



EUROPEAN COMMISSION

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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)

{SWD(2012) 273 final}

{SWD(2012) 274 final}

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

The current EU regulatory framework for medical devices, other than *in vitro* diagnostic medical devices, consists of Council Directive 90/385/EEC on active implantable medical devices (AIMDD)<sup>1</sup> and Council Directive 93/42/EEC on medical devices (MDD)<sup>2</sup> which cover a huge spectrum of products. The MDD divides them into four classes of risk: class I (low risk, e.g. sticking plasters, corrective glasses), class IIa (medium-low risk, e.g. tracheal tubes, dental filling material), class IIb (medium-high risk, e.g. X-ray machines, bone plates and screws) and class III (high risk, e.g. heart valves, total hip replacements, breast implants). Active implantable medical devices (e.g. pacemakers, implantable defibrillators) covered by the AIMDD fall *de facto* into class III.

The two Directives, adopted in the 1990s, are based on the ‘New Approach’ and aim to ensure the smooth functioning of the internal market and a high level of protection of human health and safety. Medical devices are not subject to any pre-market authorisation by a regulatory authority but to a conformity assessment which, for medium and high risk devices, involves an independent third party, known as ‘notified body’. Notified bodies, of which there are around 80 across Europe, are designated and monitored by the Member States and act under the control of the national authorities. Once certified, devices bear the CE marking which allows them to circulate freely in the EU/EFTA countries and Turkey.

The existing regulatory framework has demonstrated its merits but has also come under harsh criticism, in particular after the French health authorities found that a French manufacturer (*Poly Implant Prothèse*, PIP) had for several years apparently used industrial silicone instead of medical grade silicone for the manufacture of breast implants contrary to the approval issued by the notified body, causing harm to thousands of women around the world.

In an internal market with 32 participating countries<sup>3</sup> and subject to constant technological and scientific progress, substantial divergences in the interpretation and application of the rules have emerged, thus undermining the main objectives of the Directives, i.e. the safety of medical devices and their free movement within the internal market. Moreover, regulatory gaps or uncertainties exist with regard to certain products (e.g. products manufactured utilising non-viable human tissues or cells; implantable or other invasive products for cosmetic purposes).

This revision aims to overcome these flaws and gaps and to further strengthen patient safety. A robust, transparent and sustainable regulatory framework should be put in place that is ‘fit for purpose’. This framework should be supportive of innovation and the competitiveness of the medical device industry and should allow rapid and cost-efficient market access for innovative medical devices, to the benefit of patients and healthcare professionals.

This proposal is adopted alongside a proposal for a Regulation on *in vitro* diagnostic medical devices (IVDs), such as blood tests, which are covered by Directive 98/79/EC of the

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<sup>1</sup> OJ L 189, 20.7.1990, p. 17.

<sup>2</sup> OJ L 169, 12.7.1993, p. 1.

<sup>3</sup> EU Member States, EFTA countries and Turkey.

European Parliament and of the Council (IVDD)<sup>4</sup>. The horizontal aspects that are common to both sectors are aligned whilst the specific features of each sector require separate legal acts.

## 2. RESULTS OF CONSULTATIONS WITH INTERESTED PARTIES AND IMPACT ASSESSMENTS

In preparation for the impact assessment on this proposal and the proposal for a Regulation on IVDs, the Commission held two public consultations, the first from 8 May to 2 July 2008, and the second from 29 June to 15 September 2010. In both public consultations, the general principles and minimum standards for consultation of interested parties by the Commission were applied; responses received within a reasonable period after the deadlines were taken into account. After analysing all the responses, the Commission published a summary outcome and the individual responses on its website<sup>5</sup>.

The majority of respondents to the 2008 public consultation (in particular Member States and industry) considered the proposed revision to be premature. They pointed to Directive 2007/47/EC of the European Parliament and of the Council<sup>6</sup>, which amended the AIMDD and the MDD and was to be implemented by 21 March 2010, and also to the New Legislative Framework for the Marketing of Products which was due to enter into force with effect from 1 January 2010, and argued that it would be advisable to wait for these changes to be implemented, in order to assess the need for further adjustments better.

The 2010 public consultation focussed on aspects related to the revision of the IVDD and showed wide support for this initiative, linked to the revision of the regulatory framework for medical devices in general.

During 2009, 2010 and 2011, the issues to be tackled in the revision of the regulatory framework for medical devices were regularly discussed at meetings of the Medical Devices Expert Group (MDEG), the Competent Authorities for Medical Devices (CAMD) and specific working groups in the fields of notified bodies, borderline and classification, clinical investigation and evaluation, vigilance, market surveillance, *in vitro* diagnostics medical devices (IVD) and in an *ad hoc* working group on Unique Device Identification (UDI). A special meeting of the MDEG was held on 31 March and 1 April 2011 to discuss issues related to the impact assessment. Moreover, the Heads of Medicines Agencies (HMA) and the CAMD organised joint workshops on the development of the legal framework for medical devices on 27 April and 28 September 2011.

A further special meeting of the MDEG was held on 6 and 13 February 2012 to discuss issues related to the two legislative proposals, based on working documents containing initial drafting proposals. Written comments made on these working documents were taken in account for the further development of the proposals.

In addition, the Commission's representatives regularly participated in conferences to present ongoing work on the legislative initiative and hold discussions with stakeholders. Targeted meetings took place at senior level with representatives from associations representing industry, notified bodies, healthcare professionals and patients.

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<sup>4</sup> OJ L 331, 7.12.1998, p. 1.

<sup>5</sup> See [http://ec.europa.eu/health/medical-devices/documents/revision/index\\_en.htm](http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm).

<sup>6</sup> OJ L 247, 21.9.2007, p. 21.

Aspects linked to the appropriate regulatory framework were also discussed in the course of the ‘Exploratory Process on the Future of the Medical Device Sector’ organised by the Commission from November 2009 to January 2010. On 22 March 2011, the Commission and the Hungarian Presidency organised a high-level conference on innovation in medical technology, the role of the medical device sector in addressing the healthcare challenges facing Europe and the appropriate regulatory framework for this sector to meet the needs of tomorrow. This conference was followed by Conclusions of the Council of the European Union on innovation in the medical device sector adopted on 6 June 2011<sup>7</sup>. In its Conclusions, the Council requested the Commission to adapt the EU medical device legislation to the needs of tomorrow so as to achieve a suitable, robust, transparent and sustainable regulatory framework, which is central to fostering the development of safe, effective and innovative medical devices for the benefit of European patients and healthcare professionals.

Triggered by the PIP breast implants scandal, the European Parliament adopted on 14 June 2012 a Resolution on defective silicone gel breast implants made by the French company PIP<sup>8</sup> also calling on the Commission to develop an adequate legal framework to guarantee the safety of medical technology.

### **3. LEGAL ELEMENTS OF THE PROPOSAL**

#### **3.1. Scope and definitions (Chapter I)**

The scope of the proposed Regulation corresponds to a large extent to the combined scopes of Council Directives 90/385/EEC and 93/42/EEC, i.e. it covers all medical devices other than *in vitro* diagnostic medical devices. On the one hand, however, the scope is extended to some products currently not covered by the AIMDD/MDD. And on the other hand, some products which, in some Member States, are placed on the market as medical devices are excluded from its scope.

The extension of the scope concerns:

- products manufactured utilising non-viable human tissues or cells, or their derivatives, that have undergone substantial manipulation (e.g. syringes prefilled with human collagen), unless they are covered by Regulation (EC) No 1394/2007 on advanced therapy medicinal products<sup>9</sup>. Human tissues and cells, or products derived from human tissues or cells, that are not substantially manipulated and that are regulated by 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>10</sup> are not covered by the proposal;
- certain implantable or other invasive products without a medical purpose that are similar to medical devices in terms of characteristics and risk profile (e.g. non-corrective contact lenses, implants for aesthetic purposes);

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<sup>7</sup> OJ C 202, 8.7.2011, p. 7.

<sup>8</sup> Resolution of 14 June 2012 (2012/2621(RSP)); P7\_TA-PROV(2012)0262, <http://www.europarl.europa.eu/plenary/en/texts-adopted.html>.

<sup>9</sup> OJ L 324, 10.12.2007, p. 121.

<sup>10</sup> OJ L 102, 7.4.2004, p. 48.

Additional provisions as regards products that are not covered by the Regulation have been included, more to clarify the scope with a view to ensuring harmonised implementation than to substantially change the scope of the EU legislation. They concern:

- products that contain or consist of viable biological substances (e.g. living micro-organisms);
- food covered by Regulation (EC) No 178/2002 on general principles and requirements of food law<sup>11</sup> (e.g. this may affect certain slimming products); in return, medical devices are excluded from the scope of Regulation 178/2002 (diagnostic probes or cameras, even when introduced orally, are therefore clearly excluded from the food legislation).

As regards products composed of substances or combinations of substances that are intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body, the borderline between medicinal products and medical devices is difficult to draw. To ensure a high level of safety of those products regardless of their qualification, those products which fall under the definition of a medical device are classified in the highest risk class and should comply with the relevant requirements of Annex I of 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>12</sup>.

To support Member States and the Commission in determining the regulatory status of products, the Commission may set up, in accordance with its internal rules<sup>13</sup>, a group of experts from various sectors (such as medical devices, IVDs, medicinal products, human tissues and cells, cosmetics and biocides).

The definitions section has been significantly extended, aligning the definitions in the field of medical devices with well established European and international practice, such as the New Legislative Framework for the Marketing of Products<sup>14</sup> and guidance documents produced by the Global Harmonization Task Force (GHTF) for medical devices<sup>15</sup>.

### **3.2. Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement (Chapter II)**

This chapter contains provisions that are typical for product-related internal market legislation and sets out the obligations of the relevant economic operators (manufacturers, authorised representatives of non-EU manufacturers, importers and distributors). The regulatory instrument of ‘common technical specification’ (CTS), which has proven useful in the context of the IVDD, has been introduced in the broader field of medical devices to allow the Commission to further specify the general safety and performance requirements (laid down in

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<sup>11</sup> OJ L 31, 1.2.2002, p. 1.

<sup>12</sup> OJ L 311, 28.11.2001, p. 67.

<sup>13</sup> Communication from the President to the Commission of 10.11.2010, Framework for Commission Expert Groups: Horizontal Rules and Public Registers, C(2010)7649 final.

<sup>14</sup> Consisting of Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30, and Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L 218, 13.8.2008, p. 82.

<sup>15</sup> <http://www.ghtf.org/>

Annex I) and the requirements on clinical evaluation and post-market clinical follow-up (laid down in Annex XIII). Such requirements however, leave manufacturers the possibility of adopting other solutions that ensure at least an equivalent level of safety and performance.

The legal obligations on manufacturers are proportionate to the risk class of the devices they produce. For example, this means that even though all manufacturers should have a quality management system (QMS) in place to ensure that their products consistently meet the regulatory requirements, the QMS-related responsibilities are stricter for manufacturers of high risk devices than for manufacturers of low risk devices. Manufacturers of medical devices for an individual patient, so called 'custom-made devices', must ensure that their devices are safe and perform as intended, but their regulatory burden remains low.

Key documents for the manufacturer to demonstrate compliance with the legal requirements are the technical documentation and the EU declaration of conformity to be drawn up in respect of devices placed on the market. Their minimum contents are laid down in Annexes II and III.

The following concepts are also new in the field of medical devices:

- A requirement has been introduced that within the manufacturer's organisation a 'qualified person' should be responsible for regulatory compliance. Similar requirements exist in EU legislation on medicinal products and in the national laws transposing the AIMDD/MDD in some Member States.
- Since in the case of 'parallel trade' with medical devices application of the principle of free movement of goods varies considerably from one Member State to another and, in many cases, *de facto* prohibits this practice, clear conditions are set for enterprises involved in relabelling and/or repackaging medical devices.
- Patients who are implanted with a device should be given essential information on the implanted device allowing it to be identified and containing any necessary warnings or precautions to be taken, for example indication as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.
- In accordance with Article 12a of the MDD, introduced by Directive 2007/47/EC, the Commission had to prepare a report on the reprocessing of medical devices and submit, where appropriate, a legislative proposal on this issue. On the basis of the Commission's findings set out in its report of 27 August 2010<sup>16</sup>, which took into account the opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of 15 April 2010, the proposal contains strict rules on the reprocessing of single-use devices in order to ensure a high level of protection of health and safety whilst allowing this practice to further develop under clear conditions. Reprocessing of single-use devices is considered as manufacture of new devices so that the reprocessors must satisfy the obligations incumbent on manufacturers. The reprocessing of single-use devices for critical use (e.g. devices for surgically invasive procedures) should, as a general rule, be prohibited. Since

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<sup>16</sup> Report from the Commission to the European Parliament and the Council on the issue of reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC, COM(2010)443 final.

certain Member States may have particular concerns in terms of safety regarding the reprocessing of single-use devices, they retain their right to maintain or impose a general ban on this practice including the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing and on the access of reprocessed single-use devices to their market.

### **3.3. Identification and traceability of devices, registration of devices and economic operators, summary of safety and clinical performance, Eudamed (Chapter III)**

This chapter addresses one of the main shortcomings of the current system: its lack of transparency. It consists of:

- a requirement that economic operators must be able to identify who supplied them and to whom they have supplied medical devices;
- a requirement that manufacturers fit their devices with a Unique Device Identification (UDI) which allows traceability. The UDI system will be implemented gradually and proportionate to the risk class of the devices;
- a requirement that manufacturers/authorised representatives and importers must register themselves and the devices they place on the EU market in a central European database;
- an obligation for manufacturers of high-risk devices to make publicly available a summary of safety and performance with key elements of the supporting clinical data;
- and the further development of the European databank on medical devices (Eudamed), set up by Commission Decision 2010/227/EU<sup>17</sup>, which will contain integrated electronic systems on a European UDI, on registration of devices, relevant economic operators and certificates issued by notified bodies, on clinical investigations, on vigilance and on market surveillance. A large part of the information in Eudamed will become publicly available in accordance with the provisions regarding each electronic system.

The establishment of a central registration database will not only provide a high level of transparency but also do away with diverging national registration requirements which have emerged over recent years and which have significantly increased compliance costs for economic operators. It will therefore also contribute to reducing the administrative burden on manufacturers.

### **3.4. Notified bodies (Chapter IV)**

Proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system which has come under severe criticism in recent years due to significant differences as regards, on the one hand, the designation and monitoring of notified bodies and, on the other, the quality and depth of the conformity assessment performed by them, in particular in their assessment of the manufacturers' clinical evaluation.

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<sup>17</sup> OJ L 102, 23.4.2010, p. 45.

In line with the New Legislative Framework for the Marketing of Products, the proposal sets out requirements for national authorities responsible for notified bodies. It leaves the ultimate responsibility for designating and monitoring notified bodies, based on stricter and detailed criteria laid down in Annex VI, with the individual Member State. The proposal thus builds on existing structures already available in most Member States instead of lifting the responsibility to the Union level which might have caused concerns in terms of subsidiarity. But any new designation and, in regular intervals, the monitoring of notified bodies are made subject to 'joint assessments' with experts from other Member States and the Commission, thus ensuring an effective control at Union level.

At the same time, the position of notified bodies vis-à-vis manufacturers will be significantly strengthened, including their right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on devices. The proposal also requires rotation of the notified body's personnel involved in the assessment of medical devices at appropriate intervals to strike a reasonable balance between the knowledge and experience required to carry out thorough assessments and the need to ensure continuous objectivity and neutrality in relation to the manufacturer subject to those assessments.

### **3.5. Classification and conformity assessment (Chapter V)**

The proposal keeps to the well established approach (in Europe and internationally) of dividing medical devices into four classes, taking account of the potential risks associated with the technical design and manufacture. The classification rules (laid down in Annex VII) have been adapted to technical progress and experience gained from vigilance and market surveillance. For example, further to incidents that had occurred to blood plasma donors and a request submitted by France, aphaeresis machines have been moved from class IIb to class III. Active implantable medical devices and their accessories have been classified in the highest risk class (class III) to maintain the same level of safety as provided by Council Directive 90/385/EEC.

The classification of a medical device determines the applicable conformity assessment procedure for which the proposal follows the general lines of the AIMDD/MDD. The conformity assessment procedure for class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturer in view of the low level of vulnerability associated with these products. However, when class I devices have a measuring function or are sold sterile, a notified body must verify the aspects related to the measuring function or to the sterilisation process. For devices of classes IIa, IIb and III, an appropriate level of involvement of a notified body is compulsory proportionate to the risk class, with devices of class III requiring explicit prior approval of the design or of the type of the device and of the quality management system before they may be placed on the market. In the case of class IIa and IIb devices, the notified body checks the quality management system and, for representative samples, the technical documentation. After initial certification, notified bodies must regularly conduct surveillance assessments in the post-market phase.

The different conformity assessment procedures during which the notified body audits the manufacturer's quality management system, checks the technical documentation, examines the design dossier or approves the type of a device are laid down in Annexes VIII to X. They have been tightened and streamlined. The proposal reinforces the powers and responsibilities of notified bodies and specifies the rules according to which notified bodies perform their assessments, both in the pre-market and the post-market phase (e.g. documentation to be submitted, scope of the audit, unannounced factory inspections, sample checks) to ensure a



level playing field and avoid notified bodies being overly lenient. Manufacturers of custom-made devices continue to be subject to a specific procedure (laid down in Annex XI) which does not involve a notified body.

In addition, the proposal introduces the obligation for notified bodies to notify an expert committee (see below under 3.8.) of new applications for conformity assessment of high-risk devices. On scientifically valid health grounds, the expert committee will have the power to request the notified body to submit a preliminary assessment on which the committee can issue comments within a deadline of 60 days<sup>18</sup>, before the notified body can issue a certificate. This scrutiny mechanism empowers the authorities to have a 'second look' at individual assessments and make their views heard before a device is placed on the market. A similar procedure is currently already applied for medical devices manufactured utilising animal tissues (Commission Directive 2003/32/EC<sup>19</sup>). Its use should be the exception rather than the rule and should follow clear and transparent criteria.

