Notified Body CER Review Readiness Checklist

Avoid Common Clinical Evaluation Deficiencies Under EU MDR

Clinical Evaluation Reports (CERs) are one of the most frequently challenged documents during **EU MDR technical documentation review by notified bodies**.

Common deficiencies include incomplete literature reviews, weak equivalence justification, poor benefit-risk analysis, and insufficient linkage to risk management and post-market data.

This checklist helps manufacturers assess whether their **CER documentation is ready for notified body review**.

Key Regulatory References

- **EU MDR Article 61 — Clinical Evaluation**
- **EU MDR Annex XIV Part A — Clinical Evaluation Requirements**
- **EU MDR Annex XIV Part B — Post-Market Clinical Follow-up (PMCF)**
- **EU MDR Annex I — General Safety and Performance Requirements (GSPR)**
- **EU MDR Annex II — Technical Documentation**
- **EU MDR Annex III — Post-Market Surveillance**

Guidance Documents

- **MEDDEV 2.7/1 Rev 4 — Clinical Evaluation**
- **MDCG 2020-13 — Clinical Evaluation Assessment Equivalence**
- **MDCG 2020-6 — Summary of Safety and Clinical Performance (SSCP)**
- **MDCG 2020-1 — Clinical Evidence under MDR / IVDR**

Standards

- **ISO 14971:2019 — Risk Management**
- **ISO 14155:2020 — Clinical Investigation**
- **ISO/TR 20416:2020 — Post-Market Surveillance**

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1. Clinical Evaluation Strategy

Notified bodies first evaluate whether the **clinical evaluation approach is clearly defined**.

☐ Clinical Evaluation Plan (CEP) documented
(EU MDR Annex XIV Part A)

☐ Clinical evaluation scope aligned with device classification
(EU MDR Article 61)

☐ Clinical evidence sources clearly identified

☐ Clinical evaluation methodology justified

☐ State-of-the-art analysis completed
(MEDDEV 2.7/1 Rev 4)

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2. Device Description & Intended Use

Incomplete device description is a **common deficiency observed by notified bodies**.

☐ Device design and mechanism of action described
(EU MDR Annex II)

☐ Intended purpose clearly defined

☐ Target patient population identified

☐ Clinical indications and contraindications documented

☐ Device variants and accessories described

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3. Equivalence Justification

Equivalence claims are **one of the most scrutinized aspects** of CER reviews.

☐ Equivalent device clearly identified

☐ Technical equivalence demonstrated

☐ Biological equivalence demonstrated

☐ Clinical equivalence demonstrated

☐ Access to equivalent device technical documentation available

Reference

EU MDR **Annex XIV**
MDCG **2020-13**

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4. Literature Search Methodology

Weak literature review methodology is a **major cause of CER rejection**.

☐ Systematic literature search protocol documented

☐ Databases used clearly defined
(PubMed, Embase, Google Scholar etc.)

☐ Search keywords and Boolean operators defined

☐ Inclusion and exclusion criteria justified

☐ Literature screening methodology documented

Reference

MEDDEV **2.7/1 Rev 4 Section 8**

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5. Literature Evidence Appraisal

Notified bodies evaluate whether **scientific publications are critically analysed**.

☐ Study design evaluated

☐ Sample size and statistical significance assessed

☐ Clinical endpoints reviewed

☐ Study limitations identified

☐ Bias and methodological weaknesses discussed

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6. Clinical Performance Evaluation

CER must clearly demonstrate **device effectiveness**.

☐ Clinical outcomes analysed

☐ Device performance compared to state-of-the-art

☐ Evidence relevance justified

☐ Clinical benefit demonstrated

Reference

EU MDR **Article 61**

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7. Safety Evaluation

Notified bodies assess whether **device safety is comprehensively evaluated**.

☐ Adverse events analysed

☐ Safety data from clinical studies evaluated

☐ Post-market safety data reviewed

☐ Known risks clearly identified

Reference

EU MDR **Annex I**
ISO **14971**

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8. Benefit-Risk Assessment

CER must clearly demonstrate that **benefits outweigh risks**.

☐ Residual risks identified

☐ Risk mitigation strategies described

☐ Clinical benefits clearly justified

☐ Benefit-risk conclusion supported by clinical evidence

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9. Integration with Risk Management

Clinical evaluation must be **linked with the risk management process**.

☐ Risk management file reviewed

☐ Clinical risks reflected in CER

☐ Residual risks addressed

Reference

ISO **14971:2019**

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10. Post-Market Clinical Evidence

Notified bodies expect CERs to integrate **post-market data**.

☐ PMS data included

☐ Complaint data evaluated

☐ Literature monitoring performed

☐ PMCF strategy defined

Reference

EU MDR **Annex XIV Part B**
ISO/TR **20416**

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11. SSCP Alignment

For applicable device classes, CER conclusions must align with **SSCP documentation**.

☐ SSCP prepared

☐ Clinical evidence summary consistent with CER

☐ Safety and performance data aligned

Reference

EU MDR **Article 32**
MDCG **2020-6**

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12. Technical Documentation Integration

Clinical evaluation must align with the broader **technical documentation package**.

☐ Clinical evaluation linked with GSPR checklist

☐ Clinical data supports intended purpose

☐ CER integrated with risk management and PMS documentation

Reference

EU MDR **Annex II & III**

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13. Final CER Readiness Assessment

Before submitting to a notified body confirm:

☐ Clinical evaluation plan implemented

☐ CER follows MEDDEV 2.7/1 Rev 4 structure

☐ Literature review methodology documented

☐ Evidence traceability maintained

☐ Clinical conclusions clearly justified

☐ CER updated with latest PMS data

How Syrma Johari MedTech Supports CER Development

Syrma Johari MedTech supports manufacturers with:

• Clinical Evaluation Plan (CEP) development
• Clinical Evaluation Report (CER) preparation
• Systematic literature review using **PubMed, Embase, Google Scholar**
• SSCP authoring for EU MDR compliance
• IVDR Performance Evaluation Reports (PER)
• Clinical evidence lifecycle management aligned with PMS and PMCF

Need Help Preparing for Notified Body CER Review?

Syrma Johari MedTech helps manufacturers develop **robust clinical evaluation documentation aligned with EU MDR and global regulatory expectations.**

Contact our regulatory team to discuss your **CER readiness and clinical evidence strategy.**