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Subject:	Proposal for a Regulation of the European Parliament and of the Council on <b>medical devices</b> and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

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Delegations will find in the Annex to this document a consolidated text for the Annexes to the proposed Regulation mentioned above prepared by the Latvian Presidency with a view to the Council (EPSCO) on 19 June 2015.

At its meeting on 10 June 2015, the Permanent Representatives Committee agreed to forward the text in the Annex to this Note to the Council with a view to reaching a Partial General Approach (excluding recitals).

New text compared to the Commission proposal is written in ***bold italics***. Deletions are marked by ~~strikethrough~~.

ANNEX I

**GENERAL SAFETY AND PERFORMANCE REQUIREMENTS**

**I. General requirements**

1. Devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose, ~~taking into account the generally acknowledged state of the art.~~ They shall ***be safe and effective and*** shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, ***taking into account the generally acknowledged state of the art.***

~~This shall include:~~

- ~~- reducing as far as possible the risk of use error due to ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and~~
- ~~- consideration of the technical knowledge, experience, education and training, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).~~

***1aa. The requirements in this annex to reduce risks as far as possible mean reduce risks as far as possible without adversely affecting the risk benefit ratio.***

- 1a. *The manufacturer has to establish, implement, document and maintain a risk management process. ~~To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable.~~*

*The risk management process must include:*

- (a) ~~identification and analysis identify of known or reasonably foreseeable hazards and estimate the associated risks arising from the intended use and reasonably foreseeable misuse;~~*
- (b) ~~elimination and reduction of risks according to clause 2;~~*
- (c) ~~proliferation of training to users.~~*

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

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

2. The *risk control measures* solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. ~~The~~ ***In selecting the most appropriate solutions, the*** manufacturer shall ~~***establish, implement, document and maintain a continuous risk management process to allow***~~ apply the following principles in the priority order listed:
- (a) ~~***to identify and analyse***~~ known or ~~***reasonably***~~ foreseeable hazards and estimate the associated risks arising from the intended use and reasonably foreseeable misuse;
  - (b) ~~***to***~~ eliminate ***or reduce*** risks as far as possible ***and appropriate*** through inherently safe design and ~~***construction***~~ manufacture ~~***and appropriate***~~;
  - (c) ***where appropriate, take*** ~~***to implement***~~ reduce as far as possible the remaining risks by taking adequate protection measures, including alarms ***if necessary, in relation to risks that cannot be eliminated***; and
  - (d) ~~***to***~~ provide ***information for safety (warnings/precautions/contraindications) and, where appropriate,*** training to users.

***The manufacturer shall*** ~~and/or~~ inform users of any residual risks.

2b. ***In eliminating or reducing risks related to use error the manufacturer shall apply the following principles:***

- ***reducing as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and***
- ***consideration of the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).***

3. The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions. ~~When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.~~
4. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected ~~by~~ **during** transport and storage ~~conditions~~ (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.
5. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the *evaluated* benefits to the patient *and/or user* of the achieved performance of the device during normal conditions of use.

**~~5a. Demonstration of conformity with the general safety and performance requirements must include a clinical evaluation in accordance with Article 49 and Annex XIII.~~**

6. For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, the general requirements set out in Sections 1 and 5 shall be understood that the device, when used under the conditions and for the purposes intended, shall not present any risk or only the ~~minimum~~ **maximum** acceptable risks related to the product's use which is consistent with a high level of protection for the safety and health of persons.

***6a. Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in chapter II of this Annex.***

## II. Requirements regarding design and construction

### 7. Chemical, physical and biological properties

- 7.1. The devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Chapter I ‘General Requirements’. Particular attention shall be paid to:
- (a) the choice of materials *and substances* used, particularly as regards toxicity and, where appropriate, flammability;
  - (b) the compatibility between the materials *and substances* used and biological tissues, cells, and body fluids taking account of the intended purpose of the device *and, where relevant, absorption, distribution, metabolism and excretion*;
  - (bb) *the impact of processes on material properties*;**
  - (c) where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand;
  - (d) the ~~choice~~ *mechanical properties* of *the* materials used, reflecting, where appropriate, matters such as *strength, ductility, fracture resistance* ~~hardness~~, wear *resistance* and fatigue *resistance* ~~strength~~;
  - (e) *surface properties*;**
  - (f) *confirming that the device meets any defined chemical and/or physical specifications*.**
- 7.2. The devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed and to the duration and frequency of exposure.

- 7.3. The devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their ~~normal~~***intended*** use ~~or during routine procedures~~; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these medicinal products and that both the performance of the medicinal products and of the devices are maintained in accordance with their respective indications and intended use.
- 7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible ~~and appropriate~~ the risks posed by substances ***or particles, including wear debris, degradation products, processing residues***, that may ~~leach, or leak~~ ***be released*** from the device. Special attention shall be given to substances ***or particles*** which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006<sup>1</sup>, and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)<sup>2</sup>.

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

<sup>2</sup> OJ L 136, 29.5.2007, p. 3.

If devices, or parts thereof, that are intended

- to be invasive devices and to come into contact with the body of the patient ~~for short- or long-term~~, or
- to (re)administer medicines, body liquids or other substances, including gases, to/from the body, or
- to transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

contain, in a concentration of 0.1% **or above** by mass of the ~~plasticised material~~ **devices or parts thereof as mentioned** ~~or above, phthalates~~ **substances** which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 **or have endocrine disrupting properties as described in the first paragraph**, these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing **such substances** ~~phthalates~~. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

- 7.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible ~~and appropriate~~ risks posed by the unintentional ingress ~~or egress~~ of substances into ~~or from~~ the device taking into account the device and the nature of the environment in which it is intended to be used.



7.6. The devices shall be designed and manufactured in such a way as to reduce ~~to a minimum~~ **as far as possible and appropriate** the risks linked to the size and the properties of particles used **which are released into the patient's or user's body, unless they come into contact with the intact skin only**. Special **attention shall be given to nanomaterials** ~~care shall be applied when devices contain or consist of nanomaterial that can be released into the patient's or user's body.~~

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

8.1. The devices and manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:

- (a) allow easy handling,  
~~and, where necessary,~~
- (b) reduce as far as possible ~~and appropriate~~ any microbial leakage from the device and/or microbial exposure during use,
- (c) prevent microbial contamination of the device or **its content such as specimens or fluids**.

**8.1a. Where necessary devices shall be designed to facilitate its safe cleaning, disinfection, and/or resterilisation.**

8.2. Devices labelled as having a ~~special microbiological~~ **specific microbial** state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

- 8.3. Devices delivered in a sterile state shall be designed, manufactured and packaged ~~in a non-reusable pack, and/or~~ according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened **at the point of use**. ***These measures shall ensure that the integrity of the sterile packaging is clearly evident to the final user.***
- 8.4. Devices labelled ~~either as sterile or as having a special microbiological state~~ shall have been processed, manufactured, **packaged** and, if applicable, sterilised by appropriate, validated methods.
- 8.5. Devices intended to be sterilised shall be manufactured **and packaged** in appropriately **and controlled** (~~e.g. environmental~~) conditions **and facilities**.
- 8.6. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.
- 8.7. The labelling of the device shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition **additional to the symbol used to indicate that a product is sterile**.

**9. Devices incorporating a substance considered to be a medicinal product and devices *that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally that are absorbed by or locally dispersed in the human body***

9.1. In the case of devices referred to in the first subparagraph of Article 1(4), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as laid down in the applicable conformity assessment procedure in this Regulation.

9.2. Devices that are composed of substances or combinations of substances *that are* intended to be ~~ingested, inhaled or administered rectally or vaginally~~ *introduced into the human body*, and that are absorbed by or *locally* dispersed in the human body shall comply, *where applicable and limited to the aspects not covered by this Regulation*, ~~by analogy~~, with the relevant requirements laid down in Annex I to Directive 2001/83/EC *for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as laid down in the applicable conformity assessment procedure in this Regulation.*

## 10. Devices incorporating materials of biological origin

10.1. For devices manufactured utilising tissues or cells, or their derivatives, of human origin which are *non-viable or rendered non-viable* covered by this Regulation in accordance with point (e) *and (ea)* of Article 1(2) the following applies:

- (a) Donation, procurement and testing of tissues and cells of human origin used for the manufacture of devices shall be made in accordance with Directive 2004/23/EC.
- (b) The processing, preservation and any other handling of those tissues and cells shall be carried out so as to provide ~~optimal~~ safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.
- (c) ~~It shall be ensured that the traceability system for devices manufactured utilising those human tissues or cells is complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.~~

10.2. For devices manufactured utilising tissues or cells, or their derivatives, of animal origin which are non-viable or rendered non-viable the following applies:

- (a) Where feasible taking into account the animal species, tissues and cells of animal origin shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained *by manufacturers*.
- (b) Processing, preservation, testing and handling of tissues, cells and substances of animal origin shall be carried out so as to provide ~~optimal~~ safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, *except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device*.

- (c) In the case of devices manufactured utilising tissues or cells of animal origin as referred to in Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin<sup>3</sup> the particular requirements laid down in that Regulation shall apply.

10.3. For devices manufactured utilising other non-viable biological substances the following applies:

In the case of biological substances other than those referred to in Sections 10.1. and 10.2., the processing, preservation, testing and handling of those substances shall be carried out so as to provide ~~optimal~~ safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

## **11. ~~Interaction of devices with their environment~~ *Construction and environmental properties***

11.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, *electrical* or mechanical coupling, shall be designed and constructed in such a way as to **avoid** ~~minimize all possible risks from incorrect~~ *misconnection*.

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<sup>3</sup> OJ L 212, 9.8.2012, p. 3.

11.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible ~~and appropriate~~:

- (a) the risk of injury, ~~to the patient, user or other persons~~ in connection with their physical *features, including the volume/pressure ratio, dimensional* and *where appropriate* ergonomic features;
- (b) ~~the risk of use error due to the ergonomic features, human factors and the environment in which the device is intended to be used;~~
- (c) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;
- (d) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;
- (e) the risk associated with the possible negative interaction between software and the *IT* environment within which it operates and interacts;
- (f) the risks of accidental ingress of substances into the device;
- (g) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;
- (h) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

11.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices whose intended ~~use purpose~~ includes exposure to or use in association with flammable *or explosive* substances or substances which could cause combustion.

- 11.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance, ~~where such is necessary to achieve the performances intended,~~ can be done safely **and effectively**.
- 11.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such ~~as~~ **a** way that the interoperability **and compatibility are** ~~is~~ reliable and safe.
- 11.6. Any measurement, monitoring or display scale shall be designed in line with ergonomic principles, taking account of the intended **users and the environmental condition in which the devices are intended to be used** ~~purpose of the device~~.
- 11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or ~~of any~~ **related** waste substances by the user, patient or other person. **To that end, manufacturers shall investigate and test procedures and measures by which their devices can be safely disposed after use. These procedures shall be described in the instruction for use.**

## **12. Devices with a diagnostic or measuring function**

- 12.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, ~~based on appropriate scientific and technical methods~~. The limits of accuracy shall be indicated by the manufacturer.
- 12.2. The measurements made by devices with a measuring function and expressed in legal units shall conform to the provisions of Council Directive 80/181/EEC<sup>4</sup>.

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<sup>4</sup> OJ L 39, 15.2.1980.

## 13. Protection against radiation

### 13.1. General

- (a) Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to ~~any emitted~~ radiation shall be reduced as far as possible ~~and appropriate~~, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.
- (b) The operating instructions for devices emitting **hazardous** radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of ~~eliminating~~ **reducing** the risks inherent ~~in~~ **to installation to a level as low as reasonably achievable.**

### 13.2. Intended radiation

- (a) Where devices are designed to emit hazardous, ~~or potentially hazardous~~, levels of ~~visible and/or invisible~~ radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.
- (b) Where devices are intended to emit ~~potentially~~ hazardous, visible and/or invisible radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.

### 13.3. Unintended radiation

Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as **reasonably achievable** ~~possible and appropriate~~.

### 13.4. Ionising radiation

- (aa) ***Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Council Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.***



- (a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible *practicable*, the quantity, geometry and ~~energy distribution~~ (or quality) of radiation emitted can be varied and controlled taking into account the intended use.
- (b) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.
- (c) Devices emitting ionising radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam characteristics in terms of type of radiations, energy *and*, where appropriate, ~~energy distribution~~ *the quality of radiation*.

**14. ~~Software incorporated in devices and standalone software~~ *Electronic programmable systems - Devices that incorporate electronic programmable systems***

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

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

14.3. Software referred to in this Section that are intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise). ***The manufacturer shall describe minimum requirements on hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.***

## **15. Active devices and devices connected to them**

15.1. For ***non - implantable*** active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible ~~and appropriate~~ consequent risks.

15.2. Devices where the safety of the patients depends on an internal power supply shall be equipped with a means of determining the state of the power supply ***and an appropriate warning or indication if, or if necessary before, the capacity of the power supply becomes critical.***

15.3. Devices where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure.

15.4. Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

15.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible ~~and appropriate~~ the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.

15.6. Devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

15.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed ~~and maintained~~ as indicated by the manufacturer.

***15.8. Devices shall be designed and manufactured in such a way as to avoid unauthorized access to the device as far as possible that would hamper the device to run as intended.***

***15a. Particular requirements for active implantable devices***

***15a.1. Active implantable devices must be designed and manufactured in such a way as to remove or minimize as far as possible:***

- *risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,*
- *risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment,*
- *risks which may arise where maintenance and calibration are impossible, including:*
  - *excessive increase of leakage currents,*
  - *ageing of the materials used,*
  - *excess heat generated by the device,*
  - *decreased accuracy of any measuring or control mechanism.*

***15a.2. Active implantable devices must be designed and manufactured in such a way as to ensure***

- *if applicable, the compatibility of the devices with the substances they are intended to administer,*
- *the reliability of the source of energy,*

**15a.3. *The active implantable devices and, if appropriate, their component parts must be identified to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices and their component parts.***

**15a.4. *Active implantable devices must bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and year of manufacture); it must be possible to read this code, if necessary, without the need for a surgical operation.***

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

16.1. Devices shall be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

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

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

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

16.5. Errors likely to be made when fitting or refitting, ~~or connecting or reconnecting,~~ certain parts ~~before or during use~~ which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

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

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

## **17. Protection against the risks posed to the patient or user by supplied energy or substances**

17.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to assure the safety of the patient and of the user.

17.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

17.3. The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.

## 18. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

18.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.

18.2. Devices for use by lay persons shall be designed and manufactured in such a way as to

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

18.3. Devices for use by lay persons shall, where ~~reasonably possible~~ **appropriate**, include a procedure by which the lay person

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

### III. Requirements regarding the information supplied with the device

#### 19. Label and instructions for use

##### 19.1. General requirements regarding the information supplied by the manufacturer

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:

- (a) The ~~medium~~, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may include separate information for the professional user and the lay person.
- (b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.

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

- (c) ~~For~~ *By way of exception, no such instructions for use are needed for* devices ~~of in~~ class I and IIa, ~~instructions for use are not needed or may be abbreviated if~~ *they* the device can be used safely ~~and as intended by the manufacturer~~ without any such instructions ~~for use~~.
- (d) Labels shall be provided in a human-readable format ~~but~~ *and* may be supplemented by machine-readable ~~forms~~ *information*, such as radio-frequency identification (RFID) or bar codes.
- (e) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent and *only* under the conditions set out in Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices.

- (f) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contraindications, precautions or warnings in the information supplied by the manufacturer.
- (g) Where appropriate, this information should take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CTS. In areas for which no standards or CTS exist, the symbols and colours shall be described in the documentation supplied with the device.

## **19.2. Information on the label Labelling**

The label shall bear the following particulars *following particulars shall appear on the device or where not practical or appropriate on the trade packaging:*

- (a) The name or trade name of the device.
- (b) The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device.
- (c) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business ~~at which he can be contacted and his location be established.~~
- (cc) *The Single Registration Number of the manufacturer in accordance with Article 25a.*
- (d) ~~For imported devices~~ *If the manufacturer has his registered place of business not within the Union, the name and address, registered trade name or registered trade mark of the authorised representative established within the Union and the address of his registered place of business at which he can be contacted and his location be established and its Single Registration Number in accordance with Article 25a.*
- (e) Where applicable, an indication that the device contains or incorporates,
  - a medicinal substance, including a human blood or plasma derivative, or
  - tissues or cells, or their derivatives, of human origin, or
  - tissues or cells, or their derivatives, of animal origin as referred to in Commission Regulation (EU) No 722/2012.



- (f) ~~Where applicable, an indication that the device incorporates or consists of nanomaterial unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.~~
- (fa) ***Where applicable, an indication that the device contains substances which are carcinogenic, mutagenic or toxic to reproduction or have endocrine disrupting properties in accordance with section 7.4.***
- (g) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate.
- (h) ~~Where applicable~~ the unique device identification (UDI) ***carrier according to Article 24 and Annex V Part C.***
- (i) An unambiguous indication of the date until when the device may be used safely, expressed at least as the year and month, where this is relevant.
- (j) Where there is no indication of the date until when it may be used safely, the ~~year~~ ***data*** of manufacture. This ~~year~~-***data*** of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable.
- (k) An indication of any special storage and/or handling condition that applies.
- (l) If the device is supplied sterile, an indication of its sterile state and the sterilisation method.
- (m) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device as relevant, and to any other person where appropriate. This information may be kept to a minimum in which case more detailed information should appear in the instructions for use.
- (n) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union.
- (o) If the device is a single use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles.
- (p) If the device is custom made, ~~an indication of that fact~~ ***the words "custom – made device"***.

