Appendix 1 – Clinical Evaluation Plan

Commented [13A1]: Clinical Evaluation Plan must be created by a Clinical Evaluator.

Device name	
Date	
Clinical Evaluator	

Commented [13A2]: Include the name of the medical device or family of medical devices for which you are creating this Clinical Evaluation Plan.

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

1. Scope of the clinical evaluation

1.1. Identification of device(s)

Product details	
[illegible]	
Dimension, sizes	
[illegible]	
Accessories	
[illegible]	

Commented [13A4]: Mention all devices covered by this Clinical Evaluation Plan, products, models, sizes, software versions, accessories, their proprietary names, code names assigned during device development.

Commented [13A5]: You can delete rows that are not [illegible]

Commented [13A6]: Please write in the classification of the [illegible]

1.2. Identification of manufacturer

Legal Manufacturer

Commented [13A7]: Please write manufacturer's full name and addresses for all manufacturers' locations.

1.3. Device description

[illegible]

Commented [13A8]: Please include concise physical and [illegible]

Technology used
[illegible]

Commented [13A9]: Please include information about [illegible]

1.4. Intended purpose

[illegible]
[illegible]
Warnings
Precautions

Commented [13A10]: Write in the exact description of the intended purpose as described in the device's IFU.

[illegible]

Commented [13A11]: Please include information about all [illegible]

Commented [13A12]: Please include information about all warnings. If there are no warnings, write N/A (Not Applicable).

Commented [13A13]: Please include information about all precautions that should be taken. If there are no precautions, write N/A (Not Applicable).

1.5. Current status of the device

[illegible] ☐ YES ☐ NO	Availability Date:
CE mark ☐ YES ☐ NO	
[illegible]	
[illegible]	

Commented [13A15]: Please include the date when the device [illegible]

[illegible]

Commented [13A14]: Please choose the one that applies.

Commented [13A16]: Please choose the one that applies if the medical device is CE marked or not.

Commented [13A17]: If medical device is not CE marked, you can delete these rows.

[illegible]	
[illegible]	

Other regions in which the device is certified				
Region	[illegible]	[illegible]	[illegible]	Validity

Commented [13A18]: Please include information about each region in which the device is certified.

1.6. Device change history

[illegible]
Identification of changes

Commented [13A19]: Please include brief information about [illegible]

Commented [13A20]: Please include brief information about [illegible]

1.7. Residual risk that has clinical significance

[illegible]

Commented [13A21]: Please include information about the [illegible]

1.8. Applicable harmonized standards, non-harmonized standards, and other guidance documents

Harmonized standards	
Mark of the standard	[illegible]

Commented [13A22]: List all of the applicable regulations, standards, and other guidance.

Commented [13A23]: Harmonized standards for the EU market can be found on the following link: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

Harmonized standards for the USA market you can find can be found on the following link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Commented [13A25]: E.g. Medical devices — Quality management systems,
Requirements for regulatory purposes

Commented [13A24]: E.g. ISO 13485:2016

Non-harmonized standards	
[illegible]	[illegible]

Other guidelines documents	
[illegible]	[illegible]

1.9. Other aspects

Other aspects of relevance

Commented [13A26]: Mention any other aspects with an [illegible]

2. Clinical evaluation stages and methods

2.1. Hazards identified to be possibly related to clinical use

Hazard	[illegible]

Commented [13A27]: Please list possible hazards that can arise [illegible]

2.2. Data source(s) and type(s) of data to be used in the clinical evaluation

[illegible]
[List documents]
[illegible]

Commented [13A28]: List here all pre-market clinical [illegible]

Commented [13A29]: State here with which device equivalence [illegible]

Period covered by search	
[illegible]	
Included filters for search	
[illegible]	
Keywords	
[illegible]	

Commented [13A30]: Usually it is Pubmed, Medline.

Commented [13A31]: Usually it is clinical trials, randomized control trials, clinical study, human, full articles.

Commented [13A32]: Usually it is review articles, meta-analysis, in vitro, studies on animals, articles that have only abstracts.

2.3. Appraisal of the data

Commented [13A33]: For more details, see section 9.3 of MEDDEV 2.7.1, rev 4.

[illegible] about safety or performance).

[illegible]

Based on their scientific validity and relevance, the data should be weighted according to their relative contributions.

Signed .....

[Name]

Date .....

Commented [13A34]: This document must be signed by the Clinical Evaluator and dated.

You can sign this document with a digital signature or print the document and sign it in hardcopy.