Appendix 2 – Clinical Evaluation Report

Commented [13A1]: The Clinical Evaluation Report must be conducted by a Clinical Evaluator or team of evaluators.

All sections from this report are mandatory and should not be deleted (according to MEDDEV 2.7.1/Rev 4).

[illegible]	
Date	
[illegible]	
[illegible]	

Commented [13A2]: Include the name of the medical device or [illegible]

Commented [13A3]: Please include the name of the main Clinical Evaluator who created this report.

Commented [13A4]: Please include the names of the members [illegible]

1. Scope of the clinical evaluation

1.1. Identification of device(s)

Product details	
Name of medical [illegible]	
[illegible]	
Software version	
[illegible]	
[illegible]	

Commented [13A5]: Mention all devices covered by this Clinical [illegible]

Commented [13A6]: You can delete rows that are not [illegible]

Commented [13A7]: Please write in the classification of the [illegible]

1.2. Identification of manufacturer

[illegible]

Commented [13A8]: Please write the manufacturer's full name and addresses for all manufacturers' locations.

1.3. Device description

[illegible]

Commented [13A9]: Please write in: [illegible]

[illegible]
[illegible]

Commented [13A10]: Please include information about [illegible]

Commented [13A11]: Make a list of all variations, dimensions, [illegible]

1.4. Intended purpose

Intended use/purpose in alignment with Instructions for Use (IFU)
[illegible]
[illegible]
Precautions

Commented [13A12]: Write in the exact description of the intended purpose as described in the device's IFU.

Commented [13A13]: Please include information about all [illegible]

Commented [13A14]: Please include information about all warnings. If there are no warnings, write N/A (Not Applicable).

Commented [13A15]: Please include information about all precautions. If there are no precautions, write N/A (Not Applicable).

2. Clinical background, current knowledge, state of the art

2.1. Clinical background

Clinical background

Commented [13A16]: Identification of medical fields concerned/relevant medical conditions.

2.2. Literature research strategy

[illegible]

Commented [13A17]: Write in a brief summary and [illegible]

2.3. Appraisal criteria

[redacted]

Commented [13A18]: Write in a brief summary of appraisal [redacted]

2.4. Applicable standards and guidance documents

Standards/regulations/guidance documents

Commented [13A19]: Write in all applicable regulations, standards, and other guidance documents.

2.5. Medical field concerned by the device

[redacted]

Commented [13A20]: Write in the description, natural course, [redacted]

2.6. [redacted]

Commented [13A21]: Write in the description of available [redacted]

2.7. Device users

Commented [13A22]: Write in information about types of [redacted]

2.8. [redacted]

Nr.	[redacted]	[redacted]

Commented [13A23]: Write in acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I of MDR.

Commented [13A24]: Write in indication.

Commented [13A25]: Write in benefit-risk ratio.

3. Clinical evaluation

3.1. Type of evaluation

The clinical evaluation is based on	Applicable (yes/no)
[illegible]	
[illegible]	
[illegible]	

3.2. Demonstration of equivalence

	[Your device]	[Equivalent device]
[illegible]		
Model		
[illegible]		
[illegible]		
Accessories		
[illegible]		
[illegible]		
[illegible]		
Clinical characteristics		
[illegible]		
Source of data:		
Conclusion		

Pictures:

Commented [13A26]: If clinical data is not deemed appropriate, include considerations according to Section 10.3. of MEDDEV 2.7.1/rev 4.

Commented [13A27]: Characteristics between your medical [illegible]

Commented [13A28]: Write in the name of your device.

Commented [13A29]: Write here the equivalent device's exact name.

Commented [13A30R29]:

Commented [13A31]: Write in the exact model of your device and of the equivalent device in the appropriate field.

Commented [13A32]: Write in here the dimensions of your device and the equivalent device.

Commented [13A33]: Write in here the software version of the devices.
If the devices don't have a software version, you can delete this row.

Commented [13A34]: Write in here the accessories of the devices.
If the devices don't have accessories, you can delete this row.

Commented [13A35]: Write in the regulations applicable for each of the devices.

Commented [13A36]: Write in here the technical [illegible]

Commented [13A37]: Write here the biological characteristics [illegible]

Commented [13A38]: Write here the clinical characteristics of [illegible]

Commented [13A39]: If the equivalent device is not CE-marked, justification for the use of such device must be provided.

