MEDICAL DEVICES

REGULATION (EU) No. 2017/745 (MDR)

APPLICATION GUIDE

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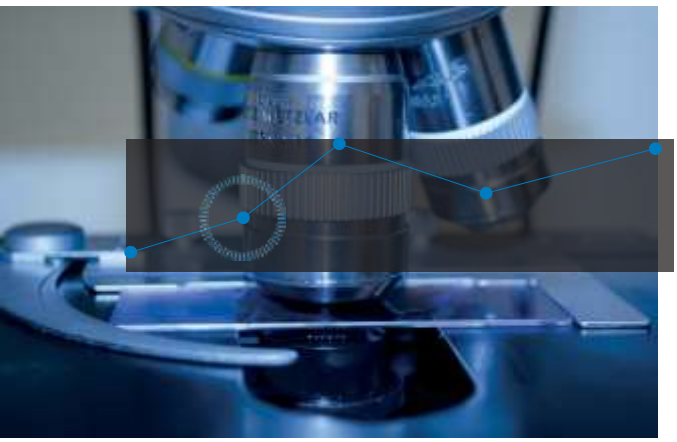

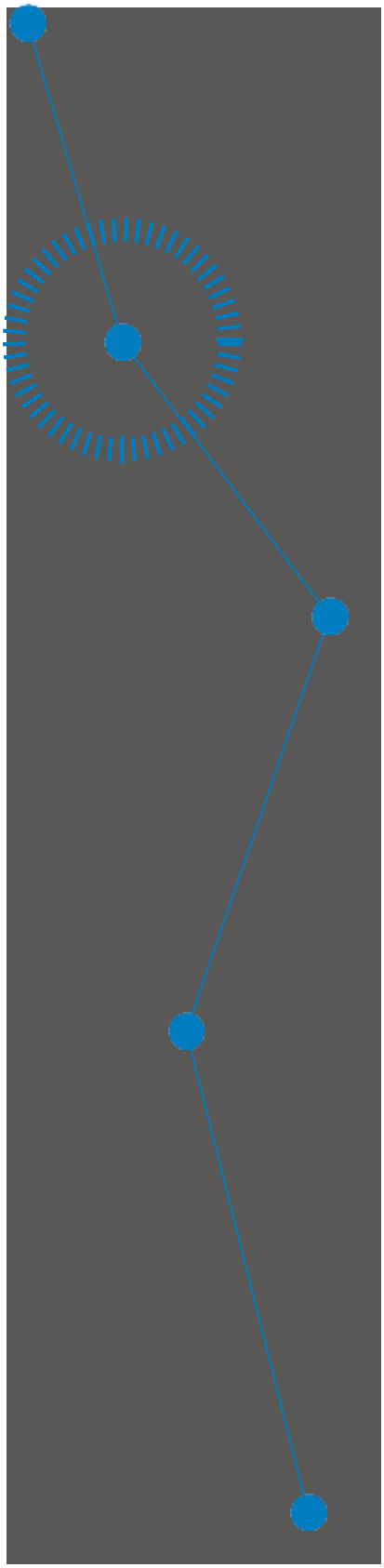

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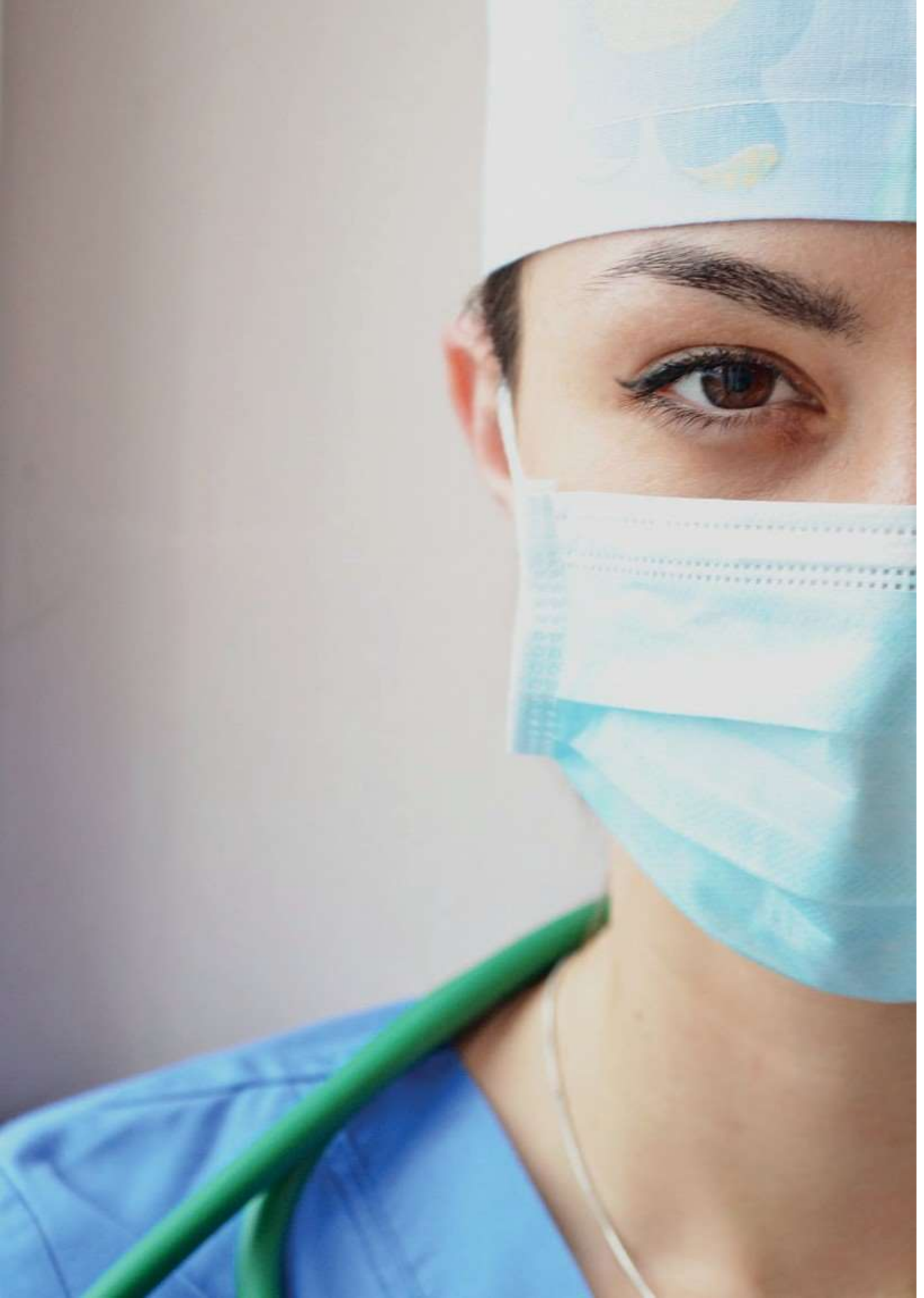


