

# THE NEW 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 will replace 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 new MDR.

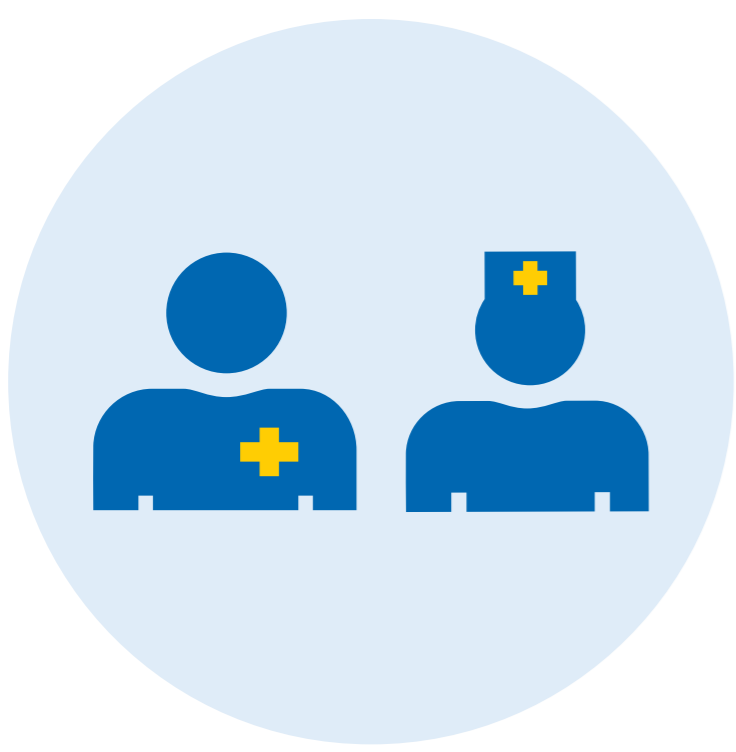
## About the European Union (EU)



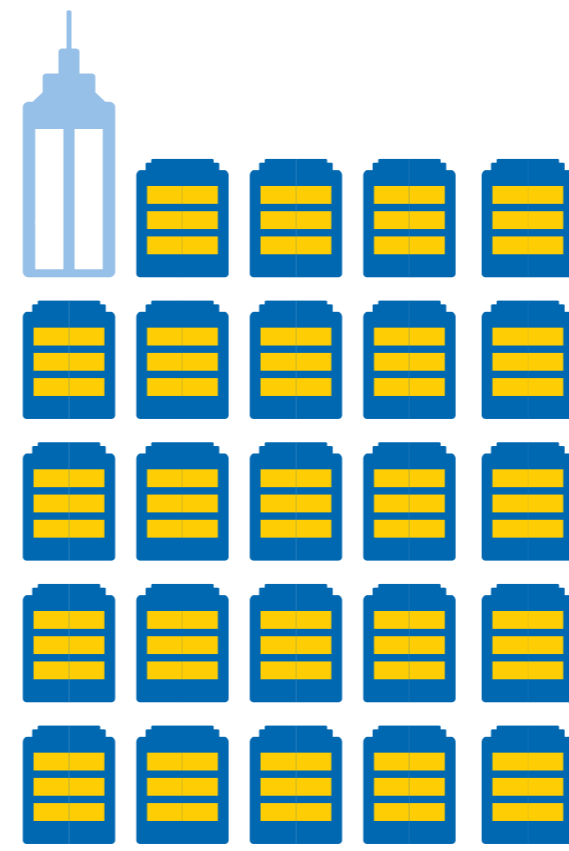
The EU population numbers more than **500 million**