### **3.6. Clinical evaluation and clinical investigations (Chapter VI)**

Building on the current Annex X of the MDD, this chapter lays down the key obligations of manufacturers as regards the performance of the clinical evaluation needed to demonstrate the safety and performance of their devices. More detailed requirements are set out in Annex XIII which addresses the pre-market clinical evaluation and post-market clinical follow-up that together constitute a continuous process during the life cycle of a medical device.

The process for conducting clinical investigations (the equivalent of clinical trials in the field of medicinal products), which is currently described in basic terms in Article 15 of the MDD, is further developed. First of all, the concept of 'sponsor' is introduced and aligned with the definition used in the recent Commission's Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use which aims at repealing Directive 2001/20/EC<sup>20</sup>.

The sponsor can be the manufacturer, his authorised representative or another organisation, in practice often a 'contract research organisation' conducting clinical investigations for the manufacturers. The scope of the proposal, however, remains restricted to clinical investigations carried out for regulatory purposes, i.e. for obtaining or confirming regulatory approval for market access. Non-commercial clinical investigations that do not pursue a regulatory purpose are not covered by this Regulation.

In accordance with recognised international ethical principles, every clinical investigation must be registered in a publicly accessible electronic system which the Commission will set up. 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 future EU database to be set up in accordance with the future Regulation on clinical trials on medicinal products for human use.

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<sup>18</sup> In accordance with Article 3(3) of Regulation (EEC, EURATOM) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits, OJ L 124, 8.6.1971, p. 1) days referred to in this Regulation mean calendar days.

<sup>19</sup> OJ L 105, 26.4.2003, p. 18. This directive will be replaced by Commission Regulation (EU) No 722/2012 (OJ L 212, 9.8.2012, p. 3) with effect from 29 August 2013.

<sup>20</sup> COM(2012)369.

Before commencing a clinical investigation, the sponsor must submit an application to confirm that there are no health and safety or ethical aspects which would oppose it. A new possibility will be opened up for sponsors of clinical investigations to be conducted in more than one Member State: in future, they may submit a single application through the electronic system to be set up by the Commission. As a consequence, the health and safety aspects regarding the device intended for clinical investigation will be assessed by the Member States concerned under the direction of a coordinating Member State. The assessment of intrinsically national, local and ethical aspects (e.g. liability, suitability of the investigators and investigation sites, informed consent) will, however, need to be carried out at the level of each Member State concerned which will retain the ultimate responsibility for deciding whether the clinical investigation may be conducted on its territory. In line with the above-mentioned Commission's Proposal for a Regulation on clinical trials on medicinal products, also this proposal leaves it to the Member States to define the organisational set-up at national level for the approval of clinical investigations. In other words, it moves away from a legally required dualism of two distinct bodies, i.e. a national competent authority and an ethics committee.

### **3.7. Vigilance and market surveillance (Chapter VII)**

A well functioning vigilance system is the 'backbone' of a robust regulatory framework in this sector because complications with medical devices that are designed to be implanted or to operate for many years or even decades might come to light only after a certain period of time. The main progress which the proposal will bring in this field is the introduction of an EU portal where manufacturers must report serious incidents and corrective actions they have taken to reduce the risk of recurrence. The information will be automatically forwarded to the national authorities concerned. Where the same or similar incidents have occurred, or where a corrective action has to be taken, in more than one Member State, a coordinating authority will take the direction in coordinating the analysis of the case. The emphasis is placed on work- and expertise-sharing to avoid inefficient duplication of procedures.

As regards market surveillance, the main objectives of the proposal are 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.

### **3.8. Governance (Chapters VIII and IX)**

The Member States will be responsible for implementation of the future Regulation. A central role in achieving harmonised interpretation and practice will be assigned to an expert committee (the Medical Device Coordination Group or MDCG) made up of members appointed by the Member States due to their role and experience in the field of medical devices and chaired by the Commission. The MDCG and its subgroups will allow to build a forum for discussions with stakeholders. The proposal creates the legal basis that for specific hazards or technologies EU reference laboratories, a concept that has proven successful in the food sector, may in the future be designated by the Commission.

As regards the management at EU level, the impact assessment identified as preferred policy options either the extension of the responsibility of the European Medicines Agency (EMA) to medical devices or the management of the medical devices regulatory system by the Commission. Taking into account the clear preference expressed by stakeholders, including many Member States, the proposal mandates the Commission to provide technical, scientific and logistic support to the MDCG.

### **3.9. Final provisions (Chapter X)**

The proposal empowers the Commission to adopt, where appropriate, either implementing acts to ensure uniform application of the Regulation or delegated acts to complement the regulatory framework for medical devices over time.

With this proposal, other Union legislation is amended where a link exists with medical devices. In the case of medicinal product/medical device combination products that are regulated under Directive 2001/83/EC, the AIMDD and MDD already require the device part to comply with the applicable essential requirements set out in the medical device legislation. However, compliance with this requirement is not currently verified as part of the authorisation process for the medicinal product. Annex I of Directive 2001/83/EC, which lays down the content of an application for marketing authorisation, is therefore amended to require the applicant to submit evidence (e.g. an EU declaration of conformity or a certificate issued by a notified body) that the device part is in conformity with the applicable general safety and performance requirements of the future Regulation on medical devices.

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products<sup>21</sup> is amended to empower the Commission to determine whether or not a product falls within the definition of a cosmetic product. Such possibility already exists in the AIMDD and the MDD and is kept in this proposal. It also exists in the new Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products<sup>22</sup>. This will facilitate the adoption of EU-wide decisions regarding 'borderline' cases where the regulatory status of a product needs to be clarified.

The Food Regulation 178/2002 is amended to exclude medical devices from its scope (see 3.1. above).

The new Regulation will become applicable three years after its entry into force to allow manufacturers, notified bodies and Member States time to adapt to the new requirements. The Commission needs time to put in place the IT infrastructure and the organisational arrangements necessary for the functioning of the new regulatory system. The designation of notified bodies pursuant to the new requirements and process needs to start shortly after the entry into force of the Regulation in order to ensure that by the date of its application, sufficient notified bodies are designated in accordance with the new rules to avoid any shortage of medical devices on the market. Special transitional provisions are foreseen for the registration of medical devices, relevant economic operators and certificates issued by notified bodies to allow for a smooth transition from registration requirements at national level to a central registration at EU level.

The future Regulation replaces and repeals Council Directives 90/385/EEC and 93/42/EEC.

### **3.10. Union competence, subsidiarity and legal form**

The proposal has a 'double legal basis', i.e. Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU). With the entry into force of the Lisbon Treaty, the legal base for the establishment and functioning of the internal market, on which

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<sup>21</sup> OJ L 342, 22.12.2009, p. 59.

<sup>22</sup> OJ L 167, 27.6.2012, p.1.

the current Medical Devices Directives were adopted, has been complemented by a specific legal basis to set high standards for the quality and safety of devices for medical use. In regulating medical devices, the Union is exercising its shared powers under Article 4(2) of the TFEU.

Under the current Medical Devices Directives, devices that bear the CE marking can, in principle, move freely within the EU. The proposed revision of the existing directives, which will integrate the changes introduced by the Lisbon Treaty regarding public health, can be achieved only at Union level. This is necessary in order to improve the level of protection of public health for all European patients and users, and also to prevent Member States from adopting diverging product regulations which would result in further fragmentation of the internal market. Harmonised rules and procedures allow manufacturers, especially SMEs which make up more than 80% of the sector, to reduce costs related to national regulatory differences, while ensuring a high and equal level of safety throughout the Union. In accordance with the principles of proportionality and subsidiarity, as set out in Article 5 of the Treaty on European Union, this proposal does not go beyond what is necessary in order to achieve those objectives.

The proposal takes the form of a Regulation. This is the appropriate legal instrument as it imposes clear and detailed rules which will become applicable in a uniform manner and at the same time throughout the Union. Diverging transposition of the AIMDD and MDD by Member States has led to different levels of health and safety protection and created obstacles to the internal market which only a Regulation can avoid. Replacing the national transposition measures also has a strong simplification effect since it allows economic operators to conduct their business on the basis of a single regulatory framework, rather than a 'patchwork' of 27 national laws.

The choice of a Regulation, however, does not mean that decision-making is centralised. Member States retain their competence for implementing the harmonised rules, e.g. as regards approval of clinical investigations, the designation of notified bodies, the assessment of vigilance cases, the conduct of market surveillance and enforcement action (e.g. penalties).

### **3.11. Fundamental Rights**

In line with the Charter of Fundamental Rights of the EU, this proposal seeks to ensure a high level of human health protection (Article 35 of the Charter) and consumer protection (Article 38) by assuring a high level of safety of medical devices made available on the Union market. The proposal affects the freedom of economic operators to conduct business (Article 16) but the obligations imposed on manufacturers, authorised representatives, importers and distributors of medical devices are necessary to guarantee a high level of safety of those products.

The proposal sets guarantees for the protection of personal data. In respect to medical research, the proposal requires that any clinical investigation with participation of human subjects is conducted respecting the human dignity, the right to physical and mental integrity of the persons concerned and the principle of free and informed consent, as required by Articles 1, 3(1) and 3(2)(a) of the Charter.

## **4. BUDGETARY IMPLICATIONS**

The budgetary implications of this proposal are as follows:

- Costs for the further development of the Eudamed databank (one-off costs and maintenance);
- Commission staff to organise and participate in 'joint assessments' of notified bodies;
- Costs for national assessors participating in 'joint assessments' of notified bodies in accordance with the Commission's rules on the reimbursement of expenses incurred by experts;
- Commission staff to provide scientific, technical and logistic support to the MDCG, to its sub-groups and to the coordinating Member States in the fields of clinical investigations and vigilance;
- Commission staff to manage and further develop the EU regulatory framework for medical devices (functioning of this Regulation and preparation of delegated/implementing acts) and to support Member States in ensuring its effective and efficient implementation;
- Costs for organising meetings of the MDCG and its sub-groups and of the Committee under Regulation 182/2011, including reimbursement of their members, appointed by the Member States, to ensure a high level of coordination between Member States;
- Costs for the establishment and management of the scrutiny mechanism in respect of conformity assessments by notified bodies for high risk devices, including the technical infrastructure for data-exchange;
- Costs for running EU reference laboratories when these are designated;
- Costs for participation in international regulatory cooperation.

Details of the costs are set out in the legislative financial statement. A thorough discussion on the costs is contained in the impact assessment report.

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>23</sup>,

Having regard to the opinion of the Committee of the Regions<sup>24</sup>,

After consulting the European Data Protection Supervisor<sup>25</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>26</sup> and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices<sup>27</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>23</sup> OJ C [...], [...], p. [...].

<sup>24</sup> OJ C [...], [...], p. [...].

<sup>25</sup> OJ C [...], [...], p. [...].

<sup>26</sup> OJ L 189, 20.7.1990, p. 17.

<sup>27</sup> OJ L 169, 12.7.1993, p. 1.

- (2) This Regulation aims to ensure the functioning of the internal market as regards medical devices, taking as a base a high level of protection of health. 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.
- (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, 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.
- (6) A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Union.
- (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>28</sup> should be amended to exclude medical devices from its scope.

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<sup>28</sup> OJ L 31, 1.2.2002, p.1.

- (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. If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls within the definition of a medical device or of an accessory to a medical device. 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>29</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>30</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 is incomplete in respect of certain products manufactured utilising non-viable human tissues or cells that have undergone substantial manipulation and that are not covered by 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>31</sup>. Whilst donation, procurement and testing of the human tissues and cells used for the manufacture of those products should remain within the scope of 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>32</sup>, the finished product should come under the scope of this Regulation. Human tissues and cells that are not substantially manipulated, such as human demineralised bone matrix, and products derived from such tissues and cells, should not be covered by this Regulation.
- (11) Certain implantable and other invasive 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.
- (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 that contain living biological substances of other origin are also not covered by this Regulation.
- (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

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<sup>29</sup> OJ L 342, 22.12.2009, p. 59.

<sup>30</sup> OJ L 311, 28.11.2001, p. 67.

<sup>31</sup> OJ L 324, 10.12.2007, p. 121.

<sup>32</sup> OJ L 102, 7.4.2004, p. 48.



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>33</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 that can be released to the human body and those devices should be subject to the most severe conformity assessment procedure.

- (14) Aspects addressed by Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC<sup>34</sup> and aspects addressed by Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC<sup>35</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 those Directives.
- (15) This Regulation should include requirements regarding the design and manufacture of medical devices emitting ionizing radiation without affecting the application of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation<sup>36</sup> nor of Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure and repealing Directive 84/466/Euratom<sup>37</sup> which pursue other objectives.
- (16) It should be made clear that the requirements of this Regulation also apply to the countries that have entered into international agreements with the Union which confer on that country the same status as a Member State for the purpose of application of this Regulation, as it is currently the case with the Agreement on the European Economic Area<sup>38</sup>, the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment<sup>39</sup> and the Agreement of 12 September 1963 establishing an association between the European Economic Community and Turkey<sup>40</sup>.
- (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>41</sup> as well as devices used in the context of a commercial activity to provide a diagnostic or

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<sup>33</sup> OJ L 275, 20.10.2011, p. 38.

<sup>34</sup> OJ L 390, 31.12.2004, p. 24

<sup>35</sup> OJ L 157, 9.6.2006, p. 24.

<sup>36</sup> OJ L 159, 29.6.1996, p. 1.

<sup>37</sup> OJ L 180, 9.7.1997, p. 22.

<sup>38</sup> OJ L 1, 3.1.1994, p. 3.

<sup>39</sup> OJ L 114, 30.4.2002, p. 369.

<sup>40</sup> OJ L 217, 29.12.1964, p. 3687.

<sup>41</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.

therapeutic service to persons within the Union must comply with the requirements of this Regulation at the latest when the product is placed on the market or the service is provided in the Union.

- (18) It is appropriate to adapt the general safety and performance requirements to technical and scientific progress, for example for software that is 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.
- (19) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No [...] on European standardisation<sup>42</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>43</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 technical specifications which provide a means to comply with general safety and performance requirements and requirements for clinical evaluation and/or post-market clinical follow-up.
- (21) The definitions in the field of medical devices, for example regarding economic operators, clinical investigations and vigilance, should be aligned with well-established practice at Union and international level in order to enhance legal certainty.
- (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>44</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>45</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 as laid down in 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

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<sup>42</sup> OJ L [...], [...], p. [...].

<sup>43</sup> OJ L 331, 7.12.1998, p. 1.

<sup>44</sup> OJ L 218, 13.8.2008, p. 30.

<sup>45</sup> OJ L 218, 13.8.2008, p. 82.

legal requirements and thus to improve regulatory compliance by the relevant operators.

- (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 enhance legal certainty.
- (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 plan in place which should be proportionate to the risk class and the type of the medical device.
- (27) It should be ensured that supervision and control of the manufacture of medical devices is carried out within the manufacturer's organisation by a person 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. The tasks of an authorised representative should be defined in a written mandate with the manufacturer which for example may allow the authorised representative to lodge an application for a conformity assessment procedure, to report events under the vigilance system or to register devices placed on the Union market. The mandate should empower the authorised representative to duly fulfil certain defined tasks. 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 qualified person but, with a view to the authorised representative's tasks, could also be satisfied by a person with qualification in 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 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>46</sup> in other relevant sectors and existing good practices in the field of medical devices.
- (31) The findings of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), established by Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field

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<sup>46</sup> Judgment of the Court of 28 July 2011 in joined cases C-400/09 and C-207/10.

of consumer safety, public health and the environment and repealing Decision 2004/210/EC<sup>47</sup>, in its scientific opinion of 15 April 2010 on the safety of reprocessed medical devices marketed for single-use, and of the Commission in its report of 27 August 2010 to the European Parliament and the Council on the issue of reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC<sup>48</sup>, call for regulation of the reprocessing of single-use devices in order to ensure a high level of protection of health and safety whilst allowing this practice to further develop under clear conditions. By reprocessing a single-use device its intended purpose is modified and the reprocessor should therefore be considered the manufacturer of the reprocessed device.

- (32) Patients who are implanted with a device should be given essential information related to the implanted device allowing it to be identified and containing any necessary 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.
- (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.
- (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 purchase-policy and stock-management by hospitals.
- (35) Transparency and better information are essential 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.
- (36) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding medical devices on the market and the relevant economic operators, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, 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

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<sup>47</sup> OJ L 241, 10.9.2008, p. 21.

<sup>48</sup> COM(2010)443 final.

Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices<sup>49</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, in this case, to report serious adverse events. 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 national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.
- (38) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC 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>50</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 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>51</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 high-risk medical 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.
- (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.
- (41) The position of notified bodies vis-à-vis manufacturers should be strengthened, including their right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on medical devices to ensure continuous compliance by manufacturers after receipt of the original certification.
- (42) For high risk medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding novel devices, devices for which a novel

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<sup>49</sup> OJ L 102, 23.4.2010, p. 45.

<sup>50</sup> OJ L 281, 23.11.1995, p. 31.

<sup>51</sup> OJ L 8, 12.1.2001, p. 1.

technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk medical device before submitting the application to the notified body.

- (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.
- (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, with medical devices in class III requiring explicit prior approval of their design and manufacture before they can be placed on the market.
- (45) The conformity assessment procedures should be simplified 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.
- (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 and the most recent (2008) version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects to ensure that clinical investigations conducted in the Union are accepted elsewhere and that clinical investigations conducted outside the Union in accordance with international guidelines can be accepted under this Regulation.
- (48) An electronic system should be set up at Union level to ensure that every clinical investigation is registered 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) Sponsors of clinical investigations to be conducted in more than one Member State should be given the possibility 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 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. Each Member State should retain the ultimate responsibility for deciding whether the clinical investigation may be conducted on its territory.
- (50) Sponsors should report certain adverse events occurring during clinical investigations to the Member States concerned, which 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 only cover clinical investigations which pursue regulatory purposes laid down in this Regulation.
- (52) In order to better protect health and safety regarding devices on the market, the vigilance system 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) Healthcare professionals and patients should be empowered 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 assessment 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.
- (55) The reporting of serious adverse events 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.

