



Clinical Evaluation Plan (CEP) Template

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Template Use

This Clinical Evaluation Plan (CEP) Template is specifically designed, and intended for straightforward transfer of information to the associated Clinical Evaluation Report (CER) Template.

Although each clinical evaluation is unique in its design, the sections of this CEP Template include all the fundamental components of an EU MDR 2017/745-compliant CEP. Moreover, the structure and sections as well as their order and content follow the MEDDEV 2.7/1 Rev. 4 guidelines and Medical Device Coordination Group (MDCG) 2020-6 recommendations conforming to the expectations by the Notified Body (NB). This enables content of the finalized CEP to be directly copied into the equivalent sections of the associated CER Template, with only minor modifications to the tense as instructed throughout.

- For more information on the EU MDR 2017/745, visit <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745>
- For more information on MDCG guidelines, visit https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
- For more information on MEDDEV 2.7/1 Rev. 4 guidelines, visit <https://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native>

Note that, although the EU MDR 2017/745 became effective on May 2017, the transition period for the remediation of MDD-compliant clinical evaluations to MDR-compliant clinical evaluations has been extended to December 2027 for Class III and Class IIb devices, and to December 2028 for Class IIa and Class I devices.

The integration of automated formatting features through the customized Styles gallery, and the exceptional ease of using this CEP Template allow experienced authors to save valuable time by eliminating labor-intensive generation of standard

verbiage and repetitive formatting, and offer novice writers clear guidance to create MDR-compliant, high-quality documents that ensure consistency across other CEPs.

Taking into account the various types of clinical devices with different classifications, and Intended Purpose-associated statements, such as Intended Use, Indications for Use, Contraindications, Target Patient Population, Users, Warnings, Cautions, Warnings, Claims, and Clinical Benefits, CEP authors should work with their device development team members (i.e., Research and Development, Regulatory Affairs, Clinical Affairs, Medical Affairs, Manufacturing, Post-Market Surveillance, Post-Market Clinical Follow-up, etc.) to ensure that the document's content and data are presented in a clear and concise manner, which may require this template to be modified accordingly, so that it is in line with the device's unique aspects and specific characteristics.

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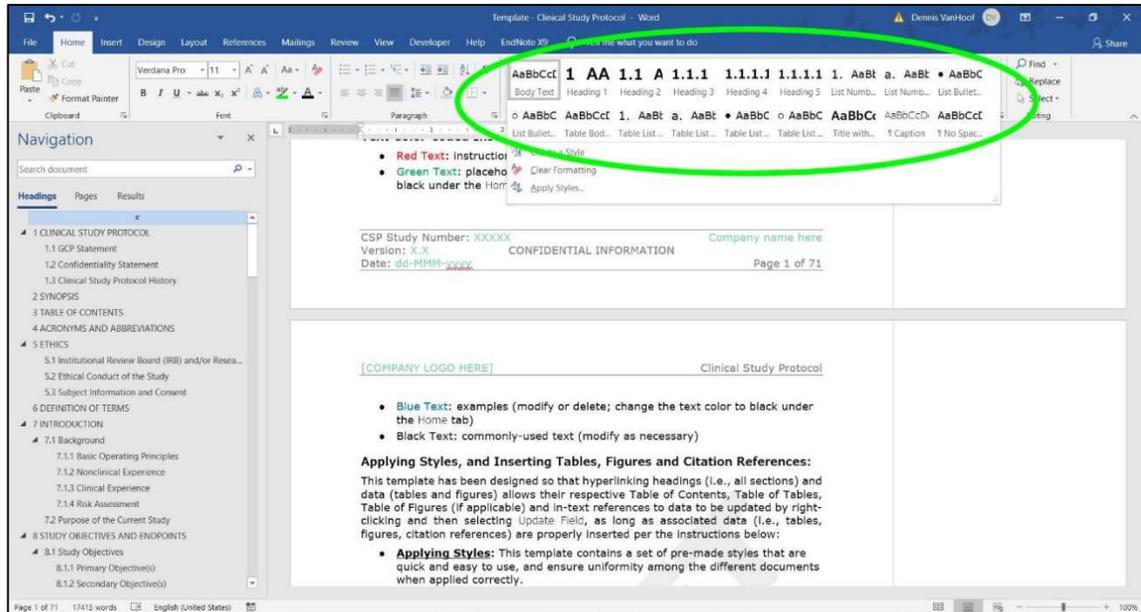
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Applying Styles, and Inserting Tables, Figures and Citation References

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This template has been designed so that hyperlinking the headings of sections and other data (e.g., tables and figures) allows their respective Table of Contents (TOC), Table of Tables, Table of Figures (if applicable) and in-text references to data to be updated by right-clicking on the TOC, and then selecting Update Field, as long as associated data (e.g., tables, figures, citation references) are properly inserted per the instructions outlined below.

