Clinical Evaluation Report

in accordance with MEDDEV 2.7/1 revision 4

and in compliance with

Council Directive 93/42/EEC as amended by directive 2007/47/EC

Council Directive 90/385/EEC as amended by directive 2007/47/EC

Product
//Product name

0 Index

1 Summary

//Executive summary (may be used for external purposes, if needed)

2 Scope of the clinical evaluation (Plan)

2.1 Identification of device(s)

Product
//Mention all devices covered by this clinical evaluation report, products, models, sizes, software versions, accessories, their proprietary names, code names assigned during device development
Classification and Product Identification
//Risk class, 510(k) number, UMDNS; GMDN, etc

2.2 Identification of manufacturer

Legal Manufacturer
//Name and address of the manufacturer.

2.3 Governing directive

Medical Device according to
AIMDD as amended by directive 2007/47/EC
MDD as amended by directive 2007/47/EC

//delete if not applicable

2.4 Device description

Description in alignment with technical documentation
// Concise physical and chemical description, including materials; picture or drawing of the device.
Reference to technical documentation
//give reference

2.5 Intended use/purpose

Intended use/purpose in alignment with Instructions for use (IFU)
// Exact description of the intended purpose as described in the device's IFU (In exceptional cases where an instruction for use is not required, describe the generally recognized modalities of use)
//with exact medical indications (if applicable): Name of disease or condition, clinical form, stage, severity, symptoms or aspects to be treated/ managed/ diagnosed, target patient population, target user group. Intended application of the device.
//and contraindications; warnings/cautions
Reference to technical documentation
//give reference

2.6 Device claims

Claims in alignment with available promotional materials
// Claims on clinical performance and clinical safety foreseen by the manufacturer.
Reference to technical documentation/other documents
//give reference

2.7 Status of the device

Current status of device
// Whether the device is already CE marked or not
Reference to technical documentation/other documents
//give reference

2.8 Device Change History

Comments on significant changes
// Changes since the last report,

2.8.1 Identification of changes

Section	Change
//reference to section	//Short reason why new information has been introduced and what was modified.

2.9 Other aspects

Other aspects of relevance
// Mention any other aspects with an impact on this clinical evaluation. If no other aspects need to be considered, mark with n.a.

3 Clinical background, current knowledge, state of the art

This chapter gives an overview on the medical fields concerned and the relevant medical conditions.

3.1 Identification of pertinent data

//Brief summary and justification of the literature search strategy.

3.2 Appraisal criteria used

//Brief summary of appraisal criteria used.

3.3 Applicable standards and guidance documents

- Council Directive 90/385/EEC as amended by directive 2007/47/EC
- Council Directive 93/42/EEC as amended by directive 2007/47/EC
- Medizinproduktegesetz
- MEDDEV 2.7/1 revision 4
- ISO 14155-1: Clinical investigation of medical devices for human subjects - Good clinical practice. 2011
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC62366 Medical devices - Application of usability engineering to medical devices

//Mention additional applicable standards and guidance documents, delete if not applicable

3.4 Medical field concerned by the device

//Description, natural course and consequences of the medical conditions concerned.
Whether there are different clinical forms, stages and severities of the conditions.
Frequency in the general population, by age group, gender, ethnicity, familiar predispositions, genetic aspects.

3.5 Therapeutic Alternatives

//Description of available therapeutic/ management/ diagnostic options, historical context and developments, summary of advantages and disadvantages of the different options, benefit/ risk profiles and limitations in relation to the different clinical forms, stages, and severities of the medical conditions and in relation to different target populations.
Description of the benefits and risks (nature, extent, probability, duration, frequency), acceptability of undesirable side-effects and other risks (including the nature, severity, probability and duration of acceptable harm).
Hazards due to substances and technologies that could be relevant to the device under evaluation. The mechanisms of harm, clinical aspects of minimisation and management of side effects and other risks.

3.6 Device users

//mention types of users.

3.7 Unmet medical needs

// Summary according to Annex 8, if applicable

4 Device under evaluation

In this section the approach of clinical evaluation is laid out. It contains the evaluation of equivalence to other devices taken into consideration and includes stages 1 to 3 of the clinical evaluation process.

4.1 Type of evaluation

The clinical evaluation at hand is based on	Applicable (yes/no)
scientific literature currently available (section 4.3.2), and/or	
clinical investigations made (section 4.3.1)	
Non-clinical data only (see justification below)	
Justification if demonstration of conformity with essential requirements based on clinical data is not deemed appropriate	
Where demonstration of conformity with Essential Requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given:	

4.2 Demonstration of Equivalence

If applicable, the demonstration of equivalence is performed in appendix “Demonstration of Equivalence” of the clinical evaluation at hand.

Body of evidence is based on	Applicable (yes/no)
equivalent medical device/s	
Justification for not claiming equivalence	
//Provide justification in case no clinical data from other devices will be considered.	
Aspects covered by evaluation of equivalence	
//Whether the comparison carried out covers all products/ models/ sizes/ settings/ accessories and the entire intended use of the device under evaluation, or only certain products/ models/ sizes/ settings/ accessories, or selected aspects of the intended use, which ones.	
Conclusions concerning equivalence	
//Conclusions whether equivalence is demonstrated or not; if it is demonstrated, confirmation that the differences are not expected to affect the clinical performance and safety of the device under evaluation; description of any limitations and gaps.	

