EU MDR Conformity Assessment Options for Medical Devices

Determining the proper path to CE marking for your products

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Introduction

From May 26, 2021, new devices intended to be marketed in the European Union (EU) must comply with the Medical Device Regulation 2017/745 (MDR). In January 2023, the European Commission (EC) issued a proposal to extend the transitional period under Article 120 for the MDR until 2027 or 2028: this extension was to give more time to manufacturers and to address the paucity of Notified Bodies (NB) available to perform CE certifications. This quickly led to Regulation 2023/607.

Certificates issued by NBs in accordance with Directives 90/385/EEC (Active Implantable Medical Devices Directive (AIMD)) and 93/42/EEC (Medical Devices Directive (MDD)) valid before May 26, 2021, and that have not been withdrawn afterwards shall remain valid until the date set out in the next paragraph applicable for the relevant risk class of the devices provided the devices are compliant to amending Regulation 2023/607:

(a) Dec. 31, 2027, for all Class III devices, and for Class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;

(b) Dec. 31, 2028, for Class IIb devices other than those covered by point (a) of this paragraph, for Class IIa devices, and for Class I devices placed on the market in sterile condition or having a measuring function.

Devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of an NB, for which the declaration of conformity (DoC) was drawn up prior to May 26, 2021, and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of an NB, may be placed on the market or put into service until December 31, 2028, provided the devices are compliant with amending Regulation 2023/607.

Devices covered by a valid certificate, or a DoC drawn up prior to May 26, 2021 and up-classified under the MDR may be placed on the EU market or put into service until these dates only if the following conditions as described in Regulation 2023/607 are met:

"(a) those devices continue to comply with AIMD or MDD, as applicable;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do 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;

(d) no later than May 26, 2024, the manufacturer has put in place a quality management system (QMS) in accordance with Article 10(9);

(e) no later than May 26, 2024, the manufacturer or the authorized representative (AR) has lodged a formal application with a NB and, no later than September 26, 2024, the NB and the manufacturer have signed a written agreement."

Certificates issued by an NB in accordance with those Directives that were still valid on May 26, 2021, and that have expired before March 20, 2023, shall be valid until these same dates only if one of the following conditions is fulfilled:

(a) Before the date of expiry of the certificate, the manufacturer and an NB have signed a written agreement.

(b) A competent authority (CA) of a Member State (MS) has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure.

The common requirements applicable to medical devices are delineated in Annex I General Safety and Performance Requirements of the MDR. Compliance with the General Safety and Performance Requirements (GSPR) generally entails compliance with European Norm (EN) harmonized standards, published in the Official Journal of European Union (OJEU), and with common specifications (CS), adopted by acts. Compliance with EN harmonized standards and CS presumes compliance with the relevant GSPR.

In addition to compliance with the GSPR, medical device manufacturers must select an appropriate route to conformity assessment (Annexes IX through XI). Device classification partially determines the route. Classification of a medical device in the EU is regulated by Annex VIII of the MDR and results in four classes (I, IIa, IIb, and III) taking into account the intended purpose of the devices and their inherent risks. The classification rules in Annex VIII of the MDR assign a class to the medical device considering mainly the duration of use and the invasiveness. Depending on the medical device class, the manufacturer may choose the appropriate conformity assessment route to demonstrate compliance with the Regulation.