Commented [13A40]: Write in here the source(s) from where [illegible]

Commented [13A41]: Write in here the conclusion: [illegible]

Commented [13A42]: Include picture(s) of the equivalent device.

3.3. Clinical data generated and held by the manufacturer

Reference list of all documents	

3.4. Clinical data from literature

3.5. Summary and appraisal of clinical data

3.6. Analysis of the clinical data

3.6.1. Requirement on safety

[illegible] Protocol and that all the hazards, information on risk mitigation, and other clinically relevant information have been identified appropriately.

Safety risks from device risk management documentation [reference documentation]

ID	[illegible]	[illegible]
X		

[illegible]

Risks	[illegible]	[illegible]

[illegible]
☐ YES ☐ NO

Commented [13A43]: For details, please see section 8.1 from [illegible]

Commented [13A44]: Write in a brief summary and [illegible]

Commented [13A45]: Write in here analyses of all results from the chosen scientific papers included in the Literature Research Protocol.

[illegible]

Commented [13A46]: Write in a complete reference to risk [illegible]

Commented [13A47]: Analysis of whether there are special [illegible]

Commented [13A48]: Write in your control measures for minimizing this risk (records, education, certificates, etc.)

Commented [13A49]: Include all risks that need clinical evaluation.

Commented [13A50]: Analysis of whether there are special [illegible]

Commented [13A51]: Write in your control measures for minimizing this risk (records, education, certificates, etc.)

Commented [13A52]: Check the one that applies.

The safety characteristics and intended use purpose of the device require the following precautions:
The foreseen users of the device are adequate:
All training requirements and precautions are listed in the IFU. If not, the following requirements and/or precautions should be included:
☐ YES ☐ NO
Training requirements and/or precautions that should be included:
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.
☐ YES ☐ NO
Justification

Commented [13A53]: List the precautions required when using the device.

Commented [13A54]: List the users that can use the device.

Commented [13A55]: Check the one that applies.

Commented [13A56]: Write in a list of training requirements

Commented [13A57]: Check the one that applies.

Commented [13A58]: If you answered NO, write in

3.6.2. Requirement on acceptable benefit/risk ratio

Summary of the total experience with the device, including numbers and characteristics of patients exposed to the device and duration of follow-up is:	
Clinical investigations	
PMCF	
Other user experience	
Market experience	
Nature, severity/severity, probability, duration of benefits to the patients and of side effects and other risks:	
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:	

Commented [13A59]: Write in a summary of above mentioned aspects.

Commented [13A60]: Write in a summary of above mentioned aspects including detailed descriptions of all aspects of intended use

3.6.3. Requirement on performance

3.6.4. Requirement on acceptability of side effects

4. Conclusions

Statement	Answer	Justification
The existing data are sufficient to verify that the [redacted]		
The benefit/risk profile according to current [redacted]		
[redacted] information is suitable for the intended users and sufficiently covers all usability aspects.		
[redacted]		
There is full consistency between the clinical data, [redacted] documentation for the device under evaluation.		
[redacted]		

Commented [13A61]: Write in a description of clinical [redacted]

Commented [13A62]: Write in a summary of conformity assessment with requirement on acceptability of undesirable side [redacted]

Commented [13A63]: Please elaborate each answer using proofs/conclusions from the previous sections of the report.

Commented [13A64]: If, for any of the statements, the answer [redacted]

sufficiently discussed and follow-up measures during PMS are addressed.		
[illegible]		
New or additional PMS activities, including PMCF [illegible]		

Commented [13A65]: This includes uncertainties regarding [illegible]

5. Date of the next clinical evaluation

Date of next update	[illegible]

6. Attached documents

Commented [13A66]: This is a list of documents that should be attached to the Clinical Evaluation Report.

- Literature Research Protocol
- Declaration of Interest
- CV from the evaluator
- Complete list of medical devices (if needed)

Commented [13A67]: If there is more than one Clinical [illegible]

Commented [13A68]: If there is more than one Clinical Evaluator, you should attach the CV for each of the evaluators.

Commented [13A69]: The complete list of medical devices [illegible]