1 | ENTRY INTO FORCE AND APPLICATION

Regulation (EU) No. 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices (hereinafter, the "MDR") repealing Directive 90/385/EEC (hereinafter, the "AIMDD") and Directive 93/42/EEC (hereinafter, the "MDD"), **entered into force on 25 May 2017 and will be applied from 26 May 2020**.

Note: A European Regulation comes into force with a "binding" value without the need to be transposed into national laws. Each Member State may, with specific laws, introduce restrictions in addition to those prescribed by the Regulation itself.

2 | TRANSITIONAL PROVISIONS

a) The EC Certificate issued in accordance with the MDD or AIMDD before 25 May 2017 remains valid until the expiry of the term indicated on the certificate itself, in accordance with the EC Certificate issued in accordance with Annex IV to the MDD or AIMDD, which expires on 27 May 2022.

b) The EC Certificate issued in accordance with the MDD or AIMDD issued from 25 May 2017 remains valid until 26 May 2024 or until the expiry of the term indicated on the certificate itself if prior to 26 May 2024.

Note: From 27/05/2024, only medical devices conforming to the MDR with a valid EU certificate of conformity issued in accordance with the MDR may be placed on the market.

As from 26 May 2020, the validity of the EC Certificates under the MDD and the AIMDD in the terms indicated above and the consequent possibility of placing on the market the medical devices covered by these certificates, are subject to the following conditions:

- No changes to the design and intended use of the Medical Device;
- Application of the requirements of the MDR for post-market surveillance, market surveillance, vigilance, registration of economic operators and Devices; these requirements replace the corresponding provisions of the MDD/AIMDD.

Note: If EUDAMED is not fully operational on 26 May 2020, the corresponding provisions of the Directive shall continue to apply and the obligations and requirements relating to EUDAMED shall apply from the dates referred to in Article 123 section 3, paragraphs d) - e).

As from 27 May 2025, medical devices placed on the market under the MDD/AIMDD may no longer be made available on the market.

3 | SCOPE OF THE MDR

The MDR **regulates**:

- **Medical devices for human use and their accessories** (ref. art. 1, p.1 of the MDR);
- **Device not placed on the market** but used in the context of a commercial activity **to provide a diagnostic or therapeutic service** through information society services or other means of communication (ref. art. 6 of the MDR);
- **Products that are not intended for medical use and listed in Annex XVI** (ref. art. 1, p. 2 and Annex XVI of the MDR),

hereinafter, the "Device" or the "Devices".

The following products are excluded from the scope of the MDR:

- Medicinal products as defined in Article 1, point 2 of Directive 2001/83/EC;
- Advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;
- Cosmetic products covered by Regulation (EC) No 1223/2009;
- Products containing or consisting of viable biological materials or viable organisms, including living micro-organisms, bacteria, fungi or viruses, in order to achieve or contribute to the intended use of the product;
- Foods covered by Regulation (EC) No 178/2002.

Definitions (ref. art. 2 of the MDR):
***(1) Medical device**: any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the Manufacturer to be used on humans, alone or in combination, for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, forecasting, prognosis, treatment or mitigation of diseases, — diagnosis, monitoring, treatment, mitigation or compensation of an injury or disability, — study, replacement or modification of the anatomy or of a physiological or pathological process or state, — to provide information through the in vitro examination of samples taken from the human body, including donated blood and tissues, and which do not exert in or on the human body the principal action for which they are intended by pharmacological, immunological or metabolic means, but the function of which may be assisted by such means. The following products are also considered Medical Devices: — Devices for the control of conception or aid for conception, — products specifically intended for the cleaning, disinfection or sterilisation of the devices referred to in article 1, paragraph 4, and those referred to in the first sub-paragraph of this point.*
***(2) Accessory of a Medical Device**: a product which, although not itself a Medical Device, is intended by the Manufacturer to be used with one or more specific Medical Devices, in particular to enable the latter to be used in accordance with their intended purpose, or specifically and directly to assist the medical function of the Medical Device or Devices in relation to their intended use.*
***(5) Implantable device**: any Device, including those which are partly or wholly absorbed, designed to: — be totally implanted in the human body, or — replace an epithelial surface or the ocular surface by clinical intervention and to remain there after surgery. Any device intended to be partially introduced into the human body by clinical intervention and to remain there after surgery for a period of at least 30 days is also considered to be an implantable device.*

4 | GENERAL

The MDR:

- It is the only regulatory act for medical devices including active implantable medical devices;
- It introduces new classification rules and modifies some of the MDD rules, making the classification criteria more stringent (ref. Annex XVIII of the MDR);
- It has 4 classes of risk: I, IIA, IIB and III (Active implantable medical devices are in Class III);
- It introduces economic operators (Manufacturer, Authorised Representative, Importer and Distributor) and defines their specific obligations;
- It introduces the need for the Manufacturer to have financial coverage and a person responsible for compliance;
- It strengthens the need for the Manufacturer to have:
  - A risk management system,
  - A post-market surveillance system,
  - A system for reporting incidents;
- It strengthens the need for the Manufacturer to demonstrate compliance with clinical data;
- It introduces the drafting of new documents by the Manufacturer:
  - Safety and clinical performance summary for Class III Devices and Implantable Devices,
  - Post-market surveillance report for Class I Devices and Periodic safety update report for Class IIA, IIB and III Devices,
  - Trend reporting,
  - Card for patients with implantable devices;
- It strengthens the concept of traceability of devices with the creation of the UDI system;
- It strengthens the use of EUDAMED for the collection of Device information in a single European database;
- It eliminates conformity assessment procedures based on product quality assurance (Annex VI of the MDD) and statistical product verification (Annex IV of the MDD with sampling).