- Applying Styles:** This template contains a set of 18 pre-made styles (see the available styles of the Styles gallery displayed in the green oval below) that are quick and easy to use, and ensure uniformity among the different documents when applied correctly.

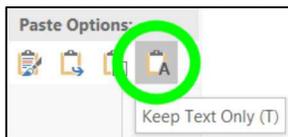


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- **Citation References:** To insert a new citation reference (i.e., a reference to journal article, book, report, poster, website, etc.), first go to the Reference Tab and select Insert Citation. Then select Add new source, choose the appropriate Type of source, and fill out the required information. The reference should appear in Section 11 after updating that field. To then insert a citation somewhere in the text to reference in the reference list, place the cursor where the citation needs to be inserted, go to the Reference Tab and select Insert Citation, and then choose the appropriate reference from the presented list. To reference this reference list somewhere else in the text with a clickable link, place the cursor where the clickable link needs to be inserted, go to the Reference Tab, select Cross-reference, and look under Reference type for section 11, and then insert the cross reference by choosing Heading number under the Insert reference to drop-down menu.

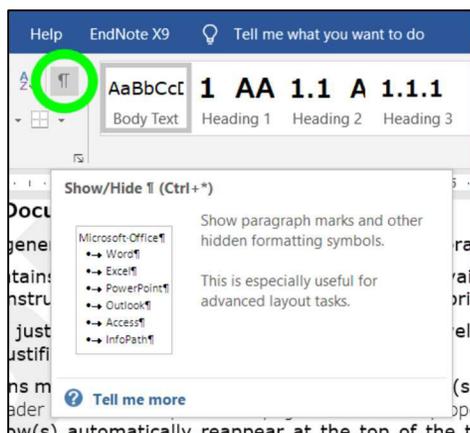
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When a table spans multiple pages, select the descriptive top row(s) of the table, and use Repeat as header row at the top of each page under Table properties to have the descriptive top row(s) automatically reappear at the top of the table parts across multiple pages.

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Per international standards, it is advised to use a 2-number day (dd), 3-letter capitalized month (MMM), and 4-number year (yyyy) dating format (separated by hyphens) as exemplified: August 9th, 2021 would be written as 09-AUG-2021.

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TITLE PAGE

Clinical Evaluation Plan

for

Device Name(s)

Version X.X

dd-MMM-yyyy

Company name

Address

City, State and Zip Code

Country

Confidentiality Statement

This document is confidential. It contains proprietary information of **company name**. Any viewing or disclosure of such information that is not authorized in writing by **company name** is strictly prohibited. Such information may be used solely for the purpose of reviewing the Clinical Evaluation Plan (CEP).

Clinical Evaluation Plan History

Version	Date	Description
1.0	dd- MMM -yyyy	Initial Clinical Evaluation Plan (CEP).

Add a new row for each new version, and briefly summarize (e.g., as bullet points) the edits in the Description.

SAMPLE

SIGNATURE PAGE

Clinical Evaluation Plan Number: XXXXX

Version: X.X

 First and surname
Head of Medical Affairs
 Company name
 Phone: +1 (XXX) XXX-XXXX
 E-Mail: XXXXX@XXXX.com

 First and surname
Medical Writer
 Company name
 Phone: +1 (XXX) XXX-XXXX
 E-Mail: XXXXX@XXXX.com

 Signature

 Date
 (dd-MMM-yyyy)

 Signature

 Date
 (dd-MMM-yyyy)

 First and surname
Subject Matter Expert
 Company name
 Phone: +1 (XXX) XXX-XXXX
 E-Mail: XXXXX@XXXX.com

 First and surname
Head of Regulatory Affairs
 Company name
 Phone: +1 (XXX) XXX-XXXX
 E-Mail: XXXXX@XXXX.com

 Signature

 Date
 (dd-MMM-yyyy)

 Signature

 Date
 (dd-MMM-yyyy)

 First and surname
Head of Clinical Affairs
 Company name
 Phone: +1 (XXX) XXX-XXXX
 E-Mail: XXXXX@XXXX.com

 First and surname
*Any other department representative
 as needed*
 Company name
 Phone: +1 (XXX) XXX-XXXX
 E-Mail: XXXXX@XXXX.com

 Signature

 Date
 (dd-MMM-yyyy)

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 Date
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2 ACRONYMS AND ABBREVIATIONS

Below are commonly-used acronyms and abbreviations. Carefully check for usage in this document and add/delete rows as necessary. Keep in alphabetical order.

