Elexes

EU MDR 2017/745 Compliance Checklist for Medical Device Companies

Classification & Strategy

- Device classification verified per Annex VIII
- Intended purpose and risk class defined
- The route of conformity assessment is identified

Documentation Requirements

- Technical Documentation (Annex II & III) compiled
- Completed GSPR checklist
- Clinical Evaluation Report (CER)PMS, PSUR and PMCF plans in place

Notified Body Engagement

- Notified Body selected and contract signed
- Assessment schedule confirmed
- Previous certifications (if applicable) reviewed

UDI & Registration

- Basic UDI-DI assigned and registered
- EUDAMED registration completed

Internal Readiness

- Quality Management System aligned with ISO 13485
- Internal team trained on MDR requirements
- Gap analysis conducted between MDD and MDR