- (57) The Member States shall levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies.
- (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.
- (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>52</sup>, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.
- (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. This should also lead to more efficient use of scarce resources 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 implemented at Union level based on sound scientific evidence.
- (62) The Union 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) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the products subject to this Regulation that are similar to medical devices but do not necessarily have a medical purpose; adaptation of the definition of nanomaterial to technical progress and to developments at Union and international level; adaptation to technical progress of the general safety and performance requirements, of the elements to be addressed in the technical documentation, of the minimum content of the EU declaration of conformity and of the certificates issued by notified bodies, of the

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<sup>52</sup> OJ L [...], [...], p. [...].



minimum requirements to be met by notified bodies, of the classification rules, of the conformity assessment procedures, and of the documentation to be submitted for the approval of clinical investigations; the establishment of the UDI system; the information to be submitted for the registration of medical devices and certain economic operators; the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical investigations; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

- (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>53</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; of the codes defining the notified bodies' scopes of designation; and of the model for certificates of free sale, given that those acts have a procedural character and do not directly impact 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 in exceptional cases; relating to the Commission's position whether a provisional national measure against a medical device presenting a risk or a provisional national preventive health protection measure is justified or not; and relating to the adoption of a Union measure against a medical device presenting a risk, imperative grounds of urgency so require.
- (68) To allow economic operators, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements to be taken for its proper application. 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 become fully effective only 18 months after the date of application of this

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<sup>53</sup> OJ L 55, 28.2.2011, p. 13.

Regulation. During this transitional period, 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 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 in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directives to avoid multiple registrations.

- (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.
- (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:

# Chapter I

## Scope and definitions

### Article 1

#### Scope

1. This Regulation establishes rules to be complied with by medical devices and accessories to medical devices that are placed on the market or put into service in the Union for human use.

For the purposes of this Regulation, medical devices and accessories to medical devices shall hereinafter be referred to as ‘devices’.

2. This Regulation shall not apply to:
  - (a) *in vitro* diagnostic medical devices covered by Regulation (EU) [.../...];
  - (b) medicinal products covered by Directive 2001/83/EC and advanced therapy medicinal products covered by Regulation (EC) No 1394/2007. In deciding whether a product falls under Directive 2001/83/EC or Regulation (EC) No 1394/2007 or under this Regulation, particular account shall be taken of the principal mode of action of the product;
  - (c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or used in accordance with the manufacturer's instructions, 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 human or animal origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable.

However, human tissues and cells that are non-viable or are rendered non-viable and that have undergone only non-substantial manipulation, in particular those listed in Annex I of Regulation (EC) No 1394/2007, and products derived from such tissues and cells, shall not be considered devices manufactured utilising tissues or cells of human origin or their derivatives;
  - (f) products that contain or consist of biological substances or organisms other than those referred to in points (c) and (e) that are viable, including living micro-organisms, bacteria, fungi or virus;
  - (g) food covered by Regulation (EC) No 178/2002.
3. Any device which, when placed on the market or used in accordance with the manufacturer's instructions, 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, unless it is covered by Article 1(3) of that Regulation. The relevant general safety and performance requirements set out in Annex I of that Regulation shall apply as far as the safety and performance of the *in vitro* diagnostic medical device part are concerned.

4. Where a device, when placed on the market or used in accordance with the manufacturer's instructions, 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 not ancillary to that of the device, the product shall be governed by Directive 2001/83/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.

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 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. 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 1(4) of Directive 2004/108/EC and within the meaning of Article 3 of Directive 2006/42/EC.
7. This Regulation shall not affect the application of Council Directive 96/29/Euratom nor of Council Directive 97/43/Euratom.
8. This Regulation shall not affect national laws which require that certain devices may only be supplied on a medical prescription.
9. References to a Member State in this Regulation shall be understood as including any other country with which the Union has concluded an agreement which confers on that country the same status as a Member State for the purpose of application of this Regulation.

## *Article 2* *Definitions*

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

Definitions related to devices:

- (2) '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, 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 process or state,
  - control or support of conception,
  - disinfection or sterilisation of any of the above-mentioned products,

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.

The implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.

- (3) '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 or assist the device(s) to be used in accordance with its/their intended purpose(s);
- (4) 'custom-made device' means any device specifically made in accordance with a written prescription of a doctor of medicine, of a dental practitioner or of any other 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.

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

- (5) 'active device' means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated 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.

Stand alone software shall be considered an active device;

- (6) ‘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;

- (7) ‘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;
- (8) ‘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;
- (9) ‘single-use device’ means a device that is intended to be used on an individual patient during a single procedure.

The single procedure may involve several uses or prolonged use on the same patient;

- (10) ‘single-use device for critical use’ means a single-use device intended to be used for surgically invasive medical procedures;
- (11) ‘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;
- (12) ‘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;
- (13) ‘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;
- (14) ‘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;

- (15) ‘non-viable’ means having no potential for metabolism or multiplication;
- (16) ‘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.

For the purposes of the definition of nanomaterial, ‘particle’, ‘agglomerate’ and ‘aggregate’ are defined as follows:

- ‘particle’ means a minute piece of matter with defined physical boundaries;
- ‘agglomerate’ 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;
- ‘aggregate’ means a particle comprising of strongly bound or fused particles;

Definitions related to the making available of devices:

- (17) ‘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;
- (18) ‘placing on the market’ means the first making available of a device, other than an investigational device, on the Union market;
- (19) ‘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:

- (20) ‘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.

For the purposes of the definition of manufacturer, fully refurbishing is defined as 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;

- (21) ‘authorised representative’ means any natural or legal person established within the Union who has received and accepted a written mandate from a

manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

- (22) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market;
- (23) '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;
- (24) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (25) 'health institution' means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;
- (26) 'user' means any healthcare professional or lay person who uses a device;
- (27) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;
- (28) '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:

- (29) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;
- (30) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;
- (31) 'notified body' means a conformity assessment body designated in accordance with this Regulation;
- (32) '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:

- (33) 'clinical evaluation' means the assessment and analysis of clinical data pertaining to a device in order to verify the safety and performance of the device when used as intended by the manufacturer;
- (34) 'clinical investigation' means any systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a device;
- (35) 'investigational device' means any device being assessed for safety and/or performance in a clinical investigation;



- (36) ‘clinical investigation plan’ means the document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation;
- (37) ‘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,
  - published and/or unpublished reports 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;
- (38) ‘sponsor’ means an individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical investigation;
- (39) ‘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;
- (40) ‘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 extending the duration of hospitalisation,
    - (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
  - foetal distress, foetal death or a congenital abnormality or birth defect;
- (41) ‘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 vigilance and market surveillance:

- (42) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;
- (43) 'withdrawal' means any measure aimed at preventing a device in the supply chain from further being made available on the market;
- (44) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and any unexpected undesirable side-effect;
- (45) '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;
- (46) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation;
- (47) '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;
- (48) 'field safety notice' means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;
- (49) 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that products 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;

Definitions related to standards and other technical specifications:

- (50) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No [.../...];
- (51) 'common technical specifications' means a document other than a standard that prescribes technical requirements that provide a means to comply with the legal obligation applicable to a device, process or system.

11. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in the last subparagraph of number (1) of paragraph 1, in the light of technical progress and taking into account the similarity between a medical device and a product without a medical purpose in respect of their characteristics and risks.

12. 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) 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*

13. The Commission may, at the request of a Member State or on its own initiative, 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).
14. 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.

**Chapter II**  
**Making available of devices, obligations of economic operators,  
reprocessing, CE marking, free movement**

*Article 4*  
*Placing on the market and putting into service*

15. 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.
16. 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.
17. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 49.
18. Devices that are manufactured and used within a single health institution shall be considered as being put into service. The provisions regarding CE marking referred to in Article 18 and the obligations laid down in Articles 23 to 27 shall not apply to those devices, provided that manufacture and use of those devices occur under the health institution's single quality management system.
19. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance

requirements set out in Annex I, including the information supplied by the manufacturer.

*Article 5*  
*Distance sales*

20. 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 at the latest when the device is placed on the market.
21. 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 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 to a natural or legal person established in the Union shall comply with this Regulation.

*Article 6*  
*Harmonised standards*

22. 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 plan, clinical investigations, clinical evaluation or post-market clinical follow-up.

23. 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.

*Article 7*  
*Common technical specifications*

24. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evaluation and post-market clinical follow-up set out in Annex XIII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).

25. Devices which are in conformity with the CTS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CTS or parts thereof.
26. Manufacturers shall comply with the CTS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.

*Article 8*  
*General obligations of the manufacturer*

27. 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.
28. Manufacturers shall draw up the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.

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

29. Where compliance of a device 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.
30. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 45, available to the competent authorities for a period of at least five 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.

Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide, upon request by a competent authority, a summary technical documentation (STED) and grant access to the full technical documentation upon request.

31. 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 CTS by reference to which conformity of a product is declared shall be adequately taken into account. Proportionate to the risk class and the type of device, manufacturers of devices, other than custom-made or investigational devices, shall institute and keep up to date a quality management system that shall address at least the following aspects:

- (a) the responsibility of the management;

- (b) resource management, including selection and control of suppliers and sub-contractors;
  - (c) product realisation;
  - (d) processes for monitoring and measurement of output, data analysis and product improvement.
32. Proportionate to the risk class and the type of device, manufacturers of devices, other than custom-made devices, shall institute and keep up to date a systematic procedure to collect and review experience gained from their devices placed on the market or put into service and to apply any necessary corrective action, hereinafter referred to as ‘post-market surveillance plan’. The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market clinical follow-up in accordance with Part B of Annex XIII. Where post-market clinical follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.
- If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.
33. 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 which can be easily understood by the intended user or patient. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user or patient.
34. Manufacturers 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 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 accordingly.
35. Manufacturers shall, in response to a reasoned 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 which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service.
36. 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.

*Article 9*  
*Authorised representative*

37. A manufacturer of a device that is placed on the Union market, or bears the CE marking without being placed on the Union market, who does not have a registered place of business in a Member State or does not carry out relevant activities at a registered place of business in a Member State, shall designate a single authorised representative.
38. The designation 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.
39. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative.

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

- (e) keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any supplement issued in accordance with Article 45 at the disposal of competent authorities for the period referred to in Article 8(4);
- (f) in response to a reasoned request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device;
- (g) cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;
- (h) 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;
- (i) terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.

To allow the authorised representative to fulfil the tasks mentioned in this paragraph, the manufacturer shall at least ensure that the authorised representative has permanent immediate access to the necessary documentation in one of the official Union languages.

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

42. 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, the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects:

- (j) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;
- (k) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;
- (l) the transfer of documents, including confidentiality aspects and property rights;
- (m) 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*

43. Importers shall place on the Union market only devices that are in conformity with this Regulation.
44. Before placing a device on the market importers shall ensure the following:
- (n) that the appropriate conformity assessment procedure has been carried out by the manufacturer;
  - (o) that an authorised representative in accordance with Article 9 has been designated by the manufacturer;
  - (p) that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer;
  - (q) that the device bears the required CE marking of conformity;
  - (r) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use and EU declaration of conformity;



- (s) 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. Where the device presents a risk, the importer shall inform the manufacturer and his authorised representative to that effect, as well as the competent authority of the Member State in which he is established.

45. 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.
46. Importers shall ensure that the device is registered in the electronic system in accordance with Article 25(2).
47. 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.
48. When deemed appropriate with regard to the risks presented by a device, importers shall, in order to protect the health and safety of patients and users, carry out sample testing of marketed products, investigate complaints and keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and shall keep the manufacturer, authorised representative and distributors informed of such monitoring.
49. 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 and, if appropriate, take the necessary corrective action to bring that device into conformity, withdraw or recall it. Where the device presents a 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.
50. 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.
51. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 45, can be made available to those authorities, upon request. By written mandate, the importer and the authorised representative for the device in question may agree that this obligation is delegated to the authorised representative.

52. Importers shall, in response to a request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. This obligation shall be considered fulfilled when the authorised representative for the device in question provides the required information. Importers shall cooperate with a competent national authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

*Article 12*  
*General obligations of distributors*

1. 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 product bears the required CE marking of conformity;
  - (b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);
  - (c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 24 and Article 11(3) respectively.

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. Where the device presents a risk, the distributor shall inform the manufacturer and, where applicable, his authorised representative and the importer to that effect, as well as the competent authority of the Member State in which he is established.

3. Distributors 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.
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 and make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they 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.

6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation 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 national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market.

### *Article 13*

#### *Person responsible for regulatory compliance*

1. Manufacturers shall have available within their organisation at least one qualified person who possesses expert knowledge in the field of medical devices. The expert knowledge 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 an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;
  - (b) five 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 expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.

This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by Commission Recommendation 2003/361/EC<sup>54</sup>.

2. The qualified person shall at least be responsible for ensuring the following matters:
  - (a) that the conformity of the devices is appropriately assessed before a batch is released;
  - (b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
  - (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.
3. The qualified person shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

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<sup>54</sup> OJ L 124, 20.5.2003, p. 36

4. Authorised representatives shall have available within their organisation at least one qualified person who possesses expert knowledge regarding the regulatory requirements for medical devices in the Union. The expert knowledge 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 an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;
  - (b) five 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;
  - (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(1), 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 that is not possible, 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. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. 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*

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.
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 90/385/EEC or Directive 93/42/EEC may be reprocessed.
3. In the case of reprocessing of single-use devices for critical use, only reprocessing that is considered safe according to the latest scientific evidence may be carried out.
4. The Commission, by means of implementing acts, shall establish and regularly update a list of categories or groups of single-use devices for critical use which may be reprocessed in accordance with paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
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 may maintain or introduce national provisions prohibiting, within its territory, on grounds of protection of public health specific to that Member State 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 of reprocessed single-use devices.

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

#### *Article 16* *Implant card*

1. The manufacturer of an implantable device shall provide together with the device an implant card which shall be made available to the particular patient who has been implanted with the device.
2. This card shall contain the following:
  - (a) the information allowing identification of the device, including the Unique Device Identification;
  - (b) 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 or environmental conditions;
  - (c) any information about the expected lifetime of the device and any necessary follow-up.

The information shall be written in a way that is readily understood by a lay person.

#### *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 the 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 a doctor of medicine, a dental practitioner or an authorised person 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) 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 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:
  - other devices bearing the CE marking;
  - *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) [.../...];
  - other products which are in conformity with the legislation applicable to those products.
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, 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.
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 paragraph 1 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 significantly changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating 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 of the device shall be considered a device.

#### *Article 22*

##### *Free movement*

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*

For devices, other than custom-made or investigational devices, economic operators shall be able to identify the following, for the period referred to in Article 8(4):

- (a) any economic operator to whom they have supplied a device;
- (b) any economic operator who has supplied them with a device;
- (c) any health institution or healthcare professional to whom they have supplied a device.

Upon request, they shall inform the competent authorities thereof.

#### *Article 24*

##### *Unique Device Identification system*

1. For devices, other than custom-made and investigational devices, a system for Unique Device Identification shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices and shall consist of the following:
  - (a) production of a UDI that comprises the following:
    - (i) a device identifier specific to a manufacturer and a device model, providing access to the information laid down in Part B of Annex V;
    - (ii) a production identifier that identifies data related to the unit of device production;
  - (b) placement of the UDI on the label of the device;
  - (c) storage of the UDI by the economic operators and the health institutions through electronic means;
  - (d) establishment of an electronic system on UDI.
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 for the period to be determined in the designation which shall at least be three 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 and concerning manufacturers that place an UDI on the label of their device in accordance with the entity's system;
    - (iii) to remain in compliance with the criteria for designation and the terms of designation during the period for which it is designated.
3. Before placing a device on the market, the manufacturer shall assign to the device a UDI provided by an entity designated by the Commission in accordance with paragraph 2, if that device belongs to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.
4. The UDI shall be placed on the label of the device, in accordance with the conditions laid down by a measure referred to in point (c) of paragraph 7. It shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 61 and shall be included in the implant card referred to in Article 16. The device identifier shall appear on the EU declaration of conformity referred to in Article 17 and in the technical documentation referred to in Annex II.
5. Economic operators and health institutions shall store and keep, by electronic means, the device identifier and the production identifier of the devices which they have supplied or they have been supplied with, if they belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.
6. The Commission, in cooperation with the Member States, shall set up and manage an electronic system on UDI to collate and process the information mentioned in Part B of Annex V. This information shall be accessible to the public.
7. The Commission shall be empowered to adopt delegated acts in accordance with Article 89:
- (a) determining the devices, categories or groups of devices whose identification shall be based on the UDI system as set out in paragraphs 1 to 6, and the timelines for implementing this. Following a risk-based approach, implementation of the UDI system shall be gradual, starting with devices falling in the highest risk class;

- (b) specifying the data to be included in the production identifier which, following a risk based approach, may vary depending on the risk class of the device;
  - (c) defining the obligations of economic operators, of health institutions and of professional users, in particular regarding allocation of the numeric or alphanumeric characters, placement of the UDI on the label, storage of information in the electronic system on UDI and use of the UDI in documentation and reporting related to the device provided for in this Regulation;
  - (d) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress.
8. When adopting the measures referred to in paragraph 7, the Commission shall take into account the following:
- (a) the protection of personal data;
  - (b) the legitimate interest in protecting commercially sensitive information;
  - (c) the risk-based approach;
  - (d) the cost-effectiveness of the measures;
  - (e) the convergence of UDI systems developed at international level.

#### *Article 25*

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

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary and proportionate to describe and identify the device and 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.
2. Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer or his authorised representative shall submit to the electronic system the information referred to in paragraph 1.
3. Within one week after placing a device, other than a custom-made or investigational device, on the market, importers shall submit to the electronic system the information referred to in paragraph 1.
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 two years after submission of the information in accordance with paragraphs 2 and 3, and then every second year, the relevant economic operator shall confirm the accuracy of the data. In the event of failure to confirm within six months

of the due date, any Member State may take measures to suspend or otherwise restrict the making available of the device in question 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.
7. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending the list of information to be submitted as set out in Part A of Annex V in the light of technical progress.

