COUNCIL OF THE EUROPEAN UNION

Brussels, 22 January 2014

Interinstitutional File:
2012/0266 (COD)
2012/0267 (COD)

5458/14

LIMITE

PHARM 10
SAN 30
MI 52
COMPET 30
CODEC 123

NOTE

from:	General Secretariat of the Council
to:	Working Party on Pharmaceuticals and Medical Devices
No. Cion prop.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1 14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
No. Prev. doc.	5095/14 PHARM 4 SAN 8 MI 8 COMPET 9 CODEC 22
Subject:	Proposal for a Regulation of the European Parliament and of the Council on **medical devices**, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 Proposal for a Regulation of the European Parliament and of the Council on ***in vitro* diagnostic medical devices** – *Presidency proposal for Chapters II and III*

Delegations will find in the Annexes the Presidency draft text for Chapters II and III of the above mentioned proposals, submitted for their agreement.

Text Conventions:

Additions to the Commission proposals are indicated in **bold underlined**.

Deletions to the Commission proposal are indicated with ~~strikethrough~~.

Proposal for a Regulation on *in vitro* diagnostic medical devices

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

Article 4
Placing on the market and putting into service

1. A device may be ~~placed~~ **made available** on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.

3. Demonstration of conformity with the general safety and performance requirements shall ~~be based on~~ **include a** clinical **evaluation** ~~evidence~~ in accordance with Article 47.

4. Devices that are manufactured and used within a single health institution shall be considered as being put into service.

5. With the exception of Article 59(4) **and the relevant general safety and performance requirements set out in Annex I,** the requirements of this Regulation shall not apply to devices ~~classified as class A, B and C, in accordance with the rules set out in Annex VII, and~~ manufactured and used only within a single health institution, provided **the following conditions are met:**

   (a) manufacture and use **of the device** occur solely under ~~the health institution's~~ ***a*** single quality management system, ~~and~~

(b) the health institution is ~~compliant with~~ **accredited to** standard EN ISO 15189 or any other equivalent recognised standard~~. Member States may require that the health institutions submit to~~

(c) the **recipient patient or patient group's specific needs cannot be met by a device available on the market,**

(d) **the health institution provides information on the use of such devices to their** competent authority**, which shall include a justification of their manufacturing, modification or use.**

Member States shall make publically available a list of ***all*** such devices which have been manufactured and used on their territory**. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices in relation to aspects that are not covered by this Regulation** and may make the manufacture and use of the devices concerned subject to further safety requirements.

~~Devices classified as class D in accordance with the rules set out in Annex VII, even if manufactured and used within a single health institution, shall comply with the requirements of this Regulation. However, the provisions regarding CE marking set out in Article 16 and the obligations referred to in Articles 21 to 25 shall not apply to those devices.~~

~~The Commission shall be empowered to adopt delegated acts in accordance with Article 85, 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.~~

These provisions do not apply to devices which are manufactured on an industrial scale and which are used within the framework of a commercial diagnostic service.

Article 4a

Genetic information, counselling and informed consent

1. **A device may only be used for the purpose of a genetic test in the premises of an accredited according to ISO 15189 and 17025 or equivalent standard(s) labouratory if the referral is granted by persons admitted to the medical profession under the applicable national legislation after a personal consultation.**

2. **A device may be used for purposes of a genetic test only in a way that the rights, safety and well-being of the subjects are protected and that the clinical data generated in the course of the genetic testing are going to be reliable and robust.**

3. **Information: Before using a device for the purpose of a genetic test the person mentioned in paragraph 1 shall provide the person concerned with appropriate information on the nature, the significance and the implications of the genetic test.**

4. **Genetic counselling: Appropriate genetic counselling is mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. It shall include medical, ethical, social, psychological and legal aspects and has to be addressed by physicians, geneticists and bio-scientists qualified in genetic counselling.**

   The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family, including possible implications concerning procreation choices.

5. **Consent: A device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally.**

6. **Testing of minors: In case of minors the informed consent of the parents or legal representative shall be obtained; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor. In case of incapacitated adults not able to give informed legal consent, the informed consent of the legal representative shall be obtained; consent must represent the presumed will and may be revoked at any time, without detriment to the person.**

7. **A device may only be used for the determination of sex in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender specific hereditary diseases. By way of derogation from Article 2(1) and (2) this also applies to products which are not intended to fulfil a specific medical purpose.**

8. **The direct-to-patient making available on the market of genetic self-test devices is prohibited.**

9. **The above provisions on the use of devices for the purpose of genetic tests do not prevent the Member States from maintaining or introducing for reasons of health protection or reasons of public health and order more stringent national legislation in this field**

Article 5

Distance sales

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation at the latest when the device is placed on the market.

2. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but is used in the context of a commercial activity, **whether in return for payment or free of charge**, for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication**, directly or through intermediaries,** to a natural or legal person established in the Union shall comply with this Regulation.

3. **Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.**

4. **A Member State on grounds of protection of public health, may require ~~from~~ the natural or legal person providing information society services to ~~stop~~ cease its activity**.

