mantrasystems

Clinical Evaluation Report Template

Produce EU MDR-compliant CERs for any class of medical device using a proven start-to-finish methodology

Edition 4.0

Free sample

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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 a point-in-time summary of the ongoing process of medical device clinical evaluation.

A clinical evaluation is performed through the objective assessment of 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.

Edition revisions

Our Clinical Evaluation Report Template has been refined and expanded following our experiences within the industry throughout 2021. Edition 3 adds an additional seven pages of content and improves on the last edition in the following areas:

- Section 4.6 has been expanded
- Section 7 has been reorganised
- Sections 8.7, 8.8, 9.4 & 9.5 have been added
- General minor improvements throughout

With our promise of 'A lifetime of free revisions', previous buyers of our template will receive these updates for no additional cost. We strongly recommend CER writers review the entire document and use Edition 3 from now on for writing their reports.

1. Administrative particulars

GUIDANCE

This introductory section has three subsections:

1. Title page
2. Contents page
3. Administrative particulars summary

The **title page** should show an image of the device, the title "[product name] Clinical Evaluation Report", the name of the manufacturer, and the month / year of completion of the CER. The title page will not be assessed by the regulatory reviewer.

The **contents page** should show the sections and subsections that constitute the CER itself, with appropriate page numbers referenced. Using heading styles in a word processor will enable this section to be built and updated automatically.

The **administrative particulars summary** section is intended to give a reviewer quick access to key facts about the subject device.

REQUIRED

The administrative particulars summary should provide quick-reference access to the following information, ideally formulated in a table on a single page:

- Device name, model and type (if relevant)
  - e.g. Sublima Hip third generation, Cobalt Chrome edition
- Basic UDI system (if available)
- Product GMDN code (if available)
- Risk Classification
  - Don't worry about justification here - simply list. Justification will come later.
- Manufacturer name, address and Single Registration Number (SRN) if known
- Intended purpose of device
  - this should be identical to the full wording of Intended Purpose in main section of CER and the device IFU.
- CER authors details - name, date completed. Include a statement that "**author's up-to-date CVs are provided as an appendix to this Report".**
- Date completed.

GUIDANCE

If preferred, the Administrative Particulars section may be populated at the end of the writing process using information from the main body of the CER.

2. Executive Summary

INSTRUCTION

Write this section last!

Although the Executive Summary will be one of the first parts of the final CER, **do not try to populate the Executive Summary** until the main body of the CER has been completed.

GUIDANCE

The Executive Summary should be a brief summary (2-3 pages) of the detail of the CER that follows. The Executive Summary should enable the reader to get a quick feel for the "story" told by the main body of the CER.

Content of the Executive Summary should include a statement that:

TRANSPOSE

The subject of this clinical evaluation is the [device name] manufactured by [manufacturer name and address]. The device is intended to [set out intended purpose].

REQUIRED

- A paragraph summarising the target medical condition
- A paragraph summarising the technology in the device (or how it works) and its applicability to the target condition
- If incorporating a claim of equivalence, name the device and give the manufacturer name and address

A statement that:

TRANSPOSE

This clinical evaluation is based on a comprehensive analysis of available clinical evidence related to the safety, performance and intended purpose of the subject and equivalent device. The analysis was made against following standards:

- safety and performance benchmarks relating to comparable alternative devices
- relevant MDR Annex I GSPRs
- safety and performance relative to historical safety of subject device
- evidence of clinical benefit and benefit-risk acceptability.

Having performed a clinical evaluation as described in this report, the [subject device] has been demonstrated to have an acceptable benefit-risk profile, to be suitable for its intended purpose, and to conform with the relevant General Safety and Performance Requirements as specified in Annex I MDR.

This CER supports ongoing approval of the [subject device].

INSTRUCTION

Structure the Executive Summary in a way that mirrors the structure of the main body of the CER, including a short summary of the "highlights" and main findings of each section.

3. Scope of the clinical evaluation

3.1. Objective

Begin this section with text that resembles the following, adapted according to the specifics of the subject device:

TRANSPOSE

The objective of this Clinical Evaluation Report (CER) is to obtain, identify, summarise, appraise and analyse all available clinical data that relates to the safety and performance of the subject device [and equivalent device-if applicable], when used as intended, in order to determine:

- That the device is suitable for its intended purpose
- The degree to which conformity with the relevant General Safety and Performance Requirements in Annex I of the Medical Device Regulation 2017 / 745 has been demonstrated
- The acceptability of the benefit-risk profile of the device.

