
- auditing and certification activities to auditing or certification organisations;
- allocation of work to external experts for specific conformity assessment activities;
- final review and decision making functions.

- 3.4.2. Where a notified body subcontracts certain conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place, and shall ensure that:
- the subcontractor meets the relevant requirements of this Annex;
  - subcontractors and external experts do not further subcontract work to organisations or personnel;
  - the natural or legal person that applied for conformity assessment has been informed of this.

Any subcontracting or consultation of external personnel shall be properly documented and shall be subject to a direct written agreement covering, among others, confidentiality and conflict of interests. The notified body shall take full responsibility for the tasks performed by subcontractors.

- 3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel *in vitro* diagnostic medical devices or technologies, the notified body shall have adequate own competence in each product area for which it is designated to lead the overall conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.

### **3.5. Monitoring of competences, training and exchange of experience**

- 3.5.1. The notified body shall establish procedures for the initial evaluation and on-going monitoring of the competence, conformity assessment activities and performance of all internal and external personnel and subcontractors, involved in conformity assessment activities.

- 3.5.2. It shall review at regular intervals, the competence of its personnel, identify training needs and draw up a training plan to maintain the required level of qualification and knowledge of individual personnel. This review shall as a minimum, verify that personnel:
- are aware of the current *in vitro* diagnostic medical device Regulation, relevant harmonised standards, CS, guidance documents and the results of the coordination activities according to Section 1.6 of this Annex;
  - take part in the internal exchange of experience and the continuous training and education programme according to Section 3.1.2a.

## **4. PROCESS REQUIREMENTS**

### **4.2. General**

The notified body shall have in place documented processes and sufficiently detailed procedures for the conduct of each conformity assessment activity for which it is designated, comprising the individual steps from pre-application activities until decision making and surveillance and taking into account, when necessary, the respective specificities of the devices.

The requirements outlined in Sections 4.4., 4.5., 4.8. and 4.9. shall be internal activities of the notified body and shall not be subcontracted.

### **4.3. Notified body quotations and pre-application activities**

The notified body shall

- publish a publicly available description of the application procedure by which manufacturers can obtain certification by the notified body. This description shall include which languages are acceptable for submission of documentation and for any related correspondence,
- have documented procedures relating to, and documented details about, fees charged for specific conformity assessment activities and any other financial conditions relating to its assessment activities for devices,

- have documented procedures in relation to advertising of its conformity assessment services. These shall ensure that advertising or promotional activities in no way imply or could lead to inference that their conformity assessment will offer manufacturers earlier market access or be quicker, easier or less stringent than other notified bodies,
- have documented procedures requiring the review of pre-application information including the preliminary verification that the product is covered by this Regulation and its classification prior to issuing any quotation to the manufacturer relating to a specific conformity assessment,
- ensure that all contracts relating to the conformity assessment activities covered by this Regulation are established directly between the manufacturer and the notified body and not with any other organisation.

#### **4.4. Application and contract review**

The notified body shall require a formal application signed by the manufacturer or an authorised representative containing all of the information and manufacturer's declarations required by the relevant conformity assessment annexes VIII to X.

The contract between the notified body and the manufacturer shall take the form of a written agreement signed by both parties. It shall be kept by the notified body. This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required by this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, restrict or withdraw certificates issued and the right of the notified body to fulfil its information obligations.

The notified body shall have documented procedures to review applications, addressing:

- the completeness with respect to the requirements provided in the respective Annex under which approval has been sought,
- the verification of the qualification of the products covered by the application as devices and their specific classification(s),
- the legal applicability of the conformity assessment route chosen by the applicant,

- the ability of the notified body to assess the application based on their designation, and
- the availability of sufficient and appropriate resources.

The outcome of this review shall be documented. Refusals or withdrawals of applications shall be notified to the European databank and shall be accessible to other notified bodies.

#### **4.5. Allocation**

The notified body shall have documented procedures to ensure that all conformity assessment activities are conducted by appropriately authorised and qualified personnel who are sufficiently experienced in the evaluation of the devices, systems and processes and related documentation that are subject to conformity assessment.

For each application, the notified body shall determine the resource needs and identify one individual responsible for ensuring that the assessment of each application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources/personnel are utilised for individual tasks of the assessment. The allocation of tasks required for the conformity assessment and any changes subsequently made to this allocation shall be documented.

#### **4.6. Conformity assessment activities**

##### **4.6.1. General**

The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.

The notified body shall have sufficient expertise, facilities and detailed documented procedures to effectively conduct the conformity assessment activities, taking account of the specific requirements set out in Annex VIII, IX and X of this Regulation for which it is designated, including the requirements:

- to appropriately plan the conduct of each individual project; these shall ensure that the composition of the assessment teams assures experience with the technology concerned, continuous objectivity and independence, which shall include provision for rotation of the members of the assessment team at appropriate intervals,
- to detail the rationale for fixing time limits for completion of conformity assessment activities,
- to assess the manufacturer's technical documentation and the solutions adopted to meet the Requirements laid out in Annex I,
- to review the manufacturer's procedures and documentation relating to performance evaluation,
- to address the interface with the risk management process and the appraisal and analysis of the performance evaluation and its relevance to demonstrate conformity to the relevant requirements in Annex I,
- to carry out the "specific procedures" in the case of devices incorporating medicinal substances, human blood derivatives or in the case of devices manufactured utilising non-viable tissues or cells,
- to assess, in the case of devices falling into class B or C, on a representative basis the technical documentation,
- to plan and periodically carry out appropriate surveillance audits and assessments, to carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits,
- relating to the sampling of devices to verify that the manufactured device is in conformity with the technical documentation, these shall define the relevant sampling criteria and testing procedure prior to sampling,
- to evaluate and verify a manufacturer's compliance with relevant Annexes.

Specific requirements of a notified body in conducting conformity assessment activities, including quality management system audits, technical documentation assessment and performance evaluation can be found in the relevant conformity assessment Annexes VIII to X.

The notified body shall, when relevant, take into consideration harmonised standards, even if the manufacturer does not claim compliance, available CS, guidance and best practice documents.

#### 4.6.2. Quality management system audits

- (a) As part of the quality management system assessment activity, the notified body shall prior to the audit and in accordance with its documented procedures:
- assess the documentation submitted according the relevant conformity assessment Annex and establish an audit programme which clearly identifies the number and sequence of activities required to demonstrate complete coverage of a manufacturer's quality management system and to determine whether it meets the requirements of this Regulation,
  - determine interfaces and responsibilities between different manufacturer sites, as well as the identification of relevant suppliers and/or subcontractors of the manufacturer, including consideration of the need to specifically audit any of these suppliers and/or subcontractors,
  - clearly define, for each audit identified in the audit programme, the objectives, criteria and scope of the audit and shall draw up an audit plan adequately addressing and taking account of the specific requirements for the devices, technologies and processes covered,
  - establish and maintain, for class B and C devices, a sampling plan for the assessment of technical documentation as referred to in Annex II covering the range of such devices comprised by the manufacturer's application. This plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate,

- select and assign appropriately qualified and authorised personnel for conducting the individual audits. The respective roles, responsibilities and authorities of the team members shall be clearly defined and documented.
- (b) According to the audit programme established, the notified body shall, in accordance with its documented procedures:
- audit the manufacturer's quality management system, which shall ensure that the devices covered conform to the relevant provisions of this Regulation, which apply to devices at every stage, from design through final inspection to ongoing surveillance, and determine if the requirements of this Regulation are met,
  - review and audit the manufacturer's processes/subsystems, based on relevant technical documentation – in particular for design and development, production and process controls, product documentation, purchasing controls including verification of purchased devices, corrective and preventive actions including post-market surveillance and post-market performance follow-up requirements and provisions adopted by the manufacturer including those in relation to fulfilling the general safety and performance requirements to determine whether the manufacturer meets the requirements referred to in the relevant conformity assessment annex. Documentation shall be sampled to reflect the risks associated with the intended use for the device, the complexity of the manufacturing technologies, the range and classes of devices produced and any available post-market surveillance information.
  - if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers,
  - conduct assessments of the technical documentations according to the established sampling plan and taking account of Section 4.6.4. of this Annex for performance evaluation.



- the notified body shall ensure that audit findings are appropriately and consistently classified in accordance with the requirements of this Regulation and with relevant standards/best practice documents developed or adopted by the MDCG.