4.1 | Structure of the MDR

Heading	Articles	
I	1 to 4	Scope and definition
II	5 to 24	Making available on the market and putting into service of Devices, obligations of economic operators, reconditioning, CE marking, free movement
III	25 to 34	Identification and traceability of Devices, registration of devices and economic operators, summary of safety and clinical performance and European database of Medical Devices
IV	35 to 50	Notified Bodies
V	51 to 60	Classification and conformity assessment
VI	61 to 82	Clinical assessment and clinical investigations
VII	83 to 100	Post-market surveillance,vigilance and market surveillance
VIII	101 to 108	Cooperation between Member States, Medical Devices coordination group, specialised laboratories, expert groups and Device registers
IX	109 to 113	Confidentiality, data protection, financing and penalties
X	113 to 123	Final provisions

Annex	
I	General requirements of safety and performance
II	Technical documentation
III	Technical documentation on post-market surveillance
IV	EU Declaration of conformity
V	CE Marking and conformity
VI	Information to be submitted following registration of Devices and economic operators in accordance with article 29, paragraph 4 and article 31; basic data to be provided to the UDI database together with the UDI-DI in accordance with articles 28 and 29; and UDI system
VII	Requirements to be met by notified bodies
VIII	Classification criteria
IX	Conformity assessment based on the quality management system and on the assessment of the technical documentation
X	Conformity assessment based on type examination
XI	Conformity assessment based on verification of product conformity
XII	Certificates issued by a notified body
XIII	Procedure for custom-made devices
XIV	Clinical evaluation and post-market clinical follow-up
XV	Clinical investigations
XVI	List of groups of products not intended for medical use referred to in article 1, paragraph 2
XVII	Correlation table

5 | MAIN CHANGES AND IMPORTANT ASPECTS INTRODUCED BY THE MDR

5.1 | Placing on the market and putting into service

A Device may be placed on the market or put into service only if it complies with the MDR (ref. art. 5, p.1 of the MDR).
A Device must meet the general safety and performance requirements of Annex I of the applicable MDR, taking into account its intended use (art. 5, p.2 of the MDR).
The demonstration of compliance with these requirements must include a clinical assessment (art. 5, p.3 of the MDR).

The manufacturer may use harmonised product and system standards, including European Pharmacopoeia monographs, to demonstrate compliance with the requirements of the MDR.

Note: The references of the harmonised standards are published in the Official Journal of the European Union (ref. art. 8 of the MDR).

The Commission adopts **Common Specifications** (CS) if:
- There are no harmonised standards;
- The existing harmonised standards are not sufficient;
- Public health concerns need to be addressed.

The CS cover safety and performance requirements, technical documentation, clinical evaluation, post-market clinical follow-up and clinical investigation of Devices.

The CS are mandatory for products that are not intended for medical use (ref. art. 9 of the MDR).

Definitions (ref. art. 2 of the MDR):
(12) Intended use: *The use for which a Device is intended according to the indications provided by the Manufacturer on the label, in the instructions for use or in the material or in the promotion or sales statements and as specified by the Manufacturer in the clinical assessment.*
(27) Making available on the market: *the supply of a Device, other than a Device under investigation, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.*
(28) Placing on the market: *the first making available of a Device, other than a Device under investigation, on the Union market.*
(29) Putting into service: *stage at which a Device, other than a Device under investigation, has been made available to the end user as being ready for first use on the Union market according to its intended use.*

5.2 | MDR Economic Operators

The MDR defines the following **economic operators**:
- **Manufacturer** (ref. art. 10 of MDR), "*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** (ref. art. 11 and 12 of MDR), "*any natural or legal person established in the Union who has received and accepted from the Manufacturer, established outside the Union, a written mandate authorising him to act on behalf of the Manufacturer in relation to certain activities concerning the latter's obligations under this regulation*";
- **Importer** (ref. art. 13 of MDR), "*any natural or legal person established within the Union that places a device from a third country on the Union market*";
- **Distributor** (ref. art. 14 of MDR), "*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*".

The Manufacturer is responsible for:

- Ensuring that the Device is designed and manufactured in accordance with the requirements of the MDR;
- Drawing up, managing and keeping up to date the **complete technical documentation referred to in Annexes II and III of the MDR**, including the clinical assessment;
- Drawing up the EU declaration of conformity; this declaration must contain all the elements indicated in **Annex IV of the MDR and must be drawn up in an official language of each Member State in which the Device is made available;**
- Prior to placing on the market, affixing the CE marking on the Device in accordance with Annex V of the MDR;
- Keeping the declaration of conformity, EU certificate and technical documentation **for 10 years** (15 years for implantable devices) **from the date the last Device was placed on the market**;
- **Registering as a Manufacturer and registering the Device with the UDI system**;
- Implementing **a quality management system including the post-market surveillance system and the risk management system**;
- Informing other economic operators, the competent Authority and the Notified Body in case of a non-compliant Device;
- Recording and reporting incidents and **safety corrective actions** in the context of surveillance;
- Cooperate with the competent authorities, **supplying (if requested) samples of the Device**;
- Having adequate **financial cover**;
- Having a **person responsible for compliance** (different figure from the legal representative). This person must:
    - Be internal to the organisation; only in the case of micro and small enterprises can the person be external to the organisation, available on a permanent and continuous basis;
    - Meet the qualification criteria defined in art. 15, p.1 of the MDR;
    - Carry out the tasks defined in art. 15, p.3 of the MDR.

Note: The above obligations apply to all Manufacturers, irrespective of the conformity assessment procedure chosen.

The Authorised Representative is mandatory for the Manufacturer who is not established in an EU country and must be designated by written agreement with the description of all his tasks and responsibilities as defined in Art. 11 p. 3 of the MDR.
The Authorised Representative must have at his disposal a person responsible for compliance with the regulations, on a permanent and continuous basis.
The Authorised Representative shall be liable in the event of default by the Manufacturer and to the same extent as the Manufacturer itself.

Note: The change of Authorised Representative must be managed by written agreement between the Manufacturer, the new Authorised Representative and, if possible, the outgoing Authorised Representative (ref. art. 12 of the MDR).