The Clinical Evaluation is also intended to establish:

- Any previously unrecognised hazard(s) or hazardous situation(s)
- Whether any previously-identified and acceptable risk(s) have been rendered unacceptable by clinical data that has subsequently come to light.

This Clinical Evaluation Report (CER) reflects the entirety of the available clinical evidence relating to the subject device [and equivalent device if applicable]. Data sources include:

- pre-market data and quality assurance testing information
- evidence of clinical performance of the device
- the results of systematic literature searches
- post market surveillance data comprising customer feedback and vigilance data
- risk analysis data.
- [anything else that is relevant]

The present clinical evaluation has been performed in accordance with MedDev guideline 2.7/1 rev 4 (2016) “Clinical Evaluation: A Guide for Manufacturers and Notified Bodies”, MDGC guidelines 2020-13 and 2020-6, MDR Annex XIV Part A, and internal procedures and templates

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 to in the conclusion of the CER.

REQUIRED

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

TRANSPOSE

This report examines the general 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), suitability for intended purpose, and demonstrate an acceptable benefit-risk profile for the device.

REQUIRED

It is then necessary to formulate a specific hypothesis based around performance criteria relating to the specific device. Often, this will rely upon the results of a literature review that has been completed in the past which may reveal key performance criteria for the device.

EXAMPLE

The subject device will show a reduction in Pain VAS (quantitative measure) that is at least of the same magnitude as that seen following use of comparable alternative devices.

The subject device will demonstrate a frequency and severity of adverse events that are no greater than those seen in relation to comparable alternatives.

3.3. Device overview

3.3.1. General description of the device

REQUIRED

Provide a full description of the medical device. Include:

- A statement that "The subject of this Clinical Evaluation Report is the [device name] manufactured by [manufacturer name, address]"
- Detail any specific model numbers/versions, and how the UDI for each device is constructed (if available).
- Describe whether the device is invasive or non-invasive, single-use or reusable
- What is it designed to do? What type of condition is it intended to treat?

    - e.g. "The subject device is in the field of treating osteoarthritis of the hip."
- What (if anything) does the device normally engage with, screw into, or combine with? How does this interaction take place, and under what conditions of use?
- Which overall category does it belong to (e.g. “endoscopes”, “total hip replacements”)? Is it used for treatment, management or diagnosis of disease?
- Is the device sterile or non-sterile?
- What is its stated shelf-life?
- Are there any device variants?
    - If not, state that the device is available as a single variant.
    - If yes, describe all the variants and explain how they differ from one another. Include manufacturer's description of device history (changes over time, introduction of variants, etc) along with a description of reasons for such changes and variants. It is often beneficial to draw up a table for each variant specifying size, materials, and other features that will enable a comparison between variants.
- Include the manufacturer's description of different sizes, configurations or formulations of the device
- Does the device have any secondary or alternative primary uses? If not, state not. If so, describe and explain them.
- Who is the device intended to be used by?
    - e.g. "the intended use population is laypersons in the home environment"
    - e.g. "the intended use population is healthcare professionals in the operating theatre environment".

EXAMPLE

The subject of this Clinical Evaluation Report is the Plasmatron 3.4 manufactured by Fictional Medical Ltd of Fictional House, Some Road, Somewhere, XX10 1XX. It is an updated product version that has entirely replaced the Plasmatron 2.0, now discontinued, following customer feedback relating to the 2.0 version. The general UDI system is XXX/YYY/Plasma/45.

The Plasmatron 3.4 is a non-invasive, single use, sterile device. It is designed to slot into the grey port of electronic plasma beams, in order to enable the introduction of super-heated air into the plasma beam from within a single, sealed system. This is used as a component of an electro-surgery system intended to treat deep cerebral tumours that are otherwise inaccessible.

The device is supplied sterile and has a shelf life of two years from the date of sterilization. Any units outside of the 2-year shelf life should not be used and should be disposed of in accordance with disposal instructions provided in the IFU.

The Plasmatron 3.4 is available in only a single version with no variants. No secondary or alternative primary uses exist for the device. The Plasmatron 3.4 is intended to be used by interventional radiologists who have been appropriately trained in its use according to the device IFU.

3.4. Device classification

REQUIRED

Is the subject device a medical device according to definitions in Article 2 MDR? If so, describe how/why, referring to and quoting the relevant parts of the Article 2 definition.

EXAMPLE

The Plasmatron 3.4 produced by Fictional Medical Ltd meets the definition of a “medical device” in Article 2 of the Medical Devices Regulation (EU) 2017/745 of the European Parliament. Its intended purpose is to be used for the treatment or alleviation of disease in human beings, and it does not achieve its principal intended action through pharmacological, immunological or metabolic means.

