FOR-DND-011

Clinical Evaluation Plan (CEP) <Name of the Device>

Template revision	Version	Brief description or reason for the revision	Approved by <@name>, <function>, on
	x		yyyy/mm/dd

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Status of the record

State: Review

Approvals	Reviewer	Status	Date	Comment
Approval		PENDING		

Version history of the record

Change History

Page Version	Date	Comment
Current Version (v. x)	<Date>	QA Manager

Signatures required for the record

Meaning (Prepared by, Reviewed by, Approved by, Read and understood)	Function of signatories	Name of signatories

1. Introduction

(Product Name) are medical devices intended to (Intended Use).

(Brief history)

According to Articles 10.3 and 61 of Regulation (EU) 2017/745, the demonstration of conformity with the relevant general safety and performance requirements set out in Annex I, and the acceptability of the benefit/risk ratio, shall include a clinical evaluation per Annex XIV to Regulation (EU) 2017/745 as amended. This document describes the planned activities for the clinical evaluation of (Product Name).

This document defines the planned strategy, scope, and methodology for the clinical evaluation of the device.

It does not contain conclusions regarding conformity, safety, or performance, which are documented separately in the Clinical Evaluation Report.

2. Purpose and scope

(Select)

For the pre-market approval of the device, a Clinical Evaluation Plan is established by the team of evaluators.

(Or)

The Clinical Evaluation Plan is reviewed considering the experience gained in the Post-Marketing phase.

This Clinical Evaluation Plan describes the planned activities for the clinical evaluation of (Product Name). It includes a defined process for the retrieval and appraisal of pertinent clinical data from scientific literature (i.e. published studies, reviews) and clinical investigations to support the safety and performance of (Product Name). The current plan takes into account the evaluation performed at the date of revision, whose results are reported in the Clinical Evaluation Report. The focus point for future clinical evaluation is included.

Table 1: Aspects Considered in the Clinical Evaluation Plan

Aspects	Pre-market	Post-market	Chapter
Description of the device	X	X	9
Points of attention	X	X	14.2
Claimed equivalence	X		13
Risk analysis	X	X	11
Current state of the art	X	X	8.4
Data sources	X	X	12.3
Impact on Design Changes		X	9.10
New specific clinical concerns		X	11.2
PMS Data review		X	
PMS Planning	X	X	Refer to Clinical Evaluation Report

3. Objective

The objective of this clinical evaluation plan is to outline the strategy for the clinical evaluation of (Product Name) aimed at demonstrating conformance with the relevant general safety and performance requirements 1 and 8 set out in Annex I Medical Device Regulation 2017/745 (refer to Annex 1), as they relate to device safety and performance as well as acceptability of the risk/benefit profile and side-effects. It includes a defined process for the collection of relevant clinical data from public databases that can be used to support the safety and performance of (Product Name).

4. Applicable regulations and guidelines

MD Regulation	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices
IVDR Regulation	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices
MEDDEV 2.7/1	Clinical evaluation: Guide for manufacturers and Notified Bodies
MEDDEV 2.12/2	Post-Market Clinical Follow-up studies: Guide for manufacturers and Notified Bodies
ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice
ISO 14971	Application of risk management to medical devices
ICH E6(R1)	Guideline on Good Clinical Practice

5. Documents

Title	Number
Design Descriptions/Specifications	

The complete template is included in ReadySet

ISO 13485 QMS framework for Confluence – azbc.be