- (q) *An indication that the device is a medical device.* If the device is intended for clinical investigation only, ~~an indication of that fact~~ *the words “exclusively for clinical investigation.”*
  
- (r) *In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, via parenteral administration or administered on skin or mucous membrane and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent(s) responsible for achieving the principal intended action.*
  
- (s) *for active implantable devices the serial number and for other implantable devices the serial number or the lot number.*

**19.2a. On the sterile pack:**

- (a) *an indication permitting this packaging to be recognized as such,*
- (b) *a declaration that the device is in a sterile condition,*
- (c) *the method of sterilization,*
- (d) *the name and address and Single Registration Number of the manufacturer,*
- (e) *a description of the device,*
- (f) *if the device is intended for clinical investigations, the words: ‘exclusively for clinical investigations’,*
- (g) *if the device is custom-made, the words ‘custom-made device’,*
- (h) *the month and year of manufacture,*
- (i) *an indication of the time limit for using or implanting a device safely,*
- (j) *symbol to check the IFU when the sterile pack is damaged etc.*

### 19.3. Information in the instructions for use

The instructions for use shall contain the following particulars:

- (a) The particulars referred to in points 19.2. (a), (c), (e), (f), ~~(fa)~~, (k), (l), ~~and (n) and r~~.
- (b) The device's intended purpose *with clear specification of target group(s), indications, contraindications* including the intended user (e.g. professional or lay person), as appropriate.  
**(bb) where applicable a specification of clinical benefits to be expected, where applicable, together with links to the summary of safety and performance according to article 26.**
- (c) The performance *characteristics* of the device ~~intended by the manufacturer~~.
- (ca) Where applicable, information allowing the physician to select a suitable device and the corresponding software and accessories.**
- (d) Any residual risks, contraindications and any ~~expected and foreseeable~~ undesirable side-effects, including information to be conveyed to the patient in this regard.
- (e) Specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it.
- (f) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilisation, final assembly, calibration, etc.).
- (g) Any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons.
- (h) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:
  - details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection;
  - identification of any consumable components and how to replace them;
  - information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;
  - methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing devices.
- (i) If the device is supplied sterile, instructions in the event of the sterile packaging being damaged *or unintentionally opened* before use.

- (j) If the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation.
- (k) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, ~~decontamination~~, packaging and, where appropriate, the validated method of re-sterilisation ***appropriate to the Member State(s) where the device is placed on the market.*** Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.
- (ka) An indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.***
- (l) If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. ***This information shall be based on a discrete section of the manufacturer risk management documentation, where these characteristics and technical factors shall be addressed in detail*** If in accordance with point c) of Section 19.1 no instructions for use are needed, the information shall be made available to the user upon request.
- (m) For devices intended for use together with other devices and/or general purpose equipment:
- information to identify such devices or equipment, in order to obtain a safe combination, and/or
  - information on any known restrictions to combinations of devices and equipment.
- (n) If the device emits ~~hazardous, or potentially hazardous levels of~~ radiation for medical purposes:
- detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation;
  - the means of protecting the patient, user, or other person from unintended radiation during use of the device.

- (o) Information that allows the user ~~and/or patient~~ to be informed and *to brief the patient* of any warnings, precautions, *contra - indications* measures to be taken and limitations of use regarding the device. This information should cover, where appropriate:
- warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;
  - warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
  - warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures (e.g. electromagnetic interference emitted by the device affecting other equipment);
  - if the device is intended to administer medicinal products, tissues or cells, or their derivatives, of human or animal origin or biological substances, any limitations or incompatibility in the choice of substances to be delivered;
  - warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device;
  - precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user;

- (oa) In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications, undesirable side effects and risks relating to overdose.**
- (ob) in the case of implantable devices the overall qualitative and quantitative information on the materials and substances to which patients can be exposed.**
- (p) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:
- infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);
  - physical hazards (e.g. from sharps).
- (q) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.
- (r) For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, information regarding the absence of a clinical benefit and the risks related to the use of the device.
- (s) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use.
- (t) A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established.
- (u) Information to be supplied to the patient with an implanted device according to Article 16.**

## TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary technical documentation (STED) to be drawn up by the manufacturer ***shall be presented in a clear, organized, readily searchable and unequivocal way and*** shall include in particular the following elements: ***described in this Annex. The STED shall summarize the elements of the technical documentation.***

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

#### 1.1. Device description and specification

- (a) product or trade name and a general description of the device including its intended purpose ***and intended user;***
- (b) the UDI device identifier ***and the Basic UDI devices identifier*** as referred to in item (i) of point (a) of Article 24(1) attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;]
- (c) the intended patient population and medical conditions to be diagnosed, ~~and/or~~ treated ***and/or monitored*** and other considerations such as patient selection criteria, ***indications, contraindications, warnings;***
- (d) principles of operation of the device ***and its mode of action scientifically demonstrated, if necessary;***
- (e) risk class and ***the justification of*** the applicable classification rule according to Annex VII;
- (f) an explanation of any novel features;
- (g) a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it;

- (h) a description or complete list of the various configurations/variants of the device that will be made available;
- (i) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality **and, where relevant, its qualitative and quantitative composition**. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;
- (j) a description of the (raw) materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;
- (k) technical specifications (features, dimensions and performance attributes) of the medical device and any variants/**configurations** and accessories that would typically appear in the product specification made available to the user, e.g. in brochures, catalogues and the like.

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

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

## 2. INFORMATION SUPPLIED BY THE MANUFACTURER

- (a) a complete set of
  - the label(s) on the device and on its packaging (**single unit packaging, sales packaging, transport packaging in case of specific management conditions**), **in the languages accepted in the Member States where the device is envisaged to be sold**;
  - the instructions for use **in the languages accepted in the Member States where the device is envisaged to be sold**;
- (b) ~~a list of the language variants for the Member States where the device is envisaged to be marketed.~~



### 3. DESIGN AND MANUFACTURING INFORMATION

- (a) Information to allow ~~the a general~~ understanding of the design stages applied to the device and the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information needs to be provided for the audit of the quality management system or other applicable conformity assessment procedures;
  - (aa) ***Complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;***
- (b) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

### 4. GENERAL SAFETY AND PERFORMANCE REQUIREMENT

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

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

## 5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT

The documentation shall contain ~~a summary of~~

- (a) the risk/benefit analysis referred to in Sections 1 and 5 of Annex I, and
- (b) the solutions adopted and the results of the risk management referred to in Section 2 of Annex I.

## 6. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results of ***all the*** verification and validation testing and/or studies undertaken ***and their critical analysis*** to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

### 6.1. Pre-clinical and clinical data

- (a) results of (engineering, laboratory, simulated use, animal) tests and evaluation of published literature applicable to the device ***and taking into account its intended purpose*** or substantially similar devices regarding the pre-clinical safety of the device and its conformity with the specifications;
- (b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding ***in particular:***
  - biocompatibility ***of the device including the identification of*** (~~identifying~~ all materials in direct or indirect contact with the patient or user);
  - physical, chemical and microbiological characterisation;
  - electrical safety and electromagnetic compatibility;
  - software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);

- stability/shelf life;
- ***performance and safety.***

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances shall be demonstrated.

Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision, e.g. biocompatibility testing on the identical materials was conducted when these were incorporated in a previous version of the device that has been legally placed on the market or put into service;

- (c) the ***clinical evaluation and*** report ~~and~~ ~~on~~ the clinical evaluation ***plan*** in accordance with Article 49(5) and Part A of Annex XIII ***and its updates;***
- (d) the PMCF plan and PMCF evaluation report in accordance with Part B of Annex XIII or any justification why a PMCF is not deemed necessary or appropriate ***applicable.***

## **6.2. Additional information in specific cases**

- (a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, referred to in the first subparagraph of Article 1(4), a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.
- (b) Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are covered by this Regulation in accordance with point (e) of Article 1(2), a statement indicating this fact. In this case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 10.1. or 10.2., respectively, of Annex I.

- (ba) *in the case of devices that are composed of substances or combination of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions, or otherwise justification for the absence of such studies, regarding:*
- *absorption, distribution, metabolism and excretion;*
  - *possible interactions, or of their products of metabolism, with other devices, medicinal products or other substances, considering the target population, and their associated medical conditions;*
  - *local tolerance;*
  - *toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable according to total exposure to the device.*
- (c) In the case of devices placed on the market in a sterile or defined microbiological condition a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.
- (d) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.
- (e) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/**configuration** including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

## **TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE**

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

### **1.1. Post-market surveillance plan in accordance with Article 60b**

*The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 60a.*

**(a)** *The post-market surveillance plan shall see to the collection and utilization of available information, in particular:*

- *information concerning serious incidents, including periodic safety update report, and field safety corrective actions,*
- *records referred to not serious incident and data on any undesirable side effects,*
- *and information on trend reporting,*
- *relevant specialist or technical literature, databases and/or registers,*
- *information, including feedbacks and complaints, provided by users, distributors, importers,*
- *publicly available information about similar medical devices.*

**(b)** *The post-market surveillance plan shall include at least:*

- *a proactive and systematic process to collect any information referred to in paragraph (a) the process shall allow a correct characterization of the performance of the devices also comparing the device with the similar products available on the market;*

- *effective and appropriate methods and processes to assess the collected data;*
- *suitable indicators and threshold values that shall be used in the continuous reassessment of the risk benefit analysis and of the risk management as referred to in Sections I of Annex I;*
- *effective and appropriate methods and tools to investigate complaints or market experiences collected in the field;*
- *methods and protocols to manage the events subject to trend report as provided in Article 61a, including those to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;*
- *methods and protocols to communicate effectively with Competent Authorities, Notified Bodies, economic operators, users and patients;*
- *reference to procedures to fulfil the manufacturers obligations laid down in Articles 60a, 60b and 60c;*
- *systematic procedures to identify and initiate appropriate measures including corrective actions;*
- *effective tools to trace and identify devices for which corrective actions might be necessary;*
- *a post-market clinical follow-up plan according to Part B of Annex XIII, or any justification why a post-market clinical follow-up is not deemed necessary or appropriate.*

**1.2 Post-market clinical follow-up evaluation report in accordance with Part B of Annex XIII.**

**1.3 Periodic safety update report referred to in Article 60c.**

## ANNEX III

### EU DECLARATION OF CONFORMITY

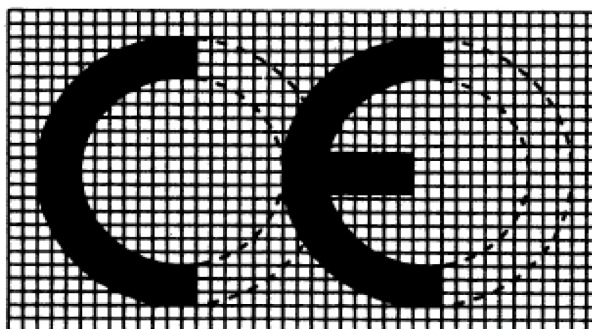
1. Name, registered trade name or registered trade mark, *single registration number referred to in Article 25a* of the manufacturer, and, if applicable, his authorised representative, and the address of their registered place of business where they can be contacted and their location be established;
2. A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;
3. The UDI device identifier as referred to in item (i) of point (a) of Article 24(1) as soon as identification of the device that is covered by the declaration shall be based on a UDI system;
4. Product ~~or~~ *and* trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered by the declaration (it may include a photograph, where appropriate), *including its intended purpose*. Except for the product or trade name, the information allowing identification and traceability may be provided by the device identifier referred to in point 3;
5. Risk class of the device in accordance with Annex VII;
6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;
7. References to the relevant harmonised standards or ~~CTS~~ *CS* used in relation to which conformity is declared;

8. Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued;
9. Where applicable, additional information;
10. Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.



## CE MARKING OF CONFORMITY

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



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

ANNEX V

**INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF  
DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH  
ARTICLE 25a**

**AND**

**CORE DATA ELEMENTS TO BE PROVIDED TO OF THE UDI DATA BASE  
TOGETHER WITH THE DEVICE IDENTIFIER IN ACCORDANCE  
WITH ARTICLE 24a**

**AND**

**THE EUROPEAN UNIQUE DEVICE IDENTIFICATION SYSTEM**

**PART A**

**INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES  
ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 25a**

Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the following information *referred to in points 1 to 4a and ensure that the information referred to in other points is complete, correct and updated by the relevant party.*÷

1. economic operator's role (manufacturer, authorised representative, or importer),
  2. name, address and contact details of the economic operator,
  3. where submission of information is completed by another person on behalf of any of the economic operators mentioned under point 1, the name, address and contact details of this person,
  4. UDI device identifier, or where identification of the device is not yet based on a UDI system, the data elements laid down in points 5 to 21 of Part B of this Annex,
- 4a. name address and contact details of the person responsible for regulatory compliance (qualified person) according to article 13,**

5. type, number and expiry date of certificate and name or identification number of the notified body that has issued the certificate (and link to the information on the certificate entered by the notified body in the electronic system on certificates),
6. Member State where the device shall or has been placed on the market in the Union,
7. in case of devices classified as classes IIa, IIb or III: Member States where the device is or shall be made available,
8. ~~in case of imported device: country of origin,~~
9. risk class of the device (***if applicable the highest from the portfolio of the manufacturer***),
10. reprocessed single use device (y/n),
11. presence of a substance which, if used separately, may be considered to be a medicinal product and name of this substance,
12. presence of a substance which, if used separately, may be considered a medicinal product derived from human blood or human plasma and name of this substance,
13. presence of human tissues or cells, or their derivatives (y/n),
14. presence of animal tissues or cells, or their derivatives, as referred to in Commission Regulation (EU) No 722/2012 (y/n),
15. where applicable, single identification number of the clinical investigation(s) conducted in relation to the device (or link to the clinical investigation registration in the electronic system regarding clinical investigations),
16. in case of devices listed in Annex XV, specification whether the intended purpose of the device is other than a medical purpose,
17. in case of devices designed and manufactured by another legal or natural person as referred in Article 8(10), the name, address and contact details of that legal or natural person,
18. in case of devices classified as class III or implantable devices, the summary of safety and clinical performance,
19. status of the device (on the market, no longer manufactured, withdrawn from the market, recalled).

## PART B

### **CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI DEVICE IDENTIFIER IN ACCORDANCE WITH ARTICLE 24a**

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

1. quantity per package configuration,
2. if applicable, *the Basic UDI-DI according to article 24 (4b) and* ~~alternative or~~ additional identifier(s),
3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number),
4. if applicable, the unit of use device identifier (when a UDI is not assigned to the device at the level of its unit of use, a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient),
5. name and address of the manufacturer (as indicated on the label),
- 5a. *the single registration number according to article 25a (2),***
6. if applicable, name and address of the authorised representative (as indicated on the label),
7. ~~Global Medical Device Nomenclature (GMDN) code~~ *according to article 23a or* ~~internationally recognised nomenclature code,~~
- 7a. *risk class of the device,***
8. if applicable, trade/brand name,
9. if applicable, device model, reference, or catalogue number,
10. if applicable, clinical size (including volume, length, gauge, diameter),
11. additional product description (optional),
12. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),
13. if applicable, additional trade names of the device,
14. labelled as single use device (y/n),
15. if applicable, restricted number of reuses,
16. device packaged sterile (y/n),
17. need for sterilisation before use (y/n),
18. labelled as containing latex (y/n),

19. labelled as containing DEHP (y/n),
20. URL for additional information, e.g. electronic instructions for use (optional),
21. if applicable, critical warnings or contraindications.
22. *status of the device on the market (~~choice box, stop of placing no more placed on the market, recalled, FSA initiated~~).*

## **PART C**

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

~~*This Part of the Annex is based on international guidance and is describing in more detail the European Unique Device Identification System – particularly by providing definitions that are of specific relevance for Chapter III and Annex V. It applies to all products to be placed on the market that are medical devices as defined in paragraph 1 of Article 2.*~~

#### **1. Definitions**

##### ***Automatic Identification and Data Capture (hereinafter AIDC)***

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

##### ***Basic UDI-DI***

*The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and shall be referenced in relevant certificates and declarations of conformity. In instances when a UDI is not labelled at the level of the device unit of use (e.g. several device units contained in a plastic bag) it is also the purpose of the Basic UDI DI to associate the use of a device to/on a patient to data related to that patient.*

### *Configurable medical device system*

*A configurable medical device system is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be medical devices itself in themselves and/or non-medical devices. Configurable devices include Examples are Computed Tomography (CT) systems, Ultrasound systems, Anaesthesia systems, Physiological Monitoring systems, Radiology Information System (RIS).*

### *Configuration*

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

*Examples: Configurations include inter alia*

- (a) CT: gantries, gantry, tubes, tables, consoles are and other items of equipment that can be configured/combined to deliver an intended function in computed tomography.*
- (b) Anaesthesia: ventilators, breathing circuits, vaporizers are items of equipment that can be configured/combined to deliver an intended function used for anaesthesia.*

### *Device Identifier (hereinafter UDI-DI)*

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

*Examples of the UDI-DI include GSI GTIN (Global Trade Item Number), HIBC-LIC (Labeller Identification Code), ISBT 128-PPIC (Processor Product Identification Code).*

### *Human Readable Interpretation (hereinafter HRI)*

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

~~Label [already described in chapter I article 2 (11)]~~

~~Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.~~

~~Own Brand or Private Labeller [maybe to be moved to chapter I article 2]~~

~~An Own Brand or Private Labeller re-labels a device from a 3<sup>rd</sup> party with his own name without making any further substantial changes to the device thereby taking responsibility for it as the manufacturer.~~

*Packaging levels*

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

*Note: This does not include shipping containers.*

*Production Identifier (hereinafter UDI-PI)*

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

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

*Radio Frequency Identification (hereinafter RFID)*

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

*Shipping containers*

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

***Unit of Use UDI-DI (hereinafter UoU) UDI-DI***

***The UoU UDI-DI is a special Basic UDI-DI assigned to an individual medical device, in instances when a UDI is not labelled at the level of the device unit of use (e.g. several units contained in a plastic bag). Its purpose is to associate the use of a device to/on a patient related or to associate a device to data referenced in certificates or Declarations of Conformity (DoC).***

