THE European Union Medical Device Regulation (MDR)

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 **€140 billion**[2]

The EU medical device industry employs nearly **760,000**[2]

The EU medical device sector is comprised of 33,000 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

2020 – New devices and devices without a valid MDD/AIMDD certificate are required to meet MDR requirements from 26 May 2020

2024 – Extended transition period ends on 26 May 2024 for devices with valid MDD/AIMDD certification

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://ec.europa.eu/eurostat/cache/digpub/demography/bloc-1a.html?lang=en
[2] https://www.medtecheurope.org/wp-content/uploads/2021/06/medtech-europe-facts-and-figures-2021.pdf

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