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

2017

MDR came into force on 25 May 2017

2021

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

2024

END

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

2025

Additional period to sell the devices in warehouses

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.

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