***Unique Device Identification***

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

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

***UDI system [already described in article 24?]***

***The UDI system is the framework for:***

- 1) UDI production,***
- 2) UDI application on the label or on the device, and***
- 3) UDI database fundamental contents.***

***UDI Carrier***

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

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

***UDI database***

***The UDI database contains identifying information and other elements associated with the specific medical device. The UDI database contains no UDI-PI.***



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

- 2.1. The marking of the UDI is an additional requirement – it does not replace any other marking or labelling requirements described in Annex I of this regulation.**
- 2.2. The manufacturer ~~has to~~ shall create and maintain globally unique UDIs on his devices.**
- 2.3. Only the manufacturer ~~can~~ may establish the UDI on the device or its packaging.**
- 2.4. Only coding standards offered by assigning entities designated by the European Commission according to article 24(2) ~~can~~ may be used by the manufacturers.**

## **3. The UDI**

- 3.1. A UDI shall be assigned to the device itself or its package. Higher levels of packaging shall have their own UDI.**
- 3.2. Shipping containers shall ~~should~~ be exempted. As an example, UDI is not required on a logistics unit; when a healthcare provider orders multiple ~~medical~~ devices using the UDI or model number of individual devices and the manufacturer places these devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) is not subject to UDI requirements.**
- 3.3. The UDI shall contains two parts: an UDI-DI and an UDI-PI.**
- 3.4. The UDI-DI ~~should~~ shall be globally unique at all levels of device packaging.**
- 3.5. If a lot number, serial number, software ~~version~~-identification or expiration date appears on the label, ~~they~~ it shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does NOT need to be included in the UDI-PI. If there is only a manufacturing date on the label, this ~~should~~ shall be used as the UDI-PI.**
- ~~3.6. When a UDI is not assigned to the device at the level of its unit of use, then a UoU UDI-DI should shall be assigned and related pieces of informations shall be provided to the UDI database[for example, a UoU UDI-DI would be assigned to an individual electrode when the electrode is distributed in a package of 10— and lowest level UDI is assigned to that package of 10].~~**

- 3.7. *Each component, ~~sub-system or accessory~~ that is considered a ~~medical~~ device and is commercially available on its own ~~needs~~ shall be assigned a separate UDI unless the components are part of a configurable ~~medical device system~~ that is marked with its own UDI.*
- 3.8. *Systems and procedure packs according to Article 20 ~~Kits should~~ shall ~~have~~ be assigned and bear their own UDI.*
- 3.9. *The manufacturer shall assigns the UDI to a device following the relevant coding standard.*
- 3.10. *A new UDI-DI ~~and or UoU UDI-DI~~ is shall be required whenever there is a change that could lead to misidentification of the ~~medical~~ device and/or ambiguity in its traceability, in particular any change of one of the following UDI database data elements require ~~determines the need for a new UDI-DI~~:*
- (a) *Brand Name or Trade name,*
  - (b) *Device version or model,*
  - (c) *~~Clinical Size (including Volume, Length, Gauge, Diameter),~~*
  - (d) *Labelled as single use,*
  - (e) *Packaged sterile,*
  - (f) *Need for sterilization before use,*
  - (g) *Quantity of devices provided in a package,*
  - (h) *Critical warnings or contraindications: e.g. containing latex or DEHP.*
- 3.11. *At a minimum, a new UDI-DI ~~and or UoU UDI-DI~~ is shall be required whenever there is a change that could lead to misidentification of the ~~medical~~ device and/or ambiguity in its traceability.*
- 3.12. *Manufacturers who repackages and/or relabels ~~Reprocessors of medical devices, remanufacturers,~~ and with their own label ~~Private (Own Brand) Labellers~~ shall retain record of the Original Equipment Manufacturer's (OEM) UDI.*
4. *UDI Carrier*
- 4.1. *The UDI Carrier (AIDC and HRI representation of the UDI) shall be placed on the label or on the device itself and on all higher levels of device packaging. Higher levels do not include shipping containers.*

- 4.2. *In case of significant space constraints on the unit of use UoU package the UDI carrier may be placed on the next higher package level.*
- 4.3. *For ~~The UDI Carrier for~~ single use ~~medical~~ devices of class I and IIa packaged and labelled individually ~~does not need to be the UDI Carrier~~ shall not be required to appear on ~~its~~ the package but ~~rather~~ it shall appear on a higher level of packaging e.g. a carton containing several individually packaged devices. However when the healthcare provider is not expected to have access (home healthcare settings) to the higher level of device packaging, the UDI ~~should~~ shall be placed on ~~its~~ the package of the individual device.*
- 4.4. *For ~~Medical~~ devices exclusively intended for retail Point of Sale (POS) ~~do not need to encode~~ the Production Identifiers in AIDC shall not be required to appear on the point of sale package.*
- 4.5. *When AIDC carriers other than the UDI Carrier are part of the product labelling, the UDI Carrier shall be readily identifiable.*
- 4.6. *If linear bar codes are used, the UDI-DI and UDI-PI ~~can~~ may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.*
- 4.7. *If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be ~~favoured~~ required to appear on the label. For ~~However for~~ devices indented to be used outside of healthcare facilities such as devices for home care, ~~warrant the use of the HRI~~ shall however appear on the label even if this means that there is no space for the ~~over~~ AIDC.*
- 4.8. *The HRI format shall follow the rules of the UDI code issuing organization.*
- 4.9. *If the manufacturer is using RFID technology, a linear or 2D bar code according to the standard provided by the assigning entities shall also be provided on the label.*

*4.10. Medical devices that are reusable ~~should have~~ shall bear a UDI Carrier on the device itself. The UDI Carrier of reusable ~~medical~~ devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses ~~should~~ shall be permanent and readable after each process performed to make the device ready for the next use for the intended lifetime of the device. The requirement of this section shall not apply to any device that meets any of the following criteria:*

- (a) Any type of direct marking would interfere with the safety or performance of the device;*
- (b) The device cannot be directly marked because it is not technologically feasible.*

*4.11. The UDI Carrier ~~should~~ shall be readable during normal use and throughout the intended life of the ~~medical~~ device.*

*4.12. If the UDI Carrier is readily readable and in the case of AIDC scanable through the ~~medical~~ device's package, then the placing of the UDI Carrier ~~does not also need to be~~ shall not be required to appear on the package shall not be required.*

*4.13. A single finished ~~medical~~ device made up of multiple parts that ~~have to~~ must be assembled before first use may ~~have~~ bear the UDI Carrier on only ~~on~~ one part.*

*4.14. The placement of the UDI Carrier ~~should be done in a way~~ shall be placed so that the AIDC ~~method~~ can be accessed during normal operation or storage.*

*4.15. The bar code carrier(s) that include(s) UDI data identifiers "UDI-DI" and "UDI-PI" may also include essential data for the ~~medical~~ device to operate or other data related to logistics etc.. The UDI issuing agencies shall identify these additional data elements by application identifiers or flag characters.*

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

*5.1. The UDI database shall support the use of all ~~the~~ core UDI database data elements.*

*5.2. ~~No product commercially confidential product information shall be included in the UDI database.~~*

- 5.3. ~~The manufacturer is~~ shall be responsible for the initial submission and updates ~~to~~ of the identifying information and other ~~medical~~ device data elements in the UDI database.
- 5.4. Appropriate methods/procedures for validation of the provided data shall be implemented.
- 5.5. ~~The manufacturers~~ shall periodically reconfirm all the data relevant to ~~their~~ ~~medical~~ devices he has placed on the market, except for ~~discontinued~~ ~~medical~~ devices that are no more available on the market.
- 5.6. ~~The core data elements in the UDI database shall be accessible to the public free of charge.~~
- 5.7. The presence of the ~~medical~~ device UDI-DI in the UDI database does not mean that the ~~medical~~ device is in conformity with this Regulation ~~authorized in all jurisdictions.~~
- 5.8. The database ~~should~~ shall allow for the linking of all the packaging levels of the ~~medical~~ device.
- 5.9. The data for new UDI-DI ~~must~~ shall be available at the time the ~~medical~~ device is placed on the market.
- 5.10. ~~Manufacturers should~~ shall update the relevant UDI database record within 30 days when a change is made to an element that does NOT require a new UDI-DI.
- 5.11. The UDI database shall use internationally accepted ~~the HL7 Structured Product Labelling (SPL)~~ standards for data submission and updates. Additional submission means ~~could~~ may, however, also be accommodated.
- 5.12. The core elements are the minimum elements needed to identify a ~~medical~~ device throughout its distribution and use.
- 5.13. The design of the UDI database ~~should~~ shall support the ~~official~~ languages required in the Member States where the ~~medical~~ device is placed on the market. The use of free-text fields ~~should~~ shall, however, be minimized in order to reduce ~~the burden of language~~ translations.
- 5.14. Data relating to ~~discontinued~~ ~~medical~~ devices that are no more available on the market shall be retained in the UDI database.

**6. Rules for specific device types**

**6.1. Implantable devices**

*The ~~Implantable devices should follow the rules listed below~~ shall apply for implantable devices:*

**6.1.1. All unit packs of implantable devices (lowest level of packaging) ~~need to~~ shall be identified/ or AIDC marked with an UDI (UDI-DI + UDI-PI);**

**6.1.2. The PI shall have at least the following characteristics:**

**(a) the serial number for active implantable devices,**

**(b) the serial number ~~for other implantable devices~~ or lot number for other implantable devices;**

**6.1.3. The UDI of the implantable device ~~must~~ shall be identifiable prior to implantation.**

**6.2. Reusable devices requiring cleaning, disinfection, sterilisation or refurbishing between uses**

**6.2.1. The UDI of ~~these products~~ such devices shall be placed on the device and be readable after each procedure to make the device ready for the next use;**

**6.2.2. The PI characteristics (e.g. lot or serial number) shall be defined by the manufacturer.**

**6.3. Systems and procedure packs according to article 20**

**6.3.1. The manufacturer of the System or procedure pack ~~is~~ shall be responsible for identifying the ~~Kit~~ system or procedure pack with a UDI including both UDI-DI and UDI-PI;**

**6.3.2. ~~Medical device contents of Kits~~ system or procedure packs ~~should have~~ shall bear a UDI Carrier on their packaging or on the device itself.**

**Exemptions:**

**(a) Individual single-use disposable ~~medical~~ devices within a System or procedure pack, whose uses are generally known to the persons by whom they are intended to be used, and which are not intended for individual use outside the context of the System or procedure pack ~~do~~ shall not be required to bear their own UDI Carrier.**

**(b) ~~Medical~~ devices that are ~~normally~~ exempted from ~~having~~ bearing a UDI Carrier on the relevant level of packaging ~~do not need to have~~ shall not be required to bear a UDI Carrier when ~~placed~~ included within a System or procedure pack.**

**6.3.3. Placement of the UDI Carrier on Systems or procedure packs:**

- (a) ~~The System or procedure pack UDI Carrier is generally~~ shall as a general rule be affixed to the outside of the packaging;**
- (b) ~~The UDI Carrier must~~ shall be readable, or in the case of AIDC scannable, whether placed on the outside of the System or procedure pack package or inside a transparent package.**

**6.4. Configurable ~~medical devices systems~~**

**~~For configurable medical device systems the rules listed below shall be followed apply for configurable medical devices systems:~~**

- 6.4.1. ~~A UDI is~~ shall be allocated to the ~~entire~~, configurable medical device system in its entirety and ~~is~~ shall be called the ~~System~~ Configurable device UDI.**
- 6.4.2. ~~The system~~ Configurable device UDI-DI ~~is~~ shall be allocated to ~~defined~~ groups of configurations, not per configuration within the group. A group of configurations is defined as the collection of possible configurations for a given ~~product device line~~ as described in the technical documentation ~~a regulatory file~~.**
- 6.4.3. ~~A system~~ Configurable device UDI-PI ~~is~~ shall be allocated to each individual Configurable device system. ~~A later change of a component, sub-systems or accessory of the system does shall not change the UDI-PI of the system.~~**
- 6.4.4. ~~The carrier of the System~~ Configurable device UDI ~~should~~ shall be ~~put~~ placed on the assembly that is most unlikely ~~does not get~~ to be exchanged ~~in its~~ during the lifetime of the system and ~~should~~ shall be identified as the ~~System~~ Configurable device UDI.**
- 6.4.5. ~~Each component, sub-system or accessory that is considered a medical device and a distributed or supplied unit~~ is commercially available on its own ~~needs~~ shall be assigned a separate UDI;**

**6.5. Medical Device Software**

**6.5.1. UDI Assignment Criteria**

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

*The ~~version number of the~~ Software identification ~~is~~ shall be considered the manufacturing control mechanism and shall be displayed in the UDI-PI.*

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

*~~Major Software revisions shall be identified with a new UDI-DI;~~*

*~~Major Software revisions are meant as complex or significant changes affecting~~*

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

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

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

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

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

*Minor revisions shall be identified by manufacturer-specific identification. ~~methods (e.g. version, revision number, serial number, etc...).~~*



### 6.5.2. *UDI Placement Criteria for Software*

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

**MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES****1. Organisational and general requirements****1.1. Legal status and organisational structure**

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

**1.1.5.** The *notified body shall clearly document its* organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel *who may have an* ~~with~~ influence upon the performance and results of the conformity assessment activities ~~shall be clearly documented.~~

**1.1.6.** *The notified body shall identify the top-level management that have overall authority and responsibility for each of the following:*

- *the provision of adequate resources for conformity assessment activities;*
- *the development of procedures and policies for the operation of the notified body;*
- *the supervision of implementation of the procedures, policies and quality management systems;*
- *the supervision of the notified body's finances;*
- *the activities and decisions taken by the notified body, including contractual agreements;*
- *the delegation of authority to personnel and/or committees, where necessary, for the performance of defined activities ; and*
- *the interaction with the national authority responsible for notified bodies and the obligations regarding communications with other Competent Authorities, the Commission and other notified bodies.*

## **1.2. Independence and impartiality**

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

*This does not preclude conformity assessment activities for competing manufacturers.*

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

- *be linked to any organisation which itself provides consultancy services as referred to in the previous indent.* This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

**1.2.3a. *Involvement in consultancy services in the field of medical devices prior to taking up employment with a notified body shall be fully documented at the time of employment and potential conflicts of interests shall be monitored and resolved according to criteria set out in this Annex. Personnel who were former employees or provided consultancy services in the field of medical devices for a specific client, prior to taking up employment with a notified body shall not be assigned for conformity assessment activities for that specific client or companies belonging to the same group for a period of 3 years.***

1.2.4. The impartiality of the notified bodies, of their top level management and of the assessment personnel shall be guaranteed. The remuneration of the top level management and assessment personnel of a notified body shall not depend on the results of the assessments.

1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests must be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, ***including the activities of its owners*** do not affect its independence, impartiality or objectivity of its conformity assessment activities.

1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC ***in relation to fees.***

1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.

### **1.3. Confidentiality**

**1.3.1. *The notified body shall have documented procedures in place ensuring that confidentiality of the information which comes into its possession during the performance of the conformity assessment activities is observed by its personnel, committees, subsidiaries, subcontractors, any associated body or personnel of external bodies, except when disclosure is required by law.***

1.3.2. The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation ***or any provision of national law giving effect to it***, except in relation to the national authorities responsible for notified bodies, competent authorities ***for medical devices in the Member States*** or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

### **1.4. Liability**

**1.4.1.** The notified body shall take out appropriate liability insurance ~~that corresponds to the conformity assessment activities for which it is notified, including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless~~ liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

**1.4.2. *The scope and overall financial value of liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk profile of the devices certified by the notified body. The liability insurance shall cover cases where the notified body may be obliged to withdraw, restrict or suspend certificates.***

## **1.5. Financial requirements**

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

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

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

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

~~1.6.2. The notified body shall adhere to a code of conduct, addressing among other things, ethical business practices for notified bodies in the field of medical devices, [that is accepted by the national authorities responsible for notified bodies]. The code of conduct shall provide for a mechanism of monitoring and verification of its implementation by notified bodies.~~

## **2. Quality management requirements**

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

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

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

2.3. ***The notified body top management shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation including subsidiaries and subcontractors being involved in conformity assessment activities according to this Regulation.***

2.4. ***The notified body shall require all personnel to formally commit themselves by a signature or equivalent to comply with the procedures defined by the notified body. The commitment shall consider aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with clients. The personnel will be required to complete written statements indicating their compliance to confidentiality, independence and impartiality principles.***



### 3. Resource requirements

#### 3.1. General

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

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

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

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

3.1.2. ~~At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.~~

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

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

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

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

### 3.2. Qualification criteria in relation to personnel

- 3.2.1. The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, **technical documentation** ~~design dossier~~ file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of human and animal origin, clinical evaluation) covered by the scope of designation.
- 3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 33, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined **at least** for the assessment of ~~biocompatibility aspects~~ **the pre-clinical evaluation**, clinical evaluation, **tissues and cells of human and animal origin, functional safety, software, packaging, drug device combination products, ingested products** and the different types of sterilisation processes.

