Medical Devices Regulation (MDR)

Medical devices are subject to Regulation (EU) 2017/745 (MDR). The affected devices must be properly installed, maintained, and used in accordance with its intended purpose. They shall meet the general safety and performance requirements set out in Annex I of the MDR unless otherwise described in Article 5 (5).

“Medical Devices” means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

Medical devices need to be registered according to:

- Article 25 - Identification within the supply chain
- Article 26 - Medical devices nomenclature
- Article 27 - Unique Device Identification system
- Article 28 - UDI database
- Article 29 - Registration of devices
- Article 30 - Electronic system for registration of economic operators
- Article 31 - Registration of manufacturers, authorised representatives and importers
- Article 32 - Summary of safety and clinical performance
- Article 33 - European database on medical devices
- Article 34 - Functionality of Eudamed

Medical devices must be classified as described in Annex VIII according to the intended purpose and the inherent risks. Depending on the classification the conformity assessment is based on an appropriate quality management system and assessment of technical documentation, type examination or product conformity verification.

For relevant devices there are requirements about hazardous substances regarding design and manufacture listed in Annex I Chapter II, restricting the concentration to 0,1 % (w/w) of carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008.

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