#### *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. 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.
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*

1. The Commission 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 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 be conducted in more than one Member State to comply with information 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 as integral parts:
  - (a) the electronic system on UDI referred to in Article 24;

- (b) the electronic system on registration of devices and economic operators referred to in Article 25;
  - (c) the electronic system on information on certificates referred to in Article 45(4);
  - (d) the electronic system on clinical investigations referred to in Article 53,
  - (e) the electronic system on vigilance referred to in Article 62;
  - (f) the electronic system on market surveillance referred to in Article 68.
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.
  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.
  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, 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).
  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.

## Chapter IV

### Notified bodies

#### *Article 28*

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

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 third-party conformity assessment tasks under this Regulation shall designate an authority 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 or 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. It shall be organised so that each decision relating to notification of a conformity assessment body is taken by personnel different from those who carried out the assessment of the conformity assessment body.
4. It shall not perform any activities that conformity assessment bodies perform nor provide consultancy services on a commercial or competitive basis.
5. The national authority responsible for notified bodies shall safeguard the confidentiality of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.
6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Without prejudice to Article 33(3), where a national authority is responsible for the designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall be consulted on all aspects specifically related to medical devices.

7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto.
8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.

The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission may participate in the review. The outcome of the peer-review shall be communicated to all Member States and to the Commission and a summary of the outcome shall be made publicly available.

#### *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 to fulfil their tasks for which they are designated in accordance with this Regulation. Minimum requirements to be met by notified bodies are set out in Annex VI.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum requirements in Annex VI, in the light of technical progress and considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices.

#### *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 relevant 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.
3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the agreement of the legal or natural person that applied for conformity assessment.
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 notification*

1. A conformity assessment body shall submit an application for notification 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, the conformity assessment procedures and the devices for which the body claims to be competent,



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, the relevant documentation may be submitted in form of a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008. The conformity assessment body shall be presumed to be in conformity with the requirements covered by the certificate delivered by such accreditation body.

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 check that the application referred to in Article 31 is complete and draw up a preliminary assessment report.
2. It 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'). Upon request by the Commission, the report shall be submitted by the authority in up to three official Union languages.
3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least two experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies. The list shall be drawn up by the Commission in cooperation with the MDCG. At least one of these experts shall be a representative of the Commission who shall lead the joint assessment team.
4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 31 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. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 31(2), unless the Commission representative mentioned in Article 32(3) requests the on-site assessment.

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 with respect to the assessment of the application. Divergent opinions shall be identified in the assessment report of the national authority responsible.

5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.
6. The joint assessment team shall provide its opinion regarding the assessment report and the draft notification within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification which the relevant national authority 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 for the application for notification 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 33*  
*Notification procedure*

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.
2. Member States may notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.
3. Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall provide, prior to the notification, a positive opinion on the notification and its scope.
4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures and the type of devices which the notified body is authorised to assess.

The Commission may, by means of implementing acts, set up a list of codes and the corresponding types of devices to define 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 advisory procedure referred to in Article 88(2).

5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the 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 provide the Commission and the other Member States with 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. It shall furthermore submit evidence of the availability of competent personnel for monitoring the notified body in accordance with Article 28(6).
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 effect of the notification shall be suspended. In this case, the Commission shall bring the matter before the MDCG within 15 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 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.
9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully or partially, the Commission shall publish the notification accordingly.
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.

#### *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 is accepted in accordance with Article 33. It shall assign a single identification number even when the body is notified under several Union acts.
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 activities for which they have been notified, accessible to the public. The Commission shall ensure that the list is kept up to date.

#### *Article 35*

##### *Monitoring of notified bodies*

1. The national authority responsible for notified bodies shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.

Notified bodies shall, without delay, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities,

subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.

2. Notified bodies shall respond without delay to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission unless there is a legitimate reason for not doing so in which case both sides may consult the MDCG. The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated confidential.
3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the requirements set out in Annex VI. This assessment shall include an on-site visit to each notified body.
4. Three years after notification of a notified body, and again every third year thereafter, the 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 32(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI.
5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.

*Article 36*  
*Changes to notifications*

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification. The procedures described in Article 32(2) to (6) 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).
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, the authority shall suspend, restrict, or fully or partially withdraw the notification, 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 notification.

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 notification.

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available for the national authorities responsible for notified bodies and for market surveillance at their request.
4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the change to the notification have an impact on the certificates issued by the notified body and, within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States. Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.
5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:
  - (a) in the case of suspension of a notification: on condition that, within three months of the suspension, either the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or another notified body confirm in writing that it is assuming the functions of the notified body during the period of suspension;
  - (b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

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

#### *Article 37*

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

1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. It may also commence such investigations on its own initiative.

2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.
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 notification 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.

#### *Article 38*

##### *Exchange of experience between national authorities responsible for notified bodies*

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.

#### *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.

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

#### *Article 40*

##### *Fees*

1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 31(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

# 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 their intended purpose 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.

At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision.

3. The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, decide on the 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.

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

4. In the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 as regards the following:
  - (a) deciding that a device, or category or group of devices, should, by way of derogation from the classification criteria set out in Annex VII, be classified in another class;
  - (b) amending or supplementing the classification criteria set out in Annex VII.

## 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.
2. Manufacturers of devices classified as class III, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance and design dossier examination 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.

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.

In the case of devices that are covered by this Regulation in accordance with point (e) of Article 1(2), the notified body shall follow the consultation procedure as specified in Section 6.2 of Chapter II 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 full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of the design documentation within the technical documentation on a representative basis. 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.
4. Manufacturers of devices classified as class IIa, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of the design documentation within the technical documentation on a representative basis. 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 or have a measuring function, the manufacturer shall apply the procedures set out in Annex VIII, except for its Chapter II, or in Part A of Annex X. However, involvement of the notified body shall be limited:



- (a) in the case of devices placed on the market in sterile condition, to the aspects of manufacture concerned with securing and maintaining sterile conditions,
  - (b) in the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements.
6. Manufacturers may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question.
7. Manufacturers of custom-made devices shall follow the procedure set out in Annex XI and draw up the statement set out in that Annex before placing the device on the market.
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. 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 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 design documentation within 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 factory inspections 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, design dossier examination 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).

11. In the light of technical progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 28 to 40, or of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the conformity assessment procedures set out in Annexes VIII to XI.

*Article 43*  
*Involvement of notified bodies*

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 more than one notified body for the same conformity assessment activity.
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.
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 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 44*  
*Mechanism for scrutiny of certain conformity assessments*

1. Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class III, with the exception of applications to supplement or renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 19.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 26. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.
2. Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4). In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.

Within 5 days after receipt of the request by the MDCG, the notified body shall inform the manufacturer thereof.

3. The MDCG may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period

and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.
5. Where deemed necessary for the protection of patient safety and public health, the Commission, may determine, by means of implementing acts, specific categories or groups of devices, other than devices of class III, to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Measures pursuant to this paragraph may be justified only by one or more of the following criteria:

- (a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;
  - (b) an 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 case of failure;
  - (c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;
  - (d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;
  - (e) public health concerns regarding a specific category or group of devices or the technology on which they are based.
6. The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.
  7. The Commission shall set up the technical infrastructure for the data-exchange by an electronic means between notified bodies and MDCG for the purposes of this Article.
  8. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those

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

*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.
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 Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on certificates issued by notified bodies. The notified body shall enter into this electronic system 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 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 outgoing notified body and the incoming 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;
  - (d) the date as of which the incoming notified body assumes full responsibility for the conformity assessment tasks.
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.
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. Upon request by a Member State and where this is in the interest of public health or patient safety in more than one Member State, the Commission 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, the Member State in which the manufacturer has its registered place of business shall issue a certificate of free sale declaring that the manufacturer is properly established and that the device in question bearing the CE-marking in accordance with this Regulation may be legally marketed in the Union. The certificate of free sale shall be valid for the period indicated on it which shall not exceed five years and shall not exceed the validity of the certificate referred to in Article 45 issued for the device in question.

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. Manufacturers shall conduct a clinical evaluation in accordance with the principles set out in this Article and Part A of Annex XIII.
2. A clinical evaluation shall follow a defined and methodologically sound procedure based on either of 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 and the device to which the data relate are equivalent,
    - the data adequately demonstrate compliance with the relevant general safety and performance requirements;
  - (b) a critical evaluation of the results of all clinical investigations performed in accordance with Articles 50 to 60 and Annex XIV;
  - (c) a critical evaluation of the combined clinical data referred to in points (a) and (b).
3. 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 data obtained from the implementation of the manufacturer's post-market surveillance plan referred to in Article 8(6).
5. The clinical evaluation and its outcome shall be documented in a clinical evaluation report referred to in Section 6 of Part A of Annex XIII which shall be included or

fully referenced in the technical documentation referred to in Annex II relating to the device concerned.

#### *Article 50*

##### *General requirements regarding clinical investigations*

1. Clinical investigations shall be subject to Articles 50-60 and Annex XIV if they are conducted for one or more of the following purposes:
  - (a) to verify that, under normal conditions of use, devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of a medical device referred to in number (1) of Article 2(1), and achieve the performances intended as specified by the manufacturer;
  - (b) to verify that devices achieve the intended benefits to the patient as specified by the manufacturer;
  - (c) to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.
2. Where the sponsor is not established in the Union, he shall ensure that a contact person is established in the Union. That contact person shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that contact person shall be considered as communication to the sponsor.
3. Clinical investigations shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in a clinical investigation are protected and that the clinical data generated in the clinical investigation are going to be reliable and robust.
4. Clinical investigations shall be designed, conducted, recorded and reported in accordance with the provisions of Articles 50 to 60 and of Annex XIV.

#### *Article 51*

##### *Application for clinical investigations*

1. Before making the first application, the sponsor shall procure from the electronic system referred to in Article 53 a single identification number for a clinical investigation conducted in one site or multiple sites, in one or more than one Member State. The sponsor shall use this single identification number when registering the clinical investigation in accordance with Article 52.
2. The sponsor of a clinical investigation shall submit 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. Within six 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.

Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical investigation shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

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 six days for the sponsor to comment or to complete the application.

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 considered as withdrawn.

Where the Member State has not notified the sponsor according to paragraph 2 within three days following receipt of the comments or of the completed application, the clinical investigation shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

4. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 2 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the time periods referred to in paragraphs 2 and 3.
5. The sponsor may start the clinical investigation in the following circumstances:
  - (a) in the case of investigational devices classified as class III and implantable or long-term invasive devices classified as class IIa or IIb, as soon as the Member State concerned has notified the sponsor of its approval;
  - (b) in the case of investigational devices other than those referred to in point (a) immediately after the date of application provided that the Member State concerned has so decided and that evidence is provided that the rights, safety and well-being of the subjects to the clinical investigation are protected;
  - (c) after the expiry of 35 days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.
6. Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the investigation site(s) and the investigators involved, as well as free of any other undue influence.

Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken into account.



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.

#### *Article 52*

#### *Registration of clinical investigations*

1. Before commencing the clinical investigation, the sponsor shall enter in the electronic system referred to in Article 53 the following information regarding the clinical investigation:
  - (a) the single identification number of the clinical investigation;
  - (b) the name and contact details of the sponsor and, if applicable, his contact person established in the Union;
  - (c) the name and contact details of the natural or legal person responsible for the manufacture of the investigational device, if different from the sponsor;
  - (d) the description of the investigational device;
  - (e) the description of the comparator(s), if applicable;
  - (f) the purpose of the clinical investigation;
  - (g) the status of the clinical investigation.
2. Within one week of any change occurring in relation to the information referred to in paragraph 1, the sponsor shall update the relevant data in the electronic system referred to in Article 53.
3. The information shall be accessible to the public, through the electronic system referred to in Article 53, 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 sensitive information;
  - (c) effective supervision of the conduct of the clinical investigation by the Member State(s) concerned.
4. No personal data of subjects participating in clinical investigations shall be publicly available.

*Article 53*  
*Electronic system on clinical investigations*

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to create the single identification numbers for clinical investigations referred to in Article 51(1) and to collate and process the following information:
  - (a) the registration of clinical investigations in accordance with Article 52;
  - (b) the exchange of information between the Member States and between them and the Commission in accordance with Article 56;
  - (c) the information related to clinical investigations conducted in more than one Member State in case of a single application in accordance with Article 58;
  - (d) reports on serious adverse events and device deficiencies referred to in Article 59(2) in case of a single application in accordance with Article 58.
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 [...] of Regulation (EU) No [.../...]. With the exception of the information referred to in Article 52, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 determining which other information regarding clinical investigations collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [.../...]. Article 52(3) and (4) shall apply.

*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. Article 50(1) to (3), Article 52, Article 55, Article 56(1), Article 57(1), the first subparagraph of Article 57(2) 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 introduces modifications to a clinical investigation that are likely to have a substantial impact on the safety or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, he shall notify 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.
2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 30 days after notification, unless the Member State concerned has notified the sponsor of its refusal based on considerations of public health, patient safety or public policy.

*Article 56*  
*Information exchange between Member States*

1. Where a Member State has refused, suspended or terminated a clinical investigation, or has called for a substantial modification or temporary halt of 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 its 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 Member State shall inform all the other Member States and the Commission of that fact, by means of the electronic system referred to in Article 53.

*Article 57*  
*Information by the sponsor in the event of temporary halt or termination of a clinical investigation*

1. If the sponsor has temporarily halted a clinical investigation on safety grounds, he shall inform the Member States concerned within 15 days of the temporary halt.
2. The sponsor shall notify each Member State concerned of the end of a clinical investigation in relation to that Member State, providing a justification in the event of early termination. That notification shall be made within 15 days from the end of the clinical investigation in relation to that Member State.

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. Within one year from the end of the clinical investigation, the sponsor shall submit to the Member States concerned a summary of the results of the clinical investigation in form of a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV. Where, for scientific reasons, it is not possible to submit the clinical

investigation report within one year, 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 an explanation.

#### *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. If that Member State does not wish to be the coordinating Member State, it shall agree, within six days of submission of the single application, with another Member State concerned that the latter shall be the coordinating Member State. If no other Member State accepts to be the coordinating Member State, the Member State proposed by the sponsor shall be the coordinating Member State. If another Member State than the one proposed by the sponsor becomes coordinating Member State, the deadline referred to in Article 51(2) shall start on the day following the acceptance.
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 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 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 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, except for the documentation submitted in accordance with Sections 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV. Article 51(2) to (4) shall apply to each Member State in relation to the verification that the documentation submitted in accordance with Sections 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV is complete;
  - (b) establish the results of the coordinated assessment in a report to be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 51(5).
4. The substantial modifications 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 Article 55 shall be carried out under the direction of the coordinating Member State.

5. For the purpose of Article 57(3), the sponsor shall submit the clinical investigation report to the Member States concerned by means of the electronic system referred to in Article 53.
6. The Commission shall provide secretarial support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.

#### *Article 59*

##### *Recording and reporting of 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 in view of the purposes referred to in Article 50(1);
  - (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:
  - (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.

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.
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.

#### *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 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 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 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.

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

# Chapter VII

## Vigilance and market surveillance

### SECTION 1 – VIGILANCE

#### *Article 61*

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

1. Manufacturers of devices other than custom-made or investigational devices, shall report through the electronic system referred to in Article 62 the following:
  - (a) any serious incident in respect of devices made available on the Union market;
  - (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.

Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

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, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 62(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.
3. The Member States shall take all appropriate measures to encourage 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 such reports 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 incident. The manufacturer shall ensure the appropriate follow-up.

The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients.

4. Manufacturers of custom-made devices shall report any serious incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the device in question has been made available.

*Article 62*  
*Electronic system on vigilance*

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:
  - (a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 61(1);
  - (b) the periodic summary reports by manufacturers referred to in Article 61(2);
  - (c) the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 63(1);
  - (d) the reports by manufacturers on trends referred to in Article 64;
  - (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 (7).
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.
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 and field safety corrective actions referred to in points (a) and (b) of Article 61(1), the periodic summary reports referred to in Article 61(2), the reports on serious incidents referred to in the second subparagraph of Article 63(1) and the trend reports referred to in Article 64 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:
  - (a) the Member State where the incident occurred;
  - (b) the Member State where the field safety corrective action is being or is to be undertaken;
  - (c) the Member State where the manufacturer has his registered place of business;



- (d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.

### *Article 63*

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

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.

If in the case of reports received in accordance with Article 61(3) the competent authority ascertains that the reports relate to a serious incident it shall notify without delay those reports to the electronic system referred to in Article 62, unless the same incident has already been reported by the manufacturer.

2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They 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. They shall monitor the manufacturer's investigation of the incident.
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 inform the relevant competent authority for medicinal products, or the European Medicines Agency (EMA), that was consulted by the notified body in accordance with the second subparagraph of Article 42(2).

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 the third subparagraph of Article 42(2).

4. After carrying out the assessment, the evaluating competent authority shall, through the electronic system referred to in Article 62, 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 the users of the device in question are informed without delay of the corrective action taken by means of a field safety notice. 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 of this Article, the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

The manufacturer shall enter the field safety notice in the electronic system referred to in Article 62 through which that notice shall be accessible to the public.

6. The competent authorities shall designate a coordinating competent authority to coordinate their assessments referred to in paragraph 2 in the following cases:
- (a) where similar serious incidents related to the same device or type of device of the same manufacturer occur in more than one Member State;
  - (b) where the field safety corrective action is being or is to be undertaken in more than one Member State.

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

The coordinating competent authority shall inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

7. The coordinating competent authority shall carry out the following tasks:
- (a) to monitor the investigation of the serious incident by the manufacturer and the corrective action to be taken;
  - (b) to consult with the notified body that issued a certificate in accordance with Article 45 for the device in question regarding the impact of the serious incident on the certificate;
  - (c) to agree with the manufacturer and the other competent authorities referred to in points (a) to (c) of Article 62(5) on the format, content and frequency of periodic summary reports in accordance with Article 61(2);
  - (d) to agree with the manufacturer and other competent authorities concerned on the implementation of the appropriate field safety corrective action;
  - (e) to inform the other competent authorities and the Commission, through the electronic system referred to in Article 62, of the progress in and the outcome of its assessment.

