EMC Testing of Medical Devices intended for Europe

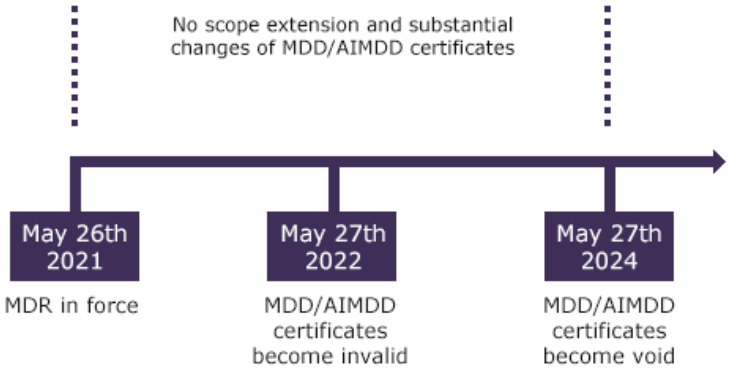
CE marking is a legal requirement for medical devices intended for sale in Europe, the directives that specifically apply to medical devices manufacturers are:

- The EMC Directive 2014/30/EU / Electromagnetic Compatibility Regulations - sets the requirements for the control of emissions and immunity standards for all electrical and electronic products.
- The Medical Device Regulation (MDR) 2017/745 - applies to all general Medical Devices and Active Implantable Medical Devices not covered by the In Vitro Diagnostics Regulation. The MDR supports the evolving technological and scientific progress requirements for medical devices.
- The In Vitro Diagnostics Regulation (IVDR) 2017/746 - is the Regulation for placing on the market, making available and putting into service of in vitro diagnostic medical devices on the European market.

Replacing the previous directives, the Medical Device, Active Implantable and In-Vitro Diagnostic Directives (MDD (93/42/ECC), AIMDD (90/385/EEC), and IVDD (98/79/EC) in a complete overhaul of the legal regulations for medical devices.

Manufactures of medical devices should check the requirements of the MDR and have a thorough understanding of the legislation, consulting the reclassification of certain product groups as well as the legislations wider definition of medical devices. More guidance for manufactures can be viewed here.

Timeline



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