Technical & Quality Document Requirements for IVDs & Medical Devices

LFH REGULATORY
Regulation Made Simple

Use the below checklist to identify your technical and quality documentation for your compliance check

Organisation Documents	MD	IVD
CE Certificate/UKCA Certificate (not applicable for self-certified)	☐	☐
Liability Insurance	☐	☐
Proof of EU registration and EU Rep (if applicable)	☐	☐
Technical Documentation Audit Report from NB (not applicable for self-certified)	☐	☐

Technical File Contents	MD	IVD
Declaration of Conformity (DoC)	☐	☐
Index of Technical File	☐	☐
Essential Requirements Checklist (ERC) or General Safety and Performance Requirements (GSPR)	☐	☐
Device Description and Intended Use including the Classification Rationale	☐	☐
Packaging & Labelling	☐	☐
Instructions for Use (IFU)	☐	☐
Risk Management File (Risk Management Plan & Report)	☐	☐
Clinical Evaluation Plan & Report	☐	
Performance Evaluation Plan & Report		☐
Post Market Surveillance Plan & Report	☐	☐
Biological Evaluation	☐	
Scientific Validity Report (SVR)		☐
Design Verification Information: i.e., Mechanical Testing, Sterilisation Validation, Chemical Characterisation etc.	☐	☐
Manufacturing Processes including Process Validation	☐	☐

Quality Management Documents	MD	IVD
Post Market Surveillance	☐	☐
Vigilance	☐	☐
Field Safety Notice (FSN) & Field Safety Corrective Action (FSCA)	☐	☐
Complaint Handling	☐	☐

Missing Documents

If you are missing any of the listed documentation above, reach out to our Medical Device Compliance Team today who will be able to support you to create these.

Contact Us:

www.lfhregulatory.co.uk/contact-us

Dedicated UKRP

LFH Regulatory will act on your behalf to register your devices with the Medicines and Healthcare products Regulatory Agency (MHRA), under the UK Medical Device Regulations 2002 (UK MDR 2002) to allow you to sell your device on the UK market. In preparation we will require the documentation listed in this checklist prior to registering your products. If you would like us to act as your dedicated UKRP (UK Responsible Person), get in contact today.