

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.

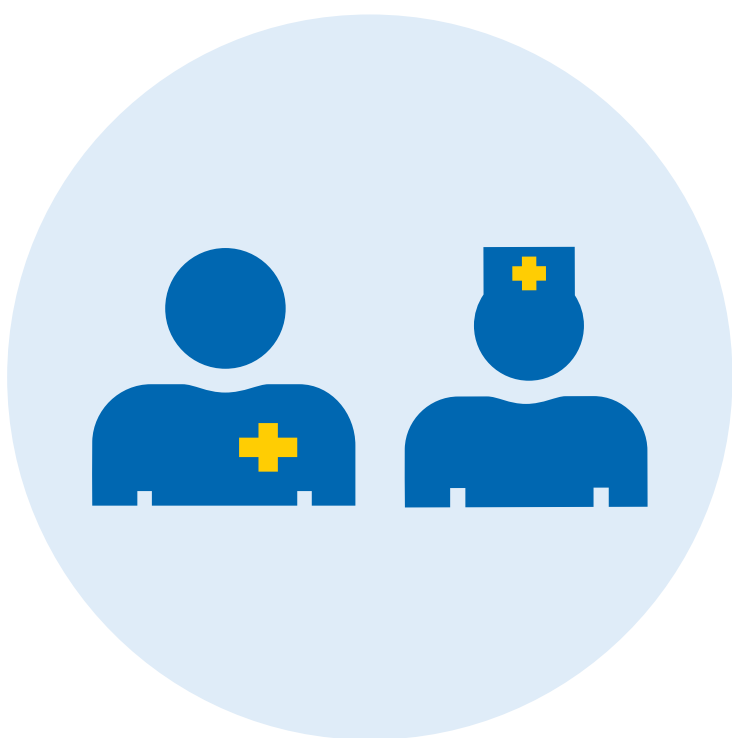
About the European Union (EU)



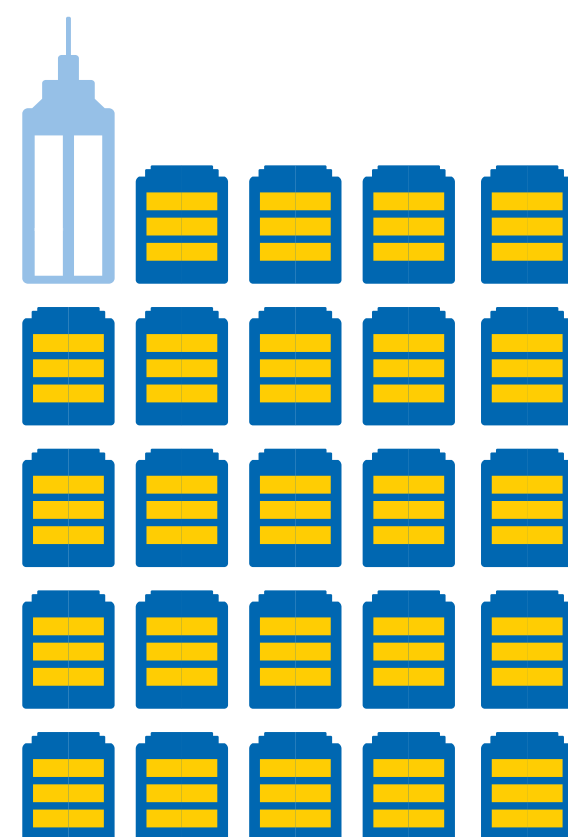
The EU population numbers more than **447 million**¹