#### 4.6.3. Product verification

##### Assessment of the technical documentation

For assessment of the technical documentation conducted in accordance with Annex VIII Chapter II, the notified body shall have sufficient expertise, facilities and detailed documented procedures providing for:

- the allocation of appropriately qualified and authorised personnel for the examination of the individual aspects (use of the device, biocompatibility, performance evaluation, risk management, sterilisation, etc.),
- the assessment of the technical documentation taking account of Sections 4.6.4. and 4.6.5. of this Annex and the assessment of conformity of the design with the provisions of this Regulation. This examination shall include the assessment of the implementation and the results of incoming, in-process and final inspections. If further tests or other evidence is required to allow for the assessment of conformity with the requirements of the Regulation, the notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

##### Type-examinations

The notified body shall have detailed documented procedures, sufficient expertise and facilities for the type-examination of devices according to Annex IX including capacity to:

- examine and assess the technical documentation taking account of Sections 4.6.4. and 4.6.5. of this Annex and verify that the type has been manufactured in conformity with that documentation.
- establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility.
- document its rationale for the selection of those parameters.

- carry out the appropriate examinations and tests in order to verify that the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation. This shall include all necessary tests to verify that the manufacturer has applied the relevant standards.
- agree with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the notified body.
- assume full responsibility for test results. Test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

#### Verification by examination and testing of every product batch

The notified body shall:

- have detailed documented procedures, sufficient expertise and facilities for the verification by examination and testing of every product batch according to Annex VIII and Annex X;
- establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility in order to:
  - = for devices in class C, in accordance with Annex VIII and Annex IX, verify the conformity of the device with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them,
  - = for devices in class B, in accordance with Annex VIII, confirm the conformity with the technical documentation referred to in Annex II and with the requirements of this Regulation which apply to them,
 and document its rationale for the selection of those parameters;
- have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of the Regulation by examining and testing every product batch as specified in Annex X, Section 5;
- have documented procedures providing for agreement with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the notified body;

- assume full responsibility for test results in accordance with documented procedures. Test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

#### 4.6.4. Performance evaluation assessment

The notified body assessment of procedures and documentation shall address the results of literature search and all validation, verification and testing performed and conclusions drawn and shall typically include considerations of alternative materials and substances to be used and of the packaging, stability/shelf life of the finished device. Where no new testing has been undertaken by the manufacturer or for deviations from procedures, the notified body shall appropriately challenge the justification presented by the manufacturer.

The notified body shall have documented procedures in place relating to the review of a manufacturer's procedures and documentation relating to performance evaluation both for initial conformity assessment and on an ongoing basis. The notified body shall examine, validate and verify that the manufacturer's procedures and documentation adequately address:

- the planning, conduct, assessment, reporting and updating of the performance evaluation according to Annex XII, post-market surveillance and post-market performance follow up,
- the interface with the risk management process,
- the appraisal and analysis of the available data and its relevance to demonstrate conformity to the relevant requirements in Annex I,
- the conclusions drawn with regard to the clinical evidence and elaboration of the performance evaluation report.

These procedures shall take into consideration available CS, guidance and best practice documents.

The notified body assessment of performance evaluation according to Annex XII shall include:

- the intended use specified by the manufacturer and claims for the device defined by him,
- the planning of the performance evaluation,
- the methodology for the literature search,
- relevant documentation to the literature search,
- the performance studies,
- post-market surveillance and post-market performance follow up,
- validity of claimed equivalence to other devices, the demonstration of equivalence, the suitability and conclusions data from equivalent and similar devices,
- the performance evaluation report.

In relation to data from performance studies included within the performance evaluation, the notified body shall ensure that the conclusions drawn by the manufacturer are valid in the light of the performance studies submitted to the competent authority.

The notified body shall ensure that the performance evaluation adequately addresses the relevant safety and performance requirements in Annex I, that it is appropriately aligned with the risk management, performed in accordance with Annex XII and that it is appropriately reflected in the information provided relating to the device.

#### 4.6.5. “Specific Procedures”

The notified body shall have detailed documented procedures, sufficient expertise and facilities for the “specific types of devices” according to Annex VIII, Section 6, for which it is designated.

In the case of companion diagnostics the notified body shall have documented procedures in place that relate to the requirements of this Regulation for consultation of the European Medicines Agency or a medicinal products competent authority during its assessment of such a device.

#### **4.7. Reporting**

The notified body shall:

- ensure that all steps of the conformity assessment are documented so that the conclusions of the assessment are clear and demonstrate compliance with the requirements of this Regulation and can provide objective evidence of this to persons that are themselves not involved in the assessment, for example personnel in designating authorities,
- ensure that records for quality management system audits are available that are sufficient to provide a discernible audit trail,
- clearly document the conclusions of its assessment of the performance evaluation in a performance evaluation assessment report,
- for each specific project provide a detailed report which shall be based on a standard format containing a minimum set of content determined by the Medical Device Coordination Group.

The notified body report shall:

- clearly document the outcome of its assessment and draw clear conclusions on the verification of the manufacturer's conformity to the requirements of this Regulation,
- make a recommendation for review and final decision-making by the notified body; this recommendation shall be clearly signed off by the responsible notified body personnel,
- be provided to the manufacturer.

#### **4.8. Review**

The notified body shall prior to making a final decision ensure:

- that personnel assigned for review and decision making on specific projects are appropriately authorised and are different from those personnel who have conducted the assessments,
- that the report(s) and supporting documentation needed for decision making, including close out of nonconformities raised during assessment, are complete and sufficient with respect to the scope of the application,
- that no unresolved nonconformities exist that prevent issuance of an EU certificate.

#### **4.9. Decisions and certifications**

The notified body shall have documented procedures for decision making including responsibilities for the issuance, suspension, restriction and withdrawal of certificates. These procedures shall include the notification requirements according to Chapter V of this Regulation. These procedures shall allow it to:

- decide, based on the assessment documentation and additional information available whether the requirements of the Regulation are fulfilled,
- decide based on the results of their assessment of the performance evaluation and risk management if the PMS plan, including whether the PMPF is adequate and on specific milestones for further review by the notified body of the up to date performance evaluation,
- decide whether specific conditions or provisions need to be defined for the certification,
- decide, based on the novelty, risk classification, performance evaluation and outputs from the risk analysis of the device, on a period for certification not exceeding five years,
- clearly document decision making and approval steps including approval by signature of the responsible individuals,
- clearly document responsibilities and mechanisms for communication of decisions, in particular, if the final signatory of a certificate differs from the decision maker(s) or does not fulfil the requirements outlined in Section 3.2.7. of this Annex,
- issue a certificate(s) according to the minimum requirements defined in Annex XI for a period of validity not exceeding five years and shall indicate if there are specific conditions or limitations associated with the certification,
- issue a certificate(s) for the applicant alone and shall not issue certificates covering multiple entities,
- ensure that the outcome of the assessment and the resultant decision is notified to the manufacturer and entered into the European databank according to Article 43(4).

#### **4.10. Changes and modifications**

The notified body shall have documented procedures and contractual arrangements with manufacturers in place relating to the information obligations and the assessment of changes to:

- the approved quality management system(s) or the product-range covered,
- the approved design of a device,
- the approved type of a device,
- any substance incorporated in or utilised for the manufacturing of a device and being subject to “specific procedures” according to Section 4.6.5.

These procedures and contractual arrangements shall include processes for checking the significance of changes.

In accordance with its documented procedures, the notified body shall:

- ensure that manufacturers submit plans for such changes and relevant information relating to the change for prior approval,
- assess the changes proposed and verify whether after these changes the quality management system or the design/type of a device still meets the requirements of this Regulation,
- notify the manufacturer of its decision and provide a (supplement) report, which shall contain the justified conclusions of its assessment/audit.

#### **4.11. Surveillance activities and post-certification monitoring**

The notified body shall have documented procedures:

- defining how and when surveillance activities of manufacturers are to be conducted. These shall include provisions for unannounced on-site audits to manufacturers and when applicable subcontractors and suppliers, carrying out product tests and the monitoring of compliance to any conditions on manufacturers associated with certification decisions, *e.g.* updates to clinical data at defined intervals,

- for screening relevant sources of scientific and clinical data and post-market information relating to the scope of its designation. Such information shall be taken into account in the planning and conducting of surveillance activities,
- to review vigilance information accessible according to Article 64a in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.

The notified body shall, upon receipt of information about vigilance cases from the manufacturer or the competent authorities, decide about the following options:

- that no action is required as the vigilance case is clearly not related to the certification granted,
- observation of the manufacturer's and competent authorities activities and the results of the manufacturer's investigation to allow a conclusion that the certification granted is not endangered or adequate corrective action has been performed,
- performance of extraordinary surveillance measures (document review, short-notice or unannounced audit, product testing, etc.) if it is likely that the certification granted is endangered,
- increasing the frequency of surveillance audits,
- reviewing specific products or processes during the next audit of the manufacturer, or
- any other relevant measure.