Importer and Distributor are responsible for:

- Checking that the requirements of the MDR are met;
- Observing storage and transport conditions;
- Recording complaints, non-compliant Devices, recalls and withdrawals;
- Notifying the Manufacturer and the Authorised Representative of any incidents;
- If he considers that the Device is not compliant, not placing such Device on the market or not making it available and informing the Manufacturer, the Authorised Representative and in case of serious risk, also the competent Authority;
- Keeping a copy of the declaration of conformity and the EU certificate for 10 years (15 years for implantable devices);
- Making the documentation available to the competent Authority.

In addition, the **Importer** must indicate on the Device or on its packaging (or in a document accompanying it) his name, trade name or registered trademark, his registered office and the address at which he can be contacted.

5.2.1 | Cases in which Manufacturers' obligations apply to Importers, Distributors or other persons

A Distributor, Importer or other natural or legal person assumes the obligations of the Manufacturers in relation to one of the following cases (ref. art. 16 of the MDR):

a) If he makes a Device available on the market under his own name, trade name or registered trademark, except where a Distributor or Importer enters into an agreement with a Manufacturer under which the Manufacturer is indicated as such on the label and is responsible for compliance with the obligations incumbent upon Manufacturers under the MDR;
b) If he changes the intended use of a Device already placed on the market or put into service;
c) If he modifies a Device already placed on the market or put into service in such a way that its compliance with the applicable requirements may be compromised.

The following are not considered to be modifications that would compromise the conformity of the Device with the applicable requirements:

a) The supply, including the translation of the Device information (labels and instructions for use);
b) Changes to the outer packaging of a Device already placed on the market, including a change in the size of the packaging, if repackaging is necessary to market the Device in the Member State concerned and if carried out under conditions that do not alter the original condition of the Device.

In these cases the Distributor or Importer must indicate on the Device or on its packaging (or in a document accompanying it) his name, trade name or registered trademark, his registered office and the address at which he can be contacted.

Distributors and importers ensure that they have a quality management system in place that includes procedures for translating information and relabelling/repackaging. This system must be approved by a Notified Body under the MDR which issues an EU Quality Management System Certificate under Article 16 of the MDR.

5.3 | Registration of economic operators and of Devices

Manufacturer, Authorised Representative and Importer must register in EUDAMED by entering the information on the economic operator as required in Annex VI Part A, p. 1 of the MDR (ref. art. 31 of the MDR), obtaining a **unique registration number** (SRN).
The economic operator must:

- Update data within one week in case of changes in relation to the information entered;
- Confirm data within one year and every 2 years thereafter.

Note: If the intervention of a Notified Body is required, the SRN must be indicated in the application for certification.

The Manufacturer is responsible for registering the Device (ref. art. 29 of the MDR). Before placing on the market, the Manufacturer:

- Assigns a basic UDI-DI to the Device through the Issuing Bodies appointed by the Commission;
- Enters the information related to the Device (ref. Annex VI Part A point 2 of the MDR) in EUDAMED;
- Indicates the basic UDI-DI in the declaration of conformity;
- Applies the UDI vector on the Device label and on all external packaging levels.

Note: In the case of Class III, Class IIB implantable and Class IIB devices with Annex X and XI procedures, the basic UDI-DI is indicated in the application for certification and is shown in the certificate.

After placing on the market:

- The Manufacturer keeps the list of all UDIs in the technical documentation up to date;
- All economic operators register and keep records of the UDIs of Class III implantable Devices and of all those that will be indicated by the Commission.

Definitions (ref. art. 2 of the MDR):
15) Unique Device Identifier - UDI: *A series of numeric or alphanumeric characters created on the basis of internationally accepted Device identification and coding standards and allowing the unambiguous identification of specific Devices on the market.*

5.4 | EUDAMED

EUDAMED is the European Database of Devices and contains:

- Electronic system related to the registration of Devices;
- UDI database;
- Electronic system for the registration of economic operators;
- Electronic system for Notified Bodies and certificates;
- Electronic system for clinical investigations;
- Electronic system for post-market vigilance and surveillance;
- Electronic system for market surveillance.

5.5 | Disposable devices: Reconditioning

Reconditioning is the process performed on a used Device to allow safe reuse and includes (ref. art. 17 of the MDR):

- Cleaning, disinfection, sterilisation and associated procedures;
- Testing and restoring the technical and functional safety of the used Device.

The natural or legal person who reconditions a disposable Device becomes the Manufacturer of the reconditioned Device and must meet the "*Manufacturers' obligations*" as per art. 10 of the MDR.
The reconditioning of disposable Devices must be permitted by the Member State through national provisions.

Note: The Notified Body intervenes to verify compliance with the relevant CS adopted by the Commission.

5.6 | Summary of safety and clinical performance

The Manufacturer draws up a Safety and Clinical Performance Summary (SCPS) for **Implantable Devices and Class III Devices**, indicating on the instructions for use or on the labels where this summary can be found (ref. art. 32 of the MDR).

The SCPS must:

- Contain all the elements indicated in art. 32 p. 2 of the MDR;
- Be written in such a way as to be clear to the intended user and, where appropriate, to the patient;
- Be part of the documentation to be submitted to the Notified Body, which will validate it as part of the conformity assessment procedure and enter it in EUDAMED;
- It is updated with data collected as part of post-market surveillance.

Note: The European Commission may, by means of implementing acts, define the form and presentation of the data to be included in the SCPS.

5.7 | Risk analysis

As part of its quality management system, the Manufacturer must implement a **risk management system** in accordance with the requirements of Annex I, point 3, of the MDR to ensure that:

- All known and foreseeable risks and unwanted side effects are minimised and are acceptable in relation to the benefits - arising from the performance of the Device under normal conditions of use - assessed for the patient and/or user.
- The **link between risk management and pre-clinical and clinical evaluation is sufficiently detailed**; in particular, the results of pre-clinical and clinical evaluation have been taken into account for risk management (e.g. available pre-clinical and clinical literature is used to identify hazards); the results of laboratory tests and clinical trials are used as control measures to reduce the risks associated with the Device) and the results of risk management provide information about the adequacy of pre-clinical and clinical assessment (e.g. the results of risk management are used to identify the need to perform new tests related to the safety of the Device and to conduct new clinical investigations to ensure that the Device is appropriate for the purpose intended by the Manufacturer).

