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

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Delegations will find the consolidated text of the draft Regulation on medical devices in the Annex to this Note. This is a "clean" version without any difference between "new text" and text from the Commission proposal.

In this revised version of the draft Regulation on medical devices errors discovered during the translation of the text set out in document 10617/16 have been corrected. The corrections concern: Recital (11), Recital (13), Recital (14), Recital (32), Recital (49), Recital (51a), Article 1(6), Article 8(1b), Article 32(2), Article 33(5), Paragraphs 2 and 3 of Article 36, Article 42(3a), Article 50(5)(j), Article 50cd(1)(f), Article 51(4a), Article 51a(4)(ca), Paragraphs 3 and 3da in Article 58, Article 67(1e), Article 67(1f), Article 69, Article 75b(1)(c), Article 81a(5), Article 81a(6)(b), Article 81a(7), the heading of Article 86a, paragraphs 2, 3 and 5 of Article 89, Article 97(3)(ba), Sections 7.4.1. and 7.4.3. in Annex I, the heading of Section 11. in Annex I, Points (a) and (o) in Section 19.3. in Annex I, the last bullet point in Point (b) in Section 1.1. in Annex IIa, Section 4. in Annex III, the second bullet point in Section 1.2.3. in Annex VI, the second bullet point in Point (b) in Section 4.6.2. in Annex VI, Section 6.9. in Annex VII, the second bullet point in Section 4.2. in Annex VIII, Section 5. in Annex XII, and Sections 1.8. and 3.15. in Chapter II in Annex XIV.

The text in the Annex to this Note is identical to that in the Annex to document 11662/16. The difference between this Note and that document is thus simply that in this Note the corrections are listed above.

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Proposal for a  
**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and**  
**Regulation (EC) No 1223/2009**  
(Text with EEA relevance)

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

Whereas:

- (1) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices<sup>3</sup> and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices<sup>4</sup> constitute the Union regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

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<sup>1</sup> OJ C 133, 9.5.2013, p. 52.

<sup>2</sup> The Committee of the Regions decided to refrain from giving an opinion.

<sup>3</sup> OJ L 189, 20.7.1990, p. 17.

<sup>4</sup> OJ L 169, 12.7.1993, p. 1.

- (2) This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for those medical devices by ensuring, among other things, that data generated in clinical investigations is reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.
- (2a) This Regulation does not seek to harmonise rules relating to the further making available on the market of devices after they have already been put into service. e.g. in the context of second-hand sales.
- (3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety.
- (4) To the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative the International Medical Devices Regulators Forum (IMDRF), should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification criteria, conformity assessment procedures and clinical investigations.

- (5) For historic reasons active implantable medical devices, covered by Directive 90/385/EEC, and other medical devices, covered by Directive 93/42/EEC, were regulated in two separate legal instruments. In the interest of simplification, both directives, which have been amended several times, should be replaced by a single legislative act applicable to all medical devices other than *in vitro* diagnostic medical devices.
- (7) The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as *in vitro* diagnostic medical devices, medicinal products, cosmetics and food. Therefore, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>5</sup> should be amended to exclude medical devices from its scope.
- (8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. In order to ensure consistent qualification across all Member States, particularly with regard to borderline cases, the Commission may, on its own initiative or at a duly substantiated request of a Member State, having consulted the MDCG, decide on a case-by-case basis whether or not a product or groups of products fall within the scope of this Regulation. When deliberating the regulatory status of products in borderline cases involving medicinal products, human tissues and cells, biocidal products or food products, the Commission should ensure an appropriate level of consultation of the EMA, the ECHA and the EFSA, as relevant.

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<sup>5</sup> OJ L 31, 1.2.2002, p.1.

- (8a) Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility to take an EU-wide decision regarding the regulatory status of a product should also be introduced in Regulation No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.<sup>6</sup>
- (9) Products which combine a medicinal product or substance and a medical device, are regulated either under this Regulation or under Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.<sup>7</sup> It should be ensured that appropriate interaction exists between the two legislative acts in terms of consultations during the pre-market assessment and exchange of information on vigilance cases occurring with combination products. For medicinal products that integrate a medical device part, compliance with the general safety and performance requirements of the device part should be adequately assessed in the context of the marketing authorisation. Directive 2001/83/EC should therefore be amended.
- (10) Union legislation, in particular Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004<sup>8</sup> and Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>9</sup>, is incomplete in respect of certain products manufactured utilising derivatives of tissues or cells of human origin that are non-viable or are rendered non-viable. Such finished products utilising those derivatives should come under the scope of this Regulation, provided they comply with the definition of a medical device, or are covered by this Regulation.

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<sup>6</sup> OJ L 342, 22.12.2009, p. 59.

<sup>7</sup> OJ L 311, 28.11.2001, p. 67.

<sup>8</sup> OJ L 324, 10.12.2007, p. 121.

<sup>9</sup> OJ L 102, 7.4.2004, p. 48.

- (11) Certain groups of products for which the manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation. In order for manufacturers to be able to demonstrate conformity of such products, the Commission should adopt common specifications at least on application of risk management and, where necessary clinical evaluation regarding safety applicable to those products. These common specifications should be developed specifically for a group of products without a medical purpose and should not be used for conformity assessment of the analogous devices with a medical purpose.

Devices with both a medical and a non-medical intended purpose should fulfil both the requirements applicable to devices with and to devices without a medical purpose.

- (12) Like for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products utilising viable biological substance of other origin in order to achieve or support the intended purpose of the product are also not covered by this Regulation.
- (12a) The requirements laid down in Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components<sup>10</sup> should continue to apply.

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<sup>10</sup> OJ L 33, 8.2.2003, p. 30

- (13) There is scientific uncertainty about the risks and benefits of nanomaterials used for medical devices. In order to ensure a high level of health protection, free movement of goods and legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial<sup>11</sup>, with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles for which there is a high or medium potential for internal exposure, those devices should be subject to the most severe conformity assessment procedure. In preparation of implementing acts regulating the practical and uniform application of the corresponding requirements, the relevant scientific opinions of the relevant scientific committees should be taken into account.
- (14) Aspects addressed by Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility<sup>12</sup> are an integral part of the general safety and performance requirements for medical devices. Consequently, this Regulation should be considered a *lex specialis* in relation to that Directive.
- (15) This Regulation should include requirements regarding the design and manufacture of medical devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom<sup>13</sup> which pursues other objectives.

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<sup>11</sup> OJ L 275, 20.10.2011, p. 38.

<sup>12</sup> OJ L 96, 29.3.2014. p. 79.

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



- (15a) This Regulation includes requirements regarding the design, safety and performance characteristics of medical devices intended to prevent occupational injuries, including protection from radiation.
- (17) It should be made clear that medical devices offered to persons in the Union by means of information society services within the meaning of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations<sup>14</sup> as well as devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union must comply with the requirements of this Regulation when the product is placed on the market or the service is provided in the Union.
- (18a) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is qualified as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being application is not a medical device. The qualification of software, either as device or accessory, is independent of its location or type of interconnection between the software and a device.

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<sup>14</sup> OJ L 204, 21.7.1998, p. 37, as amended by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998, OJ L 217, 5.8.1998, p. 18.

- (19) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council<sup>15</sup> should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.
- (20) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices<sup>16</sup> allows the Commission to adopt common technical specifications for specific categories of *in vitro* diagnostic medical devices. In areas where no harmonised standards exist or where they are not sufficient, the Commission should be empowered to lay down specifications which provide a means to comply with general safety and performance requirements and requirements for clinical investigations and clinical evaluation and/or post-market clinical follow-up.
- (20a) Common specifications should be developed after consulting the relevant stakeholders and taking account of European and international standards.
- (21) The definitions in the field of medical devices, regarding the device itself, the making available of devices, economic operators, users and specific processes, the conformity assessment, clinical investigations and clinical evaluations, vigilance and market surveillance, standards and other technical specifications, should be aligned with well-established practice at Union and international level in order to enhance legal certainty.

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<sup>15</sup> OJ L 316, 14.11.2012, p. 12.

<sup>16</sup> OJ L 331, 7.12.1998, p. 1.

- (22) The rules applicable to medical devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93<sup>17</sup> and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.<sup>18</sup>
- (23) The rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to medical devices and their accessories covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.
- (24) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, building on the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the different parts of this Regulation, to enhance understanding of the legal requirements and thus to improve regulatory compliance by the relevant operators.
- (24a) For the purpose of this Regulation the activities of distributors include acquisition, holding, and supplying of medical devices.
- (25) Several of the obligations on manufacturers, such as clinical evaluation or vigilance reporting, that were set out only in the annexes of Directives 90/385/EEC and 93/42/EEC should be incorporated into the enacting provisions of this Regulation to facilitate its application.

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<sup>17</sup> OJ L 218, 13.8.2008, p. 30.

<sup>18</sup> OJ L 218, 13.8.2008, p. 82.

(25aaa) Health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby addressing, not on an industrial scale, target patient group specific needs which cannot be met at the appropriate level of performance by an equivalent device available on the market.

(25aa) It should be noted that the notion of health institution does not cover establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres. As a result, the exemption applicable to health institutions does not apply to those establishments.

(25a) In view of the fact that natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law, it is appropriate to require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability under Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products<sup>19</sup>. Those measures should be proportionate to the risk class, type of device and the size of the enterprise.

In this context it is also appropriate to lay down rules concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

(26) To ensure that medical devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of their medical devices is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance system in place which should be proportionate to the risk class and the type of the medical device. In addition, in order to minimize risks or prevent incidents related to medical devices, manufacturers should establish a system for risk management and a system for reporting of incidents and field safety corrective actions.

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<sup>19</sup> OJ L 210, 7.8.85, p. 29.

- (26a) The risk management system should be carefully aligned with and reflected in the clinical evaluation for the medical device, including the clinical risks to be addressed as part of clinical investigations, clinical evaluation and post-market clinical follow up. Both the risk management and clinical evaluation processes should be inter-dependent and should be regularly updated.
- (27) It should be ensured that supervision and control of the manufacture of and the post-market surveillance and vigilance activities of medical devices are carried out within the manufacturer's organisation by a person responsible for regulatory compliance who fulfils minimum conditions of qualification.
- (28) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the medical devices produced by those manufacturers and in serving as their contact person established in the Union. Given that pivotal role, for the purposes of enforcement it is appropriate to make the authorised representative legally liable for defective medical devices in case a manufacturer established outside the Union has not complied with its general obligations. The liability of the authorised representative provided for in this Regulation is without prejudice to the provisions of Council Directive 85/374/EEC, and accordingly the authorised representative is jointly and severally liable with the importer and the manufacturer.

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

- (28a) Where, in the course of a clinical investigations, damage caused to the subject leads to the civil or criminal liability of the investigator or the sponsor, the conditions for liability in such cases, including issues of causality and the level of damages and sanctions, should remain governed by national law.

- (29) To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of a medical device.
- (30) Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 of the Treaty on the Functioning of the European Union (TFEU) subject to the limitations set by the protection of health and safety and by the protection of intellectual property rights provided by Article 36 TFEU. Application of this principle is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging, should therefore be specified in this Regulation, taking into account the case-law of the European Court of Justice<sup>20</sup> in other relevant sectors and existing good practices in the field of medical devices.
- (31) The reprocessing and further use of single-use devices (SUDs) may only take place where permitted by national law, and in respect of the requirements laid down in this Regulation. By reprocessing a single-use device with the view to make it suitable for further use within the Union the reprocessor should be considered the manufacturer of the reprocessed device. By way of derogation, Member States may decide that the reprocessing and re-use of SUDs within a health institution may vary from the obligations of the manufacturer described in this Regulation. In principle this is only permitted when adequate common specifications are in place and if appropriate national regulations exist and are applied in the reprocessing of these devices which ensure at least the same level of security as in case of the corresponding initial SUDs. This also applies if the reprocessing is carried out by an external reprocessor on behalf of a health institution.
- (32) Patients who are implanted with a device should be given clear and easily accessible essential information allowing the implanted device to be identified and other relevant information about the device, including any necessary health risk warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

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<sup>20</sup> Judgment of the Court of 28 July 2011 in joined cases C-400/09 and C-207/10.

- (33) Medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation. However Member States should be allowed to decide whether to restrict the use of any specific type of medical device in relation to aspects that are not covered by this Regulation.
- (34) The traceability of medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.
- (34a) The UDI system should apply to all medical devices placed on the market except custom-made devices and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the European Unique Device Identification System to become functional in time for the application of this regulation detailed rules should be laid down in this Regulation.
- (35) Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

- (35a) To facilitate the functioning of the European Databank on medical devices (Eudamed), an internationally recognised medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons obliged to use that nomenclature under this Regulation. Furthermore this nomenclature should be provided, where reasonably practicable free of charge, also to other stakeholders.
- (36) One key aspect is the creation of a central database that should integrate different electronic systems to collate and process information regarding medical devices on the market and the relevant economic operators, certain aspects of conformity assessment, notified bodies, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices<sup>21</sup>.
- (37) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on clinical investigations should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and to report serious adverse events, device deficiencies and related updates. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

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<sup>21</sup> OJ L 102, 23.4.2010, p. 45.



- (38) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC<sup>22</sup> of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>23</sup> applies to the processing of personal data carried out in the Member States, under the supervision of the Member States competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001<sup>24</sup> of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data<sup>25</sup> applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In accordance with Article 2(d) of Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.
- (39) For class III medical devices and implantable devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.
- (39a) The summary of safety and clinical performance should include in particular the place of the device in the context of diagnostic or therapeutic options taking into account the clinical evaluation of the device when compared to the other diagnostic or therapeutic alternatives and the specific conditions under which this device and its alternatives may be considered.

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<sup>22</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

<sup>23</sup> OJ L 281, 23.11.1995, p. 31.

<sup>24</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

<sup>25</sup> OJ L 8, 12.1.2001, p. 1.

- (39b) The sponsor should submit a summary of results of the clinical investigation easily understandable to the intended user together with the clinical investigation report, where applicable, within the timelines. Where it is not possible to submit the summary of the results within the defined timelines for scientific reasons, the sponsor should justify this and specify when the results are going to be submitted.
- (40) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.
- (40a) The outcome of the Notified Body's assessment of the manufacturer's technical documentation and clinical evaluation documentation should be critically evaluated by the national authority responsible for notified bodies and sampled as part of the risk based approach to the oversight and monitoring activities of the notified body.
- (41) The position of notified bodies vis-à-vis manufacturers should be strengthened, including their right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on medical devices to ensure continuous compliance by manufacturers after receipt of the original certification.
- (41a) To increase transparency on the oversight of notified bodies by national authorities, the responsible authorities should publish information on their provisions on the assessment, designation and monitoring of notified bodies for medical devices. In accordance with good administrative practice this information should be kept up to date by the national authority in particular to reflect relevant, significant or substantive changes to the procedures.
- (41aa) The Member State in which a notified body is located should be responsible for enforcing the requirements of this regulation with regard to that notified body.

- (41b) In particular in view of the responsibility of Member States for the organisation and delivery of health services and medical care, Member States may lay down additional requirements on notified bodies designated for conformity assessment of devices based on their territory as concerns issues that are not regulated in this Regulation. That possibility is without prejudice to more specific horizontal EU legislation on notified bodies and equal treatment of notified bodies.
- (42) For class III implantable medical devices and Class IIb active medical devices intended to administer and/or remove a medicinal product experts panels should be requested, notwithstanding certain exemptions, to scrutinise the preliminary assessment conducted by notified bodies on clinical data and competent authorities should be informed about devices which have been granted a certificate following this conformity assessment procedure. This clinical evaluation consultation should lead to a harmonised evaluation on high risk medical devices by sharing expertise on clinical aspects and elaborating common specifications on categories of devices that have undergone this consultation process.
- (42a) For class III devices a manufacturer may consult voluntarily an expert panel on its clinical development strategy and on proposals for clinical investigations.
- (43) It is necessary, in particular for the purpose of the conformity assessment procedures, to maintain the division of medical devices into four product classes in line with international practice. The classification rules, which are based on the vulnerability of the human body taking into account the potential risks associated with the technical design and manufacture of the devices, need to be adapted to technical progress and experience gained from vigilance and market surveillance. To maintain the same level of safety as provided by Directive 90/385/EEC, active implantable medical devices and their accessories should be in the highest risk class.

- (43a) Rules applied to invasive devices did not sufficiently consider the level of invasiveness and potential toxicity of products which were introduced into the human body. In order to achieve a suitable risk based classification of substance-based medical devices, it is necessary to introduce specific classification rules for these types of devices. The classification criteria should take into account the place where the device performs its action in or on the human body or is introduced or applied and cases where a systemic absorption of the substance, or the product(s) of its metabolism, is present.
- (44) The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products. For medical devices in classes IIa, IIb and III, an appropriate level of involvement of a notified body should be compulsory.
- (45) The conformity assessment procedures should be strengthened and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.
- (45a) It is appropriate that certificates of free sale contain information that makes it possible to use the European databank on medical devices (Eudamed) in order to obtain information on the device and in particular whether it is on the market, withdrawn from the market or recalled and on any certificate on its conformity.

- (46) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements should be based on clinical data that, for class III medical devices and implantable medical devices should, as a general rule, be sourced from clinical investigations to be carried out under the responsibility of a sponsor who can be the manufacturer or another legal or natural person taking responsibility for the clinical investigation.
- (47) The rules on clinical investigations should be in line with major international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects to facilitate that the results of clinical investigations conducted in the Union could be accepted as documentation outside the Union and to facilitate that results of clinical investigations conducted outside the Union in accordance with international guidelines can be accepted within the Union. In addition the rules should be in line with the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.
- (47a) It should be left to the Member State concerned to determine the appropriate body or bodies to be involved in the assessment of the application to conduct a clinical investigation and to organise the involvement of ethics committees within the timelines for the authorisation of that clinical investigation as set out in this Regulation. Such decisions are a matter of internal organisation for each Member State. When determining the appropriate body or bodies, Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available.

- (48) An electronic system should be set up at Union level to ensure that every clinical investigation is recorded and reported in a publicly accessible database. To protect the right to the protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union, no personal data of subjects participating in a clinical investigation should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical investigations on medical devices should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.
- (49) Where a clinical investigation is to be conducted in more than one Member State, Member States should have the possibility to allow the sponsor to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the investigational device and of the scientific design of the clinical investigation to be conducted in several Member States, such single application should facilitate the voluntary coordination between the Member States under the direction of a coordinating Member State. The coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical investigation, including informed consent.

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

- (50) Sponsors should report certain adverse events and device deficiencies occurring during clinical investigations to the Member States concerned. Member States should have the possibility to terminate or suspend the investigations if considered necessary to ensure a high level of protection of the subjects enrolled in a clinical investigation. Such information should be communicated to the other Member States.
- (51) This Regulation should cover clinical investigations intended to gather clinical evidence and which pursue regulatory purposes laid down in this Regulation as well as setting out basic requirements regarding ethical and scientific assessments for other types of clinical investigations of medical devices.
- (51a) Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activities. To this end manufacturers should establish a comprehensive post-market surveillance (PMS) system, set up under the quality management system and based on a PMS plan. Relevant data and information gathered through PMS, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentations, such as risk assessment, clinical evaluation and should serve the purpose of transparency.
- (51aa) It should be left to Member States to determine the legally designated representatives of incapacitated persons and minors, however incapacitated subjects, minors, pregnant women and breastfeeding women require specific protection measures.

- (51m) The principles of replacement, reduction and refinement in the area of animal experimentation laid down in the Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes<sup>26</sup> should be observed. In particular, the unnecessary duplication of tests and studies on vertebrates should be avoided.
- (52) In order to better protect health and safety regarding devices on the market, the electronic system on vigilance for medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.
- (53) Member States should take appropriate measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents. Healthcare professionals, users and patients should be empowered and enabled to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers and share the information with their peers when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.
- (54) The evaluation of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State with the objective of sharing resources and ensuring consistency regarding the corrective action.
- (54a) The competent authorities should take into account, where appropriate, the information provided by and views of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.

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<sup>26</sup> OJ L 276, 20.10.2010, p. 33.



- (55) The reporting of serious adverse events or device deficiencies during clinical investigations and the reporting of serious incidents occurring after a medical device has been placed on the market should be clearly distinguished to avoid double reporting.
- (56) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.
- (56a) Any statistically significant increase in the number or severity of incidents or expected side effects that could have a significant impact on the risk-benefit determination and which may lead to unacceptable risks should be reported to the competent authorities in order to permit their assessment and the adoption of appropriate measures.
- (57a) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement.
- (58) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the level and structure of the fees to ensure transparency. In order to ensure transparency the structure and level of fees should be publicly available on request.
- (59) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States based on their role and expertise in the field of medical devices and *in vitro* diagnostic medical devices should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [.../...] on *in vitro* diagnostic medical devices<sup>27</sup>, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. The MDCG should be able to establish subgroups in order to provide necessary in-depth technical expertise in the field of medical devices and *in vitro* diagnostic medical devices.

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<sup>27</sup> OJ L [...], [...], p. [...].

- (59a) Experts panels and expert laboratories should be appointed by the Commission on the basis of up-to-date clinical, scientific or technical expertise, with the aim to provide scientific, technical and clinical assistance to the Commission, MDCG, manufacturers and notified bodies in relation to the implementation of this regulation. Moreover, expert panels should fulfil the tasks of providing an opinion on the clinical evaluation in the case of high risk implantable devices.
- (60) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is fundamental for ensuring a consistently high level of health and safety within the internal market, in particular in the areas of clinical investigations and vigilance. The principle of coordinated exchange and assessment should also apply across other authority activities described in this Regulation, such as notified body designation and should be encouraged in the area of market surveillance of medical devices. Joint working, coordination and communication of activities should also lead to more efficient use of resources and expertise at national level.
- (61) The Commission should provide scientific, technical and corresponding logistic support to the coordinating national authority and ensure that the regulatory system for medical devices is effectively and uniformly implemented at Union level based on sound scientific evidence.
- (62) The Union and, where appropriate, the Member States should actively participate in international regulatory cooperation in the field of medical devices to facilitate the exchange of safety-related information regarding medical devices and to foster the further development of international regulatory guidelines promoting the adoption of regulations in other jurisdictions with a level of health and safety protection equivalent to that set by this Regulation.
- (63) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

- (64) It is appropriate to empower the Commission to adopt delegated acts in order to supplement or amend certain non-essential provisions of this Regulation pursuant to Article 290 of the Treaty on the Functioning of the European Union. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with preparation of delegated acts.
- (65) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>28</sup>.
- (66) The advisory procedure should be used for the adoption of the form and presentation of the data elements of the manufacturers' summary of safety and clinical performance; and of the model for certificates of free sale, given that those acts have a procedural character and do not directly have an impact on the health and safety at Union level.
- (67) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures imperative grounds of urgency so require.

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<sup>28</sup> OJ L 55, 28.2.2011, p. 13.

- (68) To allow economic operators, especially SMEs, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation and to ensure its proper application, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements to be taken . However, parts of the Regulation that affect directly Member States and the Commission should be implemented as soon as possible. It is particularly important that by the date of application, a sufficient number of notified bodies are designated in accordance with the new requirements to avoid any shortage of medical devices on the market.
- (69) In order to ensure a smooth transition to the registration of medical devices, of relevant economic operators and of certificates, the obligation to submit the relevant information to the electronic systems put in place by this Regulation at Union level should, in case the corresponding IT systems are developed according to plan, become fully effective only 18 months after the date of application of this Regulation. During this transitional period certain provisions of Directives 90/385/EEC and 93/42/EEC should remain in force. However, economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered to be in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directives to avoid multiple registrations.
- (69b) In order to provide for a smooth introduction of the UDI system, the effective obligation to place the UDI carrier on the label of the device should moreover vary from one year to five years after the date of application of this Regulation depending upon the class of the medical device concerned.