In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to:

- conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in Section 4.6.,
- ensure that it adequately assesses the manufacturer's documentation on, and application of, the provisions on vigilance, the post-market surveillance plan (including post-market performance follow-up),



- sample and test devices and technical documentations, during audits, according to pre-defined sampling criteria and testing procedures to ensure that the manufacturer continuously applies the approved quality management system,
- ensure that the manufacturer complies with the documentation and information obligations laid down in the respective Annex(es) of this Regulation and that his procedures take into account best practices in implementation of quality management systems,
- ensure that the manufacturer does not use quality management system or device approvals in a misleading manner,
- gather sufficient information to determine if the quality management system continues to comply with the requirements of this Regulation,
- if non-conformities are detected ask the manufacturer for corrections, corrective actions, when applicable preventative actions, and
- when necessary, impose specific restrictions on the relevant certificate or suspend or withdraw it.

The notified body shall, if listed as part of the conditions for certification:

- conduct an in depth review of the up to date performance evaluation of the manufacturer based on post-market surveillance, post-market performance follow up and clinical literature relevant to the condition being treated or similar devices,
- clearly document the outcome of this review and address any specific concerns or conditions to the manufacturer,
- ensure that the updated performance evaluation is appropriately reflected in the Instructions For Use and Summary of Safety and Performance Data.

#### **4.12. Re-certification**

The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates shall occur at least every 5 years.

The notified body shall have documented procedures relating to EU technical documentation assessment renewals and EU type-examination renewals that shall require the manufacturer to submit a summary on changes and scientific findings for the device, including:

- all changes to the originally approved device, including changes not yet notified,
- experience gained from post -market surveillance,
- experience from risk-management,
- experience from updating the proof of compliance with the general safety and performance requirements,
- experience from reviews of the performance evaluation, including the results of any performance studies and post-market performance follow up,
- changes of the requirements, of components of the device or of the scientific or regulatory environment,
- changes of applied or new (harmonised) standards, CS or equivalent documents,
- changes in medical, scientific and technical knowledge, such as:
  - = new treatments,
  - = changes in test methods,
  - = new scientific findings on materials, components, etc., also with respect to biocompatibility,
  - = experience from market research on comparable devices,
  - = data from registers/registries,
  - = experience from performance studies with comparable devices.

The notified body shall have documented procedures to assess this information and shall pay particular attention to clinical data from post-market surveillance and PMPF activities undertaken since the previous (re-)certification, including appropriate updates to manufacturer's performance evaluation reports.

For the decision on the extension the notified body shall use the same methods and principles as for the initial decision. If necessary, separate forms shall be established taking into account the above mentioned steps, *e.g.* for application and application review.

## CLASSIFICATION CRITERIA

### 1. IMPLEMENTING RULES FOR THE CLASSIFICATION RULES

- 1.1. Application of the classification rules shall be governed by the intended purpose of the devices.
- 1.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.
- 1.3. Accessories are classified in their own right separately from the device with which they are used.
- 1.4. Software, which drives a device or influences the use of a device, falls automatically in the same class as the device.  
If the software is independent of any other device, it is classified in its own right.
- 1.5. Calibrators intended to be used with a device shall be classified in the same class as the device.
- 1.6. Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.
- 1.7. The manufacturer shall take into consideration all the rules in order to establish the proper classification for the device.
- 1.8. Where a device has multiple intended purposes stated by the manufacturer, which place the device into more than one class, it shall be classified in the higher class.
- 1.9. If several classification rules apply to the same device the rule resulting in the higher classification shall apply.
- 1.10. Each of the rules applies to first line assays, confirmatory assays and supplemental assays.

## 2. CLASSIFICATION RULES

### 2.1. Rule 1

Devices intended for the following purposes are classified as **class D**:

- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration.
- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation.
- Devices intended to be used to determine the infectious load of a life-threatening disease where its monitoring is critical in the process of patient management.

### 2.2. Rule 2

Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration, are classified as **class C**, except when intended to determine any of the following markers:

- ABO system [A (ABO1), B (ABO2), AB (ABO3)];
- Rhesus system [RH1 (D), RHW<sub>1</sub>, RH2 (C), RH3 (E), RH4 (c), RH5 (e)];
- Kell system [Kel1 (K)];
- Kidd system [JK1 (Jka), JK2 (Jkb)];
- Duffy system [FY1 (Fya), FY2 (Fyb)]

in which case they are classified as **class D**.

### 2.3. Rule 3

Devices are classified as **class C** if they are intended:

- (a) for detecting the presence of, or exposure to, a sexually transmitted agent;
- (b) for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation;
- (c) for detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, *foetus* or embryo being tested, or to the individual's offspring;
- (d) for pre-natal screening of women in order to determine their immune status towards transmissible agents;
- (e) for determining infective disease status or immune status, if there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;
- (f) to be used as companion diagnostics;
- (fa) to be used for disease staging, if there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;
- (fb) to be used in screening, diagnosis, or staging of cancer;
- (g) for human genetic testing;
- (h) for monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;
- (i) for management of patients suffering from a life-threatening disease or condition;
- (j) for screening for congenital disorders in the embryo or *foetus*;
- (k) for screening for congenital disorders in new-born where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.

#### 2.4. Rule 4

- (a) Devices intended for self-testing are classified as **class C**, except for devices for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, *erythrocytes*, *leucocytes* and bacteria in urine, which are **Class B**.
- (b) Devices intended for near-patient testing are classified in their own right.

#### 2.5. Rule 5

The following devices are classified as **class A**:

- (a) products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures related to a specific examination;
- (b) instruments intended by the manufacturer specifically to be used for *in vitro* diagnostic procedures;
- (c) specimen receptacles.

#### 2.6. Rule 6

Devices not covered by the above-mentioned classification rules are classified as **class B**.

#### 2.7. Rule 7

Devices which are controls without a quantitative or qualitative assigned value are classified as **class B**.

## CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF THE TECHNICAL DOCUMENTATION

### Chapter I: Quality Management System

1. The manufacturer shall establish, document and implement a quality management system as described in Article 8(5) of this Regulation and maintain its effectiveness through the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 3, and is subject to audit as laid down in Sections 3.3. and 3.4. and to the surveillance as specified in Section 4.
- 3. Quality management system assessment**
- 3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:
  - the name and address of the registered place of business of the manufacturer and any additional manufacturing site covered by the quality management system, and, if the application is lodged by the authorised representative, his name and address of his registered place of business as well,
  - all the relevant information on the device or group of devices covered by the quality management system,
  - a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,
  - a draft of an EU declaration of conformity in accordance with Article 15 and Annex III for the device model covered by the conformity assessment procedure,
  - the documentation on the quality management system,

- a documented description of the procedures in place to fulfil the obligations imposed by the quality management system and required by this Regulation and the undertaking by the manufacturer to apply these procedures,
- a description of the procedures in place to keep the quality management system adequate and efficacious and an undertaking by the manufacturer to apply these procedures,
- the documentation on the post-market surveillance system, including, when applicable, a plan for the post-market performance follow-up, and the procedures put in place to ensure compliance with the obligations emanating from the provisions on vigilance set out in Articles 59 to 64a,
- a description of the procedures in place to keep up to date the post-market surveillance system, including, when applicable, a plan for the post-market performance follow-up, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 59 to 64a, as well as the undertaking by the manufacturer to apply these procedures,
- documentation on the performance evaluation plan,
- a description of the procedures in place to keep up to date the performance evaluation plan taking into account the state of the art.

3.2. Implementation of the quality management system shall ensure the compliance with the provisions of this Regulation. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

- (a) the manufacturer's quality objectives;



- (b) the organisation of the business and in particular:
- the organisational structures with clear assignment to critical procedures, the responsibilities of the managerial staff and their organisational authority,
  - the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and of device, including control of devices which fail to conform,
  - where the design, manufacture, and/or final verification and testing of the devices, or elements of any of these, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,
  - where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;
- (c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, and the corresponding documentation as well as the data and records arising from those procedures and techniques, where these procedures and techniques shall specifically address:
- the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures,
  - identification of applicable general safety and performance requirements and solutions to address these, under consideration of applicable CS and harmonized standards or equivalent solutions,
  - the risk management according to Section 1a of Annex I,
  - the performance evaluation, according to Article 47 and Annex XII, including post-market performance follow-up,
  - the solutions to address the applicable specific requirements regarding design and construction, including appropriate preclinical evaluation, addressing specifically Chapter II of Annex I,

- the solutions to address the applicable specific requirements regarding the information to be supplied with the device, addressing specifically Chapter III of Annex I,
  - the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture,
  - management of design or quality management system changes;
- (d) the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which will be used and the relevant documents,
- (e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it shall be possible to trace back the calibration of the test equipment adequately.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annex II.

