Clinical Evaluation Report

1. Purpose and Scope

According to the Regulation (EU) 2017/745, Article 61 and ANNEX XIV, the evaluation of the clinical performance and safety as well as the clinical benefit must be based on clinical data and is required for all medical device classes. The clinical evaluation report and the clinical data on which it is based, verifies the clinical safety and performance of the [device name].

A clinical evaluation plan [Reference] is in place and this clinical evaluation report is carried out in accordance with the plan.

2. Definitions

Definition / Abbreviation	Description
MDR	Regulation (EU) 2017/745
[...]	[...]

3. Product Information

Manufacturer:
Product name:
Product models:
CE marking:
Classification:

3.1 Intended Use

Add intended use.

3.2 Patient Population

Add patient population

3.3 Intended Medical Indication

Add intended medical indication

3.4 Contraindications

If none, state as follows: There are no known specific situations that contraindicate the use of this device.

3.5 Operating Principle

Offer a detailed overview of the device, encompassing its name, models, sizes, and components across hardware, software, and accessories. Clearly categorize the device, such as a biological artificial aortic valve, and outline its physical and chemical attributes, technical specifications, and mechanical traits. Specify sterilization methods, radioactivity considerations, and operational principles. Detail materials used, particularly those in contact with the patient, and any inclusion of medicinal substances, animal tissues, or blood components. Incorporate a visual representation, and note the device's class, global market entry, and specific product configurations. Highlight innovative features relevant to ongoing assessments and address unmet medical needs. Provide concise step-by-step application procedures, elucidate performance in different modes, and describe the device's workflow.

3.6 User Profile

Describe the typical user of the software. Some ideas could be: Qualifications, prior training (for your software), technical proficiency, time spent using the software.

3.7 User Environment Including Hardware / Software

Describe the typical use environment. What sort of devices is this running on? Does the software only run on one device or multiple devices? Is it loud and chaotic like in an emergency ward? How's the lighting? Also, add other software or hardware which is required by your device. Most commonly, apps require users to have a smartphone with a compatible operating system (iOS / Android).

4. Clinical Benefits

Describe the intended clinical benefit(s) of the device.

5. Clinical Claims

All claims can be found in the table below. These claims will be thoroughly examined as part of the literature search in the clinical evaluation.

No.	Claim	Source	Reference
1	Our device reduces procedure time by 20%	Website / promotional material	Usability study / Literature analysis (addressed in clinical evaluation report) / verification and validation / PMS data; PMCF data

No.	Claim	Source	Reference
...			

If there are no claims: No claims require validation through the clinical evaluation

6. Context of the Medical Device

6.1 Developmental Context

Provide an overview of the device's developmental context, including its current market presence in Europe or other countries, the duration of its presence, and the quantity of devices placed on the market. Consider incorporating information from relevant publications to enrich this chapter.

6.2 State of the Art

Outline the state of the art and the medical alternatives of the device. Summarise guidance documents, common specifications or health technology assessment report, which could help describing the state of the art. Usually, review articles provide a broad overview on the state of the art and medical alternatives.

7. Clinical Evidence

Clinical evaluation is an on-going process, conducted throughout the life cycle of a MDSW. Both favorable and unfavorable data considered in the clinical evaluation shall be included in the technical documentation.

Three key components will be taken into account when compiling clinical evidence:

Valid clinical association

- Demonstrate that it corresponds to the clinical situation, condition, indication or parameter defined in the intended purpose of the MDSW

Technical performance

- Demonstration of the MDSW's ability to accurately, reliably and precisely generate the intended output, from the input data.

Clinical performance

- Demonstration of a MDSW's ability to yield clinically relevant output in accordance with the intended purpose

7.1 Valid Clinical Association

Valid clinical association is understood as the extent to which, the MDSW's output (e.g. concept, conclusion, calculations) based on the inputs and algorithms selected, is associated with the targeted physiological state or clinical condition. This association should be well founded or clinically accepted. The valid clinical association of a MDSW should demonstrate that it corresponds to the clinical situation, condition, indication or parameter defined in the intended purpose of the MDSW.

> Example: MDSW that detects heart arrhythmia by analysing auscultation sound obtained by a digital stethoscope requires demonstrating valid clinical association of the association between abnormal cardiac sounds and heart arrhythmia. Evidence supporting valid clinical association can be generated e.g. through literature research, professional guidelines, proof of concept studies, or manufacturer's own clinical investigations/clinical performance studies.

