MDR - THE NEW EU MEDICAL DEVICE REGULATION











DIRECTIVE 90/385/EEC –
Active Implantable
Medical Devices

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

MDD/AIMDD certificates START OF MDD/AIMDD Regular VALIDITY MDR certificates become invalid by this process according to date at the latest 26, 26, 27, Annex IV/4 become invalid By requesting in-vitro diagnostic medical devices (Class D) an extension (Manufacturers in-vitro diagnostic medical devices (Class C) must meet certain requirements, see respective medical devices (Custom-made, Class II) regulation) in-vitro diagnostic medical devices (Class A sterile and B) medical devices (higher-risk, non-exempted class IIb implants and class III) medical devices (low-risk)

