

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.

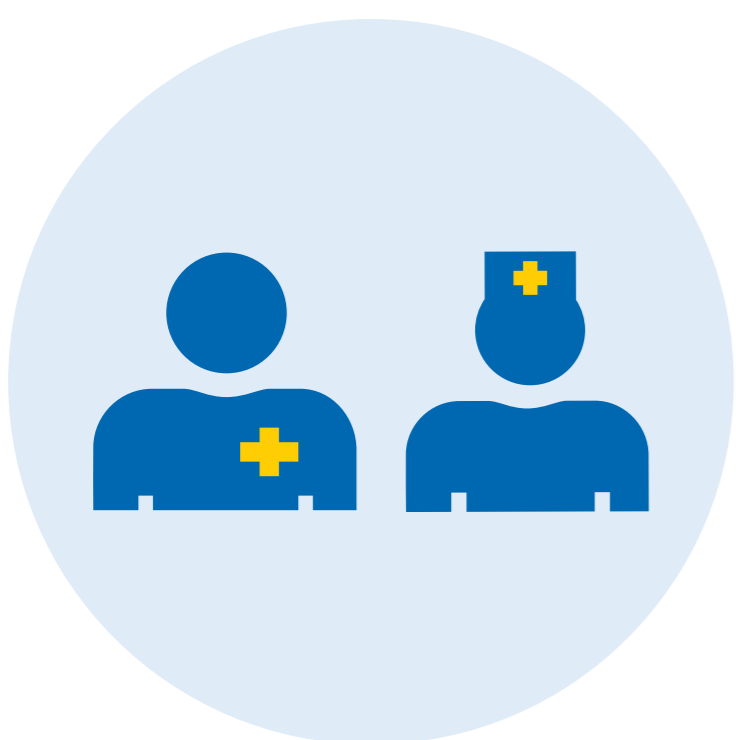
About the European Union (EU)



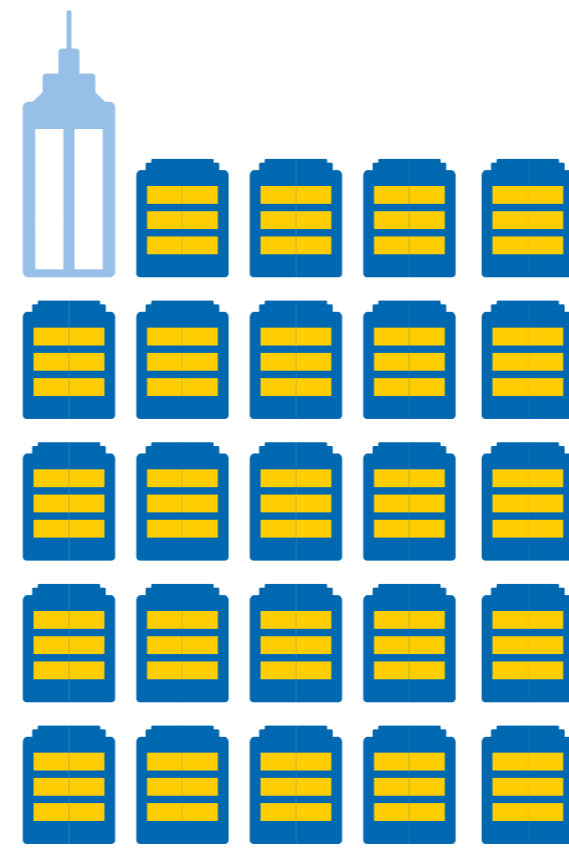
The EU population numbers more than **447 million**¹



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 enterprises²

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

MDR came into force on 25 May 2017



2017

2020

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



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

2024

Key changes



Product scope expansion



Implementation of unique device identification



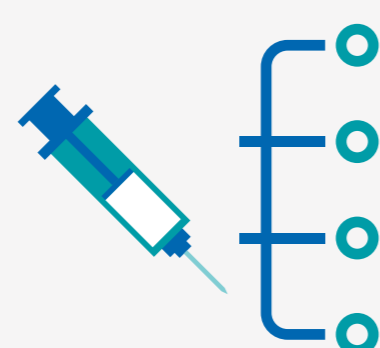
Rigorous post-market oversight



Identification of person responsible for regulatory compliance



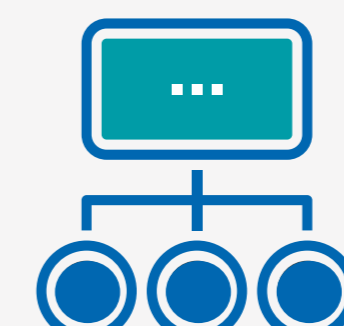
Common specifications



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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