

# Overview of the EU MDR and the CE marking process

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The EU Medical Device Regulation (EU MDR) is applicable to products intended for use in humans that fulfill the definition of medical devices per Article 2(1) and/or their accessories per Article 2(2) and are intended for the EU market. Devices and accessories for use in clinical investigations conducted in the EU also fall within the scope of the EU MDR. The regulations is not applicable to products that contain or consist of viable biological material or viable organisms, including living microorganisms, bacteria, fungi, or viruses, to achieve or support the intended purposes of these products.

**Keywords** – amendment, compliance, DoA, sell-off period, transition

## **Introduction**

The EU MDR<sup>1</sup> brings about an unprecedented change in the regulation of medical devices in the member states. New EU regulations governing the production and distribution of medical devices were first introduced publicly on 22 February 2017. The transition to the EU MDR affects medical devices not only in the European region but in the countries that rely on the Conformité Européenne (CE) marking process to gain market clearance in their respective country. Before the EU MDR, the CE mark was based on compliance with the EU Medical Device Directive (MDD) 93/42/EEC and the Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC, as applicable. Compliance is critical for maintaining legacy products on the market and for launching new products.

The EU MDR amends Directive 2001/83/EC, Regulation (EC) No. 178/2002, and Regulation (EC) No. 1223/2009 and repeals the AIMDD and MDD. The aim of the revised regulations is to ensure:

- A consistently high level of health and safety protection for EU citizens using these products,
- The free and fair trade of the products throughout the EU, and

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- That EU legislation is adapted to the significant technological and scientific progress occurring in this sector over the past 20 years.

### Transition timeline

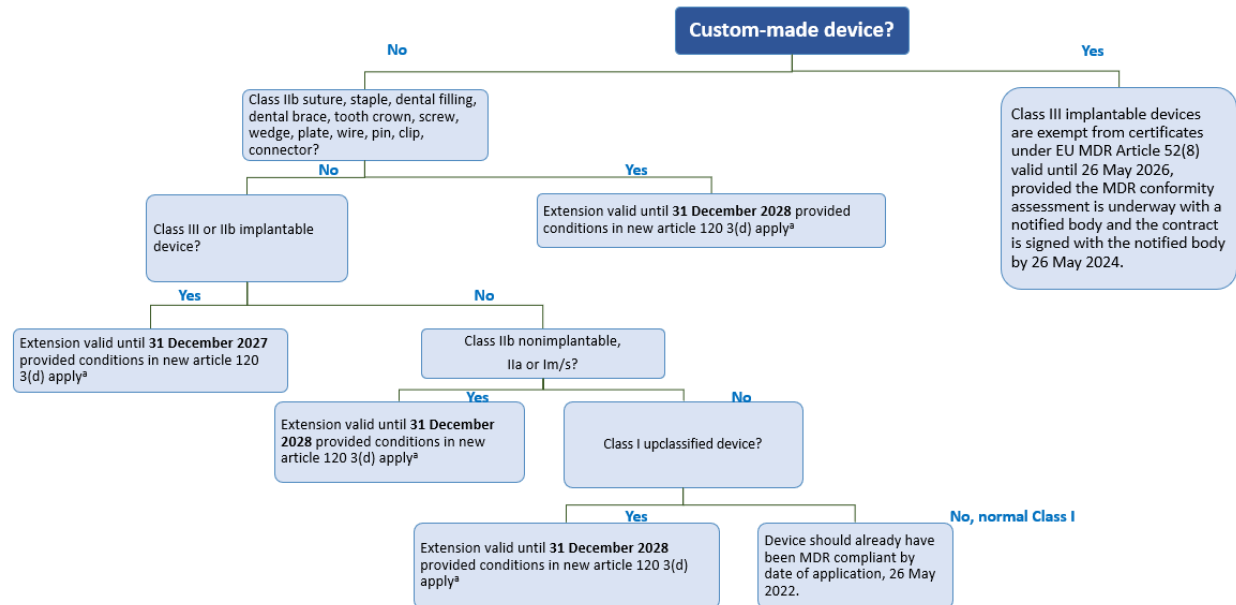
The EU MDR 2017/745 date of application (DoA) was originally defined as 26 May 2024 but has been pushed out to 31 December 2027 or 31 December 2028, depending on the risk class of the device per Regulation (EU) 2023/607 on 15 March 2023<sup>2</sup> (**Figure 1**). Depending on the risk class of the device, the transition period is extended as follows under the conditions enacted in Article 120(3c):

- Class III and Class IIb implantable devices, to 31 December 2027;
- Class IIb nonimplantable devices, to 31 December 2028;
- Class IIa devices, to 31 December 2028;
- Class I measuring and Class I sterile devices, to 31 December 2028;
- Devices not requiring notified body intervention under the MDD but now requiring notified body intervention under the EU MDR, to 31 December 2028; and
- Class III custom-made implantable devices, to 26 May 2026 to allow more time for the manufacturers to obtain certification of their quality management system (QMS) by a notified body. A formal application is required to be lodged with the notified body by May 2024 and an assigned written agreement in place between the manufacturer and the notified body by September 2024 in accordance with Section 4.3 Annex VII of Regulation (EU) 2023/607.

