mantrasystems

Clinical Evaluation Report template

Powerful EU MDR CER template developed by clinical experts

Version 2.0

Contents

Introduction

The Clinical Evaluation Report (CER) is an important technical document that must be produced in relation to every medical device under the MDR. It documents the process and conclusions of the process of clinical evaluation of a medical device.

A clinical evaluation is performed through the objective assessment all clinical evidence relating to the subject medical device, whether favourable or unfavourable, in order to determine whether a device meets its obligations under the MDR. Specifically, it considers whether evidence supports conformity with all relevant General Safety and Performance Requirements (GSPRs), conformity with the device's intended purpose, and a favourable benefit-risk profile.

A CER consists of the following sections:

- Administrative particulars and details of authors and reviewers
- Executive summary
- Hypothesis and objectives
- Device description, classification, variants and manufacturer details
- Clinical field summary, providing evidence-based information about the target condition and patient population. This section should explore comparable alternatives to the subject device in order to determine safety and performance benchmarks and to establish state-of-the-art.
- Summary of the clinical evaluation plan including a list of GSPRs that apply to the device
- Common specifications and harmonised standards applied
- Equivalence (if relevant)
- Objective and systematic clinical literature review following a defined identification and appraisal plan. Includes favourable and unfavourable data, and incorporates evidence generated and held by manufacturer as well as external/independent data.
- Analysis of the extent to which appraised data demonstrates conformity with relevant GSPRs and a favourable benefit-risk profile
- A conclusion that outlines overall whether MDR conformity and an acceptable benefit-risk profile has been demonstrated
- CER revision dates
- Author CVs

How to use this template

This document provides a template that describes, step-by-step, how to construct a CER for MDR compliance.

The template is arranged into numbered sections that reflect the full range of requirements for clinical evaluation in the MDR. **Your completed CER should be organised according to the sections in this template, as relevant.** Each section contains some or all of the following:

REQUIRED

Required information provides an outline for section content and is often written as a set of questions. These address the bulk of the content required for the CER and responding to the questions in prose will populate the section.

INSTRUCTION

Instructions should be followed in order to meet requirements.

GUIDANCE

Outlines the purpose of the section and gives general guidance and background information.

TRANSPOSE

These short sections should be added as written into the completed CER, with modifications as needed to make them device-specific.

EXAMPLE

Illustrative examples use fictional medical devices to give guidance on structure and writing style. Any cross-applicability to 'real' devices is unintended.

Structure

It is essential that the CER is well-structured. It is recommended that the user follows the structure of headings, subheadings and sub-subheadings in this template. This will help ensure that the resulting CER will be well organised and will address all aspects of MDR clinical evaluation.

This document is constructed in accordance with guidelines documented in MEDDEV 2.7/1 rev 4, The Medical Device Regulation (MDR) 2017 / 745, and relevant 2019 and 2020 MDCG guidelines.

Each section that follows should be understood to constitute a section of the CER, with the section title representing the main heading for that section.

CER writing tips

1. Write objectively and in the third-person
2. Define all terms used
3. Ensure that all points made are referenced. Avoid "naked" opinions that are unsubstantiated
4. If using a text editor such as Microsoft Word, use the "styles" function "heading 1", "heading 2" for headings and sub-headings in the document. This then enables automatic construction of a table of contents that will auto-update to any subsequent changes.

Support

Contact our team with any questions you may have while using this template and for information about our CER review services:

- contact@mantrasystems.co.uk
- www.mantrasystems.co.uk/contact

CER Review service

We also offer a bespoke CER Review service, facilitating direct and focused CER feedback from our MDR-trained medical professionals. Please contact us to discuss this service in more detail.

3. Scope of the clinical evaluation

3.1 Objective

[REDACTED]

3.2 Hypothesis

GUIDANCE

The purpose of the hypothesis is to provide a scientific structure to the CER. Stating a hypothesis at the start of the CER enables it to be tested through the identification, appraisal, and analysis of clinical evidence that follows. The hypothesis will be referred back to in the conclusion of the CER.

REQUIRED

State a hypothesis that will be tested by the process of clinical evaluation. The following example, adapted accordingly, would be appropriate:

EXAMPLE

> This report examines the hypothesis that the body of data collectively will evidence conformity of the subject device with the relevant MDR Annex I General Safety and Performance Requirements (GSPRs), and demonstrate an acceptable benefit-risk profile for the device.
>
> It is performed in accordance with MedDev guideline 2.7/1 rev 4 (2016) “Clinical Evaluation: A Guide for Manufacturers and Notified Bodies”, relevant MDCG guidelines from 2019 and 2020, and MDR Annex XIV.

3.5 Manufacturer and sales history

INSTRUCTION

Begin this subsection by outlining who manufactures the device. Give the name of the manufacturer, their address, and explain their experience in this field. State whether the manufacturer has any relevant credentials (e.g. ISO 13485-based quality system) and if so, list them.

REQUIRED

Is an authorised representative (AR) involved in the device's route from manufacturer to market (this normally applies when manufacturers based outside the EU choose to market the device in Europe, requiring use of an authorised representative)? If so, provide details of the AR.

When was the device first CE-marked? (if in-market). In which countries/territories is the device sold? How many units have been sold to date?

EXAMPLE

> The Plasmatron 3.4 is manufactured and marketed by Fictional Medical Ltd of Fictional House, Some Road, Somewhere, XX10 1XX. The device has been CE marked since 2012 and is currently sold directly by the manufacturer in the United Kingdom, France, Germany, Spain, Italy and Denmark.
>
> There have been three significant modifications or alterations since initial release of the device, with the present version entirely replacing all previous versions. To date, according to sales data held by the manufacturer [REF], the manufacturer has sold 9,567 individual units of the device.