Article 6

Harmonised standards

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

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

2. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia.

Article 7

Common ~~technical~~ specifications

1. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission**, after having consulted the MDCG and the MDAC,** shall be empowered to adopt common ~~technical~~ specifications (~~CTS~~ ***CS***) 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 evidence and post-market follow-up set out in Annex XII **or the requirements regarding clinical investigations set out in Annex XIII.** The ~~CTS~~ ***CS*** shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).

2. Devices which are in conformity with the ~~CTS~~ ***CS*** referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those C~~T~~S or parts thereof.

3. Manufacturers shall comply with the ~~CTS~~ ***CS*** unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.

Article 8

General obligations of the manufacturer

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

2. Manufacturers shall draw up **and keep up to date** the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.
The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.

3. Where compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance evaluation, shall draw up an EU declaration of conformity in accordance with Article 15, which shall accompany the device, and affix the CE marking of conformity to the device in accordance with Article 16.

4. Manufacturers shall comply with the obligations related to the UDI system referred to in Articles 24 and with the registration obligations referred to in Article 25.

5. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any amendments and supplements, issued in accordance with Article 43, available to the competent authorities for a period of at least five ten years after the last device covered by the declaration of conformity 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, **the manufacturer shall provide the full technical documentation and/or** a summary technical documentation (STED) and grant access to the full technical documentation upon request.

6. 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~~ **Manufacturers** of devices, other than devices for performance evaluation, shall institute**, document, implement** and keep up to date a quality management system that ~~shall address at least~~ **that minimizes the possibility of non-conformance to the provisions of this regulation in** ~~least~~ the ~~following aspects~~ **most effective manner.**

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

(a) **QMS shall address at least the following aspects: a strategy for regulatory compliance, including compliance with conformity assessment procedures and management change;**

(b) **identification of applicable general safety and performance requirements and exploration of options to address these;**

(c) the responsibility of the management;

(d) resource management, including selection and control of suppliers and ~~sub-contractors~~**subcontractors;**

(e) **[risk management according to section I.2 of Annex I];**

(f) **clinical evaluation, according to Art. 47 and Annex XII, including post-market clinical follow-up**;

(g) product realisation**, including planning, design, development, production and service provision;**

(h) **control of the UDI-Code assignments to all relevant devices ensuring consistency of information provided according to article 23;**

(i) **setting-up, implement and maintain a systematic post-market surveillance plan according to Art.xx;**

(j) **handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;**

(k) **[processes for reporting of serious incidents and field safety corrective actions in the context of vigilance];**

(l) **management of corrective and preventive actions and verification of their effectiveness**;

(m) processes for monitoring and measurement of output, data analysis and product improvement.

7. ~~Proportionate to the risk class and the type of device, manufacturers~~ **Manufacturers** of devices shall ~~institute~~ **implement** 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 follow-up in accordance with Part B of Annex XII. Where post-market 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 **inform the notified body concerned including immediate notification to Eudamed as established by Article 25**.

The manufacturer shall draw-up an annual report setting out the results of post-market surveillance. That report shall be part of the technical documentation

8. Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 17 of Annex I in an official Union language which can be easily understood by the intended user. 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. **The particulars on the label shall be easily legible, clearly comprehensible and indelible**.

For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the language(s) of the Member State where the device reaches its intended user.

9. 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 **accordingly** the distributors and, where applicable, the authorised representative ~~accordingly~~ **and the importers**.

10. 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~~**The competent authority may make a request that the manufacturer provide free samples of the device or, where impracticable, grant access to the device. Manufacturers** 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.
If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may suspend the incriminated device until its demonstration of conformity to the essential requirements.

11. Where manufacturers have their devices designed and manufactured by another legal or natural person, the information on the identity of that person shall be part of the information to be submitted in accordance with Article 23.

12. **In case of bankruptcy of the manufacturer, the manufacturer or his authorised representative shall provide all the technical documentation and the post-market surveillance plan of devices which he has placed on the market or for which he has been designated by the competent authority of the Member State in which he is established.**

13. **Manufacturers of medical devices shall have an insurance or equivalent financial guarantee to cover any damage to health due to safety problems of medical devices. They shall also assume the costs of removal, repair or replacement of products deriving from these situations.**

Article 9

Authorised representative

1. 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.

2. 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.

3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative. **The authorised representative shall provide a copy of the mandate to the importer, pursuant to Article 11(2)(a), and, upon request, to the competent authority.**
   The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:

   (a) ~~keep~~**keep at his registered place of business** a **copy of** the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any ~~supplement~~ **amendments and supplements** issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);

   (b) **comply with the registration obligations laid down in Article 23(2), (4) and (5);**

   (c) 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 **in an official Union language which can be easily understood by that authority**;

   d. forward to the manufacturer any request by a competent authority for samples, or access to a device and verify that the competent authority receives the samples or gets access to the device;

(e) cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;

(f) 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;

(g) 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 **permanently available and rapid** access to the necessary documentation in one of the official Union languages **which can be easily understood by the authorised representative**.

4. 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).

5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

6. Any reference in this Regulation to the competent authority of the Member State where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.