(70) Directives 90/385/EEC and 93/42/EEC should be repealed to ensure that only one set of rules applies to the placing of medical devices on the market and the related aspects covered by this Regulation. However, in order to ensure a smooth transition from the old regime to the new regime, it is appropriate to provide that Commission Regulation (EU) No 207/2012 and Commission Regulation (EU) No 722/2012 should remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation. Also Commission Decision 2010/227/EU adopted in implementation of those Directives and Directive 98/79/EC should remain in force and continue to apply until the date when the European databank on medical devices set up pursuant to this Regulation and Regulation (EU) No [future Regulation on In Vitro Diagnostic Medical Devices] is fully functional. Conversely, no such maintenance in force is required for Commission Directives 2003/12/EC and 2005/50/EC and Commission Implementing Regulation (EU) No 920/2013.

(70a) The European Data Protection Supervisor has given an opinion<sup>29</sup> pursuant to Article 28(2) of Regulation (EC) No 45/2001<sup>30</sup>.

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

HAVE ADOPTED THIS REGULATION:

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<sup>29</sup> OJ C [...], [...], p. [...].

<sup>30</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

# Chapter I

## Scope and definitions

### *Article 1*

#### *Scope*

1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices and accessories to medical devices for human use in the Union. This regulation also applies to clinical investigations on medical devices conducted in the Union.
- 1a. This regulation shall also apply to the groups of products without an intended medical purpose that are listed in Annex XV as from the date of application of common specifications adopted pursuant to Article 7, taking into account the state of the art, and in particular existing standards for analogous devices with a medical purpose, based on a similar technology. The common specifications for a group of products listed in that annex shall address, at least, application of risk management as set out in Annex I for the group of products and, where necessary, clinical evaluation regarding safety.

The necessary common specifications shall be adopted at the latest on the date of application of this Regulation. They shall apply as from six months after their entry into force or from the date of application of this Regulation, whichever is the latest.

Notwithstanding Article 96, Member States' measures regarding the qualification of the products covered by Annex XV as medical devices pursuant to Directive 93/42/EEC shall remain valid until the date of application pursuant to the first subparagraph of the required Common Specifications for that group of products.

- 1aa. Devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose.

- 1b. For the purposes of this Regulation, medical devices, accessories to medical devices and products listed in Annex XV to which this Regulation applies pursuant to paragraph 1a shall hereinafter be referred to as ‘devices’.
- 1c. Where justified in view of the similarity between a device with a medical purpose placed on the market and a product without a medical purpose in respect of their characteristics and risks, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in Article 1(1a), by adding new groups of products, in order to protect the health and safety of users or other persons or other aspects of public health.
2. This Regulation shall not apply to:
- (a) *in vitro* diagnostic medical devices covered by Regulation (EU) [.../...];
  - (b) medicinal products as defined in Directive 2001/83/EC. In deciding whether a product falls under Directive 2001/83/EC or under this Regulation, particular account shall be taken of the principal mode of action of the product.
  - (ba) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;
  - (c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or put into service, such blood products, plasma or cells, except for devices referred to in paragraph 4;
  - (d) cosmetic products covered by Regulation (EC) No 1223/2009;
  - (e) transplants, tissues or cells of animal origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or are rendered non-viable.
  - (ea) transplants, tissues or cells of human origin or their derivatives covered by Directive 2004/23/EC, or products containing or consisting of them, unless a device is manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;
  - (f) products, other than those referred to in points (c), (e) and (ea), that contain or consist of viable biological substances or organisms, including living micro-organisms, bacteria, fungi or virus in order to achieve or support the intended purpose of the product;
  - (g) food covered by Regulation (EC) No 178/2002.

3. Any device which, when placed on the market or put into service incorporates as an integral part an *in vitro* diagnostic medical device as defined in Article 2 of Regulation (EU) [...] [on *in vitro* diagnostic medical devices] shall be governed by this Regulation. The requirements of that Regulation shall apply to the *in vitro* diagnostic medical device part.
4. Where a device, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation.

However, if the action of the medicinal substance is principal, not ancillary to that of the device, the product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004, as applicable. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.

5. Where a device is intended to administer a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, that device shall be governed by this Regulation, without prejudice to the provisions of Directive 2001/83/EC and Regulation (EC) No 726/2004 with regard to the medicinal product.

However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, the product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004, as applicable. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.



- 5a. Where a device, when placed on the market or put into service, incorporates, as an integral part, tissues or cells of human origin or their derivatives with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation. In this case the provisions for donation, procurement and testing laid down in Directive 2004/23/EC shall apply.

However, if the action of the tissues or cells or their derivatives is principal, not ancillary to that of the device and the product is not governed by Regulation (EC) No 1394/2007, the product shall be governed by Directive 2004/23/EC. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.

6. This Regulation is a specific Union legislation within the meaning of Article 2(3) of Directive 2014/30/EU.

- 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<sup>31</sup> shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in chapter II of Annex I of this Regulation.

7. This Regulation shall not affect the application of Council Directive 2013/59/Euratom.

- 7a. This Regulation shall not affect the right of a Member State to restrict the use of any specific type of device in relation to aspects not covered by this Regulation.

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<sup>31</sup> OJ L 157, 9.6.2006, p. 24

8. This Regulation shall not affect national law concerning the organisation, delivery or financing of health services and medical care, such as, the requirement that certain medical devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or apply certain medical devices or that their application must be accompanied by specific professional counselling.
- 8a. Nothing in this Regulation shall restrict the freedom of press or the freedom of expression in the media in so far as those freedoms are guaranteed in the Union and in the Member States, in particular under Article 11 of the Charter.

## *Article 2*

### *Definitions*

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

Definitions related to devices:

- (1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
  - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
  - providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,
- and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.

- (2) ‘accessory to a medical device’ means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s);
- (3) ‘custom-made device’ means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;

- (4) ‘active device’ means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose or by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices.

Software shall be considered an active device;

- (5) ‘implantable device’ means any device, including those that are partially or wholly absorbed, which is intended
- to be totally introduced into the human body or
  - to replace an epithelial surface or the surface of the eye,
- by clinical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be considered an implantable device;
- (6) ‘invasive device’ means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body;
- (7) ‘generic device group’ means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;
- (8) ‘single-use device’ means a device that is intended to be used on an individual patient during a single procedure.
- (8a) ‘falsified device’ means any device with a false presentation of its identity, and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights.
- (9a) ‘procedure pack’ means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose;
- (9b) ‘system’ means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose;

- (10) ‘intended purpose’ means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;
- (11) ‘label’ means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;
- (12) ‘instructions for use’ means the information provided by the manufacturer to inform the user of the device’s intended purpose and proper use and of any precautions to be taken;
- (13) ‘Unique Device Identification’ (‘UDI’) means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;
- (14) ‘non-viable’ means having no potential for metabolism or multiplication;
- (14a) ‘derivative’ means a “non-cellular substance” extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case shall not contain any cells or tissues;
- (15) ‘nanomaterial’ means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm;

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials;

- (15aa) ‘particle’, for the purposes of the definition of nanomaterial in paragraph 1(15), means a minute piece of matter with defined physical boundaries;
- (15ab) ‘agglomerate’, for the purposes of the definition of nanomaterial in paragraph 1(15), means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
- (15ac) ‘aggregate’, for the purposes of the definition of nanomaterial in paragraph 1(15), means a particle comprising of strongly bound or fused particles;
- (15a) ‘performance’ means the ability of a device to achieve its intended purpose as claimed by the manufacturer;
- (15d) ‘risk’ means the combination of the probability of occurrence of harm and the severity of that harm;
- (15e) ‘benefit-risk determination’ means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;
- (15f) ‘compatibility’ is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:
- perform without losing or compromising the ability to perform as intended, and/or
  - integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or
  - be used together without conflict/interference or adverse reaction.

- (15g) ‘interoperability’ is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to
- exchange information and use the information that has been exchanged for correct execution of specified function without changing the content of the data, and/or
  - communicate with each other, and/or
  - work together as intended.

Definitions related to the making available of devices:

- (16) ‘making available on the market’ means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (17) ‘placing on the market’ means the first making available of a device, other than an investigational device, on the Union market;
- (18) ‘putting into service’ means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

Definitions related to economic operators, users and specific processes:

- (19) ‘manufacturer’ means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark.
- (19a) ‘fully refurbishing’, for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

- (20) ‘authorised representative’ means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the European Union, to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;
- (21) ‘importer’ means any natural or legal person established within the Union who places a device from a third country on the Union market;
- (22) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market, up until the point of putting into service;
- (23) ‘economic operators’ means the manufacturer, the authorised representative, the importer, the distributor and the person referred to in Article 20(1) and 20(3);
- (24) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;
- (25) ‘user’ means any healthcare professional or lay person who uses a device;
- (26) ‘lay person’ means an individual who does not have formal education in a relevant field of healthcare or medical discipline;
- (27) ‘reprocessing’ means the process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used device;

Definitions related to conformity assessment:

- (28) ‘conformity assessment’ means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;



- (29) ‘conformity assessment body’ means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;
- (30) ‘notified body’ means a conformity assessment body designated in accordance with this Regulation;
- (31) ‘CE marking of conformity’ or ‘CE marking’ means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

Definitions related to clinical evaluation and clinical investigations:

- (32) ‘clinical evaluation’ means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;
- (33) ‘clinical investigation’ means any systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a device;
- (34) ‘investigational device’ means any device being assessed for safety and/or performance in a clinical investigation;
- (35) ‘clinical investigation plan’ means a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organisation and conduct of a clinical investigation;

- (36) ‘clinical data’ means the information concerning the safety or performance that is generated from the use of a device and that are sourced from the following:
- clinical investigation(s) of the device concerned,
  - clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated,
  - reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated,
  - other clinical data coming from the post-market surveillance system, in particular the post-market clinical follow-up;
- (37) ‘sponsor’ means an individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical investigation;
- (37a) ‘subject’ means an individual who participates in a clinical investigation;
- (37b) ‘clinical evidence’ means the clinical data and clinical evaluation results, pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer;
- (37c) ‘clinical performance’ means the ability of a device to achieve its intended purpose as claimed by the manufacturer, including any direct or indirect medical effects on humans as well as the clinical benefit on patients resulting from the technical or functional, including diagnostic characteristics of a device, when used as intended by the manufacturer;
- (37d) ‘clinical benefit’ means the positive impact of a device on the health of an individual, to be specified as meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis or a positive impact on patient management or public health;

- (37h) ‘investigator’ means an individual responsible for the conduct of a clinical investigation at a clinical investigation site;
- (37k) ‘informed consent’ means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation;
- (37l) ‘ethics committee’ means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;
- (38) ‘adverse event’ means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device;
- (39) ‘serious adverse event’ means any adverse event that led to any of the following:
- death,
  - serious deterioration in the health of the subject, that resulted in any of the following:
    - (i) life-threatening illness or injury,
    - (ii) permanent impairment of a body structure or a body function,
    - (iii) hospitalisation or prolongation of patient hospitalisation,
    - (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
    - (v) chronic disease,
  - foetal distress, foetal death or a congenital physical or mental impairment or birth defect;

- (40) ‘device deficiency’ means any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;

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

- (40a) ‘post market surveillance’ means all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;
- (40b) ‘market surveillance’ means the activities carried out and measures taken by public authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;
- (41) ‘recall’ means any measure aimed at achieving the return of a device that has already been made available to the end user;
- (42) ‘withdrawal’ means any measure aimed at preventing a device in the supply chain from further being made available on the market;
- (43) ‘incident’ means any malfunction or deterioration in the characteristics or performance of a device made available on the market including use-error due to ergonomic features, any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;

(44) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

- death of a patient, user or other person,
- temporary or permanent serious deterioration of the patient's, user's or other person's state of health,
- serious public health threat;

(44a) 'serious public health threat' means any event which could result in imminent risk of death, serious deterioration in state of health, or serious illness that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time;

(45) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation;

(46) 'field safety corrective action' means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

(47) 'field safety notice' means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;

Definitions related to standards and other technical specifications:

(49) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;

(50) 'common specifications' (CS) means a document other than a standard that prescribes technical and/or clinical requirements that provide a means to comply with the legal obligations applicable to a device, process or system.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to adapt the definition of nanomaterial set out in number (15) and the related definitions in numbers (15aa), (15ab) and (15ac) of paragraph 1 in view of technical and scientific progress and taking into account definitions agreed at Union and international level.

### *Article 3*

#### *Regulatory status of products*

1. Without prejudice to Article 2(2) of Directive 2001/83, at a duly substantiated request of a Member State, the Commission shall, after consulting the MDCG, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
  - 1a. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1.
  2. The Commission shall ensure the sharing of expertise between Member States, in the fields of medical devices, *in vitro* diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.
  - 2a. When deliberating the regulatory status of products involving medicinal products, human tissues and cells, biocides or food products, the Commission shall ensure an appropriate level of consultation of the EMA, the ECHA and the EFSA, as relevant.

## Chapter II

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

#### *Article 4*

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

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.
2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.
3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 49.
4. Devices that are manufactured and used within health institutions shall be considered as being put into service.
  - 4a. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that the following conditions are met:
    - (aa) the device is not transferred to another legal entity,
    - (a) manufacture and use of the devices occur under appropriate quality management systems,

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

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

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



5. The Commission may adopt implementing acts to ensure the uniform application of Annex I, to the extent necessary to resolve issues of divergent interpretation and practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

#### *Article 5*

##### *Distance sales*

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

## *Article 5a*

### *Claims*

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

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

## *Article 6*

### *Use of Harmonised standards*

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

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

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

2. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, provided references to those monographs have been published in the Official Journal of the European Union.

## *Article 7*

### *Common specifications*

1. Without prejudice to Articles 1(1a) and 15(1c) and the deadline laid down therein, where no harmonized standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II, the clinical evaluation and post-market clinical follow-up set out in Annex XIII or the requirements regarding clinical investigation set out in Annex XIV. The CS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).
2. Devices which are in conformity with the CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CS or parts thereof.
3. Manufacturers shall comply with the CS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.
4. Notwithstanding paragraph 3, manufacturers of products listed in Annex XV shall comply with the relevant common specifications for those products.

## *Article 8*

### *General obligations of the manufacturer*

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.
  - 1a. Manufacturers shall establish, execute, maintain and document a system for risk management as described in Section 1a in Annex I.
  - 1b. Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 49 and Annex XIII, including post-market clinical follow-up ('PMCF').
2. Manufacturers of devices other than custom made devices shall draw up and keep up to date the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annexes II and IIa.

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annexes II and IIa.

- 2a. Manufacturers of custom-made devices shall draw up, keep up to date and keep available to competent authorities documentation pursuant to Section 2 of Annex XI.
3. Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 17, and affix the CE marking of conformity in accordance with Article 18.
  - 3b. Manufacturers shall comply with the obligations related to the UDI system referred to in Article 24 and with the registration obligations referred to in Article 24a, 24b and 25a.

4. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any amendments and supplements, issued in accordance with Article 45, available to the competent authorities for a period of at least ten years after the last device covered by the declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

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

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

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

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

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

- (aa) a strategy for regulatory compliance, including compliance with conformity assessment procedures and management of modifications to the devices covered by the system;
  - (ab) identification of applicable general safety and performance requirements and exploration of options to address these;
    - (a) the responsibility of the management;
    - (b) resource management, including selection and control of suppliers and sub-contractors;
  - (ba) risk management according to Section 1a of Annex I;
  - (bc) clinical evaluation, according to Article 49 and Annex XIII, including post-market clinical follow-up;
  - (c) product realisation, including planning, design, development, production and service provision;
    - (ca) control of the UDI-Code assignments to all relevant devices ensuring consistency of information provided according to Article 24a and 24b;
    - (cb) setting-up, implementation and maintenance of a systematic post-market surveillance system according to Article 60a;
    - (cc) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;
    - (cd) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;
    - (ce) management of corrective and preventive actions and verification of their effectiveness;
    - (d) processes for monitoring and measurement of output, data analysis and product improvement.
6. Proportionate to the risk class and the type of device, manufacturers of devices shall implement and keep up to date the post-market surveillance system referred to in Article 60a.
7. Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 19 of Annex I in an official Union language(s) determined by the Member State where the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible, clearly comprehensible to the intended user or patient.

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

Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 45, in particular, of the non-compliance and of any corrective action taken.

- 8a. Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Article 61 and 61a.
9. Manufacturers shall, upon request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority where the manufacturer has his registered place of business may require that the manufacturer provide samples of the device free of charge or, where impracticable, grant access to the device. Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

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

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

10. Where manufacturers have their devices designed and manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 25.
13. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.

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

#### *Article 9*

##### *Authorised representative*

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



3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative. The authorised representative shall provide a copy of the mandate to the competent authority, upon request.

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

- (aa) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
  - (a) keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any amendments and supplements issued in accordance with Article 45 at the disposal of competent authorities for the period referred to in Article 8(4);
  - (ab) comply with the registration obligations laid down in Article 25a and verify that the manufacturer has complied with the registration obligations laid down in Article 24a and 24b;
  - (b) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device in an official Union language determined by the Member State concerned;
  - (ba) forward to the manufacturer any request by a competent authority where he has his registered place of business for samples, or access to a device and verify that the competent authority receives the samples or gets access to the device;
  - (c) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
  - (d) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
  - (e) terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.
4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (1a), (1b), (2), (3), (3b), (5), (6), (7) and (8).

- 4a. Without prejudice to paragraph 4, where the manufacturer is not established in any Member State, and has not complied with the obligations laid down in Article 8, the authorised representative shall be legally liable for defective devices on the same basis as, jointly and severally, with the manufacturer.
5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefore.
6. Any reference in this Regulation to the competent authority of the Member State where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.

#### *Article 10*

##### *Change of authorised representative*

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

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

## *Article 11*

### *General obligations of importers*

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.
  
2. In order to place a device on the market importers shall verify the following:
  - (a) that the device has been CE marked and that the declaration of conformity of the device has been drawn up;
  - (b) that a manufacturer is identified and, that an authorised representative in accordance with Article 9 has been designated by the manufacturer;
  - (e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;
  - (f) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 24.

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

3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or on its packaging or in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.
  
4. Importers shall verify that the device is registered in the electronic system in accordance with Article 24b. Importers shall add their details to the registration according to Article 25a.

5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I and shall comply with the conditions set by the manufacturer, where available.
6. Importers shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.
7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative. Importers shall co-operate with the manufacturer, his authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, withdraw or recall it is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 45 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.
8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and his authorised representative.
9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any amendments and supplements, issued in accordance with Article 45.

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

## *Article 12*

### *General obligations of distributors*

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

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

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

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

## *Article 13*

### *Person responsible for regulatory compliance*

1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:
  - (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;
  - (b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their requisite expertise referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.

- 1a. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC are not required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.
2. The person responsible for regulatory compliance shall at least be responsible for ensuring the following matters:
  - (a) that the conformity of the devices is appropriately checked in accordance with the quality management system under which these devices are manufactured before a product is released;
  - (b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
  - (ba) that the post-market surveillance obligations in accordance with Article 8(6) are complied with;

- (c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;
- (d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.

If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1 and 2, their respective areas of responsibility shall be stipulated in writing.

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



## Article 14

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

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

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (19) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient.

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:
  - (a) provision, including translation, of the information supplied by the manufacturer in accordance with Section 19 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State;
  - (b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

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

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

4. At least 28 calendar days prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 calendar days, he shall submit to the competent authority a certificate, issued by a notified body referred to in Article 29, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

## Article 15

### *Single-use devices and their reprocessing*

0. Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this article.
1. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations related to traceability of the reprocessed device, in accordance with Chapter III on the Identification and Traceability of devices. The reprocessor shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.
  - 1a. By way of derogation from paragraph 1, as regards single-use devices that are reprocessed and used within a health institution, Member States may decide not to apply all rules relating to manufacturers' obligations laid down in this Regulation provided that they ensure that:
    - (a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in points (aa), (a), (c), (d), (da), (e) and (f) of Article 4(4a) are complied with;
    - (b) the reprocessing is performed according to common specifications, detailing the requirements:
      - on risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original product as well as of its planned application after reprocessing,
      - on the validation of procedures for the entire process, including cleaning steps,
      - on the product release and performance testing,
      - on the quality management system,
      - on the reporting of incidents involving devices that have been reprocessed, and
      - on the traceability of reprocessed devices.

Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed device the patient is treated with.

Member States shall notify the Commission and the other Member States of the national provisions, introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.

- 1b. Member States may choose to apply provisions referred to in paragraph 1a also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution provided that the reprocessed device in its entirety is returned to that health institution and the reprocessor complies with the requirements referred to in paragraph 1a(a) and 1a(b).
- 1c. The Commission shall adopt the necessary common specifications referred to in paragraph 1a(b) by the date of application of this regulation in accordance with Article 7(1). Those common specifications shall be consistent with the latest scientific evidence and shall address the application of the general requirements on safety and performance laid down in in this regulation. In case common specifications are not adopted by the date of application of this regulation, reprocessing shall be performed according to relevant harmonized standards and national provisions that ensure compliance with the requirements outlined in paragraph 1a(b). The compliance with the common specifications or, in the absence of common specifications, the relevant harmonized standards and the national provisions, shall be certified by a notified body.
2. Only single-use devices that have been placed on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with Directive 93/42/EEC may be reprocessed.
3. Only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out.
5. The name and address of the legal or natural person referred to in paragraph 1 and the other relevant information in accordance with Section 19 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

6. A Member State that permits reprocessing of single-use devices may maintain or introduce stricter national provisions restricting or prohibiting, within its territory, the following:
  - (a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;
  - (b) the making available or further use of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of the national provisions. The Commission shall keep the information publicly available.

7. The Commission shall by [date 4 years after the date of application of this regulation] draw up a report on the operation of this article and submit it to the European Parliament and to the Council. On the basis of this report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.

#### *Article 16*

##### *Implant card and information to be supplied to the patient with an implanted device*

1. The manufacturer of an implantable device shall provide together with the device the following:
  - (a) information allowing the identification of the device, including the device name, serial number, batch code or lot number, the Unique Device Identification, the device model, as well as the name, address and the URL of the website of the manufacturer;
  - (c) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;
  - (d) any information about the expected lifetime of the device and any necessary follow-up;
  - (e) any other information to assure a safe use of the device by the patient, including the information in Annex I, Section 19.3. Point (ob).

- 1a. The above mentioned information shall be made available for the particular patient who has been implanted with the device by any means that can allow a rapid access to the information and stated in the language(s) determined by the concerned Member State. The information shall be written in a way that is readily understood by a lay person. The information mentioned in this article shall be updated where appropriate and updates shall be available to the patient via the URL for the website mentioned in paragraph 1 point (a).

In addition, the manufacturer shall provide the information under paragraph 1, point (a) on a card delivered with the device.

- 1aa. Member States shall require health institutions to make the information mentioned in this article available to the patients who have been implanted, together with the implant card, which shall bear their identity.
- 1ab. The following implants shall be exempted from the obligations laid down in this article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates wires, pins, clips and connectors. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend this list by adding other types of implants to it or removing implants therefrom.

#### *Article 17*

##### *EU declaration of conformity*

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.
3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.

#### *Article 18*

##### *CE marking of conformity*

1. Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex IV.
2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided.
4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 42. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.
6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.

#### *Article 19*

##### *Devices for special purposes*

1. Member States shall not create any obstacle to the following devices:
  - (a) investigational devices which are supplied to an investigator for the purpose of clinical investigation if they meet the conditions laid down in Articles 50 to 60 and in Annex XIV;
  - (b) custom-made devices which are made available on the market if they comply with Article 42(7), 42(7a) and Annex XI.

Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 54.

2. Custom-made devices shall be accompanied by the statement referred to in Section 1 of Annex XI which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

Member States may require that the manufacturer of a custom-made device submit to the competent authority a list of such devices which have been made available in their territory.