Note that abbreviated terms should be spelled out and the abbreviation indicated in parentheses at first appearance in the text.

AE	Adverse Event
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
CAPA	Corrective and Preventive Action
CDP	Clinical Development Plan
CEP	Clinical Evaluation Plan
CER	Clinical Evaluation Report
DAEN	Database of Adverse Event Notifications
ER	Essential Requirement
EU	European Union
FDA	Food and Drug Administration
GMDNS	Global Medical Device Nomenclature System
GSPR	General Safety and Performance Requirement
IFU	Instructions for Use
IMDRF	International Medical Device Regulators Forum
MAUDE	Manufacturer and User Facility Device Experience
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive
MDR	Medical Device Regulation
MHRA	Medicines and Healthcare Products Regulatory Agency
PICO	Patient characteristics, type of Intervention, Comparator group(s)/Control(s), and Outcome(s)/endpoint(s)
PMC	PubMed Central
PMCF	Post-market Clinical Follow-up
PMS	Post-market Surveillance
PSUR	Periodic Safety Update Report
R&D	Research and Development

RCT	Randomized Controlled Trial
SOTA	State-of-the-Art
TGA	Therapeutic Goods Administration
TPLC	Total Product Life Cycle
UDI-DI	Unique Device Identification-Device Identifier
US	United States
WET	Well-Established Technology

SAMPLE

3 EXECUTIVE SUMMARY

3.1 Background

Provide the device name and model, and its device classification with a reference to the European Union (EU) Medical Device Regulation (MDR) 2017/745, Annex VIII.

If applicable, indicate since when the device was cleared for use in the United States (US) through the Food and Drug Administration (FDA) 510(k) pathway, and provide the certificate number.

If applicable, indicate since when the device was first CE-marked under the Medical Device Directive (MDD) 93/42/EEC on Medical Devices, and provide the certificate number.

If applicable, indicate since when the device was first CE-marked under the EU MDR 2017/745, and provide the certificate number.

3.2 Purpose

The purpose of this Clinical Evaluation Plan (CEP) is to define the scope, and to document the approach for the clinical evaluation of the **device name** to assess conformity to the European Union (EU) Medical Device Regulation (MDR) 2017/745. The clinical evaluation is intended to assess the performance and safety as well as the acceptability of the benefit/risk ratio of the subject device by identifying, appraising, and analyzing pertinent clinical and non-clinical data to determine whether the device under evaluation is in compliance with the General Safety and Performance Requirements (GSPRs) detailed in the EU MDR 2017/745 Annex I. Non-clinical tests held by the manufacturer **and post-market clinical experience data from regions in which the subject device is already available** will also be included in the evaluation.

The CEP is the document that provides the framework for the process of the clinical evaluation to be conducted for the generation of a Clinical Evaluation Report (CER). The CEP specifies the intended purpose of the subject device, identifies the GSPRs that require support from clinical data, and outlines how the clinical evaluation will be conducted. The documented information includes device specifications, safety and performance claims, and other aspects necessary to compile the CER.

The subsequent CER is an output of the clinical evaluation process to document the collection, appraisal, and analysis of the available clinical data relevant to the subject device, and to determine whether there is sufficient clinical evidence on the safety and performance in accordance with the intended purpose of the device. In addition, the CER documents the benefit-risk profile, including side effects in the intended target patient populations, and medical indications, if applicable, by assessing the clinical benefits against the potential hazards and patient harms, as informed by the risk management and Post-market Surveillance (PMS) documentation. The report

also evaluates the acceptability of the benefit-risk profile based on the current knowledge/state-of-the-art (SOTA) in the concerned medical field.