Article 10

Change of authorised representative

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

(a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;

(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional **sales** material~~;~~**(s) or statement(s);**

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or to the incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as authorised representative.

Article *11*

General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.

In order to place a device on the market importers shall ~~ensure~~ **verify** the following:

~~that the appropriate conformity assessment procedure has been carried out by the manufacturer;~~

(a) that an authorised representative in accordance with Article 9 has been designated by the manufacturer **and that the authorised representative is notified of the devices that the importer is placing on the market**;

(b) that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer;

(c) that the device bears the required CE marking of conformity;

(d) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use and EU declaration of conformity;

(e) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 22.

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market until it has been brought into conformity. ~~Where the device presents a risk~~, the **The** importer shall inform the manufacturer and**, where applicable,** his authorised representative to that effect, as well as**, of any suspected non-conformities and, where the device presents a risk, he shall also inform** the competent authority of the Member State in which he is established.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or**, where that is not possible for practical reasons,** on its packaging or**, where impracticable,** in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall ~~ensure~~**verify** that the device is registered in the electronic system in accordance with Article 23(2).~~)~~**, comply with their obligations laid down in paragraphs 3 to** 5 **of that Article and add their details to that registration. Importers shall also verify that the registration includes details on the authorised representative and shall inform the relevant authorised representative if it is not the case.**

5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I **and shall comply with the conditions set by the manufacturer, where available**.

6. ~~When deemed appropriate~~

Where a risk has been identified 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~~**. They shall** keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and ~~shall keep~~**provide** the manufacturer, authorised representative and distributors informed ~~of such monitoring.~~ **with any information requested by them**.

7. Importers who consider or have reason to believe that a device which they have ~~placed~~**made available** on the market is not in conformity with this Regulation shall immediately inform the manufacturer and**, where applicable,** his authorised representative and, if**. Where** appropriate, ~~take~~**importers shall co-operate with the manufacturer and, where applicable, his authorised representative or the competent authorities to ensure that** the necessary corrective action to bring that device into conformity, withdraw or recall it **is taken**. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.

8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have ~~placed~~**made available** on the market shall immediately forward this information to the manufacturer and his authorised representative**, as well as the competent authorities of the Member States where he is aware that the device has been made available**.

9. 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 43, 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.~~**and mandate between the manufacturer and authorised representative at the disposal of the market surveillance authorities.**

10. 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 national authority may make a request that** the ~~authorised representative for~~ **importer provide free samples of** the device in question ~~provides~~**or, where impracticable, grant access to** the ~~required information~~**device**. 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. **In the context of their activities,** ~~W~~ **w**hen making a device available on the market, distributors shall act with due care in relation to the requirements applicable **and make available on the market only those devices that are in conformity with this Regulation**.

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;- **and is accompanied by the required EU declaration of conformity;**
   (b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(~~7~~**x**);
   (c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 22 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 ~~as~~**of any suspected non-conformities and, if the device presents a risk, he shall also inform** 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 **and shall comply with the conditions set by the manufacturer, where available.** .

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~~**. Where appropriate, distributors shall co-operate with the manufacturer and, where applicable his authorised representative and the importer, and with any competent authority to ensure** 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, **and, where applicable, the notified body that issued a certificate for the device in accordance with Article 43**, 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**, as well as the competent authorities of the Member States in which they are aware that device has been made available. They shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative informed of such monitoring and provide them with any information upon their request**.

6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation 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. **The competent authority may also request that the distributor provide, free samples of the device or, where impracticable, grant access to the device.**

Article 13

Person responsible for regulatory compliance

1. Manufacturers shall have ~~available within~~ **permanently and continuously at** their ~~organisation~~**disposal,** at least one ~~qualified~~ person **responsible for regulatory compliance** who possesses expert knowledge in the field of *in vitro* diagnostic 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~~**a course recognized as** equivalent ~~course of study, in natural sciences,~~ **by the Member States concerned, in** medicine, pharmacy, engineering or another relevant ~~discipline~~**sciences**, and at least two years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic ~~medical~~ devices;
   (b) five years of professional experience in regulatory affairs **related to devices including experience** in quality management systems relating to *in vitro* diagnostic ~~medical~~ devices.

2. The qualified person **responsible for regulatory compliance** shall at least be responsible for ensuring the following matters:
   (a) that the conformity of the devices is appropriately ~~assessed~~**checked in accordance with the quality system under which these devices are manufactured** 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 post-market surveillance obligations according in accordance with Article8(x) that the existing information concerning risks connected to devices is collected and evaluated and the necessary measures are co-ordinated as well as** (c) that the reporting obligations in accordance with Articles 59 to 64 **concerning risks related to devices** are fulfilled

d) in the case of investigational devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects, that the statement referred to in Section 4.1 of Annex XIII is issued;

(e) **collection and evaluation of existing information concerning risks connected to devices and co-ordination the necessary measures. He/she is responsible for the fulfilment of reporting obligations in so far as they concern risks related to devices**

3. The ~~qualified~~ person **responsible for regulatory compliance** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

4. Authorised representatives shall have available within their organisation at least one ~~qualified~~ person **responsible for regulatory compliance** who possesses expert knowledge regarding the regulatory requirements for *in vitro* diagnostic 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 *in vitro* diagnostic medical devices;

(b) five years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

Article 14

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

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if he does any of the following:
   (a) makes available on the market a device under his name, registered trade name or registered trade mark;
   (b) changes the intended purpose of a device already placed on the market or put into service;
   (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

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

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

3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where that is not ~~possible~~**impracticable**, on its packaging or in a document accompanying the device.

