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**NOTE**

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| From: | General Secretariat of the Council |
| To: | Council |
| Subject: | Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I<br>*- General approach* |

Delegations will find in Annex the compromise proposed by the Presidency for the above-mentioned proposal.

**ANNEX**

# REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

(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), point (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[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

[1] OJ C […], […], p. […].
[2] OJ C […], […], p. […].

Whereas:

(1) Regulations (EU) 2017/745[3] and (EU) 2017/746[4] of the European Parliament and of the Council establish regulatory frameworks to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, respectively, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC[5] and 93/42/EEC[6] and in Directive 98/79/EC of the European Parliament and of the Council[7], such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and require the setting up of the European database on medical devices (Eudamed) to enable transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.

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3 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

4 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj).

5 Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17, ELI: http://data.europa.eu/eli/dir/1990/385/oj).

6 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1, ELI: http://data.europa.eu/eli/dir/1993/42/oj).

7 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, ELI: http://data.europa.eu/eli/dir/1998/79/oj).

(2) The extension of the transitional periods provided for in Article 120 of Regulation (EU) 2017/745 and Article 110 of Regulation (EU) 2017/746 mitigated the risk of shortages of medical devices and *in vitro* diagnostic medical devices in the Union, but did not address underlying structural problems related to the implementation of both Regulations.

(3) In its targeted evaluation[8] of Regulations (EU) 2017/745 and (EU) 2017/746, the Commission confirmed that the Regulations have strengthened the regulatory framework through stricter requirements on the designation and oversight of notified bodies, the conduct of conformity assessments, and the generation of clinical evidence. However, the evaluation also highlighted several shortcomings and inefficiencies in the regulatory framework, resulting in unnecessary burdens for manufacturers. Overly complex and often disproportionate requirements, costly, lengthy and unpredictable conformity assessment procedures affect the availability of devices, the competitiveness of manufacturers in the Union, in particular of small and medium-sized enterprises, and innovation in medical technology. This has a negative impact on the level of healthcare and patient safety in the Union.

(4) To address the shortcomings identified, the existing rules should be simplified, and administrative burden should be reduced without jeopardising the high level of public health and patient safety. Moreover, the predictability and cost-efficiency of the application of both Regulations should be enhanced to achieve their initial objectives.

[8] SWD(2025)1051.

(5) Regulation (EU) 2017/745 includes in its scope certain groups of devices which are similar to medical devices but for which the manufacturer claims only an aesthetic or another non-medical purpose. To enhance legal certainty and to ensure consistency, it should be clarified which accessories for such products without a medical purpose are also included within the scope of Regulation (EU) 2017/745.

(6) The provisions in Regulation (EU) 2017/745 should be adapted to Regulation (EU) 2024/1938 of the European Parliament and of the Council[9], the new Union legislation in the area of substances of human origin (SoHO).

(7) To avoid a double layer of regulatory requirements, products that combine a medical device and an *in vitro* diagnostic medical device should be subject either to Regulation (EU) 2017/745 or to Regulation (EU) 2017/746, depending on the product's principal mode of action, whilst the general safety and performance requirements of the other Regulation should apply to the part of the device that has an ancillary function.

(7a) For integral products combining a medical device and an in vitro diagnostic medical device, the determination of whether the action of one component is principal or ancillary should be based on objective criteria, including the primary intended purpose of the product, the relevance of the component for clinical decision-making, the risks related to the interaction with the body and its functional contribution to the overall safety and performance of the integral product.

[9] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety of substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).

(8) The definition of nanomaterial in Regulation (EU) 2017/745 does not reflect the state of the art and fast-changing environment surrounding the definition and application of the framework to nanomaterials. Commission Recommendation of 10 June 2022 on the definition of nanomaterial provides a generally understood concept of nanomaterial that will be taken into account for the application of this Regulation.[10] The definition of nanomaterial in this Regulation should therefore be removed.

(9) Clinical data are an important source of information for demonstrating the safety and performance of a device. However, the process of generating clinical data is often lengthy and costly. The definition of clinical data should be clarified to enable the use of data generated through studies and other clinical experience that are published in peer-reviewed scientific literature.

(10) Devices that are well-established technologies are part of generic device groups that have a stable, acceptable, and well-understood risk profile and favourable record of safety. They are therefore subject to certain exemptions or more proportionate requirements in Regulation (EU) 2017/745. To make the application of those provisions more flexible and future-proof, a definition of the term ‘well-established technology devices’ should be included in that Regulation, based on guidance developed by the Medical Device Coordination Group[11], and the existing lists of devices in Articles 52 and 61 of Regulation (EU) 2017/745 should be replaced by a reference to the newly defined term.

[10] Commission Recommendation of 10 June 2022 on the definition of nanomaterial, C/2022/3689 (OJ C 229, 14.6.2022, p. 1).

[11] MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC; A guide for manufacturers and notified bodies (April 2020).

(11) To ensure legal certainty and to safeguard the principle of free movement of goods, the coordination mechanism between national competent authorities for decisions on the regulatory status of a product and on the classification of a device, should be streamlined and, where appropriate, involve external expertise from an expert panel, supported by the European Medicines Agency (the Agency). The use of that mechanism should be aimed at ensuring a coherent application of the regulatory framework. Any reassessment of the regulatory status of such products should be based on objective scientific, technical and regulatory grounds. The decision on the regulatory status, however, should remain with the national authorities or, where appropriate, with the Commission acting through implementing acts. Where the product is covered by a valid certificate issued by a notified body under this Regulation, such doubts or concerns should be based on specific and substantiated evidence indicating that the regulatory status of the product may differ from that established in the context of the conformity assessment procedure.

(12) The manufacture and use of devices within health institutions ('in-house devices') under certain conditions is essential for the provision of health care in cases where the needs of the target patient group cannot be met by devices available on the market. While the strict conditions for the exemption of such in-house devices from most of the requirements set out in Regulation (EU) 2017/745 or Regulation (EU) 2017/746 should in principle remain in place, including the requirement that they should not be manufactured on an industrial scale, some flexibility should be introduced in order to remove unnecessary administrative burden on health institutions, to promote clinical research on in-house devices and to enable the access of patients to in-house devices where no alternatives exist. For example, some documentation obligations should be removed, especially under Regulation (EU) 2017/746 for health institutions accredited to EN ISO 15189. The transfer of an in-house device to another health institution should be possible in exceptional circumstances where justified in the interest of public health, patient health or patient safety or to prepare or respond to a public health emergency. Also, to provide legal certainty for health institutions, when a device becomes available on the market that serves the target patient group's needs in an equivalent manner to the in-house device, the health institution should have a reasonable transition period until the exemption for in-house manufacturing ceases to apply.

(12a) In-house devices have specific characteristics and are produced on a reduced scale. While such devices could themselves be artificial intelligence (AI) systems or could incorporate AI systems, including as a safety component, which might have important effects on patient health, they are not subject to third-party conformity assessment procedures. As a consequence, in-house devices are not high-risk AI systems within the meaning of Regulation 2024/1689. In order to ensure a high level of device safety, if an in-house device incorporates an AI system or is itself an AI system and would be subject to the involvement of a notified body in its conformity assessment procedure were it manufactured outside the conditions for exemption of in-house devices, it should also be subject to the requirements for high-risk AI systems laid down in this Regulation.

(13) Laboratories that conduct clinical research in the context of clinical trials of medicinal products subject to Regulation (EU) No 536/2014 often develop tests in-house to meet patient needs in clinical trials. Where those tests are not manufactured on an industrial scale and are not commercialised, the situation of such laboratory-developed tests is similar to in-house devices manufactured and used within a health institution. The exemption from certain requirements of Regulation (EU) 2017/746, as provided for in Article 5(5) of that Regulation, should therefore also apply to laboratory-developed tests used exclusively for clinical trials.

(14) To ensure a level playing field between devices sold online and those sold via traditional distribution channels, certain information requirements applicable to distance sales should be strengthened. In particular, it should be clarified that Member States may also order, on grounds of public health, the cessation of activity of providers of diagnostic or therapeutic services by way of information society services, as defined in Directive (EU) 2015/1535 of the European Parliament and of the Council[12], without prejudice to national law regulating the medical profession.

(15) While it should remain the responsibility of each Member State to determine the language in which information should be supplied to the users within their territory, Member States should consider accepting such information in other languages of the Union, taking into account the technical knowledge, experience, education or training of the average intended users in order to reduce costs for translations.

[12] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1, ELI: http://data.europa.eu/eli/dir/2015/1535/oj).

(17a) Where manufacturers have their devices designed or manufactured by another legal or natural person, the manufacturer is expected to hold the full technical documentation in order to demonstrate that the medical device placed on the market, under their own name, meets the requirements of this Regulation. Where the manufacturer does not hold the rights related to product design or manufacturing, a technical file with redacted proprietary information could be accepted as long as the redacted information is not essential for conformity assessment and these redactions are as limited as possible. In those cases, the manufacturer should have contractual arrangements in place that ensure full disclosure of all applicable information by the legal or natural person that designed or manufactured the device to the notified body or any national competent authority.

(18) To facilitate the reporting and information exchange regarding cases of interruption or discontinuation of supply of certain devices that could result in serious harm or a risk of serious harm to patients or public health, as laid down in Regulations (EU) 2017/745 and (EU) 2017/746, and to enhance legal certainty regarding the devices that are subject to that information obligation, a central IT tool should be made available. Moreover, the Agency in collaboration with the Medical Devices Coordination Group (MDCG) should develop a methodology to identify devices, or categories of devices, for which an interruption or discontinuation of supply would result in an unacceptable risk of serious harm to patients or public health in the Union. The Commission, by means of implementing acts and taking into account the proposal by the Agency based on that methodology, should be empowered to adopt, publish and keep up to date a list of critical devices for which an interruption or discontinuation of supply would result in an unacceptable risk of serious harm to patients or public health in the Union, covered by additional information obligations. Economic operators should establish, maintain and keep up to date a shortage prevention plan for those critical devices. The support provided by the Agency in situations of interruption or discontinuation of supply should also take into account the contribution provided by the Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Regulation (EU) 2022/123 of the European Parliament and of the Council[13]. To ensure a high level of public health protection, continuous access and availability of medical devices and *in vitro* diagnostic medical devices, and to strengthen health emergency preparedness and response, Member States and the Commission should have the possibility to request manufacturers of devices, which are included in the list of devices, to provide information regarding risks and weaknesses within the supply chain that may affect the supply of such devices. That information can be used for assessing possible vulnerabilities in the supply chain of critical devices, for example within the framework of the MDSSG.

[13] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).

(19) Having regard to advances in digital communication and digital compliance tools and in order to reduce administrative burden, it should be specified that communication between the relevant actors and compliance with legal obligations, including the drawing up of documentation, reports and other documents as well as conformity assessment procedures should in principle be possible in digital form. The manufacturer should ensure that the digital format is suitable for and agreed with the notified body or competent authority or national authorities responsible for notified bodies as applicable.

(20) To simplify rules and reduce compliance costs, some overly prescriptive requirements, such as the qualification requirements for the person responsible for regulatory compliance or the permanent and continuous availability of that person when not part of the manufacturer's organisation, should be adapted. Also, reporting and certification requirements regarding the repackaging or relabelling of devices that are already placed and further distributed within the internal market, for example outside the manufacturer's official distribution schemes, should be simplified.

(22) The unique device identification (UDI) system and the registration of devices in the European database for medical devices (Eudamed) are fundamental tools for ensuring the traceability and transparency of devices made available on the Union market. To enhance clarity and legal certainty, the respective provisions related to those tools laid down in Regulations (EU) 2017/745 and (EU) 2017/746 should be clarified and streamlined.

(23) The use of artificial intelligence in medical devices and in vitro diagnostic medical devices can help foster innovation and improve diagnosis and treatment of patients. The parallel implementation of Regulations (EU) 2017/745 and (EU) 2017/746, as applicable, and of the requirements stemming from Regulation (EU) 2024/1689[14] of the European Parliament and of the Council is deemed to lead to overlaps of requirements, excessive administrative burden for economic operators and stifle innovation. To prevent those overlaps and reduce administrative burdens, as well as to streamline the regulatory framework for artificial intelligence-enabled devices, the references to Regulations (EU) 2017/745 and (EU) 2017/746 in Annex I to Regulation (EU) 2024/1689 should therefore be moved from Section A to Section B. The application of Regulation (EU) 2024/1689 to those high-risk AI systems should be limited to the relevant provisions applicable to Section B under that Regulation. When adopting implementing acts on general safety and performance requirements relating specifically to artificial intelligence in accordance with Regulation (EU) 2017/745 or Regulation (EU) 2017/746 the Commission should take into account the relevant requirements for high-risk AI systems set out in Regulation (EU) 2024/1689. Notified bodies that are designated to assess high-risk AI systems falling under Regulations (EU) 2017/745 or (EU) 2017/746, as applicable, are assumed to meet equivalent standards of independence, impartiality and professional integrity as notified bodies under Regulation (EU) 2024/1689. In accordance with Article 168(7) TFEU, the Member States are responsible for the definition of their health policy and for the organisation and delivery of health services and medical care. Those responsibilities include the management of health services and medical care and especially the allocation of the resources assigned to them. This Regulation is to respect such responsibilities in its design and implementation.

[14] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).

(24) The summary of safety and clinical performance under Regulation (EU) 2017/745 and the summary of safety and performance under Regulation (EU) 2017/746 ensure transparency regarding the clinical evidence on which the safety and performance assessment of the device is based. As the drawing up and updating of such a summary is costly, the range of devices subject to that requirement should be clearly limited to those devices for which a systematic assessment of the device's technical documentation is required pursuant to Regulations (EU) 2017/745 and (EU) 2017/746. Moreover, the summary should be drawn up in a way that is clear for the intended user of the device. To reduce burden and enhance cost-efficiency, additional versions for other persons, such as patients where they are not users of the device, should not be required. Moreover, as the draft summary is in any case part of the documentation to be submitted to the notified body, a separate validation of the summary by the notified body should not be required. In addition, duplication of information to be provided in the summary and in the instructions for use should be avoided.

(25) In accordance with Regulations (EU) 2017/745 and (EU) 2017/746, notified bodies exercise a key function in the medical device regulatory system as the issuance of a certificate by a notified body is a prerequisite for market access of most devices. In order to ensure that devices benefit from uniform and predictable conditions for market access, the accountability of notified bodies and the degree of harmonisation of their conformity assessment activities should therefore be enhanced. For that purpose, the process for the assessment of applicant notified bodies and their designation should be streamlined. Moreover, the oversight of notified bodies should be tightened, including through the involvement of joint assessment teams in the monitoring of notified bodies. In light of such changes, the full reassessment of notified bodies every five years is no longer required and should therefore be removed.

(26) To streamline the assessment and monitoring of notified bodies, the joint assessment teams should include the national authority responsible for the notified body as well as experts appointed by the Commission in consultation with the MDCG.

(26-a) The Commission should be empowered, by means of implementing act, to establish the structure and level of certain fees and the principles governing the fee reductions in the context of the funding of activities related to designation and monitoring of notified bodies. Those implementing acts should take into account the size, portfolio and scope of designation of the notified bodies concerned.

(26a) Regulatory disputes can arise between the manufacturer and the notified body in relation to the notified body's application of the relevant requirements in these Regulations. Where, after exhausting the notified body's complaint and appeal procedure, such disputes remain unresolved, these disputes could be raised with the authority responsible for notified bodies, to hear and decide as appropriate. This is not intended to resolve assessment disputes on clinical, scientific or technically substantiated issues.

(27) Even though most notified bodies are private for-profit entities, they exercise their function in the public interest. With regard to manufacturers that are micro or small enterprises within the meaning of Commission Recommendation 2003/361/EC[15], notified bodies should provide the possibility to defer part of the payment of fees until the relevant conformity assessment activity is finalised. With regard to orphan devices, notified bodies should therefore be required to reduce their fees for conformity assessment activities. Such reductions should remain proportionate and take into account the economic viability, where applicable, of notified bodies, in particular as regards those notified bodies which are micro or small sized enterprises.

(27a) When duly justified, the authority responsible for notified bodies, upon request by the MDCG, should be empowered to instruct a notified body to accept a manufacturer's request for conformity assessment activities. This should remain an exceptional measure. It should therefore be applied only where other urgency measures available under this Regulation cannot be applied effectively, or where those measures are not suitable or sufficient to safeguard public health or patient health or safety.

(29) Devices are classified in different classes depending on their level of risk. Some of the classification rules should be adapted to reflect the inherent risk of devices, resulting in a lower risk classification.

[15] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

(29a) For the purpose of these classification rules, clinical management includes the management of a person's health or medical condition for a medical purpose which should be understood in accordance with the definition of 'medical device', where software is intended to inform or drive decisions or actions relating to that purpose, whether by the patient, a caregiver or a healthcare professional. When classifying software, the classification should be based on the software's actual functionality, capabilities and reasonably foreseeable use, taking into account the full range of medical purposes, functions, patient populations and conditions that the software is designed to support or enable in its intended use environment. Disclaimers or restrictions that are not effectively implemented through technical limitations of the software should not affect the applicable regulatory requirements.

(30) For lower and medium-risk devices, the involvement of notified bodies in the conformity assessment process should be reduced so that it is proportionate to the risk class of the device. For example, for class IIa and non-implantable class IIb devices, or certain class C devices, where the notified body is to assess the technical documentation on a sampling basis, it should be clarified that the technical documentation assessment is only needed for one representative device per category of devices or generic device group or, in the case of class B devices, only for one representative device per class B product portfolio. The technical documentation of additional representative devices as part of conformity assessment should only be assessed on duly justified grounds. Surveillance activities by notified bodies should be risk-based, proportionate, and should allow for reduced assessments for manufacturers that demonstrate good compliance. As class A sterile devices are of low risk, notified body involvement for those devices should be removed.

(30a) Onsite inspections are a key component of competent authority market surveillance checks on the conformity characteristics and performance of devices. This ensures that medical devices remain safe and manufacturers comply with relevant requirements. While the scope and focus of these inspections is different from the surveillance audits and assessments conducted by notified bodies, these surveillance approaches may be viewed as complementary. In certain circumstances, such as where the inspection is being conducted proactively and not in response to a specific safety issue identified, a favourable outcome of the competent authority's market surveillance inspection may be indicative of high levels of compliance by the manufacturer. This in turn provides a practical level of oversight which should be considered within the notified bodies' risk-based approach to determine the necessary frequency of surveillance audits and assessments and the sampling of technical documentation during those audits and assessments.

(31) To support innovation and the development and availability of breakthrough technology, of devices intended for small groups of patients and of essential paediatric devices, the conformity assessment procedures should be adapted to address the specific situation of those devices. For that purpose, criteria for breakthrough devices, orphan devices and essential paediatric devices, should be included, based on guidance developed by the Medical Device Coordination Group. If the status as a breakthrough device, orphan device or essential paediatric devices is confirmed by an expert panel, the review of the device by the notified body should be prioritised, if necessary with additional advice from the expert panels, and the notified body should offer priority access to supports for the manufacturer, including structured dialogues. Where an expert panel has confirmed the status of a device as a breakthrough device, orphan device, or essential paediatric device, this should be stated, as applicable, in the device's instructions for use and on Eudamed.

(32) The clinical evaluation consultation procedure provided for in Regulation (EU) 2017/745 is a tool to scrutinise the assessment of notified bodies regarding certain high-risk devices. The procedure should be focused on devices where that exceptional scrutiny gives an additional assurance for patient safety. The scope of the clinical evaluation consultation procedure should therefore be limited to class III implantable devices, removing from its scope class IIb active devices intended to administer or remove a medicinal product. However, there should be the possibility to add specific types of high-risk devices to the scope of the clinical evaluation consultation procedure by way of delegated act, where justified on grounds of patient safety.

(32a) To ensure that clinical investigations accurately represent the target population in all its diversity, and to enhance the medical devices available for vulnerable populations, medical devices which are likely to offer significant clinical benefit should be fully and appropriately studied in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical investigations. This is without prejudice to the requirement for each clinical investigation to be ethically reviewed prior to its commencement, in accordance with national law. This is in line with the 2024 version of the World Medical Association's Declaration of Helsinki.

(33) The performance evaluation assessment procedure provided for in Regulation (EU) 2017/746 is not effective for certain class D devices as it mixes up the responsibilities of expert panels and notified bodies. It should therefore be removed and replaced with an early scientific advice process for high-risk *in vitro* diagnostic medical devices that provides for the possibility of manufacturers to seek advice from expert panels on their performance evaluation strategy.

(34) When the validity of a certificate for medical devices or for *in vitro* diagnostic medical devices issued by a notified body expires, notified bodies are to assess whether the certificate can be renewed. This creates administrative burden, uncertainty and unnecessary costs. The maximum validity period of certificates issued by notified bodies should therefore be removed for lower and medium-risk devices, unless the notified body considers it necessary to limit the validity on justified grounds, such as in the case of a certificate issued with conditions where the manufacturer has to collect additional clinical data after certification in the post-market phase. Recurring recertification cycles of high-risk devices should be replaced by a single point in time reassessment.

(35) In order to respond to a public health emergency at Union level recognised in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council[16], or to ensure the supply of medical devices and *in vitro* diagnostic medical devices falling under the definition of medical countermeasures within the framework of Council Regulation (EU) 2022/2372[17], the Commission, after consulting the MDCG, should be able to authorise, by means of implementing acts, the placing on the market or putting into service of devices for which a conformity assessment in accordance with Regulations (EU) 2017/745 and (EU) 2017/746 has not been carried out. Moreover, where specific CE marked devices are needed, for example in greater numbers or with an adapted intended purpose, to respond to a public health emergency or a disaster or crisis, Member States, or the Commission, should be able to exempt manufacturers from certain requirements related to the manufacturing, design or intended purpose of the device.

[16] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

[17] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2024, p. 64, ELI: http://data.europa.eu/eli/reg/2022/2372/oj).

(36) To ensure that the legal framework governing the highly innovative sectors of medical devices and in vitro medical devices is future-proof and able to support innovation, Member States and the Commission should be able to establish regulatory sandboxes in the field of medical devices or in vitro diagnostic medical devices to facilitate the development and testing of innovative devices under strict oversight and before their placing on the market. Those regulatory sandboxes, along with advice from expert panels on clinical development strategies and performance evaluations, and requests to competent authorities on the regulatory status of a product, should be available to manufacturers, including early-stage start-ups and device developers.

(37) Directive 2010/63/EU of the European Parliament and the Council[18] prescribes that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of an animal-based procedure. Non-animal tests such as New Approach Methodologies (NAMs), which include innovative *in-vitro* (cell or tissue-based), *in-chemico* (chemical-based), *in-silico* (computer-based) approaches, or combinations of these, can increasingly replace or complement animal-based tests for safety and performance studies. The use of non-animal methods, including NAMs, to provide scientific evidence in clinical and non-clinical studies should therefore be promoted.

[18] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276 20.10.2010, p. 33, ELI: http://data.europa.eu/eli/dir/2010/63/2019-06-26 ).

(38) As the safety and performance of many devices other than high-risk devices can be sufficiently demonstrated using non-clinical data, including NAMs, the possibility to use non-clinical data to confirm the safety and performance of a device in the conformity assessment should therefore be made more prominent in Regulation (EU) 2017/745. Provisions should be introduced to enable the Commission, in consultation with the MDCG, to adopt implementing acts to ensure the uniform application of the use of non-clinical data in that context.

(39) Clinical data are often available for devices that are equivalent to the device under conformity assessment. In order to make the conditions under which manufacturers can claim equivalence more flexible, the requirement in Regulation (EU) 2017/745 for a contract with the manufacturer of the equivalent device granting access to its technical documentation should therefore be removed. The manufacturer should have sufficient access to relevant information on the design, materials and the clinical evaluation of the equivalent device. The equivalence criteria should be adapted to allow more flexibility; however, those adaptations should avoid chains of equivalent devices leading to inappropriate compounding of reliance on a small volume of clinical data.

(40) Post-market clinical follow-up (PMCF) is an important requirement in Regulation (EU) 2017/745 to identify any safety issues that might appear during real world use of the device. To reduce the number of reports that manufacturers are required to draw up, manufacturers should be able to include the findings of the PMCF directly in the updated clinical evaluation report, without the need to draw up a separate PMCF evaluation report.

(41) The obligation to prepare a periodic safety update report (PSUR) is an important tool provided for in Regulations (EU) 2017/745 and (EU) 2017/746 that requires manufacturers to verify the safety and performance of a device during its lifetime. In order to avoid unnecessary costs and administrative burden for manufacturers and to make the obligation more proportionate, the frequency for updating the PSUR should be reduced depending on the risk class of the device. For class III devices or class IIb implantable devices, other than well-established technology devices, the PSUR and their evaluation by notified bodies should be made available through the electronic system on vigilance and on post-market surveillance. While such reports and evaluations are not made publicly available, they are beneficial sources of information which competent authorities may choose to consider as part of targeted vigilance or market surveillance activities.

(42) Unnecessary overlaps and duplication of assessments between different actors in the regulatory system negatively impact the efficiency and consistency of that regulatory system. Therefore, the roles and responsibilities of competent authorities and notified bodies, in particular regarding the assessment of vigilance cases, should be clarified and any unnecessary elements removed.

(44) Regulation (EU) 2024/2847 of the European Parliament and of the Council[19] requires manufacturers to notify actively exploited vulnerabilities and severe incidents having an impact on the security of products with digital elements in order to ensure that the relevant national computer security incident response teams (CSIRTs) designated as coordinators, and the European Union Agency for Cybersecurity (ENISA), have an adequate overview of vulnerabilities and incidents impacting the internal market. Medical devices and *in vitro* diagnostic medical devices, however, are exempted from Regulation (EU) 2024/2847. While cybersecurity related incidents need to be reported in accordance with existing vigilance rules in Regulations (EU) 2017/745 and (EU) 2017/746 when they qualify as serious incidents, cybersecurity related incidents that do not concern public health or patient safety, are not reported. This is an important cybersecurity gap. Manufacturers of connected devices should therefore be obliged to also notify those incidents to the CSIRTs and ENISA through Eudamed. Where a competent authority, following notification from a CSIRT or ENISA that further action may be required, considers that a cybersecurity event should also be reported as a serious incident in accordance with existing vigilance rules in Regulations (EU) 2017/745 and (EU) 2017/746, it should request an explanatory statement from the manufacturer. Where the competent authority does not agree with the conclusion of the statement provided by the manufacturer, it may request the manufacturer to submit the appropriate report, in accordance with existing vigilance provisions in Regulations (EU) 2017/745 and (EU) 2017/746. The competent authorities should cooperate with the CSIRTs designated as coordinators of the Member States in which the device has been made available, and with ENISA.

[19] Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).

(45) The key actors under Regulations (EU) 2017/745 and (EU) 2017/746, namely manufacturers, Member States, notified bodies, the MDCG and the Commission, should have access to experts with relevant scientific, clinical and technical expertise. Enhanced coordination and access to expertise result in a predictable and reliable regulatory framework. The type of expertise available in the expert panels range of areas in which expert panels provide advice and their involvement in the regulatory system set out in Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be expanded. The mandate of the Agency to support the expert panels in coordinating their Union activities in accordance with Regulation (EU) 2022/123 should be amended accordingly.

(46) Regulations (EU) 2017/745 and (EU) 2017/746 provide for a decentralised regulatory system. Effective coordination between national authorities is essential to ensure the smooth functioning of the internal market and a coherent application of the requirements laid down in the Regulations to ensure a uniform high level of protection of patient safety and public health. For an effective and efficient coordination, national authorities need scientific, technical and administrative support, which can be provided in the most adequate way by the Agency, as it already manages the medical device expert panels. The Agency should therefore be mandated to provide the necessary technical, scientific and administrative support to facilitate the cooperation, coordination and exchange of experience between national competent authorities to facilitate uniform practical application of Regulations (EU) 2017/745 and (EU) 2017/746.

(47) The Union participates in the International Medical Device Regulators Forum (IMDRF)[20], which is a voluntary group of regulators from around the world that aims to accelerate international regulatory harmonisation and convergence in the field of medical devices and *in vitro* diagnostic medical devices. To a large extent, the Union regulatory system for medical devices reflects guidelines developed in the framework of the IMDRF. To increase efficiency, reduce duplication of regulatory efforts and promote global convergence, the Commission within the limits of the tasks conferred upon it and in consultation with the MDCG, should make use of and build on international regulatory cooperation mechanisms. For that purpose, notified bodies and competent authorities could take into consideration for their own decisions the outcome of assessments, audits, inspections, and other regulatory decisions carried out or taken by authorities or bodies that participate in the relevant reliance mechanism or programme, such as the Medical Device Single Audit Program (MDSAP).

(49) Regulation (EU) 2017/746 introduced specific provisions for companion diagnostics. In light of the experience gained from the application of those provisions, it is necessary to clarify in the definition of companion diagnostics that a companion diagnostic may be linked to more than one medicinal product. Moreover, to avoid any unnecessary duplication in the assessment of companion diagnostics, it should be clarified that the consultation of a medicinal products authority should only be necessary regarding novel companion diagnostics and that a consulted medicinal products authority should not repeat the assessment carried out by a notified body.

[20] International Medical Device Regulators Forum (IMDRF) | International Medical Device Regulators Forum

(50) Performance studies are an important source of clinical evidence for *in vitro* diagnostic medical devices. The rules applicable to the conduct of performance studies should be simplified in cases where they do not present any additional risks to the subjects of the study, such as in cases where the study involves low-risk procedures for the collection of specimens such as routine blood sampling, or where studies on companion diagnostics are conducted using left-over samples.

(51) The transition from the previous regulatory framework to that under Regulations (EU) 2017/745 and (EU) 2017/746 has led to the discontinuation of certain devices intended for small groups of patients, as the costs for the transition made it economically difficult for manufacturers to undertake conformity assessment in accordance with those Regulations. The discontinuation of those orphan devices jeopardises the level of care and patient protection, where no alternative diagnosis or treatment methods are available. Manufacturers should therefore be allowed, subject to certain conditions, to continue marketing orphan devices that were lawfully marketed in accordance with the Directives 90/385/EEC, 93/42/EEC and 98/79/EC without the need to conduct a conformity assessment procedure pursuant to Regulations (EU) 2017/745 and (EU) 2017/746.

(52) Certain Annexes to Regulations (EU) 2017/745 and (EU) 2017/746, which further specify the obligations and requirements applicable to notified bodies, economic operators and devices, should be aligned with the changes made in the corresponding provisions of those Regulations and to reflect the same objectives, namely simplification, burden reduction, enhanced cost-efficiency of the certification process and further digitalisation.

(53) To reduce costs and length of conformity assessment procedures for medical devices that integrate a medicinal substance or a SoHO, the consultation of the medicinal products authorities or the SoHO authorities should be streamlined.

(54) Regulations (EU) 2017/745 and (EU) 2017/746 delegated to the Commission the power to adopt delegated acts in accordance with Article 290 TFEU in order to amend certain non-essential provisions in Regulations (EU) 2017/745 and (EU) 2017/746. Having regard to the experience with the application of those Regulations and the necessity to maintain a level of flexibility regarding the often very technical and procedural requirements in the Regulations, the power to adopt delegated acts should be provided, with appropriate framing, for other non-essential provisions in Regulations (EU) 2017/745 and (EU) 2017/746, where necessary.

(55) Regulations (EU) 2017/745 and (EU) 2017/746 conferred on the Commission the power to adopt implementing acts. In order to ensure uniform conditions of implementation of those Regulations additional implementing powers should be conferred on the Commission.

(56) Since the objectives of this Regulation, namely simplification and burden reduction of the rules on medical devices and on *in vitro* diagnostic medical devices, while preserving the objectives of Regulations (EU) 2017/745 and (EU) 2017/746 as such, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, 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 those objectives.

