Elexes

CER Clinical Evaluation Readiness Checklist

Initial Readiness & Device Profiling

- Clearly outline the device's medical purpose and intended population
- Confirm applicable MDR classification rules and rationale
- Assemble existing clinical, risk, and performance documentation
- Identify legacy, benchmark, or competing devices for comparison

Evaluation Strategy & Framework

- Draft a structured Clinical Evaluation Strategy
- Define inclusion/exclusion criteria for literature selection
- Establish measurable safety and performance benchmarks
- Align evaluation goals with GSPRs and MDR Annex XIV

Data Gathering & Evidence Mapping

- Collect clinical experience and internal performance data
- Execute a documented literature search across selected databases
- Integrate vigilance records and complaint trend analysis
- Include relevant PMCF study plans, interim results, or survey outcomes

Clinical Assessment & Synthesis

- Evaluate relevance and strength of all data sets
- Analyze risk vs. benefit in the context of residual risks
- Document alignment between clinical outcomes and intended claims
- Cross-reference findings with PMS and RMF outputs

Finalization & Submission Readiness

- Structure the CER per MDR Annex XIV Part A and MEDDEV guidance
- Conduct expert peer review by qualified evaluators
- Incorporate the CER into the complete technical documentation
- Prepare responses for potential Notified Body feedback