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

4. 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 27, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

Article 15

EU declaration of conformity

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

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.

3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.

Article 16

CE marking of conformity

1. Devices, other than devices for performance evaluation, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex IV [**accompanied by the indication "*in-vitro diagnostic* medical device", in accordance with Annex xx.]**

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided.

4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 40. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.

6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.

Article 17

Devices for special purposes

1. Member States shall not create any obstacle to devices for performance evaluation which are supplied for that purpose to labouratories or other institutions, if they meet the conditions laid down in Articles 48 to 58.

2. Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 52.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided such devices are not used on specimens taken from the participants and **the expression "demonstration devices" is visibly affixed on those devices** 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 18

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;
   – medical devices bearing the CE marking in conformity with Regulation (EU) [Ref. of future Regulation on medical devices];
   – other products which are in conformity with the legislation applicable to those products **only when they are used within the medical procedure or their presence in the system or procedure pack is justified**.

2. In the statement, the person referred to in paragraph 1 shall declare the following:
   a) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions;
   b) that he packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;
   c) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market **in his own name** shall, at his choice, follow one of the procedures referred to in Annex VIII or in 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 the 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 40.

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 17 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 19

Parts and components

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

2. ~~An article that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics of the device shall be considered a device.~~

Article 20

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.

Article 20a

Promotion

1. Where medical devices are being promoted, no gifts, pecuniary advantages or benefits in kind may be supplied, offered, promised or accepted, unless they are inexpensive and relevant to the practice of medicine.

2. Hospitality at events for purely professional and scientific purposes or at sales promotion events shall always be strictly limited to the main objective of the event and to what is strictly necessary to attend said event.

3. Services rendered by healthcare professionals as part of the marketing or promotion of medical devices, shall be based on a written agreement detailing at least the exact nature of the services and remuneration. Remuneration shall be proportionate to the services rendered.

4. Existing measures and trade practices in Member States relating to prices, margins and discounts shall not be affected by paragraphs 1, 2 and 3. 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.

Chapter III

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

Article 21

Identification within the supply chain

For **all** devices, other than devices for performance evaluation, 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~~**economic operators** shall inform the competent authorities thereof.

For procedure packs, this Article shall also apply to the natural or legal person referred to in Article 18(1).

Article 22

Unique device identification system

1. For devices, other than devices for performance evaluation, 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 **its packaging and, where applicable, on the device itself**;

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~~**a maximum of five** 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~~**five** 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**, its packaging, and, where applicable, on the device itself**, 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 59. The device identifier shall appear on the EU declaration of conformity referred to in Article ~~17~~**15**and in the technical documentation referred to in Annex II. 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, **as determined by a measure referred to in point (b) of paragraph 7. Health institutions shall store and keep, by electronic means, the device identifier and the production identifier of the devices which 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~~**b**) of paragraph ~~7~~**9.**

5. 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.

6. The Commission shall be empowered to adopt ~~delegated~~ **implementing** acts in accordance with **the examination procedure referred to in with** Article 85:
   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, **higher levels of packaging and on the device itself, ,** storage of information **by the economic operator and** in the electronic system on UDI, and use of the UDI in documentation and reporting related to the device provided for in this Regulation;

(2) **defining the devices, categories or groups of devices for which storage of the device identifier and production identifier by electronic means shall be required by healthcare institutions;**

a) **The Commission shall be empowered to adopt delegated acts in accordance with Article 85** amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress.

7. When adopting the measures referred to in paragraph ~~7~~**9**, 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.

the need to avoid duplications in the UDI system.

Article 23

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~~ **procedure packs other than for professional use only, and to identify economic operators involved in the supply chain of 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 **manufacturer and, where applicable, the authorised representative and the importer** economic operators are laid down in Part A of Annex V**. Distributors shall identify themselves in the system by introducing their name, address and contact details.**

2. Before a device, other than a device for performance evaluation, 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 device for performance evaluation, on the market, importers shall submit to **verify that the device registered in** the electronic system the information referred to in **in accordance with** paragraph ~~1.~~**2 and shall add their details to that registration. Importers shall also verify that the registration includes the details of the authorised representative and shall inform the relevant authorised representative if this is not the case.**

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~~**85** amending the list of information to be submitted as set out in Part A of Annex V in the light of technical progress.