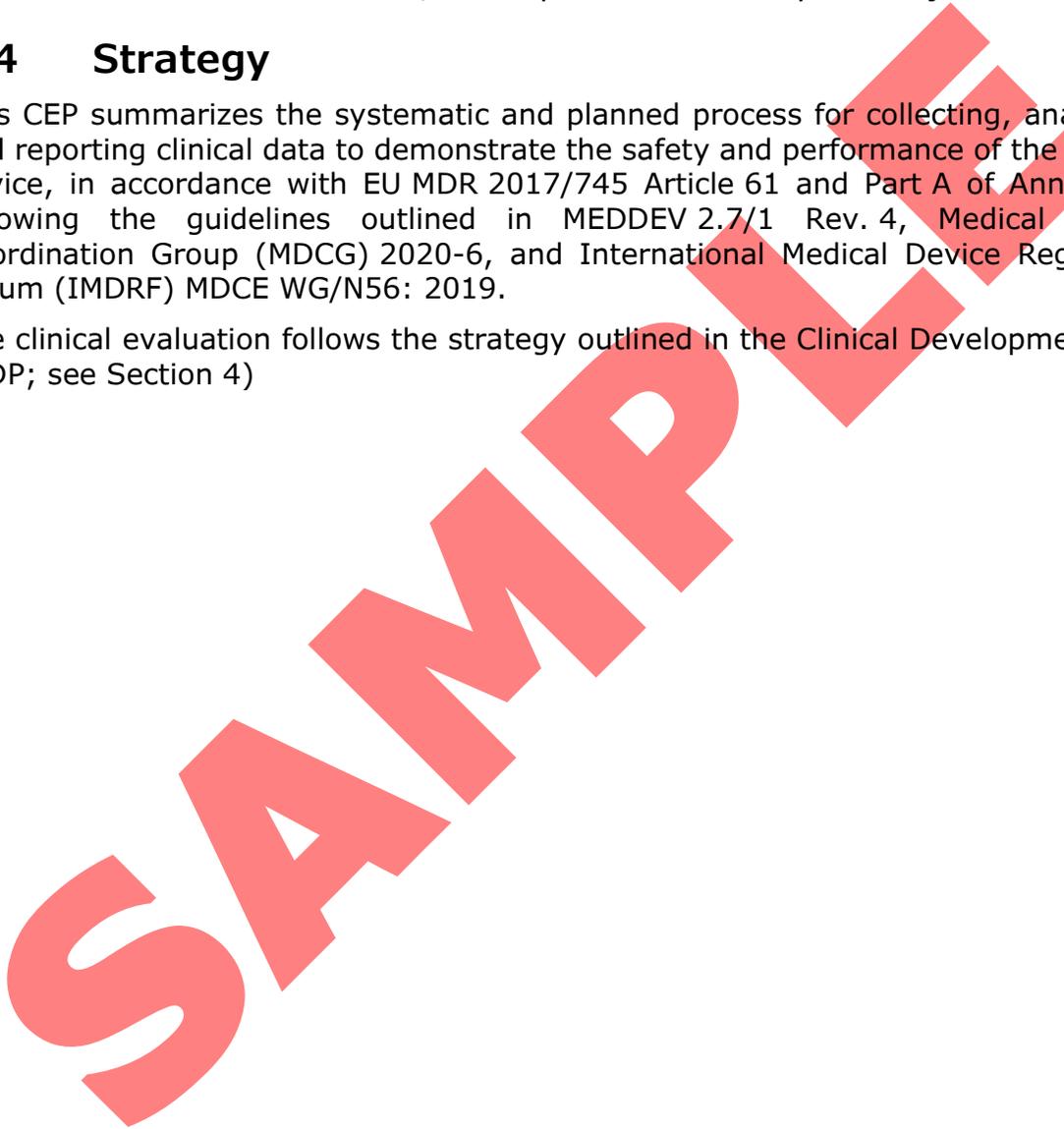
3.3 Scope

The scope of this CEP is limited to the planning and documentation of the conformity assessment of the EU MDR 2017/745 requirements for only the subject device.

3.4 Strategy

This CEP summarizes the systematic and planned process for collecting, analyzing, and reporting clinical data to demonstrate the safety and performance of the subject device, in accordance with EU MDR 2017/745 Article 61 and Part A of Annex XIV, following the guidelines outlined in MEDDEV 2.7/1 Rev. 4, Medical Device Coordination Group (MDCG) 2020-6, and International Medical Device Regulators Forum (IMDRF) MDCE WG/N56: 2019.

