[Organization logo]

[Organization name]

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PROCEDURE FOR CLINICAL EVALUATION

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [13A2]: Adapt to the existing practice in organization.

Distribution list

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Copy No.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	13485Academy	Basic document outline

Table of Contents

1. Purpose, scope and users

The purpose of this procedure is to provide a system for performing clinical evaluation of the medical devices produced in [Organization name], to demonstrate medical device safety and effectiveness.

Users of this document are [top management], Management Representative, and Clinical Evaluator.

2. Reference documents

- ISO 13485:2016 standard, clause 7.3.7
- MDR 2017/745, Annex XIV
- MEDDEV 2.7.1/rev 4

3. Clinical Evaluator

[Job title] will appoint a person(s) who will perform clinical evaluation, called the Clinical Evaluator.

[redacted]

[redacted]

The Clinical Evaluator, with respect to the particular device under evaluation, must have knowledge of the device technology and its application, diagnosis and management of the conditions intended to be [redacted]

As a general principle, Clinical Evaluators must possess knowledge of at least the following:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted] and experience in medical writing, systematic review, and clinical data appraisal).

The Clinical Evaluator must be familiar with the guidelines from the Medical Device Regulation [redacted]

[redacted]

[redacted] done, outside the current work as an evaluator. The Declaration of Interest must be dated and signed both by the evaluator and the [top management] of the [Organization name].

Commented [13A4]: Please include the name of your company.

Commented [13A5]: E.g. CEO, Managing Director

Commented [13A6]: This should be someone from the top management, e.g. CEO, Managing Director.

Commented [13A7]: Usually the Clinical Evaluator is a medical doctor or nurse that has experience in usage of the particular medical device.

Commented [13A8]: Please include the name of your company.

Commented [13A9]: This is a mandatory request from the [redacted]

Commented [13A10]: These are mandatory requests from the [redacted]

Commented [13A11]: Please include other regulatory requirements relevant for your medical device.

Commented [13A12]: This should be someone from the top management, e.g. CEO, Managing Director.

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4. Clinical Evaluation

The Clinical Evaluator performs the clinical evaluation in order to obtain and evaluate all available clinical data on the medical device or equivalent devices in order to determine whether the device in question is both safe and effective, as well as to demonstrate compliance of said device with the General safety and performance requirements (Annex I, 2017/745 MDR).

The Clinical Evaluator performs the clinical evaluation based on a comprehensive analysis of available pre- and post-market clinical data relevant to the intended use of the device in question, including clinical performance data and safety data. During the clinical evaluation the Clinical Evaluator must include in the analysis both the specific medical device in question, as well as any data relating to devices claimed as equivalent by the manufacturer.

The Clinical Evaluator must perform the clinical evaluation during the conformity assessment process of the medical device, before marketing and launching the medical device on the market. In order to perform the clinical evaluation, the Clinical Evaluator must prepare the Clinical Evaluation Plan. After the clinical evaluation is performed, the Clinical Evaluator must prepare the Clinical Evaluation Report. Once the medical device is launched on the market, the Clinical Evaluator must perform clinical evaluation periodically as new clinical safety and performance information about the device is obtained during its use. The information resulted from the clinical evaluation is included into the ongoing risk analysis and may result in changes of device use.

The Clinical Evaluator must perform clinical evaluation once per year for implantable medical devices and class III medical devices, and every two years for other medical devices.

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5. Clinical Evaluation Plan

The Clinical Evaluator is responsible for preparing the Clinical Evaluation Plan.

The Clinical Evaluation Plan must include information concerning the safety or performance of the medical device that is generated from the use of the device, which is sourced from the following:

- clinical investigation(s) of the device concerned
- clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated
- reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated
- clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up

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6. Clinical Evaluation Report

[redacted]

The Clinical Evaluation Report must outline:

- [redacted]
- [redacted]
- how the referenced information (recognized standards and/or clinical data) demonstrate the clinical performance and safety of the device in question;
- [redacted]
- [redacted]
- [redacted]

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The Clinical Evaluation Report will be signed and dated by the evaluator(s) and accompanied by the [redacted]

7. Managing records kept on the basis of this document

Record name	Code	Storage			Responsibility
		Retention time	Location	Protection	
Clinical Evaluation Plan	PR.19.1	2 years	[office of [job title]]	Records are stored in file cabinet [describe name/location]	Clinical Evaluator
Clinical Evaluation Report	PR.19.2	2 years	[office of [job title]]	Records are stored in file cabinet [describe name/location]	Clinical Evaluator
Literature Research Protocol	PR.19.3	2 years	[office of [job title]]	Records are stored in file cabinet [describe name/location]	Clinical Evaluator
Declaration of Interest	PR.19.4	2 years	[office of [job title]]	Records are stored in file cabinet [describe name/location]	Top management

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Commented [13A18]: Adapt the information in this column to the normal practice in your company.

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8. Appendices

- Appendix 1 – Clinical Evaluation Plan
- Appendix 2 – Clinical Evaluation Report
- Appendix 3 – Literature Research Protocol
- Appendix 4 – Declaration of Interest

[job title]
[name]

_____
[signature]

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