(57) Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be amended accordingly.

(58) In order to allow all affected parties sufficient time to take the necessary measures to comply with this Regulation, the application of certain provisions should be deferred. However, provisions that do not require time for preparation should be applicable from the date of the entry into force of this Regulation.

(59) This Regulation introduces binding requirements for cross-border digital public services within the meaning of Regulation (EU) 2024/903 of the European Parliament and of the Council[21]. An interoperability assessment has therefore been completed. The Digital Dimensions chapter of the Legislative Financial and Digital Statement constitutes the resulting report,

HAVE ADOPTED THIS REGULATION:

[21] Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) (OJ L 2024/903, 22.3.2024, ELI: http://data.europa.eu/eli/reg/2024/903/oj).

*Article 1*

**Amendments to Regulation (EU) 2017/745**

Regulation (EU) 2017/745 is amended as follows:

(1) Article 1 is amended as follows:

(a) the first subparagraph of paragraph 2 is replaced by the following:

‘This Regulation shall also apply, as from the date of application of common specifications adopted pursuant to Article 9, to the groups of products without an intended medical purpose that are listed in Annex XVI. This Regulation shall also apply to accessories for such products, provided that common specifications have been adopted for those accessories pursuant to Article 9. The common specifications for each of the groups of products listed in Annex XVI and, where relevant, for those accessories, shall address, at least, application of risk management as set out in Annex I and, where necessary, clinical evaluation regarding safety, taking into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology.’;

(b) paragraph 4 is replaced by the following:

‘4. For the purposes of this Regulation, medical devices, accessories for medical devices, and products listed in Annex XVI and their accessories, to which this Regulation applies pursuant to paragraph 2 shall hereinafter be referred to as ‘devices’.’;

(c) in paragraph 6, point (a) is replaced by the following:

‘(a) in vitro diagnostic medical devices covered by Regulation (EU) 2017/746, without prejudice to paragraph 7;’;

(cc) in paragraph 6, point (g) is replaced by the following:

‘(g) any of the following:

- organs intended for transplantation falling within the scope of Directive 2010/53/EU of the European Parliament and of the Council* or
- substances of human origin as defined in Article 3(1) of Regulation (EU) 2024/1938 of the European Parliament and of the Council**, or their derivatives, or products containing or consisting of them.

However, this Regulation does apply to devices manufactured utilising derivatives of substances of human origin which are non-viable or are rendered non-viable.

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* Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).

** Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14, ELI: http://data.europa.eu/eli/dir/2010/53/oj).’;

(d) paragraph 7 is replaced by the following:

‘7. Any device which, when placed on the market or put into service, incorporates as an integral part an in vitro diagnostic medical device as defined in Article 2, point (2), of Regulation (EU) 2017/746 that has an action ancillary to that of the device in which it is incorporated, shall be governed by this Regulation. In that case, the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/746 shall apply with regard to the safety and performance of the in vitro diagnostic medical device part.

However, if the action of the in vitro diagnostic medical device is principal and not ancillary to that of the device in which it is incorporated, the integral product shall be governed by Regulation (EU) 2017/746. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply with regard to the safety and performance of the device part.’;

(e) paragraph 10 is amended as follows:

(i) the first subparagraph is replaced by the following:
‘Any device which, when placed on the market or put into service, incorporates, as an integral part, non-viable substances of human origin, or their derivatives, that have an action ancillary to that of the device in which they are incorporated shall be assessed and authorised in accordance with this Regulation, without prejudice to Article 2(8) of Regulation 2024/1938.’;

(ii) the second subparagraph, first sentence, is replaced by the following:
‘However, if the action of those substances of human origin, or their derivatives is principal and not ancillary to that of the device and the product is not governed by Regulation (EC) No 1394/2007, the product shall be governed by ‘Regulation (EU) 2024/1938.’;

(2) Article 2 is amended as follows:

(a) in point (1), the second subparagraph is replaced by the following:

'The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4), with the exception of products specifically intended for the cleaning, disinfection or sterilisation of accessories to Annex XVI products.';

(b) point (7) is replaced by the following:

'(7) 'generic device group' means a set of devices having the same or similar intended purposes and a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;';

(c) points (18), (19), (20) and (21) are deleted;

(d) point (48) is replaced by the following:

'(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from any of the following:

- clinical investigations of the device concerned or of a device for which equivalence to the device concerned can be demonstrated;
- other studies published in peer-reviewed scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated;
- other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated;
- clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;';

(e) the following points (72), (74), (75) and (76) are added:

‘(72) ‘well-established technology device’ means a device that fulfils all the following criteria:

(a) it is part of a generic device group that is characterised by all the following:

- it has a stable, acceptable, and well understood risk profile, with a demonstrable, favourable track record of safety;
- the clinical performance characteristics of the generic device group are acceptable, well-understood, and sufficiently documented based on relevant clinical and post-market surveillance data, taking into account the expected lifetime of the device and the state of the art;
- one or more of the devices in the generic device group have been continuously made available on the Union market for at least ten years; and
- the characteristics of devices in the generic device group are stable, as demonstrated by no significant changes to the design or intended purpose over the past ten years.

(b) the design of the device is simple, stable and similar to other devices in the generic device group.

(74) ‘regulatory sandbox’ means a controlled environment set up by a competent authority which offers manufacturers the possibility, before placing the product on the market or putting it into service, to develop, test, validate and use, where appropriate in real-world conditions, an innovative product or technology potentially falling within the scope of this Regulation, pursuant to a sandbox plan for a limited time under regulatory supervision;

(75) ‘sandbox plan’ means a document agreed between the participating manufacturer(s) and the competent authority, describing the objectives, responsibilities, processes, conditions, timeframe, methodology and requirements for the activities carried out within the regulatory sandbox;

(76) ‘Union regulatory sandbox’ means a controlled environment set up by the Commission for testing alternative or new regulatory requirements or enforcement practices and appraising their validity in comparison with existing requirements and practices under this Regulation for a limited time.’;

(3) Articles 3 and 4 are replaced by the following:

*‘Article 3*

**Amendment and implementation of certain definitions**

2. In order to ensure the uniform application of the definition of well-established technology devices set out in Article 2, point (72), the Commission shall, in consultation with the MDCG, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall include exhaustive list of devices that fall under the definition, and may include an indicative, non-exhaustive list of devices that do not fall under that definition. The Commission shall update the lists in light of available scientific or technical evidence. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

*Article 4*

**Regulatory status of products**

1. Upon a duly substantiated request by a manufacturer or an authorised representative, or on its own initiative, the competent authority of the Member State in which the manufacturer or authorised representative is established (the 'responsible competent authority') shall, after obtaining information from the manufacturer or authorised representative and, where applicable, the notified body that issued the certificate for that product, determine whether a specific product of the manufacturer falls within the definition of a medical device as set out in Article 2(1) or the definition of 'accessory for a medical device' set out in Article 2(2), or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex ('the regulatory status of a product').

3. Where a competent authority (the 'initiating competent authority'), on the basis of information obtained through vigilance activities, market surveillance activities or any other relevant information, has justified doubts as to the regulatory status of a product for which neither the manufacturer nor the authorised representative is established within its Member State, the competent authority shall refer the matter to the responsible competent authority and inform the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) and the Commission of the referral, providing justification for its doubts about the regulatory status.

4. Following consultation with the initiating competent authority and after having obtained information from the manufacturer or authorised representative, and, where applicable, the notified body, the responsible competent authority shall decide the regulatory status of the concerned product within 6 months from the date of referral. The responsible competent authority shall communicate its decision to the initiating competent authority and the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a), and the Commission.

5. Where a competent authority does not agree with the decision of the regulatory status by the responsible competent authority, or where the responsible competent authority has not communicated its decision within the period referred to in paragraph 4, that competent authority shall consult the group of national competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) providing justification for its doubts about the regulatory status, who shall issue an opinion on the regulatory status of the product.

6. Taking into account the opinion of the group of national competent authorities referred to in paragraph 5, or where no opinion has been issued within three months, a Member State may request the Commission to decide on the regulatory status of the specific product, by means of implementing acts.

7. The Commission shall consult the MDCG and may consult the relevant expert panel for their scientific advice. The Commission shall set a time-limit for the MDCG to adopt its opinion. The time limit shall not be shorter than 90 days.

7a. The manufacturer or authorised representative, as well as the notified body that issued the certificate, if applicable, shall be provided with the opportunity to present their positions on the regulatory status of the product to the competent authorities, MDCG or the relevant expert panel, as applicable.

8. Where the determination of the regulatory status of a product involves questions concerning the borderline between medicinal products, substances of human origin (SoHO), biocidal products, food, cosmetics or any other products regulated under Union legislation and medical devices, the Agency in fulfilling its tasks described in Article 106b shall ensure an appropriate level of consultation with the other relevant Union bodies established under the applicable legislation, including, the relevant bodies of the Agency responsible for medicinal products in accordance with Article 148, letter (l), of [Pharma Reg], the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).

11. Within 180 days of the request from a Member State referred to in paragraph 6, the Commission, after having consulted the MDCG, shall decide on the regulatory status of the product by means of implementing acts in accordance with the examination procedure referred to in Article 114(3). In adopting its decision, the Commission shall take the utmost account of the advice and opinions issued by the expert panel and the MDCG, respectively.

By way of derogation from the first subparagraph, the Commission may decide, in the absence of an opinion of the MDCG adopted by a majority of members pursuant to Article 103, paragraph 4, within the time-limit referred to in paragraph 7, not to adopt a decision on the regulatory status of the product.

12. The opinions and decisions on the regulatory status of a product, and the advice of the expert panel delivered in accordance with this Article shall be made publicly available, without disclosing any confidential information as referred to in Article 109.

13. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.

14. The Commission may, by means of implementing acts, lay down the procedure, including timelines, for the application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

(5) Article 5 is amended as follows:

(a) paragraph 5 is amended as follows:

(i) the first subparagraph is amended as follows:

(1) point (a) is replaced by the following:

‘(a) the devices are not transferred to another legal entity. Exceptionally, a device may be transferred to another health institution where there is a duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency.

Where such transfers occur, the transferring health institution shall notify the competent authority of the Member State in which it is based and provide the justification. In the case of transfers to a health institution in another Member State, the receiving health institution shall also notify the competent authority of the Member State in which it is based and provide the justification.’;

(1a) point (aa) is added:

‘(aa) the devices are not manufactured on an industrial scale.’;

(2) point (d) is replaced by the following:

‘(d) upon request by a competent authority, the health institution provides information on the use of such devices and the justification referred to in point(c);’;

(3) point (f) is replaced by the following:

‘(f) the health institution draws up documentation that is sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met;’;

(4) point (g) is deleted;

(ii) the second sentence of the second subparagraph is replaced by the following: ‘Member States shall retain the right to restrict the manufacture, the use, or the transfer of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.’;

(iia) the third subparagraph is deleted.

(iii) The following subparagraphs are added:
‘For the purposes of the first subparagraph, point (a), in the case of a transfer of the device to another health institution, the transferring and receiving health institutions shall ensure traceability of the device. This information shall be made available to a competent authority upon request.
For the purposes of the first subparagraph, point (c), from the date that the health institution becomes aware that the target patient group's specific needs can be met by an equivalent device available on the market and, where applicable, registered on Eudamed, it may continue to manufacture and use its device for a maximum period of 7 years.

Member States may require health institutions to report serious incidents related to the device to the competent authority of the Member State in which they are established. In such cases, the competent authorities shall record centrally at national level reports they receive from health institutions and shall monitor the reports received in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

For the purposes of the first subparagraph, point (h), where the device is transferred in accordance with point (a), both the transferring and the receiving health institution shall report to each other any serious incident related to the device.';

(b) the following paragraphs 7 and 8 are added:

'7. By 1 July 2028, the Commission shall adopt an implementing act specifying technical requirements related to cybersecurity as referred to in point 17.4 of Annex I. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 114(3).

8. By 1 July 2028, the Commission shall adopt implementing acts pursuant to paragraph 6 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council***, or devices referred to in Article 10-a, first paragraph, point b, taking into account the requirements set out in Chapter III, Section 2, of that Regulation.

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*** Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).';

(6) Article 6 is amended as follows:

(a) the following paragraph 2a is inserted:

‘2a. Any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall provide in the offer at least the information referred to in Annex I, Section 23.2, points (a) to (d) and (m), and access to the instructions for use.’;

(b) paragraphs 3 and 4 are replaced by the following:

‘3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity drawn up in accordance with Article 19 or the statement drawn up in accordance with Article 21(2) for the device concerned and cooperate with the competent authorities of the Member State where the device or the service is offered.

4. A Member State may, on grounds of protection of public health, require a provider of a service as defined in Article 1(1), point (b), of Directive (EU) 2015/1535, or a provider of a service in accordance with paragraph 2, to cease its activity.’;

(7) in Article 7, the following subparagraph is added:

‘Without prejudice to national law regarding the exercise of the medical profession, the first subparagraph shall also apply to devices used for the provision of a service referred to in Article 6(2).’;

(8) in Article 9(1), the first sentence is replaced by the following:

'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, by means of implementing acts, adopt common specifications (CS) in respect of the requirements set out in this Regulation, in particular the reports and plans to be drawn up by manufacturers, the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the conformity assessment procedures set out in Annexes IX to XI and the procedure for custom-made devices set out in Annex XIII, the clinical evaluation and post-market clinical follow-up set out in Annex XIV or the requirements regarding clinical investigation set out in Annex XV.';

(9) Article 10 is amended as follows:

(d) in paragraph 11, the following subparagraph is added:

'When determining the official language of the Union in which the information set out in Section 23 of Annex I or other information to be provided by the manufacturer shall be made available, Member States shall consider accepting another official language of the Union in which the information is made available, taking into consideration the technical knowledge, experience, education or training of the average intended user(s).';

(g) paragraph 15 is replaced by the following:

'15. Where manufacturers have their devices designed or 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 29(1).';

(h) in paragraph 16, '85/374/EEC' is replaced by '(EU) 2024/2853****.

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****Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC (L, 2024/2853, 18.11.2024, ELI: http://data.europa.eu/eli/dir/2024/2853/oj).';

(9a) the following Article 10-a is inserted:

*'Article 10-a*

**Deployment of certain Artificial Intelligence medical devices**

'1. This Article shall apply to the following devices:

(a) high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council; or

(b) without prejudice to Regulation (EU) 2024/1689, devices referred to in Article 5, paragraph 5, that are Class I sterile devices, Class I devices with a measuring function, Class I reusable surgical instruments, Class IIa devices, Class IIb devices or Class III devices, in accordance with the rules set out in Annex VIII, and that incorporate an AI system that is intended to be used as a safety component of that device, or the AI system is itself the device.

2. Member states shall ensure that when deployers use the devices referred to in paragraph 1 in a health setting, they do so only when all of the following conditions are met:

(a) the deployer has taken appropriate technical and organisational measures to ensure they use such devices in accordance with the instructions for use accompanying the device;

(b) the deployer has assigned human oversight to natural persons who have the necessary competence, training and authority as well as the necessary support;

(c) the deployer monitors the operation of such devices on the basis of the instructions for use;

(d) the deployer keeps the logs automatically generated by such devices to the extent such logs are under the deployer's control, for a period appropriate to the intended purpose of those devices, of at least six months;

(e) to the extent the deployer exercises control over the input data, the deployer ensures that input data is relevant and sufficiently representative in view of the intended purpose of the device;

(f) the deployer cooperates with the relevant competent authorities in any action those authorities take in relation to the device in order to implement this Article.

3. For the purposes of this Article, 'deployer' shall be understood as any natural or legal person, public authority, agency or other body using any of the devices referred to in paragraph 1 under its authority except where they are used in the course of a personal non-professional activity.';

(10) Article 10a is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Where a manufacturer anticipates an interruption or a discontinuation of the supply of a device, other than a custom-made device, and where it is reasonably foreseeable that such interruption or discontinuation could result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer shall inform the competent authority of the potentially affected Member State(s) and the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom it directly supplies the device, of the anticipated interruption or discontinuation.

The information referred to in the first subparagraph shall, other than in exceptional circumstances, be provided at least six months before the anticipated interruption or discontinuation. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority.’;

(b) the following paragraphs 4, 5, 5a and 6 are added:

‘4. The Commission, in cooperation with the Agency, and in consultation with the MDCG, shall set up, maintain, and manage an IT system to facilitate the reporting and information exchange regarding cases of interruption or discontinuation of the supply of devices in accordance with paragraphs 1, 2, 4, 5, 5a and 6. That IT system shall be integrated in or interoperable with the European database on medical devices referred to in Article 33 and shall be accessible to manufacturers, competent authorities, health institutions, and healthcare professionals. It shall also enable health institutions and healthcare professionals to inform competent authorities about the unavailability or the immediate risk of unavailability of devices needed for the exercise of their professional activity. Information referred to in paragraph 6 shall be accessible exclusively to the Commission, the Agency and the competent authorities.

5. The Agency, in particular through the Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Article 21 of Regulation (EU) 2022/123*****, and in collaboration with the MDCG, shall develop a methodology to identify devices as referred to in paragraph 1 for which an interruption or discontinuation of supply would result in an unacceptable risk of serious harm to patients or public health in the Union, consisting of criteria based on the criticality of their intended purpose, and the availability of appropriate alternatives to those devices. Based on that methodology, the Agency, in particular through the MDSSG and in collaboration with the MDCG and in agreement with the Commission, shall propose a list of devices, or categories of devices, that are deemed to meet those criteria on the basis of the available information, including the information referred to in paragraph 1. The Commission shall, by means of implementing acts and taking into account the list proposed by the Agency, and those criteria, adopt, publish and keep up to date a list of devices, or categories of devices, for which an interruption or discontinuation of supply would result in serious harm or risk of serious harm to patients or public health in the Union, and to which paragraphs 1, 2, 3, 4, 5a and 6 shall apply. The methodology shall be drawn up and published within one year from the date of application of this Regulation. The list of devices, or categories of devices, shall be developed within one year from the date of the development of the methodology. The list shall be reviewed and updated regularly, to ensure its continued relevance and accuracy. For the purpose of this paragraph, the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and of consumers may be consulted as necessary.

For the purposes of paragraphs 5a and 6, the obligations shall only apply to devices included in the list drawn up in accordance with this paragraph, when available.

5a. Economic operators shall establish, maintain and keep up to date a shortage prevention plan for the devices included in the list adopted in accordance with paragraph 5. Shortage prevention plans shall be made available to the competent authority upon request. They shall be developed on the basis of a risk-based approach and shall identify specific measures and actions to be taken in the event of an actual supply interruption.

6. The competent authorities of the Member States or the Commission may request the manufacturers of devices included in the list drawn up in accordance with paragraph 5 to provide and keep up to date, through the IT system referred to in paragraph 4, all necessary information regarding risks and weaknesses within the supply chain which may affect the supply of such devices, including manufacturing sites, their addresses and manufacturing stage they cover, the existence of any backup sites, production capacity and volume of sales. Manufacturers of those devices shall register on the IT system referred to in paragraph 4 and be identifiable as such to the Commission and the competent authorities.

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***** Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).';

(11) in Article 11, paragraph 4 is replaced by the following:

‘The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (5), (6), (7), (9), (10), (11) and (12).’;

(12) in Article 14, paragraph 2 is amended as follows:

(b) the second subparagraph is replaced by the following:

‘In order to meet the requirements referred to in the first subparagraph, the distributor may apply a sampling method that is representative of the devices supplied by that distributor.’;

(13) Article 15 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘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 medical devices.

The requisite expertise shall be demonstrated by either of the following:

(a) successful completion of a university degree in law, medicine, pharmacy, engineering or another relevant discipline, or an equivalent qualification in relevant studies, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) two years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.

The person responsible for regulatory compliance shall keep up to date the knowledge necessary to fulfil this role.';

(b) paragraph 2 is replaced by the following:

'2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC****** shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person at their disposal.

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******Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).';

(c) in paragraph 3, point (c) is replaced by the following:

'(c) the post-market surveillance obligations are complied with in accordance with Article 83;';

(d) paragraph 6 is replaced by the following:

'6. Authorised representatives shall have at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The availability of the person responsible for regulatory compliance shall be proportionate to the number of manufacturers represented by the authorised representative as well as to the risk class of the devices manufactured by them.

The requisite expertise shall be demonstrated by either of the following:

(a) successful completion of a university degree in law, medicine, pharmacy, engineering or another relevant discipline, or an equivalent qualification in relevant studies, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) two years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

The person responsible for regulatory compliance shall keep up to date the knowledge necessary to fulfil this role.';

(14) Article 16 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the introductory wording is replaced by the following:
'A distributor, an importer or another natural or legal person who makes a device available on the market, or places a device on the market or puts it into service shall assume the obligations incumbent on manufacturers if it does any of the following:';

(ii) the second subparagraph is replaced by the following:
'The first subparagraph shall not apply to any healthcare professional or any other person who, while not considered a manufacturer, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.';

(b) paragraph 4 is replaced by the following:

‘4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities referred to in points (a) and (b) of paragraph 2 shall inform the manufacturer. Member States may request distributors or importers to inform the competent authority of the Member State in which they plan to make the device available of the intention to make the repackaged or relabelled device available.’;

(15) Article 17 is amended as follows:

(-a) paragraph 1 is replaced by the following:

‘1. Until the date of application of common specifications regarding the reprocessing of single use devices adopted in accordance with Article 9, reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.

The Commission shall adopt the CS referred in the first subparagraph by XX December 2029, which shall detail requirements concerning:

(a) risk management, including the analysis of the construction, material and related properties of the single-use device (reverse engineering), analysis of the conditions of the used single use device and the suitability of its reprocessing;

(b) the validation of procedures for the entire reprocessing process, including necessary cleaning, disinfection and, where applicable sterilisation processes;

(ba) performance testing and product release;

(c) the quality management system;

(d) the traceability of reprocessed devices, including reprocessing cycles;

(e) information regarding the safety and performance of the single-use device that has been reprocessed, including changes of its design or intended purpose, serious incidents, field safety corrective actions or other safety-relevant information.

By way of derogation from Article 9(3), reprocessors of single-use devices referred to in paragraph 2 shall comply with the relevant CS.';

(a) paragraph 2 is replaced by the following:

'2. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a manufacturer for the purpose of Article 4(10) of Directive (EU) 2024/2853.

In addition to the conformity assessment procedure applicable pursuant to Article 52(3), (4), (6), or (7) regarding the reprocessed single-use device, a notified body shall assess compliance with the CS referred to in Article 17(1) in the framework of that conformity assessment procedure.';

(aa) in paragraph 3, point (a), '(g)' is deleted;

(ab) in paragraph 8, the following subparagraph is added:

'The manufacturer of the original single-use device shall not bear any liability for the reprocessed single-use device.';

(ac) in paragraph 9, the first sentence is replaced by the following:

'Notwithstanding paragraph 1, a Member State may maintain or introduce national provisions that are stricter than those laid down in this Regulation and which restrict or prohibit, within its territory, the following:';

(b) Paragraph 10 is deleted;

(16) Article 18 is amended as follows:

(a) in paragraph 1, second subparagraph, the first sentence is replaced by the following: 'The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the patient who has been implanted with the device, by any means accessible by the intended patient, including in printed, electronic or digital format, that allow rapid access to that information. This shall be stated in the language(s) determined by the concerned Member State.';

(17) in Article 19, the following paragraph 2a is inserted:

'2a. Declarations of conformity in accordance with paragraphs 1 and 2 may be provided in electronic form.';

(18) in Article 22, paragraph 2 is replaced by the following:

‘2. The statement made pursuant to paragraph 1 shall contain at least the following information:

(a) an identification of the devices and, where applicable, other products included in the system or procedure pack, including where applicable their Basic UDI-DI;

(b) where applicable, an identification of the notified body involved in the sterilisation activities referred to in paragraph 3;

(c) a declaration by the natural or legal person that:

(i) they have verified the mutual compatibility of the devices and, if applicable, other products in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;

(ii) they have packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;

(iii) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.’;

(19) Article 27 is amended as follows:

(a) in paragraph 1, after point (b) the following point (ba) is inserted:

‘(ba) a Basic UDI-DI, as defined in Part C of Annex VI;’;

(b) paragraph 2 is amended as follows:

(i) point (d) is replaced by the following:

‘(d) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions;’

(ii) in point (e), the following point (iv) is added:

‘(iv) offer its system for the assignment of UDIs to manufacturers that are micro and small enterprises within the meaning of Recommendation 2003/361/EC taking into account the specific needs of such enterprises.’;

(c) paragraph 3 is replaced by the following:

‘3. Before placing a device, other than a custom-made device, or investigational device, on the market, the manufacturer shall, in accordance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2, assign to the device a Basic UDI-DI and a UDI as defined in Part C of Annex VI. If applicable, the manufacturer shall assign a UDI to all higher levels of packaging.

(d) the following paragraphs 3a and 3b are inserted:

‘3a. Before placing on the market a system or procedure pack pursuant to Article 22(1) and (3), the natural or legal person responsible shall assign to the system or procedure pack, in accordance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2, a Basic UDI-DI and UDI as defined in Part C of Annex VI. If applicable, the natural or legal person responsible shall assign a UDI to all higher levels of packaging.

3b. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in Article 52(4), second and third subparagraphs, the manufacturer shall assign a Basic UDI-DI referred to in paragraph 1 of this Article before the manufacturer applies to a notified body for that assessment.’;

(e) in paragraph 10, points (a) and (b) are replaced by the following:

‘(a) amending the list of information set out in Parts A and B of Annex VI in the light of technical progress;

(b) amending Annex VI in the light of experience obtained from the implementation of the UDI system, or in the light of international developments and technical progress in the field of Unique Device Identification.’;

(ea) in paragraph 11, the following point (c) is added:

‘(c) determining, following consultation with the MDCG and other stakeholders, the UDI-related obligations included in this Article, Article 29 and Annex VI Part C that shall not apply to certain devices, categories or groups of devices in view of the highly individualised characterisation of those devices. In such cases, the Commission shall, by means of implementing acts, define the specific device obligations.’;

(21) Article 29 is replaced by the following:

*'Article 29*

**Registration of devices and systems or procedure packs**

1. Before placing a device, other than a custom-made device or investigational device, on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part A, Section 2 and Part B of Annex VI related to that device. The manufacturer shall keep the information provided to the UDI database updated and shall update any changes without undue delay, and in any event no later than 30 days after the change occurs.

2. Before placing on the market a system or procedure pack as referred to in Article 22(1) and (3), the natural or legal person responsible shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part A, Section 2 and Part B of Annex VI related to that system or procedure pack. The natural or legal person referred to in Article 22(1) shall keep up to date the information provided to the UDI database within 30 days from any change that occurred.

3. For devices that are the subject of a conformity assessment as referred to in Article 52(3), first subparagraph, and in Article 52(4), fourth subparagraph, the notified body shall confirm in Eudamed that the information referred to in Section 2.2 of Part A of Annex VI is correct.

3a. The data referred to in Part A, Section 2, entered pursuant to paragraphs 1 and 2, shall be accessible to the public, except the information regarding the other legal or natural person that designed and manufactured the device referred to in Part A, Section 2.13, of Annex VI.';

(22) Article 30 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘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 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative, the importer and the person referred to in Article 22(1). The details regarding the information to be provided to that electronic system by the economic operators are laid down in Part A, Section 1, of Annex VI.’;

(b) in paragraph 2, the following sentence is added:

‘Where national distributor databases require information on devices, where feasible, such databases shall allow for the retrieval of the device information from the electronic systems referred to in Article 33(2), points (a) and (b).’;

(23) Article 31 is amended as follows:

(a) the title is replaced by the following:

‘Registration of economic operators’;

(b) paragraphs 1 and 2 are replaced by the following:

‘1. Before placing a device, other than a custom-made device or investigational devices, on the market, manufacturers, authorised representatives, importers and persons referred to in Article 22(1) of this Regulation shall, in order to register, submit to the electronic system referred to in Article 30 the information referred to in Part A, Section 1, of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 52, the information referred to in Part A, Section 1, of Annex VI shall be provided to that electronic system before applying to the notified body.

2. The competent authority shall verify the data entered pursuant to paragraph 1, obtain a single registration number ('SRN') from the electronic system referred to in Article 30 and issue it to the manufacturer, the authorised representative, the importer or the person referred to in Article 22(1).';

(c) in paragraph 4, the words 'one week' are replaced by the words 'two weeks';

(d) paragraph 6 is deleted;

(e) paragraph 7 is replaced by the following:

'7. The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 30 shall be accessible to the public, except the information regarding the person responsible for regulatory compliance referred to in Part A, Section 1.4, of Annex VI.';

(f) paragraph 8 is replaced by the following:

'8. The competent authority may use the data to charge the manufacturer, the authorised representative, the importer or the person referred to in Article 22(1) a fee pursuant to Article 111.';

(24) Article 32 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. For class IIb implantable devices and for class III devices, other than custom-made or investigational devices and well-established technology devices, the manufacturer shall draw up a summary of safety and clinical performance.

The summary of safety and clinical performance shall be written in a way that is clear to the intended user and shall be made available to the public via Eudamed.

The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52. The manufacturer shall ensure that the summary of safety and clinical performance is available in Eudamed as part of the information on the device to be provided pursuant to Article 29(1) and mention on the label or instructions for use where that summary is available.';

(b) in paragraph 2, point (h) is replaced by the following:

'(h) information on any residual risks, undesirable effects, any warnings and precautions.';

(25) Article 33 is amended as follows:

(-a) in paragraph 1 the following subparagraph is added:

'Eudamed shall be the principal database that supports this Regulation.';

(a) in paragraph 2, the following subparagraph is added:

'By way of derogation from the first subparagraph, the Commission, in consultation with the MDCG, may decide not to include one or more of the electronic systems referred to in that subparagraph in Eudamed where it is necessary, due to operational or technical reasons, to achieve the purposes referred to in the first subparagraph of paragraph 1. In these cases, the Commission shall ensure those electronic systems are interoperable with Eudamed.';

(b) paragraph 3 is replaced by the following:

'3. When designing Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed, the Commission shall give due consideration to compatibility with national databases and national web-interfaces to allow for import and export of data.';

(c) paragraph 4 is replaced by the following:

‘4. The data shall be entered into Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed, by the Member States, notified bodies, economic operators and sponsors as specified in the provisions on the electronic systems referred to in paragraph 2. The Commission shall provide for technical and administrative support to users of Eudamed.’;

(d) paragraph 5 is replaced by the following:

‘5. All the information collated and processed by Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed, shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent specified in the provisions on the electronic systems referred to in paragraph 2.

The Commission shall ensure that public parts of Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed, are presented in a user-friendly and easily searchable format.’;

(e) paragraph 6 is replaced by the following:

‘6. Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed, shall contain personal data only insofar as necessary for the electronic systems to collate and process information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of data subjects for periods no longer than those referred to in Article 10(8).’;

(ea) paragraph 7 is replaced by the following:

‘7. The Commission shall ensure that personal data processed within Eudamed is protected in accordance with Union law. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data are deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than 60 days after a request is made by a data subject.’;

(f) Paragraph 8 is replaced by the following:

‘8. The Commission shall, by means of implementing acts, lay down the detailed arrangements necessary for the setting up and maintenance of Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). When adopting those implementing acts, the Commission shall ensure that, as far as possible, the systems are developed in such a way as to avoid having to enter the same information twice within the same electronic system or in different electronic systems.’;

(g) paragraph 9 is replaced by the following:

‘9. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered to be the controller of Eudamed and its electronic systems as well as, where applicable, any of the electronic systems that are not included in Eudamed.;’

(26) Article 34(1) is replaced by the following:

‘1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed.’;

(27) Article 35 is amended as follows:

(a) the following paragraph 6a is inserted:

‘6a. Without prejudice to other contractual, administrative or judicial remedies, including the notified body’s complaint and appeal procedures [pursuant to Annex VII, Section 2.2], a manufacturer or a notified body may raise with the authority responsible for notified bodies, in a duly substantiated manner, any regulatory unresolved dispute arising between the manufacturer and the notified body in relation to the notified body’s activities in applying requirements set out in Annex VII and the involvement of the notified body in the conformity assessment in accordance with procedural requirements set out in Article 52 and Annexes IX, X and XI. The authority shall hear and decide within 150 days, without prejudice to extension of that period, where duly justified. Where the manufacturer is established in another Member State than the notified body, the authority responsible for the notified body shall consult the competent authority of the Member State where the manufacturer is established.