### 3.3. Audit

- (a) The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 3.2. Where the manufacturer uses a harmonised standard or a CS related to quality management system, it shall assess conformity with those standards or CS. Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonised standards or CS conform to the requirements covered by the standards or CS.
- (b) The audit team shall include at least one member with past experience of assessments of the technology concerned in accordance with sections 4.4. to 4.6. of Annex VI. In circumstances where this experience is not immediately obvious or applicable the notified body shall provide a documented rationale for the allocation of this auditor. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.

- (c) Moreover, in the case of devices classified as class C, the quality management system assessment shall be accompanied by the assessment of the technical documentation for devices selected on a representative basis in accordance with provisions in Sections 5.3a to 5.3e of Chapter II of this Annex. In choosing representative sample(s) the notified body shall take into account the guidance developed and published by the MDCG according to Article 77 and in particular, the novelty of the technology, the potential impact on the patient and standard medical practice , similarities in design, technology, manufacturing and where applicable sterilisation methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample(s) taken.
- (d) If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the audit and a reasoned report.

3.4. The manufacturer shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. The notified body shall assess the changes proposed, determine the need for additional audits and verify whether after these changes the quality management system still meets the requirements referred to in Section 3.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.

#### **4. Surveillance assessment applicable to devices classified as class C and D**

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.

- 4.2. The manufacturer shall authorise the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular:
- the documentation on the quality management system,
  - the documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the post-market performance follow-up plan for a selection of devices, and of the provisions on vigilance set out in Articles 59 to 64a,
  - the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 2 of Annex I,
  - the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
- 4.3. The notified body shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan. This shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.
- 4.4. The notified body shall randomly perform at least once every five years unannounced on-site audits to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment. The notified body shall establish a plan for the unannounced on-site audits which shall not be disclosed to the manufacturer.

Within the context of such unannounced on-site audits, the notified body shall test an adequate sample from the production or the manufacturing process to verify that the manufactured device is in conformity with the technical documentation. Prior to the unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure.

Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation. Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer with an on-site audit report which shall include, if applicable, the result of the sample test.

- 4.5. In the case of devices classified as class C, the surveillance assessment shall also include assessment of the technical documentation in accordance with the provisions in Sections 5.3a to 5.3e of Chapter II of this Annex of the device(s) concerned on the basis of further representative sample(s) chosen in accordance with the rationale documented by the notified body in accordance with point (c) of Section 3.3.
- 4.6. The notified body shall ensure that the composition of the assessment team assures experience with the evaluation of the devices, systems and processes concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall not lead and attend an audit for more than three consecutive years in respect to the same manufacturer.
- 4.7. If the notified body establishes a divergence between the sample taken from the production or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

## Chapter II: Assessment of the technical documentation

### 5. Assessment of the technical documentation of the device and batch verification applicable to devices in class D

- 5.1. In addition to the obligation imposed by Section 3, the manufacturer of devices classified as class D shall lodge with the notified body referred to in Section 3.1 an application for the assessment of the technical documentation relating to the device which he plans to place on the market or put into service and is covered by the quality management system referred to in Section 3.
- 5.2. The application shall describe the design, manufacture and performances of the device in question. It shall include the technical documentation as referred to in Annex II.

In the case of devices for self-testing or near-patient testing, the application shall also include the aspects referred to in Section 6.1, point b).

- 5.3. The notified body shall examine the application employing staff with proven knowledge and experience in the evaluation of the technology, and the devices concerned and the evaluation of clinical evidence. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.
- 5.3a. The notified body shall in particular review the clinical evidence presented by the manufacturer in the performance evaluation report according to Annex XII Section 1.4.2. The notified body shall employ device reviewers with sufficient clinical expertise, including the use of external clinical expertise with direct and current experience on the clinical application of the device in question for the purposes of this review.

- 5.3b. The notified body shall, in circumstances when the clinical evidence is based on data, in total or in part, from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of this route, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalency, the relevance and adequacy of the data to demonstrate conformity.
- 5.3c. The notified body shall ensure the adequacy of the clinical evidence and the performance evaluation and verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. This review shall include consideration of the adequacy of the benefit-risk determination, the instructions for use, the user training, the manufacturer's post-market surveillance plan, and include a review of the need for, and adequacy of, the post-market performance follow up proposed, where applicable.
- 5.3d. The notified body shall consider based on its assessment of the clinical evidence, the performance evaluation, and the benefit-risk determination if specific milestones are required to be defined to allow for review by the notified body on updates to the clinical evidence based on post-market surveillance and post-market performance follow up data.
- 5.3e. The notified body shall clearly document the outcome of its assessment in the performance evaluation assessment report.

- 5.4. Before issuing an EU technical documentation assessment certificate, the notified body shall request a reference laboratory, where designated in accordance with Article 78, to verify the claimed performance and the compliance of the device with the CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The verification shall include laboratory tests by the reference laboratory according to Article 40(2).

In addition, the notified body shall, in the cases referred to in Article 40(2a), consult the relevant experts referred to in Article 81a of Regulation (EU) [Ref. of future Regulation on medical devices] following the procedure laid down in Article 40(2a) on the performance evaluation report of the manufacturer.

The reference laboratory shall provide a scientific opinion within 60 days.

The scientific opinion of the reference laboratory and, where the procedure laid down in Article 40(2a) is applicable, the views of the experts consulted, and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the reference laboratory, and, where applicable, by the experts consulted in accordance with Article 40(2a), when making its decision. The notified body shall not deliver the certificate if the scientific opinion of the reference laboratory is unfavourable.

- 5.5. The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a performance evaluation assessment report.

If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the assessment, the conditions of validity, the data needed for identification of the approved device, and, where appropriate, a description of the intended purpose of the device.



- 5.6. Changes to the approved device shall receive further approval from the notified body which issued the EU technical documentation assessment certificate, wherever the changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the applicant plans to introduce any of the above mentioned changes he shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 40 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide him with a supplement to the EU technical documentation assessment certificate.

Where the changes could affect compliance with the CS or with other solutions chosen by the manufacturer which were approved through the EU technical documentation assessment certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.

The reference laboratory shall provide a scientific opinion within 60 days.

The approval of any change to the approved device shall take the form of a supplement to the EU technical documentation assessment certificate.

- 5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer shall send samples of the manufactured batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings.
- 5.8. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

## **6. Assessment of the technical documentation of specific types of devices**

- 6.1. Assessment of the technical documentation of devices for self-testing and devices for near-patient testing classified as class B, C or D
- (a) The manufacturer of devices for self-testing and devices for near-patient testing classified as class B, C and D shall lodge with the notified body referred to in Section 3.1 an application for the assessment of the technical documentation.
  - (b) The application shall enable the design of the device characteristics and performance(s) to be understood and shall enable conformity with the design related requirements of this Regulation to be assessed. It shall include:
    - test reports, including results of studies carried out with intended users;
    - where practicable, an example of the device; if required, the device shall be returned on completion of the technical documentation assessment;
    - data showing the suitability of the device in view of its intended purpose for self-testing or near patient-testing;
    - the information to be provided with the device on its label and its instructions for use.

The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of this Regulation.

- (ba) The notified body shall verify the compliance of the devices with the relevant requirements set out in Annex I of this Regulation.
- (c) The notified body shall assess the application employing staff with proven knowledge and experience regarding the technology concerned and the intended purpose of the device and provide the manufacturer with a technical documentation assessment report.
- (d) If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the assessment, the conditions of validity, the data needed for the identification of the approved devices and, where appropriate, a description of the intended purpose of the device.
- (e) Changes to the approved device shall receive further approval from the notified body which issued the EU technical documentation assessment certificate, wherever the changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the applicant plans to introduce any of the above mentioned changes he shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 40 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide him with a supplement to the EU technical documentation assessment certificate.

## 6.2. Assessment of the technical documentation of companion diagnostics

- (a) The manufacturer of a companion diagnostic shall lodge with the notified body referred to in Section 3.1 an application for the assessment of the technical documentation.
- (b) The application shall enable the characteristics and performance(s) of the device to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed, in particular, with regard to the suitability of the device in relation to the medicinal product concerned.