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 secretarial support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

*Article 64*  
*Trend reporting*

Manufacturers of devices classified in class IIb and III shall report to the electronic system referred to in Article 62 any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons 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 established in the manufacturer's conformity assessment. Article 63 shall apply.

*Article 65*  
*Documentation of vigilance data*

Manufacturers shall update their technical documentation with information on incidents received from healthcare professionals, patients and users, serious incidents, field safety corrective actions, periodic summary reports referred to in Article 61, trend reports referred to in Article 64 and field safety notices referred to in Article 63(5). They shall make this documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued.

*Article 66*  
*Implementing acts*

The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of Articles 61 to 65 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) harmonised forms for the reporting of serious incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers as referred to in Articles 61 and 64;
- (c) timelines for the reporting of serious incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 61 and 64;

- (d) harmonised forms for the exchange of information between competent authorities as referred to in Article 63.

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

## **SECTION 2 – MARKET SURVEILLANCE**

### *Article 67*

#### *Market surveillance activities*

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, where necessary and justified, enter the premises of economic operators and take the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary.
2. The Member States shall periodically 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.
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. Where appropriate, the competent authorities of the Member States shall agree on work-sharing 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. 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 68*

#### *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:
  - (a) information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 70(2), (4) and (6);

- (b) information in relation to compliant devices presenting a risk to health and safety referred to in Article 72(2);
  - (c) information in relation to formal 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).
2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States and to the Commission.

#### *Article 69*

##### *Evaluation regarding devices presenting a risk to health and safety at national level*

Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, 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. The relevant economic operators shall cooperate as necessary with the competent authorities.

#### *Article 70*

##### *Procedure for dealing with non-compliant devices presenting a risk to health and safety*

1. Where, having performed an evaluation pursuant to Article 69, the competent authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or 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, proportionate to the nature of the risk.
2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States 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 68.
3. The economic operators shall 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 provisional 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 and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 68.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification 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 of any additional 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 68.
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 a provisional measure taken by a Member State, that measure shall be deemed justified.
8. All Member States shall ensure that appropriate restrictive measures are taken without delay in respect of the device concerned.

#### *Article 71*

#### *Procedure 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 provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall 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. Where, in the situations referred to in Articles 70 and 72, 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).

3. On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts referred to in paragraphs 1 and 2 in accordance with the procedure referred to in Article 88(4).

#### *Article 72*

##### *Procedure for dealing with compliant devices presenting a risk to health and safety*

1. Where, having performed an evaluation pursuant to Article 69, a Member State finds that although a device has been legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.
2. The Member State shall immediately notify the Commission and the other Member States of the measures taken, by means of the electronic system referred to in Article 68. That information shall include the data necessary for the identification of the device concerned, the origin and the supply chain of the device, the findings of the Member State's evaluation specifying the nature of the risk involved and the nature and duration of the national measures taken.
3. The Commission shall evaluate the provisional national measures taken. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the measure is justified. 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).
4. Where 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.

#### *Article 73*

##### *Formal non-compliance*

1. Without prejudice to Article 70, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance where it makes one of the following findings:
  - (a) that the CE marking has been affixed in violation of the formal requirements laid down in Article 18;
  - (b) that the CE marking has not been affixed to a device contrary to Article 18;

- (c) that the CE marking has been inappropriately affixed in accordance with procedures in this Regulation on a product that is not covered by this Regulation;
  - (d) that the EU declaration of conformity has not been drawn up or is not complete;
  - (e) that the information to be supplied by the manufacturer on the label or in the instructions for use is not available, not complete or not provided in the language(s) required;
  - (f) that the technical documentation, including the clinical evaluation, is not available or not complete.
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 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 68.

*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 the making available on the market or putting into service of such device or 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 order to protect the health and safety of patients, users or other persons or other aspects of public health, it may take any necessary and justified provisional 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 68.
3. The Commission shall assess the provisional national measures taken. The Commission shall decide, by means of implementing acts, whether the national measures are justified or not. 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 may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(4).

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 shall be empowered to adopt delegated acts in accordance with Article 89 to take the necessary and duly justified measures.

Where in this case imperative grounds of urgency so require, the procedure provided for in Article 90 shall apply to delegated acts adopted pursuant to this paragraph.

*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 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 serious 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 before any measure is adopted. If action has been taken without the economic operator's 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.
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 inform the relevant notified body of the measure taken.

**Chapter VIII**  
**Cooperation between Member States, Medical Device**  
**Coordination Group, EU reference laboratories, 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 competent authorities to the Commission which shall publish a list of competent authorities.

2. For the implementation of Articles 50 to 60, the Member States may designate a national contact point other than a national authority. In this case, references to a competent authority in this Regulation shall be understood as including the national contact point.

*Article 77*  
*Cooperation*

1. The competent authorities of the Member States shall cooperate with each other and with the Commission and exchange with each other the information necessary to enable this Regulation to be applied uniformly.
2. Member States and the Commission shall participate 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, on a 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, 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 functioning of sub-groups.

The rules of procedure shall enter into force after receiving a favourable opinion from the Commission.

*Article 79*  
*Support by the Commission*

The Commission shall support the functioning of the cooperation between national 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;
- (b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;
- (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 by manufacturers and the assessment by notified bodies;
- (d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical investigations, vigilance and market surveillance;

- (e) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;
- (f) to contribute to harmonised administrative practice with regard to medical devices in the Member States.

*Article 81*  
*European Union reference laboratories*

1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.
2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:
  - (a) to provide scientific and technical assistance to the Commission, the Member States and notified bodies in relation to the implementation of this Regulation;
  - (b) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;
  - (c) to set up and manage a network of national reference laboratories and publish a list of the participating national reference laboratories and their respective tasks;
  - (d) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and market surveillance;
  - (e) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;
  - (f) to contribute to the development of standards at international level;
  - (g) to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation.
3. EU reference laboratories shall satisfy the following criteria:
  - (a) to have appropriately qualified staff with adequate knowledge and experience in the field of the medical devices for which they are designated;
  - (b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;
  - (c) to have the necessary knowledge of international standards and best practices;
  - (d) to have an appropriate administrative organisation and structure;

- (e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks.
4. EU reference laboratories may be granted a Union financial contribution.
- The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.
6. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 for the following purposes:
- (a) amending or supplementing the tasks of EU reference laboratories referred to in paragraph 2 and the criteria to be satisfied by EU reference laboratories referred to in paragraph 3.
  - (b) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU Reference Laboratory for providing scientific opinions in response to consultations by notified bodies in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.
7. EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts, shall take appropriate measures, including the withdrawal of the designation.

*Article 82*  
*Conflict of interests*

1. Members of the MDCG and staff of the EU reference 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. Upon request, the declaration of interests shall be accessible to the public. 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 be requested to declare their interests 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 to gather post-market experience related to the use of such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of 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 medical 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 Directive 95/46/EC and Regulation (EC) No 45/2001;
  - (b) commercial interests of a natural or legal person, including intellectual property rights;
  - (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 remain confidential unless the originating authority has agreed to its disclosure.
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 to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

*Article 86*  
*Levy of fees*

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. They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.

*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.
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 the delegated acts referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), 42(11), 45(5), 51(7), 53(3), 74(4) and 81(6) is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), 42(11), 45(5), 51(7), 53(3), 74(4) and 81(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.
3. The delegation of power referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), 42(11), 45(5), 51(7), 53(3), 74(4) and 81(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication 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.
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 any of the Articles listed in paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two 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 may be extended by two months at the initiative of the European Parliament or the Council.

#### *Article 90*

#### *Urgency procedure for delegated acts*

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 89. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.

#### *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>55</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

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<sup>55</sup> OJ L [...], [...], p. [...].



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, unless the authority is advised by its experts for medical devices that involvement of a notified body is not required.'

*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>56</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.

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 become void at the latest two years after the date of application of this Regulation.

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<sup>56</sup> OJ L [...], [...], p. [...].

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.
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.
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 [date of application] until [18 months after date of application], comply with Article 25(2) and (3) 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) 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.

*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.

*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 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 which are repealed with effect from [18 months after date of application].

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:
  - (a) Article 25(2) and (3) and Article 45(4) shall apply from [18 months after date of application referred to in paragraph 2];
  - (b) Articles 28 to 40 and Article 78 shall apply from [six 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 notification in accordance with Article 31 of this Regulation.

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

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

## GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

### I. General requirements

1. Devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose, taking into account the generally acknowledged state of the art. They shall 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.

This shall include:

- reducing as far as possible the risk of use error due to ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
  - consideration of the technical knowledge, experience, education and training, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).
2. The solutions 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. The manufacturer shall apply the following principles in the priority order listed:
    - (a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;
    - (b) eliminate risks as far as possible through inherently safe design and manufacture;
    - (c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; and
    - (d) provide training to users and/or inform users of any residual risks.
  3. The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.

4. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.
5. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the benefits to the patient 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 requirements set out in Sections 1 and 5 shall be understood that the device, when used under the conditions and for the purposes intended, shall not present any risk or only the minimum acceptable risks 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 construction**

7. Chemical, physical and biological properties
  - 7.1. The devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Chapter I 'General Requirements'. Particular attention shall be paid to:
    - (a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;
    - (b) the compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the device;
    - (c) where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand;
    - (d) the choice of materials used, reflecting, where appropriate, matters such as hardness, wear and fatigue strength.
  - 7.2. The devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed and to the duration and frequency of exposure.
  - 7.3. The devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these medicinal products and that both the performance of the medicinal products and of the devices are maintained in accordance with their respective indications and intended use.

- 7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006<sup>57</sup>, and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)<sup>58</sup>.

If devices, or parts thereof, that are intended

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

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

- 7.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.
- 7.6. The devices shall be designed and manufactured in such a way as to reduce to a minimum the risks linked to the size and the properties of particles used. Special care shall be applied when devices contain or consist of nanomaterial that can be released into the patient's or user's body.

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<sup>57</sup> OJ L 353, 31.12.2008, p. 1.

<sup>58</sup> OJ L 136, 29.5.2007, p.3.

8. Infection and microbial contamination
  - 8.1. The devices and manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:
    - (a) allow easy handling,  
and, where necessary,
    - (b) reduce as far as possible and appropriate any microbial leakage from the device and/or microbial exposure during use,
    - (c) prevent microbial contamination of the device or specimen.
  - 8.2. Devices labelled as having a special microbiological state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.
  - 8.3. Devices delivered in a sterile state shall be designed, manufactured and packaged in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.
  - 8.4. Devices labelled either as sterile or as having a special microbiological state shall have been processed, manufactured and, if applicable, sterilised by appropriate, validated methods.
  - 8.5. Devices intended to be sterilised shall be manufactured in appropriately controlled (e.g. environmental) conditions.
  - 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.
9. Devices incorporating a substance considered to be a medicinal product and devices composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally
  - 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 combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.
10. Devices incorporating materials of biological origin
- 10.1. For devices manufactured utilising tissues or cells, or their derivatives, of human origin which are covered by this Regulation in accordance with point (e) of Article 1(2) the following applies:
- (a) Donation, procurement and testing of tissues and cells of human origin used for the manufacture of devices shall be made in accordance with Directive 2004/23/EC.
  - (b) The processing, preservation and any other handling of those tissues and cells shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.
  - (c) It shall be ensured that the traceability system for devices manufactured utilising those human tissues or cells is complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC<sup>59</sup>.
- 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.
  - (b) Processing, preservation, testing and handling of tissues, cells and substances of animal origin shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.
  - (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

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<sup>59</sup> OJ L 33, 8.2.2003, p. 30.



implantable medical devices and medical devices manufactured utilising tissues of animal origin<sup>60</sup>, the particular requirements laid down in that Regulation shall apply.

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

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

11. Interaction of devices with their environment

- 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 or mechanical coupling, shall be designed and constructed in such a way as to minimize all possible risks from incorrect connection.

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

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

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<sup>60</sup> OJ L 212, 9.8.2012, p. 3.

- (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 purpose includes exposure to or use in association with flammable substances or substances which could cause combustion.
- 11.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.
- 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 is reliable and safe.
- 11.6. Any measurement, monitoring or display scale shall be designed in line with ergonomic principles, taking account of the intended purpose of the device.
- 11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or of any waste substances by the user, patient or other person.
12. Devices with a diagnostic or measuring function
- 12.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.
- 12.2. The measurements made by devices with a measuring function and expressed in legal units shall conform to the provisions of Council Directive 80/181/EEC<sup>61</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 any emitted radiation shall be reduced as far as possible and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.
  - (b) The operating instructions for devices emitting radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the

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<sup>61</sup> OJ L 39, 15.2.1980.

patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

### 13.2. Intended radiation

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

### 13.3. Unintended radiation

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

### 13.4. Ionising radiation

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

## 14. Software incorporated in devices and standalone software

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

14.2. For devices that incorporate software or for standalone software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, 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).
15. Active devices and devices connected to them
  - 15.1. For active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.
  - 15.2. Devices where the safety of the patients depends on an internal power supply shall be equipped with a means of determining the state of the power supply.
  - 15.3. Devices where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure.
  - 15.4. Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.
  - 15.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.
  - 15.6. Devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.
  - 15.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.
16. Protection against mechanical and thermal risks
  - 16.1. Devices shall be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.
  - 16.2. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.
  - 16.3. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

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

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

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

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

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

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

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

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

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

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

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

- ensure that the device is easy to use by the intended user at all stages of the procedure, and
- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.

- 18.3. Devices for use by lay persons shall, where reasonably possible, include a procedure by which the lay person
- can verify that, at the time of use, the device will perform as intended by the manufacturer, and
  - if applicable, is warned if the device has failed to provide a valid result.

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

#### 19. Label and instructions for use

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

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

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

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

- (c) For devices of class I and IIa, instructions for use are not needed or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.
- (d) Labels shall be provided in a human-readable format but may be supplemented by machine-readable forms, 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 under the conditions set out in Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices<sup>62</sup>.

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<sup>62</sup> OJ L 72, 10.3.2012, p. 28.

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

## 19.2. Information on the label

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 at which he can be contacted and his location be established.
- (d) For imported devices, the name, registered trade name or registered trade mark of the authorised representative established within the Union and the address of his registered place of business at which he can be contacted and his location be established.
- (e) Where applicable, an indication that the device contains or incorporates
  - a medicinal substance, including a human blood or plasma derivative, or
  - tissues or cells, or their derivatives, of human origin, or
  - tissues or cells, or their derivatives, of animal origin as referred to in Commission Regulation (EU) No 722/2012.
- (f) Where applicable, an indication that the device incorporates or consists of nanomaterial unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.
- (g) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate.
- (h) Where applicable, the unique device identification (UDI).
- (i) An unambiguous indication of the date until when the device may be used safely, expressed at least as the year and month, where this is relevant.

- (j) Where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable.
- (k) An indication of any special storage and/or handling condition that applies.
- (l) If the device is supplied sterile, an indication of its sterile state and the sterilisation method.
- (m) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device as relevant, and to any other person where appropriate. This information may be kept to a minimum in which case more detailed information should appear in the instructions for use.
- (n) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union.
- (o) If the device is a single use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles.
- (p) If the device is custom made, an indication of that fact.
- (q) If the device is intended for clinical investigation only, an indication of that fact.

### 19.3. Information in the instructions for use

The instructions for use shall contain the following particulars:

- (a) The particulars referred to in points 19.2. a), c), e), f), k), l) and n).
- (b) The device's intended purpose including the intended user (e.g. professional or lay person), as appropriate.
- (c) The performance of the device intended by the manufacturer.
- (d) Any residual risks, contraindications and any expected and foreseeable undesirable side-effects, including information to be conveyed to the patient in this regard.
- (e) Specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it.
- (f) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilisation, final assembly, calibration, etc.).
- (g) Any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons.
- (h) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:



- details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection;
  - identification of any consumable components and how to replace them;
  - information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;
  - methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing devices.
- (i) If the device is supplied sterile, instructions in the event of the sterile packaging being damaged before use.
- (j) If the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation.
- (k) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilisation. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.
- (l) If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with point c) of Section 19.1 no instructions for use are needed, the information shall be made available to the user upon request.
- (m) For devices intended for use together with other devices and/or general purpose equipment:
- information to identify such devices or equipment, in order to obtain a safe combination, and/or
  - information on any known restrictions to combinations of devices and equipment.
- (n) If the device emits hazardous, or potentially hazardous levels of radiation for medical purposes:
- detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation;
  - the means of protecting the patient, user, or other person from unintended radiation during use of the device.
- (o) Information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information should cover, where appropriate:

- warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;
  - warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
  - warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures (e.g. electromagnetic interference emitted by the device affecting other equipment);
  - if the device is intended to administer medicinal products, tissues or cells, or their derivatives, of human or animal origin or biological substances, any limitations or incompatibility in the choice of substances to be delivered;
  - warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device;
  - precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user.
- (p) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:
- infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);
  - physical hazards (e.g. from sharps).
- (q) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.
- (r) For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, information regarding the absence of a clinical benefit and the risks related to the use of the device.
- (s) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use.

- (t) A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established.

**TECHNICAL DOCUMENTATION**

The technical documentation and, if applicable, the summary technical documentation (STED) to be drawn up by the manufacturer shall include in particular the following elements:

**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,
- (b) the UDI device identifier as referred to in item (i) of point (a) of Article 24(1) attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;
- (c) the intended patient population and medical condition to be diagnosed and/or treated and other considerations such as patient selection criteria;
- (d) principles of operation of the device;
- (e) risk class and the applicable classification rule according to Annex VII;
- (f) an explanation of any novel features;
- (g) a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it;
- (h) a description or complete list of the various configurations/variants of the device that will be made available;
- (i) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality. 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 and accessories that would typically

appear in the product specification made available to the user, e.g. in brochures, catalogues and the like.

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

- (a) an overview of the manufacturer's previous generation(s) of the device, if such exist;
- (b) an overview of the manufacturer's 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;
  - the instructions for use;
- (b) a list of the language variants for the Member States where the device is envisaged to be marketed.