Certificates that were valid on 26 May 2021 and have expired in the meantime will be valid until the new dates under certain conditions listed below:

- Devices continue to comply with the EU AIMDD 90/385/EEC or EU MDD 93/42/EEC;
- There are no significant changes in the design and intended purpose of the device;
- Devices should not present an unacceptable risk to the health or safety of patients, users, or other persons;
- The manufacturer is required to put a QMS in place no later than 26 May 2024; and
- The manufacturer has lodged a formal application in accordance with the EU MDR for conformity assessment no later than 26 May 2024, and the notified body and the manufacturer have signed a written agreement no later than 26 September 2024.

**Figure 1. The proposed new EU MDR timeline per EU 2023/607 regulation<sup>2</sup>**



<sup>a</sup>For example, MDR quality management system implemented and notified body accepted MDR application and contract for legacy devices or substitute with notified body by 26 May 2024.

### Device classification

Devices are classified by intended purpose, according to a ruled-based system; inherent risk; and mode of action under the EU MDR Article 51<sup>1</sup> and Medical Device Coordination Group (MDCG) guidance document 2021-24.<sup>3</sup>

The EU MDR classifies medical devices based on those three elements in accordance with the classification rules set out in Annex VIII of the EU MDR 2017/745.<sup>1</sup> The classification rules are subdivided into four groups:

- Rules 1-4, noninvasive devices
- Rules 5-8 (including active implantable devices), invasive devices
- Rules 9-13, active devices
- Rules 14-22, special devices

Within each rule, the devices are classified as Class I, IIa, IIb, and III in ascending order of perceived risks. Furthermore, Class I devices are further categorized into sterile, measuring, and reusable (I<sub>r</sub>, I<sub>m</sub>, and I<sub>s</sub>, respectively) surgical devices. The risk class of a device indicates what needs to be done to obtain the CE certificate of the EU MDR.

The MDCG 2021-24 is not a European Commission document and is therefore not considered legally binding. It has been endorsed by the MDCG established under Article 103 of EU MDR 2017/745. The MDCG is composed of

representatives of all EU member states and is chaired by a representative of the European Commission.

### **Deletion of the sell-off period<sup>2</sup>**

The sell-off period requirement previously provided in Article 120(4)<sup>1</sup> of the EU MDR 2017/745 has been deleted per the EU MDR 2023/607 to avoid unnecessary disposal of safe medical devices. Therefore, the devices placed on the EU market before 26 May 2021 in accordance with the EU MDD/AIMDD or after 26 May 2021 during the transitional provision provided in Article 120 of the EU MDR 2023/607 – that is, until 31 December 2027 or 31 December 2028, depending upon the classification of a device – may continue to be placed on the market without any limitation in time and without prejudice to the device's shelf life or expiry date.

### **Conformity assessment process**

The conformity assessment process is enacted in Article 52 of the EU MDR 2017/745, which defines the compliance requirements for a device. The conformity assessment process for each risk class of device is provided in Annexes IX to XI. The higher the risk class of a device, the greater the involvement of a notified body. The EU declaration of conformity is a formal document that officially confirms the product fulfills all the necessary requirements of the CE directive.

Additionally, the conformity assessment procedure for custom-made or investigational devices is provided in Annex XIII and Article 82, respectively, of the EU MDR. The manufacturer also needs to comply with either Chapter I of Annex IX or Part A of Annex XI for Class III implantable custom-made devices.