- (c) The notified body shall, before issuing an EU technical documentation assessment certificate for the companion diagnostic and on the basis of the draft summary of safety and performance and the draft instructions for use, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') established by Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>31</sup>, regarding the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA. If the medicinal product is authorised, or if an application for its authorisation has been submitted, the notified body shall consult the medicinal products competent authority, or the EMA, that is responsible for the authorisation.
- (d) The medicinal product competent authority or the EMA consulted pursuant to point (c) shall give its opinion, within 60 days after receipt of valid documentation. This 60-day period may be extended once for a further 60 days on justified grounds. The opinion and any possible update shall be included in the documentation of the notified body concerning the device.
- (e) The notified body shall give due consideration to the opinion referred to in point (d) when making its decision. The notified body shall convey its final decision to the medicinal products competent authority concerned or to the EMA consulted pursuant to point (c). The EU technical documentation assessment certificate shall be delivered in accordance with point (d) of Section 6.1.

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<sup>31</sup> OJ L 136, 30.4.2004, p. 1.

- (f) Before changes affecting the performance and/or the intended use and/or the suitability of the device in relation to the medicinal product concerned are made, the manufacturer shall inform the notified body of the changes. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 40 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case the notified body shall assess the changes and consult the medicinal products competent authority or the EMA that was involved in the initial consultation. The medicinal products competent authority or the EMA consulted pursuant to this point shall give its opinion within 30 days after receipt of the valid documentation regarding the changes. A supplement to the EU technical documentation assessment certificate shall be issued in accordance with point (e) of Section 6.1.

### **Chapter III: Administrative provisions**

7. The manufacturer or where the manufacturer does not have a registered place of business in a Member State his authorised representative shall, for a period ending at least ten years after the last device has been placed on the market, keep at the disposal of the competent authorities:
- the declaration of conformity,
  - the documentation referred to in the fifth indent of Section 3.1. and in particular the data and records arising from the procedures referred to in point (c) of Section 3.2.,
  - the changes referred to in Section 3.4.,
  - the documentation referred to in Sections 5.2. and point (b) of Section 6.1., and
  - the decisions and reports from the notified body as referred to in Sections 3.3., 4.3., 4.4., 5.5., 5.6., 5.8., points (c), (d) and (e) of Section 6.1., point (e) of Section 6.2. and point (f) of Section 6.2.

8. Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the first sentence of the preceding paragraph in case the manufacturer, or his authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of this period.

**CONFORMITY ASSESSEMENT BASED ON TYPE EXAMINATION**

1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the production covered fulfil the relevant provisions of this Regulation.

2. **Application**

The application shall include:

- the name and address of the registered place of business of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the registered place of business of the authorised representative,
- the technical documentation referred to in Annex II and Annex IIa. The applicant shall make a representative sample of the production in question, hereinafter referred to as 'type' available to the notified body. The notified body may request other samples as necessary,
- in the case of devices for self-testing or near-patient testing, test reports, including results of studies carried out with intended users, and data showing the handling suitability of the device in view of its intended purpose for self-testing or near patient-testing,
- where practicable, an example of the device. If required, the device shall be returned on completion of the technical documentation assessment;
- data showing the suitability of the device in view of its intended purpose for self-testing or near-patient testing,
- the information to be provided with the device on its label and its instructions for use,
- a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that has been refused by another notified body or that has been withdrawn by the manufacturer before the other Notified Body made its final assessment.

### 3. **Assessment**

The notified body shall:

- 3.0. examine the application employing staff with proven knowledge and experience in the evaluation of the technology, and the devices concerned and the evaluation of clinical evidence. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.
- 3.1. examine and assess the technical documentation for conformity with the requirements of this regulation applicable to the device and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable specifications of the standards referred to in Article 6 or CS, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;
- 3.1b. review the clinical evidence presented by the manufacturer in the performance evaluation report according to Annex XII Section 1.4.2. The notified body shall employ device reviewers with sufficient clinical expertise, including the use of external clinical expertise with direct and current experience on the clinical application of the device in question for the purposes of this review.
- 3.1c. in circumstances when the clinical evidence is based on data, in total or in part, from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of this route, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalency, the relevance and adequacy of the data to demonstrate conformity.
- 3.1d. clearly document the outcome of its assessment in the performance evaluation assessment report according to Annex VIII Section 5.3e..



- 3.2. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation if the standards referred to in Article 6 or CS have not been applied; if the device is to be connected to other device(s) in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device(s) having the characteristics specified by the manufacturer;
- 3.3. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;
- 3.4. agree with the applicant on the place where the necessary assessments and tests will be carried out; and
- 3.4a. draw up an EU type-examination report on the results of the assessments and tests carried out under Sections 3.0 to 3.3.;
- 3.5. in the case of devices classified as class D, request a reference laboratory, where designated in accordance with Article 78, to verify the claimed performance and the compliance of the device with the CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The verification shall include laboratory tests by the reference laboratory according to Article 40(2).

In addition, the notified body shall, in the cases referred to in Article 40(2a), consult the relevant experts referred to in Article 81a of Regulation (EU) [Ref. of future Regulation on medical devices] following the procedure laid down in Article 40(2a) on the performance evaluation report of the manufacturer.

The reference laboratory shall provide a scientific opinion within 60 days.

The scientific opinion of the reference laboratory and, where the procedure laid down in Article 40(2a) is applicable, the views of the experts consulted, and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the reference laboratory, and, where applicable, by the experts consulted in accordance with Article 40(2a), when making its decision. The notified body shall not deliver the certificate if the scientific opinion of the reference laboratory is unfavourable.

- 3.6. For companion diagnostics, seek the opinion, on the basis of the draft summary of safety and performance and the draft instructions for use, of one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') on the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA. If the medicinal product is authorised, or if an application for its authorisation has been submitted, the notified body shall consult the medicinal products competent authority, or the EMA, that is responsible for the authorisation. The medicinal products authority or the EMA shall deliver its opinion within 60 days upon receipt of the valid documentation. This 60-day period may be extended once for a further 60 days on justified grounds. The opinion of the medicinal products authority or of the EMA and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion expressed by the medicinal products competent authority concerned or the EMA when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA consulted pursuant to this section, and
- 3.7. draw up an EU type-examination report on the results of the assessments, tests and scientific opinions under Sections 3.0 to 3.6., including a performance evaluation assessment report for devices classified as class C or D or covered by Section 2, third indent.

#### **4. Certificate**

If the type conforms to the provisions of this Regulation, the notified body shall issue an EU type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the assessment, the conditions of validity and the data needed for identification of the type approved. The certificate shall be drawn up in accordance with Annex XI. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.

#### **5. Changes to the type**

- 5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type or of its intended purpose and conditions of use.
- 5.2. Changes to the approved product including limitations of its intended purpose and conditions of use shall receive further approval from the notified body which issued the EU type-examination certificate wherever the changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.
  - 5.2a. Changes to the intended purpose and conditions of use of the approved device, with the exception of limitations of the intended purpose and conditions of use, require a new application for a conformity assessment.
- 5.3. Where the changes could affect the claimed performance or compliance with the CS or with other solutions chosen by the manufacturer which were approved through the EU type-examination certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.

The reference laboratory shall provide a scientific opinion within 60 days.

- 5.4. Where the changes affect the performance or the intended use of a companion diagnostic approved through the EU type-examination certificate or its suitability in relation to a medicinal product, the notified body shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA. The medicinal products competent authority or the EMA shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.

## **6. Administrative provisions**

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, his authorised representative shall, for a period ending at least ten years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the documentation referred to in the second indent of Section 2,
- the changes referred to in Section 5,
- copies of EU type-examination certificates, scientific opinions and reports and their additions/supplements.

Section 8 of Annex VIII shall apply.

## **CONFORMITY ASSESSMENT BASED ON PRODUCTION QUALITY ASSURANCE**

1. The manufacturer shall ensure application of the quality management system approved for the manufacture of the devices concerned and carry out the final inspection, as specified in Section 3, and is subject to the surveillance referred to in Section 4.
2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 15 and Annex III for the device model covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer ensures and declares that the devices concerned meet the provisions of this Regulation which apply to them, and in the case of Class C and Class D devices that undergo a type examination, conform to the type described in the EU type-examination certificate.

### **3. Quality management system**

- 3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body.

The application shall include:

- all elements listed in Section 3.1 of Annex VIII,
- the technical documentation as referred to in Annex II for the types approved;
- a copy of the EU-type examination certificates referred to in Section 4 of Annex IX; if the EU-type examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued is necessary.