5.8 | Clinical assessment

The Manufacturer must define, implement and maintain a procedure for planning, carrying out and updating the clinical assessment in such a way as to ensure that:

- The clinical assessment is carried out in accordance with **Chapter VI, Annex XIV and, where appropriate, Annex XV of the MDR**;
- **Clinical evidence is consistent** with the characteristics of the Device and its intended use, including clinical indications, **and is adequate** to demonstrate compliance of the Device with the applicable safety and performance requirements of Annex I of the MDR;
- The clinical evidence is sufficient and does not give rise to concerns about the determination of the risk-benefit balance;
- Where the evidence is based on data from other Devices, the **declared equivalence** between these Devices and the Device under examination in terms of clinical, biological and technical characteristics **is demonstrated**;
- Where evidence is derived from clinical investigations, the conclusions drawn by the Manufacturer are valid in the light of the approved clinical investigation plan;
- The clinical evaluation is adequately taken into account in the information provided with the Device.

The Manufacturer:

- **Prepares the clinical assessment plan in accordance with Annex XIV** part A point 1a) of the MDR;
- Identifies existing clinical data relevant to the Device and its intended use, resulting from the review of available scientific literature on the issues of safety, performance, clinical benefit to the patient, design features and intended use of the Device and/or equivalent Devices;
- Critically examines all data collected, whether favourable or unfavourable, and identifies any outstanding issues that need to be addressed;
- Produces new clinical data to address any outstanding issues by holding clinical investigations conducted in accordance with Annex XV of the MDR;
- Critically analyses clinical data, draws conclusions about the safety and performance of the Device, as well as the acceptability of the risk-benefit balance, and drafts the Clinical Assessment Report. This report is included in the technical documentation of the Device.

If the Manufacturer decides to **demonstrate compliance without clinical data** (ref. art. 61, section 10 of the MDR), the justification provided must be adequate and based on the results of risk management and pre-clinical assessment, expected performance, body-device interaction and the Manufacturer's own statements.

5.8.1 | Demonstration of equivalence

Where clinical data collected relate to similar Devices, equivalence considerations must always be based on appropriate scientific justification in terms of technical, biological and clinical characteristics that must be included and appropriately documented in the clinical assessment report.

TECHNICAL CHARACTERISTICS	BIOLOGICAL CHARACTERISTICS	CLINICAL CHARACTERISTICS
• Similar design • Similar conditions of use • Similar specifications and properties, including physicochemical properties • Similar installation methods • Similar operating principles • Similar basic performance requirements.	• Same materials or substances in contact with the same human tissues or body fluids for a contact of similar type and duration • Similar characteristics of substance release, including degradation products and releasable substances.	• Same clinical status or same purpose, including similarity of severity and stage of disease • Same part of the body • Similar population, including age, anatomy and physiology • Same type of users • Similar relevant essential performance.

Note: The characteristics are similar to such an extent that they do not produce any clinically significant differences in the safety and clinical performance of the Device

5.8.2 | Clinical investigations

Clinical investigations are mandatory for Implantable Devices and Class III Devices.
If no clinical investigation has been conducted for these Devices, the Manufacturer must provide adequate justification based on one of the following reasons (ref. art. 61 of the MDR) and included in the clinical assessment report.

Justification based on Article 61, p. 4 of the MDR:

- the Device in question was designed by making changes to a Device already marketed by the same Manufacturer,
- the Device in question is equivalent to the marketed Device in terms of biological, technical and clinical characteristics, and
- the clinical assessment of the Device already on the market is sufficient to demonstrate the conformity of the device in question.

Justification based on Article 61, p.5 of the MDR:

- the Device in question is equivalent to the Device marketed by another Manufacturer in terms of biological, technical and clinical characteristics,
- there is an agreement between the two Manufacturers allowing full and permanent access to the technical documentation of the Device already marketed by the Manufacturer of the Device in question,
- the clinical assessment of the Device already marketed is carried out in accordance with the requirements of the MDR.

Justification based on Article 61, p. 6 a) of the MDR:

- the Device in question has been placed on the market or put into service in accordance with the MDD/AIMDD,
- the clinical assessment is based on sufficient clinical data and complies with the relevant CS (if available).

Justification based on Article 61, p. 6 b) of the MDR:

- the Device is a suture material, staple, dental filling material, orthodontic appliance, dental crown, screw, wedge, plaque, prosthesis, wire, nail, clip or connector
- the clinical assessment is based on sufficient clinical data and (if available) complies with the relevant CS.

5.8.3 | Post-market clinical follow-up

The Manufacturer defines the post-market clinical follow-up (PMCF) plan for the Device or provides a reason for not having such a plan.

The PMCF plan, which is part of the post-market surveillance plan of the Device, provides for the collection and assessment of clinical data relating to the Device (CE marked) placed on the market and used in accordance with the intended use envisaged by the Manufacturer. The results of the PMCF are analysed and documented in a **PMCF assessment report which is an integral part of the clinical assessment report** (and consequently of the technical documentation).
For Implantable Devices and Class III Devices the PMCF assessment report must be updated at least once a year.

The results of the PMCF and data from the post-marketing surveillance plan are used by the Manufacturer to update the clinical assessment and the safety and clinical performance summary.

5.9 | Post-market surveillance

Within the framework of its quality management system, the Manufacturer must implement a post-marketing surveillance system that covers (ref. art. 83 of the MDR):

- The definition and implementation of a **post-marketing surveillance plan, the elements of which are defined in Annex III p. 1.1 of the MDR; this plan is part of the technical documentation** (ref. art. 84 of the MDR) and includes the PMCF plan;
- The collection, recording and analysis of data on the quality, performance and safety of the Device throughout its entire life cycle, including clinical data from the PMCF plan;
- The use of the above data to:
    - Update the risk-benefit assessment (improving risk management), design and manufacturing information, instructions for use and labelling, clinical assessment and safety and clinical performance summary,
    - Identify the need for preventive, corrective and safety corrective actions,
    - Identify opportunities to improve the usability, performance and safety of the Device,
    - Contribute, where appropriate, to the post-market surveillance of other Devices,
    - Identify and report trends;
- The consequent updating of the technical documentation;
- Preparation and updating of the **Post-market surveillance report or of the Periodic safety update report (PSUR)**.

5.9.1 | Post market surveillance report and Periodic safety update report

Class I devices	Class IIA, IIB and III devices
Post-market surveillance report	**Periodic safety update report (PSUR)**

Manufacturers of Class I Devices prepare a post-market surveillance report summarising the results and conclusions of the analysis of data collected as part of post-market surveillance. The report is updated where necessary and made available to the competent authority upon request (ref. art. 85 of the MDR).

