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2024 CE Marking Readiness Checklist for Medical Devices

Regulatory Eligibility

- Does your device currently hold a valid MDD certificate?
- Are you eligible under MDR Regulation 2023/607 transitional provisions?
- Has your quality management system (QMS) been certified or audited under MDR
- Have you submitted an MDR application to a Notified Body?

Documentation Requirements

- Updated technical documentation aligned with Annex II & III of MDR
- Clinical evaluation plan (CEP) and report (CER) prepared
- General Safety and Performance Requirements (GSPR) checklist completed
- Include conformity to UDI requirements

Notified Body Readiness

- Notified Body contract signed
- MDR audit plan established or scheduled
- Labeling updated with MDR-compliant elements

Post-Market & Vigilance

- PMS and PMCF plans updated per MDR
- Periodic Safety Update Reports (PSURs) scheduled
- Vigilance system and EUDAMED registration ready
- Trend reporting and Field Safety Corrective action procedure updated