- 3.2. Implementation of the quality management system shall ensure compliance with the type described in the EU type-examination certificate and with the provisions of this Regulation which apply to them at every stage. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and Standard Operating Procedures (SOPs), such as quality programmes, quality plans, quality manuals and quality records.

It shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 3.2. of Annex VIII.

- 3.3. The provisions of points (a) and (b) of Section 3.3. of Annex VIII, apply.

If the quality management system ensures that the devices conform to the type described in the EU type-examination certificate and conforms to the relevant provisions of this Regulation, the notified body shall issue an EU production quality assurance certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the inspection and a reasoned assessment.

- 3.4. The provisions of Section 3.4. of Annex VIII apply.

#### **4. Surveillance**

The provisions of Section 4.1., the first, second and fourth indents of Section 4.2., Section 4.3., Section 4.4., Section 4.6. and Section 4.7. of Annex VIII apply.

## **5. Verification of manufactured devices classified as class D**

- 5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate laboratory tests. The reference laboratory shall inform the notified body about its findings.
- 5.2. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

## **6. Administrative provisions**

The manufacturer or where the manufacturer does not have a registered place of business in a Member State his authorised representative shall, for a period ending at least ten years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the EU declaration of conformity,
- the documentation referred to in the fifth indent of Section 3.1 of Annex VIII,
- the documentation referred to in the eighth indent of Section 3.1 of Annex VIII, including the EU type-examination certificate referred to in Annex IX,
- the changes referred to in Section 3.4 of Annex VIII and
- the decisions and reports from the notified body as referred to in Sections 3.3., 4.3. and 4.4. of Annex VIII.

Section 8 of Annex VIII shall apply.

**CERTIFICATES ISSUED BY A NOTIFIED BODY****I. General Requirements**

1. Certificates shall be drawn up in one of the official languages of the Union.
2. Each certificate shall refer to only one conformity assessment procedure.
3. Certificates shall only be issued to one manufacturer (natural or legal person). The name and address of the manufacturer included in the certificate shall be the same as that registered in the electronic system referred to in Article 23 of this Regulation.
4. The scope of the certificates shall unambiguously describe the device(s) covered.
  - (a) EU technical documentation assessment and EU type-examination certificates shall include a clear identification (name, model, type) of the device(s), the intended purpose (as indicated by the manufacturer in the instructions for use and that has been assessed by the conformity assessment procedure), risk classification and the Basic UDI-DI unit of use as referred to in Article 22(4b).
  - (b) EU quality management system certificates shall include the identification of the devices or groups of devices, the risk classification and the intended purpose.
5. Irrespective of the description used in/with the certificate, the Notified Body shall be able to demonstrate on request, which (individual) devices are covered by the certificate. The Notified Body shall set out a system that enables the determination of the devices, including their classification, covered by the certificate.
6. Certificates shall contain, if applicable, a note that for the placing on the market of the device(s) covered by this certificate, another certificate according to this Regulation is required.
7. EU quality management system certificates for class A sterile devices shall include a statement that the Notified Body has audited the quality management system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.
8. When a certificate replaces a previous one, i.e. when it is supplemented, modified or re-issued it shall contain a reference to the previous certificate and its date of issue with identification of the changes.



## **II. Minimum content of the certificates**

1. Name, address and identification number of the notified body;
2. name and address of the manufacturer and, if applicable, of the authorised representative;
3. unique number identifying the certificate;
- 3a. the single registration number of the manufacturer according to Article 23a(2);
4. date of issue;
5. date of expiry;
6. data needed for the unambiguous identification of the device(s) where applicable as specified in Part I, Section 4 of this Annex;
- 7a. if applicable, reference to a previous certificate as specified in Section I.8 of this Annex;
8. reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;
9. examinations and tests performed, e.g. reference to relevant CS / standards / test reports / audit report(s);
10. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device(s) covered;
11. if applicable, information about the surveillance by the notified body;
12. conclusions of the notified body's conformity assessment with regard to the relevant Annex;
13. conditions for or limitations to the validity of the certificate;
14. legally binding signature of the notified body according to the applicable national law.

## PERFORMANCE EVALUATION AND POST-MARKET FOLLOW-UP

### Part A: Performance Evaluation and Clinical Performance Studies

#### 1. PERFORMANCE EVALUATION

Performance evaluation of a device is a continuous process by which data are assessed and analysed to demonstrate the scientific validity, analytical performance and clinical performance of that device for its intended purpose as stated by the manufacturer. To plan, continuously conduct and document a performance evaluation, the manufacturer shall establish and update a performance evaluation plan. The performance evaluation plan shall specify the characteristics and the performance of the device and the process and criteria applied to generate the necessary clinical evidence.

The performance evaluation shall be thorough and objective, considering both favourable and unfavourable data.

Its depth and extent shall be proportionate and appropriate to the characteristics of the device including the risks, risk class, performance and its intended purpose.

#### 1.2. Performance evaluation plan

As a general rule, the performance evaluation plan shall include at least:

- a specification of the intended purpose of the device according to Article 2 point 2;
- a specification of the characteristics of the device as described in Section 6 of Chapter II of Annex I and in point (ii) of Section 17.3.1. in Chapter III of Annex I;
- a specification of the analyte or marker to be determined by the device;
- a specification of the intended use of the device;
- identification of certified reference materials or reference measurement procedures to allow for metrological traceability;
- a clear identification of specified target groups with clear indications, limitations and contraindications;

- an identification of the general safety and performance requirements as described in Annex I Section I and Annex I Section II.6 that require support from relevant scientific validity and analytical and clinical performance data;
- a specification of methods , including the appropriate statistical tools, used for the examination of the analytical and clinical performance of the device and of the limitations of the device and information provided by it;
- a description of the state of the art, including an identification of existing relevant standards, CS, guidance or best practices documents;
- an indication and specification of parameters to be used to determine the acceptability of the benefit/risk ratio for the intended purpose(s) and for the analytical and clinical performance of the device according to the state of the art in medicine;
- for software qualified as a device, an identification and specification of reference databases and other sources of data used as the basis for its decision making;
- an outline of the different development phases including the sequence and means of determination of the scientific validity, the analytical and clinical performance, including an indication of milestones and a description of potential acceptance criteria;
- the post-market performance follow-up (PMPF) planning according to Part B of this Annex.

Where any of the above mentioned elements are not deemed appropriate in the Performance Evaluation Plan due to the specific device characteristics a justification shall be provided in the plan.

### 1.3. Demonstration of the scientific validity and the analytical and clinical performance:

As a general methodological principle the manufacturer shall:

- identify through systematic scientific literature review the available data relevant to the device and its intended purpose and identify any remaining unaddressed issues or gaps in the data;
- appraise available data by evaluating their suitability for establishing the safety and performance of the device;
- generate any new or additional data needed to address outstanding issues.

#### 1.3.1. Demonstration of the scientific validity

The manufacturer shall demonstrate the scientific validity based on one or a combination of the following sources:

- relevant information on the scientific validity of devices measuring the same analyte or marker;
- scientific (peer-reviewed) literature;
- consensus expert opinions/positions from relevant professional associations;
- results from proof of concept studies;
- results from clinical performance studies.

The scientific validity of the analyte or marker shall be demonstrated and documented in the scientific validity report.

#### 1.3.2. Demonstration of the analytical performance

The manufacturer shall demonstrate the analytical performance of the device according to all the parameters described in point (a) of Section 6(1) of Annex I, unless any omission can be justified as not applicable.

As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.

For novel markers, it may not be possible to demonstrate trueness since certified reference materials or reference measurement procedures may not be available. If there are no comparative methods, different approaches may be used if demonstrated to be appropriate (e.g. comparison to some other well-documented methods, comparison to the composite reference method). In the absence of such approaches, a clinical performance study comparing performance of the novel device to the current clinical standard practice is required.

Analytical performance shall be demonstrated and documented in the analytical performance report.

### 1.3.3. Demonstration of the clinical performance

The manufacturer shall demonstrate the clinical performance of the device according to all the parameters described in point (b) of Section 6.1. of Annex I, unless any omission be justified as not applicable.

Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:

- clinical performance studies;
- scientific peer-reviewed literature;
- published experience gained by routine diagnostic testing.

Clinical performance studies shall be performed unless it is duly justified to rely on other sources of clinical performance data.

Clinical performance shall be demonstrated and documented in the clinical performance report.

### 1.4. Clinical evidence and performance evaluation report

- 1.4.1. The manufacturer shall assess all relevant scientific validity, analytical and clinical performance data to verify the conformity of his device with the general safety and performance requirements in Annex I. The amount and quality of that data shall allow the manufacturer to make a qualified assessment whether the device will achieve the intended clinical benefit(s) and safety, when used as intended by the manufacturer. The data and conclusions drawn from this assessment shall constitute the clinical evidence for the device. The clinical evidence shall scientifically demonstrate that the intended clinical benefit(s) and safety will be achieved according to the state of the art in medicine.