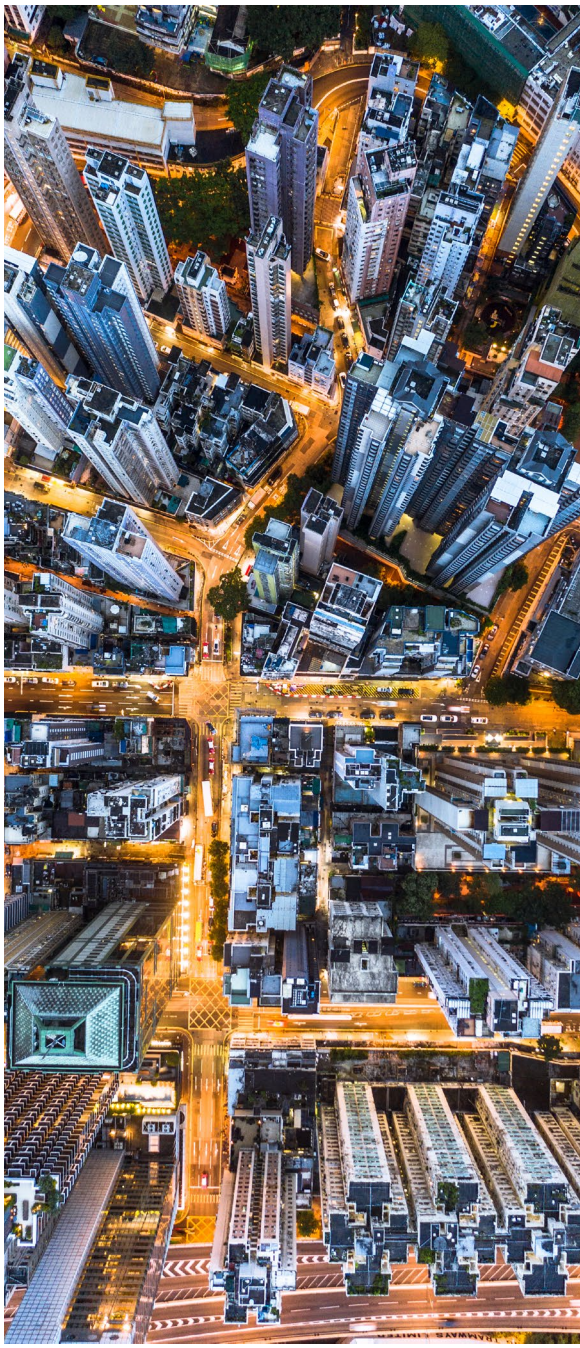
The level of control by external parties is correlated with the perceived risk associated with the device with:

- So-called “self-certification” when no external party is involved in the conformity assessment.
- Certification by an NB.
- The involvement of a CA or expert panels via EC or the Medical Device Coordination Group (MDCG).[1]

A centralized database, the European Database on Medical Devices (EUDAMED), is used to register all CE certificates issued by NBs. EUDAMED is an online electronic system that has been put in place by the EC to facilitate the regulation of medical devices and in vitro diagnostics (IVDs) throughout the EU single market. The implementation of EUDAMED in the context of the MDR has been delayed, with the new go-live date expected in Q1 2026.

The New Legislative Framework, which describes products subject to CE marking, presents manufacturers with several methods to demonstrate compliance with MDR. For medical devices that require NB involvement, a manufacturer may choose between different modules to demonstrate compliance and obtain CE marking. Below are some options, or differences, in selecting a route to conformity assessment for a particular device.

Routes of conformity



The following sections describe the options of conformity assessment routes a manufacturer may select. The routes depend on the device class, and consequently on the level of device risk, and consist of meeting the requirements of a single or combination of Annexes.

Annex IX (QMS and technical documentation) is used when a full QMS is implemented by the manufacturer. In addition, a review of technical documentation is also necessary with or without the issuance of CE certificates. Depending on the device classification, full or partial compliance with the Annex IX is required. Annex IX comprises three parts:

- Assessment of QMS via NB audit with issuance of CE marking certificate.
- Assessment of Technical documentation via NB audit with issuance of CE marking certificate.[2]
- General provisions for record retention and availability of documentation to CA. Note: this third part is not described in the Figures hereafter as it is always applicable when Annex IX is applied.

Annex X (type-examination) is used when a manufacturer wants to certify a device based on a representative sample. The NB examines and/or tests the representative sample and associated technical documentation to determine if the device meets MDR requirements and especially the GSPR.