Manufacturers of Class IIA, IIB and III devices draw up a periodic safety update report (PSUR) (ref. art. 86 of the MDR).
The PSUR is the summary document of the results and conclusions of the analysis of data collected as part of post-marketing surveillance; in particular, it contains:

- The conclusions of the analyses of all assessments of the benefits and risks of the Device;
- The outcomes and conclusions of the PMCF for the Device;
- The Device sales volume,
- An estimate of the size and other characteristics of the population that uses the Device;
- The Device frequency of use;
- The reasons for and a description of any preventive and corrective actions adopted by the Manufacturer.

Note: The data that the Manufacturer should consider are: serious incidents and safety corrective actions, minor incidents and information on any undesirable side effects, information from trend reports, specialist or technical documentation, relevant databases and/or registers, information provided by users, distributors and importers, including comments and complaints, publicly available information on similar devices, etc., PMCF data and any other relevant information.

The PSUR is an integral part of the technical documentation and must be updated with specific frequency:

- At least once a year for Class III and IIb Devices;
- Where necessary and at least every 2 years for Class IIa Devices.

For Class III devices and implantable devices, the PSUR is transmitted - via EUDAMED - to the Notified Body that issued the relevant certificate of conformity.
The Notified Body examines the PSUR and enters its assessment in EUDAMED, available to the competent authorities.

For other types of Devices, the PSUR is made available to the Notified Body and, on request, to the Competent Authorities.

5.10 | Reporting of serious incidents and safety corrective actions

Manufacturers of Devices made available on the Union market must report to the relevant competent Authorities:

a) **Any serious adverse event relating to devices made available on the market of the Union**, except for expected adverse reactions which are clearly documented in the product information and quantified in the technical documentation and which are the subject of trend reports pursuant to Article 88 of the MDR;
b) **Any safety corrective action relating to Devices** made available on the Union market, including safety corrective actions taken in a third country in relation to a Device lawfully made available also on the Union market if the corrective action in question is not caused only by the Device made available in the third country.

	Timing of reporting to the competent Authority via EUDAMED
Serious incident	Immediately after establishing the causal link, even if only reasonably possible, between the incident and the Device and **no later than 15 days after becoming aware of the incident.**
Serious threat to public health	Immediately and **no later than 2 days after becoming aware of the threat.**
Death or unexpected serious deterioration in a person's state of health	Immediately after establishing or presuming a causal link between the incident and the Device and **no later than 10 days after becoming aware of the incident.**
Safety corrective action	Without undue delay and before action is taken, except where corrective action is to be taken immediately.

To ensure prompt reporting, the Manufacturer may, where appropriate, submit an initial incomplete report, followed by a full report.

The Manufacturer may submit periodic summary reports (rather than individual reports) on serious incidents if:

- Incidents occur with the same Device or type of Device and the main cause has been identified or safety corrective action has been taken;
- If incidents are common and well documented.

Note: If the Manufacturer, after becoming aware of an incident potentially to be reported, is still uncertain about the need to report the incident, the Manufacturer must still submit a report.

Following the report of a serious incident, the Manufacturer:

- Conducts an investigation that includes the risk assessment of the accident and safety corrective action taking into account the protection of public health and criteria such as the causes, detectability and probability of recurrence of the problem, the frequency of use of the Device, the probability of occurrence of direct or indirect damage and its severity, the clinical benefit of the Device, expected and potential users and the population concerned;
- Cooperates with the competent Authorities and, where appropriate, with the Notified Body concerned;
- Draws up the final report and indicates any corrective action to be taken; this report must be sent, via EUDAMED, to the competent Authority and the Notified Body;
- Issues a safety notice, informing the users of the Device of the safety corrective actions taken.
  The safety notice is published in EUDAMED and written in an official language of the Member State where the safety corrective action is taken.
  This notice allows the correct identification of the Device concerned (with the UDI) and of the Manufacturer (with the unique registration number), specifies the reasons for the safety corrective action with reference to the malfunctioning of the Device and the associated risks for patients, users or other persons and clearly indicates all the measures that users must take.

Definitions (ref. art. 2 of the MDR):
24) Determination of the benefit-risk balance*: analysis of all benefit-risk and risk assessments which may be relevant to the use of the Device according to its intended use, when used in accordance with the intended use indicated by the Manufacturer.*
34) Incident*: any malfunction or alteration of the characteristics or performance of a Device made available on the market, including the error of use caused by the ergonomic characteristics, as well as any inadequacy in the information provided by the Manufacturer and any unwanted side effects.*
35) Serious incident*: any incident that directly or indirectly caused, may have caused or may cause any of the following consequences:*
a) death of a patient, user or other person;
b) serious deterioration, whether temporary or permanent, in the state of health of the patient, user or other person;
c) a serious threat to public health (an event which may involve an imminent risk of death, a serious deterioration in a person's state of health or a serious illness which may require prompt corrective action and which may result in a mortality rate).
62) Recall*: any measure aimed at obtaining the return of a Device that has already been made available to the end user.*
63) Withdrawal*: any measure aimed at preventing the further making available on the market of a Device in the supply chain.*
68) Safety corrective action*: a corrective action taken by a Manufacturer for technical or medical reasons to prevent or reduce the risk of serious incidents in relation to a Device made available on the market.*
69) Safety Notice*: a communication sent by a Manufacturer to users or customers in connection with a safety corrective action.*

5.11 | Trend reporting

The Manufacturer reports, through EUDAMED, **any statistically significant increase in the frequency or severity of incidents (other than serious ones) or expected undesirable side effects** that may have a significant impact on the analysis of risks and benefits and that have led or may lead to risks - for the health or safety of patients, users or other persons - that are considered unacceptable compared to the expected benefits (ref. art. 88 of the MDR). The manufacturer specifies - in the post-market surveillance plan - the methods for managing incidents, the methodology for detecting any statistically significant increase in the frequency or severity of incidents and the period of observation.

6 | CLASSIFICATION OF DEVICES AND CONFORMITY ASSESSMENT PROCEDURES

6.1 | Classification of Devices

The Devices are divided into 4 risk classes **I, IIA, IIB, III** according to their intended use and the risks involved. The classification is carried out by the Manufacturer according to **the criteria of Annex VIII of the MDR** (ref. art. 51 of the MDR).