In duly justified cases, the authority responsible for notified bodies may seek guidance from the MDCG, which it shall take duly into account.

Each authority responsible for notified bodies shall inform the Commission, the MDCG and the coordination group referred to in Article 49, at least annually about the disputes raised with it pursuant to the first subparagraph, their outcome and the parties involved. That information shall be taken into consideration in the framework of the monitoring of notified bodies in accordance with Article 44.

By way of derogation from the first subparagraph and without prejudice to other administrative or judicial remedies, a Member State may choose to assign the tasks set out in this paragraph to another authority or to an out of court dispute resolution body.';

(b) paragraph 8 is replaced by the following:

'8. The authorities responsible for notified bodies shall coordinate, within the framework of the sub-group established under Article 105a, their activities to be carried out in accordance with this Chapter, cooperate with each other and with the Commission and resolve issues of diverging opinions between themselves to ensure a harmonised application of the requirements relating to notified bodies.';

(28) Article 36 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation in the public interest. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements, as set out in further detail in Annex VII, that are necessary to fulfil those tasks in a competent, effective, independent, impartial, diligent and expeditious manner.';

(29) in Article 37, paragraph 4 is deleted;

(30) Article 39 is replaced by the following:

*'Article 39*

**Assessment of the application**

1. The authority responsible for notified bodies shall within 30 days check that the application referred to in Article 38 is complete and shall request the applicant to provide any missing information. Once the application is complete, that authority shall send it to the Commission.

2. Within 14 days of the receipt of the application referred to in paragraph 1 of this Article, the Commission, in consultation with the MCDG, shall appoint three experts, chosen from the list referred to in Article 40(2) upon their agreement and inform the authority responsible for notified bodies. In view of the specific circumstances of the application, a different number of experts may be appointed.

   At least one of the experts shall be an expert representing the Commission. The other experts shall be experts nominated by Member States other than the one in which the applicant conformity assessment body is established.

   In order to be chosen in accordance with the first subparagraph, the experts shall be competent to assess the conformity assessment activities or the scope of designation which are the subjects of the application.

3. The experts appointed in accordance with paragraph 2 and the authority responsible for notified bodies shall form a joint assessment team that shall be led by the authority responsible for notified bodies and supported by the expert(s) representing the Commission. The authority responsible for notified bodies shall ensure that the joint assessment team is fully integrated into the joint assessment process and shall work in close collaboration with the expert(s) representing the Commission.

4. Within 90 days of the appointment of the experts in accordance with paragraph 2, the joint assessment team shall review the application and supporting documentation and shall draw up a preliminary assessment report. During that period, the joint assessment team may request any clarifications or corrections from the applicant conformity assessment body. The authority responsible for notified bodies shall lead the drafting and finalisation of the preliminary assessment report.

5. Where, based on the review of the application and supporting documentation referred to in this paragraph, the joint assessment team considers that the applicant body does not and, within a reasonable period of time, will not be able to meet the requirements of this Regulation and that any further assessment in accordance with paragraphs 6 to 9 is not appropriate, it shall draw up a final assessment report and the authority responsible for the notified bodies shall reject the application.

   Where diverging opinions amongst joint assessment team experts arise regarding the continuation of the application, such diverging opinions shall be submitted to the MDCG for further opinion. The authority responsible for notified bodies shall consider such opinions and justify its reasons for accepting or rejecting the application.

6. Unless the application is rejected, the joint assessment team, led by the authority responsible for notified bodies, shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, that is to be involved in the conformity assessment process. The on-site assessment of the applicant body shall be led by the authority responsible for notified bodies.

Where an on-site assessment of the applicant body, a subsidiary or a subcontractor is temporarily impossible or impracticable due to exceptional circumstances, the joint assessment team may decide to carry out the assessment by other appropriate means.

At the end of the on-site assessment, the joint assessment team shall list for the applicant conformity assessment body any non-compliances resulting from the assessment and summarise the assessment.

7. Within 30 days after the finalisation of the on-site assessment, the authority responsible for notified bodies, on behalf of the joint assessment team, shall submit the assessment report to the applicant conformity assessment body and, where applicable, inform that body about any non-compliances resulting from the assessment.

Where the joint assessment team has not identified any non-compliances, its assessment report shall be considered the final assessment report and paragraph 11 shall apply.

8. Where the joint assessment team has identified non-compliances, the applicant conformity assessment body shall, within 30 days of receipt of the assessment report or within a timeline agreed with the joint assessment team, submit to the joint assessment team a proposed corrective and preventive action plan to address the non-compliances effectively and in a timely manner.

That plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

9. On receipt of the proposed corrective and preventive action plan referred to in paragraph 8, the joint assessment team shall assess whether the non-compliances identified during the assessment have been appropriately addressed. Where necessary, the authority responsible for notified bodies shall provide any comments on it to the applicant conformity assessment body, including requests for further clarification and modifications.

The applicant conformity assessment body and the joint assessment team shall endeavour to agree on a final corrective and preventive action plan in due course.

10. Within 45 days of receipt of evidence of the final corrective and preventive action plan, or of the moment the joint assessment team concludes that no agreement on a final plan and its implementation has been reached, the authority responsible for notified bodies shall lead the drafting and finalisation of the final assessment report. That report shall include the result of the assessment, conclusions regarding the corrective and preventive action plans and whether the non-compliances have been appropriately addressed, any issue or view in accordance with paragraph 15, and, where applicable, the recommended scope of designation.

11. The authority responsible for notified bodies shall, on behalf of the joint assessment team, submit its final assessment report to the MCDG without undue delay.

Based on the findings of the final assessment report, the authority responsible for notified bodies shall submit to the MDCG a draft decision on the designation of the notified body or reject the application.

12. Within 21 days of receipt of the draft decision on the designation referred to in paragraph 11, the MDCG shall issue a recommendation with regard to the envisaged designation, which the authority responsible for notified bodies shall duly take into consideration for its final decision on the designation of the notified body. That 21-day period may be extended once on justified grounds.

13. Where the authority responsible for notified bodies does not agree with the recommendation of the MDCG, within 30 days, it shall submit to the MDCG a duly justified request to reconsider its recommendation. Within 30 days of receipt of that request, the MDCG shall either confirm its recommendation or issue a new recommendation.

14. Where no agreement can be reached between the MDCG and the authority responsible for notified bodies, either party may refer the matter to the Commission.

Within 180 days of receipt of the referral, the Commission shall, after consulting the MDCG, the authority responsible for notified bodies and, where necessary, the applicant conformity assessment body concerned, evaluate the draft decision on the designation and decide, by means of implementing act, whether or not the draft designation is justified.

15. If, at any stage of the process, consensus cannot be reached within the joint assessment team on any issue, the authority responsible for notified bodies or the expert(s) representing the Commission may refer the issue to the MDCG, which shall provide its views without undue delay and at the latest within 60 days from the referral. In such cases, timelines for the joint assessment shall be adjusted to account for the referral to the MDCG.

16. The Commission may, by means of implementing acts, adopt measures setting out detailed arrangements specifying the procedures and any relevant documentation for the following:
    (a) the application for designation referred to in Article 38;
    (b) the assessment of the application set out in this Article;
    (c) the nomination and selection of experts referred to in Article 40;
    (d) the monitoring of notified bodies pursuant to Article 44.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

(31) Article 40 is amended as follows:
    (a) the title is replaced by the following:
    'Nomination of experts for joint assessment';

(b) paragraph 1 is replaced by the following:

‘1. All Member States that have appointed an authority responsible for notified bodies and the Commission shall nominate experts who are qualified in the assessment, designation or monitoring of conformity assessment bodies in the field of medical devices or in the assessment of manufacturers’ technical documentation and who will be available to participate in the activities referred to in Articles 39, 44 and 48. Member States that have not appointed an authority responsible for notified bodies may nominate experts who have those qualifications.’;

(32) the following Article 40a is inserted:

*‘Article 40a*

**Funding of activities related to designation and monitoring of notified bodies**

1. Conformity assessment bodies and notified bodies shall pay to the authorities responsible for notified bodies a fee for the assessment of their application for designation and their monitoring. The fee shall be proportionate to the scope of designation applied for and conformity assessment activities and be based on cost-recovery principles.

1a. Conformity assessment bodies and notified bodies shall pay to the Commission a fee for the costs associated with joint assessment and monitoring activities, including the involvement of experts nominated in accordance with Article 40 in those activities. The fees shall take into account the size and portfolio of the notified bodies concerned.

2. The Commission shall, by means of implementing acts, establish the following:

(b) The level of the fees referred to in paragraph 1a, the type of recoverable costs and other necessary implementing rules, such as the principles governing fee reductions or the payment for the experts nominated by the Member States participating in joint assessment and monitoring activities. The fees shall be set on the basis of cost-recovery principles.

When adopting implementing acts pursuant to paragraph 2, the Commission shall take into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation of experts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

2a. Until the entry into application of an implementing act referred to in paragraph 2, point (b), the costs associated with joint assessment and monitoring activities shall be covered by the Commission.';

(33) the third paragraph of Article 41 is replaced by the following:
'The Commission shall provide translations of the documentation pursuant to Articles 38 and 39, or parts thereof, into an official Union language, such as is necessary for that documentation to be readily understood by the joint assessment team referred to in Article 39(4).';

(34) Article 42 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Member States may designate conformity assessment bodies for which an assessment pursuant to Article 39 was completed and there is a recommendation of the MDCG issued in accordance with Article 39(11) or (12), or in accordance with an implementing act adopted by the Commission in accordance with Article 39(14), and which comply with this Regulation.’;

(b) paragraph 4 is replaced by the following:

‘4. The notification shall be accompanied by the recommendation of the MDCG.’;

(c) paragraphs 6 to 9 are deleted;

(d) paragraph 10 is replaced by the following:

‘10. When publishing the notification in NANDO, the Commission shall add to the electronic system referred to in Article 57 the information relating to the notification of the notified body along with the documents referred to in paragraph 4 of this Article.’;

(35) Article 44 is amended as follows:

(a) the title is replaced by the following:

‘Monitoring of notified bodies’;

(b) in paragraph 2, the second sentence is replaced by the following:

‘Notified bodies shall, upon request by their authority responsible for notified bodies, supply all relevant information and documents required to enable the authority, the joint assessment team and the Commission to verify compliance.’;

(c) the following paragraph 3a is inserted:

‘3a. The authority responsible for notified bodies shall conduct its monitoring and assessment activities in accordance with an assessment programme considering the full scope of the notified body’s activities. That programme shall ensure that the authority can effectively monitor the continued compliance of the notified body with the requirements of this Regulation and shall provide a reasoned schedule for the frequency of assessment of the notified body and, where applicable, its subsidiaries or subcontractors for a period of at least three years. The authority responsible for notified bodies shall submit the programme for monitoring or assessment for each notified body for which it is responsible to the sub-group with members representing authorities responsible for notified bodies laid down in Article 105a, MDCG and to the Commission. The authority shall address any request for clarification or modification made by the sub-group, the Commission or the MDCG.’;

(d) paragraph 4 is replaced by the following:

‘4. At least once a year, the authorities responsible for notified bodies shall assess whether each notified body established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those notified bodies still satisfy the requirements and fulfil their obligations set out in this Regulation, in particular Annex VII.

Where necessary, the assessment shall include an on-site audit of the notified body, its subsidiaries or subcontractors.

The authority, the MDCG or the Commission may request the participation of experts from the Commission and other Member States in the annual assessment of a notified body.’;

(e) the following paragraphs 4a, 4b and 4c are inserted:

‘4a. At least every three years, and proportionate to scope of designation, volume and type of conformity assessment activities and compliance history, the annual assessment of a notified body, referred to in paragraph 4 above, shall be carried out by a joint assessment team including the authority responsible for notified bodies and two experts from the list referred to in Article 40(2) appointed by the Commission in consultation with the MDCG. At least one of those experts shall be an expert representing the Commission. In view of the specific circumstances of the monitoring, the Commission may appoint a different number of experts. The joint assessment team shall be led by the authority responsible for notified bodies and supported by the expert(s) representing the Commission.

If, at any stage of the process, consensus cannot be reached within the joint assessment team on any issue, the authority responsible for notified bodies or the expert(s) representing the Commission may refer the issue to the MDCG, which shall provide its views without undue delay and at the latest within 60 days from the referral. In such cases, timelines for the joint assessment shall be adjusted to account for the referral to the MDCG.

4b. At the end of any assessment carried out pursuant to paragraph 4 or 4a, the authority responsible for notified bodies or the joint assessment team, as applicable, shall list for the notified body any non-compliances resulting from the assessment and summarise their assessment and if immediate action is required.

Within 30 days after the finalisation of the assessment, the authority responsible for notified bodies, on behalf of the joint assessment team, as applicable, shall submit the assessment report to the notified body and, where applicable, inform that body about any non-compliances resulting from the assessment.

Where non-compliances have been identified, the notified body shall submit a proposed corrective and preventive action plan to address the non-compliances effectively in a timeframe agreed with the authority responsible for notified bodies or the joint assessment team. That plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions set out therein.

The authority responsible for notified bodies or the joint assessment team, as applicable, shall assess whether the non-compliances identified during the assessment have been appropriately addressed in the plan referred to in the second subparagraph. Where necessary, the authority responsible for notified bodies shall provide any comments on the plan to the notified body, including requests for further clarification and modifications. The notified body and the authority or the joint assessment team, as applicable, shall endeavour to agree on a final corrective and preventive action plan in due course.

4c. After receipt of the final corrective and preventive action plan, or where the authority responsible for notified bodies or the joint assessment team, as applicable, have not identified non-compliances or conclude that no agreement on a final plan has been reached, the authority responsible for notified bodies, in conjunction with the joint assessment team, as applicable, shall draw up their final monitoring report which shall include the result of the assessment and, where applicable, conclusions regarding the corrective and preventive action plan and, where applicable, any recommendations regarding the notified body's designation.

The authority responsible for notified bodies, on behalf of the joint assessment team, as applicable, shall submit their final monitoring report to the MDCG and to the Commission without undue delay.

The authority responsible for notified bodies shall monitor the implementation of the corrective and preventive action plan by the notified body, as appropriate.

Where the final monitoring report concludes that the notified body no longer meets the requirements set out in this Regulation, or where the notified body fails to implement the corrective and preventive action plan, the authority responsible for notified bodies shall follow the procedure set out in Article 46(4).';

(f) paragraph 5 is replaced by the following:

'5. The monitoring of notified bodies by the authority responsible for notified bodies shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, whilst such personnel are in the process of conducting quality management system assessments at a manufacturer's facility.';

(g) in paragraph 6, the first subparagraph is replaced by the following:
'The monitoring of notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance.';

(h) paragraph 8 is replaced by the following:
'8. During the monitoring of a notified body, an appropriate number of the notified body's assessments of manufacturers' quality management system and technical documentation, in particular the clinical evaluation documentation, shall be reviewed either off-site or on-site. The sampling of files shall be representative of the types and risk classes of devices certified by the notified body, in particular high-risk devices, and shall include reviewing whether the assessment by the notified body was conducted appropriately and shall check the procedures used, associated documentation and the conclusions drawn by the notified body. Such review shall include the technical documentation and clinical evaluation documentation of the manufacturer upon which the notified body has based its assessment.';

(i) paragraphs 9, 10 and 11 are deleted;

(j) paragraph 12 is replaced by the following:
'12. The authority responsible for notified bodies shall draw up an annual summary of their monitoring activities regarding notified bodies and, where applicable, subsidiaries and subcontractors. That summary shall be made publicly available through the electronic system referred to in Article 57.';

(36) Article 45 is deleted;

(37) Article 46 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

‘1. The authority responsible for notified bodies shall notify the Commission and the MDCG of any application for relevant changes to the designation of a notified body.

Unless otherwise agreed by the MDCG, the procedures set out in Articles 39 and 42 shall apply to extensions of the scope of the designation. By way of derogation from Article 39, an on-site assessment shall not be conducted where the Joint Assessment Team considers such assessment not to be necessary for the assessment of the requested scope extension.

For changes to the designation other than extensions of its scope, the procedures laid down in paragraphs 2 to 9 shall apply.

2. After having assessed the application for changes, the authority responsible for notified bodies shall notify the Commission of the relevant changes to the designation. The Commission shall without undue delay publish the amended notification in NANDO. The Commission shall also, without undue delay, enter information on the changes to the designation of the notified body in the electronic system referred to in Article 57.’;

(b) in paragraph 4, the first subparagraph is replaced by the following:

‘Where an authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in this Regulation 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 or impose conditions on the notified body, 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.’;

(38) Article 47 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Commission, in consultation 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 this Regulation. It shall ensure that the relevant authority responsible for notified bodies is informed and is given an opportunity to investigate those concerns.’;

(b) paragraph 3 is replaced by the following:

‘3. The Commission, in consultation with the MDCG, may initiate the assessment by a joint assessment team as referred to in Article 44(4a) to (4c), where 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 this Regulation and where the investigation by the authority responsible for notified bodies is not deemed to have fully addressed the concerns or upon request of the authority responsible for notified bodies. The reporting and outcome of that assessment shall follow the principles set out in Article 39.’;

(39) Article 48 is amended as follows:

(a) the title is replaced by the following:
'Exchange of experience between authorities responsible for notified bodies';

(b) paragraphs 2 to 5 are deleted;

(40) Articles 49 and 50 are replaced by the following:

*'Article 49*

**Coordination of notified bodies**

1. The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including in vitro diagnostic medical devices. The coordination group shall meet on a regular basis, at least annually, and will operate under the auspices of the MDCG.

The Commission may establish the specific arrangements for the functioning of the coordination group.

2. Notified bodies shall ensure that their technical, scientific and clinical personnel with adequate experience participate in the relevant activities of the coordination group.

3. All bodies notified under this Regulation and under Regulation (EU) 2017/746 shall actively participate in the work of the coordination group to support the implementation of this Regulation and of Regulation (EU) 2017/746 by sharing experience and developing draft common templates and draft technical guidance, to be submitted to the MDCG for approval, in order to facilitate harmonisation and common approaches regarding conformity assessment activities. They shall cooperate with each other, with the Commission, with the relevant authorities of the Member States, with expert panels and, where applicable, expert laboratories or European Union reference laboratories to ensure a harmonised application of the requirements set out in this Regulation and in Regulation (EU) 2017/746.

4. All bodies notified under this Regulation and under Regulation (EU) 2017/746 shall adhere to a code of conduct developed by the coordination group and approved by the MDCG. The code of conduct shall set out the principles of public interest, highest professional competence and integrity, impartiality, independence, transparency, proportionality, predictability and accountability to which notified bodies commit when exercising the rights and obligations conferred on them by this Regulation or Regulation (EU) 2017/746.

*Article 50*

**Access to notified bodies and fees**

1. Notified bodies shall establish lists of their fees for the conformity assessment activities that they carry out and shall make those lists publicly available. They shall notify the lists to the Commission, which shall make references to them available to the public on a dedicated website.

2. Notified bodies shall apply at least a 25 % fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a(3). The fees shall take into account the size and portfolio of the notified bodies concerned.

2a. Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of up to 50% of the fees until the relevant conformity assessment activity is finalised.

4. Notified bodies shall ensure that manufacturers, which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, have access to their conformity assessment activities in a manner that is not less favourable than the manner in which access is provided to other manufacturers.

5. Notified bodies shall deal with any request for conformity assessment activities from a manufacturer and, within 30 days of receipt of the request, inform the manufacturer accordingly.

6. When duly justified in the interest of public health or patient health or safety, and other measures cannot be applied effectively, the authority responsible for notified bodies, upon request by the MDCG, may instruct a notified body to accept a manufacturer's request for conformity assessment activities falling within that notified body's scope of designation.';

(41) Article 51 is replaced by the following:

‘1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.

2. Upon a duly substantiated request by a manufacturer or an authorised representative, or on its own initiative, the competent authority of the Member State in which the manufacturer or the authorised representative is established (the ‘responsible competent authority’) shall, after obtaining information from the manufacturer and, where applicable, the notified body that issued the certificate for that device, decides on the classification of the device of the manufacturer.

4. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the responsible competent authority. Where the notified body concerned is established in a Member State other than that of the manufacturer or the authorised representative, the responsible competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

5. Where a competent authority (the ‘initiating competent authority’), on the basis of information obtained through vigilance activities, market surveillance activities or any other relevant information, has justified doubts as to the classification of a device for which neither the manufacturer nor the authorised representative is established within its Member State, it shall refer the matter to the responsible competent authority and inform the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) and the Commission of the referral, providing justification for its doubts about the classification.

6. Following consultation with the initiating competent authority and after having obtained information from the manufacturer or authorised representative and where applicable, the notified body that issued the certificate for that device, the responsible competent authority shall decide on the classification within 6 months from the date of referral. The responsible competent authority shall issue the decision and communicate it to the initiating competent authority and the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a), and the Commission.

7. Where a competent authority does not agree with the decision taken by the responsible competent authority or where the responsible competent authority has not communicated their decision within the period referred to in paragraph 6, that competent authority shall consult the group of national competent authorities in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a), providing justification for its doubts about the classification, who shall issue an opinion on the classification of the device.

8. Taking into account the opinion of the group of national competent authorities referred to in paragraph 7, or where no opinion has been issued within three months, a Member State may request the Commission to decide on the classification of the specific product, by means of implementing acts.

9. The Commission shall consult the MDCG, and may consult the relevant expert panel for its scientific or technical advice. The Commission shall set a time-limit for the MDCG to adopt its opinion. The time limit shall not be shorter than 90 days.

9a. The manufacturer or authorised representative, as well as the notified body that issued the certificate, if applicable, shall be provided with the opportunity to present their positions on the classification of the device to the competent authorities, MDCG or the relevant expert panel, as applicable.

12. Within 180 days of the request from a Member State referred to in paragraph 8, the Commission shall propose to the Committee a decision on the classification of the device by means of implementing acts in accordance with the examination procedure referred to in Article 114(3). In adopting its decision, the Commission shall take the utmost account of the advice and opinions issued by the expert panel and the MDCG, respectively.

By way of derogation from the first subparagraph, the Commission may decide, in the absence of an opinion of the MDCG adopted by a majority of members pursuant to Article 103, paragraph 4, within the time-limit referred to in paragraph 9, not to adopt a decision on the classification of the device.

13. At the substantiated request of the MDCG, or on its own initiative, the Commission shall, decide by means of implementing acts, 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 be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.

14. In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant opinion of the MDCG and the scientific opinion of the relevant expert panel, the Commission is empowered to adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

15. The implementing acts referred to in paragraphs 13 and 14 of this Article shall be adopted in accordance with the examination procedure referred to in Article 114(3).

16. The opinions and decisions on the classification of devices, and the advice of the expert panel delivered in accordance with this Article shall be made publicly available, without disclosing any confidential information as referred to in Article 109.

17. The Commission may, by means of implementing acts, lay down the procedure, including timelines, for the application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

(43) Article 52 is amended as follows:

(a) in paragraph 3, the following subparagraph is added:

'By way of derogation from the first subparagraph, class III non-implantable devices that are well-established technology devices shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation, as specified in Sections 4.3 to 4.8 of that Annex, of one representative device per generic device group.

The representative device shall be chosen in accordance with the approach outlined in the third paragraph of Section 2.3 of Annex IX.

Where, having applied the approach in the third paragraph of Section 2.3 of Annex IX, a notified body considers it necessary, on justified grounds, to assess the technical documentation of additional representative devices due to their specific characteristics or properties, it shall document its rationale as part of the sampling plan to be drawn up in accordance with Annex VII Section 4.5.2(a).';

(b) paragraph 4 is replaced by the following:

'4. Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation, as specified in Sections 4.3 to 4.8 of that Annex, of one representative device per generic device group or, in the case of non-implantable class IIb devices that are well-established technology devices, one representative device per each category of devices.

The representative device shall be chosen in accordance with the approach outlined in the third paragraph of Section 2.3 of Annex IX.

Where, having applied the approach in the third paragraph of Section 2.3 of Annex IX, a notified body considers it necessary, on justified grounds, to assess the technical documentation of additional representative devices due to their specific characteristics or properties, it shall document its rationale as part of the sampling plan to be drawn up in accordance with Annex VII Section 4.5.2(a).

By way of derogation from the first subparagraph, for class IIb implantable devices, except well-established technology devices, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex X coupled with a conformity assessment based on product conformity verification as specified in Annex XI.';

(c) paragraph 5 is deleted;

(d) paragraph 6 is replaced by the following:

'6. Manufacturers of class IIa devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation, as specified in Sections 4.3 to 4.8 of that Annex, of one representative device for each category of devices.

Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annexes II and III coupled with a conformity assessment as specified in Section 10 or Section 18 of Annex XI. The assessment of the technical documentation shall apply for one representative device for each category of devices.

The representative device shall be chosen in accordance with the approach outlined in the third paragraph of Section 2.3 of Annex IX.

Where, having applied the approach in the third paragraph of Section 2.3 of Annex IX, a notified body considers it necessary, on justified grounds, to assess the technical documentation of additional representative devices due to their specific characteristics or properties, it shall document its rationale as part of the sampling plan to be drawn up in accordance with Annex VII Section 4.5.2(a).';

(e) paragraph 7 is amended as follows:

(i) the second sentence is replaced by the following:

'If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Section 10a of Annex XI.';

(g) in paragraph 14, the first subparagraph is replaced by the following:

‘The Commission may, by means of implementing acts, specify detailed arrangements and procedural aspects for any of the following aspects:

(a) the basis for the selection of representative device(s) for the assessment of the technical documentation as referred to in paragraphs 3, 4 and 6;

(b) the modalities of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of the technical documentation and type examination;

(d) the modalities of the conformity assessment procedures regarding breakthrough devices and orphan devices set out in Article 52a;’;

(44) the following Articles 52a and 52b are inserted:

*‘Article 52a*

**Conformity assessment of breakthrough devices, orphan devices, and essential paediatric devices**

1. For the conformity assessment of breakthrough devices, orphan devices, and essential paediatric devices, where the conformity assessment procedure requires the involvement of a notified body, the procedures laid down in Article 52 shall apply, and may, upon request by the manufacturer, be subject to the specific arrangements set out in this Article.

2. A device shall be considered a breakthrough device if it meets the following criteria:
   (a) it is expected to introduce in the Union a high degree of novelty with respect to the device technology, related clinical procedure or the application of the device in clinical practice; and
   (b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:
      (i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art;
      (ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

3. A device shall be considered an orphan device if it meets the following criteria:
   (a) it is intended for the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12 000 individuals in the Union per year; and
   (b) at least one of the following criteria is met:
      (i) there are insufficient available alternatives;
      (ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art, taking into account both device-specific factors and patient population-specific factors.

3a. A device, other than an orphan or breakthrough device, shall be considered an essential paediatric device if it meets the following criteria:

(a) it is intended exclusively for patients in the paediatric population, and

(b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:

(i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art;

(ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

4. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 shall provide an opinion with respect to confirming whether the criteria set out in paragraph 2, 3 or 3a of this Article, as applicable, are fulfilled. The opinion shall be published on a dedicated website without disclosing any confidential information as referred to in Article 109 and shall be duly taken into consideration by the manufacturer and the notified body.

5. Where the opinion of the expert panel has confirmed the fulfilment of the criteria set out in paragraph 2, 3 or 3a of this Article, the manufacturer of a breakthrough device, orphan device, or essential paediatric device, as applicable, may request advice from the expert panels referred to in Article 106 regarding its clinical development strategy and appropriate preclinical or clinical data for the clinical evaluation of the device.

6. For a breakthrough device, orphan device, or essential paediatric device, confirmed by the relevant expert panel, as applicable, the notified body involved in the conformity assessment procedure set out in Article 52 shall prioritise the conformity assessment of that device, offer priority access to supports to the manufacturer before and throughout the conformity assessment procedure, including priority access to dialogues before and after an application is lodged, in accordance with Section 1.2.9 of Annex VII, and apply, where appropriate, a rolling review with a view to reduce assessment timelines.

The notified body shall give utmost consideration to the opinion or advice provided by the expert panels in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided.

7. The notified body shall issue a certificate pursuant to Article 56 where all applicable requirements of this Regulation are fulfilled and, based on their assessment of the clinical evaluation report, the pre-market clinical evidence is deemed sufficient, even if based on limited clinical data, provided that each of the following criteria is fulfilled:
   (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical data are still required;
   (b) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market clinical follow-up activities, pursuant to an appropriate PMCF plan.

Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 56, such as a requirement for the manufacturer to conduct specific post-market clinical follow-up activities within a specified period of time.

8. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend this Article to adapt to technical or scientific progress or to take into account developments regarding conformity assessment of breakthrough devices, orphan devices, or essential paediatric devices at international level.

9. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices, orphan devices, or essential paediatric devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

*Article 52b*

**Digitalisation of technical documentation, conformity assessment and reports**

1. The manufacturer may draw up and make available in a digital format the technical documentation and any reports or other documents required pursuant to this Regulation. That digital format may be a structured machine-readable format, provided that it is possible to transform it into human-readable format, and that there is version-control to enable the conduct of retrospective conformity checks. Where the technical documentation, reports or other documents are to be submitted to and assessed by a notified body or made available to competent authorities for the purposes of market surveillance, the manufacturer shall ensure that the digital format is suitable for and agreed with the notified body or competent authority or national authorities responsible for notified bodies as applicable.

2. Where necessary to ensure that the digital format referred to in paragraph 1 is reliable, interoperable and standardised, the Commission may establish minimum requirements or functional specifications for the digital format by means of common specifications as referred to in Article 9.';

(45) in Article 53, paragraph 5 is replaced by the following:

'5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities in the public interest and 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.';

(46) Articles 54 and 55 are replaced by the following:

*'Article 54*

**Clinical evaluation consultation procedure for certain high-risk devices**

1. In addition to the procedures applicable pursuant to Article 52, a notified body shall follow the procedure regarding clinical evaluation consultation as specified in Section 5.1 of Annex IX or as referred to in Section 6 of Annex X, as applicable, when performing a conformity assessment of class III implantable devices, other than custom-made devices.

Where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 1 in order to add other types of devices to those devices that are subject to the clinical evaluation consultation procedure referred to in the first subparagraph.

2. By way of derogation from paragraph 1, the procedure referred to in that paragraph is not required in the following cases:
   (a) for a renewal of a certificate issued under this Regulation;
   (b) where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device;
   (c) where the principles of the clinical evaluation of the device type or category have been addressed in a harmonised standard referred to in Article 8 or in CS referred to in Article 9 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant harmonised standard or CS for clinical evaluation of that kind of device.

3. The notified body shall notify the competent authorities, the authority responsible for notified bodies and the Commission through the electronic system referred to in Article 57 of whether or not the procedure referred to in paragraph 1 of this Article is to be applied. That notification shall be accompanied by the clinical evaluation assessment report.

4. The notified body shall give utmost consideration to the opinion issued by the expert panel in the framework of the clinical evaluation consultation procedure. Where the notified body has not followed the views and recommendations expressed in that opinion, it shall provide a substantiated justification of the reasons therefore and its final clinical evaluation assessment report to the authority responsible for notified bodies of the Member State in which it is established, to the expert panel that issued the opinion and to the Commission.