Annex XI (product conformity verification) is generally used in association with Annex X or in combination with technical documentation (Annexes II and III) for low-risk devices. The Annex XI is composed of two parts:

- Production Quality Assurance via NB audit with issuance of CE marking certificate for ability to produce and test a device
- Product Verification via NB audit with issuance of CE marking certificate supporting the conformity of a specific batch of devices

All those annexes also require initiation of a technical file (or technical documentation) in compliance with Annex II (technical documentation) and Annex III (technical documentation on Post-Market Surveillance - PMS) depending on the devices and route of compliance.

Class I devices

The only route for a self-certified Class I medical device is to maintain technical documentation in compliance with Annex II and III. In addition, for the Class I device supplied sterile (Is), with a measuring function (Im), or reusable surgical instruments (Ir), a limited QMS must be in place to control the production (Annex XI Part A) or to control the special characteristic (e.g., sterility, measuring, reusable features) (Annex IX – Chapter I). For Class Is, Im and Ir devices, a NB will be involved to control how the QMS manages those specific features in regard to the conformity assessment procedure selected.

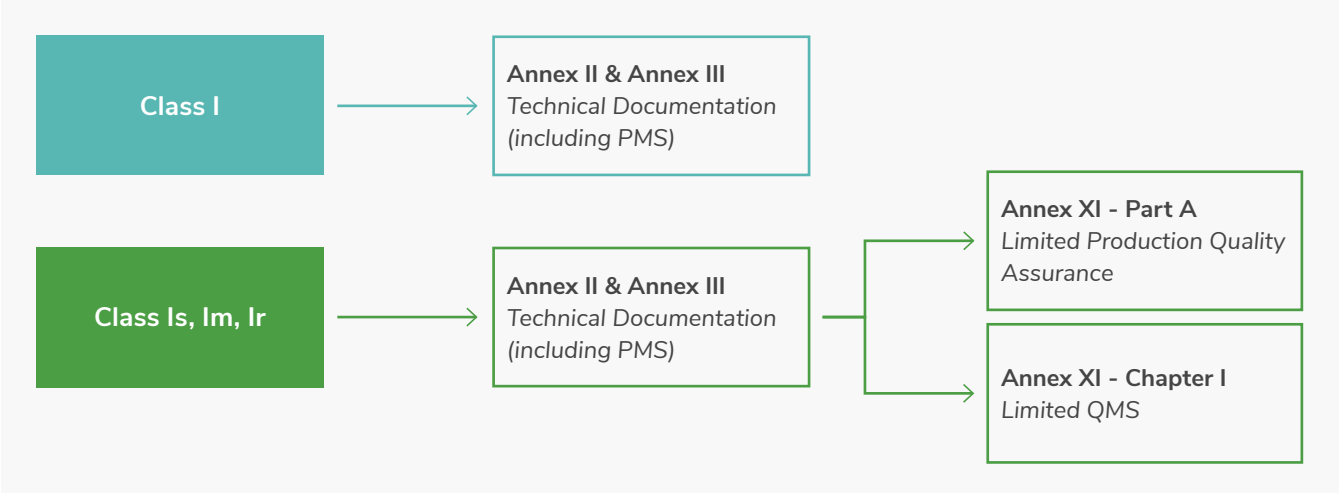


Figure 1: Conformity assessment procedures for Class I devices (Source: Emergo by UL)

Class IIa devices

The conformity assessment procedure for a Class IIa device through the review of full QMS (Annex IX) is identical to the procedure for a Class IIb non-active and non- implantable device. Alternatively, a manufacturer may build technical documentation aligned with Annex II and III and select a route of conformity assessment based on the production control (Annex XI).