The clinical evaluation follows the strategy outlined in the Clinical Development Plan (CDP; see Section 4)





Clinical Evaluation Report (CER) Template

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Template Use

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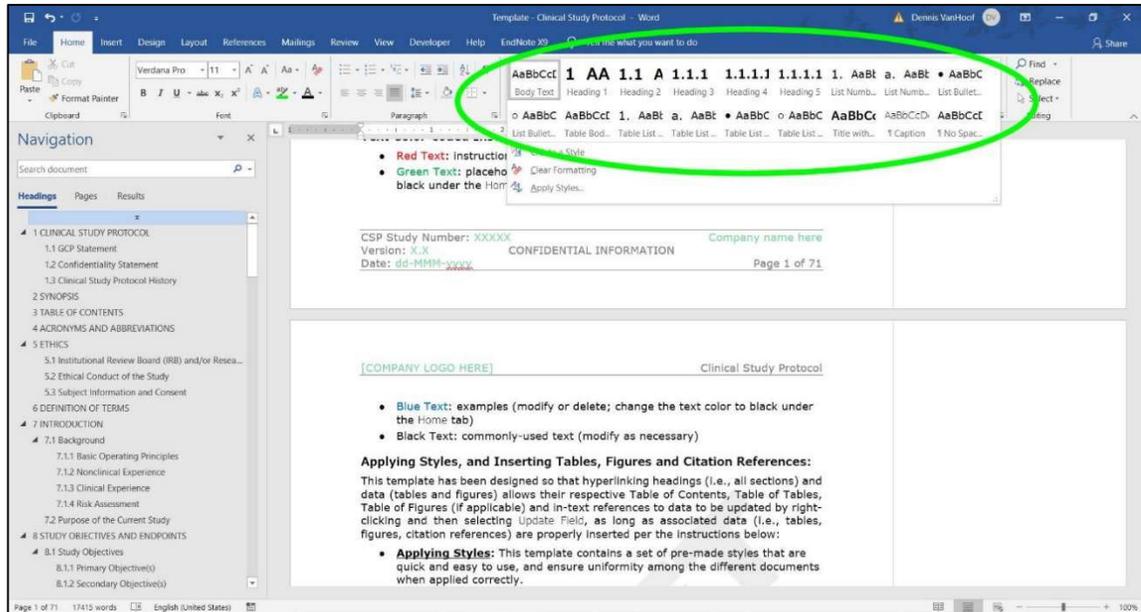
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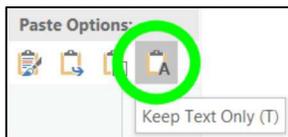


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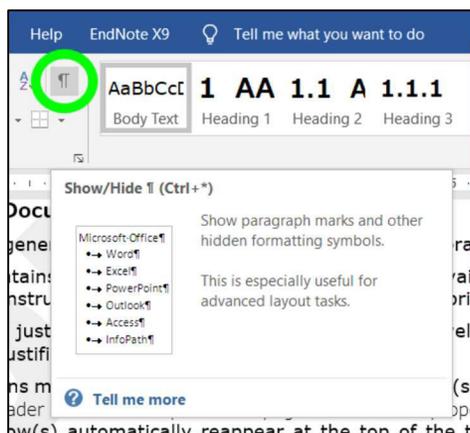
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TITLE PAGE

Clinical Evaluation Report

for

Device Name(s)

Version X.X

dd-MMM-yyyy

Company name

Address

City, State and Zip Code

Country

Confidentiality Statement

This document is confidential. It contains proprietary information of **company name**. Any viewing or disclosure of such information that is not authorized in writing by **company name** is strictly prohibited. Such information may be used solely for the purpose of reviewing the Clinical Evaluation Report (CER).

Clinical Evaluation Report History

Version	Date	Description
1.0	dd- MMM - yyyy	Initial Clinical Evaluation Report (CER).

Add a new row for each new version, and briefly summarize (e.g., as bullet points) the edits in the Description.

SAMPLE

SIGNATURE PAGE

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Version: X.X

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2 ACRONYMS AND ABBREVIATIONS

Below are commonly-used acronyms and abbreviations. Carefully check for usage in this document and add/delete rows as necessary. Keep in alphabetical order.

Note that abbreviated terms should be spelled out and the abbreviation indicated in parentheses at first appearance in the text.