*Article 55*

**Mechanism for scrutiny of conformity assessments**

1. The MDCG or the Commission may, based on reasonable concerns, and having consulted the authority responsible for notified bodies, request advice from an expert panel in relation to the safety and performance of any device which has undergone conformity assessment with the involvement of a notified body. For that purpose, the MDCG or the Commission may request the notified body that issued the certificate for the device in question to submit to the expert panel its clinical evaluation assessment report and any subsequent surveillance assessment reports regarding that device. The expert panel may request the notified body or the manufacturer to submit additional information necessary to provide its advice.

2. The MDCG or the Commission may, based on reasonable concerns, and having consulted the authority responsible for notified bodies request advice from one or more expert laboratories, based on their expertise related to laboratory testing, in relation to the safety and performance of any device which has undergone conformity assessment with the involvement of a notified body, provided that the device or the field of laboratory testing falls within the scope of designation of those expert laboratories. For that purpose, the MDCG or the Commission may request the notified body that issued the certificate for the device in question to submit to the expert laboratories its clinical evaluation assessment report, other relevant parts of the technical documentation and any subsequent surveillance assessment reports regarding that device. The expert laboratories may request the notified body or the manufacturer to submit samples of the device or any additional information necessary to provide its advice.

3. The notified body shall give utmost consideration to the advice provided by the expert panel or the expert laboratory and, where needed, take any appropriate measures, including those referred to in Article 56(3) and (4).';

(47) Article 56 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. The EU technical documentation assessment certificates or EU type examination certificates related to Class III devices and implantable Class IIb devices, other than well-established technology devices, shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the initial validity of the certificates for Class III devices and implantable Class IIb devices, other than well-established technology devices, may be extended for a further period not limited in time, based on a re-assessment after the initial five years and periodic reviews thereafter, in accordance with the applicable conformity assessment procedures and with Annex VII, Section 4.11.

All other certificates shall not be limited in time.

Notwithstanding subparagraphs 1 and 2, the notified body may limit the period of validity of certificates it issues based on duly justified grounds. In those cases, the notified body shall indicate the period of validity on the certificate.

If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.';

(b) the following paragraph 2a is inserted:

'2a. During the validity of the certificate, the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art, in accordance with Section 4.11 of Annex VII. Those reviews shall be proportionate to the risk class of the device.';

(c) paragraph 3 is replaced by the following:

'3. Notified bodies may impose conditions on the validity of the certificate, in accordance with Section 4.8 of Annex VII.';

(d) in paragraph 4, the first sentence is replaced by the following:

'Where a notified body finds that the 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 conditions 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.';

(e) in paragraph 5, the first sentence is replaced by the following:

'The notified body shall enter in the electronic system referred to in Article 57 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and conditions imposed on certificates.';

(48) Article 57 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) point (f) is replaced by the following:

‘(f) the notifications for conformity assessments and information or documents referred to in Article 54(3)’;

(49) Article 59 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. By way of derogation from Article 52, on a duly justified request, any competent authority may authorise, for a limited period of time, the placing on the market or putting into service within the territory of the Member State concerned of a specific device for which the applicable conformity assessment procedures have not been carried out, provided that the use of that device is in the interest of public health, patient safety or patient health.’;

(b) the following paragraphs 1a and 1b are inserted:

‘1a. By way of derogation from Article 6(2), on a duly justified request, any competent authority may authorise for a limited period of time, the use of a specific device that is not placed on the Union market for the provision of a diagnostic or therapeutic service referred to in that Article to (a) natural or legal person(s) established within the territory of the Member State concerned using a specific device for which the applicable conformity assessment procedures set out in this Regulation have not been carried out, provided that the provision of that service is in the interest of public health, patient safety or patient health.;

1b. Where appropriate, the competent authority may specify and impose additional conditions or limitations to the derogations referred to in paragraphs 1 and 1a, such as conditions on labelling, serious incident reporting, traceability and limitations to the number of devices.;’

(c) paragraph 2 is replaced by the following:

‘2. The Member State shall inform the Commission, the Agency, and the other Member States of any decision made on requests to authorise the placing on the market or putting into service of a device in accordance with paragraph 1, or the use of a device for the provision of a service in accordance with paragraph 1a, where such authorisation is granted for use other than for a single patient. Where relevant, the Agency shall share this information with the relevant expert panels referred to in Article 106.

The Member State shall also make information about such authorisations publicly available.’;

(d) in paragraph 3, the first subparagraph is replaced by the following:

‘Where a request pursuant to paragraph 1 or paragraph 1a has been submitted to competent authorities in more than one Member State and based on an opinion, where applicable of an expert panel referred to in Article 106, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time or number of devices the validity of an authorisation granted by a Member State in accordance with paragraph 1 or paragraph 1a to the territory of the Union, or provide an authorisation referred to in paragraph 1 or paragraph 1a for the territory of the Union. The Commission may set out the conditions under which the device may be placed on the market or put into service, or under which the diagnostic or therapeutic service may be provided. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). The Commission shall make information about such Union-wide authorisations publicly available.’;

(e) the following paragraphs 4 and 5 are added:

‘4. In the event of a public health emergency at Union level recognised in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council*******, the Commission may, by means of implementing acts, on its own initiative after consulting the MDCG, and if appropriate, the relevant expert panel, authorise the placing on the market or putting into service of a device in accordance with paragraph 3. The authorisation shall cease to apply at the latest when the recognition of the public health emergency is terminated pursuant to Article 23(2) of Regulation (EU) 2022/2371. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4).

5. The Commission may, by means of implementing acts, lay down rules further specifying the procedure set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

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******* Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).’;

(50) the following Articles 59a, 59b and 59c are inserted:

*'Article 59a*

**Derogations from certain requirements in the event of a serious cross-border threat to health, disaster or crisis**

1. Upon a duly justified request, a competent authority may authorise for a limited period of time, by way of derogation from the relevant provisions in Annexes II, III, IX, X and XI, an exemption from the requirements related to changes to the manufacturing, or design or intended purpose of a specific CE marked device, where it is in the interest of public health, patient safety or patient health, in either of the following circumstances:
   (a) a serious cross-border threat to health as defined in Article 3, point (1), of Regulation (EU) 2022/2371;
   (b) a disaster or a crisis within the meaning of Regulation (EU) …/… of the European Parliament and of the Council********+.

2. The manufacturer shall ensure that the manufactured devices remain in conformity with the relevant general safety and performance requirements set out in Annex I. The manufacturer shall ensure that any changes referred to in paragraph 1 do not adversely affect the benefit-risk ratio of the device.

3. The competent authority may request the notified body that issued a certificate for the device in question, to assist it in the assessment of a request referred to in paragraph 1.

3a. Where appropriate, the competent authority shall impose and specify conditions or limitations, as applicable, to the authorisation of exemption in accordance with paragraph 1. These may include, but are not limited to, conditions on labelling, incident reporting, traceability, and limitations on the number of devices.

4. Where applicable, the manufacturer shall keep the notified body that issued a certificate for the device in question informed about the authorisation and any changes made regarding the manufacturing, design or intended purpose of a CE marked device in accordance with the authorisation referred to in paragraph 1.

5. Where a request pursuant to paragraph 1 has been submitted to competent authorities in more than one Member State, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time or number of devices, the validity of an exemption granted by a Member State in accordance with paragraph 1 to the territory of the Union, or provide an exemption referred to in paragraph 1 for the territory of the Union. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4).

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******** Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ..., ELI ) [+] OJ: Please insert in the text the number of the Regulation contained in 2025/0223(COD) (Proposal for a Regulation on the Union Civil Protection Mechanism and Union support for health emergency preparedness and response, and repealing Decision No 1313/2013/EU) and insert the number, date, title and OJ reference of that Regulation in the footnote.'

*Article 59b*

**Regulatory sandboxes at national level**

1. Member States, on their own initiative or upon a substantiated request by a manufacturer, may establish one or more regulatory sandboxes where:
   (a) Based on available scientific data, the application of certain requirements of Chapters V or VI or of Chapters II and III of Annex I or Annexes VIII, IX, X, XI, XIV or XV to a specific device or category or group of devices would not be practicable from a technical, clinical or scientific viewpoint, and
   (b) With regard to those requirements, every precaution has been taken to protect the health and safety of patients, users, and other persons, in line with the principles set out in the Regulation.

   The Member States shall designate the competent authority that is responsible for the supervision of the regulatory sandbox. Member States may also establish regulatory sandboxes jointly with other Member States.

2. The activities within a regulatory sandbox shall take place pursuant to a specific sandbox plan that shall set out technical, clinical or scientific justification for the necessity to establish a regulatory sandbox, including at least:
   (a) the identification of the requirements of this Regulation referred to in paragraph 1, which are temporarily adapted in the regulatory sandbox;
   (b) a justification why the application of those requirements is considered not practicable and identification of mitigation measures for potential risks related to the adaptation;

(c) recommendations for alternative or mitigation measures, where appropriate;

(d) the identification of the reasonable duration of the regulatory sandbox necessary to achieve its objectives, the participants in the regulatory sandbox and their respective roles;

(e) the identification of the responsibilities and obligations of each participant in the regulatory sandbox, including the person or persons responsible for the conduct and oversight of the regulatory sandbox; and

(f) procedures for the reporting, assessment and management of incidents, serious incidents, or serious adverse events, including the implementation of appropriate corrective and preventive measures, taking into consideration paragraph 5 of this Article.

3. A regulatory sandbox shall be set up only if the following conditions are met:

(a) the device is expected to address unmet medical needs or to provide, based on available scientific data, a significant clinical benefit to patients or to the health system compared with similar existing alternatives, if any, or the state of the art;

(b) based on available scientific data, the application of the requirements of this Regulation referred to in paragraph 1 would not be practicable due to technical, clinical or scientific challenges arising from characteristics or methods related to the device.

4. The Member State may request an expert panel referred to in Article 106 to provide scientific, technical or regulatory advice on the draft sandbox plan.

5. Articles 80 and 87 shall apply, mutatis mutandis, for any serious incidents or serious adverse events that have occurred in relation to the activities taking place in the regulatory sandbox. Any participant in the regulatory sandbox shall report, without undue delay, to the competent authority that is responsible for the supervision of the regulatory sandbox about the harm that occurred in relation to the implementation of the regulatory sandbox. The competent authority shall have the power to take immediate and adequate corrective measures, including temporarily or permanently suspend participation in the sandbox, or suspend, revoke or restrict the scope of the regulatory sandbox, including amending the sandbox plan.

6. Manufacturers participating in a regulatory sandbox shall remain liable under applicable Union and national law for any damage inflicted on third parties as a result of their activities taking place in the regulatory sandbox.

7. The Member State shall inform the Commission and the MDCG about the establishment of a regulatory sandbox and keep them informed about its implementation and outcome.

8. Where a Member State has taken a measure referred to in paragraph 5 of this Article, that Member State shall communicate the corresponding decision and the grounds therefor to the Commission and the MDCG.

9. The Commission may, by means of implementing acts, lay down procedural arrangements for the application of this Article.

The implementing acts shall include at least the following:

(-a) procedures for the establishment, operation and supervision of regulatory sandboxes pursuant to this Article;

(a) procedures for the application, selection, participation, monitoring, exiting from and termination of a regulatory sandbox, including the sandbox plan and outcome;

(b) the terms and conditions and procedural obligations applicable to the participants.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

*Article 59c*

**Union regulatory sandboxes**

1. The Commission, on its own initiative, and in consultation with the MDCG, or upon a substantiated request by a Member State, may establish, by means of implementing acts for a limited time and pursuant to a specific plan, Union regulatory sandboxes, to technically adapt existing requirements applicable to a specific type of device with particular characteristics or emerging technologies, where:

(a) there is a risk that the existing requirements would not be applicable due to technical or scientific challenges arising from characteristics or technologies inherent to the device;

(b) based on scientific evidence, the adaptations are considered indispensable to adequately protect the health and safety of patients, users or other persons or other aspects of public health, in line with the principles set out in the Regulation.

Union regulatory sandboxes shall not involve the placing on the market or putting into service of devices which do not comply with this Regulation.

2. The Commission shall, following consultation with the MDCG, request an expert panel as referred to in Article 106 to provide scientific, technical or regulatory advice on the design of a Union regulatory sandbox.

3. The Commission shall consult with the MDCG about the establishment of a regulatory sandbox and keep it informed about its outcome.

4. The Commission shall, by means of implementing acts lay down detailed arrangements for the establishment, operation and supervision of Union regulatory sandboxes pursuant to this Article.

The implementing acts shall include at least the following:

(a) procedures for the application, participation, monitoring, exiting from and termination of a regulatory sandbox, including the sandbox plan and outcome;

(b) the terms and conditions, and rights and obligations applicable to the participants.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

5. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this Article based on scientific, technical or regulatory progress or developments regarding Union regulatory sandboxes, in order to specify technical, scientific and regulatory features of a Union regulatory sandbox.';

(51) in Article 60, the following paragraphs 1a and 1b are inserted:

'1a. The person referred to in Article 22(1) or (3) may request the Member State where it is established to issue a certificate of free sale for a system or procedure pack for which it has drawn up a statement in accordance with Article 22.

1b. The manufacturer or person referred to in Article 22(1) or (3) shall make the certificates of free sale issued in accordance with paragraphs 1 and 1a publicly available in Eudamed within 30 days of issuance.';

(52) Article 61 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

'1. Manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and with Part A of Annex XIV to confirm the safety and performance of the device under normal conditions of use in accordance with the intended purpose of the device, and evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I.

The manufacturer shall specify and justify the level of clinical evidence necessary to confirm the safety and performance of the device. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned.

2. For class IIb and class III devices, a manufacturer may, prior to its clinical investigation or clinical evaluation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy or proposals for clinical investigation. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the clinical evaluation report and the clinical evaluation assessment report, give due consideration to the advice of the expert panel and where they do not follow the advice, they shall provide duly justified reasons.';

(b) in paragraph 4, first subparagraph, the introductory wording is replaced by the following:
'In the case of implantable class IIb devices and class III devices, other than custom-made devices, clinical investigations shall be performed, except if:';

(c) paragraph 5 is replaced by the following:

'5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by it, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the original clinical evaluation has been performed in compliance with the requirements of this Regulation and has not already availed itself of the exception from performing a clinical investigation set out in this paragraph or paragraph 4, the manufacturer has sufficient access to relevant information on the design, materials and the clinical evaluation of the equivalent device, and the manufacturer provides clear evidence thereof to the notified body.';

(d) paragraph 6 is amended as follows:

(i) the introductory wording is replaced by the following:

'The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable class IIb devices and class III devices:';

(ii) point (b) is replaced by the following:

'(b) that are well-established technology devices for which the clinical evaluation is based on sufficient clinical evidence and is in compliance with the relevant product-specific CS or harmonised standards, where available;'

(e) paragraph 8 is deleted;

(f) paragraphs 10 and 11 are replaced by the following:

'10. Without prejudice to paragraph 4, where the confirmation of safety and performance based on clinical data is not deemed appropriate, adequate justification shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer and the data available for the generic device group. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing, in vitro, ex vivo, in silico testing, computational modelling or simulation and pre-clinical evaluation, to be adequate.

Where necessary to ensure the uniform application of this paragraph, the Commission may, in consultation with the MDCG, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

11. The clinical evaluation, its documentation and, where applicable and needed, the summary of safety and clinical performance referred to in Article 32 shall be updated throughout the life cycle of the device concerned with data and findings obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84, whenever those data and findings provide information relevant for the confirmation of safety and performance of the device. For Class IIb implantable and Class III devices, these shall be updated at least every two years.';

(g) paragraph 12 is deleted;

(54) in Article 64(1), point (g) is replaced by the following:

'(g) there are scientific grounds for expecting that participation in the clinical investigation will produce either of the following:

(i) a direct benefit to the incapacitated subject outweighing the risks and burdens involved;

(ii) some benefit for the population represented by the incapacitated subject concerned when the clinical investigation relates directly to the life-threatening or debilitating medical condition from which the subject suffers and such clinical investigation will pose only minimal risk to, and will impose minimal burden on, the incapacitated subject concerned in comparison with the standard treatment of the subject's condition.';

(55) in Article 65, point (g) is replaced by the following:

‘(g) there are scientific grounds for expecting that participation in the clinical investigation will produce either of the following:

(i) a direct benefit to the minor outweighing the risks and burdens involved;

(ii) some benefit for the population represented by the minor concerned and such a clinical investigation will pose only minimal risk to, and will impose minimal burden on, the minor in comparison with the standard treatment of the subject's condition.’;

(56) in Article 66, point (a) is replaced by the following:

‘(a) the clinical investigation 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, or if the clinical investigation has not the potential to produce such direct benefit, the following conditions are met:

(i) a clinical investigation of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;

(ii) the clinical investigation 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;

(iii) the clinical investigation poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth.’;

(58) in Article 72, the following paragraph 7 is added:

‘7. The processing of personal data in the context of a clinical investigation, including the secondary use of personal data initially collected for other investigations, may be carried out for scientific research purposes as referred to in Article 9(2), point (j), of Regulation (EU) 2016/679, without prejudice to the obligations and requirements set out in that Regulation.’;

(58a) In Article 73, paragraph 3, point (a) is replaced by the following:

‘(a) protection of personal data in accordance with Regulation (EU) 2018/1725;’;

(59) in Article 74, paragraph 1 is replaced by the following:

‘1. Where a clinical investigation is to be conducted to further assess, within the scope of its intended purpose and in accordance with its PMCF plan, a device which already bears the CE marking in accordance with Article 20(1), (‘PMCF investigation’), and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 73. The sponsor shall include the documentation referred to in Chapter II, Sections 1, 3 and 4, of Annex XV as part of the notification. Article 62(4), points (b) to (k) and (m), Article 75(1), Articles 76 and 77, Article 80(5) and (6), and the relevant provisions of Annex XV shall apply to PMCF investigations involving additional invasive or burdensome procedures.’;

(60) Article 75 is amended as follows:

(a) in paragraph 1, the first sentence is replaced by the following:

‘If a sponsor intends to introduce modifications to a clinical investigation 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 clinical data generated by the investigation, it shall notify, by means of the electronic system referred to in Article 73, the Member State(s) in which the clinical investigation is being or is to be conducted of the reasons for and the nature of those modifications.’;

(b) paragraph 2 is replaced by the following:

‘2. Where the clinical investigation has been the subject of an authorisation in accordance with Article 62(4), point (a), the Member State shall assess any substantial modification to the clinical investigation in accordance with the procedure laid down in Article 71.

The Member State shall notify the sponsor of the outcome of its assessment within 38 days of receipt of the sponsor’s notification under paragraph 1.

During its assessment, the Member State may request additional information from the sponsor. The period of 38 days shall be suspended from the date of the first request until such time as the additional information has been received.’;

(c) in paragraph 3, the introductory wording is replaced by the following:

‘The sponsor may implement the modifications referred to in paragraph 1 as soon as the Member State concerned has notified the sponsor of its authorisation or following expiry of the period defined in paragraph 2, whichever is sooner, unless:’;

(61) Article 78 is amended as follows:

(a) in paragraph 4, the second subparagraph is replaced by the following:
'The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with paragraph 11.';

(b) paragraph 5 is replaced by the following:
'5. Each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within 12 days of receipt of the request. The expiry of the last deadline pursuant to paragraph 4, point (d), shall be suspended from the date of the request until such time as the additional information has been received.';

(c) in paragraph 6, the reference to '50 days' is replaced by '30 days';

(d) the following paragraph 15 is added:
'15. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this Article in light of experience gained from the practical application of the coordinated assessment procedure, in particular as regards timelines and the authorisation of clinical investigations subject to a coordinated assessment.';

(62) Article 79 is deleted;

(64) Paragraphs 1 and 2 of Article 82 are replaced by the following:
'1. Clinical investigations, not performed pursuant to any of the purposes listed in Article 62(1) or Article 74, shall comply with the provisions of Article 62 (2) and (3), points (b), (c), (d), (f), (h) and (l) of Article 62(4) and Article 62(6).

2. In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of clinical investigations not performed for any of the purposes listed in Article 62(1) or Article 74, each Member State shall define any additional requirements for such investigations, as appropriate for each Member State concerned.';

(65) Article 83(4) is replaced by the following:
'If in the course of the post-market surveillance, a need for preventive or corrective action, or both, is identified, the manufacturer shall implement the appropriate measures. Where preventive or corrective action is taken to reduce a risk that may compromise the safety of the device, the manufacturer shall inform the competent authorities concerned. Where such corrective actions are associated with an identified serious incident or an implemented field safety corrective action, it shall be reported in accordance with Article 87.';

(66) in Article 84, the following sentence is added after the second sentence:
'The post-market surveillance plan shall specify the criteria, and timelines where relevant, for updating the Post-Market Surveillance Report as referred to in Article 85 or the Periodic Safety Update Report as referred to in Article 86.';

(66a) Article 85 is replaced by the following:
Manufacturers of custom-made and of class I devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 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 competent authority upon request.

(67) Article 86 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the first sentence is replaced by the following: ‘Manufacturers of class IIa, class IIb and class III devices, other than custom-made devices, shall prepare a periodic safety update report (‘PSUR’) for each device, or where relevant for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84, together with a description of any preventive and corrective actions taken, including their rationale.’;

(ii) the second and third subparagraphs are replaced by the following: ‘Manufacturers of class IIb and class III devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter or when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects. The PSUR shall be part of the technical documentation as specified in Annex III.

Manufacturers of class IIa devices shall update the PSUR in accordance with the criteria set out in the manufacturer’s post-market surveillance plan referred to in Article 84, and in any event when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects. The PSURs shall be part of the technical documentation specified in Annex III.’;

(iii) the fourth subparagraph is deleted.

(b) paragraph 2 is replaced by the following:

‘2. For class III devices or class IIb implantable devices, other than well-established technology devices, the notified body shall review the PSUR as part of its surveillance activities, where applicable. The manufacturer shall make such PSURs available through the electronic system referred to in Article 92. The notified body shall make its evaluation of such PSURs available through the electronic system referred to in Article 92.

For all other devices where the PSUR is applicable, the notified body shall have documented procedures for reviewing PSURs on a representative basis as part of the surveillance activities in accordance with Section 4.10 of Annex VII.’;

(68) Article 87 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, point (a) is replaced by the following:

‘(a) any serious incident involving devices made available on the Union market, except expected undesirable side-effects which are clearly documented in the device information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;’;

(ii) the second subparagraph is replaced by the following:

‘The reports referred to in the first subparagraph shall be submitted in accordance with the timelines specified in this Article through the electronic system referred to in Article 92.’;

(b) paragraph 3 is replaced by the following:

‘3. Manufacturers shall report any serious incident as referred to in paragraph 1, first subparagraph, point (a), immediately after they have established that there is a causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 30 days after they become aware of the incident.’;

(69) the following Article 87a is inserted:

*‘Article 87a*

**Reporting of actively exploited vulnerabilities and severe incidents related to devices**

1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 87, the manufacturer of a device shall inform to the computer security incident response teams (‘CSIRTs’), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), either of the following:

(a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 of the European Parliament and of the Council********* contained in the device;

(b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.

2. The manufacturer shall submit a notification of the actively exploited vulnerability or severe incident referred to in paragraph 1 through the electronic system referred to in Article 92.

   For the purposes of this notification the manufacturer shall submit:

   (a) an early warning notification of an actively exploited vulnerability or severe incident within 24 hours of the manufacturer becoming aware of it, indicating, where applicable, the Member States on the territory of which the manufacturer is aware that their device has been made available;

   (b) unless the relevant information has already been provided, a final report, no later than 30 days after a corrective or mitigating measure is available.

3. The information referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 87 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA.

4. For the purposes of this Article, the CSIRTs designated as coordinators and ENISA shall have access to Eudamed.

5. In respect of the information referred to in paragraph 1, the competent authorities shall cooperate with the CSIRTs designated as coordinators of the Member States in which the device has been made available, and with ENISA.

5a. Where a CSIRT designated as coordinator or ENISA consider that specific action may be needed to address the actively exploited vulnerability or severe incident informed in accordance with paragraph 1, they shall inform the competent authority of the Member State where the manufacturer is established and, where appropriate, may provide technical advice.';

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********* Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).';

(69a) the following Article 87b is inserted:

'Article 87b

**Reporting of serious incidents under Regulation (EU) 2024/1689**

For devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, serious incidents, related to the infringement of obligations under Union law intended to protect fundamental rights within the meaning of Article 3(49), point (c), of Regulation (EU) 2024/1689, shall be reported to the national competent authority chosen for that purpose under that Regulation by the Member States where the incident occurred.';

(70) in Article 88(1), the first sentence is replaced by the following:

‘Manufacturers shall report, by means of the electronic system referred to in Article 92, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I.’;

(71) Article 89 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Following reporting pursuant to Article 87(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include a risk assessment of the incident or field safety corrective action taking into account criteria as referred to in paragraph 3 of this Article as appropriate.

The manufacturer shall cooperate with the competent authorities during the investigations referred to in the first subparagraph 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.’;

(b) paragraph 2 is replaced by the following:

‘2. 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 87 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer.’;

(c) the following paragraph 3a is inserted:

‘3a. The competent authorities may exchange information in relation to their assessments in paragraph 3 and, where relevant, cooperate and exchange relevant information with the authorities responsible for notified bodies and the authorities responsible for market surveillance. Where appropriate, the competent authorities may also cooperate and exchange relevant information with other authorities, including in the fields of cybersecurity, artificial intelligence, and other areas where regulatory interplay exists, whose responsibilities are relevant to the performance of their vigilance activities.

The competent authority may request the notified body that issued a certificate for the device in question in accordance with Article 56 to provide assistance in evaluating a corrective action related to a serious incident or a field safety corrective action, taking into account the risk management and conformity assessment performed for the device.’;

(d) paragraph 6 is replaced by the following:

‘6. In the case of devices referred to in Article 1(8), first subparagraph, and where the serious incident or field safety corrective action is confirmed by the manufacturer to be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 shall inform the national competent authority or the EMA, which issued the scientific opinion on that substance in accordance with Article 52(9), of that serious incident or field safety corrective action.

In the case of devices falling within the scope of this Regulation in accordance with Article 1(6), point (g), or in accordance with Article 1(10), the competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall inform the competent authority for substances of human origin that was consulted by the notified body in accordance with Article 52(10), provided that the serious incident or field safety corrective action is confirmed by the manufacturer to be related to the derivatives of substances of human origin utilised for the manufacture of the device or to the non-viable substances of human origin or their derivatives that have an action ancillary to that of the device.';

(e) paragraph 7 is replaced by the following:

'7. If, after carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority identifies the need for additional corrective actions from the manufacturer to minimise the risk of recurrence of the serious incident, it shall, through the electronic system referred to in Article 92, inform, without delay, the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying events and the outcome of its assessment.';

(f) in paragraph 9, the introductory wording is replaced by the following:

'The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 whenever such coordination is needed to ensure a high level of protection of the health and safety of patients, users and other persons or the protection of public health throughout the Union, and in particular in the following cases:';

(72) in Article 91, the first subparagraph is amended as follows:

(a) the introductory wording is replaced by the following:

'The Commission may, by means of implementing acts, and after consulting the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 84 to 90 and Article 92 as regards the following:';

(b) point (b) is replaced by the following:

'(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision and content of the post-market surveillance plan, periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 84, 85, 86, 87, 88 and 89 respectively;';

(c) the following point (g) is added:

'(g) the reporting of actively exploited vulnerabilities and severe incidents as referred to in Article 87a and the reporting of serious incidents as referred to in Article 87b.';

(73) in Article 92(2), the reference to 'Article 53' is replaced by 'Article 56';

(74) Article 93 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices and on the compliance of economic operators with the obligations set out in this Regulation including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.';

(b) the following paragraph 1a is inserted:

‘1a. Member States shall ensure that their national competent authorities are provided with adequate and sufficient technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation.’;

(c) paragraph 2 is replaced by the following:

‘2. The competent authorities shall draw up annual surveillance activity plans, taking into account the European market surveillance programme, which shall be developed and maintained by the MDCG, and local circumstances.’;

(d) the following paragraph 12 is added:

‘12. The competent authorities may exchange information in relation to their market surveillance activities and, where relevant, cooperate and exchange relevant information with the authorities responsible for notified bodies and the authorities responsible for vigilance.

Where appropriate, the competent authorities may also cooperate and exchange relevant information with other authorities, including in the fields of cybersecurity, artificial intelligence, and other areas where regulatory interplay exists, whose responsibilities are relevant to the performance of their market surveillance activities.

In respect of devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, the competent authorities shall cooperate with market surveillance authorities of their Member State designated in accordance with Article 70 of Regulation (EU) 2024/1689.’;

(75) Article 94 is replaced by the following:

*'Article 94*

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

The competent authorities of a Member State shall, alone or in cooperation with the competent authorities of other Member States, carry out an evaluation of a device covering all the relevant requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device, where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) the 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;

(b) the device concerned otherwise does not comply with the requirements laid down in this Regulation.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities.

The competent authorities of the Member States may request any economic operator or notified body to submit documentation available to them, where access to such documentation is needed in the interest of public health or patient safety or health.';

(76) Article 95 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken, within the period referred to in paragraph 1, throughout the Union in respect of all the devices concerned that they have made available on the market.’;

(b) paragraph 7 is amended as follows:

(i) the first subparagraph is replaced by the following:

‘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 the notified measures taken by a Member State, those measures shall be deemed to be justified.’;

(ii) the second subparagraph is replaced by the following:

‘In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market, are taken without delay in respect of the device concerned.

Corresponding measures adopted by the other Member States pursuant to this paragraph shall be based on the notification referred to in paragraph 4. Those measures shall not be subject to the procedure referred to in paragraph 4.’;

(77) Article 96 is amended as follows:

(b) in paragraph 2, the second sentence of the first subparagraph is replaced by the following:

'If the Commission considers that the national measure is unjustified, the Member State concerned, as well as any Member State that has taken corresponding restrictive or prohibitive measures, shall withdraw the measure.';

(78) Article 97 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Where, having performed an evaluation pursuant to Article 94, 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 bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.';

(b) in paragraph 2, the first sentence is replaced by the following:

'Where the economic operator does not bring the non-compliance to an end 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 national market or to ensure that it is recalled or withdrawn from the national market.';

(c) the following paragraph 2a is inserted:

'2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.';

(80) the title of Chapter VIII is replaced by the following:

‘**COOPERATION BETWEEN MEMBER STATES, THE MDCG, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS, CONFLICTS OF INTEREST AND INTERNATIONAL COOPERATION**’;

(81) after the title of Chapter VIII, the following title is inserted:

‘**SECTION 1**

**Cooperation between Member States, the MDCG, expert panels, expert laboratories and device registers and conflict of interests**’;

(82) Article 101 is replaced by the following:

*‘Article 101*

**Competent authorities**

The Member States shall designate the competent authority or authorities responsible for the implementation and practical application of this Regulation. They shall ensure that those authorities are entrusted with sufficient powers, resources, equipment and knowledge necessary to effectively and efficiently perform their tasks pursuant to this Regulation, in practice. 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.’;

(82a) In Article 102, paragraph 1 is replaced by the following:

‘1. The competent authorities of the Member States shall cooperate with each other, with the authorities responsible for notified bodies, with the Commission and with the Agency. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.’;

(83) in Article 102, paragraph 2 is deleted;

(84) Article 103 is amended as follows:

(a) in paragraph 2, second subparagraph, the second sentence is replaced by the following: ‘They shall represent the competent authorities of the Member States and the authorities responsible for notified bodies of the Member States, as applicable.’;

(b) paragraph 7 is replaced by the following:

‘7. The MDCG shall establish standing or temporary sub-groups, including the subgroup defined in Article 105a.

