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The EU's Medical Device Regulation

Staying up-to-date
with the new requirements

The EU's Medical Device Regulation

Medical device manufacturers seeking market access to the European Union (EU) face major changes in the EU's decades-old regulatory framework. The EU's Medical Device Regulation (MDR) was officially published on 5 May 2017 and came into force on 25 May 2017. The MDR replaces the EU's previous Medical Device Directive (93/42/EEC) and the EU's Directive on active implantable medical devices (90/385/EEC).

Background

The origins of the MDR date back to 2008, when the EU Commission initiated a public consultation on the Community's existing requirements covering medical devices. This consultation produced many comments and proposals for change from a wide variety of stakeholders. As a result, the Commission released in 2012 its plan to restructure the EU's medical device regulatory framework, along with a regulation that would replace existing directives for medical devices and active implantable medical devices.

The changes and their impact

The MDR differs in several important ways from the EU's previous directives for medical devices and active implantable medical devices. Changes in the regulation include expansion of the scope of products covered, more rigorous requirements for clinical evaluation including changes to clinical investigations, mandatory unique device identification (UDI) mechanisms, and increased post-market oversight by EU Notified Bodies. Specific details on these and other changes, along with their anticipated impact include:

- **Product scope expansion** – The definition of medical devices and active implantable medical devices covered under the MDR is significantly expanded to include devices that do not have a medical intended purpose, such as coloured contact lenses and cosmetic implant devices and materials. Also for inclusion within the scope of the regulation are devices designed for the purpose of "prediction" of a disease or other health condition.

- **Reclassification of devices according to risk, contact duration and invasiveness** – Under the MDR, manufacturers must review, and if necessary update, the classification of all medical devices according to the new classification rules. Changes in classification involving another risk class may also result in changes in the conformity assessment procedures applied so far. Such changes in the conformity assessment procedure may impact on the procedures carried out with the involvement of a Notified Body. Therefore, please make sure that your Notified Body is authorised to carry out, together with you, any conformity assessment procedures which are subject to such changes.

- **More rigorous clinical evidence for class III and implantable medical devices** – Manufacturers need to conduct clinical investigations in case they do not have sufficient clinical evidence to support the claims done on both safety and performance of a dedicated device.

- **Systematic clinical evaluation of Class IIa and Class IIb medical devices** – Manufacturers need to re-prepare their clinical evaluations by considering the new wording of the regulation on when an equivalence approach and under which circumstances it is possible to justify not conducting a clinical investigation.

- **Identification of "qualified person"** – All manufacturers, whether located within or outside Europe, require to identify at least one person within their organisation who is responsible for all aspects of compliance with the requirements of the new MDR. The organisation must document the specific qualifications of this individual relative to the required tasks. Further, qualifications of responsible persons will be subject to review by Notified Bodies to ensure requisite knowledge and skill. The EU authorised representatives must likewise have such a qualified person

- **Implementation of unique device identification** – The MDR mandates the use of unique device identification (UDI) mechanisms. This requirement is expected to increase the ability of manufacturers and authorities to trace specific devices through the supply chain, and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk. To support this effort, the European Databank on Medical Devices (EUDAMED) is expected to be expanded to provide more efficient access to information on approved medical devices.

- **Rigorous post-market oversight** – The MDR grants Notified Bodies increased post-market surveillance authority. Unannounced audits, along with product sample checks and product testing will strengthen the EU's enforcement regime and help to reduce risks from unsafe devices. Annual safety and performance reporting by device manufacturers are also required in many cases.

- **Specifications** – The MDR grants Notified Bodies increased post-market surveillance authority. Unannounced audits, along with product sample checks and product testing will strengthen the EU's enforcement regime and help to reduce risks from unsafe devices. Annual safety and performance reporting by device manufacturers are also required in many cases.

- **No "grandfathering" provisions** – Under the MDR, all currently approved devices must be re-certified in accordance with the new requirements.

The MDR timeline

Manufacturers of medical devices had a transition time of four years until 25 May 2021 to meet the requirements of the MDR.

There will be exceptions for medical devices already approved. An additional 3-year transitional period is defined to allow manufacturers to place products under the existing MDD- or AIMDD-certificates on the market. However, special requirements must be met by the products and manufacturers. This additional period will end in May 2024.

It is important to note that, as an EU regulation, the MDR became immediately legally binding in all Member States of the EU on 26 May 2021.

The MDR Transition

The complex development process for medical devices, combined with the changes, are likely to make the transition a complicated and time consuming process for many device manufacturers.

Because of these complexities, medical device manufacturers are well-advised to stay current on the progress of the MDR through the regulatory approval process, as well as additional changes that may impact them. In addition, since a large number of medical devices are expected to require Notified Body review and approval, delays in the review and approval process by Notified Body should be expected. Manufacturers of currently approved devices are therefore advised to evaluate potential compliance issues and to develop a plan to address them promptly. Preparation and early action are key to ensuring a smooth transition to the MDR requirements.

How we can help?

TÜV SÜD is closely following developments related to the MDR, and will regularly provide updated information to our clients through various resources such as webinars, training, information factsheets etc. These and other resources are designed to help medical device manufacturers stay fully informed about the changes.

TÜV SÜD is one of the world's largest EU Notified Body for all types of medical devices covered by EU directives and regulations. We are also a leading global management certification body for quality management systems, including management systems applicable in the manufacture of medical devices. This unique combination of experience makes TÜV SÜD ideally suited to address the needs of medical device manufacturers seeking to achieve or maintain compliance with medical device requirements in the EU and other major markets around the world.

