Elexes

CE Marking Readiness Checklist – EU MDR Compliance for Medical Devices

Step-by-Step Readiness Evaluation

Requirement	Completed?
Device classification under EU MDR done	[ ]
Intended purpose and indications defined	[ ]
Determine the applicable EU legislation	[ ]
GSPR checklist completed	[ ]
QMS Documents compliant with MDR (Article 10), EN ISO 13485 compliant QMS	[ ]
Risk management file ready (ISO 14971)	[ ]
Clinical Evaluation Report drafted	[ ]
Labeling and IFU compliant with MDR	[ ]
UDI system (Basic UDI-DI and Carrier) and EUDAMED registration ready	[ ]
PMS, PSUR and Post market and clinical development plans available	[ ]
EU Authorized Representative appointed and EU REP agreement is available (If manufacturer is outside EU)	[ ]
Notified Body selected and contracted (if applicable)	[ ]
Declaration of Conformity drafted	[ ]