Where appropriate, representatives of the coordination group referred to in Article 49 and organisations representing the interests of the medical device industry, including micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC, healthcare professionals, laboratories, patients and consumers at Union level shall be invited to the MDCG and its sub-groups in the capacity of observers.’;

(c) paragraph 9 is replaced by the following:

‘9. The MDCG shall have the tasks laid down in Article 105 of this Regulation and Article 99 of Regulation (EU) 2017/746 and may request the standing or temporary sub-groups referred to in paragraph 7 to carry out these or other tasks under its supervision.’;

(85) Article 104 is replaced by the following:

‘The Commission shall support the functioning of the cooperation between national competent authorities, between authorities responsible for notified bodies and between national competent authorities and authorities responsible for notified bodies.

It shall organise the meetings of the MDCG and its sub-groups, participate in those meetings, provide support and ensure the appropriate follow-up.’;

(86) Article 105 is replaced by the following:

*'Article 105*

**Tasks of the MDCG**

Under this Regulation, the MDCG shall monitor and contribute to the consistent, effective and harmonised application and implementation of this Regulation. It shall in particular have the following tasks:

(a) to contribute, when needed, to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 49, including endorsement of the work programme and technical guidance developed by that group;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation;

(d) to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to this Regulation;

(e) to contribute to the development of device standards, of CS and of scientific guidelines, including product specific guidelines;

(g) 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;

(h) to contribute to harmonised administrative practice with regard to devices in the Member States;

(i) to advise the Commission, competent authorities and authorities responsible for notified bodies regarding international regulatory cooperation in accordance with Articles 108a to 108c;

(j) to conduct horizon scanning to identify technological, legal or external sectoral changes or developments which may impact the regulatory system and propose solutions;

(k) to support and oversee international initiatives aimed at improving harmonisation of regulatory operations and activities;

(m) to advise the Commission, at its request, and to assist the competent authorities of the Member States in matters concerning Union regulatory sandboxes and regulatory sandboxes at national level;

In addition to the tasks assigned to it in other provisions of this Regulation, the MDCG shall assist the Commission in the assessment of any issue related to the implementation of this Regulation.';

(86a) A new Article 105a is inserted as follows:

*'Article 105a*

**Notified Body Oversight subgroup**

The Notified Body Oversight subgroup (NBO) shall assist the MDCG on issues relating to notified bodies and conformity assessments, with the aim of consistent, effective and harmonised application and implementation of this Regulation and Regulation (EU) 2017/746 with respect to notified bodies.

The NBO shall be composed of members representing the authorities responsible for notified bodies.

Under this Regulation and under the supervision of the MDCG, the NBO shall, in particular, have the following tasks:

(a) to develop draft best practice documents relating to the activities of the authorities responsible for notified bodies, for endorsement of the MDCG;

(b) to develop draft guidance documents for notified bodies in relation to the implementation of these Regulations, for endorsement of the MDCG;

(c) to initiate the draft work programme, the draft common templates and the draft technical guidance elaborated by the coordination group of notified bodies as established pursuant to Article 49;

(d) to contribute to develop training and qualification of the experts referred to in Article 40;

(e) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV, including being consulted by the Commission on the composition of the joint assessment team referred to in Article 36;

(f) to monitor the conformity assessment activities of notified bodies;

(ff) to monitor and promote consistency in the application by the notified bodies of the provisions relating to the selection of representative devices as outlined in Article 52 and surveillance assessments as outlined in Annex IX, Section III;

(g) to promote uniform application of the designation and the surveillance activities of designating authorities;

(h) to provide the MDCG with proposals for improving harmonisation of practices amongst notified bodies and harmonisation of practices amongst designating authorities;

(i) to consider and draw from the exchange of experience referred to in Article 48 and to cooperate with the coordination group referred to in Article 49.

Where appropriate, representatives of the coordination group referred to in Article 49 shall be invited in the capacity of observers.';

(86b) Article 106 is replaced by the following:

*'Article 106*

**Expert panels**

1. The Commission shall, by means of implementing acts and following consultation with the MDCG, make provision for expert panels to be designated to provide scientific, clinical or technical opinions and advice in relation to the implementation of this Regulation and of Regulation (EU) 2017/746 to the Commission, the MDCG, Member States, notified bodies or manufacturers.

   Expert panels may be designated on a standing or temporary basis.

2. Expert panels shall consist of experts with proven up-to-date clinical, scientific, technical expertise relevant to the field of medical devices or in vitro diagnostic medical devices reflecting the diversity of scientific and clinical approaches in the Union.

   Experts shall be appointed, in consultation with the MDCG, following publication of a call for expressions of interest. Depending on the type of task and the need for specific expertise, experts may be appointed to the panels for a maximum period of three years and their appointment may be renewed.

2a. The activities of the expert panels shall facilitate effective, harmonised and evidence-based application of this Regulation and Regulation (EU) 2017/746. Experts from national competent authorities shall be appropriately integrated within the expert panel structure where necessary.

3. The experts shall observe the principles of highest scientific competence and perform their tasks with impartiality, objectivity and transparency. They shall neither seek nor take instructions from Member States, notified bodies, manufacturers or other economic operators. Each expert shall draw up a declaration of interests, which shall be made publicly available.

3a. The Agency shall establish systems and procedures to actively manage and prevent potential conflicts of interest during the appointment of experts.

4. Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals' associations.

5. Experts may be included on a central list of available experts who, whilst not being formally appointed to a panel, are available to provide advice and to support the work of the expert panels as needed.

6. Experts from notified bodies shall not be involved in the clinical evaluation consultation procedure provided for in Article 54(1) of this Regulation.

An individual expert from a notified body shall not be involved in the provision of advice on a specific device for which the expert or their notified body have been involved in the conformity assessment. An expert from a notified body shall not be involved in the conformity assessment activities regarding a specific device for which the expert was involved in the provision of advice from an expert panel.

7. In addition to the tasks assigned to them in other provisions of this Regulation and of Regulation (EU) 2017/746, the expert panels shall support the MDCG and the Commission and have the following tasks:
   (a) to provide scientific, clinical and technical advice to the Commission, the MDCG, Member States or notified bodies in relation to the implementation of this Regulation or Regulation (EU) 2017/746;
   (b) to contribute to the development and maintenance of appropriate guidance and CS supporting the implementation of this Regulation or Regulation (EU) 2017/746;
   (c) to support the MDCG and contribute to the development of standards at Union or international level, ensuring that such standards reflect the state of the art;
   (d) to contribute to the identification of concerns and emerging issues concerning the safety and performance of medical devices, including in vitro diagnostic medical devices.

8. When adopting their opinions or advice, the members of the expert panels shall use their best endeavours to reach consensus. If consensus cannot be reached, the expert panels shall decide by a majority of their members, and the opinion or advice shall mention the divergent positions and the grounds on which they are based.

9. The Commission shall require manufacturers and notified bodies to pay fees for opinions and advice provided by expert panels. The structure and the level of the fees, as well as the scale and type of recoverable costs, shall be established by the Commission by means of implementing acts, taking into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

The fees referred to in the first subparagraph shall be established in a transparent manner and on the basis of the costs for the services provided. The fees shall be reduced for manufacturers which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, including in the case of a clinical evaluation consultation procedure initiated in accordance with Section 5.1, point (c), of Annex IX involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC. The fees related to the opinions and advice provided by expert panels are payable to the Agency[22] pursuant to Article 30, point (f), of Regulation (EU) 2022/123.

10. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 7 of this Article by adding, adapting or removing tasks from the list of tasks of the expert panels.';

[22] Lawyer-linguists will make the change throughout the Regulations.

(87) the following Articles 106a and 106b are inserted:

*'Article 106a*

**Expert laboratories**

1. The Commission may, by means of implementing acts and following consultation with the MDCG, designate expert laboratories, on the basis of their expertise in the field of testing of medical devices, such as physico-chemical characterisation, microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing and any other type of testing or assessment considered relevant for the evaluation of the safety, performance or regulatory compliance of specific devices, categories or groups of devices.

   The Commission shall only designate expert laboratories for which a Member State or the Joint Research Centre has submitted an application for designation.

2. Expert laboratories shall satisfy the following criteria:
   (a) have adequate and appropriately qualified staff with adequate knowledge and experience related to the devices or in the type of laboratory testing for which they are designated;
   (b) have at their disposal the necessary equipment and reference materials to carry out the tasks assigned to them;
   (c) have the necessary knowledge of international standards and best practices;
   (d) have an appropriate administrative organisation and structure;

(e) ensure that their staff observe the confidentiality of information and data obtained in carrying out their tasks;

(f) act in the public interest and in an independent manner;

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

3. Expert laboratories may have the following tasks:

(a) to provide scientific and technical assistance to the Commission, the MDCG, the Agency, Member States and notified bodies in relation to the implementation of this Regulation, including at the request of the Commission or the MDCG and, the performance of appropriate tests, assessments or other evaluations necessary to support the assessment of the safety, performance or regulatory compliance of any device;

(aa) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices in the field of laboratory testing for which they are designated, with due consideration of comparative test results or other studies;

(b) to support the MDCG in the development and maintenance of appropriate guidance and CS supporting the implementation of this Regulation;

(c) to support the MDCG in the development of standards at Union or international level, ensuring that such standards reflect the state of the art;

(ca) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and for market surveillance;

(d) to support the MDCG in the identification and investigation by laboratory testing of concerns and emerging issues on the safety, performance or regulatory compliance of medical devices;

(e) to provide scientific and technical assistance, including independent investigations of devices, to Member States and the Commission in vigilance and market surveillance activities.

4. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 3 of this Article by adding, adapting or removing tasks from the list of tasks of the expert laboratories.

4a. The expert laboratories may establish a network in order to coordinate and harmonise their working methods with regards to testing and assessment.

5. The expert laboratories may charge fees in accordance with predetermined and transparent terms and conditions for scientific and technical assistance provided to Member States or notified bodies for carrying out the requested task. For the provision of services on request of the Commission, the MDCG, or the Agency, the expert laboratories may be granted a Union financial contribution.

5a. A financial allocation may also be made available from the general budget of the Union for the expert laboratories.

*Article 106b*

**Support by the Agency**

1. The Secretariat of the Agency established under Article 148 of [Pharma reg] shall provide support to the national competent authorities designated under this Regulation and under Regulation (EU) 2017/746 to facilitate cooperation and coordination and exchange of experience, information, and technical and scientific knowledge between them on operational regulatory activities among them and with the Commission with a view to ensuring a uniform practical application of such Regulations, in particular in the following areas:
   (a) regulatory status of products and classification of devices in accordance with Articles 4 and 51 and Annex VIII of this Regulation and Articles 3 and 47 and Annex VIII of Regulation (EU) 2017/746;
   (b) derogations from the applicable conformity assessment procedures in accordance with Articles 59 and 59a of this Regulation and Articles 54 and 54a of Regulation (EU) 2017/746;
   (c) clinical evaluation, clinical investigations, performance evaluation and performance studies in accordance with Chapter VI of this Regulation and Chapter VI of Regulation (EU) 2017/746, including support to the coordinating Member State for the coordinated assessment procedure for clinical investigations and performance studies referred to in Article 78 of this Regulation and Article 74 of Regulation (EU) 2017/746;
   (d) vigilance and market surveillance in accordance with Chapter VII of this Regulation and Chapter VII of Regulation (EU) 2017/746, including, but not limited to, the support to the coordinating competent authority for the coordinated procedure referred to in Article 89(9) of this Regulation and Article 84(9) of Regulation (EU) 2017/746;

1a. The Agency shall report to the MDCG about the exchange of experience, cooperation and coordination between competent authorities in accordance with paragraph 1 and seek MDCG's guidance on strategic priorities and unresolved issues.

2. The Agency shall provide scientific, technical and administrative support to the Commission for the establishment of Union regulatory sandboxes in accordance with Article 59c of this Regulation and Article 54c of Regulation (EU) 2017/746.

3. The Agency shall set up a support scheme for manufacturers of medical devices and in vitro diagnostic medical devices, which are micro, small and medium-sized within the meaning of Recommendation 2003/361/EC, regarding the requirements of this Regulation and of Regulation (EU) 2017/746.

4. The Agency shall have access to Eudamed and any electronic system referred to in Article 33(2) of Regulation (EU) 2017/745 or in Article 30(2) of Regulation (EU) 2017/746 that is not included in Eudamed.

5. The Agency shall have sufficient resources and knowledge in the area of medical devices and in-vitro diagnostic medical devices to effectively and efficiently perform its tasks pursuant to this Regulation.';

(88) in Article 107(1), the fourth and fifth sentences are replaced by the following:
'The declaration of interests shall be made publicly available on the Commission or the Agency website. This Article shall not apply to the representatives of stakeholder organisations participating in the MDCG or its sub-groups.';

(89) in Article 108, the first sentence is replaced by the following:
'The Commission, the Member States and the Agency shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices setting common principles to collect comparable information.';

(90) the following Section 2 is inserted after Article 108:

'***SECTION 2 – International cooperation***

*Article 108a*

**International regulatory and administrative cooperation**

1. Without prejudice to the prerogatives of the Council and the relevant procedures laid down in the Treaties, the Commission, in consultation with the MDCG, shall explore avenues to contribute to the development and adoption of global principles, standards and guidance which aim to achieve a high level of international regulatory convergence and foster innovation in the field of medical devices and in vitro diagnostic medical devices, including in relation to safety, performance, quality management systems, risk management systems, conformity assessment and post-market surveillance.

2. The Commission shall make full use of and build on, within the limits of the tasks conferred upon it, existing international cooperation mechanisms, including the International Medical Device Regulators Forum (IMDRF), the Medical Device Single Audit Programme (MDSAP) and International Standardisation Organisations, to pursue the objectives of paragraph 1.

3. In its activities in accordance with paragraphs 1 and 2, the Commission shall consult the MDCG and take into account its position. The Commission shall invite Member States to nominate experts, in view of their competence in medical devices or in vitro diagnostic medical devices, to participate in those activities.

4. The Commission, in consultation with the MDCG, may sign administrative arrangements with authorities of third countries and with international organisations on technical matters falling within the scope of this Article, including:
   (a) exchange of information and best practices;
   (b) joint or coordinated inspections and assessments;
   (c) coordinated actions relating to safety issues, including recalls or safety communications.

   Those administrative arrangements shall not create legal obligations binding upon the Union and its Member States.

   Where the Commission signs such administrative arrangements which include the exchange of information or data, the administrative arrangement shall provide for protection of such information or data in accordance with Article 109 of this Regulation or in Article 102 of Regulation (EU) 2017/746, as applicable.

5. For the purposes of carrying out the activities of the Commission and the Member States relating to international cooperation as referred to in this Article and the reliance mechanisms referred to in Article 108b, a financial allocation may also be made available from the general budget of the Union.

*Article 108b*

**Reliance mechanisms**

1. In the framework of the implementation of this Regulation or of Regulation (EU) 2017/746, as applicable, notified bodies and competent authorities may take into consideration the outcome of assessments, audits, inspections, and other regulatory decisions carried out or taken by regulatory authorities of third countries or international organisations or within the framework of international cooperation mechanisms in the field of medical devices and in vitro diagnostic medical devices, provided that the following conditions are fulfilled:
   (a) the assessments, audits, inspections, or other regulatory decisions of the regulatory authority of the third country, the international organisation or those decisions taken within the framework of an international cooperation mechanism ensure a level of health and safety protection equivalent to that required under this Regulation or Regulation (EU) 2017/746, as applicable;
   (b) effective arrangements for mutual exchange of information between the relevant regulatory authority of the third country, the international organisation or the body participating in the international cooperation mechanism and the Union are in place, providing for the confidentiality of information and data referred to in Article 109 of this Regulation or Article 102 of Regulation (EU) 2017/746, as applicable.

4. The Commission shall adopt implementing acts identifying the regulatory authorities of third countries, the international organisations or the international cooperation mechanisms, referred to in paragraph 1 and, where relevant, establishing the detailed rules for the taking into consideration of assessments, audits, inspections carried out or other relevant regulatory decisions taken for the purpose of application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

*Article 108c*

**Capacity building and technical assistance**

1. The Commission, in consultation with MDCG, may support the strengthening of regulatory capacity in third countries, including through the provision of technical assistance, training, exchange of experts, and dissemination of best practices.

2. The Commission shall invite Member States to nominate experts, in view of their competence in medical devices or in vitro diagnostic medical devices, to participate in its activities referred to in paragraph 1.

3. For the activities referred to in paragraph 1, a financial allocation may also be made available from the general budget of the Union.';

(90a) Article 110 is replaced by the following:

'1. Member States shall apply Regulation (EU) 2016/679 to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EU) 2018/1725 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.';

(91) the following Article 110a is added:

*'Article 110a*

**Submission of information or documents**

The submission of information or documents in accordance with this Regulation may take place electronically.

Member States may require that information or documents in accordance with this Regulation shall be submitted electronically to the relevant authority.';

(93) Article 112 is deleted;

(93a) the following Article 113a is inserted:

*'Article 113a*

**Economic operators non-compliance**

Without prejudice to Articles 94 to 98, where the competent authorities of a Member State find, based on data obtained from vigilance, market surveillance, or other information, that an economic operator does not comply with the obligations applicable to it set out in this Regulation, they shall require that economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.

Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned may apply penalties referred to in Article 113, or take other appropriate measures.';

(95) in Article 120, the following paragraphs 14 and 15 are added:

‘14. By way of derogation from Article 5 and from paragraphs 3 to 3e of this Article, a device as referred to in paragraph 3a or 3b of this Article that meets the criteria for an orphan device as referred to in Article 52a(3) may be placed on the market or put into service after the dates referred to in paragraphs 3a and 3b of this Article if the following conditions are met:

(a) an expert panel referred to in Article 106 has issued an opinion confirming the fulfilment of the criteria for an orphan device as referred to in Article 52a(3);

(b) there are no significant changes in the design and intended purpose of the device;

(c) the device 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.

Where a device referred to in the first subparagraph is placed on the market in accordance with this paragraph, the requirements of this Regulation shall apply with the exception of Chapter IV, Articles 52 to 59c, and Articles 61(4) and 62(1).

By way of derogation from Article 86(1), manufacturers of class IIa devices, class IIb devices and class III devices placed on the market or put into service in accordance with this paragraph shall update the PSUR at least annually. On an annual basis, the manufacturer shall submit the PSUR and, where applicable, an update of the summary of safety and clinical performance to the competent authority of the Member State in which it is established.

The competent authority of the Member State may require the manufacturer to conduct defined post-market surveillance or PMCF activities within a specified period of time to generate additional clinical data to confirm the safety and performance of the device and to evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio.

In its EU declaration of conformity, the manufacturer shall make reference to the fact that the device is an orphan device placed on the market or put into service in accordance with this paragraph.

Where the certificate is no longer valid in accordance with paragraph 2, the manufacturer shall inform the competent authority of the Member State in which it is established.

The manufacturer shall inform the intended users about the fact that the device is an orphan device placed on the market or put into service in accordance with this provision in the summary of safety and clinical performance, where applicable, and in the instructions for use.

At least every 7 years, the manufacturer shall request an opinion from an expert panel referred to in Article 106 confirming the fulfilment of the criteria for an orphan device as referred to in Article 52a(3). The expert panel opinion shall be provided to the manufacturer and the competent authority of the Member State in which the manufacturer is based.

Where the expert panel issues a negative opinion, the competent authority shall decide, with due consideration to this opinion, whether continued placing on the market or putting into service of the device in accordance with this paragraph is no longer appropriate. Where the competent authority decides this is no longer appropriate, the device may continue to be placed on the market or put into service in accordance with this paragraph for no longer than one year following the competent authority's decision, after which Article 5 shall apply.';

(95a) the following Article 120a is added:

*'Article 120a*

**Additional transitional provisions related to the amendments by Regulation (EU) […./….]**

1. By way of derogation from Article 5, and without prejudice to Articles 120(3) to (3e), devices for which a certificate was issued by a notified body in accordance with Article 56 before … [date of application of this Regulation], and devices, for which the conformity assessment procedure pursuant to Article 52 does not require the involvement of a notified body, that were registered in Eudamed in accordance with Article 29(1) before … [date of application of this Regulation] may be placed on the market or put into service, without the need to undertake a new or additional conformity assessment. Annex IX, Sections 2.4. and 4.10., Annex X, Section 5, and Annex XI, Section 6.4., as applicable, shall apply for changes requiring prior approval.

   Amendments or supplements to the certificate made after … [date of application of this Regulation], which are of an administrative nature and are not related to the conformity of the device, shall not affect the application of the first subparagraph.

2. Systems and procedure packs that were registered in Eudamed in accordance with Article 29(2) before … [date of application of this Regulation] may be placed on the market on the basis of the statement issued pursuant to Article 22 before that date, unless there is a significant change regarding the system or procedure pack for which a new statement is required.

3. Devices and systems and procedure packs lawfully placed on the market before … [date of application of this Regulation] may continue to be made available on the market or put into service.

4. Notwithstanding paragraph 1, the validity of EU technical documentation assessment certificates or EU type examination certificates related to class III devices or implantable class IIb devices issued by a notified body in accordance with Article 56 prior to … [date of application of this Regulation] for a period not exceeding five years shall, on application of the manufacturer, be extended for a further period not limited in time, based on a re-assessment in accordance with Annex VII, Section 4.11. The extension may take effect only after an initial five-year certification period has elapsed. Where the validity of an EU technical documentation assessment certificate or EU type examination certificate referred to in the first sentence was already extended based on a re-assessment in accordance with Article 56 after an initial five years period, the notified body shall extend that validity for a further period not limited in time without reassessment, unless the notified body finds that requirements of this Regulation are not met affecting the safety or performance of the device(s). Article 56(4) shall apply.

The validity of all other certificates issued by a notified body in accordance with Article 56 prior to … [date of application of this Regulation] for a period not exceeding five years shall, on application of the manufacturer, be extended for a further period not limited in time without reassessment, unless the notified body finds that requirements of this Regulation are not met affecting the safety or performance of the device(s). Article 56(4) shall apply.

After the extension of a certificate pursuant to the first and second subparagraph, the provisions on surveillance activities, including periodic reviews, in accordance with Article 56(2a) shall apply.

5. The application of a conformity assessment body for designation submitted in accordance with Article 38 before … [date of application of this Regulation] shall continue to be assessed in accordance with Article 39 and Annex VII in their form applicable before … [date of application of this Regulation], unless the conformity assessment body and the authority responsible for notified bodies of the Member State where the conformity assessment body is established agree to apply all or certain provisions of Annex VII that are applicable from … [date of this Regulation]. Designation and notification of the notified body shall follow the procedure laid down in Article 42 in its form applicable before … [date of application of this Regulation]. The authority responsible for notified bodies of the Member State where the conformity assessment body is established shall assess compliance with the requirements laid down in Annex VII in its form applicable from … [date of application of this Regulation] at the latest during its next annual assessment after designation of the notified body in the framework of its monitoring activities in accordance with Article 44.

6. Complete reassessments of notified bodies in accordance with Article 44(10), for which an on-site assessment of the notified body by the authority responsible for notified bodies and the joint assessment team has been conducted before … [date of application of this Regulation], shall continue to be conducted in accordance with Article 39 and Annex VII in their form applicable before … [date of application of this Regulation], unless the notified body and the authority responsible for notified bodies of the Member State where the notified body is established agree to apply all or certain provisions of Annex VII that are applicable from … [date of this Regulation]. The authority responsible for notified bodies of the Member State where the notified body is established shall assess compliance with the requirements laid down in Annex VII in its form applicable from … [date of application of this Regulation] at the latest during its next annual assessment after finalisation of the complete reassessment of the notified body in the framework of its monitoring activities in accordance with Article 44.

7. Where a manufacturer or an authorised representative lodged a formal application with a notified body for conformity assessment in accordance with Annex VII, Section 4.3, first subparagraph, which was formally accepted by the notified body and which has not been completed before … [date of application of this Regulation], the following shall apply:

   (a) the provisions of this Regulation in the form applicable before … [date of application of this Regulation] shall apply until the certificate is issued, unless the manufacturer and the notified body agree to apply all or certain provisions that are applicable from … [date of this Regulation] for the purposes of that conformity assessment procedure;

   (b) where the notified body finds that the relevant requirements are met, it shall issue the certificate in accordance with Article 56 in the form applicable from … [date of application of this Regulation].

8. For devices, which had undergone a conformity assessment procedure before … [date of application of this Regulation], which required a higher level of involvement of a notified body in the conformity assessment than pursuant to the provisions applicable from … [date of application of this Regulation], the notified body shall adapt the certificate issued and its surveillance activities in consultation with the manufacturer and without additional assessments.

Where the involvement of a notified body in the conformity assessment is not any more required for the device from … [date of application of this Regulation], the manufacturer may end the contract for conformity assessment activities with the notified body without giving rise to any penalty. Manufacturer and notified body shall define in an agreement the modalities of the termination with a view to avoiding disruption of the placing on the market of the device, including the date on which the certificate will become invalid and the date until when the identification number of the notified body may be indicated in the information supplied by the manufacturer.

9. For the purpose of Article 52a(4) and Article 120(14), as applicable, an opinion by an expert panel issued before … [date of entry into force of this Regulation] confirming that a device fulfils the criteria of a breakthrough device or an orphan device shall be deemed to be an opinion confirming fulfilment of the criteria set out in Article 52a(2) or (3), as applicable.

10. Requirements concerning the entering of data or notifications in Eudamed or another IT system referred to in Article 10a, Article 60(1b) and Article 87a and Annex VI, Part A, Sections 2.16 and 2.17, and Part B, Section 22, shall apply from the date corresponding to six months from the date of publication of a notice by the Commission confirming that the functionality for the entering of data or notifications in Eudamed or the other IT system is available.

11. For the purpose of the term ‘well-established technology device’ as defined in Article 2(72), the following shall apply until the application of the implementing act referred to in Article 3(2):

(a) for the purpose of Article 32(1), Article 56(2), Article 61(6), point (b), and Article 86(2), reference to well established technology devices shall be understood as referring to the devices listed in Article 61(6), point (b), in its form applicable before … [date of application of this Regulation];

(b) for the purpose of Article 52(3), 1st subparagraph, reference to well-established technology devices shall be understood as referring to the devices listed in Article 61(6), point (b), in its form applicable before … [date of application of this Regulation] that are class III non-implantable devices;

(c) for the purpose of Article 52(4), 4th subparagraph, reference to well-established technology devices shall be understood as referring to the devices listed in Article 52(4), 2nd subparagraph, in its form applicable before … [date of application of this Regulation] that are class IIb implantable devices.’;

(96) Article 121 is replaced by the following:

*‘Article 121*

**Evaluation**

No sooner than …[*Publications Office, please insert the date five years after the date of application of this Regulation*], the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council.

Member States and notified bodies shall provide the Commission with the information necessary for the preparation of that report.;’

(97) in Article 123(3), point (d), the following third subparagraph is added:
‘After the date of application of the provisions referred to in the first subparagraph of this point, where Member States maintain national databases, the relevant information available in Eudamed for those national databases shall be retrieved from Eudamed. This shall be without prejudice to the possibility for Member States to maintain or develop complementary national functionalities and data elements necessary for national market surveillance or other regulatory tasks, avoiding duplication of Union data, where possible.;’

(98) Annexes I, II, III, VI, VII, VIII, IX, X, XI, XII, XIII, XIV and XV are amended in accordance with Annex I to this Regulation.

*Article 2*

***Amendments to Regulation (EU) 2017/746***

Regulation (EU) 2017/746 is amended as follows:

(1) Article 1(4) is replaced by the following:

‘4. 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, point (1), of Regulation (EU) 2017/745 that has an action ancillary to that of the in vitro diagnostic medical device, the integral product shall be governed by this Regulation. In that case, the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 shall apply as far as the safety and performance of the medical device part are concerned.

However, if the action of the medical device is principal and not ancillary to that of the in vitro diagnostic medical device, the integral product shall be governed by Regulation (EU) 2017/745. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the in vitro diagnostic medical device part are concerned.’;

(2) Article 2 is amended as follows:

(a) in point (2), first subparagraph, point (f) is replaced by the following:

‘(f) to define or monitor therapeutic measures.’;

(b) in point (7), the introductory wording is replaced by the following:

‘‘companion diagnostic’ means a device which is essential for the safe and effective use of one or more corresponding medicinal product(s) to:’;

(c) point (8) is replaced by the following:

‘(8) ‘generic device group’ means a set of devices having the same or similar intended purposes and a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;’;

(d) the following points (76), (77) and (78) are added:

‘(76) ‘regulatory sandbox’ means a controlled environment set up by a competent authority which offers manufacturers the possibility, before placing the product on the market or putting into service, to develop, test, validate and use, where appropriate in real-world conditions, an innovative product or technology potentially falling within the scope of this Regulation, pursuant to a sandbox plan for a limited time under regulatory supervision;

(77) ‘sandbox plan’ means a document agreed between the participating manufacturer(s) and the competent authority, describing the objectives, responsibilities, conditions, timeframe, methodology and requirements for the activities carried out within the regulatory sandbox;

(78) ‘Union regulatory sandbox’ means a controlled environment set up by the Commission for testing alternative or new regulatory requirements or enforcement practices and appraising their validity in comparison with existing requirements and practices under this Regulation for a limited time.’;

(3) Article 3 is replaced by the following:

*'Article 3*

**Regulatory status of products**

1. Upon a duly substantiated request by a manufacturer or an authorised representative, or on its own initiative, the competent authority of the Member State in which the manufacturer or authorised representative is established (the 'responsible competent authority') shall, after obtaining information from the manufacturer or authorised representative and, where applicable, the notified body that issued the certificate for that product, determine whether a specific product of the manufacturer falls within the definition of an in vitro diagnostic medical device as set out in Article 2(2) or the definition of 'accessory for an in vitro diagnostic medical device' set out in Article 2(4).

3. Where a competent authority (the 'initiating competent authority'), on the basis of information obtained through vigilance activities, market surveillance activities or any other relevant information, has justified doubts as to the regulatory status of a product for which neither the manufacturer nor the authorised representative is established within its Member State, the competent authority shall refer the matter to the responsible competent authority and inform the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745 and the Commission of the referral, providing justification for its doubts about the regulatory status.

4. Following consultation with the initiating competent authority and after having obtained information from the manufacturer or authorised representative, and, where applicable, the notified body, the responsible competent authority shall decide the regulatory status of the concerned product within 6 months from the date of referral. The responsible competent authority shall communicate its decision to the initiating competent authority and the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745 and the Commission.

5. Where a competent authority does not agree with the decision of the regulatory status by the responsible competent authority, or where the responsible competent authority has not communicated its decision within the period referred to in paragraph 4, that competent authority shall consult the group of national competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745 providing justification for its doubts about the regulatory status, who shall issue an opinion on the regulatory status of the product.

6. Taking into account the opinion of the group of national competent authorities referred to in paragraph 5, or where no opinion has been issued within three months, a Member State may request the Commission to decide on the regulatory status of the specific product, by means of implementing acts.

7. The Commission shall consult the MDCG, and may consult the relevant expert panel for their scientific advice. The Commission shall set a time-limit for the MDCG to adopt its opinion. The time limit shall not be shorter than 90 days.

7a. The manufacturer or authorised representative, as well as the notified body that issued the certificate, if applicable, shall be provided with the opportunity to present their positions on the regulatory status of the product to the competent authorities, MDCG or the relevant expert panel, as applicable.

8. Where the determination of the regulatory status of a product involves questions concerning the borderline between medicinal products, substances of human origin (SoHO), biocidal products, food, cosmetics or any other products regulated under Union legislation and medical devices, the Agency in fulfilling its tasks described in Article 106b of Regulation (EU) 2017/745 shall ensure an appropriate level of consultation with the other relevant Union bodies established under the applicable legislation, including the relevant bodies of the Agency responsible for medicinal products in accordance with Article 148, letter (l), of [Pharma Reg], the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).

