Elexes

EU MDR Extension Compliance Guide – 2027/2028 Readiness

- **Device Classification** → Confirm current MDD/AIMDD classification. MDR classification (Annex VIII) may differ from MDD/AIMDD.
- **QMS Compliance** → Is your QMS certified, MDR-Compliant, and audit-ready before May 2024?
- **Notified Body Contract** → Have you signed a formal NB agreement before May 26, 2024?
- **Risk Assessment** → Is your product low-risk and compliant with existing GSPRs?
- **Legacy Device Documentation** → MDD/IVDD conformity documentation ready?
- **Extension Deadline** → Are you Class III/IIb implantable (2027) or others (Class IIb (non-implantables), IIa, and Class I (sterile or measuring) (2028)?
- **Labeling Review** → Plan to meet MDR labeling and UDI expectations
- **Post-Market Surveillance** → Strategy updated as per MDR expectations.PMS must be MDR-aligned for legacy devices under extension.
- **Timeline Monitoring** → Are you tracking regulatory updates via EU/MDCG notices?