

## CER Writing Checklist

- Clearly define the device, intended purpose, indications, and target population and scope of the evaluation
- Establish and document the current state of the art and compare the device against it.
- Provide a robust Clinical Evaluation Plan (CEP) aligned with device risk, classification, and evidence requirements.
- Identify, collect, and document all relevant clinical data from literature, PMS, PMCF, and bench testing.
- Appraise each data source for its quality, relevance, and level of clinical evidence.
- Demonstrate clinical safety, performance and an acceptable benefit-risk profile with clear linkage to the risk management file.
- Justify equivalence claims (if used) with technical, biological, and clinical comparisons.
- Cross-check all clinical evidence with risk management, PMS/PMCF data, labeling, and clinical claims.
- Ensure compliance with EU MDR Article 61 and Annex XIV requirements under Regulation (EU) 2017/745
- Include evaluator qualifications and a documented declaration of interest.
- Summarize conclusions clearly and ensuring all sections are fully referenced, traceable and internally consistent.
- Perform internal review and maintain the CER as a living document with defined update frequency and trigger-based revisions.