> The is intended to [. . .]. This is a well-established clinical procedure and clinically accepted. The valid clinical association will be demonstrated with:

> - Technical standards
> - Professional medical society guidelines
> - Systematic scientific literature review
> - Clinical investigations
> - Published clinical data (e.g. Summary of Safety and Clinical Performance (SSCP) / Summary of Safety and Performance (SSP), Registries and databases from authorities)

7.1.1 Systematic scientific literature review   Chosen source for the literature search is PubMed. The table lists the search terms used and the number of results.

No.	Search category	Search term	no. of results
1	Clinical association / state of the art		
. . .			

> Describe the total number of results and the number of duplicate publications.

Different filters, exclusion & selection criteria have been used.

> Justify the set filters, especially the timeframe and the limitation of certain evidence level.

Filter

- Publication Dates

- Article types
- Languages
- Species
- Text availability

Exclusion criteria

- Publications about animal trials
- Publications in a language other than English
- Publications published before [Date]
- Publications with no abstract
- Duplicates identified in more than one search category
- Publications with the following content are generally not relevant:
- . . .

Selection criteria

- Publications describing or focusing on the use of the medical device under evaluation
- Publications describing the use of an equivalent device
- Publications describing or focusing on comparative literature of medical alternatives and state of the art of the medical device under evaluation
- . . .

7.2 Technical Performance

According to the MDCG 2020-1 technical performance is the demonstration of the MDSW's ability to accurately, reliably and precisely generate the intended output, from the input data. Evidence supporting technical performance can be generated through verification and validation activities, e.g. unit-level, integration, and system testing or by generating new evidence through use of curated databases, curated registries, reference databases or use of previously collected patient data.

Technical performance is confirmed by the examination and provision of objective evidence that the MDSW specifications conform to user needs and intended uses, and that the requirements implemented can be consistently fulfilled. For example, performance verification and validation in the intended computing and use environments can be characterized by the demonstration of:

- availability,
- confidentiality,
- integrity,
- reliability,
- accuracy (resulting from trueness and precision),
- analytical sensitivity,
- limit of detection,

- limit of quantitation,
- analytical specificity,
- linearity,
- cut-off value(s),
- measuring interval (range),
- GENERALISABILITY,
- expected data rate or quality,
- absence of inacceptable cybersecurity vulnerabilities,
- HUMAN FACTORS ENGINEERING.

Summarize the relevant tests, validations and verifications to demonstrate that the medical deviceaccurately and consistently meets the intended purpose in real-world usage. Add subchapter if necessary.

7.3 Clinical performance

Validation of the CLINICAL PERFORMANCE is the demonstration of a MDSW's ability to yield clinically relevant output in accordance with the intended purpose. The clinical relevance of a MDSW's output is a positive impact on the health of an individual expressed in terms of measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, prediction of risk, prediction of treatment response(s), or related to its function, such as that of screening, monitoring, diagnosis or aid to diagnosis of patients, oron patient management or public health. Example for clinical performance is a retrospective study on previously obtained data. Generate evidence that shows your:SaMD has been tested in your target population and for your intended use; and that users can achieve clinically meaningful outcomes through predictable and reliable use.

Note that line with the provisions of MDR Article 61 (1), the level of clinical evidence required should be appropriate in view of the device claims and characteristics. For medical devices, where the demonstration of conformity with GSPRs based on clinical data is not deemed appropriate (MDR Article 61 (10)), the manufacturer shall duly substantiate in the technical documentation why it is adequate to demonstrate conformity based on the results of non-clinical testing methods alone, bench testing and preclinical evaluation, and usability assessment.

This means in case where your device does not produce clinical data, you can use bench testing and usability to demonstrate the clinical performance.

Summarize the clinical performance data.

7.3.1 Equivalent device

If no equivalence is claimed: No equivalent device could be identified.

General guidance including a detailed comparison table is provided in the MDCG 2020-05. Read this guidance and use the table to demonstrate equivalence if applicable.

8 Risk Management

A risk analysis, conducted in compliance with EN ISO 14971 is currently documented in the:

- SOP Risk management
- Risk Management Plan
- Risk Analysis
- Risk Management Report

8.1 Known Hazards and Risks

List hazards/ risks associated with the medical device.