The total medical device sales in the EU equals **€100 billion\***



The EU medical device industry employs nearly **600,000\***



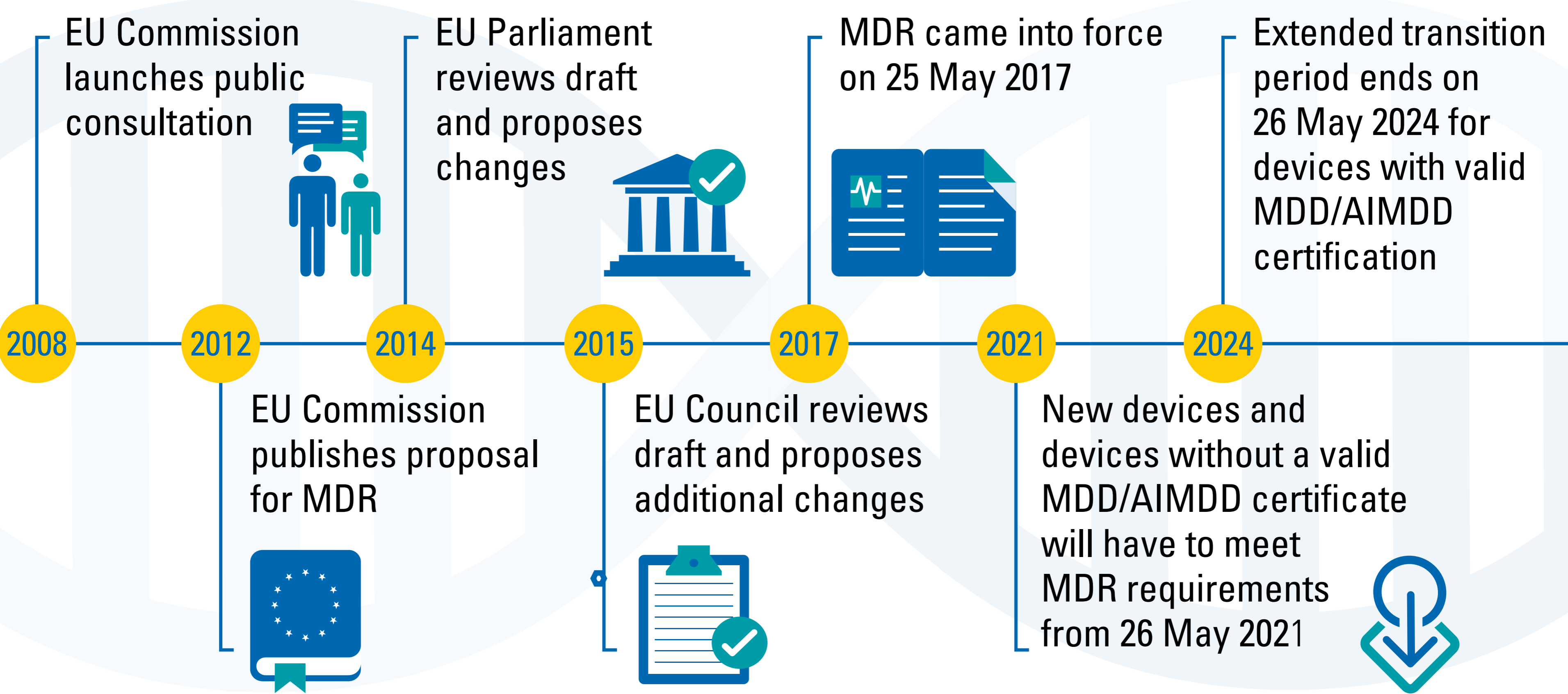
The EU medical device sector is comprised of 25,000 separate companies, of which **95%** are small and medium sized enterprises\*

## What is the MDR?

The EU Medical Device Regulation (MDR) will replace the EU's current Medical Device Directive (93/42/EEC) and the EU's Directive on active implantable medical devices (90/385/EEC). The regulation applies to all Medical Device manufacturers who intend to place their medical devices on the European market.



## Timeline of the MDR



## Key changes



Product scope expansion



Implementation of unique device identification



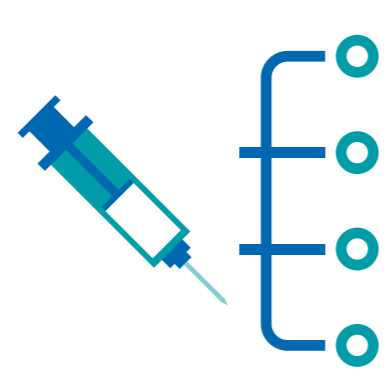
Rigorous post-market oversight



Identification of person responsible for regulatory compliance



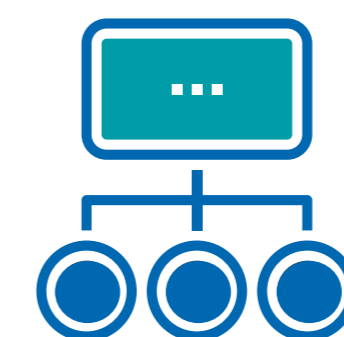
Common specifications



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

\* [https://ec.europa.eu/health/md\\_sector/overview\\_en](https://ec.europa.eu/health/md_sector/overview_en)



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