Why choose TÜV SÜD?

TÜV SÜD offers a complete range of testing, auditing and certification services to manufacturers of medical devices, helping them to manage risks and to protect and promote the health and safety of patients. Our global network of more than 750 dedicated medical health services professionals includes scientists and physicians recognised as authorities in their respective fields. These capabilities make TÜV SÜD the preferred single source for worldwide compliance with medical device regulations.

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TÜV SÜD is a premium quality, safety and sustainability company that specialises in testing, inspection, auditing and certifications. Represented in over 1000 locations worldwide, we hold accreditations in Europe, the Americas, the Middle East, Asia and Africa. By delivering services to our customers, we add tangible value to businesses, consumers and the environment.

Related services

TÜV SÜD provides the following related services:

- Global approval of medical devices (foreign affairs)
- ISO 9001 – Quality management system certification
- ISO 13485 – Quality management system certification for medical devices
- Medical device market assessment and certification
- Medical device testing

What is a medical device?

A medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more defined specific medical purposes.

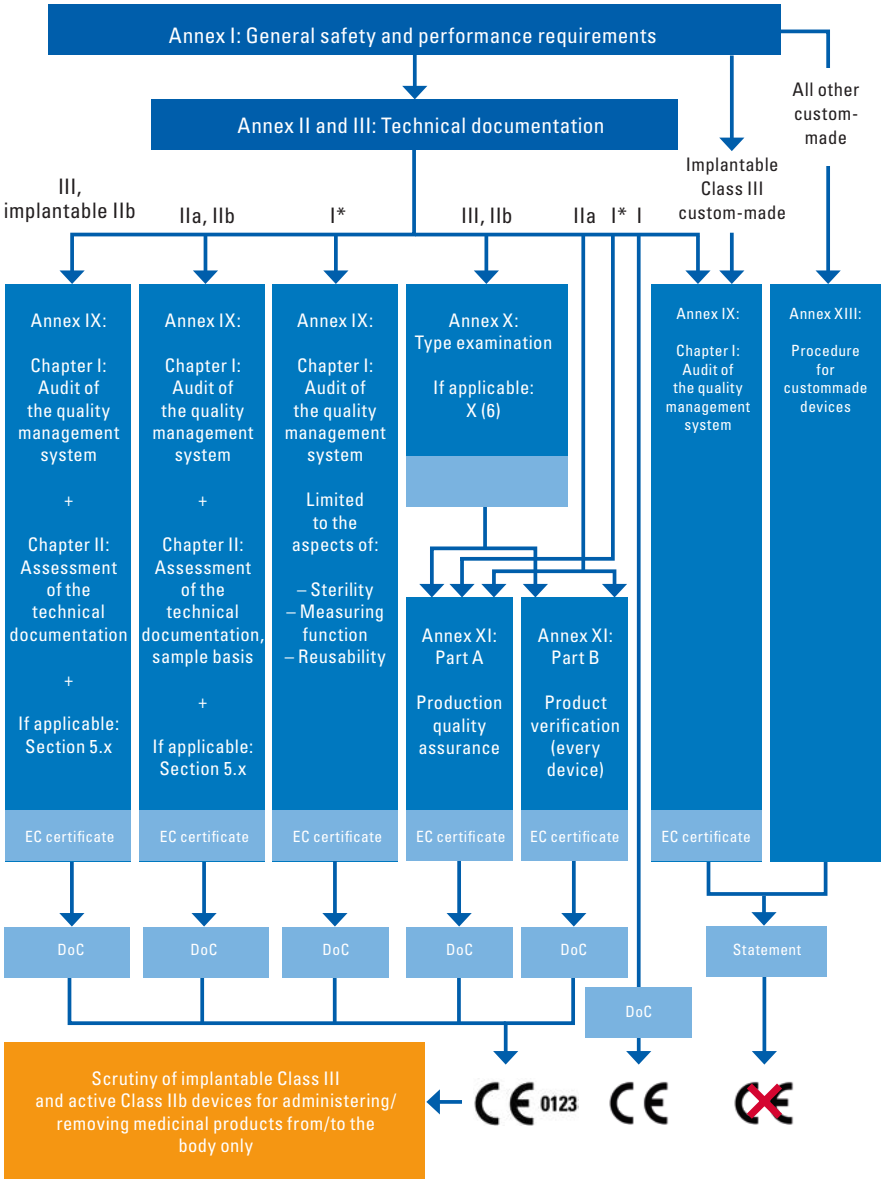
Who is a manufacturer?

The regulation defines a manufacturer as a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

Classification of medical devices by their risk potential

Annex VIII of the regulation stipulates the classification of the devices according to its risk potential, in classes I (low), IIa, IIb and III (high). Depending on the classification of the product, the conformity assessment procedures apply. The regulation includes 22 classification rules covering duration of use, level of invasiveness, location of use and energy supply.

Conformity assessment diagram



Explanation

Annex IX, Chapter I:
Quality management system, audit by Notified Body

Annex IX, Chapter II:
Assessment of the technical documentation by Notified Body

Annex IX, Section 5:
Specific procedures

Annex IX, Section 6:
Batch verification

Annex X:
EC type testing

Annex XI, Part A:
Production quality assurance

Annex XI, Part B:
Product verification

Class I*:
Class I devices that are sterile or do have a measuring function or are surgical reusable instruments

Implantable Class IIb:
Some implantable Class IIb devices are exempted from this rule.

Assessment of technical documentation for Class IIa or Class IIb according to Annex IX or Annex XI during initial audit and surveillance audits.

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