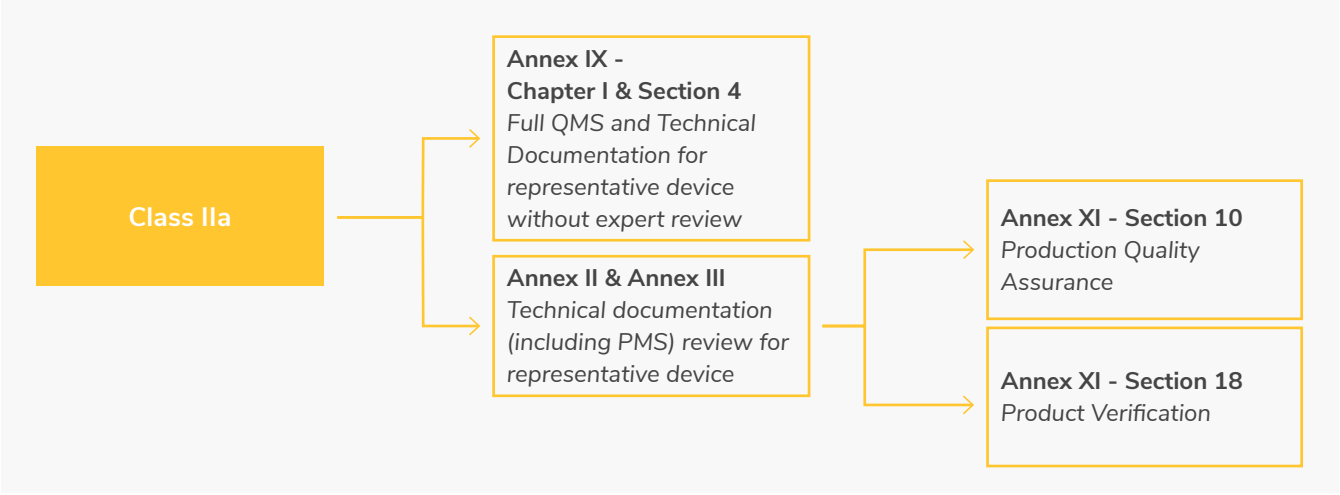


Figure 2: Conformity assessment procedures for Class IIa devices (Source: Emergo by UL)

Class IIb devices

Class IIb devices should be considered part of one of the following categories:

- Class IIb implantable device
- Class IIb active device intended to remove or administer medicinal substances
- Class IIb device not included in the categories above

The level of control for Class IIb devices is similar to Class III devices, though there is no separate CE certificate issued for the technical documentation assessment. In addition, expert panel involvement is not required in the review process unless the Class IIb device is active and intended to remove or administer a medicinal substance. Finally, the technical documentation review is performed on a representative sample of device type except for Class IIb implantable devices, for which 100% review is required.

