Regulation of Medical Devices

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This article explores the placing or making available on the market of **medical devices**, accessories for medical devices and products ('**devices**') in the European Union ('Union') in accordance with Regulation (EU) 2017/745 ('**Regulation**') on devices. A couple of articles came into force in November 2017 and one in May 2018, the remainder of the Regulation is due to come into force on 26 May 2020. The Regulation excludes ***in vitro* diagnostic devices**. For the **purpose of this Regulation**, the activities of distributors include acquisition, holding and supplying of devices.

1. Introduction

According to Article 1, the Regulation applies to:

- Placing of devices on the market;
- Making devices available on the market;
- Putting into service devices for human use and accessories for such devices in the Union;
- Clinical investigations concerning such devices and accessories conducted in the Union;
- Groups of products without an intended medical purpose that are listed in Annex XVI, taking into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology;
- Devices utilising tissues or cells of animal origin, or their derivatives during manufacture, which are non-viable or are rendered non-viable.

The Regulation does not apply to:

- In ***vitro* diagnostic medical devices** covered by Regulation (EU) 2017/746;
- Any device which, when placed on the market or put into service, incorporates as an integral part an *in vitro* diagnostic medical device;
- Medicinal products;
- Any device which is **intended to administer a medicinal product**, unless it forms a single integral product which is intended exclusively for use in the given combination and which is not reusable;
- **Advanced therapy medicinal products** covered by Regulation (EC) No 1394/2007;
- **Human blood, blood products, plasma or blood cells of human origin or devices** which incorporate, when placed on the market or put into service, such blood products, plasma or cells with

certain exceptions;

- **Cosmetic products**;

- Transplants, tissues or cells of animal origin, or their derivatives, or products containing or consisting of them; or
- **Food**.

The Regulation harmonises the laws on medical devices. The laws relating to medical devices were revised to ensure:

> …' a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation'…this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. … this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods.

2. Placing a Device on the Market

2.1 You can only place a device on the market if it complies with the Regulation (Article 5). The Regulation has general safety regulations and you will have to conform with them.

> **Placing on the market and putting into service**
>
> 1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.
> 2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.
> 3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 61.
> 4. Devices that are manufactured and used within health institutions shall be considered as having been put into
> Service.
> 5…

3. General obligations of manufacturers

.1 Manufacturers must ensure that a device placed on the market has been designed and manufactured in accordance with the Regulation. *Article 10*

- 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.

- Establish, document, implement and maintain a system for risk management.

- Conduct a clinical evaluation.
- Draw up and keep up to date technical documentation.
- Draw up an EU declaration of conformity and affix the CE marking of conformity.

Article 19

EU declaration of conformity

1. The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.
2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires an EU 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. The declaration shall contain all the 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 is empowered to adopt delegated acts in accordance with Article 115 amending the minimum content of the EU declaration of conformity set out in Annex IV in the light of technical progress.

- Comply with the obligations relating to the UDI system.
- Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof. The authorised representative must have the necessary documentation permanently available.
- Where the device presents a serious risk, manufacturers shall immediately inform the competent authority.
- Have a system for recording and reporting of incidents and field safety corrective actions.
- Manufacturers shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device. Non-compliance may result in the prohibition or restriction of the device being withdrawn from the market or being recalled.

- ❖ Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.

Under Article 11, a manufacturer established outside the Union must have a representative in the Union to be able to place Devices on the market:

> **Authorised representative**
>
> 1. Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative.

In accordance with Article 13, importers must comply with certain obligations to be able to place Devices on the market.

Distributors also have to meet certain obligations when placing Devices on the market (Article 14):

> *Article 14*
>
> **General obligations of distributors**
>
> 1. When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.
>
> Before making a device available on the market, distributors shall verify that all of the following requirements are met

The Regulations stipulate that in certain circumstances the manufacturers, importers, distributors will have the same obligations (Article 15):

> *Article 16*
>
> **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 it does any of the following:
>
> (a) makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;
>
> (b) changes the intended purpose of a device already placed on the market or put into service;
>
> (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.
>
> The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in point (30) of Article 2, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.
>
> 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 23 of Annex I, relating to a device already placed on the market and of

further information which is necessary in order to market the device 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 device 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 packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

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

Distributors and importers shall ensure that they have 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 a 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. The quality management system shall cover, *inter alia*, 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 into conformity with this Regulation.

4. Claims on Devices

4.1 Any claims made on the label or instructions for use of a device cannot be misleading to consumers (users or patients) as prescribed by Article 7. The intended uses of the device must be in accordance with the conformity assessment carried out:

Claims

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

(a) **ascribing functions and properties to the device which the device does not have**;

(b) **creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have**;

(c) **failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose**;

(d) **suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out**.