Article 24

Summary of safety and performance

1. In the case of devices classified as class C and D, other than devices for performance evaluation, **and devices emitting ionizing radiation** the manufacturer shall draw up a summary of safety and performance. It shall be written in a way that is clear to the intended user **and, if relevant, to the patient and shall be available to the public via Eudamed**. The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article **40** and shall be validated by that body.**The manufacturer shall provide the summary with the device or otherwise mention on the label where it is available. The summary of safety and performance shall include at least the following aspects:**

(a) the intended purpose of the device;

(b) a description of the accessories, other IVD medical devices and other products that are not IVD medical devices, which are intended to be used in combination with the IVD medical device;

(c) the limitations of the device;

(d) the scientific validity;

(e) the analytical performance;

(f) the metrological traceability of assigned values;

(g) the clinical performance;

(h) the clinical evidence;

(i) the intended clinical benefit(s);

(j) the required training to users;

(k) information on any residual risks and any undesirable effects;

(l) storage conditions.

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 performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

Article 25

European databank

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

Eudamed shall include the following as integral parts:

a) the electronic system on UDI referred to in Article 22;

b) the electronic system on registration of devices and economic operators referred to in Article 23;

(c) <u>the electronic system on notified bodies referred to in Article 31(9);</u>

d) the electronic system on information on certificates referred to in Article 43(4);

e) the electronic system on interventional clinical performance studies and clinical performance studies involving risks for the subjects set up in Article 51;

f) the electronic system on vigilance referred to in Article 60;

g) the electronic system on market surveillance referred to in Article 66.

ANNEX II

Proposal for a Regulation on medical devices

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

1. A device may be ~~placed~~ **made available** on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.

3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 49.

4. Devices that are manufactured and used within 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~~ **only within the facilities of that health institution. Health institutions shall keep a list of these devices available to the competent authority of the Member State on their territory of which they are established**.

5. 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

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

Article 6

Harmonised standards

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

2. 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.

3. 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**, the references of which have been published in the Official Journal of the European Union.**

Article 7

Common ~~technical~~ specifications

1. Where no harmonized standards exist or where relevant harmonised standards are not sufficient, the Commission**, after having consulted the MDCG and the MDAC,** shall be empowered to adopt common ~~technical~~ specifications (~~CTS~~**CS**) 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 **or the requirements regarding clinical investigations set out in Annex XIV.** The ~~CTS~~**CS** shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).

2. Devices which are in conformity with the ~~CTS~~**CS** referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those ~~CTS~~**CS** or parts thereof.

3. Manufacturers shall comply with the ~~CTS~~**CS** unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.

Article 8

General obligations of the manufacturer

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

2. Manufacturers shall draw up **and keep up to date** the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.

   1. 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.

3. 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**, which shall accompany the device,** and affix the CE marking of conformity **to the device** in accordance with Article 18.

4. Manufacturers shall comply with the obligations related to the UDI system referred to in Articles 24 and with the registration obligations referred to in Article 25.

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

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

6. 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~~**CS** 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~~ **Manufacturers** of devices, other than custom-made or investigational devices, shall institute**, document, implement** and keep up to date a quality management system that ~~shall address at least~~**that minimizes the possibility of non-conformance to the provisions of this regulation in** the ~~following aspects:~~ **most effective manner.**

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

The QMS shall address at least the following aspects:

- **(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and management change;**
- **(b) identification of applicable general safety and performance requirements and exploration of options to address these;**
- **(c)** the responsibility of the management;
- **(d)** resource management, including selection and control of suppliers and ~~sub-contractors~~**subcontractors;**
- **(e) risk management according to section I.2 of Annex I;**
- **(f) clinical evaluation, according to Art. 49 and Annex XIII, including post-market clinical follow-up**;
- **(g)** product realisation**, including planning, design, development, production and service provision;**
- **(h) control of the UDI-Code assignments to all relevant devices ensuring consistency of information provided according to article 25;**
- **(i) setting-up, implement and maintain a systematic post-market surveillance plan according to Art.xx;**

(j) **handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;**

(k) **processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;**

(l) **management of corrective and preventive actions and verification of their effectiveness**;

(m) processes for monitoring and measurement of output, data analysis and product improvement.

~~Proportionate to the risk class and the type of device, manufacturers~~

7. **Manufacturers** of devices, other than custom-made devices, shall ~~institute~~**implement** 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'~~**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 **inform the notified body concerned including immediate notification to Eudamed as established by Article 27**.

The manufacturer shall draw-up an annual report setting out the results of post-market surveillance. That report shall be part of the technical documentation

8. 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. The particulars on the label shall be easily legible, clearly comprehensible and indelible.

9. 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 **accordingly** the distributors and, where applicable, the authorised representative ~~accordingly~~**and the importers**.

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

10. 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~~**The competent authority may make a request that the manufacturer provide free samples of the device or, where impracticable, grant access to the device. Manufacturers** 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. **If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may suspend the incriminated device until its demonstration of conformity to the essential requirements.**

11. 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.

12. In case of bankruptcy of the manufacturer, the manufacturer or his authorised representative shall provide all the technical documentation and the post-market surveillance plan of devices which he has placed on the market or for which he has been designated by the competent authority of the Member State in which he is established.

