Medical Device Regulation

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Reference list for Class I medical device manufacturers[1]

This guide does not purport to be an interpretation of law and/or regulations; it is not an exhaustive listing but provides some examples of the key essential requirements; this document is for guidance purposes only. All medical device manufacturers must comply with the entirety of Regulation 2017/745 on medical devices as per specifications laid down in the regulation and associated implementing acts/regulations.

Qualification and Classification	Regulation 2017/745
☐ Is the product a medical device under MDR?	Article 2
☐ Is the product a Class I medical device under MDR?	Article 51 Annex VIII
☐ Is your Class I device up classified under MDR?	Corrigendum 13081/19

Processes and Systems	Regulation 2017/745
☐ Is there a Quality Management System (QMS) established, documented, implemented and maintained?	Article 10 (9)
☐ Is there a risk management system established, documented, implemented and maintained?	Article 10 (2) Annex I Section 3
☐ Is there a clinical evaluation planned, conducted and documented?	Article 10 (3) Article 61 Part A Annex XIV
☐ Is there a Person Responsible for Regulatory Compliance (PRRC) identified within the organisation?	Article 15
☐ Is there financial coverage/liability for defective devices put in place?	Article 10 (16)
☐ Is the device and manufacturer registered in EUDAMED (once available) and with the relevant national authority and UDI obligations fulfilled?	Article 27 Article 29 Article 30
☐ Is there a post-market surveillance system documented and in place including a post-market surveillance plan?	Article 10 (10) Article 83 (1) Article 84
☐ Is there a system for reporting incidents and Field Safety Corrective Actions (FSCA) in place?	Article 10 (13) Article 87 Article 88

1 Regulation (EU) 2017/745 on medical devices (MDR)

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Conformity Assessment and CE marking	Regulation 2017/745
☐ Is the General Safety and Performance Requirements (GSPR) fulfilled?	Annex I
☐ Is the technical documentation drawn up and requirements fulfilled?	Article 10 (4) Annex II & III
☐ Is the Instructions For Use (IFU), packaging and labelling requirements fulfilled?	Annex I, Chapter III
☐ Is a clinical investigation required?	Article 62 Annex XV
☐ Is Notified Body assessment required? (sterile/measuring/reusable)	Article 52(7)
☐ Has the device undergone the correct conformity assessment procedure by an MDR designated notified body if applicable?	Chapter I & III Annex IX or Part A Annex XI
☐ Is there a certificate of conformity issued by a notified body limited to Class I sterile/measuring/reusable functions?	Article 52 (7)
☐ Is the Declaration of Conformity drawn up?	Article 10 (6) Article 19 Annex IV
☐ Is the CE mark affixed?	Article 10 Article 20 Annex V

Other Requirements	Regulation 2017/745
☐ Is your distributor/importer informed the device is on the market under the new Regulations? Therefore, Economic Operator obligations as defined in MDR apply.	Article 13 Article 14
☐ Is there appropriate traceability within the supply chain?	Article 25 (1)
☐ Is there an EU-27 Authorised Representative designated and mandated? (if manufacturer is located outside the EU)	Article 11 (1,2)

Additional guidance

MDCG Guidance	EU Commission Factsheets	Requirements for manufacturers