MDR DESIGN DOSSIER

After reading this fact sheet you should:

- Know what MDR design dossier is and understand the requirements.
- Become familiar with the contents of a MDR design dossier.
- Have links to related resources.

Medical device companies who wish to sell their devices in the European market must obtain a CE marking. The **European Medical Device Regulation (EU) 2017/745 (MDR)** requires medical device manufacturers to provide technical documentation for their products. The technical documentation is a compilation of all relevant documents for a product and must be kept up to date throughout the entire product life cycle. It is the basis for the conformity assessment and thus for the CE marking of a product. The MDR has been fully applicable since 26 May 2021. All the steps involved in getting a CE certification are mentioned **HERE**.

What does a MDR Design Dossier include?

When CE marking a medical device, the manufacturer must present the medical device technical file to the regulatory body. According to Annex II of the **EU MDR 2017/745**, it should include the following elements:

- Description of the device and its specification, including variants and accessories.
- Labelling and packaging information.
- Instructions for use in all the EU state languages where the medical device is to be sold.
- Design and manufacturing information (details of manufacturing sites, where design and manufacturing activities are to be performed).
- Documentation demonstrating compliance with general safety and performance requirements with regards to relevant standards.
- Detailed risk analysis and risk management file.
- Product verification and validation report and other relevant documentation.
- Pre-clinical and clinical data, such as test results, clinical evaluation report and Post Market Clinical Follow-up evaluation plan.
- Post-market surveillance plan and report.
- Declaration of Conformity.

In addition to the technical file, medical device manufacturers must establish, document and implement a proper quality management system and maintain its effectiveness throughout the lifecycle of the device.

The documentation must always be up to date, including the latest modifications to the medical device or amendments in the MDR and any other relevant regulations.

According to Articles 38 and 39 of the **MDR**, all documents part of the medical device technical file must be in a language determined by the Member State concerned.

How do I file for CE certification?

According to Annex IX of the **EU MDR 2017/745**, the technical file of medical devices class IIb and class III must be assessed by a Notified Body for compliance with relevant requirements. In this regard, manufacturers must submit an application for assessment to a Notified Body, which must address the design, manufacture and performance of the medical device in question.

A notified body, in the European Union, is an organisation that has been designated by a member state to assess the conformity of certain products, before being placed on the EU market, with the applicable essential technical requirements. These essential requirements are publicised in European directives or regulations.

Where do I find these notified bodies?

A list of notified bodies can be found **HERE**. Some EU countries have more than one notified body. In Ireland, the **National Standards Authority of Ireland** is the only notified body for all of Ireland. You may reach out to any notified body across the EU to file for CE certification depending on which country is your target market.

What happens once I get the CE certification?

Health Products Regulatory Authority (HPRA) monitors the safety of medical devices in Ireland after they are placed on the market. The HPRA operates a national reporting system for medical devices. If new safety or quality information emerges, the HPRA ensures that medical device users are informed and advised as needed. They carry out on-site audits of selected manufacturers of medical devices to monitor compliance with relevant standards and legislation. They may also audit in response to a significant medical device safety or quality concern. If they identify a significant safety or quality concern with a device, there are a range of regulatory actions which can be executed to protect public health. These include changes to labelling, safety notices and recalling the product from the market. They can also request changes or modifications to the device itself.

The HPRA is an active member of EU committees and working groups involved in the assessment and development of medical devices regulation on the market.

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