13. Manufacturers of medical devices shall have an insurance or equivalent financial guarantee to cover any damage to health due to safety problems of medical devices. They shall also assume the costs of removal, repair or replacement of products deriving from these situations.

Article 9

Authorised representative

1. 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.

2. 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.

3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative. **The authorised representative shall provide a copy of the mandate to the importer, pursuant to Article 11(2)(a), and, upon request, to the competent authority.**

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

a. ~~keep~~**keep at his registered place of business a copy of** the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any ~~supplement~~**amendments and supplements** issued in accordance with Article 45 at the disposal of competent authorities for the period referred to in Article 8(4);

b. comply with the registration obligations laid down in Article 25(2), (4) and (5);

c. 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 **in an official Union language which can be easily understood by that authority**;

d. forward to the manufacturer any request by a competent authority for samples, or access to a device and verify that the competent authority receives the samples or gets access to the device;

e. cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;

f. 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;

g. terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.

To allow **for** the authorised representative to fulfill the tasks mentioned in this paragraph, the manufacturer shall at least ensure that the authorised representative has ~~permanent immediate~~ **permanently available and rapid** access to the necessary documentation in one of the official Union languages **which can be easily understood by the authorised representative**.

4. 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).

5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

6. Any reference in this Regulation to the competent authority of the Member State where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.

Article 10

Change of authorised representative

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

(a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;

(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional **sales** material~~;~~**(s) or statement(s);**

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as authorised representative.

Article 11

General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.

2. **In order to place** a device on the market importers shall ~~ensure~~ **verify** the following:

   ~~a) that the appropriate conformity assessment procedure has been carried out by the manufacturer;~~

   a) that an authorised representative in accordance with Article 9 has been designated by the manufacturer **and that the authorised representative is notified of the devices that the importer is placing on the market**

   b) that the EU declaration of conformity ~~and the technical documentation~~ has been drawn up by the manufacturer;

   c) that the device bears the required CE marking of conformity;

   d) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use ~~and EU declaration of conformity~~;

   e) 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~~ **The** importer shall inform the manufacturer and**, where applicable,** his authorised representative ~~to that effect, as well as~~**, of any suspected non-conformities and, where the device presents a risk, he shall also inform** the competent authority of the Member State in which he is established.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or**, where that is not possible for practical reasons,** on its packaging or**, where impracticable,** in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall ~~ensure~~**verify** that the device is registered in the electronic system in accordance with Article 25(2~~).~~ **), comply with their obligations laid down in paragraphs 3 to 5 of that Article and add their details to that registration. Importers shall also verify that the registration includes details on the authorised representative and shall inform the relevant authorised representative if it is not the case.**

5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I **and shall comply with the conditions set by the manufacturer, where available**.

~~6 When deemed appropriate~~

6. **Where a risk has been identified** 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,~~ **and** investigate complaints ~~and~~**. They shall** keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and ~~shall keep~~**provide** the manufacturer, authorised representative and distributors ~~informed of such monitoring.~~ **with any information requested by them.**

7. Importers who consider or have reason to believe that a device which they have ~~placed~~**made available** on the market is not in conformity with this Regulation shall immediately inform the manufacturer and**, where applicable,** his authorised representative ~~and, if~~**. Where** appropriate, ~~take~~**importers shall co-operate with the manufacturer and, where applicable, his authorised representative or the competent authorities to ensure that** the necessary corrective action to bring that device into conformity, withdraw or recall it **is taken**. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 45 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.

8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have ~~placed~~**made available** on the market shall immediately forward this information to the manufacturer and his authorised representative**, as well as the competent authorities of the Member States where he is aware that the device has been made available**.

9. 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.~~**and mandate between the manufacturer and authorised representative at the disposal of the market surveillance authorities.**

10. 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 national authority may make a request that** the ~~authorised representative for~~ **importer provide free samples of** the device ~~in question provides~~**or, where impracticable, grant access to** the ~~required information~~**device**. 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. **In the context of their activities,** ~~W~~**w**hen making a device available on the market, distributors shall act with due care in relation to the requirements applicable **and make available on the market only those devices that are in conformity with this Regulation.**

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~~;~~ **and is accompanied by the required EU declaration of conformity;**

b. the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(~~7~~**x**);

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~~**The** distributor shall inform the manufacturer and, where applicable, his authorised representative and the importer ~~to that effect, as well as~~**of any suspected non-conformities and, if the device presents a risk, he shall also inform** 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 **and shall comply with the conditions set by the manufacturer, where available.**

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~~**. Where appropriate, distributors shall co-operate with the manufacturer and, where applicable his authorised representative and the importer, and with any competent authority to ensure** 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**, and, where applicable, the notified body that issued a certificate for the device in accordance with Article 45**, 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**, as well as the competent authorities of the Member States in which they are aware that device has been made available. They shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative informed of such monitoring and provide them with any information upon their request**.

