Ref No	Rev No.	Issue Date

Clinical Evaluation report

1. Summary:

Example of content:

This section should summarize the determination of the benefit/risk profile in the intended target groups and medical indications, and the demonstration of acceptability of that profile based on the state of the art in the medical fields concerned

2. Scope of the clinical evaluation:

Example of content:

* Identification of devices covered by this clinical evaluation report, products, models, sizes, software versions, accessories, their proprietary names, code names assigned during device development.
*Name and address of the manufacturer.
*Concise physical and chemical description, including materials.
*Whether the device incorporated medicinal substances (already on the market or new), tissues, or blood products. *Mechanical and physicochemical characteristics; others (such as sterile vs. non-sterile, radioactivity etc.); picture or drawing of the device.
*Technologies used, whether the device is based on a new technology, a new clinical application of an existing technology, or the result of incremental change of an existing technology. Description of innovative aspects of the device.
*Device group the device belongs to.
*How the device achieves its intended purpose.
*Positioning in relation to available treatment/management/ diagnostic options.
*Exact description of the intended purpose as described in the device's IFU, with exact medical indications (if applicable) and contraindications; claims made in available promotional materials.
*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, single use/reusable, invasive/noninvasive, implantable, duration of use or contact with the body,

maximum number of repeat applications. *Identification of organs, tissues or body fluids contacted by the device. Precautions.
*Claims on clinical performance and clinical safety foreseen by the manufacturer.
*whether the device is on the market, since when, in what regions, history of the device, including date of past modifications with reasons and description, sales volumes.
*Changes since the last report, whether the device has been modified, identification of new products, models, sizes, software, accessories, new intended purposes, new claims, new events related to the device with an impact on clinical evaluation.
*Identification of the sections of the clinical evaluation report that are concerned with the new information and have been modified

3. Clinical Background, current knowledge, state of the art

Example of content:
*Identification of medical fields concerned/ relevant medical conditions.
*Brief summary and justification of the literature search strategy applied for retrieval of information on current knowledge/ the state of the art, including sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent. *Appraisal criteria used.
*Applicable standards and guidance documents.
*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.
*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 minimization and management of side effects and other risks.
*Types of users. Diverging opinions of professionals as to the use of the different medical options. Unmet medical needs.

4. Device under evaluation

4.1. Type of evaluation:

Whether the clinical evaluation is based on
- scientific literature currently available, and/or
- clinical investigations made

4.2. Demonstration of equivalence (if equivalence is claimed):

*Identification of the equivalent device and its manufacturer. Exact name, models, sizes, software versions, accessories, etc.
*Name of the manufacturer.
*Relationship to the device under evaluation (predecessor/ successor, others).
*Regulatory status. If the device is not CE-marked, justification for the use of the data.
*Comparison of clinical, biological and technical characteristics Justification of equivalence, description of relevant clinical, biological and technical characteristics that affect clinical properties of the device, differences between the intended purpose of the device under evaluation and the equivalent device (indications, contraindications, precautions, target patient groups, target users, mode of application, duration of use/ number of re-applications, others), type of device-body interaction. Choice, justification and validity of parameters and models for non-clinical determination of characteristics.
*Identification of pre-clinical studies carried out and literature used, concise summaries of studies and literature (methods, results, conclusions of the authors), evaluation of the methodological quality of the study or document, the scientific validity of the information.
*Comparative tabulations for the device under evaluation versus the equivalent device showing parameters relevant to the evaluation of the three characteristics. Comparative drawings or pictures of the device and the equivalent device showing the elements in contact with the body.

*Identification of differences, evaluation if differences are expected or not to influence the clinical performance and clinical safety of the device, reasons for assumptions made.
*Conclusions concerning equivalence. Whether the comparison carried out covers all products/ models/ sizes/ settings/accessories and the entire intended purpose of the device under evaluation, or only certain products/ models/ sizes/ settings/accessories, or selected aspects of the intended purpose, which ones.
*Conclusions whether equivalence is demonstrated or not; if it is demonstrated, confirmation that the differences are not expected to affect the clinical performance and clinical safety of the device under evaluation; description of any limitations and gaps.

