CE Marking & CER Readiness Checklist

1. Device Classification

✓ Confirm correct EU classification under MDR rules, considering Rule 11 and intended purpose.

2. Regulatory Pathway

✓ Define conformity route and applicable harmonised standards.

3. Clinical Evaluation Plan

✓ Prepare a documented plan with objectives and methodology, and alignment with MDR Annex XIV requirements.

4. Clinical Data Collection

✓ Gather valid clinical data from published literature, clinical investigation , and PMS.

5. Literature Search

✓ Conduct a systematic and up-to-date literature search and document the search strategy for traceability.

6. Data Analysis & Evaluation

✓ Analyse data to demonstrate clinical safety, performance, and benefit-risk.

7. CER Report Drafting

✓ Write the CER with clear conclusions and clinical justification, references, and traceability to all supporting evidence.

8. Gap Analysis

✓ Perform a gap check against MDR requirements and harmonised standards.

9. Technical File Integration

✓ Include CER and supporting evidence within the Technical File.

10. Notified Body Review (if applicable)

✓ Submit dossier to Notified Body and address any findings.

11. Post-Market Surveillance (PMS)

✓ Implement PMS plan, including PMCF if applicable, to collect real-world performance data.

12. Periodic CER Updates

✓ Schedule regular updates based on PMS and new evidence, and device risk level.

13. Evaluator Qualifications & Declaration of Interest

✓ Ensure CER evaluators are qualified and provide a documented declaration of interest.

14. Traceability to Risk Management File

✓ Cross-check all clinical evidence and conclusions with the risk management file for consistency.