

THE NEW

EUROPEAN UNION MEDICAL DEVICE REGULATION [MDR]

The EU's Medical Device Regulation (MDR), published on 5 May 2017, officially came into force on 25 May 2017. The MDR replaced the EU's former 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 which the new MDR.

ABOUT THE EUROPEAN UNION [EU]



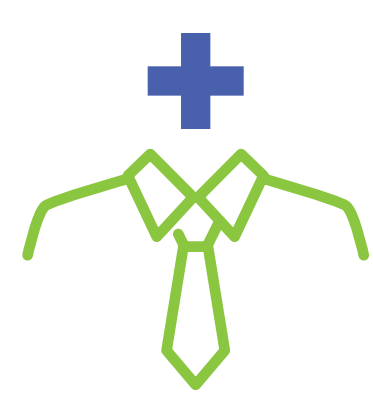
447 million

The population of the EU is over 447 million people



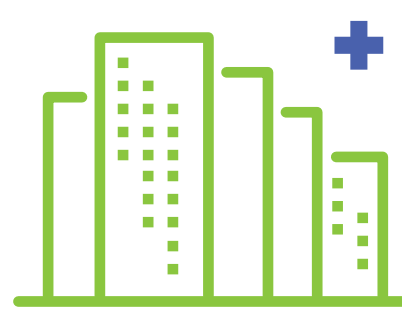
140 billion

Medical device sales in the EU equal €140 billion



730,000

The EU medical device industry employs nearly 730,000 people



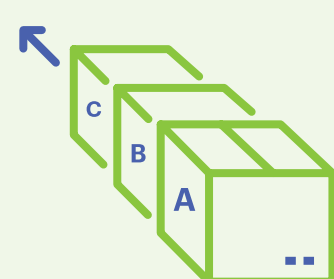
32,000

The EU medical device sector is comprised of 32,000 separate companies, 95% of which are small to medium sized enterprises

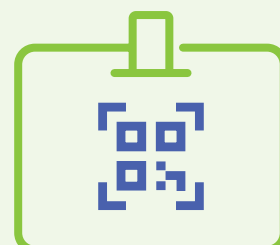
WHAT IS THE MDR?

The EU Medical Device Regulation (MDR) replaced the EU's former 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.

KEY CHANGES



Product scope expansion



Implementation of unique device identification



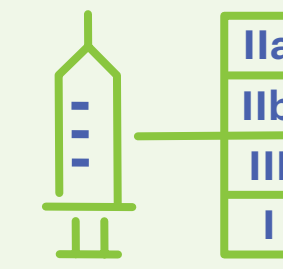
Rigorous post-market oversight



Identification of person responsible for regulatory compliance



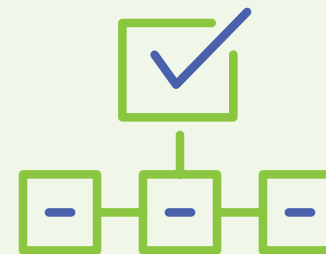
Common specifications



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



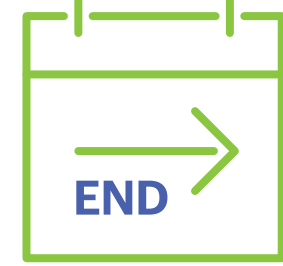
No "grandfathering" provisions

TIMELINE OF THE MDR



New devices and devices without a valid MDD/AIMDD certificate will have to meet MDR requirements from 26 May 2021

2021



Additional period to sell the devices in warehouses

2025

2017

MDR came into force on 25 May 2017



2024

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



CLASSIFICATION

Under the MD Directive, MDs are classified into 4 categories following a risk-based classification system:

CLASS I

e.g. simple bandages or wound care products



CLASS IIa

e.g. syringes for pump infusion



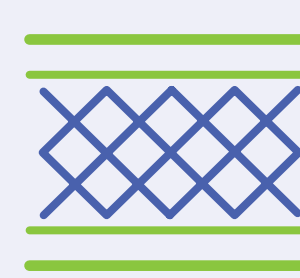
CLASS IIb

e.g. anesthesia machines



CLASS III

e.g. stents



Under the new MD regulation, the risk-based classification system contained in the current Directives has been maintained, although some changes/additions have been introduced. The principle is the same: to link the class of the device to the potential risk posed to the health of the public and an individual as a result of fault in the functioning. All MDs are classified under Class I, Class IIa, Class IIb or Class III, with Class III being the highest risk class.