4.3. Clinical data generated and held by the manufacturer:
Identification of clinical data generated and held by the manufacturer

4.4. Clinical data from literature:
Brief summary and justification of the literature search strategy applied for retrieval of clinical data, including objectives, sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent.

4.5. Summary and appraisal of clinical data:
-Feasibility Studies
- Pivotal clinical investigations
- PMCF Studies
- Other use data
Summaries of clinical data generated and held by the manufacturer and of scientific literature found to be pertinent.
Including brief summary of the studies or references (methods, results, conclusion of the authors), evaluation of their methodological quality, scientific validity of contents, relevance to the clinical evaluation, weighting attributed to the data, contents used (performance data, safety data, both) reasons for rejecting a study or document, reasons for rejecting some of its contents.

4.6. Analysis of the clinical data
4.6.1. Requirement on safety:

*Analysis whether there are special design features that pose special safety concerns (e.g. presence of medicinal, human or animal components) that where identified in the device risk management documentation and that required evaluation from a clinical perspective, and whether these have been adequately addressed.
*Whether the risks identified in the risk management documentation and literature have been adequately addressed.
*Whether all the hazards and other clinically relevant information (e.g. clinical precautions for reduction of risks, clinical management of risks) have been identified appropriately.
*Whether the safety characteristics and intended purpose of the device requires training of the end-user or other precautions, if users foreseen are adequate, if training requirements and other precautions are described in the IFU.
*Whether there is full consistency between current knowledge/ the state of the art, the available clinical data, the information materials supplied by the manufacturer, and the risk management documentation for the device.

4.6.2. Requirement on Requirement on acceptable benefit/risk profile:
*Summary of the total experience with the device, including estimated numbers and characteristics of patients exposed to the device in clinical investigations, PMCF, from other user experience, and in the market; duration of follow-up. Nature, extent/severity, probability/frequency, duration of benefits to the patients and of undesirable side-effects and other risks. For each aspect of the intended purpose, whether the benefit/risk profile including its uncertainties or unanswered questions is compatible with a high level of protection of health and safety, corresponding justifications.

4.6.3. Requirement on performance:
*Description of clinical performance. For each intended performance, extent to which evaluation of benefits is possible based on available data,limitations of the data, description of gaps, uncertainties or unanswered questions, and assumptions.
*whether available data allows adequate evaluation of performance, limitations of the data, gaps, uncertainties or unanswered questions.
*Whether there is sufficient clinical evidence for every intended performance.

4.6.4. Requirement on acceptability of side-effects:

*Whether the data available is of sufficient amount and quality for the detection of undesirable side-effects and their frequency, limitations of the data, description of gaps, uncertainties or unanswered questions, and assumptions.
*Whether the undesirable side-effects are acceptable and corresponding justifications

5. <u>Conclusions:</u>

*Clear statement concerning compliance to Essential requirements.
*Acceptability of the benefit/risk profile according to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives.
*Adequacy of the information materials supplied by the manufacturer, whether the intended purpose and risk reduction measures are adequate.
*Suitability of the device, including its IFU, for the intended users and usability aspects.
*Adequacy of claims foreseen by the manufacturer;.If there is consistency between the clinical data, the information materials supplied by the manufacturer, the risk management documentation for the device under evaluation;.
*Whether there is consistency between these documents and the current knowledge/ the state of the art;
*Description of residual risks and uncertainties or unanswered questions,how these should be followed during PMS (uncertainties regarding medium- and long term performance, safety under wide-spread use, residual risks such as undesirable side-effects and complications occurring at rates below detection possibilities of currently available clinical data, others).
*Whether these are already being addressed in ongoing PMS activities, e.g. in currently ongoing PMCF studies. *Whether new or additional PMS activities, including PMCF studies, should be foreseen

6. <u>Date of next clinical evaluation:</u>

Suggested date, justification of the date.

7. <u>Dates and signatures;</u>

*Date of the clinical evaluation report.
*Statement that the evaluators agree with the contents of the report.
*Dates, names and signatures of the evaluators.

*Final release by the manufacturer. Date, name and signature.

8. Qualification of the responsible evaluators

9. References