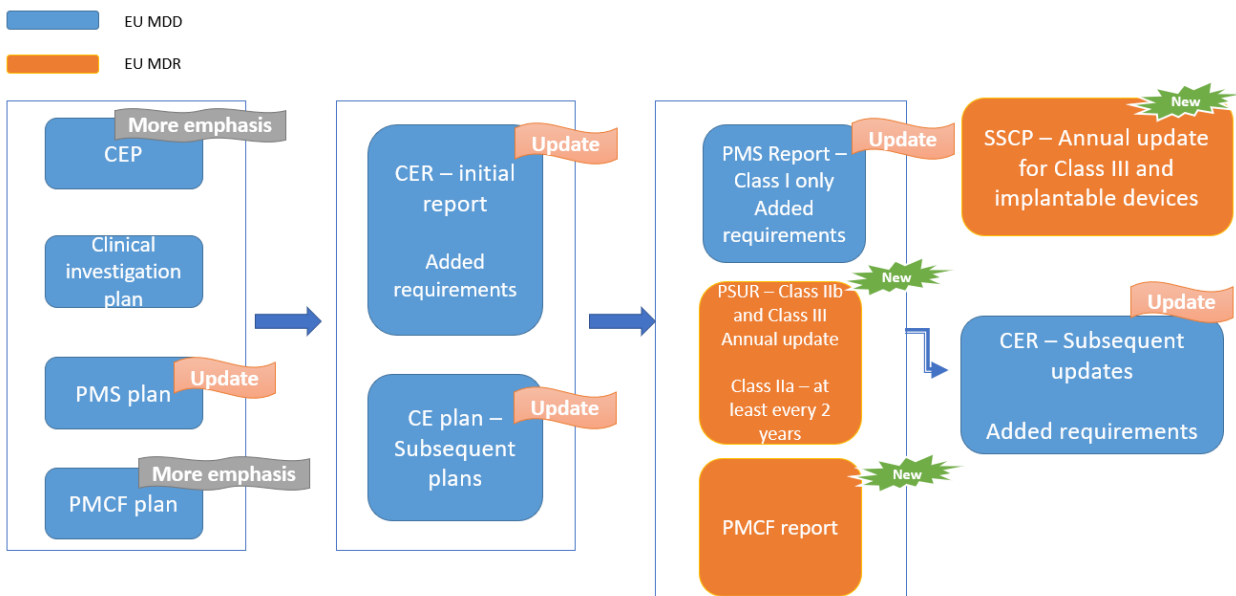
### **Clinical evaluation**

Clinical evaluation is a key regulatory requirement for medical devices and is significantly reinforced in the EU MDR compared with the AIMDD/MDD with the intention to improve public health and safety. The respective provisions for the clinical evaluation are primarily summarized in Article 61 and Annex XIV. An overview of the changes in the clinical evaluation process in transitioning from the EU MDD to the EU MDR is described in **Figure 2** (p. 4).

The main provisions include:<sup>1</sup>

- Clinical evaluation is an intrinsic part of the QMS (Article 10 (f)).
- The clinical evaluation must be established and updated according to a clinical evaluation plan (CEP), which should include specifically regulated content details (Annex XIV).
- Clinical evaluation requirements may be mandatorily regulated in product or product group-specific common specifications adopted by

**Figure 2. Updates to the clinical evaluation process in the EU MDR**



**CEP**, clinical evaluation plan; **PMS**, postmarket surveillance; **PMCF**, postmarket clinical follow-up; **CER**, clinical evaluation report; **CE**, clinical evaluation; **PSUR**, periodic safety update report; **SSCP**, summary of safety and clinical performance.

- the commission (Article 9). Further guidance, developed by expert panels, may be published by the commission as well (Article 106 (2)).
- Manufacturers may seek scientific advice from expert panels for their clinical evaluation strategy of Class III and certain Class IIb devices (Article 61(2)). Such consultation may require fees (Article 106 (13)).
- A clinical evaluation based on equivalence considerations must be based on clinical data of a single comparative device. Technical, biological, and clinical characteristics of such a comparative device should be similar to such an extent that there would be no clinically significant difference in the clinical performance and safety of the device (MDCG 2020-5).<sup>4</sup>
- For implantable devices and devices falling within Class III, clinical investigations must in general be performed to support the clinical evaluation. Exemptions may be applicable in the case of iterative product development by the same manufacturer, in the case of well-established technologies placed on the market under the AIMDD/MDD, or where a product falls in a certain group of specifically listed devices (Article 61).
- The clinical evaluation report (CER) must be updated during the lifecycle of the device. This must be done for Class III and implantable devices annually based on postmarket surveillance (PMS) data gathered. Respective reports, in particular the periodic safety update report

(PSUR) and postmarket clinical follow-up (PMCF) evaluation report (Annex XIV, Part B No. 7), must be considered.

- The CER must be part of the technical documentation and must consider favorable and unfavorable data.
- For implantable and Class III devices, the clinical evaluation must be summarized in the summary of safety and clinical performance (SSCP) document, which will be made publicly available in the European Database on Medical Devices (EUDAMED) and is also subject to updates, as applicable (Article 32).

Furthermore, a clinical evaluation consultation procedure (CECP)<sup>6</sup> is required for additional scrutiny of the quality and quantity of the clinical data per Article 54 of the EU MDR. The CECP is applicable to all Class III implantable devices and Class IIb active devices that are intended for the administration and/or removal of a medicinal product (Rule 12) except those devices that meet the following conditions according to Article 52(2) and MDCG guidance document 2019-3:<sup>7</sup>

- The renewal of the certificate is under the EU MDR,
- Device modification by the same manufacturer with no change to the intended use of the device and no overall change to the benefit-risk profile, and
- Where the notified body confirms compliance to the applicable common specification for clinical evaluation.