Note: Changes to the MDD rules and the introduction of new ones may lead to the reclassification of some Devices. Therefore, the first step for the Manufacturer will be to classify its Device according to the MDR.

MDD	*MDR*
18 Classification rules	***22 Classification rules***
- *Non-invasive devices (1 to 4)*	- *Non-invasive devices (1 to 4)*
- *Invasive devices (5 to 8)*	- *Invasive devices (5 to 8)*
- *Active devices (9 to 12)*	- *Active devices (9 to 13)*
- *Special rules (13 to 18)*	- *Special rules (14 to 22)*

Any dispute between the Manufacturer and the Notified Body concerning the classification of the Device must be reported to the **Competent Authority of the Member State in which the Manufacturer (or its Authorised Representative) is located.**

Note: If the Manufacturer (or its authorised representative) and Notified Body are established in different States, the Competent Authority is that of the State in which the Manufacturer (or its Authorised Representative) is established.

6.2| Conformity assessment procedures

Before placing a Device on the market or in service, Manufacturers assess the conformity of the Device in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI (ref. art. 52 of the MDR).

MDR Annex		MDR conformity assessment procedure		MDR certificate	Corresponding MDD/AIMDD Annex
Annex IX	Annex IX chapter II	Device design assessment	Assessment of the Device technical documentation	EU technical documentation assessment certificate	Annex II.4
	Annex IX chapter I	Assessment of the quality system (complete)	Assessment of the complete quality system applied to all of the stages - design, manufacturing and final product control, including verification of the technical documentation of the devices covered by this QS	EU quality management system certificate	Annex II except 4
Annex X		Product assessment	Assessment of the technical documentation of the Type and Performance of tests on a representative example of a given production (type verification).	EU type examination certificate	Annex III
Annex XI - part A		Assessment of the quality system (production quality assurance)	Assessment of the quality system applied to the manufacturing phase of the product, including verification of the technical documentation of the Devices covered by this QS	EU quality assurance certificate	Annex V
Annex XI - part B		Product assessment (related to production)	Assessment of the technical documentation of the Device and Performance of tests on each individual product	EU product verification certificate	Annex IV (verification of each Device)

The conformity assessment procedures applicable to each class of risk are set out below.

Device Class	Conformity assessment procedure (MDR Annexes)	Intervention of the Notified Body
I (non-sterile, without measuring function, non-reusable surgical instrument)	Declaration of conformity (Annex IV)	Not required
I sterile (IS) I with measurement function (IM) I Reusable surgical instrument (IR)	- Annex IX - chapter I *or* - Annex XI - part A	Yes, the intervention of the Notified Body is limited respectively to: □ aspects relating to establishing, securing and maintaining sterile conditions; □ aspects relating to the conformity of the Device with the metrological requirements; □ aspects relating to the reuse of the Device (cleaning, disinfection, sterilisation, maintenance and functional testing and the related instructions for use).
IIa	- Annex IX - chapter I *or* - Annex XI - Part A *or* - Annex XI - Part B	Yes
IIb (non-implantable)	- Annex IX - chapter I *or* - Annex X combined with Annex XI - Part A *or* - Annex X combined with Annex XI - Part B	Yes
IIb implantable * III ** Annex IX - Chapter II does not apply to the following implantable devices: suture materials, staples, dental filling materials, orthodontic appliances, dental crowns, screws, wedges, plates and prostheses, wires, nails, clips and connectors.*	- Annex IX chapter II combined with Annex IX - chapter I *or* - Annex X combined with Annex XI - Part A *or* - Annex X combined with Annex XI - Part B	Yes

If the conformity assessment procedure requires the intervention of a Notified Body, the Manufacturer (or its Authorised Representative) submits an Application for Certification to a designated Notified Body of its choice.

Note: The Manufacturer (or its Authorised Representative) may not submit the same Application to more than one Notified Body at the same time.

6.2.1 | Procedure for consulting the clinical assessment for certain Devices in classes III and IIB

The Clinical Assessment Consultation Procedure (CECP) is required **for Class III Implantable Devices and Class IIB Active Devices intended to administer and/or remove a medicinal product from the organism**.
The clinical assessment drawn up by the Manufacturer and the related analysis report prepared by the Notified Body are sent to the European Commission via EUDAMED and examined by a Group of experts (ref. art. 54 of the MDR).
If the Group of Experts issues a scientific opinion on the matter, the Notified Body must take due account of it when issuing the EU Certificate.

This procedure does not apply in the following cases:

- Renewal of the certification;
- The Device is a variant of a Device already marketed by the same Manufacturer for the same intended use;
- The principles of the clinical assessment of the category of Devices are defined in a CS.

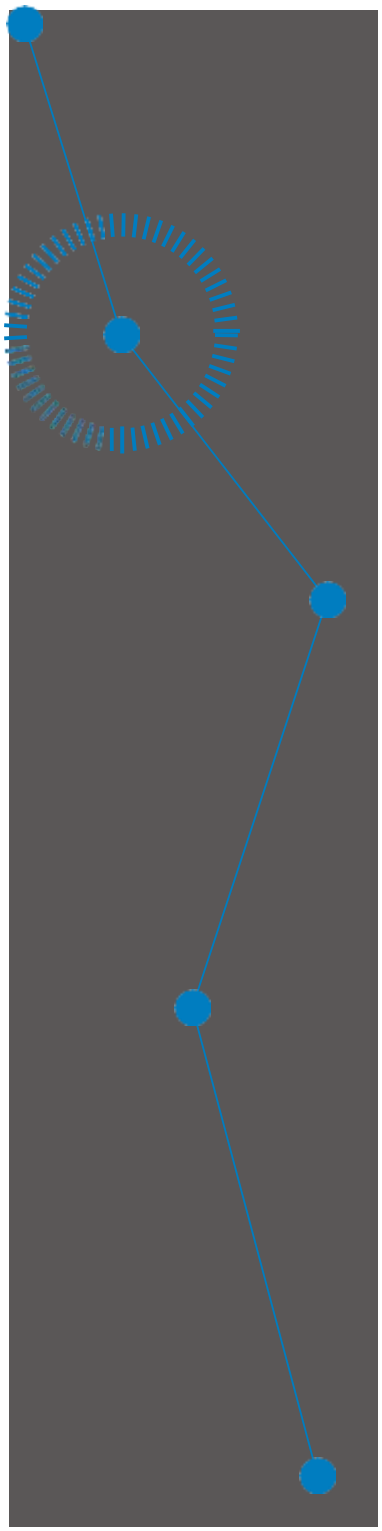
6.3 | Certificates of conformity

Certificates of conformity are issued by a Notified Body under the MDR, have a maximum validity of 5 years and can be extended for further years (maximum 5) on the basis of a new conformity assessment procedure. The **minimum contents of these certificates are indicated in Annex XII of the MDR** (ref. art. 56 of the MDR).