- 3.2.3. The personnel responsible for **establishing qualification criteria and for** authorising other personnel to perform specific conformity assessment activities ~~and the personnel with overall responsibility for the final review and decision-making on certification~~ shall be employed by the notified body itself and shall not be subcontracted. ~~These personnel altogether~~ **They** shall have proven knowledge and experience in the following:
- Union medical devices legislation and relevant guidance documents;
  - the conformity assessment procedures in accordance with this Regulation;
  - a broad base of medical device technologies, ~~the medical device industry~~ and the design and manufacture of devices;
  - the notified body's quality management system ~~and~~, related procedures **and the required qualification criteria;**

- ~~the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to medical devices as well as the relevant qualification criteria;~~
- ~~training relevant to personnel involved in conformity assessment activities in relation to medical devices;~~
- ~~the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.~~

3.2.4. ~~Notified bodies~~ **The notified body** shall have available personnel with **relevant** clinical expertise. ~~This~~ **These** personnel shall be integrated **throughout** ~~in~~ the notified body's **assessment and** decision-making process ~~in a steady way~~ in order to:

- identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;
- appropriately train external clinical experts in the relevant requirements of ~~this~~ **regulation Regulation, C S, guidance delegated and/or implementing acts, harmonised standards, and CTS and guidance documents** and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;
- be able to ~~discuss~~ **review and scientifically challenge** the clinical data contained within the manufacturer's clinical evaluation, **and** ~~with the manufacturer and with external clinical experts and to~~ appropriately guide external clinical experts **in the assessment of** the clinical evaluation **presented by the manufacturer;**
- be able to scientifically **evaluate and, if necessary,** challenge the clinical **evaluation data** presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;
- be able to ascertain the comparability and consistency of the assessments **of clinical evaluations** conducted by clinical experts;
- be able to make an ~~objective clinical judgement about the~~ assessment of the manufacturer's clinical evaluation **and a clinical judgement of the opinion provided by any external expert** and make a recommendation to the notified body's decision maker.

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

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

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

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

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

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

- *the medical devices legislation and relevant guidance documents;*
- *the medical device conformity assessments relevant to this Regulation;*
- *the types of qualifications, experience and expertise relevant to medical device conformity assessment;*

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

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

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

3.3.2. For ***all of*** its personnel referred to in Sections 3.2.3 to 3.2.67, the notified body shall establish and maintain up to date:

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

### 3.4. Subcontractors and external experts

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

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

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

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



3.4.2. Where a notified body subcontracts **certain** conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place, **and shall ensure that:**

- **the subcontractor meets the relevant requirements of this Annex;**
- **- subcontractors and external experts do not further subcontract work to organisations or personnel;**
- **where the notified body subcontracts conformity assessment activities, the client has been informed of this and has given consent.**

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

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

~~3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used.~~

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

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

3.5.2. It shall review *at regular intervals*, the competence of its personnel, and identify training needs *and draw up a training plan* in order to maintain the required level of qualification and knowledge *of individual personnel. This review shall at a minimum, verify that personnel:*

- *are aware of the current medical device legislation, relevant harmonised standards, C S, guidance documents and the results of the coordination activities according to section 1.6 of this Annex;*
- *take part in the internal exchange of experience and the continuous training and education programme according to Section 3.1. 2a.*

#### 4. Process requirements

4.1. ~~The notified body's decision-making process shall be clearly documented, including the process for the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.~~

#### 4.2. General

The notified body shall have in place a documented processes *and sufficiently detailed procedures* for the conduct of *each* the conformity assessment *activity* ~~procedures~~ for which it is designated, *comprising the individual steps from pre-application activities until decision making and surveillance and* taking into account, *when necessary*, their respective specificities *of the devices*, ~~including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.~~

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

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

The notified body shall

- *publish a publicly available description of the application procedure by which manufacturers can obtain certification by the notified body. This description shall include which languages are acceptable for submission of documentation and for any related correspondence,*
- ~~have in place documented procedures relating to, and documented details about, covering at least: fees charged for specific conformity assessment activities and any other financial conditions relating to its assessment activities for devices,~~
- ~~the application for conformity assessment by a manufacturer or by an authorised representative,~~
- ~~the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as device and its classification,~~
- ~~the language of the application, of the correspondence and of the documentation to be submitted,~~
- ~~the terms of the agreement with the manufacturer or authorised representative,~~
- ~~the fees to be charged for conformity assessment activities,~~
- ~~the assessment of relevant changes to be submitted for prior approval,~~
- ~~the planning of surveillance,~~
- ~~the renewal of certificates.~~
- *have documented procedures in relation to advertising of its conformity assessment services. These shall ensure that advertising or promotional activities in no way imply or could lead to inference that their conformity assessment will offer manufacturers earlier market access or be quicker, easier or less stringent than other notified bodies,*
- *have documented procedures requiring the review of pre-application information including the preliminary verification that the product is covered by this Regulation and its classification prior to issuing any quotation to the manufacturer relating to a specific conformity assessment,*
- *ensure that all contracts relating to the conformity assessment activities covered by this Regulation are established directly between the manufacturer and the notified body and not with any other organisation.*

#### **4.4. Application and Contract review**

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

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

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

- the completeness with respect to the requirements provided in the respective Annex under which approval has been sought,***
- the verification of the qualification of the products covered by the application as devices and their specific classification(s),***
- the legal applicability of the conformity assessment route chosen by the applicant,***
- the ability of the notified body to assess the application based on their designation,***  
***and***
- the availability of sufficient and appropriate resources.***

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

#### 4.5. Allocation

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

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

#### 4.6. Conformity Assessment Activities

##### 4.6.1. General

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

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

- *to appropriately plan the conduct of each individual project; these shall ensure that the composition of the assessment teams assures experience with the technology concerned, continuous objectivity and independence, which shall include provision for rotation of the members of the assessment team at appropriate intervals,*
- *to detail the rationale for fixing time limits for completion of conformity assessment activities,*
- *to assess the manufacturer's technical documentation and the solutions adopted to meet the Requirements laid out in Annex I,*

- *to review the manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects,*
- *to review the manufacturer's procedures and documentation relating to clinical evaluation,*
- *to address the interface with the risk management process and the appraisal and analysis of the pre-clinical and clinical evaluation and its relevance to demonstrate conformity to the relevant requirements in Annex I*
- *to carry out the "specific procedures" in the case of devices incorporating medicinal substances, human blood derivatives or in the case of devices manufactured utilising non-viable tissues or cells or in case of a product from animal origin,*
- *to assess, in the case of devices falling into class IIa or IIb, for selected devices the technical documentation,*
- *to plan and periodically carry out appropriate surveillance audits and assessments, to carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced factory visits,*
- *relating to the sampling of devices to verify that the manufactured device is in conformity with the technical documentation, these shall define the relevant sampling criteria and testing procedure prior to sampling,*
- *to evaluate and verify a manufacturer's compliance with relevant Annexes.*

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

*The notified body shall, when relevant, take into consideration harmonised standards, even if the manufacturer doesn't claim compliance, available CS, guidance and best practice document.*

#### 4.6.2. Quality management system audits

- (a) *As part of the quality system assessment activity, the notified body shall prior to the audit and in accordance with its documented procedures:*
- *assess the documentation submitted according the relevant conformity assessment Annex and establish an audit programme which clearly identifies the number and sequence of activities required to demonstrate complete coverage of a manufacturer's quality management system and to determine whether it meets the requirements of this Regulation,*
  - *determine interfaces and responsibilities between different manufacturer sites, as well as the identification of relevant suppliers and/or subcontractors of the manufacturer, including consideration of the need to specifically audit any of these suppliers and/or subcontractors,*
  - *clearly define, for each audit identified in the audit programme, the objectives, criteria and scope of the audit and shall draw up an audit plan adequately addressing and taking account of the specific requirements for the devices, technologies and processes covered,*
  - *establish and maintain, for class IIa and IIb devices, a sampling plan for the assessment of technical documentation as referred to in Annex II covering the range of such devices comprised by the manufacturer's application. This plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate [ ],*
  - *select and assign appropriately qualified and authorised personnel for conducting the individual audits. The respective roles, responsibilities and authorities of the team members shall be clearly defined and documented.*
- (b) *According to the audit programme established, the notified body shall, in accordance with its documented procedures:*
- *audit the manufacturer's quality management system, which must ensure that the devices covered conform to the relevant provisions of this Regulation, which apply to devices at every stage, from design through final inspection to ongoing surveillance, and determine if the requirements of this Regulation are met,*

- *review and audit the manufacturer's processes/subsystems, based on relevant technical documentation – in particular for design and development, production and process controls, product documentation, purchasing controls including verification of purchased devices, corrective and preventive actions including post-market surveillance and post-market clinical follow-up –, requirements and provisions adopted by the manufacturer including those in relation to fulfilling the general safety and performance requirements to determine whether the manufacturer meets the requirements referred to in the relevant conformity assessment annex. Documentation shall be sampled to reflect the risks associated with the intended use for the device, the complexity of the manufacturing technologies, the range and classes of devices produced and any available post-market surveillance information, - if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers,*
- *conduct assessments of the technical documentations according to the established sampling plan and taking account of sections 4.6.4 and 4.6.5 of this Annex for preclinical and clinical evaluations.*
- *the notified body shall ensure that audit findings are appropriately and consistently classified in accordance with the requirements of this Regulation and with relevant standards or best practice documents developed or adopted by the MDCG.*



### **4.6.3. Product verification**

#### ***Assessment of the technical documentation***

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

- ***the allocation of appropriately qualified and authorised personnel for the examination of the individual aspects ( use of the device, biocompatibility, clinical evaluation, risk management, sterilisation, etc.),***
- ***the assessment of the technical documentation taking account of sections 4.6.4 to 4.6.6 of this Annex and the assessment of conformity of the design with the provisions of this Regulation. This examination shall include the assessment of the implementation and the results of incoming, in-process and final inspections. If further tests or other evidence is required to allow for the assessment of conformity with the requirements of the Regulation, the notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.***

#### ***Type-examinations***

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

- ***examine and assess the technical documentation taking account of sections 4.6.4 to 4.6.6 of this Annex and verify that the type has been manufactured in conformity with that documentation.***
- ***establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility.***
- ***document its rationale for the selection of those parameters.***
- ***carry out the appropriate examinations and tests in order to verify that the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation. This shall include all necessary tests to verify that the manufacturer has applied the relevant standards.***

- *agree with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the notified body.*
- *assume full responsibility for test results. Test reports submitted by the manufacturer can only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.*

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

##### *The notified body shall:*

- *have detailed documented procedures, sufficient expertise and facilities for the verification by examination and testing of every product according to Annex X Part B*
- *establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility in order to:*
  - = *for devices in class IIb: verify the conformity of the device with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them,*
  - = *for devices in class IIa: confirm the conformity with the technical documentation referred to in Annex II and with the requirements of this Regulation which apply to them.*
- *document its rationale for the selection of those parameters.*
- *have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Annex X, Part B, Section 5.*
- *have documented procedures providing for agreement with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the notified body.*
- *shall assume full responsibility for test results in accordance with documented procedures. Test reports submitted by the manufacturer can only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.*

#### **4.6.4. Pre-clinical evaluation assessment**

*The notified body shall have documented procedures in place for the review of manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects. The notified body shall examine, validate and verify that the manufacturer's procedures and documentation adequately address:*

- *the planning, conduct, assessment, reporting and, where appropriate, updating of the pre-clinical evaluation, specifically of*
  - = *a scientific preclinical literature search and*
  - = *preclinical testing for example laboratory testing, simulated use testing, computer modelling, animal models,*
- *the nature and duration of body contact and the specific associated biological risks,*
- *the interface with the risk management process, and*
- *the appraisal and analysis of the available preclinical data and its relevance to demonstrate conformity to the relevant requirements in Annex I.*

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

#### **4.6.5. Clinical evaluation assessment**

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

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

*These procedures shall take into consideration available C S, guidance and best practice documents.*

*The notified body assessment of clinical evaluation according to Annex XIII shall include:*

- *the intended use specified and claims for the device defined by the manufacturer,*
- *the planning of the clinical evaluation,*
- *the methodology for the literature search,*
- *relevant documentation from the literature search,*
- *the clinical investigation,*
- *validity of claimed equivalence to other devices, the demonstration of equivalence, the suitability and conclusions data from equivalent and similar devices,*
- *post market surveillance and clinical follow up,*
- *the clinical evaluation report.*
- *justifications in relation to not performing clinical investigations or post-market clinical follow up.*

*In relation to clinical data from clinical investigations included within the clinical evaluation, the notified body shall ensure that the conclusions drawn by the manufacturer are valid in the light of the clinical investigation plan submitted to the Competent Authority.*

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

#### **4.6.6. “Specific Procedures”**

*The notified body shall have detailed documented procedures, sufficient expertise and facilities for the “specific procedures” according to Annex VIII, sections 6 and 7, Annex IX, section 6 and Annex X, section 6 for which it is designated.*

*In the case of devices manufactured utilising tissues of animal origin as referred to in Commission Regulation (EU) No 722/2012 (i.e., TSE susceptible species), the notified body shall have documented procedures in place that follow the requirements referred to in that Regulation, including the preparation of a Summary Evaluation Report for the relevant Competent Authority.*

#### **4.7. Reporting**

*The notified body shall:*

- *ensure all steps of the conformity assessment are documented so that the conclusions of the assessment are clear and demonstrate compliance with the requirements of this Regulation and can provide objective evidence of this to personnel not directly involved in the assessment, for example designating authorities,*
- *ensure that records for quality management system audits are available that are sufficient to provide a discernible audit trail,*

- *clearly document the conclusions of its assessment of the clinical evaluation in a clinical evaluation assessment report,*
- *for each specific project provide a detailed report which shall be based on a standard format containing a minimum set of content determined by the Medical Device Coordination Group.*

*The notified body reports shall:*

- *clearly document the outcome of their assessments and draw clear conclusions on verifying the manufacturer's conformity to the requirements of this Regulation,*
- *make a recommendation for review and final decision making by the notified body; this recommendation shall be clearly signed off by the responsible notified body personnel,*
- *be provided to the manufacturer.*

#### **4.8. Review**

*The notified body shall prior to making a final decision ensure:*

- *that personnel assigned for review and decision making on specific projects are appropriately authorised and are different from those personnel who have conducted the assessments,*
- *that the report(s) and supporting documentation needed for decision making, including close out of non conformities raised during assessment, are complete and sufficient with respect to the scope of the application,*
- *that no unresolved nonconformities exist that prevent issuance of an EU certificate.*

#### **4.9. Decisions and Certifications**

*The notified body shall have documented procedures for decision making including responsibilities for decision making and the issuance, suspension, restriction and withdrawal of certificates. These procedures shall include the notification requirements according to Chapter V of this Regulation. These procedures shall allow it to:*

- *decide, based on the assessment documentation and additional information available whether the requirements of the Regulation are fulfilled, decide based on the results of their assessment of the clinical evaluation and risk management if the PMS plan, including whether the PMCF is adequate and on specific milestones for further review by the notified body of the up to date clinical evaluation,*
- *decide whether specific conditions or provisions need to be defined for the certification,*
- *decide, based on the novelty, risk classification, clinical evaluation and outputs from the risk analysis of the device, on a period for certification not exceeding five years,*
- *clearly document decision making and approval steps including approval by signature of the responsible individuals,*
- *clearly document responsibilities and mechanisms for communication of decisions, in particular, if the final signatory of a certificate differs from the decision maker(s) and does not fulfil the requirements outlined in section 3.2.7 of this Annex,*
- *issue a certificate(s) according to the minimum requirements defined in Annex XII for a period of validity not exceeding five years and shall indicate if there are specific conditions or limitations associated with the certification,*
- *issue a certificate(s) for the applicant alone and shall not issue certificates covering multiple entities,*
- *ensure that the outcome of the assessment and the resultant decision is notified to the manufacturer and entered into the European databank according to Article 45(4).*

#### **4.10. Changes and modifications**

*The notified body shall have documented procedures and contractual arrangements with manufacturers in place relating to the information obligations and the assessment of changes to:*

- *the approved quality management system(s) or the product-range covered,*
- *the approved design of a device,*
- *the intended use of or claims made for the device,*
- *the approved type of a device,*
- *any substance incorporated in or utilised for the manufacturing of a device and being subject to “specific procedures” according to section 4.6.6.*

*These procedures and contractual arrangements shall include processes for checking the significance of changes.*

*In accordance with its documented procedures, the notified body shall:*

- *ensure that manufacturers submit plans for such changes and relevant information relating to the change for prior approval,*
- *assess the changes proposed and verify whether after these changes the quality management system or the design/type of a device still meets the requirements of this Regulation,*
- *notify the manufacturer of its decision and provide a (supplement) report, which shall contain the justified conclusions of its assessment/audit.*



#### **4.11. Surveillance activities and post-certification monitoring**

*The notified body shall have documented procedures:*

- *defining how and when surveillance activities of manufacturers are to be conducted. These shall include provisions for unannounced visits to manufacturers and when applicable subcontractors and suppliers, carrying out product tests and the monitoring of compliance to any conditions on manufacturers associated with certification decisions, e.g. updates to clinical data at defined intervals,*
- *for screening relevant sources of scientific and clinical data and post-market information relating to the scope of its designation. Such information shall be taken into account in the planning and conducting of surveillance activities,*
- *to review vigilance information accessible according to Article 62 in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.*

*The notified body shall, upon receipt of information about vigilance cases from the manufacturer or the Competent Authorities, decide about the following options:*

- *that no action is required as the vigilance case is clearly not related to the certification granted,*
- *observation of the manufacturer's and Competent Authorities activities and the results of the manufacturer's investigation to allow a conclusion that the certification granted is not endangered or adequate corrective action has been performed,*
- *performance of extraordinary surveillance measures (document review, short-notice or unannounced audit, product testing, etc.) if it is likely that certification granted is endangered,*
- *increasing the frequency of surveillance audits*
- *reviewing specific products or processes during the next audit of the manufacturer, or*
- *any other relevant measure.*

