

EU MDR Clinical Evaluation Compliance Checklist

A Practical Guide for Preparing CEP, CER and SSCP Documentation

Clinical evaluation is a core requirement under **EU MDR (Regulation (EU) 2017/745)**. Manufacturers must demonstrate that their medical devices achieve the intended clinical performance while maintaining an acceptable benefit-risk profile.

This checklist helps regulatory and clinical teams verify whether their **Clinical Evaluation Plan (CEP), Clinical Evaluation Report (CER), and Summary of Safety and Clinical Performance (SSCP)** align with EU MDR expectations and notified body review requirements.

1. Clinical Evaluation Plan (CEP) Checklist

The CEP defines the methodology for evaluating clinical evidence.

Strategy & Scope

- Device description and intended purpose clearly defined
- Device classification and regulatory pathway documented
- Clinical evaluation scope aligned with EU MDR Annex XIV
- Target patient population and clinical indications defined

Equivalence Strategy

- Equivalence claims supported by technical, biological, and clinical comparison
- Access to equivalent device technical documentation available
- Equivalence justification documented and scientifically supported

Literature Search Methodology

- Structured literature search protocol established
- Search keywords and Boolean strategy documented
- Inclusion and exclusion criteria defined
- Search databases identified (PubMed, Embase, Google Scholar, etc.)

Clinical Data Sources

- Published clinical literature
- Clinical investigations (if applicable)

- post-market clinical data
- PMS / PMCF data

Clinical Evaluation Methodology

- Evidence appraisal methodology defined
 - Benefit-risk evaluation framework documented
 - Data analysis methods specified
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2. Systematic Literature Review Checklist

Literature review is a **key component of clinical evidence generation.**

Database Selection

- PubMed / MEDLINE
- Embase
- Google Scholar
- Cochrane Library
- ClinicalTrials.gov

Literature Screening

- Initial publication screening completed
- Duplicate publications removed
- Relevance to device or equivalent device evaluated
- Publication date ranges considered

Scientific Appraisal

- Study quality assessed
- Clinical endpoints evaluated
- Sample size and statistical validity reviewed
- Bias and study limitations identified

Evidence Documentation

- Literature screening flow diagram prepared
 - Evidence tables developed
 - Data extraction documented
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3. Clinical Evaluation Report (CER) Checklist

The CER compiles and evaluates all clinical evidence demonstrating device safety and clinical performance.

Device & Technology Description

- Device design and mechanism of action described
- Intended use and clinical indications defined
- State of the art analysis completed

Clinical Data Analysis

- Literature evidence summarized
- Clinical investigations evaluated
- Post-market data reviewed

Safety & Performance Evaluation

- Adverse event analysis completed
- Risk management integration with ISO 14971
- Clinical benefits demonstrated

Benefit-Risk Analysis

- Residual risks identified
- Benefit-risk balance documented
- Clinical conclusions justified

CER Documentation

- CER structured according to MEDDEV 2.7/1 Rev 4
- Clinical evaluation methodology documented
- Evidence traceability maintained

4. SSCP Preparation Checklist

Under EU MDR, certain device classes must provide a **Summary of Safety and Clinical Performance (SSCP)**.

Device Overview

- Device description and intended purpose summarized
- Indications and target population described

Safety & Clinical Performance

- Clinical evidence summary provided
- Residual risks and warnings included
- Benefit-risk profile explained

Usability

- Language clear and understandable
- Suitable for healthcare professionals and patients
- Consistent with CER conclusions

5. Lifecycle Clinical Evidence Management

Clinical evaluation is **not a one-time activity**. EU MDR requires continuous evidence monitoring.

Post-Market Clinical Evidence

- PMCF strategy defined
- Clinical evidence updated through PMS activities
- CER updates scheduled based on device risk class

Continuous Evidence Monitoring

- Literature monitoring program established
- Vigilance and complaint data incorporated
- Risk management updates integrated

6. Notified Body Readiness Checklist

Before submitting technical documentation to a notified body, confirm the following:

- CEP approved and implemented
- CER demonstrates clear clinical performance
- Literature review methodology documented

- Evidence traceability maintained
 - SSCP prepared where required
 - Clinical evidence integrated with risk management
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How Syrma Johari MedTech Supports Clinical Evaluation Programs

Syrma Johari MedTech supports medical device and IVD manufacturers with:

- Clinical Evaluation Plan (CEP) development
- Clinical Evaluation Report (CER) preparation
- Summary of Safety and Clinical Performance (SSCP) documentation
- Systematic literature review and clinical evidence analysis
- IVDR Performance Evaluation Reports (PER)
- Clinical evidence updates aligned with post-market surveillance

Our multidisciplinary teams combine **regulatory expertise, clinical science, and medical writing capabilities** to deliver regulatory-ready clinical evidence packages.

Need Support for Your Clinical Evaluation Program?

Syrma Johari MedTech helps manufacturers build **robust clinical evidence strategies aligned with EU MDR, EU IVDR, and global regulatory frameworks.**

[Contact](#) our regulatory team to discuss your clinical evaluation requirements.