3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.

## *Article 20*

### *Systems and procedure packs*

1. Any natural or legal person shall draw up a statement referred to in paragraph 2 if he puts devices bearing the CE marking together with the following other devices or products, in accordance with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:
  - (a) other devices bearing the CE marking;
  - (b) *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) [.../...];
  - (c) other products which are in conformity with the legislation applicable to those products only when they are used within the medical procedure or their presence in the system or procedure pack is justified.
  
2. In the statement, the person referred to in paragraph 1 shall declare the following:
  - (a) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions;
  - (b) that he packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;
  - (c) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at his choice, follow one of the procedures referred to in Annex VIII or in Part A of Annex X. The application of those Annexes and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile package is opened or damaged. The person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.
4. Where the system or procedure pack incorporate devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, or where the sterilisation has not been carried out in accordance with the manufacturer's instructions the system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant conformity assessment procedure pursuant to Article 42. The natural or legal person shall assume the obligations incumbent on manufacturers.
5. The systems or procedure packs referred to in paragraph 1 shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraphs 1 and 3 as well as the address at which he can be contacted and his location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 19 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable to the devices put together in accordance with Article 8(4). Where these periods differ, the longest period shall apply.

## *Article 21*

### *Parts and components*

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

## *Article 22*

### *Free movement*

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

## **Chapter III**

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

#### *Article 23*

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

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

#### *Article 23a*

##### *Medical devices nomenclature*

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

## Article 24

### *Unique Device Identification system*

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

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

3. Before placing a device, other than a custom made device, on the market, the manufacturer shall assign to the device and – if applicable – to all higher levels of packaging a UDI created in compliance with the rules of an entity designated by the Commission in accordance with paragraph 2.
4. The UDI carrier shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.
  - 4a. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 61.
  - 4b. The Basic UDI device identifier ('Basic UDI-DI' as defined in Annex V Part C) of the device shall appear on the EU declaration of conformity referred to in Article 17.
  - 4c. The manufacturer shall keep up-to-date a list of all applied UDI as part of the technical documentation referred to in Annex II.
5. Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or they have been supplied with, if they belong to:
  - class III implantable devices;
  - the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.

5aa. Health institutions shall store and keep preferably by electronic means the UDI of the devices which they have supplied or they have been supplied with if they belong to class III implantable devices.

For devices other than class III implantable devices, Member States shall encourage, and may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices which they have been supplied with.

5a. Member States shall encourage, and may require, health care professionals to store and keep preferably by electronic means, the UDI of the devices which they have been supplied with.

7. The Commission may by means of implementing acts specify the modalities and the procedural aspects with a view to ensuring harmonised application of the Unique Device Identification System for any of the following aspects:

- (a) the determination of the devices, categories or groups of devices to which the obligation laid down in paragraph 5 shall apply;
- (b) the specification of the data to be included in the UDI production identifier ('UDI-PI') of specific devices or device groups;

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

7a. The Commission shall be empowered to adopt delegated acts in accordance with Article 89:

- (a) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress; and
- (b) amending or supplementing Annex V in the light of international development and technical progress in the field of unique device identification.

8. When adopting the measures referred to in paragraph 7, the Commission shall take into account the following:
- (a) confidentiality and data protection as referred to in Articles 84 and 85;
  - (c) the risk-based approach;
  - (d) the cost-effectiveness of the measures;
  - (e) the convergence of UDI systems developed at international level;
  - (f) the need to avoid duplications in the UDI system;
  - (g) the needs of the health care systems of the Member States, and where possible, the compatibility with other medical devices' identification systems that are used by stakeholders.

*Article 24a*

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

1. The Commission, after consulting the MDCG shall set up and manage an electronic system on UDI ('UDI database') to validate, collate, process and make available to the public the information mentioned in Part B of Annex V.
- 1a. When designing the UDI database the Commission shall consider the general principles on the UDI database as described in Annex V Part C section 5. The design shall, inter alia, be such that:
- no UDI production identifiers are included in the UDI database;
  - no commercially confidential product information shall be included in the UDI database.
- 1b. The core data elements in the UDI database shall be accessible to the public free of charge.
2. The technical design of the electronic system shall ensure maximum accessibility of information stored in the UDI database and allow multi user access and automatic up and downloads of information. The Commission shall provide for technical and administrative support to manufacturers and other users of the UDI database.



3. Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer shall ensure that the information referred to in Part B of Annex V of the device in question are correctly submitted and transferred to the UDI database.

*Article 24b*

*Process for registration of devices*

1. Before placing a device, other than a custom made device, on the market, the manufacturer shall, in compliance with the rules of the designated issuing entities, assign a Basic UDI-DI as defined in Annex V Part C to the device.
  - 1a. Before placing on the market a system or procedure pack according to Article 20(1) and (3), that is not a custom made device, the responsible natural or legal person shall assign in compliance with the rules of the designated issuing entities to the system or procedure pack a Basic UDI-DI as detailed in Annex V Part C 6.3 and submit to the UDI database this Basic UDI-DI and the linked information referred to in Part B of Annex V.
2. Where a manufacturer of a device, other than custom made or investigational devices, applies a conformity assessment procedure according to Article 42(3), first sentence, 42(4) or 42(5), the manufacturer shall submit to the UDI database the Basic UDI-DI and the linked information referred to in Part B of Annex V before placing the device on the market.

3. Where a manufacturer of devices, other than custom made or investigational devices, applies a conformity assessment procedure according to Article 42 paragraph 2 second sentence or paragraph 3 third sentence (EU technical documentation assessment and EU type-examination) the manufacturer shall assign the Basic UDI-DI (Annex V Part C) to the device before applying for a conformity assessment procedure by a notified body.

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

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

## *Article 25*

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

1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 25a and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.
- 1b. Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available in their territory.

3. Within two weeks after placing a device, other than a custom-made device, on the market, importers shall verify that the manufacturer or authorised representative has uploaded to the electronic system the information referred to in paragraph 1.

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

#### *Article 25a*

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

1. Manufacturers, authorised representatives and importers, who have not been registered before according to this article, shall submit to the electronic system the information referred to in Annex V, Part A, section 1, before placing a device, other than a custom-made device, on the market. In cases where the conformity assessment procedure requires the involvement of a notified body the information referred to in Annex V, Part A, Section 1 shall be submitted to the electronic system before applying to a notified body.
2. After having verified the data entered pursuant to paragraph 1, the competent authority shall procure from the electronic system referred to in Article 25 a single registration number ('SRN') and issue it to the manufacturer, the authorised representative or the importer.
3. The manufacturer shall use the single registration number when applying to a notified body for certification according to Article 43 and for entering the electronic system on UDI (in order to fulfil their obligations according to Article 24a(3) and Article 24b(1a), (2), (3) and (3a)).
4. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.

5. Not later than one year after submission of the information in accordance with paragraph 1, and then every second year thereafter, the relevant economic operator shall confirm the accuracy of the data. Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in Section 1 of Part A of Annex V. In the event of failure to confirm within six months of the due date, any Member State may take appropriate corrective measures within its territory until the obligation referred to in this paragraph is complied with.
6. The data contained in the electronic system shall be accessible to the public.
- 7a. The competent authority may use the data to administer a fee to the manufacturer, the authorised representative or the importer pursuant to Article 86.

#### *Article 26*

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

1. In the case of devices classified as class III and implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance.

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

The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 42 and shall be validated by that body. After validation the notified body shall upload this summary report to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary report is available.

- 1a. The summary of safety and clinical performance shall include at least the following aspects:
  - (a) the identification of the device and the manufacturer, including the basic UDI-DI and the single registration number;
  - (b) the intended purpose of the device, including indications, contra-indications and target populations;
  - (c) a description of the device, including a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device;
  - (d) possible diagnostic or therapeutic alternatives;
  - (e) reference to harmonized standards and common specifications;
  - (f) the summary of clinical evaluation as referred to in annex XIII, and relevant information on post market clinical follow up;
  - (g) suggested profile and training for users;
  - (h) information on any residual risks and any undesirable effects, warnings and precautions.
  
2. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

#### *Article 27*

##### *European databank on medical devices*

1. The Commission, after consulting the MDCG, shall develop and manage the European databank on medical devices (Eudamed) for the following purposes:
  - (a) to enable the public to be adequately informed about devices placed on the market, about the corresponding certificates issued by notified bodies and about the relevant economic operators;

- (b) to enable unique identification and to facilitate traceability of devices within the internal market;
- (c) to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with obligations under Articles 50 to 60;
- (d) to enable manufacturers to comply with information obligations under Articles 61 to 66;
- (e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well informed basis and to enhance the cooperation between them.

2. Eudamed shall include the following:

- (aa) the electronic system on registration of devices referred to in Article 24b(3a);
- (a) the electronic system on UDI referred to in Article 24a;
- (b) the electronic system on registration of economic operators referred to in Article 25;
- (ba) the electronic system on notified bodies and on certificates referred to in Article 45a;
- (d) the electronic system on clinical investigations referred to in Article 53;
- (e) the electronic system on vigilance and post-market surveillance referred to in Article 66a;
- (f) the electronic system on market surveillance referred to in Article 75b.

2a. When designing Eudamed the Commission shall give due consideration to the compatibility of national databases and national web-interfaces to allow for import and export of data.

3. The data shall be entered into Eudamed by the Member States, notified bodies, economic operators and sponsors as specified in the provisions concerning the electronic systems referred to in paragraph 2. The Commission shall provide for technical and administrative support to users of Eudamed.

4. All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent defined in the provisions referred to in paragraph 2.

The Commission shall ensure that public parts of Eudamed are presented in an user-friendly and easily-searchable format.

5. Eudamed shall contain personal data only insofar as this is necessary for the electronic systems referred to in paragraph 2 to collate and process the information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of the data subjects for no longer than the periods referred to in Article 8(4).
6. The Commission and the Member States shall ensure that the data subjects may effectively exercise their rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC<sup>32</sup>, respectively. They shall ensure that the data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data is deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than within 60 days after a request is made by a data subject.
7. The Commission shall, by means of implementing acts, lay down the modalities necessary for the development and management of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3). When adopting these implementing acts, the Commission shall ensure that, as far as possible, the system develops so as to avoid any requirement of double entries of the same information within the same module or in different modules of the system.

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<sup>32</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

8. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered controller of Eudamed and its electronic systems.

#### *Article 27a*

##### *Functionality of the European database portal and the Electronic system on UDI*

1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for the European database referred to in Article 27 and the Electronic system on UDI referred to in Article 24a. The Commission shall draw up a plan for the implementation of these specifications at the latest [12 months after entry into force]. This plan shall seek to ensure that the European database referred to in Article 27 is fully functional at a date that allows the Commission to publish the notice referred to in paragraph 3 at the latest [two months before the date laid down in Article 97(2)] and that all other relevant deadlines laid down in that article and in Article 90 of Regulation [ref to future Regulation on IVD] are met.
2. The Commission shall, on the basis of an independent audit report, inform the MDCG when it has verified that the European database and the Electronic system on UDI have achieved full functionality and the systems meet the functional specifications drawn up pursuant to paragraph 1.
3. The Commission shall, after consultation with the MDCG and when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the Official Journal of the European Union.



## **Chapter IV**

### **Notified bodies**

#### *Article 28*

##### *National authorities responsible for notified bodies for medical devices*

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

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

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

7. Member States shall make publicly available general information on their provisions on the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and on changes which have a significant impact on these tasks.
8. The national authority responsible for notified bodies shall participate in the peer-review activities laid down in Article 38.

#### *Article 29*

##### *Requirements relating to notified bodies*

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

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

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

- 1a. Notified bodies shall make available and submit upon request, all relevant documentation, including the manufacturer's documentation to the national authority responsible for notified bodies to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined within this Chapter.
2. In order to ensure the uniform application of the requirements set out in Annex VI, to the extent necessary to resolve issues of divergent interpretation and practical application, the Commission may adopt implementing acts in accordance with Article 88(3).

### *Article 30*

#### *Subsidiaries and subcontracting*

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

### *Article 31*

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

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

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 may be submitted in support of these requirements and shall be taken into consideration during the assessment described in Article 32. However, the applicant shall make available the full documentation to demonstrate conformity with these requirements upon request.

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

### *Article 32*

#### *Assessment of the application*

1. The national authority responsible for notified bodies shall within 30 days check that the application referred to in Article 31 is complete and shall request the applicant to provide any missing information. Once the application is complete the national authority shall send it to the Commission.

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

2. The national authority responsible for notified bodies shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the Medical Device Coordination Group established by Article 78 ('MDCG').
3. Within 14 days of the submission referred to in paragraph 2, the Commission, in conjunction with the MDCG, shall assign a joint assessment team made up of three experts, unless the specific circumstances require another number of experts, chosen from the list referred to in Article 32a. One of these experts shall be a representative of the Commission who shall coordinate the activities of the joint assessment team. The other two experts shall come from different Member States other than the one in which the applicant conformity assessment body is established.

The joint assessment team shall be comprised of competent experts which reflect the conformity assessment activities and the types of devices which are subject to the application or, in particular when this procedure is initiated in accordance with Article 37 to ensure that the specific concern can be appropriately assessed.

4. Within 90 days after assignment the joint assessment team shall review the documentation submitted with the application in accordance with Article 31. The joint assessment team may provide feedback to or require clarification from the national authority responsible for notified bodies on the application and on the planned on-site assessment.

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

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

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

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

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

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

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

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

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

5. The national authority responsible for notified bodies shall submit its final assessment report and, if applicable, the draft designation to the Commission, the MDCG and the joint assessment team.
6. The joint assessment team shall provide a final opinion regarding the assessment report prepared by the national authority responsible for notified bodies and, if applicable, the draft designation within 21 days of receipt of those documents to the Commission, which shall immediately submit this opinion to the MDCG. Within 42 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft designation which the national authority responsible for notified bodies shall duly take into consideration for its decision on the designation of the notified body.
7. The Commission may, by means of implementing acts, adopt measures setting out the modalities specifying procedures and reports for the application for designation referred to in Article 31 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

### *Article 32a*

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

1. The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of medical devices to participate in the activities outlined in Article 32 and Article 38.
2. The Commission shall maintain a list of the experts nominated pursuant to paragraph 1, together with information on their specific competence and expertise. This list shall be made available to Member States competent authorities through the electronic system referred to in Article 45a.

### *Article 32b*

#### *Language requirements*

All documents required pursuant to Articles 31 and 32 shall be drawn up in a language or languages which shall be determined by the Member State concerned.

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

The Commission shall provide necessary translations of the documentation pursuant to Article 31 and 32, or parts thereof into an official Union language such that the documents can be readily understood by the joint assessment team designated in accordance with Article 32(3).

### *Article 33*

#### *Designation and notification procedure*

0. Member States may only designate conformity assessment bodies for which the assessment pursuant to Article 32 was completed and which satisfy the requirements set out in Annex VI.



1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool developed and managed by the Commission.
  
4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities as defined in this Regulation and the type of devices which the notified body is authorised to assess and, without prejudice to Article 35, any conditions associated with the designation.
  
- 4a. The Commission shall within six months of the entry into force of this Regulation, by means of implementing acts, draw up a list of codes and corresponding types of devices to describe the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88( 3). The Commission, after consulting the MDCG, may update this list inter alia based on information arising from the coordination activities described in Article 38.
  
5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the final opinion of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.
  
6. The notifying Member State shall, without prejudice to Article 35, inform the Commission and the other Member States of any conditions associated with the designation and provide documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI.
  
7. Within 28 days of a notification, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.

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

When publishing the notification in the database of notified bodies developed and managed by the Commission, the Commission shall also add the information relating to the notification of the notified body to the electronic system referred to in Article 45a along with the documents mentioned in paragraph 5 and the opinion and responses referred to in paragraphs 8 and 8a of this Article.

10. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.
11. The conformity assessment body concerned may perform the activities of a notified body only after the notification has become valid in accordance with paragraph 10.

## *Article 34*

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

1. The Commission shall assign an identification number to each notified body for which the notification becomes valid in accordance with Article 33(10). It shall assign a single identification number even when the body is notified under several Union acts. If they are successfully designated in accordance with this regulation, bodies notified pursuant to Directives 90/385/EEC and 93/42/EEC shall retain the identification number assigned to them pursuant to those directives.
2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the conformity assessment activities as defined in this Regulation and the types of devices for which they have been notified, accessible to the public in the database of notified bodies developed and managed by the Commission. It shall also make this list available on the electronic system referred to in Article 45a. The Commission shall ensure that the list is kept up to date.

## *Article 35*

### *Monitoring and assessment of notified bodies*

0. Notified bodies shall, without delay, and at the latest within 15 days, inform the national authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.
1. The national authority responsible for notified bodies shall conduct monitoring of the notified bodies based on its territory and of their subsidiaries and subcontractors to ensure ongoing compliance with the requirements and the fulfilment of its obligations set out in this Regulation. The notified bodies shall, on request from the national authority responsible for notified bodies, supply all relevant information and documents, required to enable the authority, the Commission and other Member States to verify compliance with those criteria.

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

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

- 3a. The monitoring of notified bodies by the national authority responsible for notified bodies shall include witnessed audits of the notified body personnel, including when necessary the personnel from subsidiaries and subcontractors, when conducting quality system assessments at a manufacturer's facility.

- 3c. The monitoring of notified bodies conducted by national authorities responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance systems to help guide its activities.

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

- 3ca. The national authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or ‘for-cause’ reviews if needed to address a particular issue or to verify compliance.
- 3cb. The national authority responsible for notified bodies shall assess the notified body assessments of manufacturers’ technical and clinical documentation as further outlined in Article 35a.
- 3d. The national authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VI and shall monitor the timely implementation of corrective and preventive actions.
4. Three years after notification of a notified body, and again every fourth year thereafter, a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 31 and 32.
- 4a. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to modify the frequency of complete re-assessment referred to in paragraph 4.

5. The Member States shall report to the Commission and to the MDCG , at least once a year, on their monitoring activities regarding their notified bodies and, where applicable, subsidiaries and subcontractors. This report shall provide details of the outcome of the monitoring and surveillance activities, including activities pursuant to paragraph 3ca. This report shall be treated as confidential by the MDCG and the Commission however it shall contain a summary which shall be made publicly available.

The summary of the report shall be uploaded to the European databank referred to in Article 45a.

#### *Article 35a*

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

1. The national authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies shall assess an appropriate number of notified body assessments of manufacturers' technical documentation and clinical evaluations to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. These assessments shall be conducted both off-site and during on-site assessments.
2. The sample of files assessed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified body and in particular high risk devices, appropriately justified and documented in a sampling plan, which shall be available from the national authority responsible for notified bodies upon request of the MDCG.
3. The national authority responsible for notified bodies shall assess whether the assessment by the notified body was conducted appropriately and verify the procedures used, associated documentation and conclusions drawn by the notified body. This shall include the manufacturer's technical and clinical documentation upon which the notified body has based its assessment. These assessments shall be conducted utilising common specifications provided for in Article 7 in the conduct of the assessment.

5. These assessments shall also form part of the re-assessment of notified bodies in accordance with Article 35(4) and the joint assessment activities referred to in Article 37(2a). These assessments shall be conducted utilising appropriate expertise.
6. The MDCG may, based on the reports of these assessments by the national authority responsible for notified bodies or joint assessment teams, and inputs from the market surveillance, vigilance and post-market surveillance activities described in Chapter VII, or on the continuous monitoring of the technical progress, the identification of concerns and emerging issues on the safety and performance of devices, recommend that the sampling, either by the national authority responsible for notified bodies or as part of a joint assessment activity, shall assess a greater or lesser proportion of the clinical evaluations and technical documentation assessed by a notified body.
7. The Commission may, by means of implementing acts, adopt measures setting out the modalities, associated documents for and coordination of the technical and clinical assessments referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

### *Article 36*

#### *Changes to designations and notifications*

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the designation by the national authority responsible for notified bodies. The procedures described in Article 32 and in Article 33 shall apply to changes where they entail an extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 33(10).

- 1a. Where a notified body decides to cease its conformity assessment activities it shall inform the national authority responsible for notified bodies and the manufacturers concerned as soon as possible and in case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of activities on condition that another notified body has confirmed in writing that it will assume responsibilities for these products. The new notified body shall complete a full assessment of the devices affected by the end of that time period before issuing new certificates for those devices.
  
2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations or has not implemented the necessary corrective measures, the authority shall suspend, restrict, or fully or partially withdraw the designation, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the designation.

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

- 2a. Where the designation of a notified body has been suspended, restricted, or fully or partially withdrawn, it shall inform the manufacturers concerned at the latest within 10 days.
  
3. In the event of restriction, suspension or withdrawal of a designation, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are kept available for the national authorities responsible for notified bodies and national authorities responsible for market surveillance at their request.



4. The national authority responsible for notified bodies shall:
- assess the impact on the certificates issued by the notified body where there is a change to the designation;
  - submit a report on its findings to the Commission and the other Member States within three months after having notified the changes to the designation;
  - require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued to ensure the safety of devices on the market;
  - enter into the electronic system mentioned in Article 45(4) all certificates for which it has required suspension or withdrawal;
  - inform the competent authority for medical devices of the Member State where the manufacturer or his authorised representative has his registered place of business through the electronic system referred to in Article 45a of the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others.
5. With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in the following circumstances:
- (a) the national authority responsible for notified bodies has confirmed, within one month of the suspension or restriction, that there is no safety issue for certificates affected by the suspension or restriction;
- and
- the national authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction;

or

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

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

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

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

The Commission shall immediately enter information on the changes to the designation of the notified body into the electronic system referred to in Article 45a.

### *Article 37*

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

1. The Commission, in conjunction with the MDCG, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in Annex VI or the obligations to which it is subject. It shall ensure that the concerned national authority responsible for notified bodies is informed and is given opportunity to investigate these concerns.
2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.
- 2a. The Commission, in conjunction with the MDCG, may initiate, as applicable, the assessment process described in Article 32(3) and (4) when there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VI and when the investigation of the national authority is not deemed to have fully addressed the concerns or upon request of the national authority. The reporting and outcome of this assessment process shall follow the principles of Article 32. Alternatively, depending on the severity of the issue, the Commission in conjunction with the MDCG may request that the national authority responsible for notified bodies allow for participation of up to two experts from the list established pursuant to Article 32a in an on-site assessment as part of the planned monitoring and surveillance activities in accordance with Article 35 and as outlined in the annual plan described in paragraph 3 therein.

3. Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the designation if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.

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

#### *Article 38*

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

1. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation. This shall address elements including:
  - (a) development of best practice documents relating to the activities of the national authorities responsible for notified bodies;
  - (b) development of guidance documents for notified bodies in relation to the implementation of this Regulation;
  - (c) training and qualification of the experts referred to in Article 32a;
  - (d) monitoring of trends relating to changes to notified body designations and notifications and trends in certificate withdrawals and transfers between notified bodies;
  - (e) monitoring of the application and applicability of scope codes referred to in Article 33(4a);

- (f) development of a mechanism for peer reviews between authorities and the Commission;
  - (g) methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies for medical devices.
2. The national authorities responsible for notified bodies shall participate in a peer review every third year through the mechanism developed pursuant to Article 38(1). These reviews shall normally be conducted during on-site joint assessments described in Article 32 but alternatively on a voluntary basis may take place as part of the national authority's monitoring activities in Article 35.
  3. The Commission shall participate in the organisation and provide support to the implementation of the peer review mechanism.
    - 3a. The Commission shall compile an annual summary report of the peer review activities which shall be made publicly available.
  4. The Commission may, by means of implementing acts, adopt measures setting out the modalities and associated documents for the peer review, training and qualification mechanisms referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

*Article 39*

*Coordination of notified bodies*

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

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

The Commission may establish the modalities for the functioning of the coordination group of notified bodies.