*In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to:*

- *conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in 4.6,*
- *ensure that it adequately assesses the manufacturer's documentation on, and application of, the provisions on vigilance, the post-market surveillance plan (including post-market clinical follow-up),*
- *sample and test devices and technical documentations, during audits, according to pre-defined sampling criteria and testing procedures to ensure that the manufacturer continuously applies the approved quality management system,*
- *ensure that the manufacturer complies with the documentation and information obligations laid down in the respective Annex(es) of this Regulation and that his procedures take into account best practices in implementation of quality management systems,*
- *ensure that the manufacturer does not use quality management system or device approvals in a misleading manner,*
- *gather sufficient information to determine if the quality management system continues to comply with the requirements of this Regulation,*
- *if non-conformities are detected ask the manufacturer for corrections, corrective actions, when applicable preventative actions, and*
- *when necessary, impose specific restrictions on the relevant certificate or suspend or withdraw it.*

*The notified body shall, if listed as part of the conditions for certification:*

- *conduct an in depth review of the up to date clinical evaluation of the manufacturer based on post-market surveillance, post-market clinical follow up and clinical literature relevant to the condition being treated or similar devices,*
- *clearly document the outcome of this review and address any specific concerns or conditions to the manufacturer,*
- *ensure that the updated clinical evaluation is appropriately reflected in the Instructions For Use and Summary of Safety and Performance Data.*

#### **4.12 Re-certification**

*The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU - technical documentation assessment certificate or EU type-examination certificates shall occur at least every 5 years.*

*The notified body shall have documented procedures relating to EU technical documentation assessment renewals and EU type-examination renewals that shall require the manufacturer to submit a summary on changes and scientific findings for the device, including:*

- *all changes to the originally approved device, including changes not yet notified,*
- *experience gained from post market surveillance,*
- *experience from risk-management,*
- *experience from updating the proof of compliance with the general safety and performance requirements,*
- *experience from reviews of the clinical evaluation, including the results of any clinical investigations and post-market clinical follow up,*
- *changes of the requirements, of components of the device or of the scientific or regulatory environment,*
- *changes of applied or new (harmonised) standards, C S or equivalent documents,*

- *changes in medicine, scientific and technical knowledge, such as:*
  - = *new treatments,*
  - = *changes in test methods,*
  - = *new scientific findings on materials, components, etc., also with respect to biocompatibility,*
  - = *experience from market research on comparable devices,*
  - = *data from registers/registries,*
  - = *experience from clinical investigations with comparable devices.*

*The notified body shall have documented procedures to assess this information and shall pay particular attention to clinical data from post-market surveillance and PMCF activities undertaken during this period, including appropriate updates to manufacturer's clinical evaluation reports.*

*For the decision on the extension the notified body shall use the same methods and principles as for the initial decision. If necessary, separate forms shall be established taking into account the above mentioned steps, e.g. for application and application review.*

## CLASSIFICATION CRITERIA

### I. SPECIFIC DEFINITIONS FOR THE CLASSIFICATION RULES

#### 1. DURATION OF USE

- 1.1. 'Transient' means normally intended for continuous use for less than 60 minutes.
- 1.2. 'Short term' means normally intended for continuous use for between 60 minutes and 30 days.
- 1.3. 'Long term' means normally intended for continuous use for more than 30 days.

#### 2. INVASIVE AND ACTIVE DEVICES

- 2.1. 'Body orifice' means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma ~~or permanent tracheotomy~~.
- 2.2. 'Surgically invasive device' means
  - (a) an invasive device which penetrates inside the body through the surface of the body, **including through mucus membranes of body orifices** with the aid or in the context of a surgical operation **or other interventional procedure**;
  - (b) a device which produces penetration other than through a body orifice.
- 2.3. 'Reusable surgical instrument' means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures **such as** ~~for~~ cleaning, **disinfection** and ~~or sterilization~~ **sterilisation** have been carried out.

- 2.4. ‘Active therapeutic device’ means any active ~~medical~~ device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.
- 2.5. ‘Active device intended for diagnosis **and monitoring**’ means any active ~~medical~~ device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.
- 2.6. ‘Central circulatory system’ means the following blood vessels: *arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.*
- 2.7. ‘Central nervous system’ means the brain, meninges and spinal cord.
- 2.8. ***‘Injured skin or mucus membrane’ means an area of skin or a mucus membrane presenting a pathological change or change following disease or a wound.***

## II. IMPLEMENTING RULES FOR THE CLASSIFICATION RULES

1. Application of the classification rules shall be governed by the intended purpose of the devices.
2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

3. ~~Stand alone software~~, **Software**, which drives a device or influences the use of a device, falls automatically in the same class as the device.

If ~~stand alone~~ **the** software is independent of any other device, it is classified in its own right.

4. If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.
5. If several rules, or within the same rule several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and/or sub-rule resulting in the higher classification shall apply.
6. In calculating the duration referred to in ~~Chapter I~~, Section 1 continuous use means:
  - (a) The entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior and after the period when the use is interrupted or the device removed.
  - (b) The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.
7. A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition by itself or when it provides decisive information for the diagnosis.

### III. CLASSIFICATION RULES

#### 3. NON-INVASIVE DEVICES

##### 3.1. Rule 1

All non-invasive devices are in class I, unless one of the rules set out hereinafter applies.

##### 3.2. Rule 2

All non-invasive devices intended for channelling or storing blood, body liquids, *cells* or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in class IIa:

- if they may be connected to an active medical device in class IIa or a higher class,
- if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body *cells and* tissues, ***except for blood bags, which are in class IIb.***

In all other cases they are in class I.

##### 3.3. Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or ***administration*** ~~infusion~~ into the body are in class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in class IIa.

All non-invasive devices ***consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken off from the human body or with human embryos before their implantation or administration into the body are in class III*** ~~intended to be used for in vitro fertilisation (IVF) or assisted reproduction technologies (ART) which are liable to act with close contact on the inner or outer cells during the IVF/ART, such as washing, separating, sperm immobilising, cryoprotecting solutions, are in class IIb.~~



### 3.4. Rule 4

All non-invasive devices which come into contact with injured skin *or mucous membrane*:

- are in class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,
- are in class IIb if they are intended to be used principally *for injuries to skin or mucous membrane* ~~with wounds~~ which have breached the dermis and can only heal by secondary intent,
- are in class IIa in all other cases, including devices principally intended to manage the micro-environment ~~of a wound~~ *injured skin or mucous membrane*.

## 4. INVASIVE DEVICES

### 4.1. Rule 5

All invasive devices with respect to body orifices, other than surgically invasive devices ~~and~~ which are not intended for connection to an active medical device or which are intended for connection to *a Class I* ~~an active medical device classified as class I~~:

- are in class I if they are intended for transient use,
- are in class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in ~~the~~ a nasal cavity, in which case they are in class I,
- are in class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in ~~a~~ *the* nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in class IIa or a higher class, are in class IIa.

#### 4.2. Rule 6

All surgically invasive devices intended for transient use are in class IIa unless they:

- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,
- ~~are reusable surgical instruments, in which case they are in class I,~~
- are intended specifically for use in direct contact with the ***heart or central circulatory system or the*** central nervous system, in which case they are in class III,
- are intended to supply energy in the form of ionising radiation in which case they are in class IIb,
- have a biological effect or are wholly or mainly absorbed in which case they are in class IIb,
- are intended to administer ~~medicines~~ ***medicinal products*** by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in class IIb.

#### 4.3. Rule 7

All surgically invasive devices intended for short-term use are in class IIa unless they:

- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,
- are intended specifically for use in direct contact with the ***heart or central circulatory system or the*** central nervous system, in which case they are in class III,
- are intended to supply energy in the form of ionizing radiation in which case they are in class IIb,
- have a biological effect or are wholly or mainly absorbed in which case they are in class III,
- are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in class IIb.

#### 4.4. Rule 8

All implantable devices and long-term surgically invasive devices are in class IIb unless they:

- are intended to be placed in the teeth, in which case they are in class IIa,
- are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III,
- have a biological effect or are wholly or mainly absorbed, in which case they are in class III,
- are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in class III,
- are active implantable medical devices **and their accessories** ~~or implantable accessories to active implantable medical devices~~, in which case they are in class III,
- are breast implants, in which case they are in class III;
- are ~~hip, knee or shoulder~~ total and partial joint replacements, in which case they are in class III, with the exception of ancillary components such as screws, wedges, plates and instruments,
- are spinal disc replacement implants and implantable devices that come into contact with the spinal column, in which case they are in class III **with the exception of components such as screws, wedges, plates and instruments.**

### 5. ACTIVE DEVICES

#### 5.1. Rule 9

All active therapeutic devices intended to administer or exchange energy are in class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in class IIb.

All active devices intended to control or monitor the performance of active therapeutic devices in class IIb, or intended directly to influence the performance of such devices are in class IIb.

*All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are in class IIb.*

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable medical devices are in class III.

## 5.2. Rule 10

Active devices intended for diagnosis are in class IIa:

- if they are intended to supply energy which will be absorbed by the human body, except for devices ~~used~~ **intended** to illuminate the patient's body, in the visible spectrum,
- if they are intended to image *in vivo* distribution of radiopharmaceuticals,
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system **or diagnosis in clinical situations where the patient is in immediate danger**, in which case they are in class IIb.

Active devices intended to emit ionizing radiation and intended for ~~diagnostic or therapeutic~~ interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in class IIb.

## 5.3. Rule 11

All active devices intended to administer and/or remove ~~medicines~~ **medicinal products**, body liquids or other substances to or from the body are in class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in class IIb.

## 5.4. Rule 12

All other active devices are in class I.

## **6. SPECIAL RULES**

### **6.1. Rule 13**

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, with action ancillary to that of the devices, are in class III.

### **6.2. Rule 14**

All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in class IIb, unless they are implantable or long term invasive devices, in which case they are in class III.

### **6.3. Rule 15**

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in class IIb.

All devices intended specifically to be used for disinfecting or sterilising medical devices are in class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are in class IIb.

This rule does not apply to devices that are intended to clean medical devices other than contact lenses by means of physical action only.

### **6.4. Rule 16**

Devices specifically intended for recording of diagnostic images generated by X-ray, ~~MRI,~~  
~~ultra-sound or other diagnostic devices~~ are in class IIa.

### 6.5. Rule 17

All devices manufactured ~~utilising~~ **incorporating or consisting of** tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable are in class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable that are intended to come into contact with intact skin only.

### 6.6. ~~Rule 18~~

~~By derogation from other rules, blood bags are in class IIb.~~

### 6.7. Rule 19

All devices incorporating or consisting of nanomaterial are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.

### 6.8. ~~Rule 20~~

~~All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class III.~~

### 6.9 Rule 21

Devices that are composed of substances or combinations of substances **that are** intended to be ~~ingested, inhaled or administered rectally or vaginally~~ **introduced into the human body via a body orifice, or applied on skin** and that are absorbed by or **locally** dispersed in the human body are:

- in class III **if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose,**
- **in class III if they are intended to be introduced into the gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body,**
- **in class IIb in all other cases, except if they are applied on skin, in which case they are in class IIa.**

**6.10. Rule 22**

*All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are in class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product and those are intended to treat life threatening conditions. In this case they are in class IIb.*

**6.11. Rule 23**

*Active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determinates the patient management by the device are in class III, such as closed loop systems or automated external defibrillators.*

## CONFORMITY ASSESSMENT BASED ON ~~FULL A~~ QUALITY MANAGEMENT SYSTEM ASSURANCE AND ~~DESIGN EXAMINATION ON~~ ASSESSMENT OF THE TECHNICAL DOCUMENTATION

### Chapter I: Full Quality Assurance Management System Assurance

1. The manufacturer shall *establish, document, implement a* ~~ensure application of the~~ quality management system *as described in Article 8(5) of this Regulation and maintain its effectiveness through the life cycle* ~~approved for the design, manufacture and final inspection of the products~~ *devices* concerned. *The manufacturer shall ensure the application of the quality management system* as specified in Section 3 and is subject to audit as laid down in Sections 3.3 and 3.4 and to the surveillance as specified in Section 4.
  
2. ~~The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 17 and Annex III for the device model covered by the conformity assessment procedure. By issuing a declaration of conformity the manufacturer ensures and declares that the devices concerned meet the provisions of this Regulation which apply to them.~~
  
3. **Quality management system assessment**
  - 3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:
    - the name and address *of the registered place of business* of the manufacturer and any additional manufacturing site covered by the quality management system, and, if the application is lodged by the authorised representative, his name and *the* address *of his registered place of business* as well,
    - all the relevant information on the device or ~~device category/~~*group of devices* covered by the *quality management system* ~~procedure~~,



- a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system ~~that has been refused by another notified body,~~
- **a draft of an EU declaration of conformity in accordance with Article 17 and Annex III for the device model covered by the conformity assessment procedure,**
- the documentation on the quality management system,
- a **documented** description of the procedures in place to fulfil the obligations imposed by the quality management system ~~approved~~ **and required by this Regulation** and the undertaking by the manufacturer to apply these procedures,
- a description of the procedures in place to keep the ~~approved~~ quality management system adequate and efficacious and the undertaking by the manufacturer to apply these procedures,
- the documentation on the post-market surveillance plan, including, when applicable, a plan for the post-market clinical follow-up, and the procedures put in place to ensure compliance with the obligations emanating from the provisions on vigilance set out in Articles 61 to 66,
- a description of the procedures in place to keep up to date the post-market surveillance plan, including, when applicable, a plan for the post-market clinical follow-up, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 61 to 66 as well as the undertaking by the manufacturer to apply these procedures.

3.2. **Implementation** ~~Application~~ of the quality management system shall ensure ~~that the~~ **compliance** ~~devices conform to~~ **with** the provisions of this Regulation ~~which apply to them at every stage, from design to final inspection.~~ All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of **a quality manual and** written policies and procedures such as quality programmes, quality plans, ~~quality manuals~~ and quality records.

Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

- (a) the manufacturer's quality objectives;
- (b) the organisation of the business and in particular:
  - the organisational structures **with clear assignment to procedures**, the responsibilities of the managerial staff and their organisational authority ~~where quality of design and manufacture of the products is concerned~~,
  - the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and of ~~product~~ **device**, including control of ~~products~~ **devices** which fail to conform,
  - where the design, manufacture and/or final ~~inspection~~ **verification** and testing of the ~~products~~ **devices**, or elements **of any of these** thereof, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,
  - where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;
- (c) the procedures and techniques for monitoring, verifying, validating and controlling the design (**including procedures for preclinical and clinical evaluation**) of the devices ~~and, including~~ the corresponding documentation as well as the data and records arising from those procedures and techniques; **where these procedures and techniques shall specifically address:**
  - **the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures,**
  - **identification of applicable general safety and performance requirements and solutions to address these, under consideration of applicable C S and harmonized standards or equivalent solutions,**

- *the risk management according to section I.2 of Annex I,*
  - *the clinical evaluation, according to Article 49 and Annex XIII, including post market clinical follow-up planning,*
  - *the solutions to address the applicable specific requirements regarding design and construction, including appropriate preclinical evaluation, addressing specifically section II of Annex I,*
  - *the solutions to address the applicable specific requirements regarding the information to be supplied with the device, addressing specifically section III of Annex I,*
  - *the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture,*
  - *management of design or quality management system changes;*
- (d) the ~~inspection~~ **verification** and quality assurance techniques at the manufacturing stage and in particular:
- the processes and procedures which will be used, particularly as regards sterilisation, ~~purchasing~~ and the relevant documents,
  - ~~the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;~~
- (e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it shall be possible to trace back the calibration of the test equipment adequately.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annex II.

### 3.3. Audit

- (a) The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 3.2. ***Where the manufacturer uses a harmonised standard or a CS related to quality management system, it shall assess conformity with those standards or CS.*** Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonised standards or CFS conform to the requirements covered by the standards or CFS.
- (b) The ~~assessment~~ ***audit*** team shall include at least one member with past experience of assessments of the technology concerned ***in accordance with section 4.4 of Annex VI.*** ***In circumstances where this experience is not immediately obvious or applicable the notified body must provide a documented rationale for the allocation of this auditor.*** The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to ~~inspect~~ ***verify*** the manufacturing and other relevant processes.

- (c) Moreover, in the case of devices falling into class IIa or IIb the **quality management system assessment shall be accompanied by the assessment of technical documentation in accordance with the provisions 5.3a. to 5.3e. of Chapter II of this Annex for the selected devices.** ~~audit procedure shall include an assessment, on a representative basis, of the design documentation within the technical documentation as referred to in Annex II of the device(s) concerned.~~ In choosing representative sample(s) **device(s)**, the notified body shall take into account **the guidance developed and published by the MDCG according to Article 80 and in particular ~~take into account~~** the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical, ~~or~~ biological **or clinical** properties) that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample(s) taken.
- (d) If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU ~~full~~ quality assurance **management system** certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the audit and a reasoned ~~assessment~~ **report**.

3.4. The manufacturer shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the ~~product~~ **device-range** covered. The notified body shall assess the changes proposed, **determine the need for additional audits** and verify whether after these changes the quality management system still meets the requirements referred to in Section 3.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the **assessment, and where applicable, conclusions of additional audits** ~~and a reasoned assessment~~. The approval of any substantial change to the quality management system or the ~~product~~ **device-range** covered shall take the form of a supplement to the EU ~~full~~ quality assurance **management system** certificate.

#### 4. Surveillance assessment

- 4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.
- 4.2. The manufacturer shall authorise the notified body to carry out all the necessary audits, including ~~inspections~~ **site audits**, and supply it with all relevant information, in particular:
- the documentation on the quality management system,
  - the documentation on **any findings and conclusions resulting from the application of the post-market surveillance plan, including a *the* post-market clinical follow-up *plan for a selection of devices*, as well as, if applicable, any findings resulting from the application of the post-market surveillance plan, including the post-market clinical follow-up**, and of the provisions on vigilance set out in Articles 61 to 66,
  - the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests, the solutions adopted regarding the risk-management as referred to in Section 2 of Annex I, pre-clinical and clinical evaluation,
  - the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
- 4.3. The notified body shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan, ~~and shall supply the manufacturer with an assessment report~~. This shall include ~~inspections~~ **audits** on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such ~~inspections~~ **on-site audits**, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with an ~~inspection~~ **surveillance audit** report and, if a test has been carried out, with a test report.