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

- (a) Information to allow a general understanding of the design stages applied to the device and the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information needs to be provided for the audit of the quality management system or other applicable conformity assessment procedures;
- (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 information regarding the solutions adopted to meet the general safety and performance requirements laid down in Annex I. This information may take the form of a checklist identifying

- (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 CTS applied or other method(s) employed;
- (d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CTS or other method employed to demonstrate conformity with the general safety and performance requirements.

This information shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

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

The documentation shall contain a summary of

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

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

The documentation shall contain the results of verification and validation testing 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 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
  - biocompatibility (identifying all materials in direct or indirect contact with the patient or user);
  - physical, chemical and microbiological characterisation;
  - electrical safety and electromagnetic compatibility;
  - software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);
  - stability/shelf life.

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>63</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 report on the clinical evaluation 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 deemed necessary or appropriate.

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

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

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<sup>63</sup> OJ L 50, 20.2.2004, p. 44.

the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.



## ANNEX III

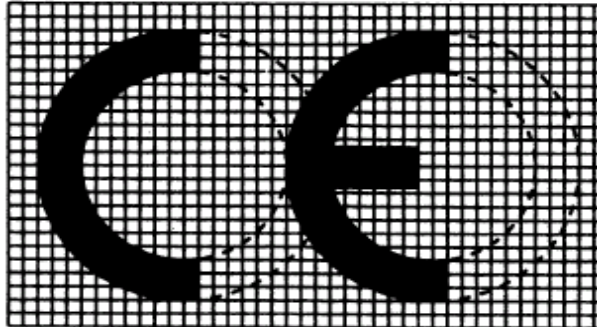
### EU DECLARATION OF CONFORMITY

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

## ANNEX IV

### 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 25**

**AND**

**DATA ELEMENTS OF THE UDI DEVICE IDENTIFIER IN  
ACCORDANCE  
WITH ARTICLE 24**

**PART A**

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

Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the following information:

1. economic operator's role (manufacturer, authorised representative, or importer),
2. name, address and contact details of the economic operator,
3. where submission of information is completed by another person on behalf of any of the economic operators mentioned under point 1, the name, address and contact details of this person,
4. UDI device identifier, or where identification of the device is not yet based on a UDI system, the data elements laid down in points 5 to 21 of Part B of this Annex,
5. type, number and expiry date of certificate and name or identification number of the notified body that has issued the certificate (and link to the information on the certificate entered by the notified body in the electronic system on certificates),
6. Member State where the device shall or has been placed on the market in the Union,
7. in case of devices classified as classes IIa, IIb or III: Member States where the device is or shall be made available,
8. in case of imported device: country of origin,
9. risk class of the device,
10. reprocessed single use device (y/n),
11. presence of a substance which, if used separately, may be considered to be a medicinal product and name of this substance,

12. presence of a substance which, if used separately, may be considered a medicinal product derived from human blood or human plasma and name of this substance,
13. presence of human tissues or cells, or their derivatives (y/n),
14. presence of animal tissues or cells, or their derivatives, as referred to in Commission Regulation (EU) No 722/2012 (y/n),
15. where applicable, single identification number of the clinical investigation(s) conducted in relation to the device (or link to the clinical investigation registration in the electronic system regarding clinical investigations),
16. in case of devices listed in Annex XV, specification whether the intended purpose of the device is other than a medical purpose,
17. in case of devices designed and manufactured by another legal or natural person as referred in Article 8(10), the name, address and contact details of that legal or natural person,
18. in case of devices classified as class III or implantable devices, the summary of safety and clinical performance,
19. status of the device (on the market, no longer manufactured, withdrawn from the market, recalled).

## **PART B**

### **DATA ELEMENTS OF THE UDI DEVICE IDENTIFIER IN ACCORDANCE WITH ARTICLE 24**

The UDI device identifier shall provide access to the following information related to the manufacturer and the device model:

1. quantity per package configuration,
2. if applicable, alternative or additional identifier(s),
3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number),
4. if applicable, the unit of use device identifier (when a UDI is not assigned to the device at the level of its unit of use, a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient),
5. name and address of the manufacturer (as indicated on the label),
6. if applicable, name and address of the authorised representative (as indicated on the label),
7. Global Medical Device Nomenclature (GMDN) code or internationally recognised nomenclature code,
8. if applicable, trade/brand name,

9. if applicable, device model, reference, or catalogue number,
10. if applicable, clinical size (including volume, length, gauge, diameter),
11. additional product description (optional),
12. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),
13. if applicable, additional trade names of the device,
14. labelled as single use device (y/n),
15. if applicable, restricted number of reuses,
16. device packaged sterile (y/n),
17. need for sterilisation before use (y/n),
18. labelled as containing latex (y/n),
19. labelled as containing DEHP (y/n),
20. URL for additional information, e.g. electronic instructions for use (optional),
21. if applicable, critical warnings or contraindications.

## MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES

### 1. ORGANISATIONAL AND GENERAL REQUIREMENTS

#### 1.1. Legal status and organisational structure

- 1.1.1. *A notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect, and shall have full documentation of its legal personality and status. This shall include information about ownership and the legal or natural persons exercising control over the notified body.*
- 1.1.2. *If the notified body is a legal entity that is part of a larger organisation, the activities of this organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented.*
- 1.1.3. *If the notified body wholly or partly owns legal entities established in a Member State or in a third country, 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.*
- 1.1.4. *The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.*

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented.

#### 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 competitor of the manufacturer.*
- 1.2.2. *The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall have procedures in place that effectively ensure 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.*
- 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, user or maintainer of the products, nor the authorised representative of any of those

parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;

- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;
- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

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

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

*1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, 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.*

*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**

The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

## 1.4. Liability

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

## 1.5. Financial requirements

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into 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.*

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

## 2. QUALITY MANAGEMENT REQUIREMENTS

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

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

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;



- corrective and preventive actions;
- complaints and appeals.

### **3. RESOURCE REQUIREMENTS**

#### **3.1. General**

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

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

This presupposes the availability within its organisation of sufficient scientific personnel who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

- 3.1.2. *At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.*
- 3.1.3. *The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel involved in conformity assessment activities and inform the personnel concerned about it.*

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

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

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, clinical evaluation and the different types of sterilisation processes.

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

- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.

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

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

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

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;
- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;
- appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

- appropriate knowledge and experience of risk management and related medical device standards and guidance documents;
- appropriate knowledge 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.

3.2.6. *The personnel responsible for carrying out audits of the manufacturer's quality management system shall have the following proven qualification:*

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

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

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

3.3.2. *For its personnel referred to in Sections 3.2.3 to 3.2.6, the notified body shall establish and maintain up to date:*

- a matrix detailing the 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.

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

- 3.4.1. *Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities. The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.*
- 3.4.2. *Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented and be subject to a written agreement covering, among others, confidentiality and conflict of interests.*
- 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 conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.*
- 3.4.4. *The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used.*

### **3.5. Monitoring of competences and training**

- 3.5.1. *The notified body shall appropriately monitor the satisfactory performance of the conformity assessment activities by its personnel.*
- 3.5.2. *It shall review the competence of its personnel and identify training needs in order to maintain the required level of qualification and knowledge.*

## **4. PROCESS REQUIREMENTS**

- 4.1. **The notified body's decision-making process shall be clearly documented, including the process for the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.**
- 4.2. **The notified body shall have in place a documented process for the conduct of the conformity assessment procedures for which it is designated taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.**
- 4.3. **The notified body shall have in place documented procedures covering at least:**
- the application for conformity assessment by a manufacturer or by an authorised representative,

- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as device and its classification,
- the language of the application, of the correspondence and of the documentation to be submitted,
- the terms of the agreement with the manufacturer or authorised representative,
- the fees to be charged for conformity assessment activities,
- the assessment of relevant changes to be submitted for prior approval,
- the planning of surveillance,
- the renewal of certificates.

## CLASSIFICATION CRITERIA

### I. SPECIFIC DEFINITIONS FOR THE CLASSIFICATION RULES

#### 1. DURATION OF USE

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

#### 2. INVASIVE AND ACTIVE DEVICES

- 2.1. **‘Body orifice’ means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.**
- 2.2. **‘Surgically invasive device’ means**
  - (a) **an invasive device which penetrates inside the body through the surface of the body, 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 for cleaning and/or sterilization have been carried out.**
- 2.4. **‘Active therapeutic device’ means any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.**
- 2.5. **‘Active device intended for diagnosis’ means any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.**
- 2.6. **‘Central circulatory system’ means the following blood vessels: arteriae pulmonales, aorta ascendens, arcus aorta, 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.**

## **II. Implementing rules for the classification rules**

1. Application of the classification rules shall be governed by the intended purpose of the devices.
2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.
3. Stand alone software, which drives a device or influences the use of a device, falls automatically in the same class as the device. If stand alone software is independent of any other device, it is classified in its own right.
4. If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.
5. If several rules, or within the same rule several sub-rules, apply to the same device based on the device’s intended purpose, the strictest rule and/or sub-rule resulting in the higher classification shall apply.
6. In calculating the duration referred to in Chapter I, Section 1 continuous use means:
  - (a) The entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior and after the period when the use is interrupted or the device removed.
  - (b) The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.
7. A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition by itself or when it provides decisive information for the diagnosis.

## **III. Classification rules**

### **3. NON-INVASIVE DEVICES**

#### **3.1. Rule 1**

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



### **3.2. Rule 2**

All non-invasive devices intended for channelling or storing blood, body liquids 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 tissues.

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 infusion into the body are in class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in class IIa.

All non-invasive devices intended to be used for in vitro fertilisation (IVF) or assisted reproduction technologies (ART) which are liable to act with close contact on the inner or outer cells during the IVF/ART, such as washing, separating, sperm immobilising, cryoprotecting solutions, are in class IIb.

### **3.4. Rule 4**

All non-invasive devices which come into contact with injured skin:

- 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 with wounds which have breached the dermis and can only heal by secondary intent,
- are in class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.

## **4. INVASIVE DEVICES**

### **4.1. Rule 5**

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

- are in class I if they are intended for transient use,

- are in class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in class I,
- are in class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a 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 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 central nervous system, in which case they are in class III,
- are intended to supply energy in the form of ionising radiation in which case they are in class IIb,
- have a biological effect or are wholly or mainly absorbed in which case they are in class IIb,
- are intended to administer medicines 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 central nervous system, in which case they are in class III,
- are intended to supply energy in the form of ionizing radiation in which case they are in class IIb,
- have a biological effect or are wholly or mainly absorbed in which case they are in class III,

- are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in class IIb.

#### **4.4. Rule 8**

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

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

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

## **5.2. Rule 10**

Active devices intended for diagnosis are in class IIa:

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

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

## **5.3. Rule 11**

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

## **5.4. Rule 12**

All other active devices are in class I.

## **6. SPECIAL RULES**

### **6.1. Rule 13**

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

### **6.2. Rule 14**

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

### **6.3. Rule 15**

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

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

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

**6.4. Rule 16**

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

**6.5. Rule 17**

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

**6.6. Rule 18**

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

**6.7. Rule 19**

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

**6.8. Rule 20**

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

**6.9. Rule 21**

Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body are in class III.

## ANNEX VIII

### CONFORMITY ASSESSMENT BASED ON FULL QUALITY ASSURANCE AND DESIGN EXAMINATION

#### Chapter I: Full Quality Assurance System

1. The manufacturer shall ensure application of the quality management system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3 and is subject to audit as laid down in Sections 3.3 and 3.4 and to the surveillance as specified in Section 4.
2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 17 and Annex III for the device model covered by the conformity assessment procedure. By issuing a declaration of conformity the manufacturer ensures and declares that the devices concerned meet the provisions of this Regulation which apply to them.
3. Quality management system
  - 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 manufacturer and any additional manufacturing site covered by the quality management system, and, if the application is lodged by the authorised representative, his name and address as well,
    - all the relevant information on the device or device category covered by the procedure,
    - a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system that has been refused by another notified body,
    - the documentation on the quality management system,
    - a description of the procedures in place to fulfil the obligations imposed by the quality management system approved and the undertaking by the manufacturer to apply these procedures,
    - a description of the procedures in place to keep the approved quality management system adequate and efficacious and the undertaking by the manufacturer to apply these procedures,
    - the documentation on the post-market surveillance plan, including, when applicable, a plan for the post-market clinical follow-up, and the procedures put in place to ensure compliance with the obligations emanating from the provisions on vigilance set out in Articles 61 to 66,

- a description of the procedures in place to keep up to date the post-market surveillance plan, including, when applicable, a plan for the post-market clinical follow-up, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 61 to 66 as well as the undertaking by the manufacturer to apply these procedures.

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

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

- (a) the manufacturer's quality objectives;
- (b) the organisation of the business and in particular:
  - the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of design and manufacture of the products is concerned,
  - the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform,
  - where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,
  - where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;
- (c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, including the corresponding documentation as well as the data and records arising from those procedures and techniques;
- (d) the inspection and quality assurance techniques at the manufacturing stage and in particular:
  - the processes and procedures which will be used, particularly as regards sterilisation, purchasing and the relevant documents,

- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
- (e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it shall be possible to trace back the calibration of the test equipment adequately.

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

### 3.3. Audit

- (a) The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 3.2. Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonised standards or CTS conform to the requirements covered by the standards or CTS.
- (b) The assessment team shall include at least one member with past experience of assessments of the technology concerned. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing and other relevant processes.
- (c) Moreover, in the case of devices falling into class IIa or IIb the audit procedure shall include an assessment, on a representative basis, of the design documentation within the technical documentation as referred to in Annex II of the device(s) concerned. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample(s) taken.
- (d) If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU full quality assurance certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the audit and a reasoned assessment.

- 3.4. The manufacturer shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system or the product-range covered. The notified body shall assess the changes proposed 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 audit and a reasoned assessment. The approval of any substantial change to the quality management system or the product-range covered shall take the form of a supplement to the EU full quality assurance certificate.



4. Surveillance assessment
  - 4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.
  - 4.2. The manufacturer shall authorise the notified body to carry out all the necessary audits, including inspections, and supply it with all relevant information, in particular:
    - the documentation on the quality management system,
    - the documentation on the post-market surveillance plan, including a post-market clinical follow-up, as well as, if applicable, any findings resulting from the application of the post-market surveillance plan, including the post-market clinical follow-up, and of the provisions on vigilance set out in Articles 61 to 66,
    - the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests, the solutions adopted regarding the risk-management as referred to in Section 2 of Annex I , pre-clinical and clinical evaluation,
    - the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
  - 4.3. The notified body shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan, and shall supply the manufacturer with an assessment report. This shall include inspections on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such inspections, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.
  - 4.4. The notified body shall randomly perform unannounced factory inspections to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer.

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

Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market to verify that the manufactured device is in

conformity with the technical documentation and/or design dossier. Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer with an inspection report which shall include, if applicable, the result of the sample check.

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

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

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

## **Chapter II: Design dossier examination**

5. Examination of the design of the device, applicable to devices classified as class III
  - 5.1. In addition to the obligations imposed by Section 3, the manufacturer shall lodge with the notified body referred to in Section 3.1 an application for examination of the design dossier relating to the device which he plans to manufacture and which falls into the device category covered by the quality management system referred to in Section 3.
  - 5.2. The application shall describe the design, manufacture and performances of the device in question. It shall include the technical documentation as referred to in Annex II; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.
  - 5.3. The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. The notified body may require the application to be completed by further tests or other evidence to allow 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.

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

- 5.4. If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU design-examination certificate. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the device.
- 5.5. Changes to the approved design shall receive further approval from the notified body which issued the EU design-examination certificate wherever the changes could affect conformity with the general safety and performance requirements of the Regulation or with the conditions prescribed for use of the device. The applicant shall inform the notified body which issued the EU design-examination certificate of any planned changes to the approved design. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU design-examination report. The approval of any change to the approved design shall take the form of a supplement to the EU design-examination certificate.
6. Specific procedures
  - 6.1. Procedure in the case of devices incorporating a medicinal substance
    - (a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, with action ancillary to that of the device, the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.
    - (b) Before issuing an EU design-examination certificate, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA'), acting particularly through its Committee on Human Medicinal Products in accordance with Regulation (EC) No 726/2004, on the quality and safety of the substance including the benefit/risk of the incorporation of the substance into the device. Where the device incorporates a human blood or plasma derivative or a substance that, if used separately may be considered to be a medicinal product falling exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA.
    - (c) When issuing its opinion, the medicinal products competent authority or the EMA shall take into account the manufacturing process and the data related to

the usefulness of incorporation of the substance into the device as determined by the notified body.

- (d) The opinion of the medicinal products competent authority or the EMA shall be drawn up
  - within 150 days after receipt of valid documentation if the substance subject to the consultation is authorised in accordance with Directive 2001/83/EC; or
  - within 210 days after receipt of valid documentation in other cases.
- (e) The scientific opinion of the medicinal products competent authority or the EMA, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.
- (f) Before changes are made with respect to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the manufacturer shall inform the notified body of the changes which shall consult the medicinal products competent authority that was involved in the initial consultation, in order to confirm that the quality and safety of the ancillary substance are maintained. The medicinal products competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk of the addition of the substance in the device. It shall provide its opinion within 30 days after receipt of the valid documentation regarding the changes.
- (g) When the medicinal products competent authority that was involved in the initial consultation has obtained information on the ancillary substance, which could have an impact on the established benefit/risk of the addition of the substance in the device, it shall provide the notified body with advice whether this information has an impact on the established benefit/risk of the addition of the substance in the device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

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

- (a) For devices manufactured utilising tissues or cells of human origin, or their derivatives, that are covered by this Regulation in accordance with point (e) of Article 1(2), the notified body shall, prior to issuing an EU design-examination certificate, submit to the competent authority designated by the Member State in accordance with Directive 2004/23/EC (hereinafter referred to as 'human tissues and cells competent authority') in which it is established 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 into the device.