*Article 40a*

*List of standard fees*

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

## **Chapter V**

### **Classification and conformity assessment**

#### **Section 1 – Classification**

##### *Article 41*

##### *Classification of medical devices*

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

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

3. At a request of a Member State the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:
  - (a) application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification;
  - (b) that a device, or category or group of devices shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities by way of derogation from the classification criteria set out in Annex VII, be reclassified.
- 3a. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 3, points (a) and (b).
- 3b. The implementing acts referred to in paragraphs 3 and 3a shall be adopted in accordance with the examination procedure referred to in Article 88(3).
4. In order to ensure the uniform application of the classification criteria set out in Annex VII, and taking account of the relevant scientific opinions of the relevant scientific committees, the Commission may adopt implementing acts in accordance with Article 88(3), to the extent necessary to resolve issues of divergent interpretation and practical application.



## Section 2 – Conformity assessment

### *Article 42*

#### *Conformity assessment procedures*

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to XI.
  - 1a. Prior to putting into service devices that are not placed on the market, with the exception of devices manufactured pursuant to Article 4(4a), manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to XI.
2. Manufacturers of devices classified as class III, other than custom-made or investigational devices, shall be subject to a conformity assessment based on quality management system assurance and assessment of the technical documentation as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.
  - 2d. In the case of devices referred to in the first subparagraph of Article 1(4), the notified body shall follow the consultation procedure as specified in Section 6.1 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.
  - 2e. In the case of devices that are covered by this Regulation in accordance with point (e) or (ea) of Article 1(2) and article 1(5a), the notified body shall follow the consultation procedure as specified in Section 6.2 of Annex VIII or Section 6 of Annex IX, as applicable.

- 2f. 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, or applied on skin and that are absorbed by or locally dispersed in the human body, the notified body shall follow the procedure as specified in Section 6.3 of Annex VIII or Section 6 of Annex IX, as applicable.
3. Manufacturers of devices classified as class IIb, other than custom-made or investigational devices, shall be subject to a conformity assessment based on quality management system as specified in Annex VIII, except for its Chapter II, with assessment of the technical documentation of at least one representative device per generic device group. By way of derogation, the assessment of the technical documentation as specified in Section 5 of Chapter II of Annex VIII shall be applicable for Class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.
- 3a. Where justified in view of technologies similar to the well-established technologies used in the devices in the list in paragraph 3 being used in other Class IIb implantable devices or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend that list by adding other types of Class IIb implantable devices to that list or removing devices therefrom.
4. Manufacturers of devices classified as class IIa, other than custom-made or investigational devices, shall be subject to a conformity assessment based on quality management system as specified in Annex VIII, except for its Chapter II, with assessment of the technical documentation of at least one representative device for each category of devices. Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annex II coupled with a conformity assessment based on product conformity verification as specified in Section 7 of Part A or Section 8 of Part B of Annex X.

5. Manufacturers of devices classified as class I, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 17 after drawing up the technical documentation set out in Annex II. If the devices are placed on the market in sterile condition, are reusable surgical instruments or have a measuring function, the manufacturer shall apply the procedures set out in Annex VIII, Chapter I (Quality Management System) and Chapter III (Administrative provisions), or in Part A of Annex X. However, the involvement of the notified body shall be limited:
  - (a) in the case of devices placed on the market in sterile condition, to the aspects concerned with establishing, securing and maintaining sterile conditions,
  - (b) in the case of devices with a measuring function, to the aspects concerned with the conformity of the devices with the metrological requirements;
  - (c) in the case of reusable surgical instruments, to the aspects related to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.
  
7. Manufacturers of custom-made devices shall follow the procedure set out in Annex XI and draw up the statement set out in Section 1 of that Annex before placing the device on the market.
  
- 7a. Manufacturers of class III custom-made implantable devices shall be subject to the conformity assessment procedure based on quality management system as specified in Chapter I of Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on a Quality Management System as specified in Part A of Annex X.
  
8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language(s) determined by the Member State concerned. Otherwise they shall be available in an official Union language acceptable to the notified body.
  
9. Investigational devices shall be subject to the requirements set out in Articles 50 to 60.

10. The Commission may, by means of implementing acts, specify or modify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:
- the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in Sections 3.3(c) and 4.5 of Annex VIII in the case of devices of classes IIa and IIb, and in Section 7.2 of Part A of Annex X in the case of devices of class IIa;
  - the minimum frequency of unannounced on-site audits and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device;
  - the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, assessment of the technical documentation and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII, Section 3 of Annex IX and Section 5 of Part B of Annex X.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

#### *Article 43*

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

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application may not be lodged in parallel with another notified body for the same conformity assessment procedure.
2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment, by means of the electronic system referred to in Article 45a.

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

*Article 43a*

*Clinical evaluation consultation procedure for certain class III and class IIb devices*

1. The notified body shall follow the procedure regarding clinical evaluation consultation as specified in Section 6.0 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable, when performing a conformity assessment of the following devices:
  - implantable Class III devicesand
  - Class IIb active devices intended to administer and/or remove a medicinal product, as referred to in section 5.3. of Annex VII (Rule 11).
- 1a. The procedure referred to in paragraph 1 is not required:
  - (a0) in the case of certificate renewal;
  - (a) where the device has been designed by modifications of a device already marketed by the same manufacturer for the same intended purpose if the modifications have been demonstrated by the manufacturer and accepted by the notified body as not adversely affecting the benefit/risk ratio; or

- (b) where the principles of the clinical evaluation of the device type or category have been addressed in a common specification referred to in Article 7 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant common specification for clinical evaluation of that kind of device.
2. Any notified body that takes a decision in accordance with paragraphs 1 and 1a shall notify the competent authorities, the national authority responsible for notified bodies and the Commission accordingly through the system referred to in Article 45a. That notification shall be accompanied by the clinical evaluation assessment report.
- 2a. The Commission shall draw up an annual overview of devices which have been subject to the procedure in section 6.0 of chapter II of annex VIII or section 6 of annex IX. The annual overview shall include the notifications of decisions in accordance with paragraph 2 and point (cab) of Section 6.0. in Chapter II of Annex VIII and a listing of the cases where the notified body did not follow the advice from the expert panel. The Commission shall submit this overview to the European Parliament, to the Council and to the MDCG.
3. The Commission shall by [date 5 year after the date of application of this regulation] draw up a report on the operation of this article and submit it to the European Parliament and to the Council. The report shall take into account the annual overviews and any available relevant recommendations from the MDCG. On the basis of this report the Commission shall, if appropriate, make proposals for amendments to this Regulation.

#### *Article 44*

##### *Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices*

1. A notified body shall notify the competent authorities of certificates it has granted to devices, the conformity assessment of which has been performed pursuant to Article 43a(1). Such notification shall take place through the electronic system referred to in Article 45a and shall include the summary of safety and clinical performance information pursuant to Article 26, the assessment report by the notified body, the instructions for use referred to in Section 19.3 of Annex I, and, where applicable, the scientific opinion of the expert panels referred to in Section 6.0 of Chapter II of annex VIII or Section 6 of Annex IX, as applicable, including, where applicable, a justification in case of divergent views between notified body and expert panel.
  - 1aa. A competent authority and, where applicable, the Commission may, based on reasonable concerns apply further procedures according to articles 35, 35a, 36, 37, 69 and, when deemed necessary, take appropriate measures according to Articles 70 and 73.
  - 1a. The MDCG and, where applicable, the Commission, may, based on reasonable concerns, request scientific advice from the expert panels in relation to the safety and performance of any device(s).

#### *Article 45*

##### *Certificates*

1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XII.

2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.
- 2a. Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or require manufacturers to undertake specific post-market clinical follow-up studies pursuant to Part B of Annex XIII.
3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.
4. The notified body shall enter into the electronic system referred to in Article 45a information regarding certificates issued, including amendments and supplements, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.
5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum content of the certificates set out in Annex XII.



## *Article 45a*

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

1. The Commission , after consulting the MDCG, shall set up and manage an electronic system to collate and process the following information;
  - (a) the list of subsidiaries referred to in Article 30(2);
  - (b) the list of experts referred to in Article 32a(2);
  - (c) the information relating to the notification referred to in Article 33(9);
  - (d) the list of notified bodies referred to in Article 34(2);
  - (e) the summary report referred to in Article 35(5);
  - (f) the notifications for conformity assessments and certificates referred to in Articles 43a(2) and 44(1);
  - (g) withdrawal of applications for the certificates referred to in Article 43(2);
  - (ga) information regarding certificates referred to in article 45(4);
  - (h) the summary of safety and clinical performance referred to in Article 26.
  
2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission, where appropriate to the notified bodies and where provided elsewhere in this regulation or in Regulation [ref of future Regulation on In vitro diagnostic medical devices] to the public.

## *Article 46*

### *Voluntary change of notified body*

1. In cases where a manufacturer terminates his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the incoming notified body and, where practicable the outgoing notified body. This agreement shall address at least the following aspects:
  - (a) the date of invalidity of certificates issued by the outgoing notified body;
  - (b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;

- (c) the transfer of documents, including confidentiality aspects and property rights;
  - (e) the date after which the conformity assessment tasks of the outgoing Notified Body is assigned to the incoming notified body;
  - (f) the last serial number or batch number for which the outgoing notified body is responsible.
2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.

#### *Article 47*

##### *Derogation from the conformity assessment procedures*

1. By way of derogation from Article 42, any competent authority may authorise, on duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 42 have not been carried out and use of which is in the interest of public health or patient safety or health.
2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.
3. Following a notification pursuant to paragraph 2, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(4).

*Article 48*

*Certificate of free sale*

1. For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, is established and that the device in question bearing the CE-marking in accordance with this Regulation may be marketed in the Union. The certificate of free sale shall set out the identification of the device in the electronic system set up under Article 24b. Where a notified body has issued a certificate referred to in Article 45, the certificate of free sale shall set out the unique number identifying that certificate, pursuant to section 3, Chapter II of Annex XII.
2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

# Chapter VI

## Clinical evaluation and clinical investigations

### *Article 49*

#### *Clinical evaluation*

1. Confirmation of conformity with the general safety and performance requirements referred to in Annex I and where applicable relevant requirements of Annex IIa under the normal conditions of the intended use of the device, and the evaluation of the 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 providing sufficient clinical evidence.

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

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

- 1a. For devices classified as class III and following the exemptions for the procedure laid down in Article 43a(1), the manufacturer may, prior to its clinical evaluation and/or investigation, consult an expert panel according to the procedure mentioned in article 81a, with the aim to review the manufacturer's intended clinical development strategy and proposals for clinical investigation(s). The manufacturer shall give due consideration to the views expressed by the expert panel. These considerations shall be documented in the clinical evaluation report referred to in paragraph 5.

The manufacturer may not evoke any rights to the views expressed by the expert panel with regard to any future conformity assessment procedure.

2. A clinical evaluation shall follow a defined and methodologically sound procedure based on the following:
- (a) a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where the following conditions are satisfied:
    - it is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate, in accordance with Section 4a of Part A of Annex XIII,and
    - the data adequately demonstrate compliance with the relevant general safety and performance requirements;
  - (b) a critical evaluation of the results of all available clinical investigations, having due regard to whether the investigations were performed in accordance with Articles 50 to 60 and Annex XIV;
  - (d) a consideration of currently available alternative treatment options for that purpose, if any.
- 2a. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed, except if:
- the device has been designed by modifications of a device already marketed by the same manufacturer,  
the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with Section 4a of Part A of Annex XIII and this demonstration has been endorsed by the notified body,
- and
- the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

In this case the notified body shall check that the PMCF plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.

In addition, clinical investigations need not be performed in the cases referred to in paragraph 2ab.

- 2aa. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by him, may also rely on paragraph 2a in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:
- the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, and
  - the original clinical evaluation has been performed in compliance with the requirements of this Regulation,
- and the manufacturer of the second device provides clear evidence thereof to the notified body.
- 2ab. The requirement to perform clinical investigations pursuant to paragraph 2a shall not apply to implantable devices and devices falling into class III:
- (a) which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation
- is based on sufficient clinical data and
  - is in compliance with the relevant product-specific common specification for the clinical evaluation of that kind of device, where such a common specification is available;
- or
- (b) that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific common specification, where such a common specification is available.

- 2ac. In cases where paragraph 2a is not applied by virtue of paragraph 2ab, this shall be justified in the clinical evaluation report by the manufacturer and in the clinical evaluation assessment report by the notified body.
- 2ad. Where justified in view of similar well-established technologies compared to those used in the devices in the list in Article 49(2ab) point (b) being used or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Articles 42(3) and 49(2ab) point (b), by adding other types of implantable or class III devices to the list or removing devices therefrom.
- 2b. In the case of the products without a medical purpose listed in Annex XV, the requirement to demonstrate a clinical benefit in accordance with this chapter and Annex XIII and Annex XIV shall be understood as a requirement to demonstrate the performance of the device. Clinical evaluations of these products shall be based on relevant data concerning safety, including data from post-market surveillance, specific post-market clinical follow-up, and, where applicable, specific clinical investigation. For these products clinical investigations shall be performed unless it is duly justified to rely on existing clinical data from an analogous medical device.
3. Except for class III and implantable devices, where demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performances intended and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, has to be duly substantiated in the technical documentation referred to in Annex II.

4. The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF according to Annex XIII Part B and the post-market surveillance plan referred to in Article 60b.

For devices classified as class III and implantable devices, the PMCF report and, if indicated, the summary of safety and clinical performance referred to in Article 26(1) shall be updated at least annually with these data.

5. The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report referred to in Section 6 of Part A of Annex XIII, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned.
6. Where necessary to ensure the uniform application of Annex XIII, the Commission may, having due regard to technical and scientific progress, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

#### *Article 50*

##### *General requirements regarding clinical investigations conducted to establish conformity of devices*

1. Clinical investigations shall be designed, authorized, conducted, recorded and reported in accordance with the provisions of Articles 50-60 and Annex XIV if they are carried out as part of the clinical evaluation for conformity assessment purposes for one or more of the following purposes:
  - (a) to establish and verify that, under normal conditions of use, a device is designed, manufactured and packaged in such a way that it is suitable for one or more of the specific purposes referred to in number (1) of Article 2(1), and achieves the performances intended as specified by its manufacturer;



- (b) to establish and verify the clinical benefits of a device as specified by its manufacturer;
- (c) to establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of a device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.

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

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

3. Clinical investigations shall be designed and conducted in a way that the rights, safety, dignity and well-being of the subjects participating in a clinical investigation are protected and prevail over all other interests and the clinical data generated are going to be scientifically valid, reliable and robust.

Clinical investigations shall be subject to scientific and ethical review. The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. Member States shall ensure that the procedures for the review by the ethics committees are compatible with the procedures set out in this Regulation for the assessment of the application for authorisation of a clinical investigation. At least one lay person shall participate in the ethical review.

5. A clinical investigation according to paragraph 1 may be conducted only where all of the following conditions are met:
- (a) the clinical investigation was subject to an authorisation by a Member State(s) concerned, in accordance with this Regulation, unless otherwise stated;
  - (b) an independent ethics committee, set up according to national law, has not issued a negative opinion valid for that entire Member State in accordance with its national law;
  - (c) the sponsor, or its legal representative or a contact person pursuant to paragraph 2, is established in the Union;
  - (cb) vulnerable populations and subjects are appropriately protected in accordance with Article 50c to 50cd;
  - (d) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;
  - (e) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent in accordance with Article 50aa;
  - (f) the subject or, where the subject is not able to give informed consent, his or her legally designated representative, has been provided with the contact details of an entity where further information can be received in case of need;
  - (h) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC<sup>33</sup> are safeguarded;
  - (i) the clinical investigation has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects and both the risk threshold and the degree of distress are specifically defined in the clinical investigation plan and constantly monitored;
  - (j) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner or any other person entitled by national law to provide the relevant patient care under clinical investigation conditions;

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<sup>33</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

- (k) no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate in the clinical investigation;
- (l) the investigational device(s) in question conform(s) to the applicable 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 subjects. This includes, where appropriate, technical and biological safety testing and pre-clinical evaluation, as well as provisions in the field of occupational safety and accident prevention, taking into consideration the state of the art;
- (m) the requirements of Annex XIV are fulfilled.

Any subject, or, where the subject is not able to give informed consent, his or her legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the clinical investigation at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC<sup>34</sup>, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

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

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<sup>34</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

*Article 50aa*

*Informed consent*

1. Informed consent shall be written, dated and signed by the person performing the interview referred to in point (c) of paragraph 2, and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 2. Where the subject is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. In that case, the witness shall sign and date the informed consent document. The subject or, where the subject is not able to give informed consent, his or her legally designated representative shall be provided with a copy of the document (or the record) by which informed consent has been given. The informed consent shall be documented. Adequate time shall be given for the subject or his or her legally designated representative to consider his or her decision to participate in the clinical investigation.
  
2. Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent shall:
  - (a) enable the subject or his or her legally designated representative to understand:
    - (i) the nature, objectives, benefits, implications, risks and inconveniences of the clinical investigations;
    - (ii) the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical investigation at any time without any resulting detriment and without having to provide any justification;
    - (iii) the conditions under which the clinical investigations is to be conducted, including the expected duration of the subject's participation in the clinical investigation; and
    - (iv) the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical investigation is discontinued;
  - (b) be kept comprehensive, concise, clear, relevant, and understandable to the intended user;

- (c) be provided in a prior interview with a member of the investigating team who is appropriately qualified according to the law of the Member State concerned;
  - (d) include information about the applicable damage compensation system referred to in Article 50d; and
  - (e) include the Union-wide unique single identification number of the clinical investigation and information about the availability of the clinical investigation results in accordance with paragraph 6.
3. The information referred to in paragraph 2 shall be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, his or her legally designated representative.
  4. In the interview referred to in point (c) of paragraph 2, special attention shall be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information.
  5. In the interview referred to in point (c) of paragraph 2, it shall be verified that the subject has understood the information.
  6. The subject shall be informed that the clinical investigation report and a summary presented in terms understandable to the intended user will be made available in the EU database, referred to in Article 27 pursuant to Article 57(3), irrespective of the outcome of the clinical investigation, and, to the extent possible, when the summaries become available.
  8. This Regulation is without prejudice to national law requiring that, in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a clinical investigation.

*Article 50c*

*Clinical investigations on incapacitated subjects*

1. In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a clinical investigation may be conducted only where, in addition to the conditions set out in Article 50(5), all of the following conditions are met:
  - (a) the informed consent of their legally designated representative has been obtained;
  - (b) the incapacitated subjects have received the information referred to Article 50aa in a way that is adequate in view of their capacity to understand it;
  - (c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to Article 50aa to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;
  - (d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation.
  - (e) the clinical investigation is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in clinical investigations on persons able to give informed consent, or by other research methods;
  - (f) the clinical investigation relates directly to a medical condition from which the subject suffers;
  - (g) there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the incapacitated subject outweighing the risks and burdens involved.
  
2. The subject shall as far as possible take part in the informed consent procedure.

*Article 50ca*

*Clinical investigations on minors*

A clinical investigation on minors may be conducted only where, in addition to the conditions set out in Article 50(5), all of the following conditions are met:

- (a) the informed consent of their legally designated representative has been obtained;
- (b) the minors have received the information referred to in Article 50aa in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;
- (c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 50aa to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;
- (d) no incentives or financial inducements are given to the subject or his or her legally designated representative except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;
- (e) the clinical investigation is intended to investigate treatments for a medical condition that only occurs in minors or the clinical investigation is essential with respect to minors to validate data obtained in clinical investigations on persons able to give informed consent or by other research methods;
- (f) the clinical investigation either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;
- (g) there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the minor subject outweighing the risks and burdens involved.
- (h) The minor shall take part in the informed consent procedure in a way adapted to his or her age and mental maturity;
- (i) If during a clinical investigation the minor reaches the age of legal competence to give informed consent as defined in the law of the Member State concerned, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical investigation.

*Article 50cb*

*Clinical investigations on pregnant or breastfeeding women*

A clinical investigation on pregnant or breastfeeding women may be conducted only where, in addition to the conditions set out in Article 50(5), the following conditions are met:

- (a) the clinical investigation has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;
- (c) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child; and
- (d) no incentives or financial inducements are given to the subject except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation.

*Article 50cc*

*Additional national measures*

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



*Article 50cd*

*Clinical investigations in emergency situations*

1. By way of derogation from point (e) of Article 50(5), from points (a) and (b) of Article 50c(1) and from points (a) and (b) of Article 50ca, informed consent to participate in a clinical investigation may be obtained, and information on the clinical investigation may be given, after the decision to include the subject in the clinical investigation, provided that this decision is taken at the time of the first intervention on the subject, in accordance with the clinical investigation plan for that clinical investigation and that all of the following conditions are fulfilled:
  - (a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical investigation;
  - (b) there are scientific grounds to expect that participation of the subject in the clinical investigation will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;
  - (c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative;
  - (d) the investigator certifies that he or she is not aware of any objections to participate in the clinical investigation previously expressed by the subject;
  - (e) the clinical investigation relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the clinical investigation is of such a nature that it may be conducted exclusively in emergency situations
  - (f) the clinical investigation poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

2. Following an intervention pursuant to paragraph 1, informed consent in accordance with Article 50aa shall be sought to continue the participation of the subject in the clinical investigation, and information on the clinical investigation shall be given, in accordance with the following requirements:
  - (a) regarding incapacitated subjects and minors, the informed consent shall be sought by the investigator from his or her legally designated representative without undue delay and the information referred to in Article 50aa shall be given as soon as possible to the subject and to his or her legally designated representative;
  - (b) regarding other subjects, the informed consent shall be sought by the investigator without undue delay from the subject or his or her legally designated representative, whichever is sooner and the information referred to in Article 50aa shall be given as soon as possible to the subject or his or her legally designated representative, whichever is sooner.

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

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

#### *Article 50d*

##### *Damage compensation*

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

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

#### *Article 51*

##### *Application for clinical investigations*

2. The sponsor of a clinical investigation shall submit by means of the electronic system referred to in Article 53 an application to the Member State(s) in which the investigation is to be conducted accompanied by the documentation referred to in Chapter II of Annex XIV. The electronic system referred to in Article 53 shall generate a Union-wide unique single identification number for this clinical investigation which shall be used for all relevant communication in relation to the clinical investigation concerned. Within ten days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical investigation falls within the scope of this Regulation and whether the application is complete.
  - 2a. Within one week of any change occurring in relation to the documentation referred to in Chapter II of Annex XIV, the sponsor shall update the relevant data in the electronic system referred to in Article 53. The Member State concerned shall be notified of the update and the changes to the documents shall be clearly identifiable.

3. Where the Member State finds that the clinical investigation applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of ten days for the sponsor to comment or to complete the application. Member States may extend this period with a maximum of 20 days where appropriate.

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

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

- 3a. The concerned Member State may also extend the period referred to in paragraph 2 and 3 each by a further 5 days.
4. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 2 or 3 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the time periods referred to in 2, 3 and 3a.
- 4a. In the period during which the application is being assessed the Member State may request additional information from the sponsor. The expiry of the period laid down in paragraph 5(b) (second indent) shall be suspended from the date of the first request until such time as the additional information has been received.

5. The sponsor may start the clinical investigation in the following circumstances:
  - (a) in the case of investigational devices classified as class I or in the case of non-invasive devices classified as class IIa or IIb, unless otherwise stated by national provisions, immediately after the validation date of the application described in paragraph 4, and provided that the competent ethics committee in the Member State concerned has not issued a negative opinion valid for that entire Member State in accordance with its national law;
  - (b) in the case of investigational devices other than those referred to in point (a) as soon as the Member State concerned has notified the sponsor of its authorisation and provided that the competent ethics committee in the Member State concerned has not issued a negative opinion valid for that entire Member State in accordance with its national law. The Member State shall notify the sponsor of the authorisation within 45 days after the validation date referred to in paragraph 4. The Member State may extend this period by a further 20 days for the purpose of consulting with experts.
  
7. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress and global regulatory developments, the requirements for the documentation to be submitted with the application for the clinical investigation that is laid down in Chapter II of Annex XIV.
  
- 7a. The Commission may adopt implementing acts in accordance with Article 88(3) in order to assure the uniform application of the requirements for the documentation to be submitted with the application for the clinical investigation that is laid down in Chapter II of Annex XIV, to the extent necessary to resolve issues of divergent interpretation and practical application.

*Article 51a*

*Assessment by Member States*

1. Member States shall ensure that the persons validating and assessing the application, or deciding on it, do not have conflicts of interest, are independent of the sponsor, the investigators involved and of persons or legal persons financing the clinical investigation, as well as free of any other undue influence.

2. Member States shall ensure that the assessment is done jointly by an appropriate number of persons who collectively have the necessary qualifications and experience.
3. Member States shall assess whether the clinical investigation is designed in such a way that potential remaining risks to subjects or third person, after risk minimization, are justified, when weighed against the clinical benefits to be expected. They shall examine, under consideration of applicable common specifications or harmonized standards, in particular:
  - (a) the demonstration of compliance of the investigational device(s) with the applicable general safety and performance requirements, apart from the aspects covered by the clinical investigation and whether, with regard to these aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, assurance of technical and biological safety testing and pre-clinical evaluation;
  - (b) whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, the equivalence of the level of protection to harmonised standards;
  - (c) the plausibility of the measures planned for the safe installation, putting into service and maintenance of the investigational device;
  - (d) the reliability and robustness of the data generated in the clinical investigation, taking account of statistical approaches, design of the investigation and methodological aspects (including sample size, comparator and endpoints);
  - (da) the requirements of Annex XIV are met.
  - (e) in the case of devices for sterile use, evidence of the validation of the manufacturer's sterilisation procedures or information on the reconditioning and sterilisation procedures which must be conducted by the investigation site;
  - (f) demonstration of safety, quality and usefulness of any components of animal or human origin or of substances, which may be considered medicinal products according to Directive 2001/83/EC.

4. Member States shall refuse the authorisation of the clinical investigation if:
  - (b) the application submitted according to Article 51 paragraph 2 remains incomplete;
  - (ca) the device or the submitted documents, especially the investigation plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the clinical investigation, in particular, is not suitable to provide evidence for the safety, performance characteristics or benefit of the device on patients, or
  - (d) the requirements of Article 50 are not met, or
  - (e) any assessment according to paragraph 3 is negative.

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

#### *Article 51e*

##### *Conduct of a clinical investigation*

1. The sponsor and the investigator shall ensure that the clinical investigation is conducted in accordance with the approved clinical investigation plan.
2. In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the clinical investigation is in compliance with the requirements of this Regulation, the sponsor shall adequately monitor the conduct of a clinical investigation. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the clinical investigation including the following characteristics:
  - (a) the objective and methodology of the clinical investigation and
  - (b) the degree of deviation of the intervention from normal clinical practice.
3. All clinical investigation information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.

4. Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves the transmission over a network.
5. Member States shall inspect on an appropriate level investigation site(s) to check that clinical investigations are conducted according to the requirements of this Regulation and to the approved investigation plan.
6. The sponsor shall establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the investigation.

### *Article 53*

#### *Electronic system on clinical investigations*

1. The Commission shall, in collaboration with the Member States, set up, manage and maintain an electronic system:
  - (aa) to create the single identification numbers for clinical investigations;
  - (ab) to be used as an entry point for the submission of all applications or notifications for clinical investigations referred to in Articles 51(2), 54, 55 and 58 and for all other submission of data, or processing of data in this context;
  - (b) for the exchange of information relating to clinical investigations in accordance with this Regulation between the Member States and between them and the Commission including those according to Article 51 and 56;
  - (ba) for information by the sponsor in accordance with Article 57, including the clinical investigation report and its summary as required in paragraph 3 of that Article;
  - (d) for reporting on serious adverse events and device deficiencies and related updates referred to in Article 59;



2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article 81 of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC<sup>35</sup> as concerns combined clinical investigations of devices with a clinical trial under that regulation.
- 2b. The information referred to in paragraph 1 except the information referred to in point b, which shall only be accessible to the Member States and the Commission, shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:
- (a) protection of personal data in accordance with Regulation (EC) No 45/2001;
  - (b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure,
  - (c) effective supervision of the conduct of the clinical investigation by the Member State(s) concerned;
- 2ba. No personal data of subjects participating in clinical investigations shall be publicly available.
- 2c. The user interface of the electronic system referred to in this Article shall be available in all official languages of the Union.

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<sup>35</sup> OJ L 158, 27.5.2014, p. 1

#### *Article 54*

##### *Clinical investigations with devices authorised to bear the CE marking*

1. Where a clinical investigation is to be conducted to further assess a device which is authorised in accordance with Article 42 to bear the CE marking and within its intended purpose referred to in the relevant conformity assessment procedure, hereinafter referred to as ‘post-market clinical follow-up investigation’, the sponsor shall notify the Member States concerned at least 30 days prior to their commencement if the investigation would submit subjects to additionally invasive or burdensome procedures. The notification shall be made by means of the electronic system referred to in Article 53. It shall be accompanied by the documentation referred to in Chapter II of Annex XIV. Article 50 paragraph 5 points (b) to (k) and (m), Article 55, Article 56, Article 57, Article 59(6) and the relevant provisions of Annex XIV shall apply.
2. If the aim of the clinical investigation regarding a device which is authorised in accordance with Article 42 to bear the CE marking is to assess such device for a purpose other than that referred to in the information supplied by the manufacturer in accordance with Section 19 of Annex I and in the relevant conformity assessment procedure, Articles 50 to 60 shall apply.

#### *Article 55*

##### *Substantial modifications to a clinical investigation*

1. If the sponsor intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, he shall notify, within one week, by means of the electronic system referred to in Article 53 the Member State(s) concerned of the reasons for and the content of those modifications. The notification shall be accompanied by an updated version of the relevant documentation referred to in Chapter II of Annex XIV, changes shall be clearly identifiable.

- 1a. The Member State shall assess the substantial modification to the clinical investigation in accordance with the procedure laid down in Article 51a.
2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 38 days after notification, unless the Member State concerned has notified the sponsor of its refusal based on Article 51a paragraph 4 or considerations of public health, subject and user safety or health, of public policy, or the ethics committee has issued a negative opinion which in accordance with the law of that Member State, is valid for that entire Member State.
3. The Member State(s) concerned may extend the period referred to in paragraph 2 by a further 7 days, for the purpose of consulting with experts.

#### *Article 56*

##### *Corrective measures to be taken by Member States and Information exchange between Member States*

- 0a. Where a Member State concerned has grounds for considering that the requirements set out in this Regulation are no longer met, it may at least take the following measures on its territory:
  - (a) withdraw or revoke the authorisation of a clinical investigation;
  - (b) suspend, temporary halt or terminate a clinical investigation;
  - (c) require the sponsor to modify any aspect of the clinical investigation.
- 0b. Before the Member State concerned takes any of the measures referred to in paragraph 0a it shall, except where immediate action is required, ask the sponsor and/or the investigator for their opinion. That opinion shall be delivered within seven days.
1. Where a Member State has taken a measure referred to in paragraph 0a or has refused a clinical investigation, or has been notified by the sponsor of the early termination of a clinical investigation on safety grounds, that Member State shall communicate this decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 53.

2. Where an application is withdrawn by the sponsor prior to a decision by a Member State, that information shall be made available through the electronic system referred to in Article 53 to all Member States and the Commission.

*Article 57*

*Information by the sponsor at the end of a clinical investigation or in the event of temporary halt or early termination*

1. If the sponsor has temporarily halted a clinical investigation or has terminated a clinical investigation early, he shall inform the Member States concerned within 15 days, through the electronic system referred to in Article 53, of the temporary halt or early termination, providing a justification. In case the sponsor has temporarily halted or early terminated the clinical investigation on safety grounds, he shall inform the Member states concerned thereof within 24 hours.
2. The sponsor shall notify each Member State concerned of the end of a clinical investigation in relation to that Member State. That notification shall be made within 15 days from the end of the clinical investigation in relation to that Member State.
  - 2a. If the investigation is conducted in more than one Member State the sponsor shall notify all Member States concerned of the overall end of the clinical investigation. That notification shall be made within 15 days from the overall end of the clinical investigation.
3. Irrespective of the outcome of the clinical investigation, within one year from the end of the clinical investigation or within three months from the early termination or halt, the sponsor shall submit to the Member States concerned through the electronic system referred to in Article 53 a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV.

It shall be accompanied by a summary presented in terms that are easily understandable to the intended user. Both the report and summary shall be submitted by the sponsor by means of the electronic system referred to in Article 53.

Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year after the completion of the investigation, it shall be submitted as soon as it is available. In this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall specify when the results of the clinical investigation are going to be submitted, together with a justification.

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

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

5. The summary and the report according to paragraph 3 shall become publicly accessible through the electronic system, at the latest when the device is registered according to Article 24b and before it is placed on the market. In cases of early termination or halt the summary and the report shall become publicly accessible immediately after submission.

If the device is not registered according to article 24b within one year after the summary and the report have been entered into the electronic system according to paragraphs 3, they shall become publicly accessible at that point in time.

#### *Article 58*

##### *Clinical investigations conducted in more than one Member State*

1. By means of the electronic system referred to in Article 53, the sponsor of a clinical investigation to be conducted in more than one Member State may submit, for the purpose of Article 51, a single application that, upon receipt, is transmitted electronically to the Member States concerned.

2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. Concerned Member States shall, within six days of submission of the application, agree on one of them taking the role of the coordinating Member State. If they do not agree on a coordinating Member State, the one proposed by the sponsor shall take that role. The deadlines referred to in Article 51(2) shall start on the day following the notification of the coordinating Member State to the sponsor (notification date).
3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation submitted in accordance with Chapter II of Annex XIV, except for Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 thereof which shall be assessed separately by each Member State concerned.

The coordinating Member State shall:

- (a) within 6 days of receipt of the single application, notify the sponsor that it is the coordinating Member State (notification date);
- (aa) within 10 days of the notification date, notify the sponsor whether the clinical investigation falls within the scope of this Regulation and whether the application is complete, except for the documentation submitted in accordance with Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV for which each Member State shall verify the completeness. Article 51(2) to (4) shall apply to the coordinating Member State in relation to the verification that the clinical investigation falls within the scope of this Regulation and that the application is complete, having taken into account considerations expressed by the other Member States concerned, except for the documentation submitted in accordance with Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV. Concerned Member States may communicate to the coordinating Member State any considerations relevant to the validation of the application within seven days from the notification date. Article 51(2) to (4) shall apply to each Member State in relation to the verification that the documentation submitted in accordance with Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV is complete;

- (b) establish the results of its assessment in a draft assessment report to be transmitted within 26 days after the validation date to the concerned Member States. Until day 38 after the validation date the other concerned Member States shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State, which shall take due account of it in the finalization of the final assessment report, to be transmitted within 45 days following the validation date to the sponsor and the concerned Member States. The final assessment report shall be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 51(5), except for Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV, which shall be assessed separately by each Member State concerned.

As concerns the assessment of the documentation related to Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV, each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within the period set by the Member State concerned which shall not exceed 12 days from the receipt of the request. The expiry of the deadline pursuant to point (b) shall be suspended from the date of the request until such time as the additional information has been received.

- 3a. For devices classified as class IIb and class III, the coordinating Member State may also extend the periods referred to in paragraph 3 by a further 50 days, for the purpose of consulting with experts. In such case, the periods referred to in paragraphs 3 of this Article shall apply *mutatis mutandis*.

- 3b. The Commission may, by means of implementing acts, set out the procedures and timescales for a coordinated assessment led by the coordinating Member State, that shall be taken into account by concerned Member States when deciding on the sponsor's application. Such implementing acts may also cover the procedures for coordinated assessment in the case of substantial modifications pursuant to paragraph 4 and in the case of reporting of events pursuant to Article 59(4) or in the case of clinical investigations of combination products between medical devices and medicinal products, where the latter are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) No 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
- 3c. Where the conclusion of the coordinating Member State is that the conduct of the clinical investigation is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State(s) concerned.

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

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

Where a Member State concerned disagrees with the conclusion, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 53, to the Commission, to all Member States concerned and to the sponsor.



- 3d. A Member State concerned shall refuse to authorise a clinical investigation if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 3c, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.13., 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV are not complied with, or where an ethics committee has issued a negative opinion which in accordance with the law of the Member State concerned is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.
- 3da. Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 53 as to whether the clinical investigation is authorised, whether it is authorised subject to conditions, or whether authorisation is refused. Notification shall be done by way of one single decision within five days from the transmission, pursuant to paragraph 3, point (b), by the coordinating Member State of the final assessment report. An authorisation of a clinical investigation subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.
- 3e. Where the conclusion of the coordinating Member State report is that the clinical investigation is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.
4. The substantial modifications as referred to in Article 55 shall be notified to the Member States concerned by means of the electronic system referred to in Article 53. Any assessment as to whether there are grounds for refusal as referred to in paragraph 3c shall be carried out under the direction of the coordinating Member State, except for substantial modifications concerning Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV, which shall be assessed by each concerned Member State on its own.
6. The Commission shall provide administrative support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.

## *Article 58a*

### *Review of coordinated procedure*

At the latest six years after the date referred to in Article 97(2), the Commission shall submit a report on experience gained from the application of Article 58 to the European Parliament and the Council and, if necessary, propose a review of Article 97(3)(d).

## *Article 59*

### *Recording and reporting of adverse events occurring during clinical investigations*

1. The sponsor shall fully record any of the following:
  - (a) an adverse event identified in the clinical investigation plan as critical to the evaluation of the results of the clinical investigation according to the clinical investigation plan;
  - (b) a serious adverse event;
  - (c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
  - (d) new findings in relation to any event referred to in points (a) to (c).
  
2. The sponsor shall report to all Member States where a clinical investigation is conducted without delay any of the following by means of the electronic system referred to in Article 53:
  - (a) a serious adverse event that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;
  - (b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
  - (c) new findings in relation to any event referred to in points (a) to (b).

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

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

3. The sponsor shall also report to the Member States concerned any event referred to in paragraph 2 occurring in third countries in which a clinical investigation is performed under the same clinical investigation plan as the one applying to a clinical investigation covered by this Regulation by means of the electronic system referred to in Article 53.
4. In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 58, the sponsor shall report any event as referred to in paragraph 2 by means of the electronic system referred to in Article 53. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Under the direction of the coordinating Member State referred to in Article 58(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a clinical investigation needs to be terminated, suspended, temporarily halted or modified.

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

5. In the case of post-market clinical follow-up investigations referred to in Article 54(1), the provisions on vigilance contained in Articles 61 to 66 shall apply instead of this Article.
6. Notwithstanding paragraph 5, this Article shall apply where a causal relationship between the serious adverse event and the preceding investigational procedure has been established.

## *Article 60*

### *Implementing acts*

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

- (a) harmonised electronic forms for the application for clinical investigations and their assessment as referred to in Articles 51 and 58, taking into account specific categories or groups of devices;
- (b) the functioning of the electronic system referred to in Article 53;
- (c) harmonised electronic forms for the notification of post-market clinical follow-up investigations as referred to in Article 54(1), and of substantial modifications as referred to in Article 55;
- (d) the exchange of information between Member States as referred to in Article 56;
- (e) harmonised electronic forms for the reporting of serious adverse events and device deficiencies as referred to in Article 59;
- (f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 59.
- (g) uniform application of the requirements regarding the clinical evidence/data needed to demonstrate compliance with the general safety and performance requirements specified in Annex I.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

*Article 60aa*

*Requirements regarding other clinical investigations*

1. Clinical investigations, not performed pursuant to any of the purposes listed in Article 50(1), shall comply with the provisions of Article 50 paragraphs 2, 3, 5 point (b), 5 point (c), 5 point (cb), 5 point (e), 5 point (h), 5 point (l) and 8 of this Regulation.
  
2. In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of the clinical investigations not performed pursuant to any of the purposes listed in Article 50(1), each Member State shall define any additional requirements for such investigations, as appropriate for each Member State concerned.

## Chapter VII

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

#### SECTION 0 – POST-MARKET SURVEILLANCE

##### *Article 60a*

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

2. For any device, proportionate to the risk class and appropriate for the type of device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system which shall be an integral part of the manufacturer's quality management system according to Article 8(6).
3. The post-market surveillance system shall be suitable to actively and systematically gather, record and analyse relevant data on the quality, performance and safety of a device throughout its entire lifetime, to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions.
4. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:
  - (a) to update the benefit risk determination and risk management, the design and manufacturing information, the instructions for use and the labelling;
  - (b) to update the clinical evaluation;
  - (c) to update the summary of safety and clinical performance as referred to in Article 26;
  - (d) for the identification of needs for preventive, corrective or field safety corrective action;
  - (e) for the identification of possibilities to improve the usability, performance and safety of the device;
  - (f) when relevant, to contribute to the post-market surveillance of other devices.
  - (g) to detect and report trends in accordance with article 61a.

The technical documentation shall be updated accordingly.

6. If in the course of the post-market surveillance a need for preventive and/or corrective action is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. When a serious incident is identified or a field safety corrective action is implemented, this shall be reported in accordance with Article 61.

#### *Article 60b*

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

The post-market surveillance system as referred to in Article 60a shall be based on a post-market surveillance plan, the requirements of which are set out in Section 1.1 of Annex IIa. For devices other than custom made-devices, the post-market surveillance plan shall be part of the technical documentation as specified in Annex II.

#### *Article 60ba*

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

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

*Article 60c*

*Periodic safety update report*

1. Per device and where relevant per category or group of devices, manufacturers of devices in class IIa, IIb and III shall prepare a periodic safety update report summarising the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex IIa together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned this report shall set out:
  - (a) the conclusion of the benefit risk determination;
  - (b) the main findings of the Post Market Clinical Follow-up Report and
  - (c) the volume of sales of devices and an estimate of the population that use the device involved and, where practicable, the usage frequency of the device.

Manufacturers of class IIb and III devices shall update the report at least annually and it shall, except in the case of custom made medical devices, be part of the technical documentation as specified in Annexes II and IIa.

Manufacturers of class IIa devices shall update the report when necessary and at least every two years; and it shall, except in the case of custom made medical devices, be part of the technical documentation as specified in Annexes II and IIa.

For custom-made devices the report shall be part of the documentation referred to in Section 2 of Annex XI.

2. Manufacturers of devices in class III or implantable devices shall submit reports by means of the electronic system referred to in Article 66a to the notified body involved in the conformity assessment in accordance with Article 42. The notified body shall review the report and add its evaluation to the database with details of any action taken. Such reports and the notified body evaluation shall be available to competent authorities through the electronic system.
3. Manufacturers of devices other than those referred to in paragraph 2, shall make reports available to the notified body involved in the conformity assessment and, upon request, to competent authorities.



## SECTION 1 – VIGILANCE

### *Article 61*

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

1. Manufacturers of devices, made available on the Union market, other than investigational devices, shall report, through the electronic system referred to in Article 66a, the following:
  - (a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 61a;
  - (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.
- 1a. As a general rule, the time period for reporting shall take account of the severity of the serious incident.
- 1b. Manufacturers shall report any serious incident as referred to in point (a) of paragraph 1 immediately after the manufacturer has established the causal relationship with their device or that such causal relationship is reasonably possible, and not later than 15 days after they have become aware of the serious incident.
- 1c. Notwithstanding paragraph 1b, in case of a serious public health threat the report shall be provided immediately, and not later than 2 days after awareness by the manufacturer of this threat.
- 1d. Notwithstanding paragraph 1b, in case of death or unanticipated serious deterioration in state of health the report shall be provided immediately after the manufacturer established or suspected a causal relationship between the device and the serious incident but not later than 10 elapsed days following the date of awareness of the serious incident.

- 1e. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.
  - 1f. If after becoming aware of a potentially reportable incident there is still uncertainty about whether the incident is reportable, the manufacturer shall submit a report within the timeframe required for that type of incident.
  - 1g. Except in cases of urgency where the manufacturer need to undertake the field safety corrective action immediately, without undue delay, the manufacturer shall report the field safety corrective action referred to in paragraph 1, point (b) in advance of the field safety corrective action being undertaken.
2. For similar serious incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 63(6), in consultation with the competent authorities referred to in point (a) of Article 66a, paragraph 7, has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. Where a single competent authority is referred to in points (a) and (b) of Article 66a, paragraph 7, the manufacturer may provide periodic summary reports on agreement with that competent authority.
  3. The Member States shall take appropriate measures such as targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1.

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

The manufacturer of the device concerned shall provide to the competent authority of the Member State where the serious incident occurred a report on the serious incident in accordance with paragraph 1, and ensure the appropriate follow-up; if the manufacturer considers that the incident is not a serious incident or an expected undesirable side effect which will be covered by trend reporting according to Article 61a, it shall provide an explanatory statement.

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

#### *Article 61a*

##### *Trend reporting*

1. Manufacturers shall report by means of the electronic system referred to in Article 66a any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable side-effects that could have a significant impact on the risk-benefit analysis referred to in Sections I.1 and I.5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period as specified in the technical documentation and product information.

The manufacturer shall define how to manage these incidents and the methodology used for determining any statistically significant increase in the frequency or severity of these incidents, as well as the observation period, in the post-market surveillance plan pursuant to Article 60b.

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

### *Article 63*

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

0. Following the reporting of a serious incident pursuant to Article 61(1), the manufacturer shall without delay perform the necessary investigations of the serious incident and the concerned devices. This shall include a risk assessment of the incident and field safety corrective action taking into account criteria outlined in paragraph 2 as appropriate.

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

1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 61 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer, and, where relevant, with the notified body concerned.

2. In the context of the evaluation referred to in paragraph 0, the national competent authority shall evaluate the risks arising from reported serious incidents and field safety corrective actions, taking into account the protection of public health and criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of direct or indirect harm and severity of that harm, clinical benefit of the device, intended and potential users, and population affected. It shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action, in particular taking into account the principle of inherent safety laid down in Annex I.

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

- 2a. The competent authority shall monitor the manufacturer's investigation of a serious incident. Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.
  - 2b. The manufacturer shall provide a final report to the competent authority setting out its findings by means of the electronic system referred to in Article 66a. The report shall set out conclusions and where relevant indicate corrective actions to be taken.
3. In the case of devices referred to in the first subparagraph of Article 1(4) and where the serious incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 6 shall, depending on whether a national competent authority for medicinal products or the European Medicines Agency (EMA) was consulted by the notified body in accordance with Article 42(2d), inform that competent authority or the EMA.

In the case of devices covered by this Regulation in accordance with point (e) of Article 1(2) and where the serious incident or field safety corrective action may be related to the tissues or cells of human origin utilised for the manufacture of the device, the competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for human tissues and cells that was consulted by the notified body in accordance with Article 42(2e).

4. After carrying out the evaluation, the evaluating competent authority shall, through the electronic system referred to in Article 66a, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence of a serious incident, including information on the underlying events and the outcome of its assessment.
5. The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. The field safety notice shall be edited in an official Union language or languages determined by the Member State where the field safety corrective action is taken. Except in case of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in cases referred to in paragraph 6 f this Article, the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

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

The manufacturer shall enter the field safety notice in the electronic system referred to in Article 66a through which that notice shall be accessible to the public.

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

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

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

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

The coordinating competent authority shall, through the electronic system referred to in Article 66a, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

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

## *Article 65a*

### *Analysis of vigilance data*

The Commission shall, in collaboration with the Member States, put in place systems and processes to proactively monitor the data available in the database referred to in Article 66a, in order to identify trends, patterns or signals in the data that may identify new risks or safety concerns.

