



# The EU's Medical Device Regulation

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## Staying up-to-date with new requirements and timelines



### 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).

From the initial publication, the MDR has been corrected and amended with the following:

Amendments:

- Regulation (EU) 2020/561 of the European Parliament and Council of, 23 April 2020
- Commission delegated Regulation (EU) 2023/502 of 1 December 2022

Corrigenda:

- Corrigendum, OJ L 117, 3.5.2019, p. 9 (2017/745)
- Corrigendum, OJ L 334, 27.12.2019, p. 165 (2017/745)

The most recent update was the amendment of Regulation (EU) 2023/607 of the European Parliament and Council of, 15 March 2023, addressing the extended transitional provisions under certain conditions.

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

#### The MDR timeline

The EU’s MDR requirements were originally scheduled to take full effect in May 2020, providing manufacturers with a three-year transition period to bring existing medical devices into compliance with the MDR’s requirements. Due to the challenges presented by the global COVID-19 pandemic, the MDR was amended in April 2020 to extend the Date of Application to 26 May 2021. As of that date, new medical devices placed in the European market must meet the requirements of the MDR.

However, the implementation of certain MDR provisions will be postponed until as late as December 2028 for medical devices that were previously approved under the Medical Devices Directive 93/42/EEC (MDD) and Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) or covered by Declaration of Conformity (DoC) issued before 26 May 2021. .





## The MDR Transition

The extended transition periods are:

- 26 May 2026 - for class III custom-made implantable devices
- 31 December 2027 - for higher-risk products (class III devices and class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 - for medium and lower risk products (other class IIb devices, class IIa devices, and class Is, Im, lr)

It's important to note that the extension of transition period to the new rules is subjected to certain conditions. More time will only be granted for products that are safe and for which manufacturers have already taken steps regarding the transition to MDR. This means that the application has to be submitted latest by 26 May 2024 and the contractual agreement with TÜV SÜD has to be concluded latest by 26 September 2024.

The extension of timelines does not apply to Class I devices that do not require a MDR certificate from a notified body. New devices and devices without a former MDD/AIMDD certificate are also required to meet the MDR requirements from 26 May 2021.

## How we can help?

It is highly advisable to stay informed about the requirements and deadlines of the MDR. Additionally, it is important to perform an assessment of how your current product portfolio may be impacted by the regulations.

TÜV SÜD continues to shift and prepare our systems and resources to provide services under the MDR legislative framework. We have and continue to clarify open questions and implement newly published information about the MDR into our processes.

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

TÜV SÜD has received a large number of requests for MDR certification. We make every possible effort to support a smooth implementation of the regulation and avoid any negative impact on the European healthcare system. It is critical that a continued supply of safe and effective medical devices is available for patients.

Due to the extensive interest in our services, TÜV SÜD has introduced an online service registration to process MDR certification requests in an efficient and timely manner. If your company would like to request MDR services from TÜV SÜD, please register your interest at our online portal at <http://www.tuvsud.com/mdrenquiry>

## 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 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.

## Add value. Inspire trust.

TÜV SÜD is a premium quality, safety and sustainability company that specialises in testing, inspection 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
- MDSAP
- IVDR regulatory approval

**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.

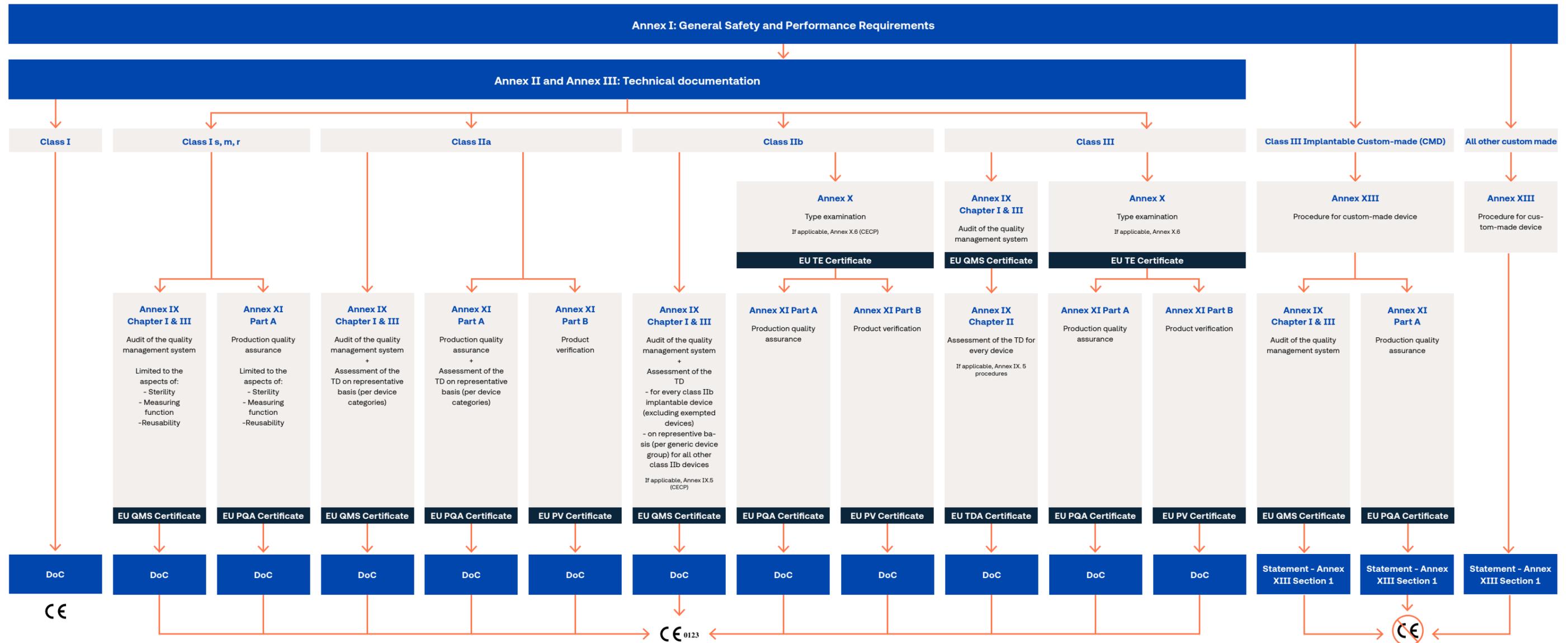
**Who is a manufacturer?**

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.

**MDR Conformity Assessment Routes**



Glossary				
<b>Class Is</b> sterile	<b>Class Ir</b> reusable surgical instrument	<b>QMS</b> Quality management system	<b>EU PV Cert.</b> EU product verification certificate	<b>EU TDA Cert.</b> EU technical documentation assessment certificate
<b>Class Im</b> measuring function	<b>DoC</b> Declaration of conformity	<b>EU PQA Cert.</b> EU production quality assurance certificate	<b>EU TE Cert.</b> EU type-examination certificate	<b>CECP</b> Clinical Evaluation Consultation Procedure