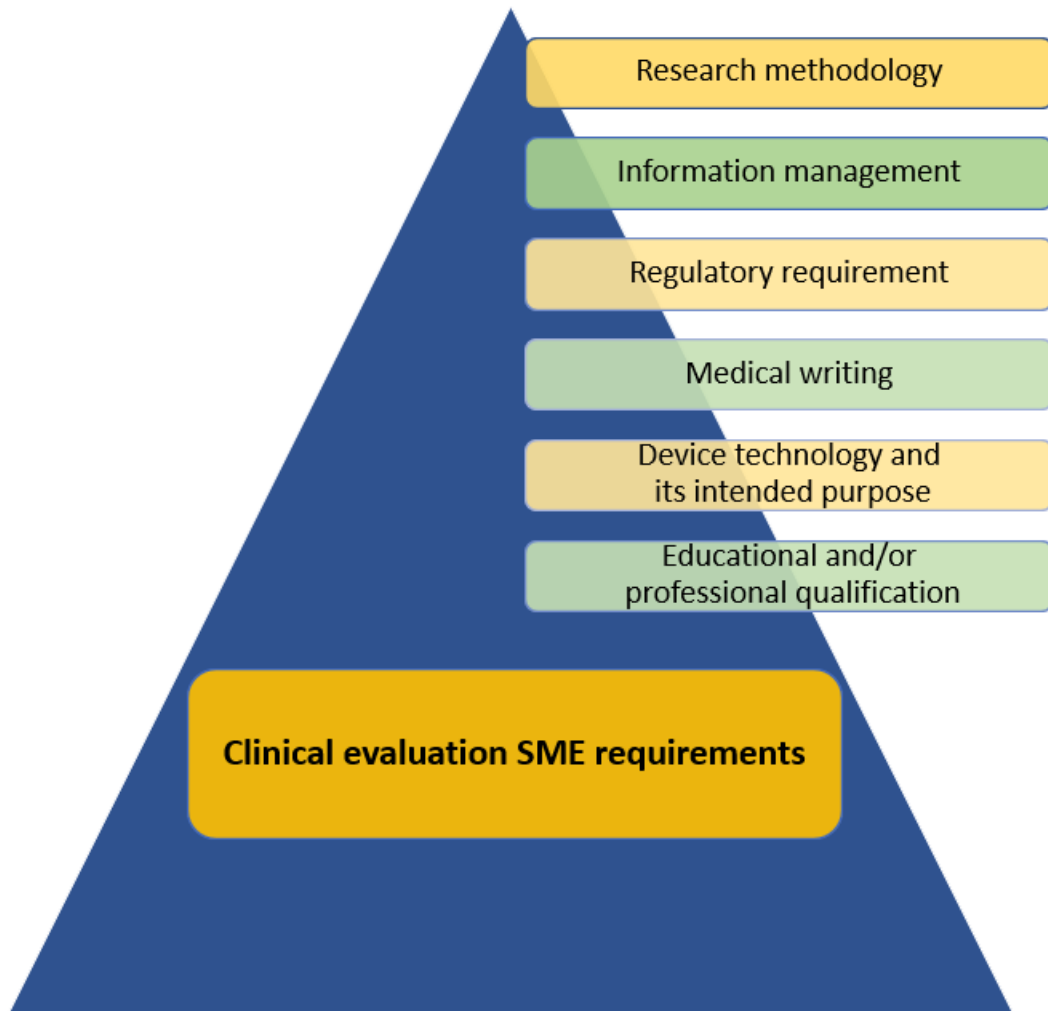
Once the clinical evaluation assessment report is available, a notified body decides whether CECP is relevant. If CECP is applicable, a process involving a panel with 10 experts<sup>8</sup> from different medical fields will be initiated by the notified body via the European Medicines Agency (EMA) as the coordinating authority. Such review may include fees for the conformity assessment applicant (Article 54 and Article 106 (13)).

Once the administration process is complete, the screening panel of the expert panel must decide within 21 days if a full consultation is required. In the case of a full consultation, the expert panel has 60 days to provide their scientific judgment to the notified body. The scientific opinion is based on the novelty and the risk-benefit profile of the device. A certification process cannot be completed by the notified body before the scientific opinion is provided by the expert panel. Therefore, manufacturers of devices within this scope should consider the 60-day period as part of the overall certification process.

### **Clinical evaluation process: Roles and responsibilities<sup>9</sup>**

The identification, appraisal, and analysis of clinical data, followed by the generation of a CEP and CER, is performed by medical affairs subject matter experts (SMEs) in conjunction with clinical and medical writing, medical safety, regulatory affairs, research and development, quality, and marketing SMEs (**Figure 3**).

**Figure 3. Requirements for medical review of the clinical evaluation report and annual updates**



**SME**, subject matter expert

MEs are required to have knowledge in the following areas according to MEDDEV 2.7/1 Rev. 4, Section 6.4:

- Medical writing (e.g., postgraduate experience in a relevant science or in medicine; training and experience in medical writing, systematic review, and clinical data appraisal)
- Regulatory requirements
- Information management (e.g., scientific background or librarianship qualification; experience with relevant databases such as Embase and Medline)
- Research methodologies such as clinical investigation design, biostatistics, etc.