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

## *Article 66*

### *Implementing acts*

The Commission may, by means of implementing acts, and after consultation of the MDCG, adopt the modalities and procedural aspects necessary for the implementation of Articles 60ba to 65a and 66a as regards the following:

- (a) typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;
- (b) the reporting of serious incidents and field safety corrective actions, field safety notices, periodic summary reports, post-market surveillance reports, periodic safety update reports and trend reports by manufacturers as referred to in Articles 60ba, 60c, 61, 61a and 63;
- (ba) standard structured forms for electronic and non-electronic reporting, including a minimum data set for reporting of suspected serious incidents by healthcare professionals, users and patients;
- (c) timelines for the reporting of field safety corrective actions, periodic summary reports, and trend reports by manufacturers, taking into account the severity of the incident to be reported as referred to in Article 61;
- (d) harmonised forms for the exchange of information between competent authorities as referred to in Article 63;



- (e) procedures for designation of a coordinating competent authority; the coordinated assessment process; tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

#### *Article 66a*

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

1. The Commission shall, in collaboration with the Member States, collate and process the following information by means of the electronic system set up pursuant to Article 27 including a link to the product information in accordance with article 24a:
  - (a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 61(1) and Article 63(2b);
  - (b) the periodic summary reports by manufacturers referred to in Article 61(2);
  - (d) the reports by manufacturers on trends referred to in Article 61a;
  - (da) the periodic safety update reports referred to in Article 60c;
  - (e) the field safety notices by manufacturers referred to in Article 63(5);
  - (f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 63(4) and (6).
2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies that issued a certificate for the device in question in accordance with Article 43.
3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.
5. The reports on serious incidents referred to in point (a) of Article 61(1) shall be automatically transmitted, upon receipt, via the electronic system, to the competent authority of the Member State where the incident occurred.
- 5a. Trend reports referred to in Article 61a(1) shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the Member State where the incidents occurred.
6. The reports on field safety corrective actions referred to in point (b) of Article 61(1) shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:
  - (a) the Member States where the field safety corrective action is being or is to be undertaken;
  - (b) the Member State where the manufacturer or his authorised representative has his registered place of business;
7. The periodic summary reports referred to in Article 61(2) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States:
  - (a) the Member State(s) participating in the coordination procedure according to Article 63(6) and that agreed on the periodic summary report;
  - (b) the Member State where the manufacturer or his authorised representative has his registered place of business.

8. The information referred to in paragraphs 5 to 7 shall be automatically transmitted, upon receipt, through the electronic system, to the notified body that issued the certificate for the device in question in accordance with Article 45.

## **SECTION 2 – MARKET SURVEILLANCE**

### *Article 67*

#### *Market surveillance activities*

1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.
  - 1a. The competent authorities shall draw up annual surveillance activities plans and allocate a sufficient number of competent human and material resources needed to carry out those activities taking into account the European market surveillance program developed by the MDCG according to Article 80 and local circumstances.
  - 1b. For the purpose referred to in paragraph 1, the competent authorities:
    - (a) may, *inter alia*, require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, where justified, provide the necessary samples of devices or access to the device free of charge; and
    - (b) shall carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.
  - 1c. The competent authorities shall prepare an annual summary of the results of the surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 75b.

- 1d. The competent authorities may confiscate, destroy or otherwise render inoperable devices presenting an unacceptable risk or falsified devices where they deem it necessary in the interest of the protection of public health.
- 1e. Following each inspection carried out for the purposes referred to in paragraph 1, the competent authority shall draw up a report the findings of the inspection concerning compliance with the legal and technical requirements applicable under this Regulation. The report shall set out any corrective actions needed.
- 1f. The competent authority which carried out the inspection shall communicate the content of this report to the inspected economic operator. Before adopting the report, the competent authority shall give the inspected economic operator the opportunity to submit comments. The final inspection report as referred to in paragraph 1e shall be entered into the electronic system provided for in Article 75b.
2. The Member States shall review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. The Member State concerned shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 75b.
3. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonized high level of market surveillance in all Member States.

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

4. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.

5. Where appropriate, the competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

*Article 69*

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

Where the competent authorities of a Member State, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe that a device:

- may present an unacceptable risk
  - = to the health or safety of patients, users or other persons,
  - or
  - = to other aspects of the protection of public health,

or

- otherwise does not comply with the requirements laid down in this Regulation, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant:

- to the risk presented by the device,

or

- to any other non-compliance of the device.

The relevant economic operators shall cooperate with the competent authorities.

## Article 70

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

1. Where, having performed an evaluation pursuant to Article 69, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the devices concerned, his authorised representatives and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period that is clearly defined and communicated to the relevant economic operator, proportionate to the nature of the risk.
2. The competent authorities shall, without delay, notify the Commission, the other Member States and the notified body that issued a certificate in accordance with Article 45 for the device concerned of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 75b.
3. The economic operators shall without delay ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.
4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it.

They shall notify the Commission, the other Member States and the notified body that issued a certificate in accordance with Article 45 for the device concerned, without delay, of those measures, by means of the electronic system referred to in Article 75b.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification and tracing of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.
6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 75b, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned.  
In the event of disagreement with the notified national measure, they shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 75b.
7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified.
8. Where paragraph 7 applies, all Member States shall ensure that appropriate restrictive or prohibitive measures, withdrawing, recalling or limiting the availability of the device on their national market are taken without delay in respect of the device concerned.

## *Article 71*

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

1. Where, within two months of receipt of the notification referred to in Article 70(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall, after consulting the concerned competent authorities and, where necessary, the concerned economic operators, evaluate the national measure. On the basis of the results of that evaluation, the Commission may decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
  
2. If the national measure is considered justified, Article 70(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

If the Commission has not adopted a decision pursuant to paragraph 1 within eight months of receipt of the notification referred to in Article 70(4), the national measures shall be considered to be justified.

- 2a. Where a Member State or the Commission consider that the risk to health and safety emanating from a device cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).



*Article 73*

*Other non-compliance*

1. Where, having performed an evaluation pursuant to Article 69, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.
2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall without delay take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article 75b.
3. The Commission may, by means of implementing acts, elaborate details on the nature of non-compliances and appropriate measures to be taken by competent authorities to ensure the uniform application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

## *Article 74*

### *Preventive health protection measures*

1. Where a Member State, after having performed an evaluation, which indicates a potential risk related to a device or a specific category or group of devices considers that, in order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, it may take any necessary and justified measures.
2. The Member State shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 75b.
3. The Commission, in consultation with the MDCG and, where necessary, the concerned economic operators, shall assess the national measures taken. The Commission may decide, by means of implementing acts, whether the national measures are justified or not. In the absence of a Commission decision within six months from their notification, the national measures shall be considered to be justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
4. Where the assessment referred to in paragraph 3 demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 88(3) to take the necessary and duly justified measures.

## *Article 75*

### *Good administrative practice*

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 70 to 74 shall state the exact grounds on which it is based. Where it is addressed to a specific economic operator, it shall be notified without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to him under the law or the administrative practice of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general scope, it shall be appropriately published.
2. Except in cases where immediate action is necessary for reasons of unacceptable risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time that is clearly defined before any measure is adopted. If action has been taken without the economic operator being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.
3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action and that the device is in compliance with the requirements of this Regulation.
4. Where a measure adopted pursuant to Articles 70 to 74 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall by means of the electronic system referred to in Article 75b inform the relevant notified body and the authority responsible for the notified body of the measure taken.

*Article 75b*

*Electronic system on market surveillance*

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:
  - (aa) summaries of the results of the surveillance activities referred to in Article 67(1c);
  - (a) information in relation to devices presenting an unacceptable risk to health and safety referred to in Article 70(2), (4) and (6);
  - (c) information in relation to non-compliance of products referred to in Article 73(2);
  - (d) information in relation to preventive health protection measures referred to in Article 74(2);
  - (e) summaries of the results of the reviews and assessments of the surveillance activities of the Member States referred to in 67(2).
  
2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and, where applicable, to the notified body that issued a certificate in accordance with Article 45 for the device concerned and be accessible to the Member States and to the Commission.
  
3. Information exchanged between Member States shall not be made public when this may impair market surveillance activities and co-operation between Member States.

## **Chapter VIII**

### **Cooperation between Member States, Medical Device Coordination Group, Expert laboratories, Expert panels and device registers**

#### *Article 76*

##### *Competent authorities*

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

#### *Article 77*

##### *Cooperation*

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

*Article 78*

*Medical Device Coordination Group*

1. A Medical Device Coordination Group (MDCG) is hereby established.
2. Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate providing expertise in the field of this Regulation, and one member and one alternate providing expertise in the field of Regulation (EU) No [.../...] [on *in vitro* diagnostic medical devices] A Member State may choose to appoint only one member and one alternate providing expertise in both fields.

The members of the MDCG shall be chosen for their competence and experience in the field of medical devices and *in vitro* diagnostic medical devices. They shall represent the competent authorities of the Member States. The names and affiliation of members shall be made public by the Commission.

The alternates shall represent and vote for the members in their absence.

3. The MDCG shall meet at regular intervals and, where the situation requires, upon request from the Commission or a Member State. The meetings shall be attended either by the members appointed for their role and expertise in the field of this Regulation, or by the members appointed for their expertise in the field of Regulation (EU) No [.../...] [on *in vitro* diagnostic medical devices], or by the members appointed for both Regulations, or their alternates, as appropriate.
4. The MDCG shall use its best endeavours to reach consensus. If such consensus cannot be reached, the MDCG shall decide by the majority of its members. Members with diverging positions may request that their positions and the grounds on which they are based are recorded in the MDCG's position.
5. The MDCG shall be chaired by a representative of the Commission. The chair shall not take part in votes of the MDCG.

6. The MDCG may invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.
7. The MDCG may establish standing or temporary sub-groups. Where appropriate, organisations representing the interests of the medical device industry, healthcare professionals, laboratories, patients and consumers at Union level shall be invited in such sub-groups in the capacity of observers.
8. The MDCG shall establish its rules of procedure which shall, in particular, lay down procedures for the following:
  - the adoption of opinions or recommendations or other positions by the MDCG, including in cases of urgency;
  - the delegation of tasks to reporting and co-reporting members;
  - the implementation of Article 82 regarding conflict of interests;
  - the functioning of sub-groups.

#### *Article 79*

##### *Support by the Commission*

The Commission shall support the functioning of the cooperation between national competent authorities. It shall, in particular, provide for the organisation of exchanges of experience between the competent authorities and provide technical, scientific and logistic support to the MDCG and its sub-groups. It shall organise the meetings of the MDCG and its sub-groups, participate in those meetings and ensure the appropriate follow-up.

*Article 80*

*Tasks of the MDCG*

The MDCG shall have the following tasks:

- (a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;
- (ac) to advise the Commission, at its request, in matters concerning the coordination group of Notified Bodies as established pursuant to Article 39;
- (c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation and investigations by manufacturers, the assessment by notified bodies and the vigilance activities;
- (ca) to contribute to the continuous monitoring of the technical progress and assessment whether the general safety and performance requirements provided in this Regulation and Regulation (EU) No [.../...] [on *in vitro* diagnostic medical devices] are appropriate to ensure safety and performance of medical devices and identify the need to amend Annex I;
- (cb) to contribute to the development of devices standards, of Common Specifications and of scientific guidelines, including product specific guidelines, on clinical investigation of certain devices in particular implantable and class III devices;
- (d) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and regulatory status of devices, clinical investigations, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance program with the objective of efficiency and harmonisation of market surveillance in the European Union, in accordance with Article 67;
- (e) to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;
- (f) to contribute to harmonised administrative practice with regard to devices in the Member States.



## Article 81a

### *Provision of scientific, technical and clinical opinion and advice*

1. The Commission shall, in consultation with the MDCG, make provision for expert panels to be appointed for the assessment of the clinical evaluation in relevant medical fields as referred to in paragraph 5a and to provide views in accordance with Article 40(2a) of Regulation (EU) [Ref. of future Regulation on *in vitro* diagnostic medical devices] on the performance evaluation of certain *in vitro* diagnostic medical devices and, where necessary, for categories or groups of devices, or for specific hazards relating to categories or groups of devices, under the principles of highest scientific competence, impartiality, independence and transparency. The same principles shall apply where the Commission decides to appoint expert laboratories in accordance with paragraph 5.
2. Expert panels and expert laboratories may be appointed in areas where the Commission, in consultation with the MDCG, has identified a need for the provision of consistent scientific, technical and/or clinical advice or laboratory expertise in relation to the implementation of this Regulation. Expert panels and expert laboratories may be appointed on a standing or temporary basis.
3. Expert panels shall consist of advisors appointed by the Commission on the basis of up-to-date clinical, scientific or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the Union. The Commission shall determine the number of members of each panel in accordance with the requisite needs.

The members of expert panels shall perform their tasks with impartiality and objectivity. They shall neither seek nor take instructions from notified bodies or manufacturers. Each member shall draw up a declaration of interests which shall be made publicly available.

The Commission shall establish systems and procedures to actively manage and prevent potential conflicts of interest.

- 3a. Expert panels shall take into account relevant information provided by stakeholders including patients organisations and healthcare professionals when preparing their scientific opinions.
4. The Commission, following consultation with the MDCG, may appoint advisors to expert panels following publication in the Official Journal of the European Union and on the Commission website following a call for expressions of interest. Depending on the type of task and the need for specific expertise, advisors may be appointed to the expert panels for a maximum period of three years and their appointment may be renewed.
- 4a. The Commission, following consultation with the MDCG, may include advisors on a central list of available experts who, whilst not being formally appointed to a panel, are available to provide advice and to support the work of the expert panel as needed. This list shall be published on the Commission website.
5. Expert laboratories may be appointed by the Commission, following consultation with the MDCG, on the basis of their expertise in physico-chemical characterisation, microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical biological/toxicological testing of specific devices, categories or groups of devices. The Commission shall only appoint expert laboratories for which a Member State or the Joint Research Centre have submitted an application for designation.
- 5aa. Expert laboratories shall satisfy the following criteria:
- (a) to have adequate and appropriately qualified staff with adequate knowledge and experience in the field of the devices for which they are designated;
  - (b) to possess the necessary equipment to carry out the tasks assigned to them;
  - (c) to have the necessary knowledge of international standards and best practices;
  - (d) to have an appropriate administrative organisation and structure;
  - (e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks;

- 5a. Expert panels appointed for the clinical evaluation in relevant medical fields shall fulfil the task specified in Article 43a(1) and 49 and Section 6.0 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.
6. Expert panels and expert laboratories may have the following tasks, depending on the requisite needs:
- (a) to provide scientific, technical and clinical assistance to the Commission and MDCG in relation to the implementation of this Regulation;
  - (b) to contribute to the development and maintenance of appropriate guidance and common specifications for clinical investigations, performance studies, clinical evaluation and PMCF, performance evaluation and post-market performance follow-up ('PMPF'), and for physico-chemical characterisation, microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing for specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices;
  - (c) to develop and review clinical evaluation guidance and performance evaluation guidance for the state of art performance of conformity assessment procedures with regard to clinical evaluation, performance evaluation, physico-chemical characterisation, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing;
  - (d) to contribute to the development of standards at international level, ensuring that these reflect the state of the art;
  - (e) to provide opinions in response to consultations by manufacturers in accordance with Article 49(1a), notified bodies and Member States in accordance with paragraphs 7-9.
  - (f) to contribute to identification of concerns and emerging issues on the safety and performance of medical devices;
  - (g) to provide views in accordance with Article 40(2a) of Regulation (EU) [Ref. of future Regulation on *in vitro* diagnostic medical devices] on the performance evaluation of certain *in vitro* diagnostic medical devices.

7. The Commission shall facilitate the access of Member States and notified bodies and manufacturers to advice provided by expert panels and expert laboratories concerning, among others, the criteria for an appropriate data set for assessment of the conformity of a device, in particular with regard to the clinical data required for the clinical evaluation and with regard to physico-chemical characterisation, and with microbiological, biocompatibility, mechanical, electrical, electronic and non-clinical toxicological testing.
8. When adopting its scientific opinion in accordance with paragraph 5a, the members of the expert panels shall use their best endeavours to reach consensus. If consensus cannot be reached, the expert panels shall decide by the majority of their members, and the scientific opinion shall mention the divergent positions and the grounds on which they are based.

The Commission shall publish the scientific opinion and advice delivered in accordance with paragraphs 5a and 7, ensuring consideration of aspects of confidentiality as set out in Article 84. The clinical evaluation guidance referred to in paragraph 6(c) shall be published following consultation with MDCG.

9. Manufacturers and notified bodies may be subject to pay fees to the Commission for the advice provided by expert panels and expert laboratories. The structure and the level of fees shall be adopted by the Commission by means of implementing acts in accordance with the examination procedure referred to in Article 88(3), taking into account the objectives of the adequate implementation of this regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels.
- 9a. The fees payable to the Commission as set by the Commission according to the procedure under paragraph 9 of this Article, shall be set in a transparent manner and on the basis of the costs for the services provided and shall be reduced in case of a clinical evaluation consultation procedure initiated in accordance with Annex VIII Section 6.0 (c) of Chapter II involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC.

10. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend or supplement the tasks of expert panels and expert laboratories referred to in paragraph 6.

#### *Article 82*

##### *Conflict of interests*

1. Members of the MDCG, its sub-groups, and members of experts panels and expert laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs. The declaration of interests shall be made publicly available on the Commission website. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG.
2. Experts and other third parties invited by the MDCG on a case-by-case basis shall declare any interests they may have in the issue in question.

#### *Article 83*

##### *Device registers*

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

## **Chapter IX**

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

#### *Article 84*

#### *Confidentiality*

1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:
  - (a) personal data in compliance with Article 85;
  - (b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights; unless disclosure is in the public interests;
  - (c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.
  
2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall not be disclosed without prior agreement with the originating authority.
  
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.
  
4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

*Article 85*

*Data protection*

1. Member States shall apply Directive 95/46/EC<sup>36</sup> to the processing of personal data carried out in the Member States pursuant to this Regulation.
2. Regulation (EC) No 45/2001<sup>37</sup> shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

*Article 86*

*Levy of fees*

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

*Article 86a*

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

- 1a. The cost associated with the joint assessment activities shall be covered by the Commission. The Commission shall lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

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<sup>36</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

<sup>37</sup> This reference should be updated following the agreement between the Institutions on the directive and regulation on personal data.

*Article 87*

*Penalties*

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



## **Chapter X**

### **Final provisions**

#### *Article 88*

##### *Committee procedure*

1. The Commission shall be assisted by a Committee on Medical Devices. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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

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

#### *Article 89*

##### *Exercise of the delegation*

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

2. The power to adopt delegated acts referred to in Articles 1(1c), 2(3), 8(2), 16(1ab), 17(4), 24(7a), 42(3a), 45(5), 49(2ad), 51(7) and 81a(10) shall be conferred on the Commission for a period of five years from the date of entry into force of this Regulation. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Articles 1(1c), 2(3), 8(2), 16(1ab), 17(4), 24(7a), 42(3a), 45(5), 49(2ad), 51(7) and 81a(10) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
- 3a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 1(1c), 2(3), 8(2), 16(1ab), 17(4), 24(7a), 42(3a), 45(5), 49(2ad), 51(7) and 81a(10) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

*Article 90a*

*Separate delegated acts for different delegated powers*

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

*Article 91*

*Amendments to Directive 2001/83/EC*

In Annex I of Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

‘(12) Where a product is governed by this Directive in accordance with the second subparagraph of Article 1(4) or the second subparagraph of Article 1(5) of Regulation (EU) [.../...] on medical devices<sup>38</sup>, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements of Annex I of that Regulation contained in the manufacturer’s EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) [.../...], the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements of Annex I of that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.’

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<sup>38</sup> OJ L [...], [...], p. [...].

## *Article 92*

### *Amendments to Regulation (EC) No 178/2002*

In the third subparagraph of Article 2 of Regulation (EC) No 178/2002, the following point (i) is added:

‘(i) medical devices within the meaning of Regulation (EU) [.../...]’<sup>39</sup>,

## *Article 93*

### *Amendments to Regulation (EC) No 1223/2009*

In Article 2 of Regulation (EC) No 1223/2009, the following paragraph is added:

‘4. In accordance with the regulatory procedure referred to in Article 32(2), the Commission may, at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product or group of products falls within the definition ‘cosmetic product’.’

## *Article 94*

### *Transitional provisions*

1. From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.
2. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 of Directive 90/385/EEC or Annex IV of Directive 93/42/EEC which shall become void at the latest two years after the date of application of this Regulation.

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<sup>39</sup> OJ L [...], [...], p. [...].

Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC after the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its delivery. They shall however become void at the latest four years after the date of application of this Regulation.

3. By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market before its date of application.
- 3a. Devices which were lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to the date referred to in Article 97(2) may continue to be made available on the market or put into service until five years after that date.
4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.
- 4a. As regards the devices subject to the consultation procedure laid down in Article 43a, paragraph 4 applies provided that the necessary appointments to the MDCG and expert panels have been made.

5. By way of derogation from Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies who, during the period from the later of the two dates referred to in Article 97(2) and 97(3)(ba) until 18 months after the later of the two dates referred to in Article 97(2) and 97(3)(ba), comply with Article 25(3) and Article 25a(1) and Article 45(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC as specified in Commission Decision 2010/227/EU.
6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC shall keep the validity indicated in the authorisation.
7. Devices falling within the scope of this Regulation in accordance with point (e) and (ea) of Article 1(2) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to the application of this Regulation may continue to be placed on the market and put into service in the Member States concerned.
8. Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to the application of this Regulation may continue to be conducted. As of the application of this Regulation, however, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with this Regulation.
9. Until the Commission in line with Article 24(2) has designated the UDI assigning entities, GS1 AISBL, HIBCC and ICCBBA shall be considered as designated UDI assigning entities.

## *Article 95*

### *Evaluation*

No later than seven years after the date of application, the Commission shall assess the application of this regulation and establish an evaluation report on the progress towards achievement of the objectives of the regulation including an assessment of resources required to implement this regulation. Special attention shall be given to the traceability of medical devices through the storage, pursuant to Article 24, of UDI by economic operators, health institutions and health professionals.

## *Article 96*

### *Repeal*

Council Directives 90/385/EEC and 93/42/EEC are repealed with effect from [*date of application of this Regulation*], with the exception of

- Article 8, Article 10, points (b) and (c) of Article 10b(1), Article 10b(2) and Article 10b(3) of Directive 90/385/EEC which are repealed with effect from the later of the two dates referred to in Article 97(2) and 97(3)(ba),
- Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC which are repealed with effect from 18 months after the later of the two dates referred to in Article 97(2) and 97(3)(ba),
- Article 10, points (c) and (d) of Article 14a(1), Article 14a(2), Article 14a(3) and Article 15 of Directive 93/42/EEC which are repealed with effect from the later of the two dates referred to in Article 97(2) and 97(3)(ba), and
- Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC which are repealed with effect from 18 months after the later of the two dates referred to in Article 97(2) and 97(3)(ba).

Notwithstanding the first subparagraph, Commission Regulation (EU) No 207/2012 and Commission Regulation (EU) No 722/2012 shall remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.