#### 1.4.2. Performance evaluation report

The clinical evidence shall be documented in a performance evaluation report. This report shall include the scientific validity report, the analytical performance report, the clinical performance report and an assessment of these reports allowing demonstration of the clinical evidence.

The performance evaluation report shall in particular include:

- the justification for the approach taken to gather the clinical evidence;
- the literature search methodology and the literature search protocol and literature search report of a literature review;
- the technology on which the device is based, the intended purpose of the device and any claims made about the device's performance or safety;
- the nature and extent of the scientific validity and the analytical and clinical performance data that has been evaluated;
- the clinical evidence as the acceptable performances against the state of the art in medicine;
- any new conclusions derived from post-market performance follow-up reports according to Part B of this Annex.

1.4.3. The clinical evidence and its assessment in the performance evaluation report shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's post-market performance follow-up plan in accordance with part B of this Annex, as part of the performance evaluation and the post-market surveillance system referred to in Article 8(6). The Performance Evaluation Report shall be part of the technical documentation. Favourable and unfavourable data considered in the performance evaluation shall also be part of the technical documentation.

## **2. CLINICAL PERFORMANCE STUDIES**

### **2.1. Purpose of clinical performance studies**

The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and/or previous experience gained by routine diagnostic testing. This information is used to demonstrate compliance with the relevant general safety and performance requirements with respect to clinical performance. When clinical performance studies are conducted, the data obtained shall be used in the performance evaluation process and be part of the clinical evidence for the device.

### **2.2. Ethical considerations for clinical performance studies**

Every step in the clinical performance study, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles.

### **2.3. Methods for clinical performance studies**

#### **2.3.1. Clinical performance study design type**

Clinical performance studies shall be designed in such a way as to maximize the relevance of the data while minimising potential bias.

#### **2.3.2. Clinical performance study plan**

Clinical performance studies shall be performed on the basis of a 'clinical performance study plan'.

The clinical performance study plan (CPSP) shall define the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study. It shall contain in particular the information as laid down below. If part of this information is submitted in a separate document, it shall be referenced in the CPSP. For studies using left-over samples, (u), (x), (y) shall not apply.

(a) Identification of the clinical performance study and the CPSP.

- (b) Identification of the sponsor – name, address of the registered place of business and contact details of the sponsor and, if applicable, the name, address of the registered place of business and contact details of his contact person/ legal representative pursuant to Article 48aa paragraph 2 established in the Union.
- (c) Information on investigator(s) (i.e. principal, coordinating, other; qualifications; contact details) and investigation site(s) (number, qualification(s), contact details) and, in the case of devices for self-testing, the location and number of lay persons involved.
- (d) The starting date and scheduled duration for the clinical performance study.
- (e) Identification and description of the device, its intended purpose, the analyte(s) or marker(s), the metrological traceability, and the manufacturer.
- (f) Information about the type of specimens under investigation.
- (g) Overall synopsis of the clinical performance study, its design type (e.g. observational, interventional) together with the objectives and hypotheses of the study, reference to the current state of the art in diagnosis and/or medicine.
- (h) A description of the expected risks and benefits of the device and of the clinical performance study in the context of the state of the art in clinical practice, and with the exception of studies using left-over samples, the medical procedures involved and patient management.
- (i) The instructions for use of the device or test protocol, the necessary training and experience of the user, the appropriate calibration procedures and means of control, the indication of any other devices, medical devices, medicinal product or other articles to be in- or excluded and the specifications on any comparator or comparative method used as reference,
- (j) Description of and justification for the design of the clinical performance study, its scientific robustness and validity, including the statistical design, and details of measures to be taken to minimise bias (e.g. randomisation) and management of potential confounding factors.
- (k) The analytical performance according to point a) of Section 6(1) of Annex I with justification for any omission.



- (l) Parameters of clinical performance according to point b) of Section 6(1) of Annex I to be determined, with justification for any omission; and with the exception of studies using left-over samples the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions
- (m) Information on the performance study population: specifications of the subjects, selection criteria, size of performance study population, representativity to target population and, if applicable, information on vulnerable subjects involved (e.g. children, immuno-compromised, elderly, pregnant women);
- (n) Information on use of data out of left over specimens banks, genetic or tissue banks, patient or disease registries etc. with description of reliability and representativity and statistical analysis approach; assurance of relevant method for determining the true clinical status of patient specimens.
- (o) Monitoring plan;
- (p) Data management;
- (q) Decision algorithms;
- (r) Policy regarding any amendments (incl. those according to Article 53) to or deviations from the CPSP, with a clear prohibition of use of waivers from the CPSP.
- (s) Accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical performance study and the return of unused, expired or malfunctioning devices.
- (t) Statement of compliance with the recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of clinical performance studies as well as with the applicable regulatory requirements.
- (u) Description of the informed consent process, including a copy of the patient information sheet and consent forms.
- (v) Procedures for safety recording and reporting, including definitions of recordable and reportable events, and procedures and timelines for reporting.
- (w) Criteria and procedures for suspension or early termination of the clinical performance study.

- (x) Criteria and procedures for follow up of subjects following completion of a performance study, procedures for follow up of subjects in the case of suspension or early termination, procedures for follow up of subjects who have withdrawn their consent and procedures for subjects lost to follow up. Procedures for communication of test results outside the study, including communication of test results to the performance study subjects.
- (y) Policy as regards the establishment of the clinical performance study report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 1 of Chapter I.
- (z) List of the technical and functional features of the device indicating those that are covered by the performance study.
- (aa) Bibliography.

Where any of the above-mentioned elements are not deemed appropriate for inclusion in the CPSP due to the specific study design chosen (e.g. use of left-over samples versus interventional clinical performance studies), a justification shall be provided.

### 2.3.3. Clinical performance study report

A 'clinical performance study report', signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol plan, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.

## 2a. OTHER PERFORMANCE STUDIES

- 2a.1. By analogy, the performance study plan (2.3.2) and the performance study report (2.3.3) shall be documented for other performance studies than clinical performance studies.

## **Part B: Post-market performance follow-up**

1. Post-market performance follow-up (PMPF) is a continuous process to update the performance evaluation referred to in Article 47 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan. To this end, the manufacturer shall proactively collect and evaluate performance and relevant scientific data from the use of a device which bear the CE marking, placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety, performance and scientific validity throughout the expected lifetime of the device, the continued acceptability of the benefit/risk ratio and to detect emerging risks on the basis of factual evidence.
- 2a. The PMPF shall be performed pursuant to a documented method laid down in a PMPF plan.
- 2a.1. The PMPF plan shall specify the methods and procedures to proactively collect and evaluate safety, performance and scientific data with the aim of
  - (a) confirming the safety and performance of the device throughout its expected lifetime,
  - (b) identifying previously unknown risks or limits to performance and contraindications,
  - (c) identifying and analysing emergent risks on the basis of factual evidence,
  - (d) assuring the continued acceptability of the clinical evidence and of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, and
  - (e) identifying possible systematic misuse.
- 2a.2. The PMPF plan shall include at least:
  - (a) the general methods and procedures of the PMPF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of performance or scientific data;
  - (b) the specific methods and procedures of PMPF to be applied (e.g. ring trials and other quality assurance activities, epidemiological studies, evaluation of suitable patient or disease registers, genetic data banks or post-market clinical performance studies);

- (c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);
- (d) a reference to the relevant parts of the performance evaluation report referred to in Section 1.5 of Part A of this Annex and to the risk management referred to in Section 1a of Annex I;
- (e) the specific objectives to be addressed by the PMPF;
- (f) an evaluation of the performance data related to equivalent or similar devices, and the current state of the art;
- (g) reference to relevant CS, standards and guidance on PMPF;
- (h) a detailed and adequately justified time schedule for PMPF activities (e.g. analysis of PMPF data and reporting) to be undertaken by the manufacturer.

- 3a. The manufacturer shall analyse the findings of the PMPF and document the results in a PMPF evaluation report that shall update the Performance Evaluation Report and be part of the technical documentation.
- 4a. The conclusions of the PMPF evaluation report shall be taken into account for the performance evaluation referred to in Article 47 and Part A of this Annex and in the risk management referred to in Section 1a of Annex I. If through the PMPF the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.
- 5. If PMPF is not deemed appropriate for a specific device then a justification shall be provided and documented within the performance evaluation report.

