Medical Device Regulation

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Reference list for Class A in-vitro diagnostic medical device manufacturers

Introductory reference list for Class A medical device manufacturers under IVDR[1]*

** This guide does not purport to be an interpretation of law and/or regulations; it is not an exhaustive listing and 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 2017/746 on medical devices as per specifications laid down in the regulation and associated implementing acts/ regulations.*

Qualification and Classification	Regulation 2017/746
☐ Is the product an in-vitro diagnostic medical device under the IVDR?	Article 2
☐ Is the product a Class A in-vitro diagnostic medical device under the IVDR?	Article 47 Annex VIII

Processes and Systems	Regulation 2017/746
☐ Is there a Quality Management System (QMS) established, documented, implemented and maintained?	Article 10 (8)
☐ Is there a risk management system established, documented, implemented and maintained?	Article 10 (2) Annex 1 section 3
☐ Is there a performance evaluation planned, conducted and documented	Article 10 (3) Article 56 Annex XIII
☐ 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 (15)
☐ Is the device and manufacturer registered in EUDAMED (once available) and with the relevant national authority and UDI obligations fulfilled?	Article 24 Article 26 Article 28
☐ Is there a post-market surveillance system documented and in place including a post-market surveillance plan?	Article 10 (9) Article 78 Article 79
☐ Is there a system for reporting incidents and Field Safety Corrective Actions (FSCA) in place?	Article 10 (12) Article 82 Article 83

1 Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)

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Conformity Assessment and CE marking	Regulation 2017/746
☐ Are the General Safety and Performance Requirements (GSPR) fulfilled?	Annex I
☐ Is the technical documentation drawn up and requirements fulfilled?	Article 10 (4) Annexes II and III
☐ Are the Instructions For Use (IFU), packaging and labelling requirements fulfilled?	Annex 1, Chapter III
☐ Is clinical evidence, a performance evaluation or performance study required?	Article 56, 57, 58 Annex XIII Part A Annex XIV
☐ Have you specified and justified the level of clinical evidence required to demonstrate conformity with the GSPR's?	Article 56
☐ Is Notified Body assessment required?	Article 48 (10)
☐ Has the IVD undergone the correct conformity assessment procedure by an IVDR designated notified body if applicable?	Annex IX Annex XI
☐ If the device is placed on the market in a sterile condition, has a notified body certificate been issued?	Article 48 (10)
☐ Is the Declaration of Conformity drawn up?	Article 10 (5) Article 17 Annex IV
☐ Is the CE mark affixed?	Article 10 Article 18 Annex V

Other Requirements	Regulation 2017/746
☐ Is your distributor/importer informed the device is on the market under the new Regulations? Therefore, Economic Operator obligations as defined in IVDR apply.	Article 13 Article 14
☐ Is there appropriate traceability within the supply chain?	Article 22 (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