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

## Article 97

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

1. This Regulation shall enter into force on the twentieth day after its publication in the *Official Journal of the European Union*.
2. It shall apply from [*three years after entry into force*].
3. By way of derogation from paragraph 2 the following shall apply:
  - (b) Articles 28 to 40 and Articles 76 and 78 shall apply from [*six months after entry into force*]. Article 77 shall apply from [*twelve months after entry into force*]. However, prior to [*date of application as referred to in paragraph 2*], the obligations on notified bodies emanating from the provisions in Articles 28 to 40 shall apply only to those bodies which submit an application for designation in accordance with Article 31 of this Regulation.
  - (ba) Without prejudice to the obligations for the Commission in accordance with Article 27a, the following provisions shall apply from [*three years after entry into force*]: Article 24a(3), the obligations to submit data to the UDI database in Article 24b, Article 25a, Article 26, Article 27(3), Article 32a(2, second sentence), Article 33(9, second subparagraph), Article 34(2), Article 35(5, second subparagraph), Article 36(4, fourth and fifth indent), Article 43(2), Article 44(1), Article 60c(2), Articles 61 and 61a, Article 63(2b), (4) and (5 third subparagraph), Article 65a, Article 67(1c), (1f) and (2), Article 70(2) and (4), Article 73(2, last sentence), Article 75(4) and Chapter VI except its Articles 49, 50, 50aa, 50c, 50ca, 50cb, 50cc and 50d, unless due to circumstances that could not reasonably have been foreseen when drafting the plan referred to in Article 27a(1) the European database referred to in Article 27 and the Electronic system on UDI referred to in Article 24a are not fully functional on [*three years after entry into force*] and as a consequence the notice referred to in Article 27a(3) has not been published before [*three years after entry into force*], in which case they shall apply from six months after the publication of that notice.
  - (bb) Article 24(3), Article 24b, Article 25(3) and Article 45(4) shall apply from 18 months after the date of application referred to in point (ba).



- (c) For implantable devices and Class III devices Article 24(4) shall apply one year after the date of application of this regulation. For Class IIa and Class IIb devices Article 24(4) shall apply three years after the date of application of this regulation. For Class I devices Article 24(4) shall apply five years after the date of application of this regulation.
- (ca) For reusable devices that shall bear the UDI Carrier on the device itself, Article 24(4) shall apply two years after the date applicable for its class of devices as stipulated in point (c).
- (d) The procedure set out in Article 58 shall, during a period of seven years following the date referred to in Article 97(2) [*date of application*], apply only to the Member States concerned which have agreed to it. After this period, this procedure shall apply to all Member States concerned by the submission of a single application by the sponsor.

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

Done at , .....

*For the European Parliament*

*For the Council*

*The President*

*The President*

## ANNEXES

- I General safety and performance requirements
- II Technical documentation
- IIa Technical documentation on post-market surveillance
- III EU Declaration of conformity
- IV CE marking of conformity
- V Information to be submitted with the registration of devices and economic operators in accordance with Article 25a and core data elements to be provided to the UDI data base together with the device identifier in accordance with Article 24a and the European Unique Device Identification System
- VI Requirements to be met by Notified Bodies
- VII Classification criteria
- VIII Conformity assessment based on a quality management system and assessment of the technical documentation
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- X Conformity assessment based on product conformity verification
- XI Procedure for custom-made devices
- XII Certificates issued by a notified body
- XIII Clinical evaluation and post-market clinical follow-up
- XIV Clinical Investigations
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- XVI Correlation table

## GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

### I. General requirements

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

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

    - (a) establish and document a risk management plan for each device;
    - (b) identify and analyse the known and foreseeable hazards associated with each device;
    - (c) estimate and evaluate the associated risks occurring during the intended use and during reasonably foreseeable misuse;
    - (d) eliminate or control these risks according to the requirements of Section 2;

- (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system on hazards and their frequency of occurrence, estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability.
- (f) based on the evaluation of the impact of information from the production phase or the post market surveillance system if necessary amend control measures in line with the requirements of Section 2.

2. Risk control measures adopted by the manufacturer for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, the manufacturer shall apply the following principles in the priority order listed:

- (b) eliminate or reduce risks as far as possible through safe design and manufacture;
- (c) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and
- (d) provide information for safety (warnings/precautions/contraindications) and, where appropriate, training to users.

The manufacturer shall inform users of any residual risks.

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

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

3. The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.
4. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.
5. All known and foreseeable risks, and any undesirable 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.
6. For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, the general safety 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 no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.

## **II. Requirements regarding design and manufacturing**

### **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;

- (ba) the compatibility between the different parts of a device which consists of more than one implantable parts;
- (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 mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;
- (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 intended use ; 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. Substances

##### 7.4.1. Design and manufacture of devices

Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.

Devices, or those parts thereof or those materials used therein:

- that are invasive and come into direct contact with the human body, or
- that (re)administer medicines, body liquids or other substances, including gases, to/from the body, or
- that transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,

shall only contain the following substances in a concentration above 0.1% weight by weight (w/w) when justified pursuant to Section 7.4.2:

- (a) substances which are 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 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>40</sup>,

or

- (b) substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either 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>41</sup> or in accordance with those criteria that are relevant to human health of the criteria established in the delegated act adopted by the Commission pursuant article 5(3), first paragraph, of Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products<sup>42</sup>.

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<sup>40</sup> OJ L 353, 31.12.2008, p. 1

<sup>41</sup> OJ L 396, 30.12.2006, p. 1

<sup>42</sup> OJ L 167, 27.06.2012, p. 1

#### 7.4.2. Justification regarding the presence of CMR substances and/ or endocrine disruptors

The justification for the presence of such substances shall be based upon:

- An analysis and estimation of potential patient or user exposure to the substance;
- An analysis of possible alternative substances, materials or designs, including, when available, information about independent research, peer reviewed studies, scientific opinions from relevant Scientific Committees and an analysis of the availability of such alternatives;
- Argumentation why possible substance and/ or material substitutes or design changes, if available, are inappropriate to maintain the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or nursing women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials;
- Where applicable and available, the latest relevant Scientific Committee guidelines in accordance with Sections 7.4.3. and 7.4.4..

#### 7.4.3. Guidelines on phthalates

For the purposes of Section 7.4. of this Annex, the Commission shall, as soon as possible and at the latest one year after the date of entry into force of this regulation, provide the relevant Scientific Committee with a mandate to prepare guidelines that shall be ready before the date of application of this regulation. The mandate for the Committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 7.4.1.. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, available alternative substances and alternative materials, designs and/ or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every 5 years, the guidelines shall be updated.

#### 7.4.4. Guidelines on other CMR or endocrine disrupting substances

Subsequently, the Commission shall mandate the relevant Scientific Committee to prepare guidelines as referred to in Section 7.4.3. also for other substances referred to in Points (a) and (b) of Section 7.4.1., where appropriate.



#### 7.4.5. Labelling

If devices, parts thereof or materials used therein as referred to in Section 7.4.1. contain substances referred to in points (a) or (b) of Section 7.4.1. in a concentration above 0.1% weight by weight (w/w), these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.

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

7.6. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be 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.

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

8.1. 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:

- (aa) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,
- (a) allow easy and safe handling,
- (b) reduce as far as possible 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 their safe cleaning, disinfection, and/or re-sterilisation.
- 8.2. Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.
- 8.3. Devices delivered in a sterile state shall be designed, manufactured and packaged 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 as sterile shall be processed, manufactured, packaged and, sterilised by appropriate, validated methods.
- 8.5. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled 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 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 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, 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 (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 safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and 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) Sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin shall be carried out so as to provide 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>43</sup> the particular requirements laid down in that Regulation shall apply.

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<sup>43</sup> OJ L 212, 9.8.2012, p. 3

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 safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

## **11. Manufacture of devices and interaction with their environment**

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 misconnection.

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

- (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;
- (c) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;
- (d) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;
- (e) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;
- (f) the risks of accidental ingress of substances into the device;

- (g) the 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 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 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 a way that the interoperability and compatibility are reliable and safe.

11.6 Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.

11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or related waste substances by the user, 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 instructions 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 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC<sup>44</sup>.

### **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 radiation shall be reduced as far as possible, 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 or potentially 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 reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance testing, the performance testing and the acceptance criteria, the maintenance procedure shall also be specified.

#### 13.2 Intended radiation

- (a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non-ionizing 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 hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.

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<sup>44</sup> OJ L 039, 15.2.1980, p.40

13.3 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 possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.

#### 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, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment.
- (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 type, energy and, where appropriate, the quality of radiation.



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

14.1. Devices that incorporate electronic programmable systems, including software, or 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 consequent risks or impairment of performance.

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

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).

14.3a. The manufacturer shall describe minimum requirements on hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

**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 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 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 shall 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 shall 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. Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.
- 15a.4. Active implantable devices shall 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 shall 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 certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

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

- 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 of energy or substances 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 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 and appropriate the risk from unintended cuts and pricks such as needle stick injuries, 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 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, , or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

- (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.
- (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) By way of exception, no such instructions for use are needed for devices in class I and IIa if they can be used safely without any such instructions.
- (d) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification (RFID) or bar codes.

- (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<sup>45</sup>.
- (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 shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

## 19.2. Information on the label

The label shall bear the following particulars:

- (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.
- (d) If the manufacturer has his registered place of business outside the Union, the name and address of the authorised representative.
- (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.
- (fa) Where applicable, labelling in accordance with section 7.4.5..
- (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) the unique device identification (UDI) carrier according to Article 24 and Annex V Part C.

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<sup>45</sup> OJ L 72, 10.3.2012, p. 28

- (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 date of manufacture. This date 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, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users.
- (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, the words “custom – made device”.
- (q) An indication that the device is a medical device. If the device is intended for clinical investigation only, 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 or applied on skin 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 batch number.



19.2a. On the sterile packaging:

The following particulars shall appear on the sterile packaging:

- (a) an indication permitting the sterile packaging to be recognized as such,
- (b) a declaration that the device is in a sterile condition,
- (c) the method of sterilization,
- (d) the name and address of the manufacturer,
- (e) a description of the device,
- (f) 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 the device safely,
- (j) an instruction to check the Instructions For Use for what to do if the sterile packaging 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 (a), (c), (e), (fa), (k), (l), (n) and (r) of Section 19.2..
- (b) The device’s intended purpose with clear specification of target group(s), indications, contraindications including the intended user, as appropriate.
- (bb) where applicable, a specification of clinical benefits to be expected.
- (bc) where applicable, links to the summary of safety and clinical performance according to Article 26.
- (c) The performance characteristics of the device.
- (ca) Where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories.
- (d) Any residual risks, contraindications and any 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 or during its use (e.g. sterilisation, final assembly, calibration, etc.), including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection.
- (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, 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 shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.
- (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 general safety and performance requirements.

- (l) If the device bears an indication that it 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 specific 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 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 of any warnings, precautions, contra - indications, measures to be taken and limitations of use regarding the device. This information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra - indications, measures to be taken and limitations of use regarding the device. This information shall cover, where appropriate:
  - warnings, precautions and/or measures to be taken in the event of malfunction of the device or 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 shall 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 thereof 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.

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

#### 1.1. Device description and specification

- (a) product or trade name and a general description of the device including its intended purpose and intended user;
- (b) the Basic UDI device identifier as referred to in item (i) of point (a) of Article 24(1) and in Part C of annex V attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;
- (c) the intended patient population and medical conditions to be diagnosed, 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;
- (da) the rationale for the qualification of the product as a device;
- (e) the risk class of the device and the justification of the classification rule(s) applied according to Annex VII;
- (f) 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 identified similar devices available on the EU or international markets, if such exist.

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

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

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

- (a) Information to allow the understanding of the design stages applied to the device;
  - (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 REQUIREMENTS**

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

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

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

The documentation shall contain

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



## 6. PRODUCT VERIFICATION AND VALIDATION

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

### 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 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 shall 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 shall 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<sup>46</sup> 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 report and its updates and the clinical evaluation plan in accordance with Article 49(5) and Part A of Annex XIII;
- (d) the PMCF plan and PMCF evaluation report in accordance with Part B of Annex XIII or any justification why a PMCF is not 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 points (e) and (ea) 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.

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<sup>46</sup> OJ L 50, 20.2.2004, p. 44

- (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.
- (bb) in the case of devices containing substances requiring justification according to Section 7.4.1. in Annex I, the justification pursuant to Section 7.4.2. in that Annex.
- (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 Section 0 of Chapter VII shall be presented in a clear, organized, readily searchable and unequivocal way and shall include in particular:

1.1. The post-market surveillance plan in accordance with Article 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 address the collection and utilization of available information, in particular:

- information concerning serious incidents, including information from periodic safety update reports, and field safety corrective actions,
- records referring to non-serious incidents and data on any undesirable side effects,
- information from trend reporting,
- relevant specialist or technical literature, databases and/or registers,
- information, including feedbacks and complaints, provided by users, distributors and importers,
- publicly available information about similar medical devices.

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

- a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterization of the performance of the devices also comparing the device with the similar products available on the market;
- effective and appropriate methods and processes to assess the collected data;

- suitable indicators and threshold values that shall be used in the continuous reassessment of the risk benefit analysis and of the risk management as referred to in Section 1a of Annex I;
- effective and appropriate methods and tools to investigate complaints or market experiences collected in the field;
- methods and protocols to manage the events subject to trend report as provided in Article 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 and users;
- 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 a justification why a post-market clinical follow-up is not applicable.

1.3 The periodic safety update report referred to in article 60c and the post-market surveillance report in article 60ba.

## ANNEX III

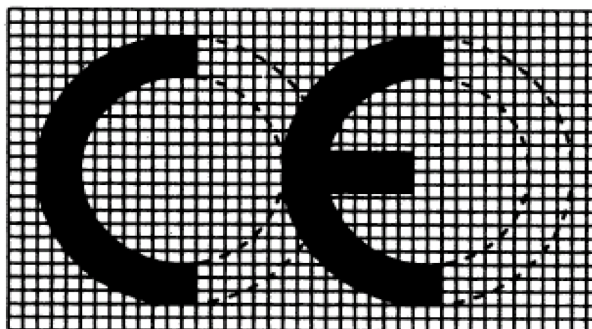
### EU DECLARATION OF CONFORMITY

1. Name, registered trade name or registered trade mark and 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 basic UDI-DI as referred to in item (i) of point (a) of Article 24(1) and in Part C of Annex V as soon as identification of the device that is covered by the declaration shall be based on a UDI system;
4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered by the declaration (it may include a photograph, where appropriate), including its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the basic UDI-DI referred to in point 3;
5. Risk class of the device in accordance with the rules set out in Annex VII;
6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;
7. References to CS used in relation to which conformity is declared;

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

## CE MARKING OF CONFORMITY

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



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



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 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 AND  
ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 25a**

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

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

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

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

- 2.4. UDI device identifier, or where identification of the device is not yet based on a UDI system, the data elements laid down in points 5 to 21 of Part B of this Annex,
- 2.5. type, number and expiry date of certificate and name or identification number of the notified body that has issued the certificate (and link to the information on the certificate entered by the notified body in the electronic system on certificates),
- 2.6. Member State where the device shall or has been placed on the market in the Union,
- 2.7. in case of devices classified as classes IIa, IIb or III: Member States where the device is or shall be made available,
- 2.9. risk class of the device,
- 2.10. reprocessed single use device (y/n),
- 2.11. presence of a substance which, if used separately, may be considered to be a medicinal product and name of this substance,
- 2.12. 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,
- 2.13. presence of human tissues or cells, or their derivatives (y/n),
- 2.14. presence of animal tissues or cells, or their derivatives, as referred to in Commission Regulation (EU) No 722/2012 (y/n),
- 2.15. 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),
- 2.16. in case of devices listed in Annex XV, specification whether the intended purpose of the device is other than a medical purpose,
- 2.17. 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,
- 2.18. in case of devices classified as class III or implantable devices, the summary of safety and clinical performance,
- 2.19. status of the device (on the market, no longer placed on the market, recalled, Field Safety Corrective Action initiated).

**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) and the following information related to the manufacturer and the device:

1. quantity per package configuration,
2. if applicable, the Basic UDI-DI according to article 24(4b) and additional identifier(s),
3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number),
4. if applicable, the unit of use device identifier (when a UDI is not assigned to the device at the level of its unit of use, a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient),
5. name and address of the manufacturer (as indicated on the label),
- 5a. the single registration number according to article 25a(2),
6. if applicable, name and address of the authorised representative (as indicated on the label),
7. Medical Device Nomenclature code according to article 23a,
- 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 in accordance with Annex I, section 7.4.5..
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, no longer placed on the market, recalled, Field Safety Corrective Action initiated)

## **PART C**

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

#### **1. Definitions**

Automatic Identification and Data Capture (hereinafter AIDC)

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

Basic UDI-DI

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

Unit of Use DI

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

Configurable device

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

Configurable devices include 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 device. The combination of items may be modified, adjusted or customized to meet a customer need.

Configurations include inter alia:

- gantries, tubes, tables, consoles and other items of equipment that can be configured/combined to deliver an intended function in computed tomography.
- ventilators, breathing circuits, vaporizers 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 device and that is also used as the "access key" to information stored in a UDI database.

## Human Readable Interpretation (hereinafter HRI)

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

## Packaging levels

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

## Production Identifier (hereinafter UDI-PI)

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

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

## Radio Frequency Identification (hereinafter RFID)

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

## Shipping containers

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

## Unique Device Identification

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

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

## UDI Carrier

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

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

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

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

## **3. The UDI**

- 3.1. A UDI shall be assigned to the device itself or its package. Higher levels of packaging shall have their own UDI.
- 3.2. Shipping containers shall be exempted. As an example, UDI is not required on a logistics unit; when a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places these devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) is not subject to UDI requirements.
- 3.3. The UDI shall contain two parts: an UDI-DI and an UDI-PI.

- 3.4. The UDI-DI shall be unique at all levels of device packaging.
- 3.5. If a lot number, serial number, software identification or expiration date appears on the label, 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 shall be used as the UDI-PI.
- 3.7. Each component that is considered a device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.
- 3.8. Systems and procedure packs according to Article 20 shall be assigned and bear their own UDI.
- 3.9. The manufacturer shall assign the UDI to a device following the relevant coding standard.
- 3.10. A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability, in particular any change of one of the following UDI database data elements require a new UDI-DI:
- (a) Brand Name or Trade name,
  - (b) Device version or model,
  - (d) Labelled as single use,
  - (e) Packaged sterile,
  - (f) Need for sterilization before use,
  - (g) Quantity of devices provided in a package,
  - (h) Critical warnings or contraindications: e.g. containing latex or DEHP.
- 3.12. Manufacturers who repackages and/or relabels devices, with their own label shall retain record of the Original Equipment Manufacturer's (OEM) UDI.

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

- 4.1. The UDI Carrier (AIDC and HRI representation of the UDI) shall be placed on the label 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 package the UDI carrier may be placed on the next higher package level.

- 4.3. For single use devices of class I and IIa packaged and labelled individually, the UDI Carrier shall not be required to appear on the package but it shall appear on a higher level of packaging e.g. a carton containing several 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 shall be placed on the package of the individual device.
- 4.4. For devices exclusively intended for retail Point of Sale (POS) the Production Identifiers in AIDC shall not be required to appear on the point of sale package.
- 4.5. When AIDC carriers other than the UDI Carrier are part of the product labelling, the UDI Carrier shall be readily identifiable.
- 4.6. If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.
- 4.7. If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label. For devices intended to be used outside of healthcare facilities such as devices for home care, the HRI shall however appear on the label even if this means that there is no space for the AIDC.
- 4.8. The HRI format shall follow the rules of the UDI code issuing organization.
- 4.9. If the manufacturer is using RFID technology, a linear or 2D bar code according to the standard provided by the assigning entities shall also be provided on the label.
- 4.10. Devices that are reusable shall bear a UDI Carrier on the device itself. The UDI Carrier of reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the next use for the intended lifetime of the device. 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 shall be readable during normal use and throughout the intended life of the device.
- 4.12. If the UDI Carrier is readily readable and in the case of AIDC scanable through the device's package, then the placing of the UDI Carrier on the package shall not be required.



- 4.13. A single finished device made up of multiple parts that must be assembled before first use may bear the UDI Carrier on only one part.
- 4.14. The UDI Carrier shall be placed so that the AIDC can be accessed during normal operation or storage.
- 4.15. The bar code carrier(s) that include(s) UDI data identifiers “UDI-DI” and “UDI-PI” may also include essential data for the device to operate or other data.

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

- 5.1. The UDI database shall support the use of all core UDI database data elements.
- 5.3. The manufacturer shall be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.
- 5.4. Appropriate methods/procedures for validation of the provided data shall be implemented.
- 5.5. The manufacturer shall periodically reconfirm all the data relevant to devices he has placed on the market, except for devices that are no more available on the market.
- 5.7. The presence of the device UDI-DI in the UDI database does not mean that the device is in conformity with this Regulation.
- 5.8. The database shall allow for the linking of all the packaging levels of the device.
- 5.9. The data for new UDI-DI shall be available at the time the device is placed on the market.
- 5.10. Manufacturers shall update the relevant UDI database record within 30 days when a change is made to an element that does NOT require a new UDI-DI.
- 5.11. Internationally accepted standards for data submission and updates shall, wherever possible, be used by the UDI Database.
- 5.12. The core elements are the minimum elements needed to identify a device throughout its distribution and use.
- 5.13. The user interface of the UDI Database shall be available in all official languages of the Union in accordance with article 53(2c). The use of free-text fields shall, however, be minimized in order to reduce translations.
- 5.14. Data relating to devices that are no more available on the market shall be retained in the UDI database.

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

### **6.1. Implantable devices**

The rules listed below shall apply for implantable devices:

6.1.1. All unit packs of implantable devices (lowest level of packaging) 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 or lot number for other implantable devices;

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

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

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

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

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

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

6.3.2. Device contents of system or procedure packs shall bear a UDI Carrier on their packaging or on the device itself.

Exemptions:

- (a) Individual single-use disposable 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 shall not be required to bear their own UDI Carrier.
- (b) Devices that are exempted from bearing a UDI Carrier on the relevant level of packaging shall not be required to bear a UDI Carrier when 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 shall as a general rule be affixed to the outside of the packaging;
- (b) The UDI Carrier 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 devices

The rules listed below shall apply for configurable devices:

6.4.1. A UDI shall be allocated to the configurable device in its entirety and shall be called the Configurable device UDI.

6.4.2. The Configurable device UDI-DI shall be allocated to groups of configurations, not per configuration within the group. A group of configurations is defined as the collection of possible configurations for a given device as described in the technical documentation.

6.4.3. A Configurable device UDI-PI shall be allocated to each individual Configurable device.

6.4.4. The carrier of the Configurable device UDI shall be placed on the assembly that is most unlikely to be exchanged during the lifetime of the system and shall be identified as the Configurable device UDI.

6.4.5. Each component that is considered a device and is commercially available on its own shall be assigned a separate UDI;

6.5. Medical Device Software

6.5.1. UDI Assignment Criteria

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

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

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

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

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

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

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

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

Minor revisions shall be identified by manufacturer-specific identification.

6.5.2. UDI Placement Criteria for Software

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

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

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

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

## **1.2. Independence and impartiality**

- 1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitors of the manufacturer. This does not preclude conformity assessment activities for competing manufacturers.

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

- 1.2.3a. Involvement in consultancy services in the field of 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 level of the remuneration for the top level management and assessment personnel of a notified body and subcontractors involved in assessment activities shall not depend on the results of the assessments. The notified body shall make publicly available the declarations of interest of its top-level management.
- 1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests 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, unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
- 1.4.2. The scope and overall financial value of the liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk profile of the devices certified by the notified body. The liability insurance shall cover cases where the notified body may be obliged to withdraw, restrict or suspend certificates.

## **1.5. Financial requirements**

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

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

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

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

## **2. QUALITY MANAGEMENT REQUIREMENTS**

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

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

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

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

### **3. RESOURCE REQUIREMENTS**

#### **3.1. General**

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

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

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

A 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.

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

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

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

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

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

3.2.1. The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, technical documentation 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 the pre-clinical evaluation, clinical evaluation, tissues and cells of human and animal origin, functional safety, software, packaging, devices that incorporate as an integral part a medicinal product, devices that are composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body and the different types of sterilisation processes.