5. Four Product Classes and Conformity Assessment

There are still four product classes:

It is necessary, in particular for the purpose of the conformity assessment procedures, to maintain the division of devices into four product classes in line with international practice. .

The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of vulnerability associated with such devices. For class IIa, class IIb and class III devices, an appropriate level of involvement of a notified body should be compulsory.

Article 51 addresses the classification of devices:

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

2. Any dispute between the manufacturer and the notified body concerned, arising from the application of Annex VIII, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in the last indent of point (b) of the second paragraph of Section 2.2 of Annex IX has its registered place of business. Where the notified body concerned is established in a Member State other than that of the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

3. At the request of a Member State the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:

(a) application of Annex VIII to a given device, or category or group of devices, with a view to determining the classification of such devices;

(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII.

4. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in points (a) and (b) of paragraph 3.

5. In order to ensure the uniform application of Annex VIII, and taking account of the relevant scientific opinions of

the relevant scientific committees, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

6. The implementing acts referred to in paragraphs 3, 4 and 5 of this Article shall be adopted in accordance with the

examination procedure referred to in Article 114(3).

Article 52 deals with conformity assessment procedures:

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

2. Prior to putting into service a device that is not placed on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

3. Manufacturers of class III devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Annex IX. Alternatively, the manufacturer may choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI.

4. Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per generic device group.

However, for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device.

Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex X coupled with a conformity assessment based on product conformity verification as specified in Annex XI.

5.Where justified in view of well-established technologies, similar to those used in the exempted devices listed in the

second subparagraph of paragraph 4 of this Article, being used in other class IIb implantable devices, or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend that list by adding other types of class IIb implantable devices to that list or removing devices therefrom.

6.Manufacturers of class IIa devices, other than custom-made or investigational devices, shall be subject to

a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device for each category of devices.

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

7.Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of

their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III. If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI. However, the involvement of the notified body in those procedures shall be limited:

(a) in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions;

(b) in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements;

(c) in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

8.Manufacturers of custom-made devices shall follow the procedure set out in Annex XIII and draw up the statement
set out in Section 1 of that Annex before placing such devices on the market.

In addition to the procedure applicable pursuant to the first subparagraph, manufacturers of class III custom-made implantable devices shall be subject to the conformity assessment as specified in Chapter I of Annex IX. Alternatively, the manufacturer may choose to apply a conformity assessment as specified in Part A of Annex XI.

9.In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7 of this Article, in the case of devices
referred to in the first subparagraph of Article 1(8), the procedure specified in Section 5.2 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

10.In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7 of this Article, in the case of devices
that are covered by this Regulation in accordance with point (f) or (g) of Article 1(6) and with the first subparagraph of Article 1(10), the procedure specified in Section 5.3 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

11.In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7, in the case of devices that are
composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the procedure specified in Section 5.4 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

12.The Member State in which the notified body is established may require that all or certain documents, including
the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 7 and 9 to 11 be made available in an official Union language(s) determined by that Member State. In the absence of such requirement, those documents shall be available in any official Union language acceptable to the notified body.

13. Investigational devices shall be subject to the requirements set out in Articles 62 to 81.

14. The Commission may, by means of implementing acts, specify detailed arrangements and procedural aspects with a view to ensuring the harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:

(a) the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in the third paragraph of Section 2.3 and in Section 3.5 of Annex IX in the case of class IIa and class IIb devices, and in Section 10.2 of Annex XI in the case of class IIa devices;

(b) the minimum frequency of unannounced on-site audits and sample tests to be conducted by

notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of the technical documentation and type examination in accordance with Sections 3.4 and 4.3 of Annex IX, Section 3 of Annex X and Section 15 of Annex XI.

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

6. Why categories of Products fall under the Regulation?

6.1 Borderline Cosmetic Products

The Regulation acknowledges that it is sometimes difficult to distinguish between a **borderline cosmetic product as a medical device** and proposes an EU wide reference for the categorisation of certain products:

Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility of taking a Union-wide decision regarding the regulatory status of a product should also be introduced in Regulation (EC) No 1223/2009 of the European Parliament and of the Council.

6.2 Products which combine a medicinal product or substance and a medical device

There are products which combine a medicinal product or substance and a medical device; such products will fall under the Regulation or Directive 2001/83/EC:

Products which combine a medicinal product or substance and a medical device are regulated either under this Regulation or under Directive 2001/83/EC of the European Parliament and of the Council. The two legislative acts should ensure appropriate interaction in terms of consultations during pre-market assessment, and of exchange of information in the context of vigilance activities involving such combination products. For medicinal products that integrate a medical device part, compliance with the general safety and performance requirements laid down in this Regulation for the device part should be adequately assessed in the context of the marketing authorisation for such medicinal products. Directive 2001/83/EC should therefore be amend…

6.3 Products similar to medical devices in terms of function

This Regulation also covers non-medical products similar to medical devices as well as products without an intended medical purpose:

Certain groups of products for which a manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation. In order for manufacturers to be able to demonstrate the conformity of such products, the Commission should adopt common specifications at least with

> regard to application of risk management and, where necessary, clinical evaluation regarding safety. Such common specifications should be developed specifically for a group of products without an intended medical purpose and should not be used for conformity assessment of the analogous devices with a medical purpose. Devices with both a medical and a non-medical intended purpose should fulfil both the requirements applicable to devices with, and to devices without, an intended medical purpose.

