Summary of Safety and Clinical Performance for [medical device]

Commented [AES1]: Include the name of the medical device or medical device group for which this summary is prepared.

Document information

Commented [AES2]: This is a mandatory section and cannot be deleted, each change in the summary, person who prepared and approved the summary, date and version must be recorded.

Version:	
Created by:	
Approved by:	
Date of version:	

Change history

Commented [AES3]: This is a mandatory section and cannot be deleted, each change in the summary must be recorded.

Date	Version	Created by	Description of change

Table of contents

1. Identification of the device

1.1. Identification of device or device family

Name of medical device or a family of medical devices	
Dimension, sizes	
[illegible]	
[illegible]	
[illegible]	

1.2. Identification of the manufacturer

Manufacturer

1.3. Device description

Description of device
List of all versions and dimensions
[illegible]
[illegible]
[illegible]

1.4. Intended purpose

Intended use/purpose in alignment with Instructions for use (IFU)

Commented [AES4]: Include information that will identify your [illegible]

Commented [AES5]: Write in the classification of the medical [illegible]

Commented [AES6]: Include concise physical and chemical descriptions, including materials; whether the device incorporated [illegible]

Commented [AES7]: Make a list of all versions, dimensions, [illegible]

Commented [AES8]: List:
•An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist; [illegible]

Commented [AES9]: Accessories means any other devices and [illegible]

Commented [AES10]: If there is no any alternative use, you [illegible]

Commented [AES11]: Provide the 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, including:
•name of disease or condition, clinical form, stage, severity
•symptoms or aspects to be treated/managed/ diagnosed
[illegible]

Target population
Indications
[illegible]
[illegible]
[illegible]
Suggested users and training needed for medical device usage

Suggested users	[illegible]

2. List of applicable standards

Name of the standard	[illegible]	[illegible]

3. Summary of residual risks

Summary of residual risks

4. Clinical evaluation

Summary of clinical evaluation report

Commented [AES12]: Include information about all [illegible]

Commented [AES13]: Include information about all warnings.

Commented [AES14]: Include information about all [illegible]

Commented [AES15]: Include information about the users of the medical device that will need training.

[illegible]

Commented [AES16]: If you are using the ISO 13485 & MDR Integrated Toolkit, you can delete a table and write: "The list of [illegible]

Commented [AES17]: List all standards used in the [illegible]

Commented [AES18]: List whether the standards is harmonized or not.

If non-harmonized standards are used in areas where there are no harmonized standards, verify the justification that the standard adequately document compliance for the requirements.

[illegible]

Commented [AES19]: Include justification for why you have [illegible]

Commented [AES20]: Include brief description of the [illegible]

Commented [AES21]: Include the Clinical Evaluation Plan, Clinical Evaluation Report, Literature Research and Review Protocol, [illegible]

Commented [AES22]: Describe briefly the conclusions from the Clinical Evaluation Report.

[illegible]

5. Post-market clinical follow-up

Summary of post-market clinical follow-up

Commented [AES23]: Include here a short description of the