EU MDR CONFORMITY ASSESSMENT OPTIONS FOR MEDICAL DEVICES

Determining the proper path to CE Marking for your products

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August 2018
Introduction

From 25 May 2020, new devices intended to be marketed in Europe (EU) must comply with the Medical Device Regulation 2017/745 (MDR). From 25 May 2020, medical devices bearing a valid CE marking may continue to be marketed in compliance with the Medical Device Directive 93/42/EEC (MDD) until the expiry date of their certificate. From 25 May 2025, all medical devices marketed in the EU must be compliant to MDR.

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 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 a Notified Body (NB);
- The involvement of a Competent Authority (CA) or expert panels via Commission or the Medical Device Coordination Group (MDCG)\(^1\).

A centralized database, EUDAMED, will be used to register all CE certificates issued by NBs. Eudamed will be accessible by all CAs, the MDCG, and the European Commission, from which additional information or measures may be requested to ensure consistent device safety and performance throughout the EU.

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.

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 (European Commission [http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail&groupDetail&groupID=3565&news=1])
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 certificate. Depending on the device classification, a 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 File/Design Dossier via NB audit with issuance of CE Marking certificate
- General provisions for record retention and availability of documentation to Competent Authority (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.

2. Note that Chapter I, Section 2.2 states that the manufacturer shall grant access of the technical documentation to the Notified Body.
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, an NB will be involved to control how the QMS manages those specific features in regard to the conformity assessment procedure selected.

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 1: Conformity Assessment Procedures for Class I Devices (Source: Emergo)

Figure 2: Conformity Assessment Procedures for Class IIa Devices (Source: Emergo)
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 with the exception of Class IIb implantable devices, for which 100% review is required.

*Except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors*
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 following the NB QMS audit and a second certificate is issued for every device after the review of 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 certification, which pertains to the state of the art and expected requirements for a company’s quality management system 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)
**Declaration of Conformity**

The EU Declaration of Conformity (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.

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, Competent Authority (CA) and Commission may take measures against NBs or manufacturers; the MDCG and Commission may also request advice from the expert panels regarding the device safety and performance, and without considering whether CE Marking certificates have been issued.

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**Additional Procedures**

For devices incorporating drugs, manufacturers must comply with Annex IX section 5.2 including verification of quality, safety, and usefulness of medicinal substance 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 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.
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, Commission, 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.

Conclusions

The transition to MDR may stretch beyond five years, but this timeline is necessary for the Commission, Competent Authorities, Notified Bodies, EUDAMED, and manufacturers to successfully move to the new legislative framework. The impact is huge and should not be underestimated by manufacturers. The classification, conformity assessment routes, and compliance to new GSPRs are the first stones to build or consolidate a new medical device business in the EU. The changes are various and numerous and must be carefully considered in terms of your QMS, in the design/manufacturing/labelling/etc. of medical devices, and in collaboration with your Notified Body. It is also important to understand that the changes are for all actors in the medical devices industry (e.g., importer, Authorized Representative, distributor) as well as parties that control the medical device industry. There will be a learning curve for all parties to properly interpret European regulatory changes and be aware of new legal expectations.
Learn More

Need help transitioning to the EU MDR? Emergo 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
- ISO 13485:2016 certification and audits

Learn more about how we can help you with European medical device compliance at EmergoByUL.com.

About the Author

Alexandre Pétiard is a Senior Quality & Regulatory Consultant at Emergo. With more than eight years of experience in regulatory affairs, his expertise includes design control support, technical file preparation, clinical evaluation report, risk management file, 510(k), quality system implementation and audits, and post-market surveillance and vigilance activities. Mr. Pétiard previously held regulatory positions at Covidien, Integra LifeSciences, and Alcis.