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



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



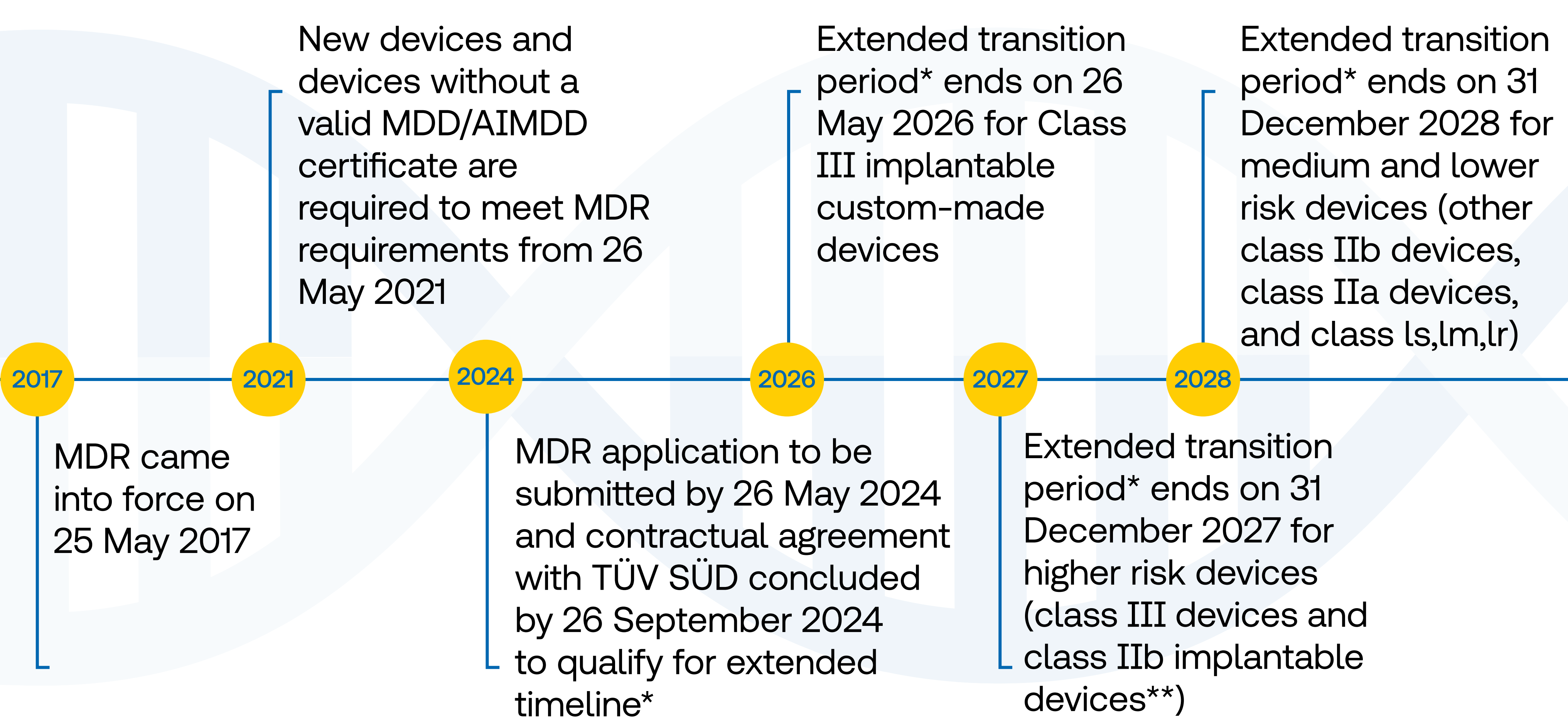
The EU medical device sector is comprised of 34,000 separate companies, of which **95%** are small and medium sized enterprises²

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



*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



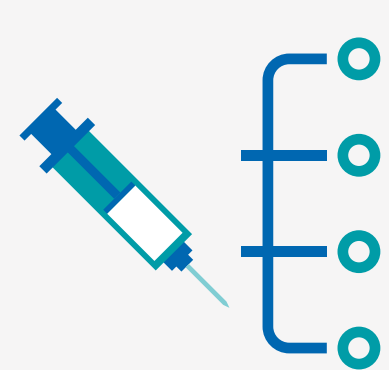
Rigorous post-market oversight



Identification of person responsible for regulatory compliance



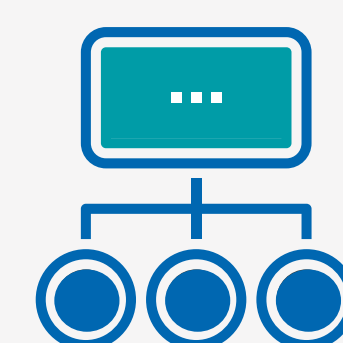
Common specifications



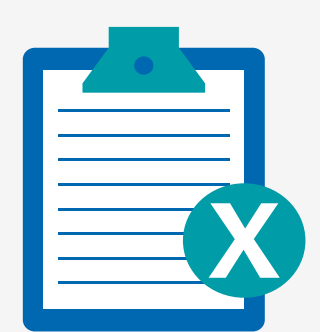
Reclassification of devices according to risk, contact duration and invasiveness



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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