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Research Solutions

Clinical Evaluation Report: Structure Template

EU MDR (2017/745) Annex XIV | MEDDEV 2.7/1 Rev 4, Appendix A9

Use this as the skeleton for a CER under EU MDR. The section order follows the proposed table of contents in MEDDEV 2.7/1 Rev 4 Appendix A9, which Notified Bodies use as their reference.

1. Summary	The device, the evidence base, and the conclusions, readable on its own.
2. Scope of the evaluation	Device description, variants and accessories covered, intended purpose, claims, and the GSPRs that need clinical evidence.
3. Clinical background and state of the art	The medical condition, current treatment options and their outcomes, applicable standards and guidance, and the benchmark the device is judged against.
4. Device under evaluation	Regulatory status, design features relevant to clinical performance, and any equivalence claim with its justification per MDCG 2020-5.
5. Identification of clinical data	The documented literature search protocol (databases, search strings, dates, inclusion and exclusion criteria) plus manufacturer data: investigations, PMCF, complaints, vigilance.
6. Appraisal	Each dataset scored for suitability and contribution using criteria defined in the CEP, recorded in appraisal tables.
7. Analysis	Whether the evidence demonstrates conformity with the relevant GSPRs, supports every claim in the IFU, and shows an acceptable benefit-risk profile against the state of the art.
8. Conclusions	Which GSPRs are met by which evidence, residual risks, evidence gaps, and what PMCF will address.
9. PMCF linkage	The open questions passed to the PMCF plan, with timelines for feeding results back.
10. Evaluator qualifications	CVs and declarations of interest for the evaluators, with clinical and methodological expertise documented.
11. References	Full citations for every source used, so each one can be retrieved.

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CER Pre-Submission Checklist

Work through this before the report goes to your Notified Body

- [ ] The CEP is in place, current, and was written before the report.
- [ ] Every GSPR the CEP flagged as needing clinical evidence is answered in the conclusions.
- [ ] The literature search matches the CEP protocol and can be re-run: databases, search strings, dates, and inclusion and exclusion criteria are all documented.
- [ ] Appraisal criteria were defined before appraisal started; every dataset has a recorded suitability and contribution score.
- [ ] Any equivalence claim is justified across clinical, technical, and biological characteristics per MDCG 2020-5.
- [ ] For an implantable or Class III equivalent device from another manufacturer: the Article 61(5) contract giving ongoing access to its technical documentation is in place.
- [ ] The state of the art section reflects current guidelines and treatment alternatives, not those at first certification.
- [ ] Every claim in the IFU and marketing materials is supported by the evidence in the report.
- [ ] The benefit-risk conclusion is consistent with the risk management file (ISO 14971).
- [ ] The PMCF plan addresses the specific gaps named in the conclusions.
- [ ] Evaluator CVs and declarations of interest are included, and their expertise matches the device's clinical field.
- [ ] The update frequency is stated and justified (at least annually for implantable, Class III, high-risk, or novel devices; every 2 to 5 years otherwise).
- [ ] For Class III and implantable devices: the SSCP is consistent with the CER.
- [ ] The report date is current relative to the stated update cycle.