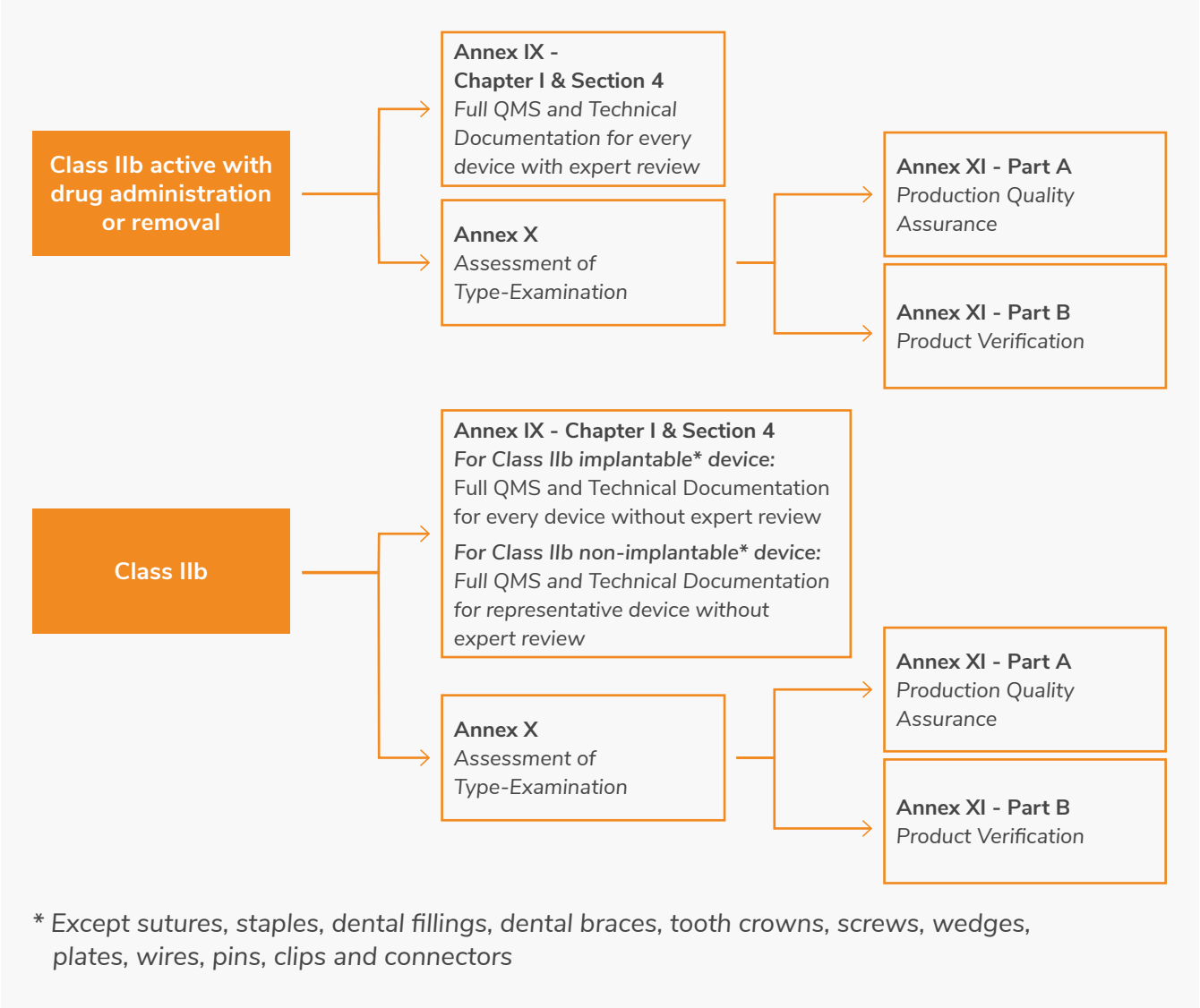


Figure 3: Conformity assessment procedures for Class IIb devices (Source: Emergo by UL)

Class III devices

For Class III medical devices, Annex IX including full quality assurance audit and full technical documentation review is a viable option. A certificate is issued after the NB QMS audit, and a second certificate for every device after reviewing the associated technical documentation. In addition, an expert panel is involved in the evaluation for Class III implantable devices.

While standards are voluntary, one way of presuming conformity to the GSPR and meeting the provisions of full quality assurance is to possess harmonized EN ISO 13485 standard certifications, which pertains to the state of the art and expected requirements for a company's QMS in the EU.

It should be noted that manufacturers of Class III medical devices also have the option to pursue Annex X, Type-Examination, in combination with Annex XI Part A or Part B and, therefore, with a QMS focused on production and controls.