## **INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND OTHER PERFORMANCE STUDIES INVOLVING RISKS FOR THE SUBJECTS OF THE STUDIES**

### **I. Documentation regarding the application for interventional clinical performance studies and other performance studies involving risks for the subjects of the studies**

For devices intended to be used in the context of interventional clinical performance studies or other performance studies involving risks for the subjects of the studies the sponsor shall draw up and submit the application in accordance with Article 48aa accompanied by the documentation as laid down below:

#### **1. Application form**

The application form shall be duly filled out containing the following information:

- 1.1. Name, address and contact details of the sponsor and, if applicable, name, address and contact details of his contact person or legal representative according to Article 48aa(2) established in the Union.
- 1.2. If different from the above, name, address and contact details of the manufacturer of the device intended for performance evaluation and, if applicable, of his authorised representative.
- 1.3. Title of the performance study
- 1.4. Single identification number in accordance with Article 49(1).
- 1.5. Status of the performance study (i.e. first submission, resubmission, significant amendment);
- 1.5a. Details/reference to the performance study plan (e.g. including details of the design phase of the performance study).

- 1.6. If resubmission with regard to same device, previous date(s) and reference number(s) of earlier submission(s) or in the case of significant amendment, reference to the original submission. The sponsor shall identify all of the changes from the previous submission together with a rationale for those changes, in particular, whether any changes have been made to address outcomes of previous competent authority or ethics committee reviews.
- 1.7. If parallel submission for a clinical trial on a medicinal product in accordance with Regulation (EU) No 536/2014, reference to the official registration number of the clinical trial.
- 1.8. Identification of the Member States and third countries in which the clinical performance study shall be conducted as part of a multicentre/ multinational study at the time of application.
- 1.9. Brief description of the device for performance study, its classification and other information necessary for the identification of the device and device type.
- 1.10. Summary of the performance study plan.
- 1.11. If applicable, information regarding a comparator device, its classification and other information necessary for the identification of the comparator device.
- 1.11a. Evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical performance study in accordance with the performance study plan.
- 1.12. Details of the anticipated start date and duration of the performance study.
- 1.13. Details to identify the notified body, if the sponsor is using one at the time of application for the performance study.
- 1.13a. Confirmation that the sponsor is aware that the competent authority may contact the ethics committee that is assessing or has assessed the application.
- 1.14. The statement referred to in Section 4.1 of this Annex.

## **2. Investigator's Brochure**

The investigator's brochure (IB) shall contain the information on the device for performance study that is relevant for the study and available at the time of application. Any updates to the brochure or other relevant information that is newly available shall be brought to the attention of the investigators in a timely manner. The IB shall be clearly identified and contain in particular the following information:

- 2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule according to Annex VII, design and manufacturing of the device and reference to previous and similar generations of the device.
- 2.2. Manufacturer's instructions for installation, maintenance, maintaining hygiene standards and use, including storage and handling requirements, as well as the label and instructions for use to the extent that this information is available. In addition, information relating to any relevant training required.
- 2.3. Analytical performance.
- 2.4. Existing clinical data, in particular the following:
  - relevant peer reviewed scientific literature and consensus expert opinions/positions from relevant professional associations available relating to the safety, performance, clinical benefits to patients, design characteristics, scientific validity, clinical performance and intended purpose of the device and/or of equivalent or similar devices;
  - other relevant clinical data available relating to the safety, scientific validity, clinical performance, clinical benefits to patients, design characteristics and intended purpose of similar devices including details of their similarities and differences.
- 2.5. Summary of the risk/benefit analysis and the risk management, including information regarding known or foreseeable risks and warnings.
- 2.6. In the case of devices that include tissues, cells and substances of human, animal or microbial origins detailed information on the tissues, cells and substances, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to the tissues, cells and substances.

2.7. A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and Common Specifications applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as these standards and CS have not or only been partly fulfilled or are lacking.

2.7a. A detailed description of the clinical procedures and diagnostic tests used in the course of the performance study and in particular information on any deviation from normal clinical practice.

**3. Clinical performance study plan** as referred to in Section 2.3.2. of Annex XII.

**4. Other information**

4.1. A signed statement by the natural or legal person responsible for the manufacture of the device for performance study that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical performance study and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the subject.

4.2. Where applicable according to national law, a copy of the opinion(s) of the ethics committee(s) concerned. When according to national law the opinion(s) of the ethics committee(s) is not required at the time of the submission of the application, copy of the opinion(s) of ethics committee(s) shall be submitted as soon as available.

4.3. Proof of insurance cover or indemnification of subjects in case of injury, according to Article 48c and the corresponding national legislation.

4.4. Documents to be used to obtain informed consent, including the patient information sheet and the informed consent document.



- 4.5 Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:
- organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;
  - a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects concerned in clinical performance studies;
  - a description of measures that will be implemented in case of data security breach in order to mitigate the possible adverse effects.
- 4.6. Full details of the available technical documentation, for example detailed risk analysis/management documentation or specific test reports shall be submitted to the competent authority reviewing an application upon request.

## **II. Other sponsor's obligations**

1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter I of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the device intended for performance study, this obligation may be fulfilled by that person on behalf of the sponsor.
2. The sponsor shall have an agreement in place to ensure that the serious adverse events are reported by the investigator(s) to the sponsor in a timely manner.
3. The documentation mentioned in this Annex shall be kept for a period of time of at least ten years after the clinical performance study with the device in question has ended, or, when the device is subsequently placed on the market, at least ten years after the last device has been placed on the market.

Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the preceding paragraph in case the sponsor, or his contact person, established within its territory goes bankrupt or ceases its activity prior to the end of this period.

4. The sponsor shall appoint a monitor that is independent from the investigation site to ensure that the clinical performance study is conducted in accordance with the Clinical Performance Study Plan, the principles of Good Clinical Practice and this Regulation.
5. The sponsor shall complete the follow-up of investigation subjects.

**CORRELATION TABLE<sup>32</sup>**

<b>Directive 98/79/EC</b>	<b>This Regulation</b>
Article 1(1)	Article 1(1)
Article 1(2)	Article 2
Article 1(3)	Number (36) of Article 2
Article 1(4)	-
Article 1(5)	Article 4(4) and (5)
Article 1(6)	Article 1(6)
Article 1(7)	Article 1(4)
Article 2	Article 4(1)
Article 3	Article 4(2)
Article 4(1)	Article 20
Article 4(2)	Article 17(1)
Article 4(3)	Article 17(3)
Article 4(4)	Article 8(7)
Article 4(5)	Article 16(6)
Article 5(1)	Article 6(1)
Article 5(2)	-
Article 5(3)	Article 7
Article 6	-
Article 7	Article 84
Article 8	Articles 67 to 70
Article 9(1) 1 <sup>st</sup> subparagraph	Article 40(5) 1 <sup>st</sup> subparagraph
Article 9(1) 2 <sup>nd</sup> subparagraph	Article 40(3) 2 <sup>nd</sup> subparagraph and (4) 2 <sup>nd</sup> subparagraph

<sup>32</sup> This annex has not been updated - it reflects the Commission proposal.

Article 9(2)	Article 40(2)
Article 9(3)	Article 40(3)
Article 9(4)	Article 40(7)
Article 9(5)	-
Article 9(6)	Article 9(3)
Article 9(7)	Article 8(4)
Article 9(8)	Article 41(1)
Article 9(9)	Article 41(3)
Article 9(10)	Article 43(2)
Article 9(11)	Article 40(8)
Article 9(12)	Article 45(1)
Article 9(13)	Article 5(2)
Article 10	Article 23
Article 11(1)	Numbers (43) and (44) of Article 2, Article 59(1) and Article 61(1)
Article 11(2)	Article 59(3) and Article 61(1) 2 <sup>nd</sup> subparagraph
Article 11(3)	Article 61(2) and (3)
Article 11(4)	-
Article 11(5)	Article 61(3) and Article 64
Article 12	Article 25
Article 13	Article 72
Article 14(1)(a)	Article 39(4)
Article 14(1)(b)	-
Article 14(2)	-
Article 14(3)	-
Article 15(1)	Article 31 and Article 32
Article 15(2)	Article 27
Article 15(3)	Article 33(1) and Article 34(2)
Article 15(4)	-
Article 15(5)	Article 43(4)

Article 15(6)	Article 43 (3)
Article 15(7)	Articles 29(2) and Article 33(1)
Article 16	Article 16
Article 17	Article 71
Article 18	Article 73
Article 19	Article 80
Article 20	Article 75
Article 21	-
Article 22	-
Article 23	Article 90
Article 24	-

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