8.2 Known Side-Effects

If applicable, please list/ describe side-effects.

8.3 Precautions and Warnings

List precautions and warnings.

8.4 Usability Engineering

Please provide a summary of the usability engineering either deriving from separate documents or the risk management.

Example of text of the conclusion might be:

The evaluation of the usability in accordance with IEC 62366-1 confirms that the design adequately reduces the risk of use error as far as possible, that the design is adequate for the intended users and that the information materials supplied by the manufacturer for the intended users are suitable.

8.5 Additional risks identified in the literature

PubMed has been searched for risks that might be associated with the use of the medical device.

Describe here the search for risks and usability related risks with the use of the device. State the filters used in your search.

Risks	Search term	No. of results
Risks associated with the device	Search term	

Describe the total number of results and the number of duplicate publications.

Usability related risks	Search term	No. of results
Risks associated with the device	Search term	

Describe the total number of results and the number of duplicate publications.

List the publications in Annex Literature accordingly.

Summary of identified risks

A general patient benefit has been identified and proven within the literature. However, some possible complications have been reported in the literature.

Limit your focus to risks that are directly or indirectly linked to the medical device. Risks related solely to the procedure, without any interaction with the medical device under evaluation, are not pertinent to this chapter or the risk-benefit assessment.

Literature ref.	Risks / Complications	Considered in risk management?
. . .	. . .	. . .

- Not one of the outlined risks pertained to an overarching product issue or design flaw. The examination of pertinent publications did not unveil any apprehensions concerning the safety. Additionally, the literature review did not uncover any risks that haven't already been addressed in the existing risk management protocols.
- Summarise the literature regarding usability.
- In the absence of usability information: A review of the literature did not uncover any additional insights regarding the usability aspects associated with the use of the . Furthermore, there is no indication in the literature of any overarching product issues or design flaws related to usability.

8.6 Conclusion of Risk Management

Example of text might be:

Risk control measures were established and executed in accordance with the Risk Management Plan. These implemented measures are

predominantly aligned with the adherence to relevant standards. Furthermore, technical control and monitoring measures were introduced and successfully validated for efficacy. The risk management process validates the adequacy of information materials provided by the manufacturer, ensuring that risk mitigation measures are accurately addressed in the Instructions for Use (IFU). Following the successful implementation of these risk control measures, both the remaining individual risks and the overall residual risks were evaluated as acceptable [Reference the Risk Management Report].

9 Post-Market Surveillance Data

Present available post-market surveillance data and delineate its significance in assessing the clinical performance and safety of the relevant medical device. If applicable, reference post-market surveillance reports or periodic safety update reports, focusing on conclusions that are relevant to the device's clinical performance and safety.

[Manufacturer] has implemented a post-market surveillance (PMS) system to promptly identify new risks not previously recognized during the extended market experience. This commitment ensures the immediate execution of corrective and preventive actions, as detailed in <reference to the post-market surveillance system.

This section further consolidates insights gained from the medical device under evaluation and/or its equivalent devices, utilizing internal and external databases. The strategy for identifying pertinent reports is tailored to each database.

Add or remove subchapters as needed. If possible, align the timeframe for database searches with that of the literature search. If an excessive number of potentially relevant results arise, opt for a restricted timeframe with justification.

9.1 Internal Vigilance System

Summarise the data regarding sales numbers and complaints.

9.2 Additional Post-Market Clinical Follow-Up Data

PMCF is planned and conducted to proactively collect and evaluate clinical data with the aim of confirming the clinical safety and performance throughout the expected lifetime of the device, ensuring the continued acceptability of identified risks and detecting emerging risks on the basis of factual evidence.

Summarise the data regarding PMCF of the device under evaluation & reference the post-market clinical follow-up plan.

9.3 Relevant Device Registers

Please summarise internal and external register data.

If no internal device register is available, example of text might be:

The manufacturer has not implemented an internal device register.

9.4 BfArM Database

Sources: https://www.bfarm.de/SiteGlobals/Forms/Suche/EN/Expertensuche_Formular.html?nn=708434&cl2C

The following search terms have been used:

Please state a timeframe of the search if restricted. The search led to <xxx> results of which only <xx> refer to the or its equivalent devices.