6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation 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. **The competent authority may also request that the distributor provide, free samples of the device or, where impracticable, grant access to the device.**

Article 13

Person responsible for regulatory compliance

1. Manufacturers shall have ~~available within~~ **permanently and continuously at** their ~~organisation~~**disposal,** at least one ~~qualified~~ person **responsible for regulatory compliance** 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~~**a course recognized as** equivalent ~~course of study, in natural sciences,~~ **by the Member States concerned, in** medicine, pharmacy, engineering or another relevant ~~discipline~~**sciences**, 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~~ **related to devices including experience** 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[1].~~

2. The ~~qualified~~ person **responsible for regulatory compliance** shall at least be responsible for ensuring the following matters:

(a) that the conformity of the devices is appropriately ~~assessed~~**checked in accordance with the quality system under which these devices are manufactured** 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 post-market surveillance obligations according in accordance with Article8(x)**

(d) **that the existing information concerning risks connected to devices is collected and evaluated and the necessary measures are co-ordinated as well as** that the reporting obligations in accordance with Articles 61 to 66 **concerning risks related to devices** are fulfilled;

(e) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued;

(f) **collection and evaluation of existing information concerning risks connected to medical devices and co-ordination the necessary measures. He/she is responsible for the fulfilment of reporting obligations in so far as they concern risks related to devices**

3. The ~~qualified~~ person **responsible for regulatory compliance** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

4. Authorised representatives shall have available within their organisation at least one ~~qualified~~ person **responsible for regulatory compliance** 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~~**impracticable**, on its packaging or in a document accompanying the device.

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

4. 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~~**Reprocessing of medical** devices~~ and their reprocessing~~*

1. Any natural or legal person who reprocesses a ~~single-use~~ device to make it suitable ~~for further use~~**to be made available on the market** 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. **The in-house manufacture obligations' exemptions of Art. 4(4) shall apply.**

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**, subject to any national provisions adopted in accordance with paragraph 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.~~

~~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).~~

~~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.~~

3. **For the purposes of this Article, and with a view to ensuring the safety of patients, users and third parties, MS may adopt provisions governing the proper reprocessing and use of medical devices, having regard, in particular to the utilisation of suitably validated procedures, the success of which can be verified**

~~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.~~

4. 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 **on the market** of reprocessed single-use devices.

5. Member States shall notify the Commission and the other Member States of the national provisions and the grounds for introducing them **pursuant of (3) & (4).** The Commission shall keep the information publicly available.

6. **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 enabling the health professional to suitably apprise the patient that a reprocessed medical device will be used on him.**

7. **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.**

Article 16

~~Implant card~~***Patient implant card and information leaflet***

1. The manufacturer of an implantable device shall provide together with the device an implant card **and an information leaflet** which shall be made available to the particular patient who has been implanted with the device.

2. ~~This~~**The** card**, which shall have the size of an identification card, to be permanently carried by the patient,** shall contain the following:
   (a) the information allowing identification of the device, including the **device name, serial number, batch code or lot number, the** Unique Device Identification**, as well as the name and address of the manufacturer**;
   (b) fields for entries to be made post-implantation by the health institution, specifying the patient's name, the date of implantation and the name of the responsible person as well as the institution carrying out the implantation;
   (c) list of the medical examinations that the patient should avoid or warn those performing them.

3. The information leaflet shall contain the following information:
   (a) the device name, as well as the name and address of the manufacturer;
   (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

4. The information **in the implant card and the information leaflet** shall be written in a way that is readily understood by a lay person. **Both documents shall be at least in the official language and, where applicable, languages of the Member State(s) where the device is made available on the market or put into service. The content of all language versions must be identical.**

5. The Commission, by means of implementing acts, shall establish a list of categories or groups of devices to which this Article shall not apply. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88 (3).

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 **accompany the device and** be translated into ~~the~~**an** official Union language or languages required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.
3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.

Article 18

CE marking of conformity

1. Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, ~~as presented in Annex IV.~~**accompanied by the indication "medical device", in accordance with Annex xx.**

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 **that such devices are not used on participants and the expression "demonstration devices" is visibly affixed on those devices** a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.

Article 20

Systems and procedure packs

1. Any natural or legal person shall draw up a statement referred to in paragraph 2 if he puts devices bearing the CE marking together with the following other devices or products, in accordance with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:

   (a) other devices bearing the CE marking;

   (b) *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) **[…/…]with the exemption of devices for self-testing;**

   (c) other products which are in conformity with the legislation applicable to those products **only when they are used within the medical procedure or their presence in the system or procedure pack is justified**.

2. In the statement, the person referred to in paragraph 1 shall declare the following:

   (a) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions;

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

   (c) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market **in his own name** shall, at his choice, follow one of the procedures referred to in Annex VIII or in Part A of Annex X. The application of those Annexes and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile package is opened or damaged. The person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.

4. Where the system or procedure pack incorporate devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, **or where the sterilisation has not been carried out in accordance with the manufacturer's instructions** the system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant conformity assessment procedure pursuant to Article 42.

5. The systems or procedure packs referred to in paragraph 1shall 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 1and 3 as well as the address at which he can be contacted and his location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 19 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable to the devices put together in accordance with Article 8(4). Where these periods differ, the longest period shall apply.