- 4.4. The notified body shall randomly perform unannounced factory ~~inspections~~ **on-site audits** to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment. The notified body shall establish a plan for the unannounced ~~inspections~~ **on-site audits** which must not be disclosed to the manufacturer.

Within the context of such unannounced ~~inspections~~ **on-site audits**, the notified body shall ~~check~~ **test** an adequate sample from the production or the manufacturing process to verify that the manufactured device is in conformity with the technical documentation ~~and/or design dossier~~. Prior to the unannounced ~~inspection~~ **on-site audits**, the notified body shall specify the relevant sampling criteria and testing procedure.

Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation ~~and/or design dossier~~. Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer with an ~~inspection~~ **on-site audit** report which shall include, if applicable, the result of the sample ~~check~~ **test**.

- 4.5. In the case of devices classified as class IIa or class IIb, the surveillance assessment shall also include ~~the assessment of the design documentation within~~ the technical documentation **in accordance with the provisions 5.3a to 5.3e of Chapter II of this Annex** of the device(s) concerned on the basis of further representative sample(s) chosen in accordance with the rationale documented by the notified body in accordance with point (c) of Section 3.3.

In the case of devices classified as class III, the surveillance assessment shall also include a ~~check~~ **test** of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, the coherence between the quantities of produced or purchased parts and/or materials and the quantities of finished ~~products~~ **devices**.

- 4.6. The notified body shall ensure that the composition of the assessment team assures experience with the *evaluation of the devices, systems and processes* ~~technology~~ concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall not lead [and attend] an audit for more than three consecutive years in respect to the same manufacturer.
- 4.7. If the notified body establishes a divergence between the sample taken from the production or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

## **Chapter II: ~~Design dossier examination~~ *Assessment of the technical documentation***

### **5. ~~Examination of the design~~ *Assessment of the technical documentation, applicable to devices classified as class III***

- 5.1. In addition to the obligations imposed by Section 3, the manufacturer shall lodge with the notified body referred to in Section 3.1 an application for ~~examination~~ *assessment* of the ~~design dossier~~ *technical documentation* relating to the device which he plans to ~~manufacture~~ *place on the market or put into service* and which falls into the device category *is* covered by the quality management system referred to in Section 3.
- 5.2. The application shall describe the design, manufacture and performances of the device in question. It shall include the technical documentation as referred to in Annex II; ~~where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.~~



5.3. The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned ***and its clinical application***. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the ***relevant*** requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

~~The notified body shall provide the manufacturer with an EU design examination report.~~

***5.3a. The notified body shall review the clinical evidence presented by the manufacturer and the related clinical evaluation conducted. The notified body shall employ device reviewers with sufficient clinical expertise, including the use of external clinical expertise with direct and current experience of the device in question or the clinical condition in which it is utilised, for the purposes of this review.***

***5.3b. The notified body shall, in circumstances when the clinical evidence is based on data, in total or in part, from devices which are claimed to be equivalent to the device under assessment, assess the suitability of this route, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalency, the relevance and adequacy of the data to demonstrate conformity. For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the notified body shall assess that specific claims are supported by specific preclinical and clinical data in the risk analysis.***

***5.3c. The notified body shall ensure the adequacy of the clinical evidence and the clinical evaluation and verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. This review should include consideration of the adequacy of the benefit-risk assessment and management, instructions for use, user training, manufacturer's post-market surveillance plan, and include the need for, and adequacy of the post-market clinical follow up plan proposed, where applicable.***

**5.3d. Based on its assessment of the clinical evidence, the clinical evaluation, and the benefit-risk assessment the notified body shall consider if specific milestones are required to be defined to allow for review by the notified body on updates to the clinical evidence based on post market surveillance and post-market clinical follow up data.**

**5.3e. The notified body shall clearly document the outcome of its assessment in the clinical evaluation assessment report.**

5.4. The notified body shall provide the manufacturer with an ~~EU design-examination~~ report **on the technical documentation assessment, including a clinical evaluation assessment report.** If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an ~~EU design-examination~~ **technical documentation assessment** certificate. The certificate shall contain the conclusions of the ~~examination~~ **assessment**, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the device.

5.5. Changes to the approved design shall receive further approval from the notified body which issued the ~~EU design-examination~~ **technical documentation assessment** certificate wherever the changes could affect ~~conformity with the general safety and performance requirements of the device Regulation or with the conditions prescribed for use of the device.~~ **Where the applicant plans to introduce any of the above mentioned changes he shall inform the notified body which issued the EU design-examination technical documentation assessment certificate thereof of any planned changes to the approved design.** The notified body shall ~~examine~~ **assess** the planned changes **and decide whether the planned changes require a new conformity assessment in accordance with Article 42 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes,** notify the manufacturer of its decision and, **where the changes are approved,** provide him with a supplement to the ~~EU design-examination technical documentation assessment certificate~~ report. The approval of any change to the approved design shall take the form of a supplement to the ~~EU design-examination certificate~~.

## 6. Specific procedures

### 6.0. Procedure in the case of implantable ~~[and-invasive]~~ devices classified as class III ~~[which are listed in annex XVa]:~~

- (a) *The notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in Article 49(5), prepare a clinical evaluation assessment report which concludes on the clinical evidence provided by the manufacturer, in particular concerning the benefit/risk determination, the consistency with the intended purpose and the PMCF plan referred to in article 8(6) and part B of Annex XIII.*

*The notified body shall transmit its clinical evaluation assessment report, along with the clinical evaluation documentation of the manufacturer referred to in ~~points~~ Sections 6.1(c) and (d) of Annex II, to the Commission, ~~at least 30 days prior to the examination of the matter by the relevant expert panel.~~ The Commission shall immediately transmit these documents to the relevant expert panel referred to in article 81a.*

- (b) *The notified body may be requested to present its conclusion to the expert panel concerned.*
- (c) *~~The~~ Without prejudice to point (ca), the expert panel shall ~~may~~ provide, within a period of ~~30~~ 60 days, a scientific opinion on the clinical ~~evidence~~ evaluation assessment report of the notified body based on the clinical evidence provided by the manufacturer, in particular concerning the benefit/risk determination, the consistency with the medical indication(s) and the PMCF plan.*
- (ca) *The expert panel may decide not to provide a scientific opinion, in which case it shall inform the notified body as soon as possible and in any event within 15 days together with the reasons for its decision, whereupon the notified body shall proceed with the conformity assessment procedure.*

*(cbæ) in case no opinion has been delivered within ~~the delay~~ a period of 30 60 days, the notified body can proceed with the assessment of the conformity of that device. ~~In case the expert panel decides not to provide a scientific opinion, this [together with a rational for its decision] shall be communicated as soon as possible but within the period of 15 days, and the notified body will proceed with the conformity assessment procedure;~~*

*(d) The notified body shall give due consideration to the views expressed in the scientific opinion of the expert panel. In case the expert panel has found that the level of clinical evidence is not sufficient or otherwise gives rise to serious concerns about the benefit/risk determination, the consistency with the intended purpose and the PMCF plan, the notified body may, if necessary, advise the manufacturer to restrict the purpose use of the device to certain numbers or groups of patients, to limit the duration of validity of the certificate, to undertake specific PMCF studies, to adapt the instructions for use or the summary of safety and clinical performance, or impose other restrictions in its conformity assessment report. The notified body shall duly justify where it has not followed the advice of expert panel in its conformity assessment report.*

*~~In case the expert panel has found that the level of clinical evidence is not sufficient or otherwise gives rise to serious concerns about the benefit/risk determination, the consistency with the intended purpose and the PMCF plan, the notified body shall explicitly address these concerns before issuing the certificate and document it in its conformity assessment report.~~*

## **6.1. Procedure in the case of devices incorporating a medicinal substance**

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, with action ancillary to that of the device, the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

- (b) Before issuing an EU ~~design examination~~ **technical documentation assessment** certificate, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA'), acting particularly through its Committee on Human Medicinal Products in accordance with Regulation (EC) No 726/2004, on the quality and safety of the substance including the benefit/risk of the incorporation of the substance into the device. Where the device incorporates a human blood or plasma derivative or a substance that, if used separately may be considered to be a medicinal product falling exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA.
- (c) When issuing its opinion, the medicinal products competent authority or the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.
- (d) The ~~opinion of the medicinal products competent authority or the EMA shall be drawn up~~ **provide to the notified body its opinion**
- ~~within 150 days after receipt of valid documentation if the substance subject to the consultation is authorised in accordance with Directive 2001/83/EC; or~~
  - within 210 days after receipt of valid documentation ~~in other cases.~~
- (e) The scientific opinion of the medicinal products competent authority or the EMA, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.

- (f) Before **any** changes ~~is~~ **are** made with respect to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the manufacturer shall inform the notified body of the changes which shall consult the ~~medicinal products competent~~ authority that was involved in the initial consultation, in order to confirm that the quality and safety of the ancillary substance are maintained. The ~~medicinal products competent~~ authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk of the addition of the substance in the device. It shall provide its opinion within ~~60~~ **30** days after receipt of the valid documentation regarding the changes. ***The notified body shall not deliver the supplement to the EU technical documentation assessment certificate if the scientific opinion is unfavourable. It shall convey its final decision to the authority concerned.***
- (g) When the ~~medicinal products competent~~ authority that was involved in the initial consultation has obtained information on the ancillary substance, which could have an impact on the established benefit/risk of the addition of the substance in the device, it shall provide the notified body with advice whether this information has an impact on the established benefit/risk of the addition of the substance in the device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

## 6.2. Procedure in the case of devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable

- (a) For devices manufactured utilising *derivatives of* tissues or cells of human origin, ~~or their derivatives,~~ that are covered by this Regulation in accordance with point (ea) of Article 1(2) *and devices that incorporate, as an integral part, tissues or cells of human origin or their derivatives covered by Directive 2004/23/EC, with action ancillary to that of the device,* the notified body shall, prior to issuing an EU ~~design-examination~~ *technical documentation assessment* certificate, *seek a scientific opinion from one of* ~~submit to the competent authority~~ *authorities* designated by the Member States in accordance with Directive 2004/23/EC (hereinafter referred to as 'human tissues and cells competent authority') ~~in which it is established~~ *on the aspects related to the donation, procurement and testing and/or the benefit/risk of the incorporation of the tissues or cells of human origin or their derivative into the device. The notified body shall submit* a summary of the preliminary conformity assessment which shall, among others, provide information about the non-viability of the human tissues or cells, their donation, procurement and testing and the benefit/risk of the incorporation of the human tissues or cells *or their derivatives* into the device
- (b) Within ~~90~~ *120* days after receipt of valid documentation, the ~~human tissues and cells competent authority may~~ *shall submit provide to the notified body* ~~comments its~~ *opinion* on aspects related to the donation, procurement and testing and/or the benefit/risk of the incorporation of the human tissues or cells into the device.

- (c) ***The scientific opinion of the human tissues and cells competent authority, and any possible update, shall be included in the documentation of the notified body concerning the device.*** The notified body shall give due consideration to ***the views expressed in the scientific opinion when making its decision*** ~~any comments received in accordance with point (b).~~ ***The notified body shall not deliver the certificate if the scientific opinion is unfavourable.*** It shall convey ***its final decision to the human tissues and cells competent authority concerned.*** ~~to the human tissues and cells competent authority an explanation as regards this consideration, including any due justification not to follow the comment received, and its final decision regarding the conformity assessment in question. The comments of the human tissues and cells competent authority shall be included in the documentation of the notified body concerning the device.~~
- (d) ***Before any change is made with respect to a non-viable human tissue or cell incorporated in a device, in particular related to its donation, testing or procurement, the manufacturer shall inform the notified body of the intended changes which shall consult the authority that was involved in the initial consultation, in order to confirm that the quality and safety of the tissues or cells of human origin or their derivatives incorporated in the device are maintained. The shall take into account the data related to the usefulness of incorporation of the tissues or cells of human origin or their derivatives into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk of the addition of the tissues or cells of human origin or their derivatives in the device. It shall provide its opinion within 60 days after receipt of the valid documentation regarding the intended changes. The notified body shall not deliver a supplement to the EU technical documentation assessment certificate if the scientific opinion is unfavourable. It shall convey its final decision to the human tissues and cells competent authority concerned.***



- (e) *In the case of devices manufactured utilising tissue which is rendered non-viable or non-viable products derived from animal tissue, as referred to in Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin, the notified body shall apply particular requirements laid down in that Regulation,*

**6.3. Procedure in the case of devices that are composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body**

- (a) *For devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, the quality and safety of the device shall be verified where applicable and limited to the requirements not covered by this Regulation, in accordance with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions.*
- (c) *In addition, for devices, or their products of metabolism, that are absorbed by the human body in order to achieve their intended purpose, the notified body shall seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA'), acting particularly through its Committee on Human Medicinal Products in accordance with Regulation (EC) No 726/2004, on the compliance of the device with the relevant requirements laid down in Annex I to Directive 2001/83/EC.*

- (d) *The opinion of the medicinal products competent authority or the EMA shall be drawn up within 150 days.*
- (e) *The scientific opinion of the medicinal products competent authority or the EMA, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.*

**7. Batch verification in the case of devices incorporating a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(4)**

Upon completing the manufacture of each batch of devices that incorporate a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(4), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

### Chapter III: Administrative provisions

8. The manufacturer or *where the manufacturer does not have a registered place of business in a Member State* his authorised representative shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:
- the *EU* declaration of conformity,
  - the documentation referred to in the ~~fourth~~ *fifth* indent of Section 3.1 and in particular the data and records arising from the procedures referred to in point (c) of Section 3.2,
  - the changes referred to in Section 3.4,
  - the documentation referred to in Section 5.2, and
  - the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.3, 5.4. and 5.5.
9. Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the first sentence of the preceding paragraph in case the manufacturer, or his authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of this period.

## CONFORMITY ASSESSEMENT BASED ON TYPE EXAMINATION

1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a *device, including its technical documentation and relevant life cycle processes and a corresponding* representative sample of the production covered fulfil the relevant provisions of this Regulation.

### 2. Application

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorized representative,
- the technical documentation referred to in Annex II ~~needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the ‘type’, with the requirements of this Regulation; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.~~ The applicant shall make a *representative sample of the production in question, hereinafter referred to as ‘type’* available to the notified body. The notified body may request other samples as necessary,
- a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that has been refused by another notified body *or that has been withdrawn by the manufacturer before the other Notified Body made its final assessment.*

### 3. Assessment

The notified body shall:

- 3.1. *examine the application employing staff with proven knowledge and experience regarding the technology concerned and its clinical application. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the relevant requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.*
  - 3.1a. *examine and assess the technical documentation for conformity with the requirements of this regulation applicable to the device, including assessment of relevant life cycle processes, as e.g. risk management, clinical evaluation and PMS and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable specifications of the standards referred to in Article 6 or CTS, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;*
  - 3.1b. *~~shall~~ review the clinical evidence presented by the manufacturer and the related clinical evaluation conducted. The notified body shall employ device reviewers with sufficient clinical expertise, including the use of external clinical expertise with direct and current experience of the device in question or the clinical condition in which it is utilised, for the purposes of this review;*
  - 3.1c. *in circumstances when the clinical evidence is based on data, in total or in part, from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of this route, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalency, the relevance and adequacy of the data to demonstrate conformity. For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the notified body shall assess that specific claims are supported by specific preclinical and clinical data in the risk analysis.*

**3.1d. clearly document the outcome of its assessment in the clinical evaluation assessment report.**

- 3.2. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation if the standards referred to in Article 6 or CFS have not been applied; if the device is to be connected to other device(s) in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device(s) having the characteristics specified by the manufacturer;
- 3.3. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;
- 3.4. agree with the applicant on the place where the necessary assessments and tests will be carried out; **and**
- 3.5. draw up an EU type-examination report on the results of the assessments and tests carried out under paragraphs 3.1 to 3.3.**

#### **4. Certificate**

If the type conforms to the provisions of this Regulation, the notified body shall issue an EU type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the assessment, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body. ***The certificate shall be drawn up in accordance with Annex XII.***

## 5. Changes to the type

- 5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type *or of its intended purpose*.
- 5.2. Changes to the approved product *including limitations of its intended purpose and use* shall receive further approval from the notified body which issued the EU type-examination certificate wherever the changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.
- 5.3. *Changes to the intended purpose and use of the approved device, with the exception of limitations of the intended purpose and use, require a new application for a conformity assessment.*

## 6. Specific procedures

The provisions regarding the specific procedures in the case of *implantable devices classified as class III, or devices incorporating a medicinal substance, or devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable, or devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body* set out in Annex VIII, Section 6, apply with the provision that any reference to an EU design-examination *technical documentation assessment* certificate shall be understood as reference to an EU type-examination certificate.

## 7. Administrative provisions

The manufacturer or his authorised representative *where the manufacturer does not have a registered place of business in a Member State* shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the documentation referred to in the second indent of Section 2,
- the changes referred to in Section 5,
- copies of EU type-examination certificates *and reports* and their additions/*supplements*.

Section 9 of Annex VIII shall apply.



