This template is provided for guidance purposes only for class IIa medical devices and must be adapted to device-specific requirements

1. Purpose & Scope

The objective of this Clinical Evaluation Plan (CEP) is to provide a documented and systematic strategy to evaluate the available clinical data related to the clinical performance and clinical safety of the *medical device name*, manufactured by *company name*

This Clinical Evaluation Plan will be performed in accordance with Article 61 and Annex XIV of Regulation (EU) 2017/745 (MDR), taking into consideration the applicable guidance documents, including MDCG 2020-6 and MEDDEV 2.7/1 Rev. 4.

The contents of this CEP have been prepared in accordance with the requirements set out in Annex XIV, Part A, point 1(a) of Regulation (EU) 2017/745 and MDCG 2020-13.
This plan covers the clinical evaluation activities to be carried out during the period from *date* to *date*.

2. Responsibilities

Evaluators: Clinical Evaluation plan process under the *manufacturer name* shall be performed by qualified team which includes *Quality Departments*
General Manager: S(he) is responsible for reviewing and approving the literature evaluation process.
Quality Management Representative: Responsible for preparing of this plan
Product Engineers: Responsible to support the Quality Management Representative and General Manager for clinical evaluation process related documentation.

3. Definitions and Abbreviations

CEP: Clinical Evaluation Plan

CER: Clinical Evaluation Report

Clinical Benefit: The positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health

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For the *medical device name*device, the clinical evaluation has been conducted using the sufficient clinical data approach in accordance with MDR (EU) 2017/745 and relevant MDCG guidance. A device-specific clinical investigation has been performed to support the clinical evidence. The clinical investigation is documented in Clinical Investigation Report No. *** , Version***, dated ***

5.2 Objective of Clinical Evaluation Plan

This plan concerns the clinical evaluation that will be performed to assess and analyze the available clinical data for *medical device name* medical device and to evaluate whether these data support and demonstrate the clinical performance, safety and the risk/benefit of the device when used as intended by the manufacturer.

5.3 Main Questions Of The Clinical Evaluation

- Do the *medical device name* or the similar medical devices compromise the clinical condition of the patient?
- Is it safe, for the patient, the use of *medical device name* or of the similar medical devices?
- Is *medical device name* medical device's performance compared to similarproducts?
- What risks or complications may be due to the use of *medical device name* medical device or similar products?
- Are the benefits of *medical device name* medical device or similar products, superior to the risks?

5.4 General Safety And Performance Requirements Of *medical device*Medical Device That Require Support From Relevant Clinical Data

A manufacturer of a medical device must demonstrate that the intended purpose and the claims made in relation to the safety and performance of the device are achieved. As a general rule, such demonstration requires clinical data.

Clinical data are data relevant to the clinical safety and performance of the device. These may include data derived from prospective and retrospective clinical investigations of the

• Evidence related to safety, including adverse events, complications, and undesirable side effects;
• Publications relevant to the intended medical purpose, indications for use, and mechanism of action of the *medical device name* Medical Device;
• Publications written in the English language;
• Publications authored by individuals with relevant scientific or clinical expertise;
• Case reports or case series specifically describing complications or adverse events associated with *intended use of the medical device*

Exclusions:
• In vitro studies not providing clinically relevant information on safety or performance and animal studies;
• Technical descriptions without clinical data;
• Reports evaluating only computational or theoretical models;
• Studies not related to the treatment of *intended use of the medical device*
• Studies involving devices or treatments with fundamentally different mechanisms of action;
• Publications lacking sufficient methodological detail to permit scientific evaluation;
• Unsubstantiated opinions or narrative reviews without clinical data;
• Studies with inadequate sample size or inappropriate statistical methods, except for case reports or case series describing adverse events or complications;
• Publications lacking adequate control or comparator, where such control is necessary for meaningful interpretation;
• Misinterpretation of data by the authors;
• Random or anecdotal experiences not supported by clinical data;
• Clinical evaluations not conducted in compliance with applicable regulatory or ethical requirements.

11.4 Evaluation Of Database Research Results

The articles will be appraised according to whether they address performance or safety or risk/benefit.

Table X: Description of the grading system for data appraisal

Suitability Criteria	Description		Grading System
Appropriate device		A1	Actual device
		A2	Equivalent device