Article 21

Parts and components

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~~ **Supporting** evidence shall be kept available to the competent authorities of the Member States.

~~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.

Article 22a

Promotion

1. **Where medical devices are being promoted, no gifts, pecuniary advantages or benefits in kind may be supplied, offered, promised or accepted, unless they are inexpensive and relevant to the practice of medicine.**
2. **Hospitality at events for purely professional and scientific purposes or at sales promotion events shall always be strictly limited to the main objective of the event and to what is strictly necessary to attend said event.**
3. **Services rendered by healthcare professionals as part of the marketing or promotion of medical devices, shall be based on a written agreement detailing at least the exact nature of the services and remuneration. Remuneration shall be proportionate to the services rendered.**
4. **Existing measures and trade practices in Member States relating to prices, margins and discounts shall not be affected by paragraphs 1, 2 and 3. 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.**

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 **all** 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~~**economic operators** shall inform the competent authorities thereof. **For procedure packs, this provision shall also apply to the natural or legal person referred to in Article 20(1).**

Article 24

Unique Device Identification system

1. For devices, other than ~~custom-made and investigational~~ devices **for performance evaluation**, 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:

   b. 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.

c. placement of the UDI on the label of the device **its packaging and, where applicable, on the device itself**;

d. storage of the UDI by the economic operators and the health institutions through electronic means;

e. establishment of an electronic system on UDI.

2. The Commission shall designate ~~one or several~~**a maximum of five** 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~~**five** 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**, its packaging, and, where applicable, on the device itself**, 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~~**59**. The device identifier shall appear on the EU declaration of conformity referred to in Article ~~17~~**15** 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, **as determined by a measure referred to in point (b) of paragraph 7. Health institutions shall store and keep, by electronic means, the device identifier and the production identifier of the devices which 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~~**b**) of paragraph ~~7.~~**9.**

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.

The requirements in paragraphs 1-6 shall apply as follows:

a. to implantable and class III devices from one year after the entry into force of delegated acts referred to in points (a) and (b) of paragraph 9 but no earlier than [three years after entry into force of this Regulation];

b. to class IIb devices from two years after the entry into force of delegated acts referred to in points (a) and (b) of paragraph 9 but no earlier than [three years after entry into force of this Regulation];

c. to class IIa devices from four years after the entry into force of delegated acts referred to in points (a) and (b) of paragraph 9;

d. to class I devices from six years after the entry into force of delegated acts referred to in points (a) and (b) of paragraph 9.

7. **In order to ensure the uniform application of the rules laid down in this Chapter, t**~~T~~he Commission **may** adopt ~~delegated~~ **implementing** acts in accordance with **the examination procedure referred to in with** Article **88(3)** ~~89:~~

~~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;~~

a. 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;

b. 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, **higher levels of packaging and on the device itself, ,** storage of information **by the economic operator and** in the electronic system on UDI, and use of the UDI in documentation and reporting related to the device provided for in this Regulation;

c. defining the devices, categories or groups of devices for which storage of the device identifier and production identifier by electronic means shall be required by healthcare institutions;

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 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~~**9**, 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.

f. the need to avoid duplications in the UDI system.

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 economic operators involved in the supply chain of** 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 **manufacturer and, where applicable, the authorised representative and the importer** economic operators are laid down in Part A of Annex V**. Distributors shall identify themselves in the system by introducing their name, address and contact details**.

2. Before a device, other than a ~~custom-made or investigational~~ device **for performance evaluation**, 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 **for performance evaluation**, on the market, importers shall ~~submit to~~ **verify that the device registered in** the electronic system ~~the information referred to in~~ **in accordance with** paragraph ~~1.~~ **2 and shall add their details to that registration. Importers shall also verify that the registration includes the details of the authorised representative and shall inform the relevant authorised representative if this is not the case.**

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. **No** 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~~**85** 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, **and devices emitting ionizing radiation** other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance. It shall be written in a way that is clear to the intended user **and, if relevant, to the patient and shall be available to the public via Eudamed.** The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 42 and shall be validated by that body. **The manufacturer shall provide the summary with the device or otherwise mention on the label where it is available. The summary of safety and performance shall include at least the following aspects:**

   (a) the intended purpose of the device;

   (b) a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device;

   (c) the limitations of the device;

   (d) the clinical performance;

   (e) the clinical evidence;

   (f) the intended clinical benefit(s) ;

   (g) the required training to users

   (h) information on any residual risks and any undesirable effects;

   (i) storage conditions.

2. The Commission may, by means of implementing ~~delegated~~ 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 ~~and extend the scope of devices for which the summary referred to in paragraph 1 is required. Those delegated~~ 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) <u>the electronic system on notified bodies referred to in Article 33(9);</u>
   (d) the electronic system on information on certificates referred to in Article 45(4);
   (e) the electronic system on clinical investigations referred to in Article 53,
   (f) the electronic system on vigilance referred to in Article 62;
   (g) 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 **without prejudice to the national laws and regulations regarding public access to documents.**

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 ~~delegating~~ acts, lay down the modalities necessary for the development and management of Eudamed. Those implementing ~~delegating~~ 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.