- The technology and medical condition intended to be treated by the device(s) under evaluation, including state of the art
- The following training and professional experience in the respective field:
  - Degree from higher education in the relevant field and five years of professional experience; or
  - Ten years of professional experience if degree is not a prerequisite for an assigned task.

The SMEs are required to provide a declaration of interest and their CV to the manufacturer. The manufacturer should keep the declaration of interest and cover financial interests outside the current work of an SME. The declaration of interest is signed by both the manufacturer and the SME.

### **Postmarket surveillance**

PMS is required in the European medical device legislation to monitor the safety and performance of a medical device after approval and prior to the market release. The EU MDR intends to reinforce and harmonize respective provisions by increasing the collaboration between member state competent authorities and improving the communication between stakeholders through EUDAMED. Although some PMS requirements remain similar to AIMDD/MDD, certain EU MDR provisions require special attention. These are:<sup>1</sup>

- Economic operators (manufacturers, importers, and distributors) have obligations in the PMS activities (Articles 11, 13, and 14). A few examples of the responsibility of economic operators include ensuring devices distributed within the EU comply with the EU MDR requirements and reporting complaints and suspected serious incidents or injuries.
- The requirement for a PMS plan is outlined in Article 84 of the EU MDR 2017/745. The purpose of PMS is to proactively and systematically collect and review experience gained from devices after receiving marketing authorization in order to identify the need for corrective or preventive actions on the device in the field (if any). This plan addresses the collection, utilization, evaluation, and analysis of the postmarket information to continually assess the benefit-risk profile of the device and take action as appropriate. The gathered data will be used to update any relevant parts of technical documentation, such as those relating to risk assessment and clinical evaluation.
- For Class I devices (including sterile, measuring function, and reusable surgical instruments), a manufacturer is required to prepare and maintain a postmarket surveillance report (PMSR) summarizing results of the PMS data as a result of the PMS plan. The PMSR should be made readily available to the competent authorities upon request (Article 85).



- The requirements for the PSUR for Class III and Class II devices are listed in Article 86. The PSUR must be updated annually for Class IIb and III devices and at least every two years for Class IIa devices.
- The introduction of EUDAMED to collate and process PMS information by means of an electronic system (Article 92).
- The requirement for the PMS plan, including the PMCF plan and report (Annex III and Annex XIV).

There is a robust relationship between PMS and other parts of the QMS and respective deliverables – in particular, the risk management report, which includes the benefit-risk analysis (Annex I); the CER (Annex XIV); the PMCF evaluation report (Annex XIV), which is part of the CER; and the SSCP document (Article 32), which will be publicly available on EUDAMED.

The EU MDR provision on PMS applies to all devices, including custom-made devices after the DoA of the EU MDR, independent of whether they are placed on the market with a valid EU MDR or AIMDD/MDD certificate or are subject to self-certification under the regulation or directives. However, it is currently understood that the technical documentation of AIMDD/MDD-certified devices are not required to be mandatorily updated after the DoA, although the PMS deliverables listed in Annex III of the EU MDR must be on file at the manufacturer. Note, also, that if EUDAMED is not functional after the DoA, the respective database electronic reporting requirements do not apply, but dispositions of Article 123 (3)(d) are applicable (refer to MDCG 2021-1).<sup>5</sup> Special rules may be adopted by the commission and member states if certain modules of EUDAMED are operational but full functionality of the complete database is not declared.

### **Vigilance**

Vigilance is a key element of the European medical device legislation as defined in Section 2 of Chapter VII. Many requirements for a vigilance process remain similar to AIMDD/MDD; however, there are certain EU MDR provisions that require special consideration. Some of those provisions are described below:<sup>1</sup>

- The reporting time for initial serious incident reports (those that are not related to patient death, unanticipated serious deterioration in the state of health, or serious public health threat) is reduced from 30 to 15 days (Article 87 (3)).
- Serious injuries that are temporary in nature are considered reportable (Article 2 (65)).
- Exemptions to classify certain events as nonserious incidents as they are available in MEDDEV 2.12/1 are not available under the EU MDR.

- The unique device identifier (UDI) information is requested for serious incident reporting and field safety corrective actions (Article 27 (5)).
- Periodic summary reports may be provided under certain conditions (Article 87 (9)).
- Known and foreseeable risk and undesirable side effects are exempted from the reporting requirements to the relevant competent authorities. (Article 87 (1)).
- Trend reporting for nonserious incidents or for expected undesirable side effects that show a statistically significant increase in frequency and severity of such incidents (Article 88).
- Framework regulations for a “coordinating competent authority” concept for vigilance report and field safety corrective action assessment (Articles 89 (8) and (9)).
- Except in cases of urgency, the field safety notice should be submitted to the evaluating competent authority or coordinating competent authority for comments (Article 89 (8)).
- Introduction of EUDAMED to collate and process vigilance report and field safety notice information (Article 92).