## CONFORMITY ASSESSEMENT BASED ON PRODUCT CONFORMITY VERIFICATION

1. The objective of the conformity assessment based on product conformity verification is to ensure that devices conform to the type for which an EU type-examination certificate has been issued and meet the provisions of this Regulation which apply to them, *including continuous life cycle processes as e.g. risk management, clinical evaluation and PMS*.
2. Where an EU type-examination certificate has been issued in accordance with Annex IX, the manufacturer can either apply the procedure set out in part A (production quality assurance) or the procedure set out in part B (product verification).
3. By way of derogation from Sections 1 and 2, this Annex can also be applied by manufacturers of devices classified as class IIa coupled with the drawing up of a technical documentation as set out in Annex II.

### PART A: PRODUCTION QUALITY ASSURANCE

1. The manufacturer shall ensure application of the quality management system approved for the manufacture of the devices concerned and carry out the final inspection, as specified in Section 3, and is subject to the surveillance referred to in Section 4.
2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 17 and Annex III for the device model covered by the conformity assessment procedure. By issuing an EU declaration of conformity the manufacturer ensures and declares that the devices concerned conform to the type described in the EU type-examination certificate and meet the provisions of this Regulation which apply to them.

### 3. Quality management system

3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:

- all elements listed in Section 3.1 of Annex VIII,
- the technical documentation as referred to in Annex II for the types approved; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request;
- a copy of the EU-type examination certificates referred to in Section 4 of Annex IX; if the EU-type examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation *and its updates* and the certificates issued is ~~sufficient~~ *necessary*.

3.2. ~~Application~~ *Implementation* of the quality management system shall ensure ~~that the~~ *compliance* ~~devices conform to~~ *with* the type described in the EU type-examination certificate and to the provisions of this Regulation which apply to them at every stage. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of *a quality manual and* written policies and such as quality programmes, quality plans, ~~quality manuals~~ and quality records.

It shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 3.2 of Annex VIII.

3.3. The provisions of points (a) and (b) of Section 3.3 of Annex VIII apply.

If the quality management system ensures that the devices conform to the type described in the EU type-examination certificate and conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality assurance certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the inspection and a reasoned assessment.

3.4. The provisions of Section 3.4 Annex VIII apply.

#### **4. Surveillance**

The provisions of Section 4.1, the first, second and fourth indents of Section 4.2, Section 4.3, Section 4.4, Section 4.6 and Section 4.7 of Annex VIII apply.

In the case of devices classified as class III, the surveillance shall also include a check of the coherence between the quantity of produced or purchased raw material or crucial components approved for the type and the quantity of finished products.

#### **5. Batch verification in the case of devices incorporating a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(4)**

Upon completing the manufacture of each batch of devices that incorporate a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(4), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

## 6. Administrative provisions

The manufacturer or *where the manufacturer does not have a registered place of business in a Member State* his authorised representative shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the EU declaration of conformity,
- the documentation referred to in the fourth indent of Section 3.1 of Annex VIII,
- the documentation referred to in the seventh indent of Section 3.1 of Annex VIII, including the EU type-examination certificate referred to in Annex IX,
- the changes referred to in Section 3.4 of Annex VIII, and
- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3 and 4.4 of Annex VIII.

Section 9 of Annex VIII shall apply.

## 7. Application to devices classified as class IIa

7.1. By way of derogation from Section 2, by virtue of the EU declaration of conformity the manufacturer ensures and declares that the devices in class IIa are manufactured in conformity with the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them.

7.2. For devices in class IIa the notified body shall assess, as part of the assessment in Section 3.3, ~~on a representative basis,~~ the technical documentation as referred in Annex II **for the selected devices** for compliance with the provisions of this Regulation; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.

In choosing representative sample(s) *of devices* the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (*e.g.* with regard to physical, chemical, ~~or~~ biological *or clinical* properties) that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample(s) *of devices* taken.

- 7.3. If the assessment in accordance with Section 7.2. confirms that the devices in class IIa conform to the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this section of this Annex.
- 7.4. Further samples *of devices* shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.
- 7.5. By way of derogation from Section 6, the manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:
- the EU declaration of conformity,
  - the technical documentation referred to in Annex II,
  - the certificate referred to in Section 7.3.

Section 9 of Annex VIII shall apply.

## PART B: PRODUCT VERIFICATION

1. Product verification is the procedure whereby after examination of every manufactured device the manufacturer, by issuing a EU declaration of conformity in accordance with Article 17 and Annex III, ensures and declares that the devices which have been subject to the procedure set out in Sections 4 and 5 conform to the type described in the EU type-examination certificate and meet the requirements of this Regulation which apply to them, ***including continuous life cycle processes***.
2. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which conform to the type described in the EU type-examination certificate and to the requirements of the Regulation which apply to them. Before the start of manufacture, the manufacturer shall prepare documents defining the manufacturing process, in particular as regards sterilisation where necessary, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

In addition, for devices placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall apply the provisions of Sections 3 and 4 of Part A of this Annex.

3. The manufacturer shall undertake to institute and keep up to date a post-market surveillance plan, including a post-market clinical follow-up, and the procedures ensuring compliance with the obligations ***of the manufacturer*** emanating from the provisions on vigilance ***and post-market surveillance*** set out in ~~Articles 61 to 66~~ ***Chapter VII***.

4. The notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the device, with the requirements of the Regulation by examining and testing every product as specified in Section 5.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

## **5. Verification by examination and testing of every product**

- 5.1. Every device is examined individually and the appropriate physical or laboratory tests defined in the relevant standard(s) referred to in Article 6 or equivalent tests *and assessments* shall be carried out in order to verify, where appropriate, the conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.
- 5.2. The notified body shall affix, or have affixed its identification number to each approved device and shall draw up an EU product verification certificate relating to the tests *and assessments* carried out.

## **6. Batch verification in the case of devices incorporating a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(4)**

Upon completing the manufacture of each batch of devices that incorporate a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(4), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

## **7. Administrative provisions**

The manufacturer or his authorised representative shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the documentation referred to in Section 2,
- the certificate referred to in Section 5.2,
- the EU type-examination certificate referred to in Annex IX.

Section 9 of Annex VIII shall apply.

## **8. Application to devices classified as class IIa**

- 8.1. By way of derogation from Section 1, by virtue of the EU declaration of conformity the manufacturer ensures and declares that the devices in class IIa are manufactured in conformity with the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them.
- 8.2. The verification conducted by the notified body in accordance with Section 4 is intended to confirm the conformity of the devices in class IIa with the technical documentation referred to in Annex II and with the requirements of this Regulation which apply to them.
- 8.3. If the verification in accordance with Section 8.2. confirms that the devices in class IIa conform to the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this section of this Annex.



8.4. By way of derogation from Section 7, the manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the technical documentation referred to in Annex II,
- the certificate referred to in Section 8.3.

Section 9 of Annex VIII shall apply.

## **CONFORMITY ASSESSMENT PROCEDURE FOR CUSTOM-MADE DEVICES**

1. For custom-made devices, *other than implantable class III devices*, the manufacturer or his authorised representative shall draw up the statement containing the following information:
  - the name and address of the manufacturer, and of any additional manufacturing sites,
  - if applicable, the name and address of the authorised representative,
  - data allowing identification of the device in question,
  - a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code,
  - the name of the ~~doctor of medicine, dental practitioner or any other~~ person authorised by national law by virtue of this person's professional qualifications who made out the prescription and, where applicable, the name of the health institution concerned,
  - the specific characteristics of the product as indicated by the prescription,
  - a statement that the device in question conforms to the general safety and performance requirements set out in Annex I and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds,
  - where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Commission Regulation (EU) No 722/2012.

2. The manufacturer shall undertake to keep available for the competent national authorities the documentation, indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Regulation.

The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph;

3. The information contained in the ~~declaration~~ **statement** concerned by this Annex shall be kept for a period of time of at least five years after the device has been placed on the market. In the case of implantable devices the period shall be at least 15 years.

Section 9 of Annex VIII shall apply.

4. The manufacturer shall undertake to review and document experience gained in the post-production phase, including a PMCF referred to in Part B of Annex XIII, and to implement appropriate means to apply any necessary corrective action. This undertaking shall include an obligation for the manufacturer to notify, in accordance with Article 61(4) the competent authorities of any serious incidents and/or field safety corrective actions immediately on learning of them.

## **MINIMUM CONTENT OF CERTIFICATES ISSUED BY A NOTIFIED BODY**

### ***I. General Requirements***

- 1. Certificates shall be drawn up in one of the official languages of the Union;***
- 2. Each certificate shall refer to only one assessment conformity procedure;***
- 3. Certificates shall only be issued to one manufacturer (natural or legal person). The name and address of the manufacturer included in the certificate must be the same as registered in the electronic system referred to in Article 25 of this Regulation;***
- 4. The scope of the certificates must unambiguously describe the device(s) covered:***
  - (a) EU technical documentation assessment and EU type-examination certificates shall include a clear identification (name, model, type) of the device(s), the intended purpose (the same included by the manufacturer in the instructions for use and that has been assessed by the conformity assessment procedure), risk classification and the unit of use Basic UDI-DI as referred to in Article 24 paragraph 4b;***
  - (b) EU quality management system certificates shall include the identification of the devices or groups of devices, the risk classification and for devices classified as Class IIb the intended purpose;***
- 5. Irrespective of the description used in/with the certificate, the Notified Body must be able to demonstrate on request, which (individual) devices are covered by the certificate. The Notified Body must set out a system that enables the determination of the devices, including their classification, covered by the certificate;***
- 6. Certificates must contain, if applicable, a note that for the placing on the market of the device(s) covered by this certificate, another certificate according to this Regulation is required;***
- 7. EU quality management system certificates for class I devices shall include a statement that the Notified Body has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions/with the conformity of the device with metrological requirements, as applicable.***

8. *For tracking information, when the certificate replaces a previous one (i.e. supplemented, modified, re-issued), a note like “this certificates replaces certificate xyz from dd/mm/yyyy”, with the identification of the change shall be included.*

## **II. Minimum content of the certificates**

1. Name, address and identification number of the notified body;
2. name and address of the manufacturer and, if applicable, of the authorised representative;
3. unique number identifying the certificate;
- 3a. the single registration number of the manufacturer according to Article 25a paragraph 2;**
4. date of issue;
5. date of expiry;
6. data needed for the *unambiguous* identification of the device(s) or, *in case of certificates covering a quality management system, groups* categories of devices covered by the certificate (*see general requirements set out in Section I.4 of this Annex*) ~~including the intended purpose of the device(s) and the GMDN code(s) or internationally recognised nomenclature code(s);~~
- ~~7. if applicable, the manufacturing facilities covered by the certificate;~~
- 7a. if applicable, reference to a replaced previous certificate (see general requirements set out in Section I.8 of this Annex);**
8. reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;
9. examinations and tests performed, e.g. reference to relevant standards / test reports / audit report(s);
10. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device(s) covered;
11. if applicable, information about the surveillance by the notified body;
12. conclusions of the notified body’s *conformity* assessment *with regard to the relevant Annex*, ~~examination or inspection;~~
13. conditions for or limitations to the validity of the certificate;
14. legally binding signature of the notified body according to the applicable national law.

**CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP****PART A: CLINICAL EVALUATION**

1. To *plan, continuously* conduct *and document* a clinical evaluation, a manufacturer shall:
  - (a) *establish and update a clinical evaluation plan, which shall include at least:*
    - *an identify identification of the general safety and performance requirements that require support from relevant clinical data;*
    - *a specification of the intended ) purpose of the device;*
    - *a clear indication of specified target groups with clear indications and contraindications;*
    - *a detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters;*
    - *a specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side effects;*
    - *an indication and specification of parameters to be used to determine the acceptability of the benefit risk ratio for the various indications and intended purpose(s) of the device according to the state of the art in medicine;*
    - *an indication how risk/benefit issues relating to specific components (e.g. use of pharmaceutical, non-viable animal/human tissues) are to be addressed;*
    - *a clinical development plan indicating progression from exploratory (e.g. first-in-man studies, feasibility, pilot studies) to confirmatory investigations (e.g. pivotal clinical investigations) and PMCF according to Part B of this Annex with an indication of milestones and a description of potential acceptance criteria;*

- (b)- identify available clinical data relevant to the device and its intended use ***purpose and eventual gaps in clinical evidence*** generated through ***a systematic*** scientific literature search, ~~clinical experience and/or clinical investigations~~;
  - (c)- appraise the clinical data sets by evaluating their suitability for establishing the safety and performance of the device;
  - (d)- generate any new or additional clinical data needed to address outstanding issues ***by properly designed clinical investigations in accordance with the clinical development plan***;
  - (e)- analyse all relevant clinical data to reach conclusions about the safety and ***clinical*** performance (***including clinical benefits***) of the device.
2. ~~Confirmation of conformity with the requirements concerning the characteristics and performances referred to in Section 1 of Annex I, under the normal conditions of use of the device, and the evaluation of the undesirable side effects and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on clinical data.~~
  3. The clinical evaluation shall be thorough and objective, considering both favourable and unfavourable data. Its depth and extent shall be proportionate and appropriate to the nature, classification, intended use ***purpose***, manufacturer's claims and risks of the device in question.
  4. ~~Clinical data relating to another device may be relevant where equivalence is demonstrated of the device subject to clinical evaluation to the device to which the data relates. Equivalence can only be demonstrated when the device that is subject to clinical evaluation and the device to which the existing clinical data relates have the same intended purpose and when the technical and biological characteristics of the devices and the medical procedures, are similar to such an extent that there would be a clinically significant difference in the safety and performance of the devices.~~

**4a. A clinical evaluation can only be based on clinical data of a similar device for which equivalence to the device in question can be demonstrated. Technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:**

- **Technical: be of similar design; used under similar conditions of use; have similar specifications and properties (e.g. physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, software algorithms); use similar deployment methods (if relevant); have similar principles of operation and critical performance requirements.**
- **Biological: Use same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables.**
- **Clinical: Used for the same clinical condition or purpose (including similar severity and stage of disease), at the same site in the body, in a similar population (including age, anatomy, physiology); have same kind of user, have similar relevant critical performance according to the expected clinical effect for a specific intended ) purpose.**

**These characteristics shall be similar to such an extent that there would be no clinically significant difference in the clinical performance and safety of the device. Considerations of equivalence must always be based on proper scientific justification. Manufacturers must be able to clearly demonstrate that they have sufficient levels of access to the data on devices to which they are claiming equivalence in order to justify that claimed equivalence.**

~~5. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed, unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.~~



6. The results of the clinical evaluation and the clinical ~~data~~ **evidence** on which it is based shall be documented in the clinical evaluation report which shall support the assessment of the conformity of the device.

The clinical ~~data~~ **evidence** together with non-clinical data generated from non-clinical testing methods and other relevant documentation shall allow the manufacturer to demonstrate conformity with the general safety and performance requirements and shall be part of the technical documentation of the device in question.

## **PART B: POST-MARKET CLINICAL FOLLOW-UP**

1. Post-market clinical follow-up, hereinafter: PMCF, is a continuous process to update the clinical evaluation referred to in Article 49 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan. To this end, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which ~~is authorised~~ ~~to~~ bears the CE marking, **placed on the market or put into service within** its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, the continued acceptability of identified risks and to detect emerging risks on the basis of factual evidence.
2. The PMCF shall be performed pursuant to a documented method laid down in a PMCF plan.
  - 2.1. The PMCF plan shall specify the methods and procedures to proactively collect and evaluate clinical data with the aim of
    - (a) confirming the safety and performance of the device throughout its expected lifetime,
    - (b) identifying previously unknown side-effects and monitoring the identified side-effects and contra-indications,
    - (c) identifying and analysing emergent risks on the basis of factual evidence,

- (d) assuring the continued acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, and
- (e) identifying possible systematic misuse or off-label use of the device with a view to verify the correctness of its intended purpose.

2.2. The PMCF plan shall **include at least:** ~~lay down, in particular~~

- (a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;
- (b) the specific methods and procedures of PMCF to be applied **such as** evaluation of suitable registers or PMCF studies;
- (c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);
- (d) a reference to the relevant parts of the clinical evaluation report referred to in Section 6 of Part A of this Annex and to the risk management referred to in Section 2 of Annex I;
- (e) the specific objectives to be addressed by the PMCF;
- (f) an evaluation of the clinical data related to equivalent or similar devices,
- (g) reference to relevant **Common Specifications**, standards and guidance on PMCF ~~[CTS]~~.
- (h) a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer.**

3. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the **clinical evaluation report and the** technical documentation.

4. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 49 and Part A of this Annex and in the risk management referred to in Section 2 of Annex I. If through the PMCF the need for **preventive and/or** corrective measures has been identified, the manufacturer shall implement them.

## CLINICAL INVESTIGATIONS

### I. General requirements

#### 1. Ethical considerations

Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, ~~as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964, and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008.~~

#### 2. Methods

2.1. Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device as well as the safety, performance and benefit/risk related aspects referred to in Article 50(1); these investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions.

*The rationale for the design and chosen statistical methodology shall be presented as further described in Section 3.6 of this Annex.*

2.2. The procedures used to perform the investigations shall be appropriate to the device under ~~examination~~ *investigation*.

*2.2a. The research methodologies used to perform the investigation shall be appropriate to the device under investigation.*

- 2.3. Clinical investigations shall be performed ***according to the evaluation plan by a sufficient number of intended users and in a clinical environment that are representative of the intended normal conditions of*** circumstances ~~similar to the normal conditions of use of the device~~ ***in the target patient population. These shall be in line with the Clinical Evaluation Plan as referred to in Part A of Annex XIII.***
- 2.4. All the appropriate ***technical and functional*** features ***of the device***, ~~including in particular those involving the safety and performances of the device, and its~~ ***their*** effect on patients ***subject outcome*** shall be ***appropriately addressed and*** examined ***by the investigational design. A list of the technical and functional features of the device and related subject outcomes shall be provided.***
- 2.4a. The endpoints of the Clinical Investigation shall address the intended purpose, clinical benefits, performance and safety of the device. The endpoints shall be determined and assessed using scientifically valid methodologies. The primary endpoint shall be appropriate to the device and clinically relevant.***
- ~~2.5. The investigations shall be performed under the responsibility of a medical practitioner or another authorised qualified person in an appropriate environment.~~
- 2.6. The medical practitioner or other authorised person shall have access to the technical and clinical data regarding the device. ***Personnel involved in the conduct of an investigation shall be adequately instructed and trained in the proper use of the investigational device, the clinical investigation plan and good clinical practice. This training shall be verified and where necessary arranged by the sponsor and documented appropriately.***
- 2.7. The clinical investigation report, signed by the medical practitioner or other authorised person responsible, shall contain a critical evaluation of all the data collected during the clinical investigation, including negative findings.

