CER Compliance Checklist: MDR-Ready Clinical Evaluation Report

- Is the device classification clearly defined per MDR?
- Does the report align with the clinical evaluation plan
- Are the indications for use and intended purpose documented?
- Is the literature review methodology transparent and reproducible?
- Have clinical data sources (published, internal, PMCF) been fully appraised?
- Are clinical safety and performance endpoints clearly assessed?
- Is equivalence scientifically justified (if claimed)?
- Does the report cite MDR Annex XIV Part A and MEDDEV 2.7/1 Rev.4?
- Is the report signed off by a Qualified Person (QP)?
- Is there a documented update schedule and version control?
- Is the CER cross-referenced within the Technical File?