The EU MDR provision on vigilance will apply to all devices after the DoA of the regulation, including those that are still placed on the market with a valid EU MDR or AIMDD/MDD certificate or prior AIMDD/MDD implementation. However, due to the EUDAMED vigilance module not being available by DoA, all EUDAMED vigilance requirements will not apply until implementation of the module (expected late 2023).

### Technical documentation<sup>2</sup>

The EU MDR Article 10 and Annexes II and III introduced the requirements for technical documentation intended to be used for registration purposes for a device to be launched in the EU and outside the EU. For custom-made devices, technical documentation is not required per Article 10 (4) and (5); however, a statement according to Annex XIII is needed when placing a device on the EU market.

Although technical documentation was already a requirement per MDD and AIMDD, the requirements under the EU MDR are more stringent and explicit. Technical documentation is a living document that summarizes the design and manufacturing of a device in accordance with the general safety and performance requirements to ensure the benefits of a device outweigh the risks. Additionally, technical documentation also includes information on the requirements for PMS set out in Annex III of the EU MDR (**Table 1**).

**Table 1. Required content in technical documentation under the EU MDR**

Annex II – Technical documentation
1. Device description and specification, including variants and accessories <ul style="list-style-type: none"> <li>1.1 Device description and specification</li> <li>1.2 Reference to previous and similar generations of the device</li> <li>1.3 Basic UDI-DI information relating to the UDI system</li> <li>1.4 Device classification per EU MDR Annex VIII</li> <li>1.5 Device identification (EMDN) and the SRN of the EU-authorized representative</li> </ul>
2. Information to be supplied by the manufacturer – labels, instructions for use, and patient implant card
3. Design and manufacturing information
4. General safety and performance requirements
5. Benefit-risk analysis and risk management
6. Product verification and validation <ul style="list-style-type: none"> <li>6.1 Preclinical and clinical data, such as test results for animal testing, bench-testing, mechanical, electrical safety and electromagnetic compatibility, software verification and validation, biocompatibility, stability (including shelf life, sterilization, packaging, etc.), evaluation of published literature applicable to the device, an SSCP for Class III implantable devices per Article 32</li> <li>6.2 Additional information required in specific cases</li> </ul>
Annex III – Technical documentation on PMS
1. The PMS plan
2. The PSUR for all Class IIa, IIb, and III devices
3. The PMSR for Class I devices

**EMDN**, European medical device nomenclature; **EU MDR**, EU Medical Device Regulation; **PMSR**, postmarket surveillance report; **PSUR**, periodic safety update report; **SRN**, single registration number; **SSCP**, summary of safety and clinical performance; **UDI**, unique device identifier; **UDI-DI**, UDI device identifier.

Medical device manufacturers, other than those producing custom-made or investigational devices, must set up an EU declaration of conformity (includes the single registration number) in accordance with Article 19 and affix the CE marking of conformity per Article 20. The technical documentation including the EU DoC and, if applicable, a copy of any relevant certificate must be kept available for a period of at least 10 years after the last device has been placed on the market, which is five years longer than required by the MDD and AIMDD. For implantable devices, the retention period is 15 years (Article 10 (8)). Upon request by competent authorities, manufacturers must provide the technical documentation in its entirety or as a summary (Article 10 (8)).

## The roles of competent authorities and notified bodies

### **Competent authorities**

Member states are responsible for the designation of competent authority or authorities per Article 101<sup>1</sup> (**Table 2**, p. 13). The competent authority is responsible for enforcing the EU MDR into national legislation. There are 27 member states plus the European Free Trade Association countries (Iceland, Liechtenstein, and Norway). This umbrella of agencies is known as the Competent Authorities for Medical Devices (CAMD). Each member state has its own competent authority responsible for providing information on national laws and regulations, guidance regarding adverse events, and enforcement-related information. The purpose of the CAMD is to improve communication and collaboration between various competent authorities to ensure compliance with the EU MDR and in turn support patient safety.

### **Notified bodies**

Each member state's competent authority has its conformity assessment bodies, also known as notified bodies. The primary function of a notified body is to ensure conformity of medical devices to the EU MDR regulations before devices are placed on the EU market.

The notified body must apply to their member state competent authority for the notified body designation. The assessment of the application is performed according to Article 39<sup>1</sup> of the EU MDR. A panel of three experts (one representative from the commission and two representatives from member states other than the one where the applicant is established) will assess the submitted application and then perform an on-site audit at the applicant's premises. A list of active notified bodies can be found on the New Approach Notified and Designated Organisations (NANDO) website.<sup>11</sup>

According to Article 44 (4),<sup>1</sup> the notified body must be evaluated at least once a year by its responsible competent authority. Additionally, a complete reassessment must be performed three years after the original notification and again every fourth year per Articles 38 and 39<sup>1</sup> of the EU MDR. In the case of any extension of its scope of designation, procedures listed in Articles 39 and 42<sup>1</sup> will apply. However, Article 46<sup>1</sup> enlists requirements for all other changes in the notified body designation, such as cessation of activity or where a member state restricts, suspends, or withdraws a notified body designation. In such cases, the manufacturer should review the impact of certificate validation per Article 46 of the EU MDR.