6.4 Use of nanomaterials in medical devices

Medical devices comprising nanomaterials should be subject to the moist stringent conformity assessment especially when such products are for internal exposure:

> In the design and manufacture of devices, manufacturers should take special care when using nanoparticles for which there is a high or medium potential for internal exposure. Such devices should be subject to the most stringent conformity assessment procedures. In preparation of implementing acts regulating the practical and uniform application of the corresponding requirements laid down in this Regulation, the relevant scientific opinions of the relevant scientific committees should be taken into account.

6.5 Software

Any **software** that is intended by a manufacturer to be used for one or more of the medical purposes fall under the Regulation:

> It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device.

7. What's new?

The Regulation introduces:

7.1 Clinical evaluation

The Regulation seeks to protect individuals ('**subjects**') participating in **clinical trials** to ensure that data generated in clinical investigations are reliable and robust:

> this Regulation sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

Article 61 deals with clinical evaluation:

> 1. Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the

> undesirable side-effects and of the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I, shall be based on clinical data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.
> The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.
> To that end, manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and Part A of Annex XIV.

7.2 Conformity for class III devices and implantable devices based on clinical data

Manufacturers must **establish a system for risk management and a system for reporting of incidents and field safety corrective actions reflected in the clinical evaluation for the device**, including the clinical risks to be addressed as part of the clinical investigation, clinical evaluation and post-market clinical follow up:

> To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the clinical investigation.

7.3 Vigilance reporting

Post market surveillance has to be carried out:

> It should be ensured that supervision and control of the manufacture of devices, and the post-market surveillance and vigilance activities concerning them, are carried out within the manufacturer's organisation by a person responsible for regulatory compliance who fulfils minimum conditions of qualification.

7.4 Liability of the authorised representative

If a manufacturer established outside the Union fails to comply with the provisions of the Regulation, **the authorised representative will be legally liable for any defective devices**:

> …the authorised representative legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations under the Regulation

7.5 Traceability of devices by means of a Unique Device Identification system (UDI system)

UDI system applies to all devices placed on the market except custom-made devices.

7.6 Creation of a European database on medical devices

A database on medical devices will be **created entitled Eudamed** to collate and process information regarding devices being sold on the market including details of relevant economic operators and aspects of conformity assessment:

Creation of a European database on medical devices (Eudamed) that should integrate different electronic systems to collate and process information regarding devices on the market and the relevant economic operators, certain aspects of conformity assessment, notified

7.7 Unannounced audits

The right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on devices to ensure continuous compliance by manufacturers after receipt of the original certification

7.8 Risk Based Classification

Rules under the old regime applied to invasive devices do not sufficiently take account of the level of invasiveness and potential toxicity of certain devices which are introduced into the human body. In order to obtain a suitable risk-based classification of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body, it is necessary to introduce specific classification rules for such devices. The classification rules should take into account the place where the device performs its action in or on the human body, where it is introduced or applied, and whether a systemic absorption of the substances of which the device is composed, or of the products of metabolism in the human body of those substances occurs.

7.9 Criminal Liability – Investigator or Sponsor of the clinical trial

Where, in the course of a clinical investigation, harm caused to a subject leads to the civil or criminal liability of the investigator or the sponsor being invoked, the conditions for liability in such cases, including issues of causality and the level of damages and sanctions, should remain governed by national law.

7.10 Reporting adverse events - reporting serious incidents and field safety corrective actions

Sponsors should report certain adverse events and device deficiencies that occur during clinical investigations to the Member States in which those clinical investigations are being conducted. Member States should have the possibility of terminating or suspending the investigations or revoking the authorisation for those investigations, if considered necessary to ensure a high level of protection of the subjects participating in a clinical investigation. Such information should be communicated to the other Member States.

Article 83 deals with Post-market surveillance system of the manufacturer:

1. For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).

2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

(a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

(b) to update the design and manufacturing information, the instructions for use and the labelling;

(c) to update the clinical evaluation;

(d) to update the summary of safety and clinical performance referred to in Article 32;

(e) for the identification of needs for preventive, corrective or field safety corrective action;

(f) for the identification of options to improve the usability, performance and safety of the device;

(g) when relevant, to contribute to the post-market surveillance of other devices; and

(h) to detect and report trends in accordance with Article 88.