The Notified Body enters in EUDAMED information on certificates issued (including any updates), suspended, limited, restored, revoked and refused.

To maintain the EU Quality Management System Certificate and the EU Quality Assurance Certificate, the Manufacturer must be available to undergo continuous surveillance and the outcomes of these audits must be positive.
In particular, the Notified Body carries out the following:

- At least once **every 12 months surveillance audits** at the Manufacturer's premises and, where appropriate, at the premises of its critical suppliers and subcontractors;
- At least once **every 5 years unannounced audits** at the Manufacturer's premises and, where appropriate, at the premises of its critical suppliers and subcontractors;



ANNEXES

ANNEX 1 - SUMMARY TABLE OF RELEVANT ASPECTS

Risk class of the Device		Art.18 Implant card	Art. 32 SCPS	Art. 52 Assessment procedures	Art. 54 and 55 CECP	Art. 61 Clinical investigation	Art. 85: Report on post-market surveillance	Art. 86: PSUR	Ann. IX and XI(A): Surveillance audit and Unannounced audit
Class III	Class III Implantable	√	√	IX (II) + IX (I) X + XI(A) X + XI (B)	√	√ except the cases in art. 61		√ once a year with EUDAMED	√
	Class III Non-Implantable		√	IX (II) + IX (I) X + XI(A) X + XI (B)		√ except the cases in art. 61		√ once a year with EUDAMED	√
Class IIB	Class IIB Implantable	√	√	IX (II) + IX (I) X + XI(A) X + XI (B)		√ except the cases in art. 61		√ once a year with EUDAMED	√
	Class IIB Implantable: sutures, pins, screws etc. (art. 52 (4 –subpar. 2)		√	IX (I) X + XI(A) X + XI (B)		√ except the cases in art. 61		√ once a year with EUDAMED	√
	Class IIB Non-Implantable			IX (I) X + XI(A) X + XI (B)				√ once a year	√
	Class IIB active to administer and/or remove a medicinal product			IX (I) X + XI(A) X + XI (B)	√			√ once a year	√
Class IIA	Class IIA Implantable	√	√	IX (I) XI(A) XI (B)		√ except the cases in art. 61		√ once every 2 years with EUDAMED	√
	Class IIA Non-Implantable			IX (I) XI(A) XI (B)				√ once every 2 years	√
Class IS, IM, IR				IX (I) XI(A)			√		√ see note 1

Note 1: In the MDR text of 05/05/2017 it is not clearly stated that the Notified Body must carry out surveillance and unannounced audits for Devices of classes IS, IM and IR. In the errata corrige, in the phase of definition by the European Commission, the obligation to carry out surveillance audits and unannounced audits for these Devices will be explained.

ANNEX 2 - TECHNICAL DOCUMENTATION AND TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

The technical documentation of the Device must be drawn up by the Manufacturer in accordance with Annex II of the MDR and includes:

- The description and specifications of the Device;
- **References to previous generations and similar versions of the Device;**
- Information on the Device (labels and instructions for use); **this information must comply with the requirements of Annex I, p. 23 of the MDR and be in an official language of each Member State where the Device is made available;**
- **Information on design and manufacture;**
- Identification and compliance with the general safety and performance requirements applicable to the Device;
- The risk/benefit analysis and risk management set out in Annex I, p. 3 of the MDR;
- Product verification and validation (**pre-clinical assessment and clinical assessment**), including additional information for specific types of Devices.

The technical documentation on the post-market surveillance of the Device must be drawn up by the Manufacturer in accordance with **Annex III** of the MDR and includes:

- **The post-marketing surveillance plan which includes the PMCF plan;**
- The Periodic Safety Update Report (PSUR) and the Post Market Surveillance Report.

ANNEX 3 - QUALITY MANAGEMENT SYSTEM

The manufacturer's quality management system (QMS) must be implemented, effective and compliant with the requirements of the MDR.

The QMS covers at least the following aspects:

- The **Manufacturer's strategy for demonstrating compliance with the MDR**, including compliance with the conformity assessment procedures and procedures for managing changes to the Devices covered by the QMS;
- The description of the quality objectives, company organisation and responsibilities;
- Resource management, including the selection and monitoring of suppliers and **subcontractors**;
- **Risk management** as referred to in Annex I, point 3 of the MDR;
- Preparation and management of the technical documentation of the Device;
- Planning, carrying out and updating of the **pre-clinical assessment**;
- Planning, carrying out and updating of the clinical assessment, in accordance with Article 61 and Annexes XIV and XV of the MDR;
- The realisation of the product, with particular attention to planning, design, development, production and provision of services;
- **The assignments and consequent verifications of the UDIs to all the Devices covered by the QMS;**
- **The entering, confirmation and updating of the information necessary for the registration of the Device and the Manufacturer in EUDAMED;**
- The preparation, implementation and maintenance of a **post-marketing surveillance system** in accordance with Article 83 of the MDR;
- The management of communication with competent Authorities, Notified Body, **other economic operators such as importers, distributors** and, where appropriate, the Authorised Representative, customers and other interested parties;
- Incident reporting, **safety corrective actions, trend reporting** in the area of supervision;
- The management of corrective and preventive actions and the verification of their effectiveness;
- Monitoring and measurement of results, analysis of data and improvement of devices.

ANNEX 4 - ACRONYMS

CECP: *Clinical Evaluation Consultation Procedure*
EUDAMED: *European database Organismo Notificato medical devices*
MDCG: *Medical Device Coordination Group*
PMCF: *Post market clinical follow-up*
PSUR: *Periodic safety update report*
SC: *Common Specification*
SSCP: *Summary of Safety and Clinical Performance*
SRN: *Single Registration Number*
UDI: *Unique device identificatio*

Useful contacts and information

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