The designation of a notified body and any additional changes are published by the commission in the NANDO database and EUDAMED.

**Table 2. List of competent authorities<sup>10</sup>**

Country	Name of the competent authority
Austria	Federal Ministry of Social Affairs, Health, Care and Consumer Protection Austrian Federal Office for Safety in Health Care (BASG)
Belgium	Federal Agency for Medicines and Health Products (FAMHP)
Bulgaria	Bulgarian Drug Agency (BDA)
Croatia	Agency for Medicinal Products and Medical Devices
Cyprus	Cyprus Medical Devices Competent Authority
Czech Republic	State Institute for Drug Control, Medical Devices Branch
Denmark	Danish Medicines Agency (DKMA)
Estonia	Health Board
Finland	Finnish Medicines Agency (FIMEA)
France	Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
Germany	Federal Ministry of Health (BMG)
Greece	National Organization for Medicines
Hungary	National Institute of Pharmacy and Nutrition (OGYEI)
Iceland	Icelandic Medicines Agency (IMA)
Ireland	Health Products Regulatory Authority (HPRA)
Italy	Directorate General of Medical Devices and Pharmaceutical Services
Latvia	Medical Device Evaluation Department
Liechtenstein	Office of Public Health
Lithuania	The State Health Care Accreditation Agency
Luxembourg	Ministry of Health
Malta	Malta Medicines Authority – Medical Devices Unit
Netherlands	Ministry of Health, Welfare and Sports
Norway	Statens legemiddelverk (Norwegian Medicines Agency)
Poland	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Portugal	Infarmed – National Authority of Medicines and Health Products
Romania	National Agency for Medicines and Medical Devices of Romania
Slovakia	State Institute for Drug Control, Medical Devices Section
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP)
Spain	Agencia Española de Medicamentos y Productos Sanitarios
Sweden	Läkemedelsverket (Swedish Medical Products Agency)
Turkey	Turkish Medicines and Medical Devices Agency (TITCK)

### Certificates issued by a notified body

The existing provisions regarding the issuance of MDD and AIMDD certificates (product and quality management) by a notified body remain applicable under the EU MDR. For example, certificates will remain valid five years from the date of issuance. However, the EU MDR certificates will be assigned new titles and will refer to the new Annex numbers – that is, Annex IX, X, or XI<sup>1</sup> – because of the update of conformity assessment procedures. **Table 3** provides a comparison between current AIMDD and MDD certificates and the new EU MDR certificates.<sup>1</sup>

**Table 3. Comparison between EU MDD/AIMDD and EU MDR certificates**

EU MDD/AIMDD		EU MDR	
Certificate	Reference	Certificate	Reference
EC Certificate Full Quality Assurance System	Annex II, excl. Section 4 MDD Annex 2, Section 2 AIMDD	EU Quality Management System Certificate	Annex XI Ch. I, III
EC Design – Examination Certificate	Annex II, Section 4 MDD Annex 2, Section 4 AIMDD	EU Technical Documentation Assessment Certificate	Annex IX Ch. II
EC Type Examination Certificate	Annex III MDD Annex 3 AIMDD	EU Type Examination Certificate	Annex X
EC Certificate of Conformity	Annex IV MDD Annex 4 AIMDD	EU Product Verification Certificate	Annex XI Part B
EC Certificate Production Quality Assurance	Annex V MDD Annex 5 AIMDD	EU Quality Assurance Certificate	Annex XI Part A
EC Certificate Product Quality Assurance System	Annex VI MDD	NA	NA
EC Declaration of Conformity	Annex VII MDD	EU Quality Management System Certificate or EU Quality Assurance Certificate	Annex IX Ch. I, III or Annex XI Part A

**AIMDD**, Active Implantable Medical Devices Directive; **EC**, European Commission, **MDD**, Medical Device Directive; **EU MDR**, EU Medical Device Regulation; **NA**, not applicable.

Per Annex XII, a typical EU MDR certificate should include the following:

- The manufacturer’s single registration number referenced in Article 31(2) and Annex XII Chapter II No. 4; and
- The details of devices covered by certificates, including the reference of the basic UDI (Article 29, Annex XII).

According to Annex IX Section 4 or Annex X, a product-specific certificate may be issued for Class III or Class IIb implantable devices with a few exceptions. In contrast, Class IIb (nonimplantable), Class IIa, and Class I devices are covered by QMS certificates. **Table 4** (p. 15) lists the overview of which EU MDR certificate may be issued by the notified body based on the device class and the manufacturer’s conformity assessment route.