3.2.3. The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall be employed by the notified body itself and shall not be an external expert or subcontracted. They shall have proven knowledge and experience in the following:

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

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

- identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;
- appropriately train external clinical experts in the relevant requirements of regulation, CS, guidance and harmonised standards and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;
- be able to review and scientifically challenge the clinical data contained within the clinical evaluation, and any associated clinical investigations, and 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 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 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. 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, pharmacy, engineering or other relevant sciences;

- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;
- knowledge of the medical device legislation, including the general safety and performance requirements laid down in Annex I;
- appropriate knowledge and experience of relevant harmonised standards, CS and guidance documents;
- appropriate knowledge and experience of risk management and related 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, 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 harmonised standards, CS 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 those audits;
- training in auditing techniques enabling them to challenge quality management systems.
- the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

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

- the 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 management system, related procedures and the required qualification criteria.
- the ability to draw up records and reports demonstrating that the conformity assessment activities have been appropriately carried out.

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

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

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

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

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

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

The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed, but nevertheless parts of these activities can be conducted by subcontractors and external auditors and experts working on behalf of the notified body. The notified body retains the full responsibility for being able to produce appropriate evidence of the competence of subcontractors and experts to fulfil their specific tasks, retains 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;
- the natural or legal person that applied for conformity assessment has been informed of this.

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

3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel, 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.

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

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

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

## **4. PROCESS REQUIREMENTS**

### **4.2. General**

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

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

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

The notified body shall

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

#### 4.4. Application and Contract review

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

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

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

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

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

## 4.5. Allocation

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

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

## 4.6. Conformity Assessment Activities

### 4.6.1. General

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

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

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

- to review the manufacturer's procedures and documentation relating to 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 on site audits,
- relating to the sampling of devices to verify that the manufactured device is in conformity with the technical documentation, these shall define the relevant sampling criteria and testing procedure prior to sampling,
- to evaluate and verify a manufacturer's compliance with relevant Annexes.

Specific requirements of a notified body in conducting conformity assessment activities, including quality management system audits, technical documentation assessment and 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 does not claim compliance, available CS, guidance and best practice documents.



#### 4.6.2. Quality management system audits

- (a) As part of the quality management system assessment activity, the notified body shall prior to the audit and in accordance with its documented procedures:
- assess the documentation submitted according the relevant conformity assessment Annex and establish an audit programme which clearly identifies the number and sequence of activities required to demonstrate complete coverage of a manufacturer's quality management system and to determine whether it meets the requirements of this Regulation,
  - determine interfaces and responsibilities between different manufacturer sites, as well as the identification of relevant suppliers and/or subcontractors of the manufacturer, including consideration of the need to specifically audit any of these suppliers and/or subcontractors,
  - clearly define, for each audit identified in the audit programme, the objectives, criteria and scope of the audit and shall draw up an audit plan adequately addressing and taking account of the specific requirements for the devices, technologies and processes covered,
  - establish and maintain, for class 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, and
  - = 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 shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

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

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,
 and document its rationale for the selection of those parameters;
- have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of the Regulation by examining and testing every product 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;
- assume full responsibility for test results in accordance with documented procedures. Test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

#### 4.6.4. Pre-clinical evaluation assessment

The notified body shall have documented procedures in place for the review of the 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, in particular of
  - = the scientific preclinical literature search and
  - = the 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 CS, guidance and best practice documents.

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

- the intended use specified by the manufacturer and claims for the device defined by him,
- 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 that all steps of the conformity assessment are documented so that the conclusions of the assessment are clear and demonstrate compliance with the requirements of this Regulation and can provide objective evidence of this to persons that are themselves not involved in the assessment, for example personnel in designating authorities,
- ensure that records for quality management system audits are available that are sufficient to provide a discernible audit trail,
- clearly document the conclusions of its assessment of the 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 report shall:

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

#### **4.8. Review**

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

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

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

The notified body shall have documented procedures for decision-making including responsibilities for the issuance, suspension, restriction and withdrawal of certificates.

These procedures shall include the notification requirements according to Chapter V of this Regulation. These procedures shall allow it to:

- decide, based on the assessment documentation and additional information available whether the requirements of the Regulation are fulfilled, decide based on the results of their assessment of the 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) or does not fulfil the requirements outlined in section 3.2.7 of this Annex,
- issue a certificate(s) according to the minimum requirements defined in Annex 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 on-site audits to manufacturers and when applicable subcontractors and suppliers, carrying out product tests and the monitoring of compliance to any conditions on manufacturers associated with certification decisions, e.g. updates to clinical data at defined intervals,
- for screening relevant sources of scientific and clinical data and post-market information relating to the scope of its designation. Such information shall be taken into account in the planning and conducting of surveillance activities,
- to review vigilance information accessible according to Article 66a in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.

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

- that no action is required as the vigilance case is clearly not related to the certification granted,
- observation of the manufacturer's and Competent Authorities activities and the results of the manufacturer's investigation to allow a conclusion that the certification granted is not endangered or adequate corrective action has been performed,

- performance of extraordinary surveillance measures (document review, short-notice or unannounced audit, product testing, etc.) if it is likely that the certification granted is endangered,
- increasing the frequency of surveillance audits,
- reviewing specific products or processes during the next audit of the manufacturer, or
- any other relevant measure.

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

- conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in Section 4.6.,
- ensure that it adequately assesses the manufacturer's documentation on, and application of, the provisions on vigilance, the post-market surveillance plan (including post-market 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 certificates or EU type-examination certificates shall occur at least every five 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, CS or equivalent documents,

- changes in medical, scientific and technical knowledge, such as:
  - = new treatments,
  - = changes in test methods,
  - = new scientific findings on materials, components, etc., also with respect to biocompatibility,
  - = experience from market research on comparable devices,
  - = data from registers/registries,
  - = experience from 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 since the previous (re-)certification, 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.
- 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;
  - (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 cleaning, disinfection and sterilisation have been carried out.

- 2.4. ‘Active therapeutic device’ means any active device, whether used alone or in combination with other 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 device, whether used alone or in combination with other 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<sup>47</sup>**

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 to a medical device are classified in their own right separately from the device with which they are used.

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<sup>47</sup> It is noted that since automatic numbering was used in the Commission proposal, the numbering of the sections in Chapter II is not consistent with that in Chapters I and III. It is suggested to leave a correction of this to the legal-linguistic revision during which either Chapter II and III switch place and the sections in Chapter II are renumbered or the section numbering in both Chapters II and III is changed.

3. Software, which drives a device or influences the use of a device, falls automatically in the same class as the device.

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

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 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 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.

### 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 which have breached the dermis or mucous membrane 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 injured skin or mucous membrane.

This rule applies also to the invasive devices that come into contact with injured mucous membrane.

## 4. INVASIVE DEVICES

### 4.1. Rule 5

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

- 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 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 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 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 medicinal products, in which case they are in class III,
- are active implantable devices or their accessories, in which case they are in class III,
- are breast implants or surgical meshes, in which case they are in class III;
- are 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 devices are in class III.

## 5.2. Rule 10

Active devices intended for diagnosis and monitoring are in class IIa:

- if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are in class I,
- 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 the 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 radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are in class IIb.

### 5.2a. Rule 10a

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, is in class IIa, except if such decisions have an impact that may directly or indirectly cause:

- the death or an irreversible deterioration of the state of health, in which case it is in class III;
- a serious deterioration of the state of health or a surgical intervention, in which case it is in class IIb.

Software intended to monitor physiological processes is in class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, in which case it is in class IIb.

All other software is in class I.

### **5.3. Rule 11**

All active devices intended to administer and/or remove 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 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 are in class IIa.

#### **6.5. Rule 17**

All devices manufactured utilising 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.

#### **6.7. Rule 19**

All devices incorporating or consisting of nanomaterial are:

- in class III if they present a high or medium potential for internal exposure;
- in class IIb if they present a low potential for internal exposure;
- in class IIa if they present a negligible potential for internal exposure.

#### **6.9. Rule 21**

Devices that are composed of substances or combinations of substances that are intended to be 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 achieve their intended purpose in the stomach or lower 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, or
  - = if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities, 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 that are intended to treat life threatening conditions, in which 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 A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF THE TECHNICAL DOCUMENTATION

## Chapter I: Quality Management System

1. The manufacturer shall establish, document and implement a quality management system as described in Article 8(5) of this Regulation and maintain its effectiveness through the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 3 and is subject to audit as laid down in Sections 3.3 and 3.4 and to the surveillance as specified in Section 4.
  
- 3. Quality management system assessment**
- 3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:
  - the name and address of the registered place of business of the manufacturer and any additional manufacturing site covered by the quality management system, and, if the application is lodged by the authorised representative, his name and the address of his registered place of business as well,
  - all the relevant information on the device or group of devices covered by the quality management system,
  - a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,
  - a draft of an EU declaration of conformity in accordance with Article 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 and required by this Regulation and the undertaking by the manufacturer to apply these procedures,

- a description of the procedures in place to keep the quality management system adequate and efficacious and the undertaking by the manufacturer to apply these procedures,
- the documentation on the post-market surveillance system, including, when applicable, a plan for the post-market 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 66a,
- a description of the procedures in place to keep up to date the post-market surveillance system, including, when applicable, a plan for the post-market clinical follow-up, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 61 to 66a as well as the undertaking by the manufacturer to apply these procedures.
- documentation on the clinical evaluation plan,
- a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.

3.2. Implementation of the quality management system shall ensure the compliance with the provisions of this Regulation. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records.

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

- (a) the manufacturer's quality objectives;
- (b) the organisation of the business and in particular:
  - the organisational structures with clear assignment to procedures, the responsibilities of the managerial staff and their organisational authority,
  - the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and of device, including control of devices which fail to conform,
  - where the design, manufacture and/or final verification and testing of the devices, or elements of any of these, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,
  - where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;
- (c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques, where these procedures and techniques shall specifically address:
  - the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures,
  - identification of applicable general safety and performance requirements and solutions to address these, under consideration of applicable CS and harmonized standards or equivalent solutions,
  - the risk management according to section 1a of Annex I,

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

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

### **3.3. Audit**

- (a) The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 3.2. Where the manufacturer uses a harmonised standard or a CS related to quality management system, it shall assess conformity with those standards or CS. Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonised standards or CS conform to the requirements covered by the standards or CS.

- (b) The audit team shall include at least one member with past experience of assessments of the technology concerned in accordance with sections 4.4. to 4.6. of Annex VI. In circumstances where this experience is not immediately obvious or applicable the notified body shall provide a documented rationale for the allocation of this auditor. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.
- (c) Moreover, in the case of devices falling into class IIa or IIb, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis in accordance with the provisions in Sections 5.3a. to 5.3e. of Chapter II of this Annex. In choosing representative sample(s) the notified body shall take into account the guidance developed and published by the MDCG according to Article 80 and in particular 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, 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 quality management system certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the audit and a reasoned report.

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

#### **4. Surveillance assessment applicable to devices classified as class IIa, IIb and III**

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.

4.2. The manufacturer shall authorise the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular:

- the documentation on the quality management system,
- the documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the post-market clinical follow-up plan for a selection of devices, and of the provisions on vigilance set out in Articles 61 to 66a,
- the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 2 of Annex I,
- the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

- 4.3. The notified body shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan. This shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.
- 4.4. The notified body shall randomly perform at least once every five years unannounced on-site audits to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment. The notified body shall establish a plan for the unannounced on-site audits which must not be disclosed to the manufacturer.

Within the context of such unannounced on-site audits, the notified body shall test an adequate sample from the production or the manufacturing process to verify that the manufactured device is in conformity with the technical documentation, with the exception of custom-made devices referred to in Article 42(7a). Prior to the unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure.

Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation, with the exception of custom-made devices referred to in Article 42(7a). Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.

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



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

In the case of devices classified as class III, the surveillance assessment shall also include a 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 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 concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall not lead [and attend] an audit for more than three consecutive years in respect to the same manufacturer.

4.7. If the notified body establishes a divergence between the sample taken from the production or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

## **Chapter II: Assessment of the technical documentation**

### **5. Assessment of the technical documentation, 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 assessment of the technical documentation relating to the device which he plans to place on the market or put into service and is covered by the quality management system referred to in Section 3.

- 5.2. The application shall describe the design, manufacture and performances of the device in question. It shall include the technical documentation as referred to in Annex II.
- 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.
- 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 and 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 shall include consideration of the adequacy of the benefit-risk assessment, and management, the instructions for use, the user training, the manufacturer's post-market surveillance plan, and include a review of the need for, and adequacy of, the post-market clinical follow up plan proposed, where applicable.
- 5.3d. The notified body shall consider based on its assessment of the clinical evidence, the clinical evaluation, and the benefit-risk determination if specific milestones are required to be defined to allow for review by the notified body on updates to the clinical evidence based on post market surveillance and post-market 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 a 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 technical documentation assessment certificate. The certificate shall contain the conclusions of the assessment, the conditions of validity, the data needed for identification of the approved design, and, where appropriate, a description of the intended purpose of the device.

5.5. Changes to the approved device shall receive further approval from the notified body which issued the EU technical documentation assessment certificate wherever the changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the applicant plans to introduce any of the above mentioned changes he shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 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 technical documentation assessment certificate.

## **6. Specific procedures**

### **6.0. Assessment procedure in specific cases of implantable devices classified as class III, and for Class IIb active devices intended to administer and/or remove a medicinal product, as referred to in section 5.3. of Annex VII (Rule 11).**

- (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, including the medical indication(s) and the plan for the Post-Market Clinical Follow-Up (PMCF) referred to in article 8(1b) 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 Sections 6.1(c) and (d) of Annex II, to the Commission.

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 expert panel shall decide, under the supervision of the Commission, on the basis of the following criteria:
  - (i) the novelty of the device or the related clinical procedure involved with possible major clinical or health impact;
  - (ii) a significantly adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure;
  - (iii) a significantly increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices.

to provide, within a period of 60 days, starting on the day of receipt of the documents from the Commission, a scientific opinion on the clinical 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. The reasons for the decision to provide a scientific opinion on the basis of the criteria in (i), (ii) and (iii) shall be included in the scientific opinion. In case the information submitted was not sufficient for the expert panel to reach a conclusion, this shall be stated in the scientific opinion.

- (ca) The expert panel may decide, under the supervision of the Commission, on the basis of the criteria laid down in point (c) not to provide a scientific opinion, in which case it shall inform the notified body as soon as possible and in any event within 21 days after receipt of the documents from the Commission. It shall within that time limit provide the notified body and the Commission with the reasons for its decision, whereupon the notified body may proceed with the certification procedure of that device.

- (cab) The expert panel shall within 21 days of receipt of the documents from the Commission notify the Commission, through the system referred to in Article 27 whether it intends to provide a scientific opinion pursuant to point (c) or whether it intends not to provide a scientific opinion pursuant to point (ca).
- (cb) in case no opinion has been delivered within a period of 60 days, the notified body may proceed with the certification procedure of that device.
- (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, including the medical indication(s), and the PMCF plan, the notified body shall, if necessary, advise the manufacturer to restrict the intended purpose of the device to certain groups of patients or medical indication(s), and/or impose 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 performance, or impose other restrictions in its conformity assessment report, as appropriate. The notified body shall provide a full justification where it has not followed the advice of the expert panel in its conformity assessment report and the Commission shall without prejudice to Article 84 make both the scientific opinion of the expert panel and the written justification provided by the notified body publicly available via Eudamed.
- (f) The Commission, after consultation with the Member States and relevant scientific experts shall provide guidance for expert panels for consistent interpretation of the criteria in point (c) before the date of application of this regulation.

## 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 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 medicinal products competent authority or the EMA shall provide its opinion to the notified body within 210 days after receipt of the valid documentation.
- (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 change is 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 authority that was involved in the initial consultation, in order to confirm that the quality and safety of the ancillary substance are maintained. The 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 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 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 that are covered by this Regulation in accordance with point (ea) of Article 1(2) and for 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 technical documentation assessment certificate, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2004/23/EC (hereinafter referred to as 'human tissues and cells competent authority') on the aspects related to the donation, procurement and testing of tissues or cells of human origin or their derivatives. 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 120 days after receipt of valid documentation, the human tissues and cells competent authority shall provide to the notified body its opinion.
- (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. 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.

- (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 human tissues and cells competent authority concerned 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 ratio 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 via a body orifice, or applied on skin 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 systemically 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 after reception of the valid documentation.
- (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 ten 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 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 registered place of business of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the registered place of business of the authorized representative,
- the technical documentation referred to in Annex II. 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:

- 3.0. 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.
- 3.1. examine and assess the technical documentation for conformity with the requirements of this regulation applicable to the device and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable specifications of the standards referred to in Article 6 or CS, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;
- 3.1b. review the clinical evidence presented by the manufacturer in the clinical evaluation report according to Annex XIII Part A, Section 1.6.. 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.

- 3.1d. clearly document the outcome of its assessment in a preclinical and clinical evaluation assessment report as part of the EU type examination report according to paragraph 3.5.
- 3.2. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation if the standards referred to in Article 6 or CS have not been applied; if the device is to be connected to other device(s) in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device(s) having the characteristics specified by the manufacturer;
- 3.3. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;
- 3.4. agree with the applicant on the place where the necessary assessments and tests will be carried out; and
- 3.5. draw up an EU type-examination report on the results of the assessments and tests carried out under sections 3.0. 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 certificate shall be drawn up in accordance with Annex XII. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.

## **5. Changes to the type**

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

## **6. Specific procedures**

The provisions regarding the specific procedures in the case of implantable devices classified as class III and Class IIb active devices intended to administer and/or remove a medicinal product, as referred to in section 5.3. of Annex VII (Rule 11), 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 via a body orifice, or applied on skin 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 technical documentation assessment certificate shall be understood as reference to an EU type-examination certificate.



## 7. Administrative provisions

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, his authorised representative shall, for a period ending at least ten years, 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, scientific opinions 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.
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;
- a copy of the EU-type examination certificates referred to in Section 4 of Annex IX; if the EU-type examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued is necessary.

3.2. Implementation of the quality management system shall ensure the compliance with the type described in the EU type-examination certificate and with the provisions of this Regulation which apply to them at every stage. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans 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 ten 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 fifth indent of Section 3.1 of Annex VIII,
- the documentation referred to in the eighth indent of Section 3.1 of Annex VIII, including the EU type-examination certificate referred to in Annex IX,
- the changes referred to in Section 3.4 of Annex VIII, and
- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3 and 4.4 of Annex VIII.

Section 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, the technical documentation as referred in Annex II for the selected devices for compliance with the provisions of this Regulation;

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, 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 ten years after the last device has been placed on the market, keep at the disposal of the competent authorities:
- the EU declaration of conformity,
  - the 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.

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 system set out in 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 ten 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 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 ten years after the last device has been placed on the market, keep at the disposal of the competent authorities:
  - the EU declaration of conformity,
  - the technical documentation referred to in Annex II,
  - the certificate referred to in Section 8.3.

Section 9 of Annex VIII shall apply.

## PROCEDURE FOR CUSTOM-MADE DEVICES

1. For custom-made 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 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 statement concerned by this Annex shall be kept for a period of time of at least ten 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.

**CERTIFICATES ISSUED BY A NOTIFIED BODY****I. General Requirements**

1. Certificates shall be drawn up in one of the official languages of the Union;
2. Each certificate shall refer to only one conformity assessment procedure;
3. Certificates shall only be issued to one manufacturer (natural or legal person). The name and address of the manufacturer included in the certificate shall be the same as registered in the electronic system referred to in Article 25 of this Regulation;
4. The scope of the certificates shall unambiguously describe the device(s) covered:
  - (a) EU technical documentation assessment and EU type-examination certificates shall include a clear identification (name, model, type) of the device(s), the intended purpose (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 shall be able to demonstrate on request, which (individual) devices are covered by the certificate. The Notified Body shall set out a system that enables the determination of the devices, including their classification, covered by the certificate;
6. Certificates shall contain, if applicable, a note that for the placing on the market of the device(s) covered by this certificate, another certificate according to this Regulation is required;

7. EU quality management system certificates for class I devices for which the involvement of a Notified Body is required pursuant to Article 42, paragraph 5 shall include a statement that the Notified Body has audited the quality management system restricted to the aspects required in that paragraph.
8. When a certificate replaces a previous one, i.e. when it is supplemented, modified or re-issued it shall contain a reference to the previous certificate and its date of issue with identification of the changes.

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

1. Name, address and identification number of the notified body;
2. name and address of the manufacturer and, if applicable, of the authorised representative;
3. unique number identifying the certificate;
- 3a. the single registration number of the manufacturer according to Article 25a paragraph 2;
4. date of issue;
5. date of expiry;
6. data needed for the unambiguous identification of the device(s) where applicable as specified in Part I, Section 4 of this Annex;
- 7a. if applicable, reference to a previous certificate as specified in Section I.8 of this Annex;
8. reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;
9. examinations and tests performed, e.g. reference to relevant CS / standards / test reports / audit report(s);
10. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device(s) covered;
11. if applicable, information about the surveillance by the notified body;
12. conclusions of the notified body's conformity assessment with regard to the relevant Annex;
13. conditions for or limitations to the validity of the certificate;
14. legally binding signature of the notified body according to the applicable national law.

**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 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 specification of intended 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 indicative list 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 purpose and any gaps in clinical evidence through a systematic scientific literature search;

- (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.
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 purpose, manufacturer's claims and risks of the device in question.
- 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.

6. The results of the clinical evaluation and the clinical 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 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.

Favourable and unfavourable data considered in the clinical evaluation shall also be part of the technical documentation.

## **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 bears the CE marking, and is 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:

- (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 1a 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.
- (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 1a 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.

#### **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 regarding the safety, performance and benefit/risk related to the device 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 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 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, in particular those involving the safety and performance, and their effect on 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.
- 2.6. The investigator 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 investigator, 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 as set out 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.
- 1.5. Status of the clinical investigation application (i.e. first submission, resubmission, significant amendment).
- 1.5a. Details/reference to the Clinical Evaluation Plan.
- 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 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.
- 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 incorporate 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, 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. A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and Common Specifications applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as these standards and CS have not or only been partly fulfilled or are lacking.

2.7a. A detailed description 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.

### **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 investigational site and the emergency contact details for the principal investigator at each site. The roles, responsibilities and qualifications of the various kinds of investigators shall be specified in the Clinical Investigation Plan.

3.1.3a. A brief description of the financing of the clinical investigation and a brief description of the agreement between the sponsor and the site.

3.1.4. Overall synopsis of the clinical investigation, in an official Union language determined by the Member State concerned;



- 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.
- 3.4. Risks and clinical benefits of the device 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 the clinical evaluation plan.
  - 3.6.2. Information on the investigational device, 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, size of investigation population, representativity of investigation population to target population and, if applicable, information on vulnerable 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 the end, halt or early termination of an investigation, for follow-up of subjects who have withdrawn their consent and procedures for subjects lost to follow up. The procedure shall for implantable devices, as a minimum, cover traceability.
- 3.15a. A description of the arrangements for taking care of the subjects after their participation in the clinical investigation has ended, where such additional care is necessary because of the subjects' participation in the clinical investigation and where it differs from that normally expected for the medical condition in question.
- 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.

- 4.2. Where applicable according to national law, copy of the opinion(s) of the ethics committee(s) concerned. When according to national law the opinion(s) of the ethics committee(s) is not required at the time of the submission of the application, a 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 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 upon request be submitted to the Competent Authority reviewing an application.

### **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 or any other event referred to in Article 59(2) are reported by the investigator(s) to the Sponsor in a timely manner.
3. The documentation mentioned in this Annex shall be kept for a period of time of at least ten years after the clinical investigation with the device in question has ended, or, when the device is subsequently placed on the market, at least ten years after the last device has been placed on the market. 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 or legal representative according to Article 50(2), 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 investigational 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 shall complete the 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 shall 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 REFERRED TO IN ARTICLE 1(1a)**

1. Contact lenses or other articles intended to be introduced into or onto the eye;
2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of 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 or other dermal or mucous membrane 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;
6. High intensity electromagnetic radiation (e.g. 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 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<sup>48</sup>**

<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

<sup>48</sup> This annex has not been updated - it reflects the Cion proposal.



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	-

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