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Clinical Evaluation Checklist

Device & Clinical Profile

- Intended purpose and medical indications are clearly defined
- Device classification confirmed under MDR/IVDR framework
- All claimed clinical benefits are documented
- Benchmark or similar devices identified (if applicable)
- Historical use and safety issues (if any) reviewed

Strategic Planning

- Clinical Evaluation Plan (CEP) developed and reviewed
- Applicable MDR Annexes, GSPRs, and MDCG guidance identified
- Evaluation methodology and endpoints outlined
- Qualified personnel assigned for CER authorship and review
- Literature review scope and databases defined

Data Collection

- Systematic literature search conducted and logged
- Clinical investigations or PMS/PMCF data compiled
- Equivalence rationale established with supporting evidence
- Vigilance data and complaint trends included (if available)

Evidence Analysis

- Benefit-risk profile documented
- Safety and performance claims backed by clinical data
- Residual risks assessed and compared with clinical outcomes
- CER includes linkages to RMF, PMS, and PMCF outputs

Review & Submission Prep

- CER structured per MDR Annex XIV and MEDDEV 2.7/1 Rev.4
- Reviewed by independent, qualified clinical evaluator(s)
- Integrated into Technical Documentation (TD)
- Internal readiness checklist completed before NB submission