Once a medical device is approved in the EU, the notified body is required to enter the corresponding EU MDR certificates and related information in EUDAMED so that the information will be made publicly available, including the amendments and supplements as well as information about suspended,

**Table 4. Different types of EU MDR certificates per conformity assessment route**

Device class	Applicable EU MDR QMS CE certificate	Applicable EU MDR product CE certificate
Class I	NA	NA
Class Is	Annex IX Ch. I, III or Annex XI Part A (limited scope)	NA
Class Im	Annex IX Ch. I, III or Annex XI Part A (limited scope)	NA
Class Ir	Annex IX Ch. I, III or Annex XI Part A (limited scope)	NA
Class IIa	Annex IX Ch. I, III <sup>a</sup>	NA
	Annex XI Part A or B	NA
Class IIb	Annex IX Ch. I, III <sup>b</sup>	NA
	Annex XI Part A or Part B	Annex X
Class IIb implantable <sup>c</sup>	Annex IX Ch. I, III	Annex IX Ch. II
	Annex XI Part A or Part B	Annex X
Class III	Annex IX Ch. I, III	Annex IX Ch. II
	Annex XI Part A or Part B	Annex X

**Im**, Class 1, measuring; **Ir**, Class I, reusable; **Is**, Class 1, sterile.

<sup>a</sup> One representative per category will be reviewed according to Annex IX Section 4. <sup>b</sup> One representative per generic group will be reviewed according to Annex IX Section 4. <sup>c</sup> Note exemptions to be certified as Class IIb devices.

reinstated, withdrawn, or refused certificates and restrictions imposed on certificates, in accordance with Article 56(5). Relevant additional regulations pertaining to the issuance and management of EU MDR certificates fall under the following statutory requirements:

- **Article 46** – Changes to designations and notifications; contains EU MDR guidance on the fate of certificates in cases where a notified body ceases its activities or the notified body designation has been suspended, restricted, or withdrawn.
- **Article 58** – Voluntary change of notified body; contains EU MDR guidance on the management of certificate validity in case a manufacturer is planning to change its notified body.

The new EU MDR guidance is also intended to clarify the impact of the collective changes. Some of the anticipated impacts include:

- Updates to product registrations in countries outside the European region (EU) are required where the current registration relies on existing AIMDD/MDD certificates.

- Some product certificates may have to be split into several certificates due to the definition of basic UDI-DI.
- Because of device specification requirements, the management of QMS certificates may become more burdensome.
- Additional liability on the manufacturers and authorized representatives for the verification of certificate information in the EUDAMED portal.
- The EU MDR requirements could entail increased notified body fees and internal certificate management costs.

### Conclusion

The new EU MDR applies to products intended to be marketed on the EU market for human use. Relevant details on the EU MDR scope and product qualification processes in the EU are documented in Article 1 and Article 4 of the EU MDR 2017/745.

The scope of the EU MDR includes the following:

- Product fulfills the definition of medical devices per Article 2 (1) or their accessories (Article 2(2));
- Per Annex XVI, there are certain product groups listed in Article 1(2) without an intended medical purpose;
- Medical devices (nonviable or viable) manufactured utilizing tissues or cells of human origins or their derivatives (refer to Article 1(6) (g)); and
- Devices that incorporate, as an integral part, nonviable tissues or cells of human origin or their derivatives that have an action ancillary to that of the device (Article 1 (10)).

Furthermore, products containing or consisting of viable biological materials or viable organisms, including living microbes, bacteria, viruses, or fungi, to achieve their intended purposes are no longer in the scope of the EU MDR.

The manufacturer is required to review the new EU MDR guidance for assessing the new and additional requirements for acquiring the new EU MDR CE mark. The new requirements constitute a considerable amount of work to update or revise the technical documentation of legacy medical devices, including labeling, clinical documentation, and PMS documentation. In a few cases, additional clinical data may need to be collected to demonstrate the safety and performance of the device, as historic equivalence statements may no longer be deemed sufficient. In addition, notified bodies must regain their designation under the EU MDR. Considering the tremendous amount of work required not only by the device manufacturer but also by the notified body and authorized representative, the DoA has been pushed out to 31 December 2027 or 31 December 2028, as applicable, to demonstrate compliance with the requirements of the EU MDR 2017/745 per Regulation (EU) 2023/607.



### Abbreviations

**AIMDD**, Active Implantable Medical Devices Directive; **CE**, Conformité Européenne; **CECP**, clinical evaluation consultation procedure; **CEP**, clinical evaluation plan; **CER**, clinical evaluation report; **DoA**, date of application; **DoC**, declaration of conformity; **EUDAMED**, European Database on Medical Devices; **EU MDR**, EU Medical Device Regulation; **MDCG**, Medical Device Coordination Group; **MDD**, Medical Device Directive; **MEDDEV**, Medical Device Directive; **NANDO**, New Approach Notified and Designated Organisations; **PMCF**, postmarket clinical follow-up; **PMS**, postmarket surveillance; **PMSR**, postmarket surveillance report; **PSUR**, periodic safety update report; **QMS**, quality management system; **SSCP**, summary of safety and clinical performance; **UDI**, unique device identifier; **UDI-DI**, UDI device identifier.

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