- (b) Within 90 days after receipt of valid documentation, the human tissues and cells competent authority may submit comments on aspects related to the donation, procurement and testing and/or the benefit/risk of the incorporation of the human tissues or cells into the device.
- (c) The notified body shall give due consideration to any comments received in accordance with point (b). It shall convey to the human tissues and cells competent authority an explanation as regards this consideration, including any due justification not to follow the comment received, and its final decision regarding the conformity assessment in question. The comments of the human tissues and cells competent authority shall be included in the documentation of the notified body concerning the device.

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 his authorised representative shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:
- the declaration of conformity,
  - the documentation referred to in the fourth 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 representative sample of the production covered fulfils the relevant provisions of this Regulation.

2. Application

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative,
- the technical documentation referred to in Annex II needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the ‘type’, with the requirements of this Regulation; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request. The applicant shall make a ‘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.

3. Assessment

The notified body shall:

- 3.1. examine and assess the technical documentation and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable specifications of the standards referred to in Article 6 or CTS , as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;
- 3.2. 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 CTS 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.

#### 4. Certificate

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

#### 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.

5.2. Changes to the approved product 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.

#### 6. Specific procedures

The provisions regarding the specific procedures in the case of 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 set out in Annex VIII, Section 6, apply with the proviso that any reference to an EU design-examination certificate shall be understood as reference to an EU type-examination certificate.

#### 7. Administrative provisions

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

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

Section 9 of Annex VIII shall apply.



## ANNEX X

### 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; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request;
    - a copy of the EU-type examination certificates referred to in Section 4 of Annex IX; if the EU-type examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and the certificates issued is sufficient.

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

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

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

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

- 3.4. The provisions of Section 3.4 Annex VIII apply.

#### 4. Surveillance

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

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

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

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

#### 6. Administrative provisions

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

- the declaration of conformity,

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

Section 9 of Annex VIII shall apply.

## 7. Application to devices classified as class IIa

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

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

In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample(s) 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 shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.

7.5. By way of derogation from Section 6, the manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the 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 emanating from the provisions on vigilance set out in Articles 61 to 66.
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 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 carried out.
6. Batch verification in the case of devices incorporating a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(4)

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

## 7. Administrative provisions

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

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

Section 9 of Annex VIII shall apply.

## 8. Application to devices classified as class IIa

8.1. By way of derogation from Section 1, by virtue of the EU declaration of conformity the manufacturer ensures and declares that the devices in class IIa are manufactured in conformity with the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them.

8.2. The verification conducted by the notified body in accordance with Section 4 is intended to confirm the conformity of the devices in class IIa with the technical documentation referred to in Annex II and with the requirements of this Regulation which apply to them.

8.3. If the verification in accordance with Section 8.2. confirms that the devices in class IIa conform to the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this section of this Annex.

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

- the declaration of conformity,
- the technical documentation referred to in Annex II,

- the certificate referred to in Section 8.3.

Section 9 of Annex VIII shall apply.

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

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

The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph;
  
3. The information contained in the declaration concerned by this Annex shall be kept for a period of time of at least five years after the device has been placed on the market. In the case of implantable devices the period shall be at least 15 years.

Section 9 of Annex VIII shall apply.

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



## ANNEX XII

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

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;
4. date of issue;
5. date of expiry;
6. data needed for the identification of the device(s) or categories of devices covered by the certificate, including the intended purpose of the device(s) and the GMDN code(s) or internationally recognised nomenclature code(s);
7. if applicable, the manufacturing facilities covered by the certificate;
8. reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;
9. examinations and tests performed, e.g. reference to relevant standards / test reports / audit report(s);
10. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device(s) covered;
11. if applicable, information about the surveillance by the notified body;
12. conclusions of the notified body's assessment, examination or inspection;
13. conditions for or limitations to the validity of the certificate;
14. legally binding signature of the notified body according to the applicable national law.

## CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

### PART A: CLINICAL EVALUATION

1. To conduct a clinical evaluation, a manufacturer shall:
  - identify the general safety and performance requirements that require support from relevant clinical data;
  - identify available clinical data relevant to the device and its intended use generated through scientific literature search, clinical experience and/or clinical investigations;
  - appraise the clinical data sets by evaluating their suitability for establishing the safety and performance of the device;
  - generate any new or additional clinical data needed to address outstanding issues;
  - analyse all relevant clinical data to reach conclusions about the safety and performance of the device.
2. Confirmation of conformity with the requirements concerning the characteristics and performances referred to in Section 1 of Annex I, under the normal conditions of use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on clinical data.
3. The clinical evaluation shall be thorough and objective, considering both favourable and unfavourable data. Its depth and extent shall be proportionate and appropriate to the nature, classification, intended use, manufacturer's claims and risks of the device in question.
4. Clinical data relating to another device may be relevant where equivalence is demonstrated of the device subject to clinical evaluation to the device to which the data relates. Equivalence can only be demonstrated when the device that is subject to clinical evaluation and the device to which the existing clinical data relates have the same intended purpose and when the technical and biological characteristics of the devices and the medical procedures applied are similar to such an extent that there would be not a clinically significant difference in the safety and performance of the devices.
5. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.

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

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

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

1. Post-market clinical follow-up, hereinafter: PMCF, is a continuous process to update the clinical evaluation referred to in Article 49 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan. To this end, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which is authorised to bear the CE marking, 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 lay down, in particular
    - (a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;
    - (b) the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;

- (c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);
  - (d) a reference to the relevant parts of the clinical evaluation report referred to in Section 6 of Part A of this Annex and to the risk management referred to in Section 2 of Annex I;
  - (e) the specific objectives to be addressed by the PMCF;
  - (f) an evaluation of the clinical data related to equivalent or similar devices,
  - (g) reference to relevant standards and guidance on PMCF.
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 technical documentation.
  4. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 49 and Part A of this Annex and in the risk management referred to in Section 2 of Annex I. If through the PMCF the need for corrective measures has been identified, the manufacturer shall implement them.

## CLINICAL INVESTIGATIONS

### I. General requirements

#### 1. Ethical considerations

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

#### 2. Methods

- 2.1. Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device as well as the safety, performance and benefit/risk related aspects referred to in Article 50(1); these investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions.
- 2.2. The procedures used to perform the investigations shall be appropriate to the device under examination.
- 2.3. Clinical investigations shall be performed in circumstances similar to the normal conditions of use of the device.
- 2.4. All the appropriate features, including those involving the safety and performances of the device, and its effect on patients shall be examined.
- 2.5. The investigations shall be performed under the responsibility of a medical practitioner or another authorised qualified person in an appropriate environment.
- 2.6. The medical practitioner or other authorised person shall have access to the technical and clinical data regarding the device.
- 2.7. The clinical investigation report, signed by the medical practitioner or other authorised person responsible, shall contain a critical evaluation of all the data collected during the clinical investigation, including negative findings.

### II. Documentation regarding the application for clinical investigation

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

#### 1. Application form

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

- 1.1. Name, address and contact details of the sponsor and, if applicable, name, address and contact details of his contact person established in the Union.
- 1.2. If different from the Section 1.1., name, address and contact details of the manufacturer of the device intended for clinical investigation and, if applicable, of his authorised representative.
- 1.3. Title of the clinical investigation.
- 1.4. Single identification number in accordance with Article 51(1).
- 1.5. Status of the clinical investigation (e.g. first submission, resubmission, significant amendment).
- 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.
- 1.7. If parallel submission for a clinical trial on a medicinal product in accordance with Regulation (EU) No [.../...] [on clinical trials on medicinal products for human use], reference to the official registration number of the clinical trial.
- 1.8. Identification of the Member States, EFTA countries, Turkey and third countries in which the clinical investigation shall be conducted as part of a multicentre/multinational study at the time of application.
- 1.9. Brief description of the investigational device (e.g. name, GMDN code or internationally recognised nomenclature code, intended purpose, risk class and applicable classification rule according to Annex VII).
- 1.10. Information as to whether the device incorporates a medicinal substance, including a human blood or plasma derivative, or whether it is manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives.
- 1.11. Summary of the clinical investigation plan (objective(s) of the clinical investigation, number and gender of subjects, criteria for subject selection, subjects under 18 years of age, design of the investigation such as controlled and/or randomised studies, planned dates of commencement and of completion of the clinical investigation).
- 1.12. If applicable, information regarding a comparator (e.g. identification of the comparator device or medicinal product).
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. It 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, and use, including storage and handling requirements, as well as the label and instructions for use to the extent that this information is available.
- 2.3. 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, software verification and validation, performance tests, evaluation of biocompatibility and biological safety.
- 2.4. Existing clinical data, in particular
  - of the relevant scientific literature available relating to the safety, performance, 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, 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 and safety related issues and any corrective actions taken;
- 2.5. Summary of the risk/benefit analysis and the risk management, including information regarding known or foreseeable risks, any undesirable effects, contra-indications and warnings.
- 2.6. In the case of devices that incorporates a medicinal substance, including a human blood or plasma derivative, or devices manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives, detailed information on the medicinal substance or on the tissues or cells, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to the substance or tissues or cells.
- 2.7. Reference to harmonised or other internationally recognised standards complied with in full or in part.
- 2.8. A clause that any updates to the IB or any other relevant information that is newly available shall be brought to the attention of the investigators.

### 3. Clinical Investigation Plan

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

#### 3.1. General

- 3.1.1. Identification of the clinical investigation and the CIP.
- 3.1.2. Identification of the sponsor.
- 3.1.3. Information on the principal investigator, coordinating investigator, including their qualifications, and on the investigation site(s).
- 3.1.4. Overall synopsis of the clinical investigation.
- 3.2. Identification and description of the device, including its intended purpose, its manufacturer, its traceability, the target population, materials coming into contact with the human body, the medical or surgical procedures involved in its use and the necessary training and experience for its use.
- 3.3. Justification for the design of the clinical investigation.
- 3.4. Risks and benefits of the device and of the clinical investigation.
- 3.5. Objectives and hypotheses of the clinical investigation.
- 3.6. Design of the clinical investigation
  - 3.6.1. General information such as type of investigation with rationale for choice, endpoints, variables.
  - 3.6.2. Information on the device to be used for the clinical investigation, on any comparator and on any other device or medication.
  - 3.6.3. Information on subjects, including size of investigation population and, if applicable, information on vulnerable populations.
  - 3.6.4. Description of the procedures related to the clinical investigation.
  - 3.6.5. Monitoring plan.
- 3.7. Statistical considerations.
- 3.8. Data management.
- 3.9. Information about any amendments to the CIP.
- 3.10. Policy regarding deviations 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. Informed consent process.



- 3.14. Safety reporting, including definitions of adverse events and serious adverse events, procedures and timelines for reporting.
- 3.15. Criteria and procedures for suspension or early termination of the clinical investigation.
- 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.
- 3.17. Bibliography.

#### 4. Other information

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

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

- 4.2. Where applicable according to national law, copy of the opinion(s) of the ethics committee(s) concerned as soon as available.
- 4.3. Proof of insurance cover or indemnification of subjects in case of injury, according to the national law.
- 4.4. Documents and procedures to be used to obtain informed consent.
- 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.

### **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 reportable events shall be provided by the investigator(s) in timely conditions.

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

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

ANNEX XV

**LIST OF PRODUCTS COVERED BY THE LAST SUBPARAGRAPH OF THE DEFINITION OF 'MEDICAL DEVICE' REFERRED TO IN NUMBER (1) OF ARTICLE 2(1)**

1. Contact lenses;
2. Implants for modification or fixation of body parts;
3. Facial or other dermal or mucous membrane fillers;
4. Equipment for liposuction;
5. Invasive laser equipment intended to be used on the human body;
6. Intense pulsed light equipment.

## ANNEX XVI

**CORRELATION TABLE**

<b>Council Directive 90/385/EEC</b>	<b>Council Directive 93/42/EEC</b>	<b>This Regulation</b>
Article 1(1)	Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2)	Article 2(1)
Article 1(3)	Article 1(3) 1 <sup>st</sup> subparagraph	Article 1(5)1 <sup>st</sup> subparagraph
-	Article 1(3) 2 <sup>nd</sup> subparagraph	Article 1(5)2 <sup>nd</sup> subparagraph
Article 1(4) and (4a)	Article 1(4) and (4a)	Article 1(4)1 <sup>st</sup> subparagraph
Article 1(5)	Article 1(7)	Article 1(6)
Article 1(6)	Article 1(5)	Article 1(2)
-	Article 1(6)	-
	Article 1(8)	Article 1(7)
Article 2	Article 2	Article 4(1)
Article 3 1 <sup>st</sup> subparagraph	Article 3 1 <sup>st</sup> subparagraph	Article 4(2)
Article 3 2 <sup>nd</sup> subparagraph	Article 3 2 <sup>nd</sup> subparagraph	-
Article 4(1)	Article 4(1)	Article 22
Article 4(2)	Article 4(2)	Article 19(1) and (2)
Article 4(3)	Article 4(3)	Article 19(3)
Article 4(4)	Article 4(4)	Article 8(7)
Article 4(5) point (a)	Article 4(5) 1 <sup>st</sup> subparagraph	Article 18(6)
Article 4(5) point (b)	Article 4(5) 2 <sup>nd</sup> subparagraph	-
Article 5(1)	Article 5(1)	Article 6(1)
Article 5(2)	Article 5(2)	Article 6(2)
Article 6(1)	Article 5(3), Article 6	-
Article 6(2)	Article 7(1)	Article 88

Article 7	Article 8	Articles 69 to 72
-	Article 9	Article 41
Article 8(1)	Article 10(1)	Number (43) and (44) of Article 2(1), Article 61(1), Article 63(1)
Article 8(2)	Article 10(2)	Article 61(3) and Article 63(1)2 <sup>nd</sup> 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	-

## LEGISLATIVE FINANCIAL STATEMENT

### **1. FRAMEWORK OF THE PROPOSAL/INITIATIVE**

- 1.1. Title of the proposal/initiative
- 1.2. Policy area(s) concerned in the ABM/ABB structure
- 1.3. Nature of the proposal/initiative
- 1.4. Objective(s)
- 1.5. Grounds for the proposal/initiative
- 1.6. Duration and financial impact
- 1.7. Management method(s) envisaged

### **2. MANAGEMENT MEASURES**

- 2.1. Monitoring and reporting rules
- 2.2. Management and control system
- 2.3. Measures to prevent fraud and irregularities

### **3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE**

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected
- 3.2. Estimated impact on expenditure
  - 3.2.1. *Summary of estimated impact on expenditure*
  - 3.2.2. *Estimated impact on operational appropriations*
  - 3.2.3. *Estimated impact on appropriations of an administrative nature*
  - 3.2.4. *Compatibility with the current multiannual financial framework*
  - 3.2.5. *Third-party participation in financing*
- 3.3. Estimated impact on revenue

## LEGISLATIVE FINANCIAL STATEMENT

### 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

#### 1.1. Title of the proposal/initiative

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.

This financial statement also includes the costs related to the Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices which is based on the same organisational and IT infrastructure established by this Proposal.

#### 1.2. Policy area(s) concerned in the ABM/ABB structure<sup>64</sup>

Health for Growth

#### 1.3. Nature of the proposal/initiative

The proposal/initiative relates to a **new action**

The proposal/initiative relates to a **new action following a pilot project/preparatory action**<sup>65</sup>

The proposal/initiative relates to **the extension of an existing action**

The proposal/initiative relates to **an action redirected towards a new action**

#### 1.4. Objectives

##### 1.4.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

In the field of medical devices, the proposals aim

1) to ensure a high level of **human health and safety**,

2) to ensure the functioning of the **internal market**, and

3) to promote **innovation** in medical technology for the benefit of patients and healthcare professionals.

##### 1.4.2. *Specific objective(s) and ABM/ABB activity(ies) concerned*

Specific objective 1: Establish mechanisms to ensure harmonised implementation of the rules on medical devices by all Member States with a sustainable, efficient and

<sup>64</sup> ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

<sup>65</sup> As referred to in Article 49(6)(a) or (b) of the Financial Regulation.



credible management at EU level with access to internal and external technical, scientific and clinical expertise, allowing improved coordination and resource-sharing between Member States.

Specific objective 2: Enhance transparency regarding medical devices on the EU market, including their traceability.

ABM/ABB activity(ies) concerned

Health for Growth

The Commission's Proposal for a Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme for the period 2014-2020 (COM[2011]709) lists contribution to the objectives of the EU legislation in the field of medical devices as one of the eligible actions to be financed by the programme.

1.4.3. *Expected result(s) and impact*

*Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.*

On patients and healthcare professionals: High level of human health and safety; cases of deliberate circumvention of the legal requirements (e.g. PIP case) are prevented or quickly identified. High level of transparency and traceability regarding medical devices on the market (e.g. publicly accessible Eudamed; UDI; implant card; summary of safety and performance) allowing better informed decision-making and follow-up. High level of confidence in the EU regulations.

On manufacturers of medical devices: Level playing field due to clearer rules and obligations, benefiting in particular the large majority of manufacturers which already comply with the spirit of the current legislation. Benefits from smoother functioning of the internal market. Support to innovation due to predictable regulatory framework conditions (e.g. early scientific advice). Lower overall administrative burdens due to central registration of devices and reporting of serious incidents.

On notified bodies: Safeguard their role in pre-market medical device assessment. Level playing field due to clearer rules and obligations, benefiting in particular those notified bodies which already comply with the spirit of the current legislation. Reinforcement of their position vis-à-vis manufacturers.

On national authorities: Reinforcement of their enforcement powers. Clear legal framework for coordination between them and resource- and work-sharing.

1.4.4. *Indicators of results and impact*

*Specify the indicators for monitoring implementation of the proposal/initiative.*

Number of patients harmed by unsafe medical devices.

Number of designated notified bodies, their areas of competence and the level of diversification.

Number of registrations (medical devices, economic operators, certificates), incident reports, single applications for clinical investigations and market surveillance measures in the Eudamed databank with its several new electronic systems.

Number of preliminary conformity assessments "called up" under the scrutiny mechanism and number of comments emitted by MDCG.

Number of coordinated actions between national competent authorities regarding post-market safety issues (vigilance and market surveillance).

Number of 'borderline cases' solved.