Ref.	Issue Date	Device	Description / Action	Relevant?

9.5 Swissmedic Database if applicable

Summarize the search in this database and use the structure provided in the BfArm example.

9.6 MHRA Database if applicable

Summarize the search in this database and use the structure provided in the BfArm example.

9.7 FDA MAUDE Database if applicable

Summarize the search in this database and use the structure provided in the BfArm example.

9.8 FDA Recall Database if applicable

Summarize the search in this database and use the structure provided in the BfArm example.

9.9 Summary and Conclusion of PMS Data

Offer a condensed overview of post-market surveillance data, incorporating considerations on risk management and usability. Enumerate identified risks aligned with the evaluation, ensuring comprehensive coverage of all risk management aspects. Specifically, focus on assessing use errors and the design of the user interface. Include details about the user profile and usage environment, if applicable.

Noteworthy complications from MHRA, Swissmedic, BfArM, and FDA databases include: • List all relevant general complications

Crucially, the scrutiny of post-market surveillance data revealed no risks unaddressed in the risk management discussion. The assessment of clinical data provides further reinforcement of the safety and performance of the device under evaluation.

10. Benefit Risk Assessment

Provide an overview about risks and benefits for the medical device and come to a final conclusion, why the probable benefits outweigh potential risks. The following list summarises an example of the evaluation of acceptability of the benefit-risk ratio. Based on the findings in the clinical data review as well as in the risk analysis, it can be inferred that the probability of a patient experiencing a substantial benefit when using the [device name] outweighs the probability of suffering harm due to a residual risk of the device significantly.

11. Summary & Conclusion

Executive Summary: This clinical evaluation represents a methodologically rigorous ongoing process encompassing the collection, assessment, and analysis of clinical data for the . The report synthesizes preclinical, non-clinical, and clinical data from diverse sources, presenting crucial information about the device's intended purpose. A comprehensive literature search, yielding a sufficient number of relevant publications (n=xx), underscores the safety and performance of the , with identified publications meeting satisfactory quality standards. The evidence supports the intended purpose, clinical performance, and benefits as outlined in informational materials. No safety-related complaints, unaddressed risks, or usability concerns were identified beyond those addressed in risk management.

Market experience, involving more than xxx units sold worldwide since xxxx, provides valuable insights. Safety-related complaints (xx) were reported, and a thorough search within clinical experience databases (MHRA, BfArM, Swissmedic, and FDA) revealed no unevaluated risks or usability aspects. Residual risks were deemed acceptable in the final risk management report, with the benefits outweighing these residual risks.

The clinical evaluation affirms compliance with relevant safety and performance requirements (Regulation (EU) 2017/745, ANNEX I, clauses 1 and 8). Overall, the clinical safety, performance, and benefits demonstrate that the <medical device> aligns with current

knowledge and technological standards.

Conclusions: The clinical evaluation confirms that the <medical device> complies with current knowledge and technological standards, is suitable for its intended purpose and users, and offers substantial clinical benefits, outweighing potential adverse effects. Evaluated clinical data, aligned with Regulation (EU) 2017/745, are scientifically sound and comprehensive, supporting the device's conformity. The analysis of literature, clinical data, and risk factors indicates that patient benefits significantly surpass the risk of residual harm, rendering further clinical investigations unnecessary.

A planned PMCF strategy, considering the clinical evaluation report's results, defines the process and frequency of activities. In summary, the clinical safety, performance, and benefits showcased in this evaluation confirm that the <medical device> adheres to relevant general safety and performance requirements (Regulation (EU) 2017/745, ANNEX I, clauses 1 and 8).

Annex

A1 References

The following table lists all relevant publications, provides a summary of the content and lists the appraisal.

Ref.	No.	Title	Summary	Indication / Application	Risks	Named Device	Benefits	Usability

A2 Selection of Literature Search Results

The following table lists all identified publications, the decision for potential relevance and final relevance.

Use the literature assessment Excel sheet and copy paste the first columns in here.

No.	References	Potentially relevant?	Relevant after reading the full text?

A3 Document References

Reference documents that you used in the CER (Risk management, Usability, bench testing summaries) here.

A4 Qualification of authors

Provide qualification and experience of the evaluators (e.g. author, reviewer and/or approver) to demonstrate that the responsible person fulfils the requirements for the accomplishment of clinical evaluations.