Critical Checks for Medical Device Technical Documentation Consistency

Risk & Clinical Alignment

- Key risks identified in the Risk Management File are addressed in the Clinical Evaluation Report (CER)
- Clinical conclusions support the overall risk-benefit assessment
- Residual risks communicated in labeling match documented risk evaluations

Claims & Labeling

- Product claims are supported by clinical, performance, or validation evidence
- Claims are consistent across labeling, IFU, CER, and marketing materials
- Intended use and indications for use are identical across all documents

PMS & Risk Management

- PMS activities address identified risks and safety concerns
- PMS findings are reflected in risk management updates where applicable

Traceability & Documentation Control

- Design inputs, outputs, verification, and validation are traceable
- Current document versions are used throughout the technical file
- Cross-references between documents are accurate and up to date

Submission Readiness

- No conflicting statements exist across risk, clinical, labeling, and PMS documents
- The technical documentation presents one consistent regulatory story