4.3 Clinical data

4.3.1 Clinical data generated and held by the manufacturer

//Disclosure of all clinical data generated and held by the manufacturer. If clinical data is available, thorough analysis based on available documentation including:

- the clinical investigation plan;
- clinical investigation plan amendments and the rationale for these changes;
- CRF templates, monitoring and audit records;
- the relevant EC documentation;
- regulatory authority approvals as required by applicable regulations;
- the signed and dated clinical investigation report or the latest intermediate report available and the latest collation on serious adverse events
- when a clinical investigation is conducted outside of the EU, an analysis whether the results are transferable to the European population;
- a gap analysis, when a clinical investigation is conducted to standards different from EN ISO 14155; the gap analysis should contain sufficient information to be read and understood by an independent party.

Add references for all documents used.

4.3.2 Clinical data from literature

//Brief summary and justification of the literature search strategy applied for retrieval of clinical data,

4.3.1 Clinical Experience

Add post market surveillance data and data identified in Safety Databases (note: if no clinical experience is available state “n/a”).

4.4 Summary and appraisal of clinical data

//Include all data from

- Feasibility studies
- Confirmatory studies
- PMCF studies
- Use data

Summary of clinical data generated and held by the manufacturer and of literature found to be pertinent.

4.5 Analysis of the clinical data

4.5.1 General Clinical and Essential Requirements

The below mentioned special design features (e.g. ease of use, durability, ergonomic design and usability, dose accuracy, microbial contamination, materials used, packaging, labelling and instructions) were identified in the device risk management documentation and pose special performance or safety concerns (e.g. presence of medicinal, human or animal components). These risks have been adequately addressed in the risk management and require assessment from a clinical perspective.

4.5.2 Requirement on safety (MDD ER1 / AIMDD ER1)

ID	Risks
RM1	//include risks that need clinical evaluation/add line if more
RM2	//add line if more are required
The risks (from risk management and literature) have been addressed by the following clinical data:	
//summary of risk related clinical data	
All hazards and other clinically relevant information have been identified appropriately. They are as follows:	
//summary of hazards and clinically relevant information	
The safety characteristics and intended use (purpose) of the device requires training of the end-user and/or	
//(yes/no)	
The safety characteristics and intended use (purpose) of the device requires the following precautions:	
//list precautions	
The foreseen users of the device are adequate. They are as follows.	
//list foreseen users	
All training requirements and precautions are listed in the IFU. If not, the following requirements and/or precautions should be included. //delete last sentence and following line, if all are included. Delete first sentence if requirements and/or precautions are missing and fill in the next line.	
//list requirements and precautions	
There is full consistency between current knowledge/ the state of the art, the available clinical data, the manufacturer's product information, and the risk management documentation for the device.	
//in case not, provide justification, if yes, delete line.	

4.5.3 Requirement on acceptable benefit/risk ratio (MDD ER1 / AIMDD ER1)

Summary of the total experience with the device, including numbers and characteristics of patients exposed to the device and duration of follow-up in	
Clinical investigations	
PMCF	
Other user experience	

and in the market: Market experience
Nature, extent/severity, probability, duration of benefits to the patients and of side-effects and other risks.
//summary of above mentioned aspects
For each aspect of the intended use, whether the benefit/risk profile including its uncertainties is compatible with a high level of protection of health and safety, corresponding justifications.
//summary of above mentioned aspects including detailed description of all aspects of intended use

4.5.4 Requirement on performance (MDD ER3 / AIMDD ER2)

Description of clinical performance. For each intended performance as listed below.

Extent to which assessment of benefits is possible based on available data, limitations of the data, description of gaps, uncertainties, and assumptions.
//summary of above mentioned aspects
Whether available data allows adequate assessment of performance, limitations of the data, gaps, uncertainties.
//summary of above mentioned aspects
Whether there is sufficient evidence for every intended performance.
//summary of above mentioned aspects

4.5.5 Requirement on acceptability of side effects (MDD ER6 / AIMDD ER5)

Description of side effects and reasoning for acceptability as listed below.

Whether the data available is of sufficient amount and quality for the detection of side-effects and their frequency, limitations of the data, description of gaps, uncertainties, and assumptions.
//summary of above mentioned aspects
Whether the side-effects are acceptable and corresponding justifications.
//summary of above mentioned aspects

5 Conclusions

The following statements are made for the device under evaluation and in view of the evaluated clinical data.
//delete if not applicable. Reword and provide justification if addressed by other means.

The existing data are/are not sufficient to verify that the device is in conformity with all the Essential Requirements pertaining to clinical performance and clinical safety.
The benefit/risk profile according to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives is acceptable.
The intended use and corresponding risk reduction measures are adequate and the product information is suitable for the intended users and sufficiently covers all usability aspects.
All claims foreseen by the manufacturer are identified and any discrepancy and gaps are fully covered by clinical data.
There is full consistency between the clinical data, the information materials supplied by the manufacturer and the risk management documentation for the device under evaluation
Residual risks and uncertainties are sufficiently identified. The acceptability for CE-marking is sufficiently discussed and follow-up measures during PMS are addressed. (This includes uncertainties regarding medium- and long term performance, safety under wide-spread use, residual risks such as side-effects and complications occurring at rates below detection possibilities of currently available clinical data, others).
Risks and uncertainties are already addressed in ongoing PMS activities (e.g. in currently ongoing PMCF studies).
New or additional PMS activities, including PMCF studies, should be foreseen. /reference to activities identified.

6 Date of the next clinical evaluation

Date of next update	Justification of the date
//date	//provide justification

7 Signatures of the responsible evaluators

Signatures of the responsible evaluators Responsibility*	Date	Signature
Author		
Co-author		
Reviewer		

Manufacturer 1		
Manufacturer 2		

*By signing this document, responsibles agree with the contents of the report.

8 Qualification of the responsible evaluators

Evidence of the evaluator qualification is given in the corresponding appendix.
Besides the evidence of qualification, a declaration of interest from each evaluator is provided and a justification of the choice of each author is given.

9 References

//list if applicable