11. Within 180 days of the request from a Member State referred to in paragraph 6, the Commission, after having consulted the MDCG, shall decide on the regulatory status of the product by means of implementing acts in accordance with the examination procedure referred to in Article 107(3). In adopting its decision, the Commission shall take the utmost account of the advice and opinions issued by the expert panel and the MDCG, respectively.

By way of derogation from the first subparagraph, the Commission may decide, in the absence of an opinion of the MDCG adopted by a majority of members pursuant to Article 103, paragraph 4, of Regulation (EU) 2017/745, within the time-limit referred to in paragraph 7, not to adopt a decision on the regulatory status of the product.

12. The opinions and decisions on the regulatory status of a product, and the advice of the expert panel delivered in accordance with this Article shall be made publicly available, without disclosing any confidential information as referred to in Article 102.

13. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.

14. The Commission may, by means of implementing acts, lay down the procedure, including timelines, for the application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).';

(5) Article 5 is amended as follows:

(a) paragraph 5 is amended as follows:

(i) the first subparagraph is amended as follows:

(1) point (a) is replaced by the following:

'(a) the devices are not transferred to another legal entity. Exceptionally, a device may be transferred to another health institution where there is a duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency.

Where such transfers occur, the transferring health institution shall notify the competent authority of the Member State in which it is based and provide the justification. In the case of transfers to a health institution in another Member State, the receiving health institution shall also notify the competent authority of the Member State in which it is based and provide the justification.';

(1a) point (aa) is added:

‘(aa) The devices are not manufactured on an industrial scale.’;

(2) point (c) is replaced by the following:

‘(c) the laboratory of the health institution is compliant with standard EN ISO 15189 or, where applicable, national provisions for quality and competence in medical laboratories, including national provisions regarding accreditation;’;

(4) point (e) is replaced by the following:

‘(e) upon request by a competent authority, the health institution provides information on the use of such devices to its competent authority and the justification referred to in point(d);’;

(5) point (f)(iii) is replaced by the following:

‘(iii) For Class A and B devices in accordance with the rules set out in Annex VIII a declaration that the health institution is accredited to the standard referred to in point (c) or that the devices meet the relevant general safety and performance requirements set out in Annex I and, where applicable, information on which requirements are not fully met with a reasoned justification therefor;

For Class C and D devices in accordance with the rules set out in Annex VIII a declaration that the devices meet the relevant general safety and performance requirements set out in Annex I and, where applicable, information on which requirements are not fully met with a reasoned justification therefor; where the health institution is accredited to the standard referred to in point (c), the declaration may be limited to the relevant general safety and performance requirements set out in Annex I which are not covered by that standard.';

(6) point (g) is replaced by the following:

'(g) as regards class D devices in accordance with the rules set out in Annex VIII, the health institution draws up documentation sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met. Where the health institution is accredited to the standard referred to in point (c), the documentation may be limited to the relevant general safety and performance requirements set out in Annex I which are not covered by that standard. Member States may apply this provision also to class C devices in accordance with the rules set out in Annex VIII;';

(7) point (h) is deleted;

(ii) the second sentence in the second subparagraph is replaced by the following: ‘Member States shall retain the right to restrict the manufacture, the use, or the transfer of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.’;

(iia) the third subparagraph is deleted;

(iii) the following subparagraphs are added:

‘For the purposes of the first subparagraph, point (a), in the case of a transfer of the device to another health institution, the transferring and receiving health institutions shall ensure traceability of the device. This information shall be made available to a competent authority upon request.

For the purposes of the first subparagraph, point (d), from the date that the health institution becomes aware that the target patient group's specific needs can be met by an equivalent device available on the market and, where applicable, registered on Eudamed, it may continue to manufacture and use its device for a maximum period of 7 years.

Member States may require health institutions to report serious incidents related to the device to the competent authority of the Member State in which they are established. In such cases, the competent authorities shall record centrally at national level reports they receive from health institutions and shall monitor the reports received in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

For the purposes of the first subparagraph, point (i), where the device is transferred in accordance with point (a), both the transferring and the receiving health institution shall report to each other any serious incident related to the device.

This paragraph shall also apply to devices manufactured and used within a laboratory that is established in the Union and provides consistent, state of the art testing services for clinical research, provided those devices are intended exclusively for use in the framework of a clinical trial subject to Regulation (EU) No 536/2014 of the European Parliament and of the Council*. Where, in this paragraph, reference is made to a health institution, such reference shall also be understood as reference to a laboratory referred to in the first sentence of this subparagraph.

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*Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).';

(b) the following paragraphs 7 and 8 are added:

‘7. By 1 July 2028, the Commission shall adopt an implementing act specifying technical requirements related to cybersecurity as referred to in point 16.4 of Annex I. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 107(3).

8. By 1 July 2028, the Commission shall adopt implementing acts pursuant to paragraph 6 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council**, or devices referred to in Article 10-a, first paragraph, point b, taking into account the requirements set out in Chapter III, Section 2, of that Regulation.

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** Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).’;

(6) Article 6 is amended as follows:

(a) the following paragraph 2a is inserted:

‘2a. Any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall provide in the offer at least the information referred to in Section 20.2., points (a) to (e) and (m), of Annex I and access to the instructions for use.’;

(b) paragraphs 3 and 4 are replaced by the following:

‘3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity drawn up in accordance with Article 17 for the device concerned and cooperate with the competent authorities of the Member State in which the device or the service is offered.

4. A Member State may, on grounds of protection of public health, require a provider of a service, as defined Article 1(1), point (b), of Directive (EU) 2015/1535, or a provider of a service referred to in paragraph 2, to cease its activity.’;

(7) in Article 7, the following subparagraph is added:

‘Without prejudice to national law regarding the exercise of the medical profession, the first subparagraph shall also apply to devices used for the provision of a service referred to in Article 6(2).’;

(8) in Article 9(1), the first sentence is replaced by the following:

'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, by means of implementing acts, adopt common specifications (CS) in respect of the requirements set out in this Regulation, in particular the reports and plans to be drawn up by manufacturers, the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the conformity assessment procedures set out in Annexes IX to XI, the performance evaluation and post-market performance follow-up set out in Annex XIII or the requirements regarding performance studies set out in Annexes XIII and XIV.';

(9) Article 10 is amended as follows:

(d) paragraph 10 is amended as follows:

(i) in the first subparagraph, the following sentence is added:

'When determining the official language of the Union in which the information set out in Section 20 of Annex I or other information to be provided by the manufacturer shall be made available, Member States shall consider accepting another official language of the Union in which the information is made available, taking into consideration the technical knowledge, experience, education or training of the average intended user(s).';

(g) paragraph 14 is replaced by the following:

‘14. Where manufacturers have their devices designed or 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 26(1).’;

(h) in paragraph 15, '85/374/EEC' is replaced by '(EU) 2024/2853***

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***Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC (L, 2024/2853, 18.11.2024, ELI: http://data.europa.eu/eli/dir/2024/2853/oj).';

(9a) the following Article 10-a is inserted:

*‘Article 10-a*

**Deployment of certain Artificial Intelligence medical devices**

‘1. This Article shall apply to the following devices:

(a) high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council; or

(b) without prejudice to Regulation (EU) 2024/1689, devices referred to in Article 5, paragraph 5, that are Class B devices, Class C devices or Class D devices, in accordance with the rules set out in Annex VIII, and that incorporate an AI system that is intended to be used as a safety component of that device, or the AI system is itself the device.

2. Member states shall ensure that when deployers use the devices referred to in paragraph 1 in a health setting, they do so only when all of the following conditions are met:

(a) the deployer has taken appropriate technical and organisational measures to ensure they use such devices in accordance with the instructions for use accompanying the device;

(b) the deployer has assigned human oversight to natural persons who have the necessary competence, training and authority as well as the necessary support;

(c) the deployer monitors the operation of such devices on the basis of the instructions for use;

(d) the deployer keeps the logs automatically generated by such devices to the extent such logs are under the deployer's control, for a period appropriate to the intended purpose of those devices, of at least six months;

(e) to the extent the deployer exercises control over the input data, the deployer ensures that input data is relevant and sufficiently representative in view of the intended purpose of the device;

(f) the deployer cooperates with the relevant competent authorities in any action those authorities take in relation to the device in order to implement this Article.

3. For the purposes of this Article, ‘deployer’ shall be understood as any natural or legal person, public authority, agency or other body using any of the devices referred to in paragraph 1 under its authority except where they are used in the course of a personal non-professional activity.’;

(10) Article 10a is amended as follows:

(a) paragraph 1 is replaced by the following:

‘Where a manufacturer anticipates an interruption or a discontinuation of the supply of a device, and where it is reasonably foreseeable that such interruption or discontinuation could result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer shall inform the competent authority of the potentially affected Member State(s) and the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom it directly supplies the device, of the anticipated interruption or discontinuation.

The information referred to in the first subparagraph shall, other than in exceptional circumstances, be provided at least six months before the anticipated interruption or discontinuation. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority.’;

(b) the following paragraphs 4, 5, 5a and 6 are added:

‘4. The Commission, in cooperation with the Agency, and in consultation with the MDCG, shall set up, maintain, and manage an IT system to facilitate the reporting and information exchange regarding cases of interruption or discontinuation of the supply of devices in accordance with paragraphs 1, 2, 4, 5, 5a and 6. That IT system shall be integrated in or interoperable with the European database on medical devices referred to in Article 30 and shall be accessible to manufacturers, competent authorities, health institutions, and healthcare professionals. It shall also enable health institutions and healthcare professionals to inform competent authorities about the unavailability or the immediate risk of unavailability of devices needed for the exercise of their professional activity. Information referred to in paragraph 6 shall be accessible exclusively to the Commission, the Agency and the competent authorities.

5. The Agency, in particular through the Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Article 21 of Regulation (EU) 2022/123****, and in collaboration with the MDCG shall develop a methodology to identify devices as referred to in paragraph 1 for which an interruption or discontinuation of supply would result in an unacceptable risk of serious harm to patients or public health in the Union, consisting of criteria based on the criticality of their intended purpose, and the availability of appropriate alternatives to those devices. Based on that methodology, the Agency, in particular through the MDSSG and in collaboration with the MDCG and in agreement with the Commission, shall propose a list of devices, or categories of devices, that are deemed to meet those criteria on the basis of the available information, including the information referred to in paragraph 1. The Commission shall, by means of implementing acts and taking into account the list proposed by the Agency, and those criteria, adopt, publish and keep up to date a list of devices, or categories of devices, for which an interruption or discontinuation of supply would result in serious harm or risk of serious harm to patients or public health in the Union and to which paragraphs 1, 2, 3, 4, 5a and 6 shall apply. The methodology shall be drawn up and published within one year from the date of application of this Regulation. The list of devices, or categories of devices, shall be developed within one year from the date of the development of the methodology. The list shall be reviewed and updated regularly, to ensure its continued relevance and accuracy. For the purpose of this paragraph, the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and of consumers may be consulted as necessary.

For the purposes of paragraphs 5a and 6, the obligations shall only apply to devices included in the list drawn up in accordance with this paragraph, when available.

5a. Economic operators shall establish, maintain and keep up to date a shortage prevention plan for the devices included in the list adopted in accordance with paragraph 5. Shortage prevention plans shall be made available to the competent authority upon request. They shall be developed on the basis of a risk-based approach and shall identify specific measures and actions to be taken in the event of an actual supply interruption.

6. The competent authorities of the Member States or the Commission may request the manufacturers of devices included in the list drawn up in accordance with paragraph 5 to provide and keep up to date, through the IT system referred to in paragraph 4, all necessary information regarding risks and weaknesses within the supply chain which may affect the supply of such devices, including manufacturing sites, their addresses and manufacturing stage they cover, the existence of any backup sites, production capacity and volume of sales. Manufacturers of those devices shall register on the IT system referred to in paragraph 4 and be identifiable as such to the Commission and the competent authorities.

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**** Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).';

(11) in Article 11, paragraph 4 is replaced by the following:

‘4. The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (5), (6), (8), (9), (10) and (11).’;

(12) in Article 14, paragraph 2 is amended as follows:

(b) the second subparagraph is replaced by the following:

‘In order to meet the requirements referred to in the first subparagraph, the distributor may apply a sampling method that is representative of the devices supplied by that distributor.’;

(13) Article 15 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘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:

(a) successful completion of a university degree in law, medicine, pharmacy, engineering or another relevant discipline, or an equivalent qualification in relevant studies, and at least one year of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices;

(b) two years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.

The person responsible for regulatory compliance shall keep up to date the knowledge necessary to fulfil this role.’;

(b) paragraph 2 is replaced by the following:

‘2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC***** shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person at their disposal.

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***** Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).’;

(c) in paragraph 3, point (c) is replaced by the following:

‘(c) the post-market surveillance obligations are complied with in accordance with Article 78;’;

(d) paragraph 6 is replaced by the following:

‘6. Authorised representatives shall have 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 availability of the person responsible for regulatory compliance shall be proportionate to the number of manufacturers represented by the authorised representative as well as to the risk class of the devices manufactured by them.

The requisite expertise shall be demonstrated by either of the following:

(a) successful completion of a university degree in law, medicine, pharmacy, engineering or another relevant discipline, or an equivalent qualification in relevant studies, and at least one year of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices;

(b) two years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.

The person responsible for regulatory compliance keep up to date the knowledge necessary to fulfil this role.';

(14) Article 16 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the introductory wording is replaced by the following:
'A distributor, an importer or another natural or legal person who makes a device available on the market, or places a device on the market or puts it into service shall assume the obligations incumbent on manufacturers if it does any of the following:';

(ii) the second subparagraph is replaced by the following:
'The first subparagraph shall not apply to any healthcare professional or any other person who, while not considered a manufacturer, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.';

(b) paragraph 4 is replaced by the following:

‘4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities referred to in points (a) and (b) of paragraph 2 shall inform the manufacturer. Member States may request distributors or importers to inform the competent authority of the Member State in which they plan to make the device available of the intention to make the repackaged or relabelled device available.’;

(15) Article 17 is amended as follows:

(a) in paragraph 1, the first sentence is replaced by the following:
‘The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered by that declaration.’;

(b) the following paragraph 2a is inserted:

‘2a. Declarations of conformity in accordance with paragraphs 1 and 2 may be provided in electronic form.’;

(17) the heading of Chapter III is replaced by the following:

‘IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES’;

(18) Article 24 is amended as follows:

(a) in paragraph 1, the following point (ba) is inserted:

‘(ba) a Basic UDI-DI, as defined in Part C of Annex VI;’;

(b) paragraph 2 is amended as follows:

(i) point (d) is replaced by the following:

‘(d) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions;’;

(ii) in point (e), the following subpoint (iv) is added:

‘(iv) offers its system for the assignment of UDIs to manufacturers that are micro and small enterprises within the meaning of Recommendation 2003/361/EC taking into account the specific needs of such enterprises.’;

(c) paragraph 3 is replaced by the following:

‘3. Before placing a device, other than a device for performance study, on the market, the manufacturer shall, in accordance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2, assign to the device, a Basic UDI-DI and UDI as defined in Part C of Annex VI. If applicable, the manufacturer shall assign a UDI to all higher levels of packaging.’;

(d) the following paragraph 3a is inserted:

‘3a. For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), Article 48(7), second subparagraph, Article 48(8), and Article 48(9), second subparagraph, the assignment of a Basic UDI-DI referred to in paragraph 1 of this Article shall be done before the manufacturer applies to a notified body for that assessment.’;

(e) in paragraph 10, points (a) and (b) are replaced by the following:

‘(a) amending the list of information set out in Parts A and B of Annex VI in the light of technical progress;

(b) amending Annex VI in the light of experience obtained from the implementation of the UDI system, or in light of international developments and technical progress in the field of Unique Device Identification.’;

(19) Article 26 is replaced by the following:

*‘Article 26*

**Registration of devices**

1. Before placing a device, other than a device for performance study, on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part A, Section 2 and Part B of Annex VI related to that device. The manufacturer shall keep the information provided to the UDI database updated and shall update any changes without undue delay, and in any event no later than 30 days after the change occurs.

2. For devices that are the subject of a conformity assessment as referred to in Article 48(3), (4), (10a) and (10b) the notified body shall confirm in Eudamed that the information referred to in Section 2.2 of Part A of Annex VI is correct.

2a. The data referred to in Part A, Section 2, entered pursuant to paragraphs 1 and 2**,** shall be accessible to the public, except the information regarding the other legal or natural person that designed and manufactured the device referred to in Part A, Section 2.13, of Annex VI.’;

(20) in Article 27(2), the following sentence is added:

‘Where national distributor databases require information on devices, where feasible, such databases shall allow for the retrieval of the device information from the electronic systems referred to in Article 30(2), points (a) and (b).’;

(21) Article 28 is amended as follows:

(a) the title is replaced by the following:

‘Registration of economic operators’;

(b) paragraphs 1 and 2 are replaced by the following:

‘1. Before placing a device or device for performance study on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 27 the information referred to in Part A**,** Section 1 of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 48, the information referred to in Part A**,** Section 1 of Annex VI shall be provided to that electronic system before applying to the notified body.

2. The competent authority shall verify the data entered pursuant to paragraph 1, obtain a single registration number (‘SRN’) from the electronic system referred to in Article 27 and issue it to the manufacturer, the authorised representative or the importer;’;

(c) in paragraph 4, the words ‘one week’ are replaced by the words ‘two weeks’;

(d) paragraph 6 is deleted;

(e) paragraph 7 is replaced by the following:

‘7. The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 27 shall be accessible to the public, except the information regarding the person responsible for regulatory compliance referred to in Part A, Section 1.4 of Annex VI.’;

(22) Article 29 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. For companion diagnostics, class C devices for self-testing and class D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance.

The summary of safety and performance shall be written in a way that is clear to the intended user and shall be made available to the public via Eudamed.

The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48. The manufacturer shall ensure that the summary of safety and performance is available to the public in Eudamed as part of the information on the device to be provided pursuant to Article 26(1) and mention on the label or instructions for use where the summary is available.’;

(b) paragraph 2 is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN, and a reference to the location of the instructions for use in Eudamed;’;

(ii) points (f), (g) and (h) are deleted;

(23) in Article 30(2), the following subparagraph is added:

‘By way of derogation from the first subparagraph, the Commission, in consultation with the MDCG, may decide not to include one or more of the electronic systems referred to in that subparagraph in Eudamed where it is necessary, due to operational or technical reasons, to achieve the purposes referred to in paragraph 1. In that case, the Commission shall ensure those electronic systems are interoperable with Eudamed.’;

(24) Article 31 is amended as follows:

(a) paragraph 6a is added:

‘6a. Without prejudice to other contractual administrative or judicial remedies, including the notified body’s complaint and appeal procedures [pursuant to Annex VII, Section 2.2], a manufacturer or a notified body may raise with the authority responsible for notified bodies, in a duly substantiated manner, any regulatory unresolved dispute arising between the manufacturer and the notified body in relation to the notified body’s activities in applying requirements set out in Annex VII and the involvement of the notified body in the conformity assessment in accordance with procedural requirements set out in Article 48 and Annexes IX, X and XI. The authority shall hear and decide within 150 days, without prejudice to extension of that period, where duly justified. Where the manufacturer is established in another Member State than the notified body, the authority responsible for the notified body shall consult the competent authority of the Member State where the manufacturer is established.

In duly justified cases, the authority responsible for notified bodies may seek guidance from the MDCG, which it shall take duly into account.

Each authority responsible for notified bodies shall inform the Commission, the MDCG and the coordination group referred to in Article 45 at least annually about the disputes raised with it pursuant to the first subparagraph, their outcome and the parties involved. That information shall be taken into consideration in the framework of the monitoring of notified bodies in accordance with Article 40.

By way of derogation from the first subparagraph and without prejudice to other administrative or judicial remedies, a Member State may choose to assign the tasks set out in this paragraph to another authority or to an out of court dispute resolution body.';

(b) paragraph 8 is replaced by the following:

'8. The authorities responsible for notified bodies shall coordinate, within the framework of the sub-group established under Article 99a, their activities to be carried out in accordance with this Chapter, cooperate with each other and with the Commission and resolve issues of diverging opinions between themselves to ensure a harmonised application of the requirements relating to notified bodies.';

(25) Article 32 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation in the public interest. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements, as set out in further detail in Annex VII, that are necessary to fulfil those tasks in a competent, effective, independent, impartial, diligent and expeditious manner.';

(26) in Article 33 paragraph 4 is deleted;

(26a) Article 35 is replaced by the following:

*'Article 35*

**Assessment of the application**

1. The authority responsible for notified bodies shall within 30 days check that the application referred to in Article 34 is complete and shall request the applicant to provide any missing information. Once the application is complete that national authority shall send it to the Commission.

2. Within 14 days of the submission referred to in paragraph 1 of this Article, the Commission, in consultation with the MDCG, shall appoint three experts chosen from the list referred to in Article 36(2) upon their agreement and inform the authority responsible for notified bodies. In view of the specific circumstances of the application, a different number of experts may be appointed.

   At least one of the experts shall be an expert representing the Commission. The other experts shall be experts nominated by Member States other than the one in which the applicant conformity assessment body is established.

   In order to be chosen in accordance with the first subparagraph, the experts shall be competent to assess the conformity assessment activities or the scope of designation which are the subjects of the application.

3. The experts appointed in accordance with paragraph 2 and the authority responsible for notified bodies shall form a joint assessment team that shall be led by the authority responsible for notified bodies and supported by the expert(s) representing the Commission. The authority responsible for notified bodies shall ensure that the joint assessment team is fully integrated into the joint assessment process and shall work in close collaboration with the expert(s) representing the Commission.

4. Within 90 days of the appointment of the experts in accordance with paragraph 2, the joint assessment team shall review the application and supporting documentation and shall draw up a preliminary assessment report. During that period, the joint assessment team may request any clarifications or corrections from the applicant conformity assessment body. The authority responsible for notified bodies shall lead the drafting and finalisation of the preliminary assessment report.

5. Where, based on the review of the application and supporting documentation referred to in this paragraph, the joint assessment team considers that the applicant body does not and, within a reasonable period of time, will not be able to meet the requirements of this Regulation and that any further assessment in accordance with paragraphs 6 to 9 is not appropriate, it shall draw up a final assessment report and the authority responsible for the notified bodies shall reject the application.

   Where diverging opinions amongst joint assessment team experts arise regarding the continuation of the application, such diverging opinions shall be submitted to the MDCG for further opinion. The authority responsible for notified bodies shall consider such opinions and justify its reasons for accepting or rejecting the application.

6. Unless the application is rejected, the joint assessment team, led by the authority responsible for notified bodies, shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, that is to be involved in the conformity assessment process. The on-site assessment of the applicant body shall be led by the authority responsible for notified bodies.

Where an on-site assessment of the applicant body, a subsidiary or a subcontractor is temporarily impossible or impracticable due to exceptional circumstances, the joint assessment team may decide to carry out the assessment by other appropriate means.

At the end of the on-site assessment, the joint assessment team shall list for the applicant conformity assessment body any non-compliances resulting from the assessment and summarise the assessment.

7. Within 30 days after the finalisation of the on-site assessment, the authority responsible for notified bodies, on behalf of the joint assessment team, shall submit the assessment report to the applicant conformity assessment body and, where applicable, inform that body about any non-compliances resulting from the assessment.

Where the joint assessment team has not identified any non-compliances, its assessment report shall be considered the final assessment report and paragraph 11 shall apply.

8. Where the joint assessment team has identified non-compliances, the applicant conformity assessment body shall, within 30 days of receipt of the assessment report or within a timeline agreed with the joint assessment team, submit to the joint assessment team a proposed corrective and preventive action plan to address the non-compliances effectively and in a timely manner.

That plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

9. On receipt of the proposed corrective and preventive action plan referred to in paragraph 8, the joint assessment team shall assess whether the non-compliances identified during the assessment have been appropriately addressed. Where necessary, the authority responsible for notified bodies shall provide any comments on it to the applicant conformity assessment body, including requests for further clarification and modifications.

The applicant conformity assessment body and the joint assessment team shall endeavour to agree on a final corrective and preventive action plan in due course.

10. Within 45 days of receipt of evidence of the final corrective and preventive action plan, or of the moment the joint assessment team concludes that no agreement on a final plan and its implementation has been reached, the authority responsible for notified bodies shall lead the drafting and finalisation of the final assessment report. That report shall include the result of the assessment, conclusions regarding the corrective and preventive action plans and whether the non-compliances have been appropriately addressed, any issue or view in accordance with paragraph 15, and, where applicable, the recommended scope of designation.

11. The authority responsible for notified bodies shall, on behalf of the joint assessment team, submit its final assessment report to the MCDG without undue delay.

    Based on the findings of the final assessment report, the authority responsible for notified bodies shall submit to the MDCG a draft decision on the designation of the notified body or reject the application.

12. Within 21 days of receipt of the draft decision on the designation referred to in paragraph 11, the MDCG shall issue a recommendation with regard to the envisaged designation, which the authority responsible for notified bodies shall duly take into consideration for its final decision on the designation of the notified body. That 21-day period may be extended once on justified grounds.

13. Where the authority responsible for notified bodies does not agree with the recommendation of the MDCG, within 30 days, it shall submit to the MDCG a duly justified request to reconsider its recommendation. Within 30 days of receipt of that request, the MDCG shall either confirm its recommendation or issue a new recommendation.

14. Where no agreement can be reached between the MDCG and the authority responsible for notified bodies, either party may refer the matter to the Commission.

Within 180 days of receipt of the referral, the Commission shall, after consulting the MDCG, the authority responsible for notified bodies and, where necessary, the applicant conformity assessment body concerned, evaluate the draft decision on the designation and decide, by means of implementing act, whether or not the draft designation is justified.

15. If, at any stage of the process, consensus cannot be reached within the joint assessment team on any issue, the authority responsible for notified bodies or the expert(s) representing the Commission may refer the issue to the MDCG, which shall provide its views without undue delay and at the latest within 60 days from the referral. In such cases, timelines for the joint assessment shall be adjusted to account for the referral to the MDCG.

16. The Commission may, by means of implementing acts, adopt measures setting out detailed arrangements specifying the procedures and any relevant documentation for the following:
    (a) the application for designation referred to in Article 34;
    (b) the assessment of the application set out in this Article;
    (c) the nomination and selection of experts referred to in Article 36;
    (d) the monitoring of notified bodies pursuant to Article 40.

    Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).';

(26b) Article 36 is amended as follows:

(a) the title is replaced by the following:

'Nomination of experts for joint assessment';

(b) paragraph 1 is replaced by the following:

'1. All Member States that have appointed an authority responsible for notified bodies and the Commission shall nominate experts who are qualified in the assessment, designation or monitoring of conformity assessment bodies in the field of in vitro diagnostic medical devices or in the assessment of manufacturers' technical documentation and who will be available to participate in the activities referred to in Articles 35, 40 and 44. Member States that have not appointed an authority responsible for notified bodies may nominate experts who have those qualifications.';

(26c) The following Article 36a is inserted:

*'Article 36a*

**Funding of activities related to designation and monitoring of notified bodies**

1. Conformity assessment bodies and notified bodies shall pay to the authorities responsible for notified bodies a fee for the assessment of their application for designation and their monitoring. The fee shall be proportionate to the scope of designation applied for and conformity assessment activities and be based on cost-recovery principles.

1a. Conformity assessment bodies and notified bodies shall pay to the Commission a fee for the costs associated with joint assessment and monitoring activities, including the involvement of experts nominated in accordance with Article 36 in those activities. The fees shall take into account the size and portfolio of the notified bodies concerned.

2. The Commission shall, by means of implementing acts, establish the following:

(b) The level of the fees referred to in paragraph 1a, the type of recoverable costs and other necessary implementing rules, such as the principles governing fee reductions or the payment for the experts nominated by the Member States participating in joint assessment and monitoring activities. The fees shall be set on the basis of cost-recovery principles.

When adopting implementing acts pursuant to paragraph 2, the Commission shall take into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation of experts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

2a. Until the entry into application of an implementing act referred to in paragraph 2, point (b), the costs associated with joint assessment and monitoring activities shall be covered by the Commission.';

(26d) The third paragraph of Article 37 is replaced by the following:

'The Commission shall provide translations of the documentation pursuant to Articles 34 and 35, or parts thereof into an official Union language, such as is necessary for that documentation to be readily understood by the joint assessment team appointed in accordance with Article 35(4).';

(26e) Article 38 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Member States may only designate conformity assessment bodies for which the assessment pursuant to Article 35 was completed and there is a recommendation of the MDCG issued in accordance with Article 35(11) or (12), or in accordance with an implementing act adopted by the Commission in accordance with Article 35(14), and which comply with this Regulation.’;

(b) paragraph 4 is replaced by the following:

‘4. The notification shall be accompanied by the recommendation of the MDCG.’;

(c) paragraphs 6 to 9 are deleted;

(d) paragraph 10 is replaced by the following:

‘10. When publishing the notification in NANDO, the Commission shall add to the electronic system referred to in Article 52 the information relating to the notification of the notified body along with the documents mentioned in paragraph 4 of this Article.’;

(26f) Article 40 is amended as follows:

(a) the title is replaced by the following:

‘Monitoring of notified bodies’;

(b) in paragraph 2 the second sentence is replaced by the following:

‘Notified bodies shall, upon request by their authority responsible for notified bodies, supply all relevant information and documents required to enable the authority, the joint assessment team and the Commission to verify compliance.’;

(c) the following paragraph 3a is added:

'3a. The authority responsible for notified bodies shall conduct its monitoring and assessment activities in accordance with an assessment programme considering the full scope of the notified body's activities. That programme shall ensure that the authority can effectively monitor the continued compliance of the notified body with the requirements of this Regulation and shall provide a reasoned schedule for the frequency of assessment of the notified body and, where applicable, its subsidiaries or subcontractors for a period of at least three years. The authority responsible for notified bodies shall submit the programme for monitoring or assessment for each notified body for which it is responsible to the sub-group with members representing authorities responsible for notified bodies laid down in Article 99a, MDCG and to the Commission. The authority shall address any request for clarification or modification made by the sub-group, the Commission or the MDCG.';

(d) paragraph 4 is replaced by the following:

'4. At least once a year, the authorities responsible for notified bodies shall assess whether each notified body established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those notified bodies still satisfy the requirements and fulfil their obligations set out in this Regulation, in particular Annex VII.

Where necessary, the assessment shall include an on-site audit of the notified body, its subsidiaries and subcontractors.

The authority, the MDCG or the Commission may request the participation of experts from the Commission and other Member States in the annual assessment of a notified body.';

(e) the following paragraphs 4a, 4b and 4c are inserted:

‘4a. At least every three years, and proportionate to scope of designation, volume and type of conformity assessment and compliance history, the annual assessment of a notified body, referred to in paragraph 4 above, shall be carried out by a joint assessment team including the authority responsible for notified bodies and two experts from the list referred to in Article 36(2) appointed by the Commission in consultation with the MDCG. At least one of those experts shall be an expert representing the Commission. In view of the specific circumstances of the monitoring, the Commission may appoint a different number of experts. The joint assessment team shall be led by the authority responsible for notified bodies and supported by the expert(s) representing the Commission.

If, at any stage of the process, consensus cannot be reached within the joint assessment team on any issue, the authority responsible for notified bodies or the expert(s) representing the Commission may refer the issue to the MDCG, which shall provide its views without undue delay and at the latest within 60 days from the referral. In such cases, timelines for the joint assessment shall be adjusted to account for the referral to the MDCG.

4b. At the end of any assessment carried out pursuant to paragraph 4 or 4a, the authority responsible for notified bodies or the joint assessment team, as applicable, shall list for the notified body any non-compliances resulting from the assessment and summarise their assessment and if immediate action is required.

