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CE Marking for Medical Devices

Medical Device Regulation (EU) 2017/745

Regulation (EU) 2017/745

The new European Medical Device Regulation (EU) 2017/745 (MDR) was published in Official Journal of the European Union on 5 May 2017 and came into force on 25 May 2017.

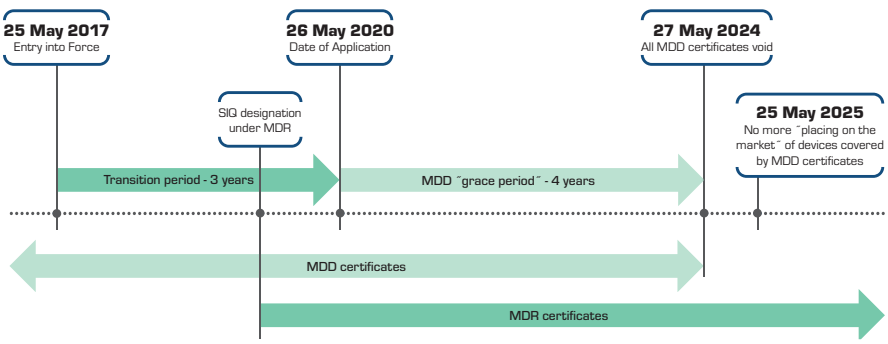
The MDR will replace the Medical Device Directive (93/42/EEC) and Active Implantable Medical Device Directive (90/385/EEC). The scope has been extended to include a number of additional devices (devices without an intended medical purpose).

The MDR will have the force of law across all EU countries, which will eliminate different EU countries interpretations and implementations of the requirements.

Manufacturers of currently approved medical devices will have a transition time of three years until 26 May 2020 to meet the requirements of the MDR.

Certificates to the MDD issued after MDR publication (25 May 2017) have full validity unless that exceeds four years after the date of application (26 May 2020).

The MDR Timeline



Why Acquire a certificate

The EU legislation (MDR) in the field of medical devices stipulate that manufacturers of medical devices must label their products with CE markings before launching them on the EU market. In this way, the manufacturers state that the medical device complies with the EU regulation in the field of medical devices and guarantee a safe and professional medical device. For class Is, Im, Ir, IIa, IIb and III (MDR) medical devices, the notified body (SIQ) must be included in the conformity assessment procedure of a medical device. Conformity with the requirements of the EU regulations for medical devices is proved by the granted EC Certificate.

A Quality Management System According to ISO 13485 and Regulation (EU) 2017/745

EN ISO 13485:2016 is a harmonized standard applied by the manufacturers of medical devices to prove the compliance of the quality system with the requirements of MDR. In addition to the requirements of the standard, the manufacturers must also include specific requirements specified by the MDR. In the conformity assessment procedures according to Annexes IX and Annex XI part A, we recommend that the manufacturer has already established a quality system according to the ISO 13485 standard.

The Certification of Medical Devices According to Regulation (EU) 2017/745

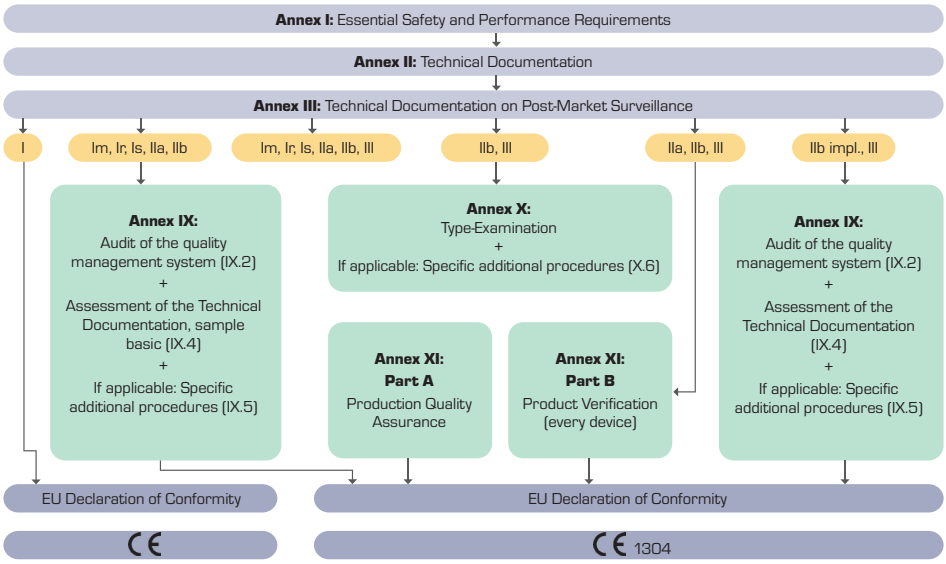
Medical devices may be launched on the EU market and labelled with the CE marking if they meet the essential requirements of the MDR.

According to the degree of risk, medical devices are classified into the following classes:

- **class I** – medical devices with a low degree of risk for users;
- **class IIa** – medical devices with a higher degree of risk for users;
- **class IIb** – medical devices with a high degree of risk for users; and
- **class III** – medical devices with the highest degree of risk for users.

The certification procedure consists of a documentation audit/technical file for a medical device and a certification audit. It is recommended that the manufacturer of medical devices has established a quality system according to the ISO 13485 standard. The audit under the Medical Device Regulation can be combined with the audit under the ISO 13485 standard. After granting the EC certificate and the certificate according to ISO 13485, we conduct annual surveillance audits of individual parts of the system to check the operation of the system and a re-assessment audit every three years. The EC certificate is valid as long as you can prove that you still comply with the requirements of the ISO 13485 standard by means of annual audits.

Conformity assessment procedures for medical devices



The main activities in the procedure for the acquisition of the CE marking:

- The classification of the medical device
- Contact with the notified body for Class Is, Im, Ir, IIa, IIb and III medical devices
- The selection of the relevant conformity assessment procedure (depending on the classification of the medical device/class and the related degree of risk for users and the manufacturer's decision)
- The decision on the establishment of the quality system under the ISO 13485 for manufacturers of class Is, Im, Ir, IIa, IIb and III medical devices (with the exception of the conformity assessment procedure according to Annex IX and Annex XI part A)
- Compliance with the essential requirements of the MDR
- Preparation of the technical file with the EC Declaration of Conformity (Annex IV of MDR)
- Conformity assessment
- Affixing the CE marking on medical devices

Technical Documentation/Technical File

In the conformity assessment procedure, the manufacturer must prepare a technical file for a medical device/group of medical devices, on the basis of which the compliance with the essential requirements of the Medical Device Directive is checked. The mandatory contents of the technical file are defined in the Annex II and Annex III of MDR. The technical file is assessed by the notified body, except in the case of class I medical devices, where this is not required.

Testing Electrical and Magnetic Safety for Active Medical Devices

In the conformity assessment procedure, the manufacturers of active medical devices must also prove compliance with the essential requirements in the field of electrical and magnetic safety. SIQ offers recognized and accredited test laboratories for testing certain types of electrical medical devices and equipment and determining electromagnetic compatibility. SIQ is a member of CB sheme.

Why SIQ

SIQ is a professional, independent and impartial institution providing complete services. We can provide you with quality services, fast completion time, flexibility, credibility, international recognition, wide level of support and competitive prices.

SIQ is a notified body with ID no. 1304 under the MDD 93/42/EEC. It is also a member of TEAM NB, the European Association for Medical Devices of Notified Bodies (NB-MED).

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