Number of devices fitted with an UDI system that is aligned with international practice.

## **1.5. Grounds for the proposal/initiative**

### *1.5.1. Requirement(s) to be met in the short or long term*

The existing regulatory framework is being criticised for not sufficiently ensuring patient safety within the internal market and for being intransparent. The criticism has become even louder after findings of the French health authorities that a French manufacturer (*Poly Implant Prothèse*, PIP) over several years apparently used industrial silicone instead of medical grade silicone for the manufacture of breast implants contrary to the approval provided by the notified body, causing harm to thousands of women around the world.

In an internal market with currently 32 participating countries (EU, EFTA, Turkey) and subject to constant technological and scientific progress, important divergences in the interpretation and application of the rules have emerged, thus undermining the directives' main objectives, i.e. the safety of medical devices and their free circulation within the internal market. Moreover, regulatory gaps or uncertainties exist with regard to certain products (e.g. products manufactured utilising non-viable human tissues or cells; implantable or other invasive products for cosmetic purposes).

The present revision aims to overcome these flaws and gaps and to put in place a robust, transparent and sustainable regulatory framework that is 'fit for purpose'.

### *1.5.2. Added value of EU involvement*

The proposed revision of the existing directives concerning medical devices, which will integrate the modification of the Lisbon Treaty regarding public health, can only be achieved at Union level. The proposals are based on Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU).

EU action is necessary to improve the level of protection of public health for all European patients and users, as well as to prevent Member States from adopting varying product regulations which would result in a further fragmentation of the internal market. Harmonised rules and procedures allow manufacturers, especially SMEs that represent more than 80% of the sector, to reduce costs related to national

regulatory differences, while ensuring a high and equal level of safety for all European patients and users. In accordance with the principles of proportionality and subsidiarity, as set out in Article 5 of the Treaty on European Union, this proposal does not go beyond what is necessary to achieve those objectives.

#### *1.5.3. Lessons learned from similar experiences in the past*

The existing directives concerning medical devices, which date back to the 1990ies, have set harmonised requirements to be met by medical devices placed on the EU market. But they have not provided for mechanisms that ensure a harmonised implementation. As mentioned under 1.5.1., important divergences in the interpretation and application of the rules have emerged, thus undermining the directives' main objectives, i.e. the safety of medical devices and their free circulation within the internal market.

In addition, lessons drawn from an analysis of the shortcomings brought to light by the PIP case have been taken into account for the drafting of these proposals.

#### *1.5.4. Coherence and possible synergy with other relevant instruments*

Enhanced coherence is expected with other legislations (e.g. concerning medicinal products, food, biocides, cosmetics) in terms of better delimitation of the respective scopes of application and/or in terms of solution of 'borderline cases'.

Synergies are expected with the legislation regarding medicinal products, in particular as regards the assessment of drug-device combination products and as regards clinical research regarding medicinal products (in the context of the revised Clinical Trials Directive) and regarding medical devices (in the context of this proposal) and/or performance evaluation studies with IVDs (in the context of the proposal for a Regulation on IVDs).

## 1.6. Duration and financial impact

Proposal/initiative of **limited duration**

- Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY
- Financial impact from YYYY to YYYY

Proposal/initiative of **unlimited duration**

- Implementation with a start-up period from 2014 to 2017,
- followed by full-scale operation.

## 1.7. Management mode(s) envisaged<sup>66</sup>

**Centralised direct management** by the Commission

**Centralised indirect management** with the delegation of implementation tasks to:

- executive agencies
- bodies set up by the Communities<sup>67</sup>
- national public-sector bodies/bodies with public-service mission
- persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

**Shared management** with the Member States

**Decentralised management** with third countries

**Joint management** with international organisations (*to be specified*)

*If more than one management mode is indicated, please provide details in the "Comments" section.*

### Comments

The Commission intends to ensure the services concerned via centralised direct management through its own services, in particular via the JRC for the technical, scientific and logistic support.

The centralised direct management by the Commission also applies to the further development and management of Eudamed (electronic systems regarding UDI; central registration of medical devices, economic operators and certificates; central reporting of

<sup>66</sup> Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: [http://www.cc.cec/budg/man/budgmanag/budgmanag\\_en.html](http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html)

<sup>67</sup> As referred to in Article 185 of the Financial Regulation.

vigilance cases; market surveillance measures; clinical investigations) and the IT tool for the notification of information regarding new applications for conformity assessment concerning high risk devices by notified bodies and 'called up' preliminary assessments by them in the context of the scrutiny mechanism.

It should be highlighted that the four **EFTA countries** (via EEA Agreement and MRA with CH) and **Turkey** (via Customs Union Agreement) will participate in the management.

## 2. MANAGEMENT MEASURES

### 2.1. Monitoring and reporting rules

*Specify frequency and conditions.*

The future Medical Device Coordination Group (MDCG), set up by this Regulation, and its special working groups will provide a regular platform to discuss issues related to the implementation of the new regulatory framework.

Ten years after entry into force, the Commission should report to the European Parliament and to the Council about the achievements of the 'medical device package'. The report should address the impact of the new rules in respect of public health and patient safety, internal market, innovativeness and competitiveness of the medical device industry (with special attention to SMEs). The Commission should consult competent authorities and stakeholders (healthcare professionals, patients, manufacturers, notified bodies) when preparing its report.

### 2.2. Management and control system

#### 2.2.1. Risk(s) identified

##### Risks related to Eudamed:

The development of the future Eudamed database would become too complex and would not meet the needs of the national competent authorities, the notified bodies, economic operators and the public at large.

The IT infrastructure would not support the registration of all medical devices placed on the EU market (several hundreds of thousands), or the reporting of serious incidents and field safety corrective actions (several thousands a years), the reporting of market surveillance measures, or the single submission of applications for clinical investigations and the reporting of related serious adverse events.

The non-public parts of the Eudamed database with sensitive personal and commercial information would disclose confidential information, e.g. due to hacking or software failure.

##### Risks related to the conformity assessment of medical devices:

By the date of application of the new Regulations, an insufficient number of notified bodies would be designated in accordance with the new requirements which would lead to a delay for manufacturers to get their devices approved.

The scrutiny mechanism would be used in a way that would delay, in a disproportionate manner, access to market of innovative medical devices.

The IT tool for the notification of information regarding new applications and/or submission of preliminary assessments by notified bodies, which contains commercially sensitive information, would disclose confidential information, e.g. due to hacking or software failure.

### 2.2.2. *Control method(s) envisaged*

#### Control methods regarding risks related to Eudamed:

The development of Eudamed is given high priority with a high level of sensitivity as regards its functioning.

Close and regular contacts between the Commission services responsible for the management of the regulatory framework and the IT developers.

Close and regular contacts between the Commission services/IT developers and the future users of the IT infrastructure.

#### Control methods regarding risks related to the conformity assessment of medical devices:

The reinforced and coordinated supervision of notified bodies in the context of the 'immediate action' initiated after the PIP scandal already takes account of the future requirements laid down in the proposal and thus supports a smooth transition.

The Commission shall create guidance to ensure a proportionate and workable operation of the new scrutiny mechanism.

The development of the IT tool is given high priority with a high level of sensitivity as regards its functioning.

### 2.3. **Measures to prevent fraud and irregularities**

*Specify existing or envisaged prevention and protection measures.*

In addition to the application of all regulatory control mechanisms, the responsible Commission's services will devise an anti-fraud strategy in line with the Commission's new anti-fraud strategy (CAFS) adopted on 24 June 2011 in order to ensure *inter alia* that its internal anti-fraud related controls are fully aligned with the CASF and that its fraud risk management approach is geared to identify fraud risk areas and adequate responses. Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases related to the financing implementing activities of the Medical Devices Regulations will be set up. In particular a series of measures will be put in place such as:

- decisions, agreements and contracts resulting from the financing implementing activities of the Medical Devices Regulations will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections;
- during the evaluation phase of a call for proposals/tender, the proposers and tenderers are checked against the published exclusion criteria based on declarations and the Early Warning System (EWS);
- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

Moreover, the Commission will control a strict application of the rules on conflict of interests provided in the proposal.



### 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

#### 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

**Operational resources which are necessary for implementation of this initiative will be covered by the allocations proposed under the Health for Growth Programme 2014-2020.**

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description: Health for Growth Programme]	Diff./non-diff. (68)	from EFTA <sup>69</sup> countries	from candidate countries <sup>70</sup>	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
3	17.03.XX.	Diff./non-diff.	YES/NO	YES/NO (to be determined whether Turkey – in the context of the Customs Union and as candidate country – should contribute.)	YES/NO	YES/NO

<sup>68</sup> Diff. = Differentiated appropriations / Non-diff. = Non-Differentiated Appropriations

<sup>69</sup> EFTA: European Free Trade Association.

<sup>70</sup> Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

### 3.2. Estimated impact on expenditure

#### 3.2.1. Summary of estimated impact on expenditure (in current prices)

EUR million (to 3 decimal places)

<b>Heading of multiannual financial framework:</b>	Number 3	Citizenship (Health for Growth Programme)
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DG SANCO			Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years		TOTAL
• Operational appropriations <sup>71</sup>										
Number of budget line: 17.03.XX <sup>72</sup>	Commitments	(1)	5,296	5,677	6,667	7,662	7,590	7,742	7,742	<b>48,376</b>
	Payments	(2)	2,648	5,486	6,172	7,165	7,626	7,666	7,742 + 3,871	<b>48,376</b>
Appropriations of an administrative nature financed from the envelope for specific programmes <sup>73</sup>										
Number of budget line:		(3)								
<b>TOTAL appropriations for DG SANCO</b>	Commitments	=1+1a +3	5,296	5,677	6,667	7,662	7,590	7,742	7,742	<b>48,376</b>
	Payments	=2+2a	2,648	5,486	6,172	7,165	7,626	7,666	7,742 + 3,871	<b>48,376</b>

<sup>71</sup> Costs for development of IT and for technical/scientific support.

<sup>72</sup> The cost of the action will be entirely covered by the envelope of the Health for Growth programme under the budgetary line related to the relevant objective of the programme.

<sup>73</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

		+3								
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• TOTAL operational appropriations	Commitments	(4)	5,296	5,677	6,667	7,662	7,590	7,742	7,742	<b>48,376</b>
	Payments	(5)	2,648	5,486	6,172	7,165	7,626	7,666	7,742 + 3,871	<b>48,376</b>
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
<b>TOTAL appropriations under HEADING 3B</b> of the multiannual financial framework	Commitments	=4+ 6	5,296	5,677	6,667	7,662	7,590	7,742	7,742	<b>48,376</b>
	Payments	=5+ 6	2,648	5,486	6,172	7,165	7,626	7,666	7,742 + 3,871	<b>48,376</b>

**If more than one heading is affected by the proposal / initiative:**

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
<b>TOTAL appropriations under HEADINGS 1 to 4</b> of the multiannual financial framework (Reference amount)	Commitments	=4+ 6								
	Payments	=5+ 6								

<b>Heading of multiannual financial framework:</b>	<b>5</b>	" Administrative expenditure "
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EUR million (to 3 decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years		TOTAL
<b>DG SANCO</b>									
• Human resources		2,413	2,413	2,413	2,413	2,413	2,413	2,413	<b>16,891</b>
• Other administrative expenditure		0,469	0,478	0,488	0,497	0,508	0,519	0,519	<b>3,478</b>
<b>TOTAL DG SANCO</b>	Appropriations	2,882	2,891	2,901	2,910	2,921	2,932	2,932	<b>20,369</b>

<b>TOTAL appropriations under HEADING 5 of the multiannual financial framework</b>	(Total commitments = Total payments)	2,882	2,891	2,901	2,910	2,921	2,932	2,932	<b>20,369</b>
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EUR million (to 3 decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years		TOTAL
<b>TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework</b>	Commitments	8,178	8,568	9,568	10,572	10,511	10,674	10,674	<b>68,745</b>
	Payments	5,530	8,377	9,073	10,075	10,547	10,598	10,674 + 3,871	<b>68,745</b>

### 3.2.2. Estimated impact on operational appropriations

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs ↓			Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years						TOTAL				
	<b>OUTPUTS</b>																	
	Type of output <sup>74</sup>	Average cost of the output	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Total number of outputs	Total cost
SPECIFIC OBJECTIVE No 1			Establish mechanisms to ensure harmonised implementation of the rules by all Member States with a sustainable, efficient and credible management at EU level with access to internal and external technical, scientific and clinical expertise, allowing improved coordination and resource-sharing between Member States															
- Output	Meetings of MDCG		80 meeting days	1,873	80 meeting days	1,910	80 meeting days	1,948	80 meeting days	1,987	80 meeting days	2,027	80 meeting days	2,068	80 meeting days	2,068		13,881
- Output	Technical and scientific opinions and advice			0,406		0,690		1,580		2,473		2,523		2,573		2,573		12,818

<sup>74</sup>

Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

- Output	Audits / 'joint assessments' of 80 notified bodies			0,416		0,424		0,433		0,442		0,450		0,459		0,459		3,083
Sub-total for specific objective N°1				2,695		3,024		3,961		4,902		5,000		5,100		5100		29,782
SPECIFIC OBJECTIVE No 2		Enhance transparency regarding medical devices on the EU market, including their traceability																
- Output	Eudamed (with 6 electronic systems: UDI, registration, certificates, clinical inv., vigilance, market surv.), as of 2018 with statistical analysis / business intelligence) for signal detection		1	2,081	1	2,122	1	2,165	1	2,208	1	2,027	1	2,068	1	2,068		14,739
- Output	Translations, info campaigns, publications etc.		tbd	0,520	tbd	0,531	tbd	0,541	tbd	0,552	tbd	0,563	tbd	0,574	tbd	0,574		3,855
Sub-total for specific objective N°2				2,601		2,653		2,706		2,760		2,590		2,642		2,642		18,594
<b>Total costs</b>				5,296		5,677		6,667		7,662		7,590		7,742		7,742		<b>48,376</b>

### 3.2.3. Estimated impact on appropriations of an administrative nature

#### 3.2.3.1. Summary

- The proposal/initiative does not require the use of administrative appropriations
- The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places)

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years	TOTAL
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<b>HEADING 5 of the multiannual financial framework</b>								
Human resources	2,413	2,413	2,413	2,413	2,413	2,413	2,413	<b>16,891</b>
Other administrative expenditure	0,469	0,478	0,488	0,497	0,508	0,519	0,519	<b>3,478</b>
<b>Subtotal HEADING 5 of the multiannual financial framework</b>	<b>2,882</b>	<b>2,891</b>	<b>2,901</b>	<b>2,910</b>	<b>2,921</b>	<b>2,932</b>	<b>2,932</b>	<b>20,369</b>

<b>Outside HEADING 5<sup>75</sup> of the multiannual financial framework</b>								
Human resources								
Other expenditure of an administrative nature								
<b>Subtotal outside HEADING 5 of the multiannual financial framework</b>								

<b>TOTAL</b>	<b>2,882</b>	<b>2,891</b>	<b>2,901</b>	<b>2,910</b>	<b>2,921</b>	<b>2,932</b>	<b>2,932</b>	<b>20,369</b>
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<sup>75</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

### 3.2.3.2. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources
- The proposal/initiative requires the use of human resources, as explained below:

*Estimate to be expressed in full amounts (or at most to one decimal place)*

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year >2019
<b>• Establishment plan posts (officials and temporary agents)</b>							
17 01 01 01 (Headquarters and Commission's Representation Offices)	19	19	19	19	19	19	19
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
<b>• External personnel (in Full Time Equivalent unit: FTE)<sup>76</sup></b>							
XX 01 02 01 (CA, INT, SNE from the "global envelope")							
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)							
<b>XX 01 04 yy<sup>77</sup></b>	- at Headquarters <sup>78</sup>						
	- in delegations						
<b>XX 01 05 02 (CA, INT, SNE - Indirect research)</b>							
10 01 05 02 (CA, INT, SNE - Direct research)							
Other budget lines (specify)							
<b>TOTAL</b>	<b>19</b>	<b>19</b>	<b>19</b>	<b>19</b>	<b>19</b>	<b>19</b>	<b>19</b>

**XX** is the policy area or budget title concerned.

**The human resources required will be met by staff from DG SANCO who are already assigned to the management of the action and who will be redeployed within DG SANCO, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints (estimated needs: 16 AD/FTE and 3 AST/FTE).**

Description of tasks to be carried out:

Officials and temporary agents	Control of appropriate implementation of this Regulation; development of delegated/implementing acts and guidance; development of new electronic systems for Eudamed (in cooperation with IT staff); organisation and direction of 'joint assessments' of notified bodies and control of designation and monitoring process by Member States; coordination of market surveillance activities with EU wide impact; follow-up of national safeguard and preventive health protection measures;
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<sup>76</sup> CA= Contract Agent; INT= agency staff ("*Intérimaire*"); JED= "*Jeune Expert en Délégation*" (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert;

<sup>77</sup> Under the ceiling for external personnel from operational appropriations (former "BA" lines).

<sup>78</sup> Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).



	international regulatory cooperation; management of Medical Device Committee (committee within the meaning of Reg. 182/2011).
External personnel	

3.2.4. *Compatibility with the current multiannual financial framework*

- Proposal/initiative is compatible with the new multiannual financial framework 2014-2020.
- Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

- Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework<sup>79</sup>.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. *Third-party contributions*

- The proposal/initiative does not provide for co-financing by third parties
- The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to 3 decimal places)

	Year N	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
<i>Specify the co-financing body</i>								
TOTAL appropriations cofinanced								

<sup>79</sup> See points 19 and 24 of the Interinstitutional Agreement.

### 3.3. Estimated impact on revenue

- Proposal/initiative has no financial impact on revenue.
- Proposal/initiative has the following financial impact:
  - 1. on own resources
  - 2. on miscellaneous revenue

EUR million (to 3 decimal places)

Budget revenue line:	Appropriations available for the ongoing budget year	Impact of the proposal/initiative <sup>80</sup>						
		2014	2015	2016	2017	Subsequent years		
Article .....		0	0	0	0	0	0	0

For miscellaneous assigned revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

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<sup>80</sup> As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.