AE	Adverse Event
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
CAPA	Corrective and Preventive Action
CDP	Clinical Development Plan
CEP	Clinical Evaluation Plan
CER	Clinical Evaluation Report
DAEN	Database of Adverse Event Notifications
ER	Essential Requirement
EU	European Union
EUDAMED	European Database for Medical Devices
FDA	Food and Drug Administration
GMDNS	Global Medical Device Nomenclature System
GSPR	General Safety and Performance Requirement
IFU	Instructions for Use
IMDRF	International Medical Device Regulators Forum
MAUDE	Manufacturer and User Facility Device Experience
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive
MDR	Medical Device Regulation
MHRA	Medicines and Healthcare Products Regulatory Agency
PICO	Patient characteristics, type of Intervention, Comparator group(s)/Control(s), and Outcome(s)/endpoint(s)
PMC	PubMed Central
PMCF	Post-market Clinical Follow-up
PMS	Post-market Surveillance
PSUR	Periodic Safety Update Report

R&D	Research and Development
RCT	Randomized Controlled Trial
SOTA	State-of-the-Art
TGA	Therapeutic Goods Administration
TPLC	Total Product Life Cycle
UDI-DI	Unique Device Identification-Device Identifier
URL	Uniform Resource Locator
US	United States
WET	Well-Established Technology

SAMPLE

3 EXECUTIVE SUMMARY

3.1 Background

Provide the device name and model, and its device classification with a reference to the European Union (EU) Medical Device Regulation (MDR) 2017/745, Annex VIII.

If applicable, indicate since when the device was cleared for use in the United States (US) through the Food and Drug Administration (FDA) 510(k) pathway, and provide the certificate number.

If applicable, indicate since when the device was first CE-marked under the Medical Device Directive (MDD) 93/42/EEC on Medical Devices, and provide the certificate number.

If applicable, indicate since when the device was first CE-marked under the EU MDR 2017/745, and provide the certificate number.

3.2 Purpose

The purpose of this Clinical Evaluation Report (CER) is to document the approach taken for the clinical evaluation of the **device name** per the Clinical Evaluation Plan (CEP) to assess conformity to the European Union (EU) Medical Device Regulation (MDR) 2017/745. The clinical evaluation is intended to assess the performance and safety as well as the acceptability of the benefit/risk ratio of the subject device by identifying, appraising, and analyzing pertinent clinical and non-clinical data to determine whether the device under evaluation is in compliance with the General Safety and Performance Requirements (GSPRs) detailed in the EU MDR 2017/745 Annex I. Non-clinical tests held by the manufacturer and post-market clinical experience data from regions in which the subject device is already available are also included in the evaluation.

The CEP is the document that provides the framework for the process of the clinical evaluation to be conducted for the generation of a CER. The CEP specifies the intended purpose of the subject device, identifies the GSPRs that require support from clinical data, and outlines how the clinical evaluation will be conducted. The documented information includes device specifications, safety and performance claims, and other aspects necessary to compile the CER.

The subsequent CER is an output of the clinical evaluation process to document the collection, appraisal, and analysis of the available clinical data relevant to the subject device, and to determine whether there is sufficient clinical evidence on the safety and performance in accordance with the intended purpose of the device. In addition, the CER documents the benefit-risk profile, including residual risks, side effects in the intended target patient populations, and medical indications, if applicable, by assessing the clinical benefits against the potential hazards and patient harms, as informed by the risk management and Post-market Surveillance (PMS) documentation. The report also evaluates the acceptability of the benefit-risk profile

based on the current knowledge/state-of-the-art (SOTA) in the concerned medical field.

3.3 Scope

The scope of this CER is limited to the documentation of the clinical evaluation for the conformity assessment of the EU MDR 2017/745 requirements for only the subject device.

3.4 Strategy

This CER summarizes the systematic process conducted for collecting, analyzing, and reporting clinical data to demonstrate the safety and performance of the subject device, in accordance with EU MDR 2017/745 Article 61 and Part A of Annex XIV, following the guidelines outlined in MEDDEV 2.7/1 Rev. 4, Medical Device Coordination Group (MDCG) 2020-6 and MDCG 2020-13, and International Medical Device Regulators Forum (IMDRF) MDCE WG/N56: 2019.

The clinical evaluation follows the strategy outlined in the Clinical Development Plan (CDP; see Section 4)

SAMPLE