## II. Documentation regarding the application for clinical investigation

For investigational devices covered by Article 50 the sponsor shall draw up and submit the application in accordance with Article 51 accompanied by the *following documents* ~~documentation~~ as *set out* ~~laid down~~ below:

### 1. Application form

The application form shall be duly filled in, containing information regarding:

- 1.1. Name, address and contact details of the sponsor and, if applicable, name, address and contact details of his contact person *or legal representative according to Article 50(2)* established in the Union.
- 1.2. If different from the Section 1.1., name, address and contact details of the manufacturer of the device intended for clinical investigation and, if applicable, of his authorised representative.
- 1.3. Title of the clinical investigation.
- 1.4. Single identification number in accordance with Article 51(1).
- 1.5. Status of the clinical investigation *application* (e.g. *i.e.* first submission, resubmission, significant amendment).
- 1.5a. Details/reference to the Clinical Evaluation Plan (e.g. including details of the design phase of the clinical investigation).**
- 1.6. If resubmission with regard to same device, previous date(s) and reference number(s) of earlier submission(s) or in the case of significant amendment, reference to the original submission. *The sponsor shall identify all of the changes from the previous submission together with a rationale for those changes, in particular, whether any changes have been made to address outcomes of previous Competent Authority or Ethics Committee reviews.*

- 1.7. If parallel submission for a clinical trial on a medicinal product in accordance with Regulation (EU) No ~~[...536/2014...]~~ [on clinical trials on medicinal products for human use], reference to the official registration number of the clinical trial.
- 1.8. Identification of the Member States, EFTA countries, Turkey and third countries in which the clinical investigation shall be conducted as part of a multicentre/multinational study at the time of application.
- 1.9. Brief description of the investigational device, ***its classification and other information necessary for the identification of the device and device type*** (~~e.g. name, GMDN code or internationally recognised nomenclature code, intended purpose, risk class and applicable classification rule according to Annex VII~~).
- 1.10. Information as to whether the device incorporates a medicinal substance, including a human blood or plasma derivative, or whether it is manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives.
- 1.11. Summary of the clinical investigation plan (objective(s) of the clinical investigation, number and gender of subjects, criteria for subject selection, subjects under 18 years of age, design of the investigation such as controlled and/or randomised studies, planned dates of commencement and of completion of the clinical investigation).
- 1.12. If applicable, information regarding a comparator device, ***its classification and other information necessary for the identification of the comparator device***.
- 1.13. Evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical investigation in accordance with the Clinical Investigation Plan.***
- 1.14. Details of the anticipated start date and duration of the investigation.***

**1.15. Details to identify the notified body, if the sponsor is using one at the point of application for clinical investigation.**

**1.16. Confirmation that the sponsor is aware that the competent authority may contact the ethics committee that is assessing or has assessed the application.**

**1.17. The statement referred to in section 4.1 of this Annex.**

## **2. Investigator's Brochure**

The investigator's brochure (IB) shall contain the clinical and non-clinical information on the investigational device that is relevant for the investigation and available at the time of application. **Any updates to the brochure or other relevant information that is newly available shall be brought to the attention of the investigators in a timely manner. The IB** shall be clearly identified and contain in particular the following information:

2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule according to Annex VII, design and manufacturing of the device and reference to previous and similar generations of the device.

2.2. Manufacturer's instructions for installation, **maintenance, maintaining hygiene standards** and use, including storage and handling requirements, as well as the label and instructions for use to the extent that this information is available. **In addition, information relating to any relevant training required.**

2.3. Pre-clinical **evaluation based on relevant pre-clinical** testing and experimental data, in particular regarding in design calculations, *in vitro* tests, *ex vivo* tests, animal tests, mechanical or electrical tests, reliability tests, **sterilisation validation**, software verification and validation, performance tests, evaluation of biocompatibility and biological safety, **as applicable.**

- 2.4. Existing clinical data, in particular
- of the relevant scientific literature available relating to the safety, performance, ***clinical benefits to patients***, design characteristics and intended purpose of the device and/or of equivalent or similar devices;
  - of other relevant clinical data available relating to the safety, performance, ***clinical benefits to patients***, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance, ***clinical benefit*** and safety related issues and any corrective actions taken;
- 2.5. Summary of the risk/benefit analysis and the risk management, including information regarding known or foreseeable risks, any undesirable effects, contra-indications and warnings.
- 2.6. In the case of devices that incorporates a medicinal substance, including a human blood or plasma derivative, or devices manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives, detailed information on the medicinal substance or on the tissues or cells, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to the substance or tissues, ~~or cells~~ ***or their derivatives, as well as substantiation of the added value of incorporation of these constituents to the clinical benefit and/or safety of the device.***
- 2.7. ~~Reference to harmonised or other internationally recognised standards~~ ***A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and Common Specifications applied, complied with in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as these standards and C S have not or only been partly fulfilled or are lacking.***



**2.7a. A detailed description as applicable of the clinical procedures and diagnostic tests used in the course of the clinical investigation and in particular information on any deviation from normal clinical practice.**

~~2.8. A clause that any updates to the IB or any other relevant information that is newly available shall be brought to the attention of the investigators.~~

### **3. Clinical Investigation Plan**

The clinical investigation plan (CIP) shall define the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation. It shall contain in particular the information as laid down below. If part of this information is submitted in a separate document, it shall be referenced in the CIP.

#### **3.1. General**

3.1.1. Identification of the clinical investigation and the CIP.

3.1.2. Identification of the sponsor – ***name, address and contact details of the sponsor and, if applicable, the name, address and contact details of his contact person/legal representative according to Article 50(2) established in the Union.***

3.1.3. Information on the principal investigator ***at each investigational site, the coordinating investigator for the investigation, the address details for each investigation site and the emergency contact details for the principal investigator at each site including their qualifications, and on the investigation site(s). The roles, responsibilities and qualifications of the various kinds of investigators have to be specified in the Clinical Investigation Plan.***

3.1.4. Overall synopsis of the clinical investigation.

- 3.2. Identification and description of the device, including its intended purpose, its manufacturer, its traceability, the target population, materials coming into contact with the human body, the medical or surgical procedures involved in its use and the necessary training and experience for its use, ***background literature search, the current state of the art in clinical care in the relevant field of application and the proposed benefits of the new device.***
- ~~3.3. Justification for the design of the clinical investigation.~~
- 3.4. Risks and ***clinical*** benefits of the device ~~and~~ ***to be examined, with justification of the corresponding specific clinical outcomes being used.***  
***Description of the relevance*** of the clinical investigation ***in the context of the state of the art of clinical practice.***
- 3.5. Objectives and hypotheses of the clinical investigation.
- 3.6. Design of the clinical investigation ***with justification of its scientific robustness and validity.***
- 3.6.1. General information such as type ***and phase*** of investigation with rationale for choice, endpoints, variables ***according to clinical evaluation plan.***
- 3.6.2. Information on the ***investigational*** device ~~to be used for the clinical investigation~~, on any comparator and on any other device or medication ***to be used in the clinical investigation.***
- 3.6.3. Information on subjects, ***selection criteria***, ~~including~~ size of investigation population, ***representativity of investigation population to target population*** and, if applicable, information on vulnerable populations ***subjects involved (e.g. children, immuno-compromised, elderly, pregnant women).***
- 3.6.3a. Details of measures to be taken to minimise bias (e.g. randomisation) and management of potential confounding factors.***

- 3.6.4. Description of the *clinical* procedures *and diagnostic methods* related to the clinical investigation *and in particular highlighting any deviation from normal clinical practice*.
- 3.6.5. Monitoring plan.
- 3.7. Statistical considerations, *with justification, including a power calculation for the sample size, if applicable*.
- 3.8. Data management.
- 3.9. Information about any amendments to the CIP.
- 3.10. Policy regarding *follow up and management of any* deviations from the CIP *at the investigational site and clear prohibition of use of waivers from the CIP*.
- 3.11. Accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical investigation and the return of unused, expired or malfunctioning devices.
- 3.12. Statement of compliance with the recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of clinical investigations of medical devices as well as with the applicable regulatory requirements.
- 3.13. *Description of the* Informed consent process.
- 3.14. Safety reporting, including definitions of adverse events and serious adverse events, *device deficiencies*, procedures and timelines for reporting.

3.15. Criteria and procedures for *follow up of subjects following completion of an investigation, procedures for follow up of subjects in the case of* suspension or early termination, ~~of the clinical investigation~~ *procedures for follow up of subjects who have withdrawn their consent and procedures for subjects lost to follow up.*

3.16 Policy as regards the establishment of the clinical investigation report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 1 of Chapter I.

**3.16a. *List of the technical and functional features of the medical device indicating those that are covered by the investigation.***

3.17. Bibliography.

#### **4. Other information**

4.1. A signed statement by the natural or legal person responsible for the manufacture of the investigational device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the subject.

~~This statement may be supported by an attestation issued by a notified body.~~

4.2. Where applicable according to national law, copy of the opinion(s) of the ethics committee(s) concerned ~~as soon as available~~. ***When according to national law the opinion(s) of the ethics committee(s) is not required at the time of the submission of the notification, copy of the opinion(s) of ethics committee(s) shall be submitted as soon as available.***

4.3. Proof of insurance cover or indemnification of subjects in case of injury, according to ***Article 50d and the corresponding*** national law.

- 4.4. Documents and procedures to be used to obtain informed consent, ***including the patient information sheet and the informed consent document.***
- 4.5. Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:
- organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;
  - a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects concerned in clinical investigations;
  - a description of measures that will be implemented in case of data security breach in order to mitigate the possible adverse effects.
- 4.6. ***Full details of the available technical documentation, for example detailed risk analysis/management documentation or specific test reports shall be submitted to the Competent Authority reviewing an application upon request.***

### **III. Other sponsor's obligations**

1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter II of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the investigational device, this obligation may be fulfilled by that person on behalf of the sponsor.
2. ***The Sponsor shall have an agreement in place to ensure that the serious adverse events are reported by the Investigator(s) to the Sponsor in a timely manner*** ~~The reportable events shall be provided by the investigator(s) in timely conditions.~~

3. The documentation mentioned in this Annex shall be kept for a period of time of at least five years after the clinical investigation with the device in question has ended, or, when the device is subsequently placed on the market, at least five years after the last device has been placed on the market. In the case of implantable devices the period shall be at least 15 years.

Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the first sentence of the preceding paragraph in case the sponsor, or his contact person, established within its territory goes bankrupt or ceases its activity prior to the end of this period.

4. *The Sponsor shall appoint a monitor that is independent from the investigation site to ensure that the investigation is conducted in accordance with the Clinical Investigation Plan, the principles of Good Clinical Practice and this Regulation.*
5. *The Sponsor is obliged to complete follow up of investigation subjects.*
6. *The Sponsor shall provide evidence to assure that the investigation is being conducted in line with Good Clinical Practice, for instance through internal or external inspection.*
7. *The Sponsor shall prepare a clinical investigation report which shall include at least the following, as set out below:*
  - *Cover/introductory page(s) indicating the title of the investigation, the investigational device, the single identification number, the CIP number and the details with signatures of the coordinating investigators and the principal investigators from each investigational site. Details of the author and date of the report.*
  - *A summary of the investigation should include the title, purpose of the investigation, description of the investigation, investigational design and methods used, the results of the investigation and conclusion of the investigation. The completion date of the investigation, and in particular details of early termination, halts or suspensions of investigations.*

- *Investigational device description, in particular clearly defined intended purpose.*
- *Clinical investigation plan summary – objectives, design, ethical aspects, monitoring and quality measures, selection criteria, target patient populations, sample size, treatment schedules, follow up duration, concomitant treatments, statistical plan (hypothesis/sample size calculation, analysis methods) and justification.*
- *Results of the clinical investigation – subject demographics, analysis of results related to chosen endpoints, details of subgroup analysis (with rationale and justification), compliance to CIP, follow up of missing data and patients withdrawing/lost to follow up from investigation.*
- *Summary of serious adverse events, adverse device effects and device deficiencies and any relevant corrective actions.*
- *Discussion/Overall conclusions – safety and performance results, assessment of risks and clinical benefits, discussion of clinical relevance in accordance with clinical state of the art, any specific precautions for specific patient populations, implications for the investigational device, limitations of the investigation.*

**LIST OF *GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE COVERED BY THE LAST SUBPARAGRAPH OF THE DEFINITION OF 'MEDICAL DEVICE' REFERRED TO IN NUMBER (1) OF ARTICLE 1 2(1a)***

1. Contact lenses *or other articles intended to be introduced into or onto the eye;*
2. ~~Implants~~ *Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of ~~modification~~ modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings;*
3. *Substances, combinations of substances, or articles intended to be used for facial ~~Facial~~ or other dermal or mucous membrane ~~fillers~~ filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing;*
4. Equipment *intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty;*
5. ~~Invasive laser equipment intended to be used on the human body;~~
6. *High intensity electromagnetic radiation (infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense ~~Intense~~ pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment;*
- 6a. *Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.*



## ANNEX XVI

**CORRELATION TABLE**

<b>Council Directive 90/385/EEC</b>	<b>Council Directive 93/42/EEC</b>	<b>This Regulation</b>
Article 1(1)	Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2)	Article 2(1)
Article 1(3)	Article 1(3) 1 <sup>st</sup> subparagraph	Article 1(5) 1 <sup>st</sup> subparagraph
-	Article 1(3) 2 <sup>nd</sup> subparagraph	Article 1(5) 2 <sup>nd</sup> subparagraph
Article 1(4) and (4a)	Article 1(4) and (4a)	Article 1(4) 1 <sup>st</sup> subparagraph
Article 1(5)	Article 1(7)	Article 1(6)
Article 1(6)	Article 1(5)	Article 1(2)
-	Article 1(6)	-
	Article 1(8)	Article 1(7)
Article 2	Article 2	Article 4(1)
Article 3 1 <sup>st</sup> subparagraph	Article 3 1 <sup>st</sup> subparagraph	Article 4(2)
Article 3 2 <sup>nd</sup> subparagraph	Article 3 2 <sup>nd</sup> subparagraph	-
Article 4(1)	Article 4(1)	Article 22
Article 4(2)	Article 4(2)	Article 19(1) and (2)
Article 4(3)	Article 4(3)	Article 19(3)

Article 4(4)	Article 4(4)	Article 8(7)
Article 4(5) point (a)	Article 4(5) 1 <sup>st</sup> subparagraph	Article 18(6)
Article 4(5) point (b)	Article 4(5) 2 <sup>nd</sup> subparagraph	-
Article 5(1)	Article 5(1)	Article 6(1)
Article 5(2)	Article 5(2)	Article 6(2)
Article 6(1)	Article 5(3), Article 6	-
Article 6(2)	Article 7(1)	Article 88
Article 7	Article 8	Articles 69 to 72
-	Article 9	Article 41
Article 8(1)	Article 10(1)	Number (43) and (44) of Article 2(1), Article 61(1), Article 63(1)
Article 8(2)	Article 10(2)	Article 61(3) and Article 63(1)2 subparagraph
Article 8(3)	Article 10(3)	Article 63(2) and (4)
Article 8(4)	Article 10(4)	Article 66
Article 9(1)	Article 11(1)	Article 42(2)
-	Article 11(2)	Article 42(4)
-	Article 11(3)	Article 42(3)
-	Article 11(4)	-
-	Article 11(5)	Article 42(5)

Article 9(2)	Article 11 (6)	Article 42(7)
Article 9(3)	Article 11(8)	Article 9(3)
Article 9(4)	Article 11(12)	Article 42(8)
Article 9(5)	Article 11(7)	-
Article 9(6)	Article 11(9)	Article 43(1)
Article 9(7)	Article 11(10)	Article 43(3)
Article 9(8)	Article 11(11)	Article 45(2)
Article 9(9)	Article 11(13)	Article 47(1)
Article 9(10)	Article 11(14)	-
-	Article 12	Article 20
-	Article 12a	Article 15
Article 9a(1) 1 <sup>st</sup> indent	Article 13(1) point (c)	-
Article 9a(1) 2 <sup>nd</sup> indent	Article 13(1) point (d)	Article 3(1)
-	Article 13(1) point (a)	Article 41(3)
-	Article 13(1) point (b)	Article 41(4) point (a)
Article 10	Article 15	Articles 50 to 60
Article 10a	Article 14	Article 25
Article 10b	Article 14a	Article 27
Article 10c	Article 14b	Article 74
Article 11(1)	Article 16(1)	Articles 33 and 34

Article 11(2)	Article 16(2)	Article 29
Article 11(3)	Article 16(3)	Article 36(2)
Article 11(4)	Article 16(4)	-
Article 11(5)	Article 16(5)	Article 45(4)
Article 11(6)	Article 16(6)	Article 45(3)
Article 11(7)	Article 16(7)	Articles 31(2) and 35(1)
Article 12	Article 17	Article 18
Article 13	Article 18	Article 73
Article 14	Article 19	Article 75
Article 15	Article 20	Article 84
Article 15a	Article 20a	Article 77
Article 16	Article 22	-
Article 17	Article 23	-
-	Article 21	-