Within 30 days after the finalisation of the assessment, the authority responsible for notified bodies, on behalf of the joint assessment team, as applicable, shall submit the assessment report to the notified body and, where applicable, inform that body about any non-compliances resulting from the assessment.

Where non-compliances have been identified, the notified body shall submit a proposed corrective and preventive action plan to address the non-compliances effectively in a timeframe agreed with the authority responsible for notified bodies or the joint assessment team. That plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions set out therein.

The authority responsible for notified bodies or the joint assessment team, as applicable, shall assess whether the non-compliances identified during the assessment have been appropriately addressed in the plan referred to in the second subparagraph. Where necessary, the authority responsible for notified bodies shall provide any comments on the plan to the notified body, including requests for further clarification and modifications. The notified body and the authority or the joint assessment team, as applicable, shall endeavour to agree on a final corrective and preventive action plan in due course.

4c. After receipt of the final corrective and preventive action plan, or where the authority responsible for notified bodies or the joint assessment team, as applicable, have not identified non-compliances or conclude that no agreement on a final plan has been reached, the authority responsible for notified bodies, in conjunction with the joint assessment team, as applicable, shall draw up their final monitoring report which shall include the result of the assessment and, where applicable, conclusions regarding the corrective and preventive action plan and, where applicable, any recommendations regarding the notified body's designation.

The authority responsible for notified bodies, on behalf of the joint assessment team, as applicable, shall submit their final monitoring report to the MDCG and to the Commission without undue delay.

The authority responsible for notified bodies shall monitor the implementation of the corrective and preventive action plan by the notified body, as appropriate.

Where the final monitoring report concludes that the notified body no longer meets the requirements set out in this Regulation, or where the notified body fails to implement the corrective and preventive action plan, the authority responsible for notified bodies shall follow the procedure set out in Article 42(4).';

(f) paragraph 5 is replaced by the following:

‘5. The monitoring of notified bodies by the authority responsible for notified bodies shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, whilst such personnel are in the process of conducting quality management system assessments at a manufacturer's facility.’;

(g) paragraph 6, first subparagraph, is replaced by the following:

‘6. The monitoring of notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance.’;

(h) paragraph 8 is replaced by the following:

‘8. During the monitoring of a notified body, an appropriate number of the notified body’s assessments of manufacturers' quality management system and technical documentation, in particular the performance evaluation documentation, shall be reviewed either off-site or on-site. The sampling of files shall be representative of the types and risk classes of devices certified by the notified body, in particular high-risk devices, and shall include reviewing whether the assessment by the notified body was conducted appropriately and shall check the procedures used, associated documentation and the conclusions drawn by the notified body. Such review shall include the technical documentation and performance evaluation documentation of the manufacturer upon which the notified body has based its assessment.’;

(i) paragraphs 9, 10 and 11 are deleted;

(j) paragraph 12 is replaced by the following:

‘12. The authority responsible for notified bodies shall draw up an annual summary of their monitoring activities regarding notified bodies and, where applicable, subsidiaries and subcontractors. That summary shall be made publicly available through the electronic system referred to in Article 52.’;

(26g) Article 41 is deleted;

(26h) Article 42 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

‘1. The authority responsible for notified bodies shall notify the Commission and the MDCG of any application for relevant changes to the designation of a notified body.

Unless otherwise agreed by the MDCG, the procedures set out in Articles 35 and 38 shall apply to extensions of the scope of the designation. By way of derogation from Article 35, an on-site assessment shall not be conducted where the Joint Assessment Team considers such assessment not to be necessary for the assessment of the requested scope extension.

For changes to the designation other than extensions of its scope, the procedures laid down in paragraphs 2 to 9 shall apply.

2. After having assessed the application for changes, the authority responsible for notified bodies shall notify the Commission of the relevant changes to the designation. The Commission shall without undue delay publish the amended notification in NANDO. The Commission shall also, without undue delay, enter information on the changes to the designation of the notified body in the electronic system referred to in Article 52.';

(b) in paragraph 4, the first subparagraph is replaced by the following:

'Where an authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in this Regulation, 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 or impose conditions on the notified body, 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.';

(26i) Article 43 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The Commission, in consultation 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 this Regulation. It shall ensure that the relevant authority responsible for notified bodies is informed and is given an opportunity to investigate those concerns.';

(b) paragraph 3 is replaced by the following:

‘3. The Commission, in consultation with the MDCG, may initiate the assessment by a joint assessment team as referred to in Article 40(4a) to (4c), where 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 this Regulation and where the investigation by the authority responsible for notified bodies is not deemed to have fully addressed the concerns or upon request of the authority responsible for notified bodies. The reporting and outcome of that assessment shall follow the principles of Article 35.’;

(26j) Article 44 is amended as follows:

(a) the title is replaced by the following:

‘Exchange of experience between authorities responsible for notified bodies’;

(b) paragraphs 2 to 5 are deleted;

(26k) Article 45 is replaced by the following:

*‘Article 45*

**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, as referred to in Article 49 of Regulation (EU) 2017/745.

All bodies notified under this Regulation shall participate in the work of that group, in accordance with that Article.’;

(26l) Article 46 is replaced by the following:

*'Article 46*

**Access to notified bodies and fees**

1. Notified bodies shall establish lists of their fees for the conformity assessment activities that they carry out and shall make those lists publicly available. They shall notify the lists to the Commission, which shall make references to them available to the public on a dedicated website.

2. Notified bodies shall apply at least a 25 % fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 48a(3). The fees shall take into account the size and portfolio of the notified bodies concerned.

2a. Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of up to 50% of the fees until the relevant conformity assessment activity is finalised.

3. Notified bodies shall ensure that manufacturers, which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, have access to their conformity assessment activities in a manner that is not less favourable than the manner in which access is provided to other manufacturers.

4. Notified bodies shall deal with any request for conformity assessment activities from a manufacturer and, within 30 days of receipt of the request, inform the manufacturer accordingly.

5. When duly justified in the interest of public health or patient health or safety, and other measures cannot be applied effectively, the authority responsible for notified bodies, upon request by the MDCG, may instruct a notified body to accept a manufacturer's request for conformity assessment activities falling within that notified body's scope of designation.';

(27) Article 47 is replaced by the following:

'1. Devices shall be divided into classes A, B, C and D, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.

2. Upon a duly substantiated request by a manufacturer or an authorised representative, or on its own initiative, the competent authority of the Member State in which the manufacturer or the authorised representative is established (the 'responsible competent authority') shall, after obtaining information from the manufacturer and, where applicable, the notified body that issued the certificate for that device, decide on the classification of the device of the manufacturer.

4. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the responsible competent authority. Where the notified body concerned is established in a Member State other than that of the manufacturer or the authorised representative, the responsible competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

5. Where a competent authority (the 'initiating competent authority'), on the basis of information obtained through vigilance activities, market surveillance activities or any other relevant information, has justified doubts as to the classification of a device for which neither the manufacturer nor the authorised representative is established within its Member State, it shall refer the matter to the responsible competent authority and inform the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745 and the Commission of the referral, providing justification for its doubts about the classification.

6. Following consultation with the initiating competent authority and after having obtained information from the manufacturer or authorised representative and where applicable, the notified body that issued the certificate for that device, the responsible competent authority shall decide on the classification within 6 months from the date of referral. The responsible competent authority shall issue the decision and communicate it to the initiating competent authority and the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745, and the Commission.

7. Where a competent authority does not agree with the decision taken by the responsible competent authority, or where the responsible competent authority has not communicated their decision within the period referred to in paragraph 6, that competent authority shall consult the group of national competent authorities in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745, providing justification for its doubts about the classification, who shall issue an opinion on the classification of the device.

8. Taking into account the opinion of the group of national competent authorities referred to in paragraph 7, or where no opinion has been issued within three months, a Member State may request the Commission to decide on the classification of the specific product, by means of implementing acts.

9. The Commission shall consult the MDCG, and may consult the relevant expert panel for its scientific or technical advice. The Commission shall set a time-limit for the MDCG to adopt its opinion. The time limit shall not be shorter than 90 days.

9a. The manufacturer or authorised representative, as well as the notified body that issued the certificate, if applicable, shall be provided with the opportunity to present their positions on the classification of the device to the competent authorities, MDCG or the relevant expert panel, as applicable.

12. Within 180 days of the request from a Member State referred to in paragraph 8, the Commission shall propose to the Committee a decision on the classification of the device by means of implementing acts, in accordance with the examination procedure referred to in Article 107(3). In adopting its decision, the Commission shall take the utmost account of the advice and opinions issued by the expert panel and the MDCG, respectively.

    By way of derogation from the first subparagraph, the Commission may decide, in the absence of an opinion of the MDCG adopted by a majority of members pursuant to Article 103, paragraph 4, of Regulation (EU) 2017/745 within the time-limit referred to in paragraph 9, not to adopt a decision on the classification of the device.

13. At the substantiated request of the MDCG, or on its own initiative, the Commission shall, decide by means of implementing acts, 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 be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.

14. In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant opinion of the MDCG and the scientific opinion of the relevant expert panel, the Commission is empowered to adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

15. The implementing acts referred to in paragraphs 13 and 14 of this Article shall be adopted in accordance with the examination procedure referred to in Article 107(3).

16. The opinions and decisions on the classification of devices and the advice of the expert panel delivered in accordance with this Article shall be made publicly available, without disclosing any confidential information as referred to in Article 102.

17. The Commission may, by means of implementing acts, lay down the procedure, including timelines, for the application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).';

(29) Article 48 is amended as follows:

(a) in paragraph 3, the second and third subparagraphs are deleted;

(b) in paragraph 4, the second subparagraph is deleted;

(c) paragraphs 5 and 6 are deleted;

(d) paragraph 7 is replaced by the following:

'7. Manufacturers of class C devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX including an assessment of the technical documentation as specified in Sections 4.3 to 4.8. of that Annex shall be done for one representative device per generic device group.

The representative device shall be chosen in accordance with the approach outlined in the third paragraph of Section 2.3 of Annex IX.

Where, having applied the approach in the third paragraph of Section 2.3 of Annex IX, a notified body considers it necessary, on justified grounds, to assess the technical documentation of additional representative devices due to their specific characteristics or properties, it shall document its rationale as part of the sampling plan to be drawn up in accordance with Annex VII Section 4.5.2(a).';

(e) in paragraph 8, the second subparagraph is deleted;

(f) paragraph 9 is replaced by the following:

'9. Manufacturers of class B devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX including an assessment of the technical documentation as specified in Sections 4.3. to 4.8. of that Annex of one representative device.

The representative device shall be chosen in accordance with the approach outlined in the third paragraph of Section 2.3 of Annex IX.

Where, having applied the approach in the third paragraph of Section 2.3 of Annex IX, a notified body considers it necessary, on justified grounds, to assess the technical documentation of additional representative devices due to their specific characteristics or properties, it shall document its rationale as part of the sampling plan to be drawn up in accordance with Annex VII Section 4.5.2(a).';

(g) the following paragraph 9a is inserted:

'9a. Manufacturers of class B devices, other than devices for performance study, may, instead of the conformity assessment procedure referred to in paragraph 9, choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI with the exception of its Section 5.';

(h) in paragraph 10, the second subparagraph is deleted;

(i) the following paragraphs 10a and 10b are inserted:

‘10a. In the case of devices for self-testing, in addition to the procedures applicable pursuant to paragraph 3, 7 or 9, the procedure specified in Section 5.1 of Annex IX shall also apply.

10b. In the case of companion diagnostics, in addition to the procedures applicable pursuant to paragraph 3, 4, 7 or 8, the procedure specified in Section 5.2 of Annex IX or in Section 3, point (k), of Annex X, as applicable, shall also apply.’;

(j) paragraph 13 is replaced by the following:

13. The Commission may, by means of implementing acts, specify the detailed arrangements and procedural aspects of the conformity assessment procedures with regard to any of the following aspects:

(a) in respect of class B and class C devices, the basis for the selection of representative device(s) for the assessment of the technical documentation as referred to in Section 2.3 of Annex IX;

(b) the modalities of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) the frequency of samples of the manufactured devices or batches of class D devices to be sent to an EU reference laboratory designated pursuant to Article 100, in accordance with Section 4.12 of Annex IX and Section 5.1 of Annex XI;

(d) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of technical documentation and type;

(e) the modalities of the conformity assessment procedures regarding breakthrough devices and orphan devices set out in Article 48a.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).’;

(30) the following Articles 48a and 48b are inserted:

*'Article 48a*

**Conformity assessment of breakthrough devices and of orphan devices**

1. For the conformity assessment of breakthrough devices and orphan devices, where the conformity assessment procedure requires the involvement of a notified body, the procedures laid down in Article 48 shall apply, and may, upon request by the manufacturer, be subject to the specific arrangements set out in this Article.

2. A device shall be considered a breakthrough device if it meets the following criteria:
   (a) it is expected to introduce in the Union a high degree of novelty with respect to the device technology or the related clinical procedure or the application of the device in clinical practice; and
   (b) it is expected to provide a significant positive clinical impact on patient or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:
      (i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art;
      (ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

3. A device shall be considered an orphan device if it meets the following criteria:
   (a) the device is intended to provide information on a disease or condition that presents in not more than 12 000 individuals in the Union per year; and
   (b) at least one of the following criteria is met:
      (i) there are insufficient available alternatives;
      (ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art.

4. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel as referred to in Article 106 of Regulation (EU) 2017/745 shall provide an opinion with respect to confirming whether the criteria set out in paragraph 2 or 3 of this Article, as applicable, are fulfilled. The opinion shall be published on a dedicated website without disclosing any confidential information as referred to in Article 102 and shall be duly taken into consideration by the manufacturer and the notified body.

5. Where the opinion of the expert panel has confirmed the fulfilment of the criteria set out in paragraph 2 or 3 of this Article, the manufacturer of a breakthrough device or of an orphan device, as applicable, may request advice from the expert panels referred to in Article 106 of Regulation (EU) 2017/745 regarding its performance evaluation strategy and appropriate analytical or clinical performance data for the performance evaluation of the device.

6. For breakthrough device or an orphan device, confirmed by the relevant expert panel, as applicable, the notified body involved in the conformity assessment procedure set out in Article 48 shall prioritise the conformity assessment of that device, offer priority access to supports to the manufacturer before and throughout the conformity assessment procedure, including priority access to dialogues referred to in section 1.2.9 of Annex VII, and apply, where appropriate, a rolling review with a view to reduce assessment timelines.

The notified body shall give utmost consideration to the opinion or advice provided by the expert panel in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided.

7. The notified body shall issue a certificate pursuant to Article 51 where, all applicable requirements of this Regulation are fulfilled and, based on their assessment of the performance evaluation report, the pre-market clinical evidence is deemed sufficient, even if based on limited clinical performance data, provided that each of the following criteria is fulfilled:
   (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical performance data are still required;
   (b) the benefit-risk ratio of the device is favourable and the manufacturer commits to providing additional data from post-market performance follow-up activities, pursuant to an appropriate PMPF plan.

Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 51, such as specific post-market performance follow-up activities to be conducted within a specified period of time.

8. The Commission is empowered to adopt delegated acts in accordance with Article 108 in order to amend this Article to adapt to technical and scientific progress and to take into account developments regarding conformity assessment of breakthrough devices or orphan devices at international level.

9. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices or orphan devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

*Article 48b*

**Digitalisation of technical documentation, conformity assessment and reports**

1. The manufacturer may draw up and make available in a digital format the technical documentation and any reports or other documents required pursuant to this Regulation. That digital format may be a structured machine-readable format, provided that it is possible to transform it into human-readable format, and that there is version-control to enable the conduct of retrospective conformity checks. Where the technical documentation, reports or other documents are to be submitted to and assessed by a notified body or made available to competent authorities for the purposes of market surveillance, the manufacturer shall ensure that the digital format is suitable for and agreed with the notified body or competent authority or national authorities responsible for notified bodies as applicable.

2. Where necessary to ensure that the digital format referred to in paragraph 1 is reliable, interoperable and standardised, the Commission may establish minimum requirements or functional specifications for the digital format by means of common specifications as referred to in Article 9.';

(31) in Article 49, paragraph 5 is replaced by the following:

'5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities in the public interest and 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.';

(32) Article 50 is replaced by the following:

*'Article 50*

**Mechanism for scrutiny of conformity assessments**

1. The MDCG or the Commission may, based on reasonable concerns, and having consulted the authority responsible for notified bodies, request advice from an expert panel in relation to the safety and performance of any device which has undergone conformity assessment with the involvement of a notified body. For that purpose, the MDCG or the Commission may request the notified body that issued the certificate for the device in question to submit to the expert panel its performance evaluation assessment report and any subsequent surveillance assessment reports regarding that device. The expert panel may request the notified body or the manufacturer to submit any additional information necessary to provide its advice.

2. The MDCG or the Commission may, based on reasonable concerns, and having consulted the authority responsible for notified bodies request advice from one or more EU reference laboratories, based on their expertise related to laboratory testing, in relation to the safety and performance of any device which has undergone conformity assessment with the involvement of a notified body, provided that the device or the field of laboratory testing falls within the scope of designation of those EU reference laboratories. For that purpose, the MDCG or the Commission may request the notified body that issued the certificate for the device in question to submit to the EU reference laboratories its performance evaluation assessment report, other relevant parts of the technical documentation and any subsequent surveillance assessment reports regarding that device. The EU reference laboratories may request the notified body or the manufacturer to submit samples of the device or any additional information necessary to provide its advice.

3. The notified body shall give utmost consideration to the advice of the expert panel or the EU reference laboratory, as applicable, and, where needed, take any appropriate measures, including those referred to in Article 51(3) and (4).';

(33) Article 51 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. The EU technical documentation assessment certificates or EU type examination certificates related to Class D devices, companion diagnostics, and Class C devices for self-testing shall be valid for the period they indicate, which shall not exceed five years.

On application by the manufacturer, the initial validity of the certificates for Class D devices, companion diagnostics, and Class C devices for self-testing, may be extended for a further period not limited in time, based on a re-assessment after the initial five years and periodic reviews thereafter, in accordance with the applicable conformity assessment procedures and with Annex VII, Section 4.11.

All other certificates shall not be limited in time.

Notwithstanding subparagraphs 1 and 2, the notified body may limit the period of validity of certificates it issues based on duly justified grounds.

In those cases, the notified body shall indicate the period of validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.';

(b) the following paragraph 2a is inserted:

'2a. During the validity of the certificate, the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art, in accordance with Section 4.11 of Annex VII. Those reviews shall be proportionate to the risk class of the device.';

(c) paragraph 3 is replaced by the following:

'3. Notified bodies may impose conditions on the validity of the certificate, in accordance with Section 4.8 of Annex VII.';

(d) in paragraph 4, the first sentence is replaced by the following:
‘Where a notified body finds that the 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 conditions 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.’;

(e) in paragraph 5, the first sentence is replaced by the following:
‘The notified body shall enter in the electronic system referred to in Article 52 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and conditions imposed on certificates.’;

(34) in Article 52, point(f) is deleted;

(35) Article 54 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. By way of derogation from Article 48, on a duly justified request, any competent authority may authorise, for a limited period of time, the placing on the market or putting into service within the territory of the Member State concerned of a specific device for which the applicable conformity assessment procedures have not been carried out, provided the use of that device is in the interest of public health, patient safety or patient health.’;

(b) the following paragraphs 1a and 1b are inserted:

‘1a. By way of derogation from Article 6(2), on a duly justified request, any competent authority may authorise for a limited period of time, the use of a specific device that is not placed on the Union market for the provision of a diagnostic or therapeutic service referred to in that Article to a natural or legal person(s) established within the territory of the Member State concerned, using a specific device for which the applicable conformity assessment procedures set out in this Regulation have not been carried out, provided the provision of such service is in the interest of public health, patient safety or patient health.

1b. Where appropriate, the competent authority may specify and impose additional conditions or limitations to the derogations referred to in paragraphs 1 and 1a, such as conditions on labelling, serious incident reporting, traceability, and limitations to the number of devices.’;

(c) paragraph 2 is replaced by the following:

‘2. The Member State shall inform the Commission, the Agency, and the other Member States of any decision made on requests to authorise the placing on the market or putting into service of a device in accordance with paragraph 1, or the use of a device for the provision of a service, in accordance with paragraph 1a, where such authorisation is granted for use other than for a single patient. Where relevant, the Agency shall share this information with the relevant expert panels referred to in Article 106 of Regulation (EU) 2017/745.

The Member State shall make information about such authorisations publicly available.';

(d) in paragraph 3, the first subparagraph is replaced by the following:
'Where a request pursuant to paragraph 1 or paragraph 1a has been submitted to competent authorities in more than one Member State and based on an opinion, where applicable, of an expert panel referred to in Article 106 of Regulation (EU) 2017/745, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time or number of devices the validity of an authorisation granted by a Member State in accordance with paragraph 1 or paragraph 1a of this Article to the territory of the Union, or provide an authorisation referred to in paragraph 1 or paragraph 1a of this Article for the territory of the Union. The Commission may set the conditions under which the device may be placed on the market or put into service, or under which the diagnostic or therapeutic service may be provided. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

The Commission shall make information about such Union-wide authorisations publicly available.';

(e) the following paragraphs 4 and 5 are added:

‘4. In the event of a public health emergency at Union level recognised in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council******, the Commission may, by means of implementing acts, on its own initiative after consulting the MDCG, and if appropriate, the relevant expert panel, authorise the placing on the market or putting into service of a device in accordance with paragraph 3. The authorisation shall cease to apply at the latest when the recognition of the public health emergency is terminated pursuant to Article 23(2) of Regulation (EU) 2022/2371. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(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 107(4).

5. The Commission may, by means of implementing acts, lay down rules further specifying the procedure set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

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****** Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).’;

(36) the following Articles 54a, 54b and 54c are inserted:

*'Article 54a*

**Derogations from certain requirements in the event of a serious cross-border threat to health, disaster or crisis**

1. Upon a duly justified request, a competent authority may authorise for a limited period of time, by way of derogation from the relevant provisions in Annexes II, III, IX, X and XI, an exemption from the requirements related to changes to the manufacturing or design or intended purpose of a specific CE marked device, where it is in the interest of public health, patient safety or patient health in either of the following circumstances:
   (a) a serious cross-border threat to health as defined in Article 3, point (1) of Regulation (EU) 2022/2371;
   (b) a disaster or a crisis within the meaning of Regulation (EU) ../…. of the European Parliament and of the Council*******+.

2. The manufacturer shall ensure that the manufactured devices remain in conformity with the relevant general safety and performance requirements set out in Annex I.

   The manufacturer shall ensure that any changes referred to in paragraph 1 do not adversely affect the benefit-risk ratio of the device.

3. The competent authority may request the notified body that issued a certificate for the device in question to assist it in the assessment of the request referred to in paragraph 1.

3a. Where appropriate, the competent authority shall impose and specify conditions or limitations, as applicable, to the authorisation of exemption in accordance with paragraph 1. These may include, but are not limited to, conditions on labelling, incident reporting, traceability, and limitations on the number of devices.

4. Where applicable, the manufacturer shall keep the notified body that issued a certificate for the device in question informed about the authorisation and any changes made regarding the manufacturing, design or intended purpose of a CE marked device in accordance with the authorisation referred to in paragraph 1.

5. Where a request pursuant to paragraph 1 has been submitted to competent authorities in more than one Member State, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time or number of devices, the validity of an exemption granted by a Member State in accordance with paragraph 1 to the territory of the Union, or provide an exemption referred to in paragraph 1 for the territory of the Union. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 107(4).

*Article 54b*

**Regulatory sandboxes at national level**

1. Member States, on their own initiative or upon a substantiated request by manufacturer may establish one or more regulatory sandboxes where:
   (a) Based on available scientific data, the application of certain requirements of Chapters V or VI or of Chapters II and III of Annexes I, or Annexes VIII, IX, X, XI, XIII or XIV to a specific device or category or group of devices would not be practicable from a technical, clinical or scientific viewpoint, and
   (b) With regard to those requirements, every precaution has been taken to protect the health and safety of patients, users, and other persons, in line with the principles set out in the Regulation.

   The Member States shall designate the competent authority that is responsible for the supervision of the regulatory sandbox. Member States may also establish regulatory sandboxes jointly with other Member States.

2. The activities within a regulatory sandbox shall take place pursuant to a specific sandbox plan that shall set out technical, clinical or scientific justification for the necessity to establish a regulatory sandbox including at least:
   (a) the identification of the requirements of this Regulation referred to in paragraph 1 are temporarily adapted in the regulatory sandbox;
   (b) a justification why the application of those requirements is considered not practicable and identification of mitigation measures for potential risks related to the adaptation;
   (c) recommendations for alternative or mitigation measures, where appropriate;
   (d) the identification of the reasonable duration of the regulatory sandbox necessary to achieve its objectives, the participants in the regulatory sandbox and their respective roles;
   (e) the identification of the responsibilities and obligations of each participant in the regulatory sandbox, including the person or persons responsible for the conduct and oversight of the regulatory sandbox;
   (f) procedures for the reporting, assessment and management of incidents, serious incidents, or serious adverse events, including the implementation of appropriate corrective and preventive measures, taking into consideration paragraph 5 of this Article.

3. A regulatory sandbox shall be set up only if the following conditions are met:
   (a) the device is expected to address unmet medical needs or to provide, based on available scientific data, a significant clinical benefit to patients or to the health system compared with similar existing alternatives, if any, or the state of the art;
   (b) based on available scientific data, the application of the requirements of this Regulation referred to in paragraph 1 would not be practicable due to technical, clinical or scientific challenges arising from characteristics or methods related to the device.

4. The Member State may request an expert panel referred to in Article 106 of Regulation (EU) 2017/745 to provide scientific, technical or regulatory advice on the draft sandbox plan.

5. Articles 76 and 82 shall apply, *mutatis mutandis*, for any serious incidents or serious adverse events that have occurred in relation to the activities taking place in the regulatory sandbox. Any participant in the regulatory sandbox shall report, without undue delay, to the competent authority that is responsible for the supervision of the regulatory sandbox about any harm that occurred in relation to the implementation of the regulatory sandbox. The competent authority shall have the power to take immediate and adequate corrective measures, including temporarily or permanently suspend participation in the sandbox, or suspend, revoke or restrict the scope of the regulatory sandbox, including amending the sandbox plan.

6. Manufacturers participating in a regulatory sandbox shall remain liable under applicable Union and national law for any damage inflicted on third parties as a result of their activities taking place in the regulatory sandbox.

7. The Member State shall inform the Commission and the MDCG about the establishment of a regulatory sandbox and keep them informed about its implementation and outcome.

8. Where a Member State has taken a measure referred to in paragraph 5 of this Article, that Member State shall communicate the corresponding decision and the grounds therefor to the Commission and the MDCG.

9. The Commission may, by means of implementing acts, lay down detailed procedural arrangements for the application of this Article.

The implementing acts shall include at least the following:

(-a) procedures for the establishment, operation and supervision of regulatory sandboxes pursuant to this Article;

(a) procedures for the application, selection, participation, monitoring, exiting from and termination of a regulatory sandbox, including the sandbox plan and outcome;

(b) the terms and conditions and procedural obligations applicable to the participants.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

*Article 54c*

**Union regulatory sandboxes**

1. The Commission, on its own initiative, and in consultation with the MDCG, or upon a substantiated request by a Member State, may establish by means of implementing acts for a limited time and pursuant to a specific plan, Union regulatory sandboxes, to technically adapt existing requirements applicable to a specific type of device with particular characteristics or emerging technologies, where there is a risk that the existing requirements:

(a) would not be applicable due to technical or scientific challenges arising from characteristics or technologies inherent to the device;

(b) based on scientific evidence, the adaptations are considered indispensable to adequately protect the health and safety of patients, users or other persons or other aspects of public health, in line with the principles set out in the Regulation.

Union regulatory sandboxes shall not involve the placing on the market or putting into service of devices which do not comply with this Regulation.

2. The Commission shall, following consultation with MDCG, request an expert panel referred to in Article 106 of Regulation (EU) 2017/745 to provide scientific, technical or regulatory advice on the design of a Union regulatory sandbox.

3. The Commission shall consult with the MDCG about the establishment of a regulatory sandbox and keep it informed about its outcome.

4. The Commission shall, by means of implementing acts lay down detailed arrangements for the establishment, operation and supervision of Union regulatory sandboxes pursuant to this Article.

Those implementing acts shall include at least the following:

(a) procedures for the application, participation, monitoring, exiting from and termination of a regulatory sandbox, including the sandbox plan and outcome;

(b) the terms and conditions, and rights and obligations applicable to the participants.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

5. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend this Article based on scientific, technical or regulatory progress or developments regarding Union regulatory sandboxes, in order to specify technical, scientific and regulatory features of a Union regulatory sandbox.

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****** Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ..., ELI). + OJ: Please insert in the text the number of the Regulation contained in 2025/0223(COD) (Proposal for a Regulation on the Union Civil Protection Mechanism and Union support for health emergency preparedness and response, and repealing Decision No 1313/2013/EU) and insert the number, date, title and OJ reference of that Regulation in the footnote.';

(37) In Article 55, the following paragraph 1a is inserted:

'1a. The manufacturer shall make the certificates of free sale issued in accordance with paragraphs 1 publicly available in Eudamed within 30 days of issuance.';

(38) Article 56 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Manufacturers shall plan, conduct and document a performance evaluation in accordance with this Article and with Part A of Annex XIII to confirm the safety and performance of the device, in particular those concerning the performance characteristics referred to in Chapter I and Section 9 of Annex I, under normal conditions of use according to the intended purpose of the device, and shall evaluate the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I.

The 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 XIII:

(a) scientific validity;

(b) analytical performance;

(c) clinical performance.

The data and conclusions drawn from the assessment of those elements shall constitute sufficient clinical evidence for the device.

The manufacturer shall conduct the performance evaluation with the aim to establish the clinical evidence and specify and justify the level of the clinical evidence necessary to confirm the safety and performance of the device and the scientific and methodological approach used to generate this clinical evidence. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

The performance evaluation, its results and the clinical evidence derived from it shall be documented in a performance evaluation report as referred to in Section 1.3 of Annex XIII, which shall be part of the technical documentation referred to in Annex II relating to the device concerned.';

(b) paragraphs 2 to 5 are deleted;

(c) paragraph 6 is replaced by the following:

‘6. The performance evaluation, its documentation and, where applicable and needed, the summary of safety and performance referred to in Article 29 shall be updated throughout the life cycle of the device concerned with data and findings obtained from implementation of the manufacturer’s PMPF plan in accordance with Part B of Annex XIII and the post-market surveillance plan referred to in Article 79, whenever those data and findings provide information relevant for the confirmation of safety and performance of the device.’;

(39) the following Article 56a is inserted:

*‘Article 56a*

**Advice from expert panels**

For class C and class D devices, a manufacturer may, prior to its clinical performance study or performance evaluation, consult an expert panel as referred to in Article 106 of Regulation (EU) 2017/745, with the aim of reviewing the manufacturer’s intended strategy for conducting a performance evaluation or proposals for any clinical performance study. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the performance evaluation report and the performance evaluation assessment report, give due consideration to the advice of the expert panel, and where they do not follow that advice, they shall provide duly justified reasons.’;

(40) Article 58 is amended as follows:

(a) in paragraph 1, point (a) is deleted;

(b) in paragraph 1, point (c) is replaced by the following:

‘(c) where the conduct of the study involves additional invasive procedures, including high-risk procedures for the collection of specimens or other procedures posing significant risk to the subjects of the studies, with the exception of low- risk procedures for the collection of specimens.’;

(c) paragraph 2 is deleted;

(d) in paragraph 5, point (a) is replaced by the following:

‘(a) the performance study is the subject of an authorisation by the Member State(s) in which the subjects for the performance study are to be enrolled, in accordance with this Regulation, unless otherwise stated;’;

(42) Article 66 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

‘The sponsor of a performance study referred to in Article 58(1) shall enter and submit an application to the Member State(s) in which the subjects for the performance study are to be enrolled (referred to for the purposes of this Article and Article 71 as ‘Member State concerned’) accompanied by the documentation referred to in Sections 2 and 3 of Annex XIII and in Annex XIV.’;

(b) paragraph 7 is replaced by the following:

‘7. The sponsor may start the performance study as soon as the Member State concerned has notified the sponsor of its authorisation and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the performance study. The Member State shall notify the sponsor of the authorisation within 45 days of the validation date of the application referred to in paragraph 5. The Member State may extend this period by a further 20 days for the purpose of consulting with experts.’;

(43) in Article 67, paragraph 2 is replaced by the following:

‘2. Member States shall ensure that the assessment is done jointly by an appropriate number of persons who collectively have the necessary qualifications and experience.’;

(44) in Article 68, the following paragraph 7 is added:

‘7. The processing of personal data in the context of a performance study, including the secondary use of personal data initially collected for other studies, may be carried out for scientific research purposes as referred to in Article 9(2), point (j), of Regulation (EU) 2016/679 *******, without prejudice to the obligations and requirements set out in that Regulation.