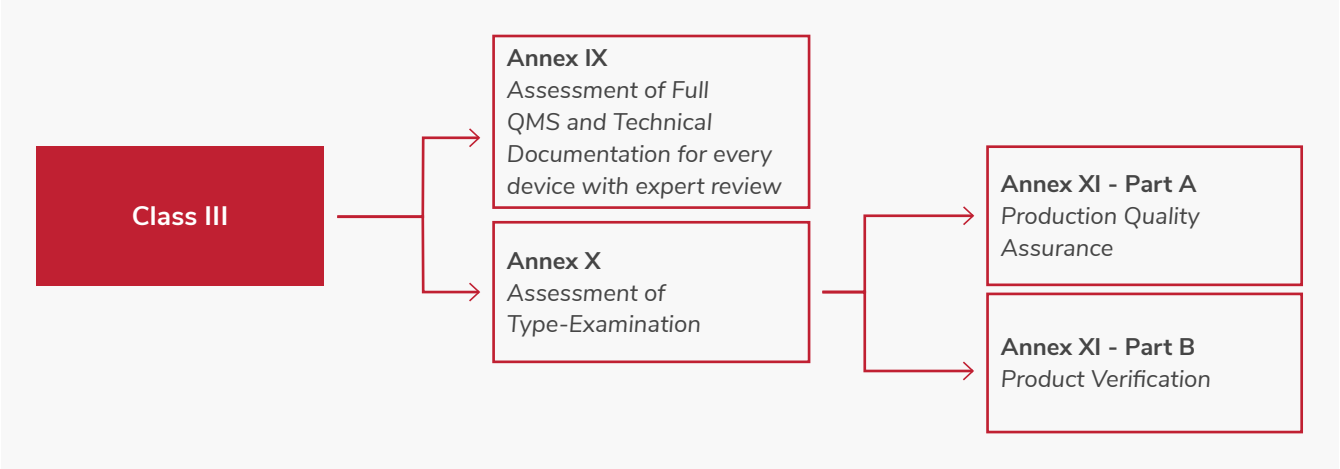


Figure 4: Conformity assessment procedures for Class III devices (Source: Emergo by UL)

Additional procedures

For devices incorporating drugs, manufacturers must comply with Annex IX section 5.2 including verification of quality, safety, and usefulness of medicinal substances in compliance with 2001/83/EC.

For devices incorporating animal or human tissues/ cells, manufacturers must comply with Annex IX section 5.3, including:

- Evaluation of donation, procurement, testing of tissues or cells of human origin or their derivatives and information about the non-viability of the human tissues or cells
- For animal tissues from Transmissible Spongiform Encephalopathy (TSE) susceptible species, e.g., bovine, evaluation of compliance with 722/2012 for devices manufactured utilizing animal tissue that is rendered non-viable or utilizing non- viable products

For devices introduced into the human body through bodily orifices or applied on the skin and intended to be absorbed or locally dispersed, the manufacturer must comply with Annex IX section 5.4, including evaluation of compliance with Annex I of 2001/83/EC for the absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances, and potential for adverse reactions.

Declaration of conformity

The EU DoC is the commitment of the manufacturer to comply with the MDR as well as all other applicable EU legislation. The DoC is required for all classes of devices and must be signed off by the manufacturer.

Scrutiny process

With the MDR, additional checkpoints of control have been defined for devices that may pose risks or health concerns.

For Class III implantable devices and Class IIb active devices intended to administer or remove drugs from the human body, an expert panel is involved to provide, if deemed necessary, its scientific opinion on the clinical evaluation the NB requires to proceed with the certification procedure.

MDCG 2019-3 Rev.1 Interpretation of Article 54(2)b of April 2020 provides clarification on the exemption for this clinical evaluation consultation procedure.

Each NB will register in EUDAMED the CE marking certificates of conformity granted to devices for which the conformity assessment has been performed. For reasonable concerns, CAs and the EC may take measures against NBs or manufacturers; the MDCG and EC may also request advice from the expert panels regarding the device safety and performance, and without considering whether CE marking certificates have been issued.

Drug device combination (DDC) product (Art. 117)

A DDC product is regulated by the medicinal product Directive 2001/83/EC (single integral product intended exclusively for use in the given combination and not reusable). However, Article 117 of the MDR applies to the device part, of the DDC product. The device part must comply with the applicable GSPR. If a DoC or a CE marking certificate is not available for this device part, a NB Opinion (NBOp.) is required based on technical documentation provided on the device part. This NB report is intended to present evidence of compliance with the relevant GSPR.

