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**PROCEDURE FOR CLINICAL EVALUATION**

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# 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.

# Reference documents

* ISO 13485:2016 standard, clause 7.3.7
* MDR 2017/745, articles 10(9), 61, Annex IX – Chapter 1, and Annex XIV – Part A
* MEDDEV 2.7.1/rev 4
* MDCG 2020-5 Clinical evaluation – Equivalence; A guide for manufacturers and notified bodies, April 2020
* MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC, April 2020
* MDCG 2020-1 Guidance for clinical evaluation (MDR) / performance evaluation (IVDR) of medical device software, March 2020
* Procedure for Post-Market Surveillance System

# Clinical evaluator

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

The clinical evaluator does not need to be an employee of [organization name].

The clinical evaluator must have a degree in the respective field from a higher education institution and five years of documented professional experience, or 10 years of documented professional experience if a degree is not a prerequisite for a given task.

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 diagnosed or managed by the device, and knowledge of medical alternatives, treatment standards, and technology (e.g., specialist clinical expertise in the relevant medical specialty).

As a general principle, clinical evaluators must possess knowledge of at least the following:

* research methodology (including clinical investigation design and biostatistics)
* information management (e.g., scientific background or librarianship qualification
* experience with relevant databases, such as Embase and MEDLINE
* regulatory requirements
* medical writing (e.g., post-graduate experience in a relevant science or in medicine; training 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 (MDR), MEDDEV 2.7.1/rev 4, and [other relevant regulatory requirements].

The clinical evaluator must provide a CV to the [job title] of [organization name].

The clinical evaluator must complete a Declaration of Interest. The Declaration of Interest must cover relevant financial interests related to the medical device for which the clinical evaluation is 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 [organization name].

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