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*******Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).’;

(44a) in Article 69, paragraph 3, point (a) is replaced by the following:

‘(a) protection of personal data in accordance with Regulation (EU) 2018/1725;’;

(45) in Article 70(1), the second and third sentences are replaced by the following:

‘The sponsor shall include the documentation referred to in Part A, Section 2, of Annex XIII and in Chapter I, Sections 1, 3 and 4, of Annex XIV. Article 58(5), points (b) to (l) and (p), Article 71(1), Articles 72 and 73, and Article 76(5) and (6), and the relevant provisions of Annexes XIII and XIV shall apply to PMPF studies involving additional invasive or burdensome procedures.’;

(46) in Article 71, paragraphs 1 and 2, and paragraph 3, introductory wording, are replaced by the following:

‘1. If a 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, it shall notify, by means of the electronic system referred to in Article 69, the Member State(s) concerned of the reasons for and the nature of those modifications. The sponsor shall include an updated version of the relevant documentation referred to in Annex XIV as part of the notification. Changes to the relevant documentation shall be clearly identifiable.

2. Where the performance study has been the subject of an authorisation in accordance with Article 58(5), point (a), the Member State shall assess any substantial modification to the performance study in accordance with the procedure laid down in Article 67.

The Member State shall notify the sponsor of the outcome of its assessment within 38 days of receipt of the sponsor's notification under paragraph 1. During its assessment, the Member State may request additional information from the sponsor. The period of 38 days shall be suspended from the date of the first request until such time as the additional information has been received.

3. The sponsor may implement the modifications referred to in paragraph 1 as soon as the Member State concerned has notified the sponsor of its authorisation, or following expiry of the period defined in paragraph 2, whichever is sooner, unless:';

(47) in Article 73(1), the first sentence is replaced by the following:
'If the sponsor has temporarily halted a performance study or has terminated a performance study early, it shall, within 15 days of the temporary halt or early termination, inform the Member State in which that performance study has been temporarily halted or terminated early, by means of the electronic system referred to in Article 69, providing a justification.';

(48) Article 74 is amended as follows:

(a) in paragraph 4, the second subparagraph is replaced by the following
'The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with paragraph 11.';

(b) paragraph 5 is replaced by the following:
'Each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within 12 days of receipt of the request. The expiry of the last deadline pursuant to paragraph 4, point (d), shall be suspended from the date of the request until such time as the additional information has been received.';

(c) in paragraph 6, the words ‘50 days’ are replaced by the words ‘30 days’;

(d) the following paragraph 15 is added:

‘15. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend this Article in light of experience gained from the practical application of the coordinated assessment procedure, in particular as regards timelines and the authorisation of performance studies subject to a coordinated assessment.’;

(49) Article 75 is deleted;

(51) Article 78(4) is replaced by the following:

‘If, in the course of the post-market surveillance, a need for preventive or corrective action, or both, is identified, the manufacturer shall implement the appropriate measures. Where preventive or corrective action is taken to reduce a risk that may compromise the safety of the device, the manufacturer shall inform the competent authorities concerned. Where such corrective actions are associated with an identified serious incident or an implemented field safety corrective action, it shall be reported in accordance with Article 82.’;

(52) in Article 79, the following sentence is added after the second sentence:

‘The post-market surveillance plan shall specify the criteria, and timelines where relevant, for updating the Post-Market Surveillance Report as referred to in Article 80 or the Periodic Safety Update Report as referred to in Article 81.’;

(53) Article 81 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the first sentence is replaced by the following:
‘Manufacturers of class C and class D devices shall prepare a periodic safety update report (‘PSUR’) for each device, or where relevant, for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79, together with a description of any preventive and corrective actions taken, including their rationale.’;

(ii) the second subparagraph is replaced by the following:
‘Manufacturers of class C and class D devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter or when there is a significant change in the benefit-risk determination or in the acceptability of erroneous results. The PSUR shall be part of the technical documentation specified in Annex III.’;

(b) paragraph 2 is replaced by the following:

‘2. For class D devices, the notified body shall review the PSUR as part of its surveillance activities, where applicable, or as part of the technical documentation review. The manufacturer shall make such PSURs available through the electronic system referred to in Article 87. The notified body shall make its evaluation of such PSURs available through the electronic system referred to in Article 87.
For all other devices where the PSUR is applicable, the notified body shall have documented procedures for reviewing PSURs on a representative basis as part of the surveillance activities in accordance with Section 4.10 of Annex VII.’;

(54) Article 82 is amended as follows:

(-a) in paragraph 1, first subparagraph, point (a) is replaced by the following:

‘(a) any serious incident involving devices made available on the Union market, except expected erroneous results which are clearly documented in the device information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 83;’;

(a) in paragraph 1, the second subparagraph is replaced by the following:

‘The reports referred to in the first subparagraph shall be submitted in accordance with the timelines specified in this Article through the electronic system referred to in Article 87.’;

(b) paragraph 3 is replaced by the following:

‘3. Manufacturers shall report any serious incident as referred to in paragraph 1, first subparagraph, point (a), immediately after they have established that there is a causal relationship between that incident and their device or that such causal relationship is reasonably possible, and not later than 30 days after they become aware of the incident.’;

(55) The following Article 82a is inserted:

*'Article 82a*

**Reporting of actively exploited vulnerabilities and severe incidents related to devices**

1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 82, the manufacturer of a device shall inform the computer security incident response teams ('CSIRTs'), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), either of the following:
   (a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 of the European Parliament and of the Council******** contained in the device;
   (b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.

2. The manufacturer shall submit a notification of the actively exploited vulnerability or severe incident referred to in paragraph 1 through the electronic system referred to in Article 87.

   For the purposes of this notification the manufacturer shall submit:
   (a) an early warning notification of an actively exploited vulnerability or severe incident within 24 hours of the manufacturer becoming aware of it, indicating, where applicable, the Member States on the territory of which the manufacturer is aware that their device has been made available;
   (b) unless the relevant information has already been provided, a final report, no later than 30 days after a corrective or mitigating measure is available.

3. The information referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 82 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA.

4. For the purposes of this Article, the CSIRTs designated as coordinators and ENISA shall have access to Eudamed.

5. In respect of the information referred to in paragraph 1, the competent authorities shall cooperate with the CSIRTs designated as coordinators of the Member States in which the device has been made available, and with ENISA.

5a. Where a CSIRT designated as coordinator or ENISA consider that specific action may be needed to address the actively exploited vulnerability or severe incident informed in accordance with paragraph 1, they shall inform the competent authority of the Member State where the manufacturer is established and, where appropriate, may provide technical advice.

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******** Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).';

(55a) The following Article 82b is inserted:

*‘Article 82b*

**Reporting of serious incidents under Regulation (EU) 2024/1689**

For in vitro diagnostic medical devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, serious incidents, related to the infringement of obligations under Union law intended to protect fundamental rights within the meaning of Article 3(49), point (c), of Regulation (EU) 2024/1689, shall be reported to the national competent authority chosen for that purpose under that Regulation by the Member States where the incident occurred.’;

(56) in Article 83(1), the first subparagraph is replaced by the following:
‘Manufacturers shall report by means of the electronic system referred to in Article 87 any statistically significant increase in the frequency or severity of incidents that are not serious incidents, which could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I or of any significant increase in expected erroneous results established in comparison with the stated performance of the device as referred to in Section 9.1, points (a) and (b), of Annex I and specified in the technical documentation and product information.’;

(57) Article 84 is amended as follows:

(-a) in paragraph 1, the first subparagraph is replaced by the following:
‘Following reporting pursuant to Article 82(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include risk assessment of the incident or field safety corrective action taking into account the criteria as referred to in paragraph 3 of this Article as appropriate.’;

(a) in paragraph 1, the second subparagraph is replaced by the following:
‘The manufacturer shall cooperate with the competent authorities during the investigations referred to in the first subparagraph 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.’;

(b) paragraph 2 is replaced by the following:

‘2. 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 82 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer.’;

(c) the following paragraph 3a is inserted:

‘3a. The competent authorities may exchange information in relation to their assessments in paragraph 3 and, where relevant, cooperate and exchange relevant information with the authorities responsible for notified bodies and the authorities responsible for market surveillance. Where appropriate, the competent authorities may also cooperate and exchange relevant information with other authorities, including in the fields of cybersecurity, artificial intelligence, and other areas where regulatory interplay exists, whose responsibilities are relevant to the performance of their vigilance activities.

The competent authority may request the notified body that issued a certificate in accordance with Article 51 for the device in question for assistance in evaluating a corrective action related to a serious incident or a field safety corrective action, taking into account the risk management and conformity assessment performed for the device.’;

(d) paragraphs 6 and 7 are replaced by the following:

‘6. In the case of a companion diagnostic and where the manufacturer confirms that the serious incident or field safety corrective action may affect the safe and effective use of the corresponding medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 shall inform the national competent authority or the EMA, which was consulted by the notified body in accordance with the procedures set out in Section 5.2 of Annex IX and Section 3, point (k), of Annex X.

7. If, after carrying out the evaluation in accordance with paragraph 3, the evaluating competent authority identifies the need for additional corrective actions from the manufacturer to minimise the risk of recurrence of the serious incident, it shall, through the electronic system referred to in Article 87, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying serious incidents and the outcome of its assessment.';

(e) in paragraph 9, the introductory sentence is replaced by the following:
'The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 whenever such coordination is needed to ensure a high level of protection of the health and safety of patients, users and other persons or the protection of public health throughout the Union, and in particular in the following cases:';

(58) Article 86 is amended as follows:

(a) in the first subparagraph, the reference to 'Articles 80 to 85 and 87' is replaced by 'Articles 79 to 85 and 87';

(b) in the first subparagraph, point (b) is replaced by the following:
'(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision and content of the post-market surveillance plan, periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 79, 80, 81, 82, 83 and 84 respectively;';

(c) the following point (g) is added:
'(g) the reporting of actively exploited vulnerabilities and severe incidents as referred to in Article 82a and the reporting of serious incidents as referred to in Article 82b.';

(59) in Article 87(2), second sentence, the reference to ‘Article 49’ is replaced by ‘Article 51’;

(60) Article 88 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices and on the compliance of economic operators with the obligations set out in this Regulation including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.’;

(b) the following paragraph 1a is inserted:

‘1a. Member States shall ensure that their national competent authorities are provided with adequate and sufficient technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation.’;

(c) paragraph 2 is replaced by the following:

‘2. The competent authorities shall draw up annual surveillance activity plans, taking into account the European market surveillance programme, which shall be developed and maintained by the MDCG, and local circumstances.’;

(d) the following paragraph 12 is added:

‘12. The competent authorities may exchange information in relation to their market surveillance activities and, where relevant, cooperate and exchange relevant information with the authorities responsible for notified bodies and the authorities responsible for vigilance.

Where appropriate, the competent authorities may also cooperate and exchange relevant information with other authorities, including in the fields of cybersecurity, artificial intelligence, and other areas where regulatory interplay exists, whose responsibilities are relevant to the performance of their market surveillance activities.

In respect of devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, the competent authorities shall cooperate with market surveillance authorities of their Member State designated in accordance with Article 70 of Regulation (EU) 2024/1689.';

(61) Article 89 is replaced by the following:

*'Article 89*

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

The competent authorities of a Member State shall, alone or in cooperation with the competent authorities of other Member States, carry out an evaluation of a device covering all the relevant requirements laid down in this Regulation relating to the risk presented by the device or to any other non-compliance of the device, where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) 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;

(b) a device concerned otherwise does not comply with the requirements laid down in this Regulation.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities.

The competent authorities of the Member States may request any economic operator or notified body to submit documentation available to them, where access to such documentation is needed in the interest of public health or patient safety or health.';

(62) Article 90 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. The economic operators referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken within the period referred to in that paragraph throughout the Union in respect of all the devices concerned that they have made available on the market.';

(b) paragraph 7 is replaced by the following:

'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 the notified measures taken by a Member State, those measures shall be deemed to be justified.

In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market, are taken without delay in respect of the device concerned.

Corresponding measures adopted by the other Member States pursuant to this paragraph shall be based on the notification referred to in paragraph 4. Those measures shall not be subject to the procedure set out in paragraph 4.';

(63) Article 91 is amended as follows:

(b) in paragraph 2, the second sentence of the first subparagraph is replaced by the following:

'If the Commission considers the national measure to be unjustified, the Member State concerned, as well as any Member State that has taken corresponding restrictive or prohibitive measures, shall withdraw the measure.';

(64) Article 92 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Where, having performed an evaluation pursuant to Article 89, 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 bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.';

(b) in paragraph 2, the first sentence is replaced by the following:

'Where the economic operator does not bring the non-compliance to an end 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 national market.';

(c) the following paragraph 2a is inserted:

'2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.';

(66) the heading of Chapter VIII is replaced by the following:
'COOPERATION BETWEEN MEMBER STATES AND EU REFERENCE LABORATORIES';

(67) Article 96 is replaced by the following:

*'Article 96*

**Competent authorities**

'The Member States shall designate the competent authority or authorities responsible for the implementation and practical application of this Regulation. They shall ensure that those authorities are entrusted with sufficient powers, resources, equipment and knowledge necessary for the effective and efficient performance of their tasks pursuant to this Regulation, in practice. 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.';

(67a) in Article 97, paragraph 1 is replaced by the following:

'1. The competent authorities of the Member States shall cooperate with each other, with the authorities responsible for notified bodies, with the Commission and with the Agency. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.';

(68) in Article 97, paragraph 2 is deleted;

(69) Article 99 is amended as follows:

(a) points (a) to (e) are replaced by the following:

‘(a) to contribute, when needed, to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 45, including endorsement of the work programme and technical guidance developed by that group;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation;

(d) to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to this Regulation;

(e) to contribute to the development of device standards and of CS and of scientific guidelines, including product specific guidelines;’;

(b) point (f) is deleted;

(c) the following points (i) to (k) are added:

‘(i) to conduct horizon scanning to identify technological, legal or external sectoral changes or developments which may impact the regulatory system and propose solutions;

(j) to support and oversee international initiatives aimed at improving harmonisation of regulatory operations and activities;

(k) to advise the Commission, at its request, and to assist the competent authorities of the Member States in matters concerning Union regulatory sandboxes and regulatory sandboxes at national level;’;

(d) the following subparagraph is added:

'In addition to the tasks assigned to it in other provisions of this Regulation, the MDCG shall assist the Commission in the assessment of any issue related to the implementation of this Regulation.';

(70) Article 100 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) point (a) is replaced by the following:

'(a) to verify the performance claimed by the manufacturer 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 Section 4.9 of Annex IX and in Section 3, point (j), of Annex X;';

(ii) point (d) is replaced by the following:

'(d) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices, where requested by the Commission, the MDCG, competent authorities, or notified bodies with due consideration of comparative test results or other studies;';

(iii) points (e) and (j) are deleted;

(iv) the following subparagraph is added:

'The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend the first subparagraph by adding, adapting or removing tasks from the list of tasks of the EU reference laboratories.';

(b) paragraph 3 is deleted;

(c) in paragraph 4, point (b) is replaced by the following:

‘(b) have at their disposal the necessary equipment and reference material to carry out the tasks assigned to them;’;

(d) in paragraph 5, point (j) is deleted;

(e) paragraph 7 is replaced by the following:

‘7. Where notified bodies 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 its tasks according to predetermined and transparent terms and conditions.

EU reference laboratories shall establish lists of their standard fees and shall make those lists publicly available. They shall notify the lists to the Commission, which shall make references to them available to the public on a dedicated website.

EU reference laboratories may charge fees in accordance with predetermined and transparent terms and conditions for scientific and technical assistance provided to the Member States for carrying out the required task. For the provision of services on request of the Commission, the MDCG, or the Agency, the EU reference laboratories may be granted a Union financial contribution.’;

(71) in Article 101 the first sentence is replaced by the following:

‘The Commission, the Member States and the Agency shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices setting common principles to collect comparable information.’;

(72) Article 103 is amended as follows:

‘(a) in paragraph 1, the reference to ‘Directive 95/46/EC’ is replaced by ‘Regulation (EU) 2016/679’;

(b) in paragraph 2, the reference to ‘Regulation (EC) No 45/2001’ is replaced by ‘Regulation (EU) 2018/1725 of the European Parliament and of the Council*********.

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********* Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).’;

(73) the following Article 103a is inserted:

*‘Article 103a*

**Submission of information or documents**

The submission of information or documents in accordance with this Regulation may take place electronically.

Member States may require that information or documents in accordance with this Regulation shall be submitted electronically to the relevant authority.’;

(75) Article 105 is deleted;

(75a) the following Article 106a is inserted:

*'Article 106a*

**Economic operators non-compliance**

Without prejudice to Articles 94 to 98, where the competent authorities of a Member State find, based on data obtained from vigilance, market surveillance, or other information, that an economic operator does not comply with the obligations applicable to it set out in this Regulation, they shall require that economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.

Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned may apply penalties referred to in Article 106 or take other appropriate measures.';

(78) in Article 110, the following paragraphs 12 and 13 are added:

'12. By way of derogation from Article 5 and from paragraphs 3 to 3e of this Article, a device as referred to in paragraph 3a or paragraph 3b of this Article that meets the criteria for an orphan device set out in Article 48a(3) may be placed on the market or put into service beyond the dates referred to in paragraphs 3a and 3b if the following conditions are met:

(a) an expert panel referred to in Article 106 of Regulation (EU) 2017/745 has issued an opinion confirming the fulfilment of the criteria for an orphan device set out in Article 48a(3);

(b) there are no significant changes to the design and intended purpose of the device;

(c) the device 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.

Where a device referred to in the first subparagraph is placed on the market in accordance with this paragraph, the requirements of this Regulation shall apply with the exception of Chapter IV, Articles 48 to 54c, and Article 58(1).

By way of derogation from Article 81(1), manufacturers of class C and class D devices placed on the market or put into service in accordance with this paragraph shall update the PSUR at least annually. On an annual basis, the manufacturer shall submit the PSUR and, where applicable, an update of the summary of safety and performance to the competent authority of the Member State in which it is established.

The competent authority of the Member State may require the manufacturer to conduct defined post-market surveillance or PMPF activities within a specified period of time to generate additional data to confirm the safety and performance of the device and to evaluate the acceptability of the benefit-risk ratio.

In its EU declaration of conformity, the manufacturer shall make reference to the fact that the device is an orphan device placed on the market or put into service in accordance with this paragraph.

Where the certificate is no longer valid in accordance with paragraph 2, the manufacturer shall inform the competent authority of the Member State in which it is established.

The manufacturer shall inform the intended users about the fact that the device is an orphan device placed on the market or put into service in accordance with this paragraph in the summary of safety and performance, where applicable, and in the instructions for use.

At least every 7 years, the manufacturer shall request an opinion from an expert panel referred to in Article 106 of Regulation (EU) 2017/745 confirming the fulfilment of the criteria for an orphan device set out in Article 48a(3) of this Regulation. The expert panel opinion shall be provided to the manufacturer and the competent authority in the Member State in which the manufacturer is based.

Where the expert panel issues a negative opinion, the competent authority shall decide, with due consideration to this opinion, whether continued placing on the market or putting into service of the device in accordance with this paragraph is no longer appropriate. Where the competent authority decides this is no longer appropriate, the device may continue to be placed on the market or put into service in accordance with this paragraph for no longer than one year following the competent authority's decision, after which Article 5 shall apply.';

(78a) The following Article 110a is added:

*'Article 110a*

**Additional transitional provisions related to the amendments by Regulation (EU) […./….]**

1. By way of derogation from Article 5, and without prejudice to Article 110(3) to (3e), devices for which a certificate was issued by a notified body in accordance with Article 51 of this Regulation before … [date of application of this Regulation] , and devices, for which the conformity assessment procedure pursuant to Article 48 does not require the involvement of a notified body, that were registered in Eudamed in accordance with Article 26(1) before … [date of application of this Regulation] may be placed on the market or put into service without the need to undertake a new or additional conformity assessment. Annex IX, Sections 2.4. and 4.11., Annex X, Section 5, and Annex XI, Section 3.4., as applicable, shall apply for changes requiring prior approval.

   Amendments or supplements to the certificate made after … [date of application of this Regulation], which are of an administrative nature and are not related to the conformity of the device, shall not affect application of the first subparagraph.

2. Devices lawfully placed on the market before … [date of application of this Regulation] may continue to be made available on the market or put into service.

3. Notwithstanding paragraph 1, the validity of EU technical documentation assessment certificates or EU type examination certificates related to class D devices, companion diagnostics, and class C devices for self-testing issued by a notified body in accordance with Article 51 prior to … [date of application of this Regulation] for a period not exceeding five years shall, on application of the manufacturer, be extended for a further period not limited in time, based on a re-assessment in accordance with Annex VII, Section 4.11. The extension may take effect only after an initial five-year certification period has elapsed. Where the validity of an EU technical documentation assessment certificate or EU type examination certificate referred to in the first sentence was already extended based on a re-assessment in accordance with Article 51 after an initial five years period, the notified body shall extend that validity for a further period not limited in time without reassessment, unless the notified body finds that the requirements of this Regulation are not met affecting the safety or performance of the device(s). Article 51(4) shall apply.

The validity of all other certificates issued by a notified body in accordance with Article 51 prior to … [date of application of this Regulation] for a period not exceeding five years shall, on application of the manufacturer, be extended for a further period not limited in time without reassessment, unless the notified body finds that the requirements of this Regulation are not met affecting the safety or performance of the device(s). Article 51(4) shall apply.

After the extension of a certificate pursuant to the first and second subparagraph, the provisions on surveillance activities, including periodic reviews, in accordance with Article 51(2a) shall apply.

4. The application of a conformity assessment body for designation submitted in accordance with Article 34 before … [date of application of this Regulation] shall continue to be assessed in accordance with Article 35 and Annex VII in their form applicable before … [date of application of this Regulation], unless the conformity assessment body and the authority responsible for notified bodies of the Member State where the conformity assessment body is established agree to apply all or certain provisions of Annex VII that are applicable from … [date of this Regulation]. Designation and notification of the notified body shall follow the procedure laid down in Article 38 in its form applicable before … [date of application of this Regulation]. The authority responsible for notified bodies of the Member State where the conformity assessment body is established shall assess compliance with the requirements laid down in Annex VII in its form applicable from … [date of application of this Regulation] at the latest during its next annual assessment after designation of the notified body in the framework of its monitoring activities in accordance with Article 40.

5. Complete reassessments of notified bodies in accordance with Article 40(10), for which an on-site assessment of the notified body by the authority responsible for notified bodies and the joint assessment team has been conducted before to … [date of application of this Regulation], shall continue to be conducted in accordance with Article 35 and Annex VII in their form applicable before … [date of application of this Regulation], unless the notified body and the authority responsible for notified bodies of the Member State where the notified body is established agree to apply all or certain provisions of Annex VII that are applicable from … [date of this Regulation]. The authority responsible for notified bodies of the Member State where the notified body is established shall assess compliance with the requirements laid down in Annex VII in its form applicable from … [date of application of this Regulation] at the latest during its next annual assessment after finalisation of the complete reassessment of the notified body in the framework of its monitoring activities in accordance with Article 40.

6. Where a manufacturer or an authorised representative lodged a formal application with a notified body for conformity assessment in accordance with Annex VII, Section 4.3, first subparagraph, which was formally accepted by the notified body and which has not been completed before … [date of application of this Regulation], the following shall apply:
   (a) the provisions of this Regulation in the form applicable before … [date of application of this Regulation] shall apply until the certificate is issued, unless the manufacturer and the notified body agree to apply all or certain provisions that are applicable from … [date of this Regulation] for the purposes of that conformity assessment procedure;
   (b) where the notified body finds that the relevant requirements are met, it shall issue the certificate in accordance with Article 51 in the form applicable from … [date of application of this Regulation].

7. For devices, which had undergone a conformity assessment procedure before … [date of application of this Regulation], which required a higher level of involvement of a notified body in the conformity assessment than pursuant to the provisions applicable from … [date of application of this Regulation], the notified body shall adapt the certificate issued and its surveillance activities in consultation with the manufacturer and without additional assessments.

   Where the involvement of a notified body in the conformity assessment is not any more required for the device from … [date of application of this Regulation], the manufacturer may end the contract for conformity assessment activities with the notified body without giving rise to any penalty. Manufacturer and notified body shall define in an agreement the modalities of the termination with a view to avoiding disruption of the placing on the market of the device, including the date on which the certificate will become invalid and the date until when the identification number of the notified body may be indicated in the information supplied by the manufacturer.

8. For the purpose of Article 48a(4) and Article 110(12), as applicable, an opinion by an expert panel issued before … [date of entry into force of this Regulation] confirming that a device fulfils the criteria of a breakthrough device or an orphan device shall be deemed to be an opinion confirming fulfilment of the criteria set out in Article 48a(2) or (3), as applicable.

9. Requirements concerning the entering of data or notifications in Eudamed or another IT system referred to in Article 10a, Article 55(1a) and Article 82a and Annex VI, Part A, Section 2.15, and Part B, Section 19 shall apply from the date corresponding to six months from the date of publication of a notice by the Commission confirming that the functionality for the entering of data or notifications in Eudamed or the other IT system is available.

10. Where a sponsor has applied for authorisation of a performance study which no longer needs authorisation in accordance with Article 58 in the form applicable from … [date of entry into force of this Regulation], the sponsor may withdraw its application and commence the performance study provided all other conditions are met.';

(79) Article 111 is amended as follows:

(a) in the first sentence, the date '27 May 2027' is replaced by the date …'[OP, please insert the date = five years after the date of entry into force of this Regulation]';

(b) the second sentence is deleted;

(80) in Article 113(3), point (f), the following subparagraph is added:
'After the date of application of the provisions referred to in the first subparagraph of this point, where Member States maintain national databases, the relevant information available in Eudamed for those national databases shall be retrieved from Eudamed. This shall be without prejudice to the possibility for Member States to maintain or develop complementary national functionalities and data elements necessary for national market surveillance or other regulatory tasks, avoiding duplication of Union data, where possible.';

(81) Annexes I, II, III, VI, VII, IX, X, XI, XII, XIII, and XIV to Regulation (EU) 2017/746 are amended in accordance with Annex II to this Regulation.

*Article 3*

***Amendments to Regulation (EU) 2022/123***

Article 30 of Regulation (EU) 2022/123 is amended as follows:

(1) the first subparagraph is replaced by the following:
'The Agency shall provide the secretariat for the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 (the 'expert panels') and shall provide the support necessary to ensure that those expert panels can efficiently perform the tasks set out in that Regulation and in Regulation (EU) 2017/746.';

(2) the second subparagraph is amended as follows:
(a) the introductory wording is replaced by the following: 'The Agency shall, in particular:'
(b) point (a) is replaced by the following:
'(a) select and appoint the experts in accordance with Article 106(2) and (5) of Regulation (EU) 2017/745 and provide administrative and technical support to the expert panels for the provision of opinions and advice;';

(c) points (c), (d) and (e) are replaced by the following:

‘(c) ensure that the work of the expert panels is carried out in an independent manner in accordance with Article 106(3) and Article 107 of Regulation (EU) 2017/745. For that purpose, the Agency shall establish systems and procedures to actively manage and prevent potential conflicts of interest;

(d) maintain and regularly update a webpage for the expert panels and make all necessary information not already publicly available in Eudamed publicly available on that webpage;

(e) publish the opinions of the expert panels in accordance with Regulation (EU) 2017/745 or Regulation (EU) 2017/746, while ensuring confidentiality in accordance with Article 109 of Regulation (EU) 2017/745 or Article 102 of Regulation (EU) 2017/746;’;

(d) in point (f), the reference to ‘Article 106(14)’ is replaced by the reference to ‘Article 106(10)’;

(e) the following point (i) is added:

‘(i) submit to the Commission a substantiated recommendation for the fees to be paid by manufacturers or notified bodies for the opinions or advice provided by expert panels, as referred to in Article 106(9) and (10) of Regulation (EU) 2017/745.’;

*Article 4*

***Amendments to Regulation (EU) 2024/1689***

Regulation (EU) 2024/1689 is amended as follows:

(-1) in Article 73, paragraph 10 is deleted;

(1) in Annex I, Section A, points 11 and 12 are deleted;

(2) in Annex I, Section B, the following points are added:

‘22. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p.1);

23. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).’

*Article 5*

**Entry into force and application**

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from …[OP please insert the date = six months after the date of entry into force of this Regulation].

3. By way of derogation from paragraph 2, the following transitional provisions shall apply:
   (a) the following provisions shall apply from …[OP please insert the date = the date of entry into force of this Regulation]:
   - Article 1, points (2), letters (a), (b), (e); (5); (8); (12); (13); (14); (15); (16); (24); (37); (39); (44); (46); (47); (48); (49); (50); (52); (58); (59); (61); (62); (67); (68); (72); (73); (91); (95); and (95a);
   - Article 2, points (2); (5); (8); (12); (13); (14); (22); (26h); (26j); (30); (32); (33); (34); (35); (36); (38); (40); (42); (44); (44a); (45); (48); (49); (53); (54); (58); (59); (70), letter (a), point (iii), letters (b), (c) and (d); (73); (78); and (78a);
   - Article 3;
   - Article 4;
   - Annex I, points (1), letter (fa); (4), letter (a), points (iii), (v) and (vi), letter (b), point (ii); (6), letters (d) and (e); (12);
   - Annex II, points (1), letter (b), points (iii) and (iv), letter (d), points (vii) and (viiii); (4), letter (a), points (iii), (iv) and (v), letter (b), point (ii); (6), letter (o); (7), letter (b), point (iv).

(b) the following provisions shall apply from… [OP please insert the date = 12 months after the date of entry into force of this Regulation];

- Article 1, points (27); (28); (87) and (88);
- Article 2, points (24); (25); and (39).

(ba) the following provisions shall apply from …[ OP please insert the date = two years after date of entry into force of this Regulation];

- Article 1, points (9a); (69) and (69a);
- Article 2, points (9a); (55) and (55a);
- Annex I, points (1), letters (c) and (ca); (2), letter (b), point (iia); (3), letter (-a);
- Annex II, points (1), letters (a) and (aa); (2), point (f), second subparagraph;

(c) the following provisions shall apply from …[ OP please insert the date = three years after date of entry into force of this Regulation];

- Article 1, points (1), letter (d);
- Article 2, points (1);
- Annex I, point (2), letter (b), point (ii);
- Annex II, point (2), point (f), first subparagraph.

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

Done at Strasbourg,

| | |
|---|---|
| *For the European Parliament* | *For the Council* |
| *The President* | *The President* |