The technical documentation shall be updated accordingly.

4. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87.

Under Article 84, the Post-market surveillance plan has to be part of the technical documentation specified in Annex II. Under Article 85, **the Post-market surveillance report must be updated when necessary and made available to the competent authority upon request**. **Periodic safety update reports are necessary under Article 86:**

1. Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

(a) the conclusions of the benefit-risk determination;

(b) the main findings of the PMCF; and

(c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of class IIb and class III devices shall update the PSUR at least annually. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as

specified in Annexes II and III.

Manufacturers of class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.

2. For class III devices or implantable devices, manufacturers shall submit PSURs by means of the electronic system

referred to in Article 92 to the notified body involved in the conformity assessment in accordance with Article 52. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the evaluation by the notified body shall be made available to competent authorities through that electronic system.

3. For devices other than those referred to in paragraph 2, manufacturers shall make PSURs available to the notified

body involved in the conformity assessment and, upon request, to competent authorities.

Article 87, manufacturers have to report serious incidents and field safety corrective actions:

1. Manufacturers of devices made available on the Union market, other than investigational devices, shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7), the following:

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

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 92.

2. As a general rule, the period for the reporting referred to in paragraph 1 shall take account of the severity of the

serious incident.

3. Manufacturers shall report any serious incident as referred to in point (a) of paragraph 1 immediately after they

have established the causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 15 days after they become aware of the incident.

4. Notwithstanding paragraph 3, in the event of a serious public health threat the report referred to in paragraph 1

shall be provided immediately, and not later than 2 days after the manufacturer becomes aware of that threat.

5. Notwithstanding paragraph 3, in the event of death or an unanticipated serious deterioration in a person's state of

health the report shall be provided immediately after the manufacturer has established or as soon as

it suspects a causal relationship between the device and the serious incident but not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.

6. Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

7. If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required in accordance with paragraphs 2 to 5.

8. Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer shall, without undue delay, report the field safety corrective action referred to in point (b) of paragraph 1 in advance of the field safety corrective action being undertaken.

9. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 89(9), in consultation with the competent authorities referred to in point (a) of Article 92(8), has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. Where a single competent authority is referred to in points (a) and (b) of Article 92(8), the manufacturer may provide periodic summary reports following agreement with that competent authority.

10. The Member States shall take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents referred to in point (a) of paragraph 1.

The competent authorities shall record centrally at national level reports they receive from healthcare professionals, users and patients.

11. Where a competent authority of a Member State obtains such reports on suspected serious incidents referred to in point (a) of paragraph 1 from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

Where the manufacturer of the device concerned considers that the incident is a serious incident, it shall provide a report in accordance with paragraphs 1 to 5 of this Article on that serious incident to the competent authority of the Member State in which that serious incident occurred and shall take the appropriate follow-up action in accordance with Article 89.

Where the manufacturer of the device concerned considers that the incident is not a serious incident or is an expected undesirable side-effect, which will be covered by trend reporting in accordance with Article 88, it shall provide an explanatory statement. If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with paragraphs 1 to 5 of this Article and require it to ensure that appropriate follow-up action is taken in accordance with Article 89.

8. CE Marking

All devices must bear the CE Marking to sure conformity with the Regulation:

> Devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to the placing on the market or putting into service of devices that comply with the requirements laid down in this Regulation. However, Member States should be allowed to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation.
>
> *Article 20*
>
> **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 V.
> 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 packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.
> 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 52. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.
> 6. Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation.

9. Key Definitions

Some key definitions under Article 2 of the Regulations are as follows:

- '**medical device**' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
  - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
  - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state

- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations; and

- which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
- devices for the control or support of conception;

- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

- '**falsified device**' means any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;

- '**intended purpose**' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;

- '**label**' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

- '**manufacturer**' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

- '**authorised representative**' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

- '**importer**' means any natural or legal person established within the Union that places a device from a third country on the Union market;

- '**distributor**' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

- '**economic operator**' means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);

- '**health institution**' means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health;

- ‘**user**’ means any healthcare professional or lay person who uses a device;

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

- ‘**CE marking of conformity**’ or ‘CE marking’ means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

- ‘**clinical evaluation**’ means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;

- ‘**clinical investigation**’ means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device;

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

10. Other non-compliance under Article 97

Non-compliance will be brought to an end within a specified timeframe as laid down by the competent authority. After such timeframe, the appropriate measures will be imposed on the operator, if still non-compliant:

1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the noncompliance.
2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1 of this Article, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 100.
3. In order to ensure the uniform application of this Article, the Commission may, by means of implementing acts, specify appropriate measures to be taken by competent authorities to address given types of non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

The annexes have not been reproduced in this article.

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