REQUIRED

What regulatory class is the device? Provide justification by directly quoting the (relevant) rules in Annex VIII MDR. Make the reasoning explicitly clear.

EXAMPLE

The Plasmatron 3.4 is classified as a Class IIb device in accordance with Annex VIII of the Medical Device Regulation 2017/745:

Rule 9: All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

Because the Plasmatron 3.4 is an active therapeutic device intended to administer energy in a potentially hazardous way, the final sentence applies and the device is Class IIb.

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.

3.6. Intended purpose

REQUIRED

What is the intended purpose of the device as written in the Instructions For Use (IFU) or other appropriate documentation? Are there any specific claims made about device performance in the device's promotional material? If so, detail them here. How does the device claim to achieve its intended purpose?

3.7. Indications, contraindications and precautions

REQUIRED

What are the medical indications and contraindications for use of the device? List them as written in the IFU or other relevant product documentation. If there are restrictions in the type of user (e.g. "indicated for use only by persons who are appropriately trained") then state so here.

Are any precautions for use mentioned by the manufacturer or specified in Instructions for Use (IFU)? If so, outline them.

3.8. Target population and medical conditions

REQUIRED

What is the target disease or condition? Is the condition categorised according to stage, severity, or symptoms?

Do not go into detail at this stage, simply give a headline summary:

EXAMPLE

> The subject device in intended to treat stage-4 osteoarthritis of the elbow in adult patients over the age of 18 years.

Add a comment:

TRANSPOSE

> Section 6 of this CER provides further details of the range of target medical conditions applicable to the subject device, along with an analysis of comparable alternatives to the subject device.

REQUIRED

Also include in this section:

- A description of what symptoms are being targeted by the device
- Describe the characteristics of the target patient population
- Describe the target medical user group
    - e.g. surgeons, rheumatologists, specialist nurses.
- Briefly describe what clinical benefit the device is supposed to bring

- e.g. faster diagnosis, alleviation of pain, improvement in public health.

3.9. Device composition and components

REQUIRED

What materials is the device made from? Does the device incorporate any medicinal substances, tissues or blood products? If so, detail how and why the device falls under the MDR. Does the device incorporate any software?

Provide a general description of the key functional elements of the device - its parts/components, formulation, composition, and functionality. Where relevant, specify the relative proportions of each material used.

What are the mechanical characteristics of the device? Insert pictures of the device (reference and identify all pictures and tables).

Technology - does the device use new or old technology, or a combination? What device aspects are novel or innovative? Explain any novel features - what is their intended benefit, and how do these features differentiate the subject device from others?

EXAMPLE

The device is composed of three moulded plastic sections bound by a central aluminium core. It has an internal lithium battery and connects to a mains power supply through a power port at the centre of the device.

The three plastic components are made from phthalate-free plastic in the proportions of 30% HPE and 70% polycarbonate. The central core is 100% 3mm-thick aluminium. The device contains no Carcinogenic, Mutagenic or substances toxic to reproduction (CMR) compounds.

The aluminium component provides strength and rigidity to the device and also serves as primary control point to which the operator's hand grasps.

[Images]

The device uses well-established technology but the use of a central aluminium core offers the novel advantage of enhanced heat dissipation, intended to prevent the device from overheating during use. Aluminium has a heat dissipation fraction of X%, compared to a maximum of Y% in alternative materials known in the art [REF]. The manufacturer claims that this can enable the device to be used for longer periods of time than competing devices, enabling it to provide a therapeutic option for brainstem tumours that require prolonged therapeutic exposure.

3.10. Accessories or compatible devices

REQUIRED

Describe any accessories to the device, and any compatible devices that it is designed to interface with. Identify whether these accessories or compatible devices are likely to have any bearing on the clinical safety or performance of the subject device. Include images or diagrams where possible, so that the reader is easily able to understand how the subject device would connect / interface with them.

3.11. Similar devices

REQUIRED

Give an overview of any similar devices that have been identified (whether in EU or in other territories). Write a paragraph on each device, summarising how they are similar to and different from the subject device. If data is available, indicate time on market and approximate sales volume of each similar device.

GUIDANCE

This section is different to that on "comparable alternatives" in a later section. A comparable alternative to a total hip replacement, for example, could theoretically include non-surgical options such as physiotherapy, steroid injection, and analgesia. A "similar device" would be another form or brand of hip implant designed to function in a similar way; it would not extend to other therapeutic options.