Main classification changes compared to MDD and consequences

Though the conformity assessment routes to CE marking have not significantly changed in the MDR compared to the MDD, there are more actors in the evaluation process, which can increase the time to obtain CE marking certification. Fortunately, review timelines for new actors (e.g., expert panels) are defined, and consequently the planning can be more predictable. However, the MDR does not provide any timeline for NB review, unlike what US FDA provides in terms of device review timeframes.

Even after the issuance of CE marking certificates, the manufacturer may be requested to provide supplemental information or to take measures by the CA, EC, or MDCG to ensure the safety and performance of medical devices in the EU.

A new Class Ir for low-risk devices has been created to control the safety related to the reusable characteristics of such surgical instruments. In addition, the list of classification rules has significantly changed and the level of control for some device types has increased due to their reclassification. Manufacturers must carefully evaluate the classification of their devices in the frame of the new MDR.

Finally, compared to the essential requirements in the MDD, the quantity of requirements in MDR's GSPR has significantly increased and, when coupled with the adoption of new requirements in CS, the current design/manufacturing/labelling/etc. of some medical devices may become obsolete. The transition to MDR must also include an evaluation of possible changes necessary to meet the new MDR requirements.

Conclusion

There are so many different types of medical devices on the market, ranging from low-risk products such as stethoscopes to high-risk devices such as pacemakers. The 2017 MDR and the In Vitro Diagnostic Medical Devices Regulation (IVDR) established a modernized and more robust EU legislative framework to support better protection of public health and patient safety. However, despite considerable progress with the implementation, the EC described the transition to the new rules as slower than anticipated. Healthcare systems throughout the EU were seen to face a risk of shortages of life-saving medical devices for patients. Short term actions to mitigate risk of shortages of life-saving devices and disruption of supply were put in place by the EC with amendments of the MDR/IVDR with the following key elements:

- Staggered and conditional extension of the transition period until 2027/2028, according to risk class of the device
- Extended validity of certificates
- Cancellation of “sell-off” date, i.e., allowing devices placed on the market before or during the transition period to continue to be made available without time limitation

The impact was indeed huge and should not have been underestimated by manufacturers. The classification, conformity assessment routes, and compliance to new GSPRs were the first stones to build or consolidate a new medical device business in the EU. Issuance of multiple MDCG guidances on various topics (and still more to come) definitely support the implementation of the requirements.

End Notes

1. MDCG members represent the Competent Authorities of the Member States. Each Member State appoints one member and one alternate each with expertise in the field of medical devices, and one member and one alternate with expertise in the field of in vitro diagnostic devices. A Member State may also appoint only one member and one alternate, each with expertise in both fields (EC **http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3565&news=1**

2. Note that Chapter I, Section 2.2 states that the manufacturer shall grant access to the technical documentation to the Notified Body.

Learn more

Need help transitioning to the EU MDR? Emergo by UL helps medical device companies with regulatory compliance and market access in Europe and other markets worldwide. Here's how we can help:

- Technical File and CER compilation and review
- European Authorized Representation
- MDR gap audits and transition consulting
- Support compliance with implementing an ISO 13485:2016 certified QMS and performing internal audits

Learn more about how we can help you achieve or maintain European medical device compliance at **EmergobyUL.com**.

About the author

Rachel Paul-Zieger has over 18 years of experience in the medical device industry as well as international experience in high-risk device regulatory submissions and quality assurance requirements. Rachel's accomplishments include: 11 FDA 510(k) clearances; more than 20 EU Technical Files/Design Dossiers; writing more than 35 Clinical Evaluation Reports; implementation of 5 quality systems to ISO 13485/CE Marking/FDA QSRs/CMDCAS; quality system gap assessment and improvements; auditing for compliance to multiple standards; conducting training to various international regulations; more than 35 global regulatory strategy analyses; and compilation and submission of numerous registration dossiers for international marketing authorization.

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