MDR – THE NEW EU MEDICAL DEVICE REGULATION

DIRECTIVE 93/42/EEC –
Medical Devices

+

DIRECTIVE 90/385/EEC –
Active Implantable
Medical Devices

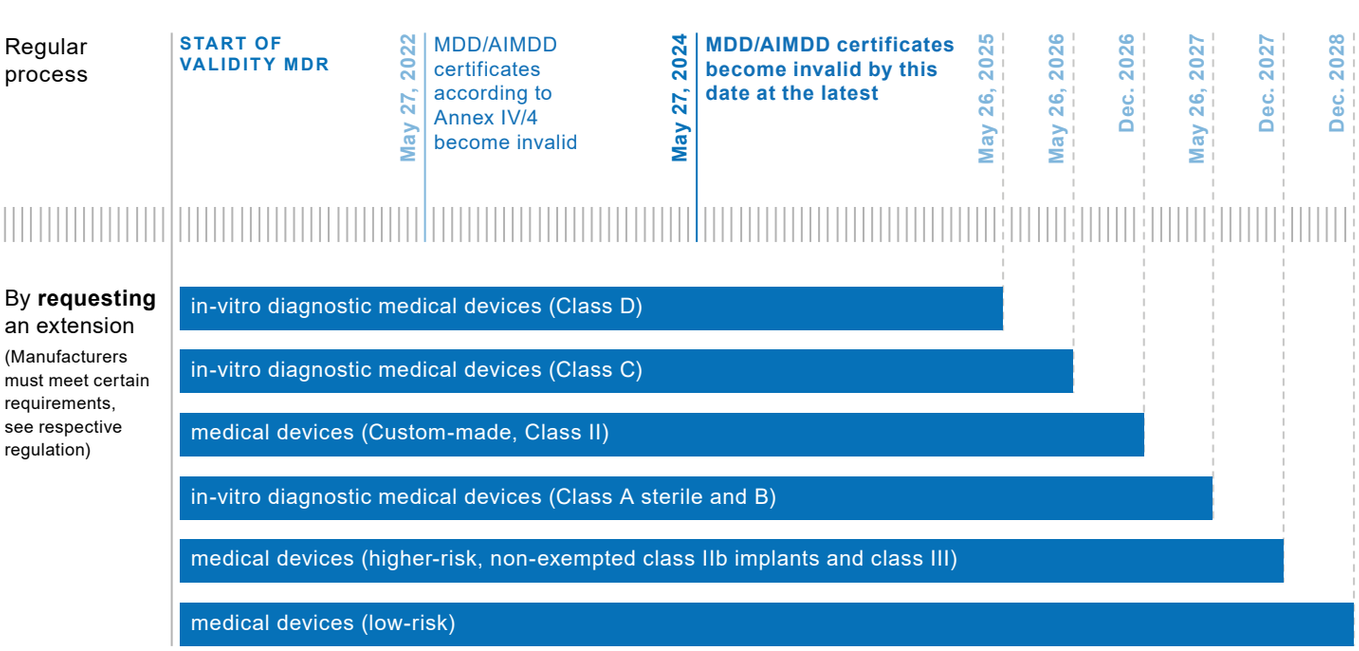
→

Medical Devices Regulation
MDR

THE MOST IMPORTANT CHANGES

- More stringent requirements for technical documentation (TD)
- More stringent requirements for clinical assessments and testing: Data collection to continue even after market launch
- Extended area of application (includes non-medical devices)
- More stringent requirements for responsible persons: Expert knowledge of medical devices
- Notified bodies more strictly regulated: New bodies to be chosen and inspected
- UDI: Unique product number for every medical device
- New scrutiny procedure for high risk medical devices
- EUDAMED: Europe-wide database for more transparency and cooperation

TRANSITION PERIODS ACCORDING TO (EU) 2022/112 IVDR AND (EU) 2023/607 MDR



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