Clinical Evaluation Plan

Device Name/ Model Name

Document Authorisation

Task	Name	Signature	Date
Document Prepared By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Reviewed By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Approved By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY

Revision History

Version	Release Date	Change History
Version Number	DD-MM-YYYY	Changes made on the particular release date mentioned in previous column.

Reference Documents

#	Reference Document
1.	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT
2.	MEDDEV 2.7/1 revision 4; CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
3.	Clinical Evaluation Report of Device Name

Table of Contents

1. Introduction

1.1. Purpose of the Clinical Evaluation Plan

The purpose of this Clinical Evaluation Plan (CEP) is to outline the approach, methodology, and criteria for evaluating the clinical safety and performance of [Device Name] in compliance with EU MDR 2017/745 requirements. This plan ensures that clinical evidence is gathered, assessed, and documented to support the device's conformity assessment.

1.2. Scope of the Clinical Evaluation

This CEP applies to the [Device Name], specifically addressing the clinical data required for the device's intended use and targeted patient population.

2. Device Description

2.1. Device Description

Provide a brief description of the device, including its key components, design, and functionalities.

2.2. Intended use and indications

State the intended use, indications, and contraindications, as specified in the device's instructions for use (IFU) and labelling.

2.3. Clinical Safety and Performance objectives

Define the safety and performance objectives of the clinical evaluation, aligned with the device's intended use and identified risks.

2.4. Intended Clinical benefits

Describe the expected clinical benefits based on the intended purpose and indications.

2.5. Device Classification

Outline the device classification per MDR Annex VIII, including applicable classification rules.

3. Regulatory Requirements

3.1. Identification of relevant GSPRs

List the MDR requirements relevant to the clinical evaluation (e.g., Annex XIV, Annex I, Article 61).

3.2. Applicable Standards and guidelines

Identify the applicable standards (e.g., ISO 14155 for clinical investigations, MEDDEV 2.7/1 Rev.4) and guidelines for the clinical evaluation of the device.

4. State of the Art Analysis

Discuss the current state of the art, including alternative treatment options, clinical outcomes, and any relevant performance benchmarks.

5. Data collection and Evaluation methods

5.1. Literature Review Plan

Outline the strategy for literature review, including search criteria, databases, and keywords used for identifying relevant clinical data.

5.2. Clinical investigations

Summarize any clinical investigations conducted, if applicable, including study design, endpoints, and relevant results.

5.3. Post-Market Surveillance Data

Describe the plan for incorporating post-market surveillance data into the clinical evaluation.

6. Clinical Evaluation process overview

An overview of activities to document the Clinical Evaluation of the device.

6.1. Identify Pertinent Clinical data

In this section, outline the process used to identify relevant clinical data that supports the safety and performance of the device. Describe the sources and types of data being considered. Emphasize how

this data was assessed for relevance, quality, and applicability to your device's intended use, target population, and indications.

6.2. Data generated and held by the manufacturer

This section should detail clinical and non-clinical data that the manufacturer has generated through internal processes or has gathered during the product lifecycle. This data collection should demonstrate that the manufacturer has systematically monitored the device's performance and safety over its lifecycle, which is crucial for maintaining compliance under EU MDR.

7. Risk-Benefit Analysis

7.1. Summary of Known and foreseeable risks

List the known risks associated with the device and potential mitigation measures.

7.2. Risks Mitigation measures

Explain the approach to risk mitigation, including relevant clinical data and findings supporting the benefit-risk profile of the device.

8. Plan for Updating the Clinical Evaluation

Outline the plan for updating the CEP and CER, including timelines and triggers for updates based on new clinical data or regulatory requirements.

9. Conclusion

Provide a concise summary of the expected clinical safety and performance of the device based on the clinical evaluation objectives.

10. References

List all references used in the preparation of the CEP, including scientific literature, standards, and guidelines.