The European Union Medical Device Regulation

The EU's Medical Device Regulation (MDR) was officially published on 5 May 2017 and came into force on 25 May 2017. The MDR replaced the EU's current Medical Device Directive (93/42/EEC) and the EU's Directive on active implantable medical devices (90/385/EEC). Find out more about the key changes of the MDR.

About the European Union (EU)

The EU population numbers more than **447 million**[1]

The total medical device sales in the EU equals **€150 billion**[2]

The EU medical device industry employs nearly **800,000**[2]

The EU medical device sector is comprised of 34,000 separate companies, of which **95%** are small and medium sized enterprises[2]

What is the MDR?

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 replaced the EU's previous Medical Device Directive (93/42/EEC) and the EU's Directive on active implantable medical devices (90/385/EEC).

Timeline of the MDR

2017 – MDR came into force on 25 May 2017

2021 – New devices and devices without a valid MDD/AIMDD certificate are required to meet MDR requirements from 26 May 2021

2024 – MDR application to be submitted by 26 May 2024 and contractual agreement with TÜV SÜD concluded by 26 September 2024 to qualify for extended timeline*

2026 – Extended transition period* ends on 26 May 2026 for Class III implantable custom-made devices

2027 – Extended transition period* ends on 31 December 2027 for higher risk devices (class III devices and class IIb implantable devices**)

2028 – Extended transition period* ends on 31 December 2028 for medium and lower risk devices (other class IIb devices, class IIa devices, and class Is,Im,Ir)

*The extension 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. 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**.

**Except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.

Key changes

- Product scope expansion
- Implementation of unique device identification
- Rigorous post-market oversight
- Identification of person responsible for regulatory compliance
- Common specifications
- Reclassification of devices according to risk, contact duration and invasiveness
- More rigorous clinical evidence for class III and implantable medical devices
- Systematic clinical evaluation of Class IIa and Class IIb medical devices
- No "grandfathering" provisions

[1] https://european-union.europa.eu/principles-countries-history/key-facts-and-figures/life-eu_en
[2] https://www.medtecheurope.org/wp-content/uploads/2022/09/the-european-medical-technology-industry-in-figures-2022.pdf

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