Technical Documentation for [medical device]

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

Document information

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

Version:	0.1
Created by:	
Approved by:	
Date of version:	

Change history

Commented [AES3]: This is a mandatory section and cannot be deleted, each change in the Technical Documentation 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

Product details	
Name of medical device or a family of medical devices	
Single registration number	
[illegible]	
[illegible]	
[illegible]	
[illegible]	
[illegible]	
Classification according to Annex VIII of 2017/745/EC and Product identification	

1.2. Identification of the manufacturer

Legal manufacturer

1.3. Device description

Description of device
List of all versions and dimensions
Reference to previous and similar generations of the device

1.4. Intended purpose

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

Commented [AES4]: Most of the sections and fields in this document are mandatory.

[illegible]

Commented [AES5]: Mention all devices' properties covered

[illegible]

Commented [AES6]: You can delete rows that are not

[illegible]

Commented [AES7]: On the following link, you can find more

[illegible]

Commented [AES8]: Write in the classification of the medical

[illegible]

Commented [AES9]: Write manufacturer's full name and addresses for all manufacturers' locations.

[illegible]

Commented [AES10]: Include concise physical and chemical descriptions, including materials; whether the device incorporated

[illegible]

Commented [AES11]: Make a list of all versions, dimensions,

[illegible]

Commented [AES12]: List:
•An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;

[illegible]

Commented [AES13]: 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

[illegible]

Contraindications
Warnings
Precautions
[illegible]
[illegible]
[illegible]
[illegible]
[illegible]
[illegible]

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

Commented [AES15]: Include information about all warnings. [illegible]

Commented [AES16]: Include information about all [illegible]

Commented [AES17]: State here whether your device does or [illegible]

Commented [AES18]: Write the sterilization method applicable to the device. [illegible]

2. Declaration of conformity

Commented [AES19]: Product's Declaration of Conformity [illegible]

Name and address of the manufacturer	
Name, registered trade name or registered trademark of medical device product code, catalogue number	
BASIC UDI	
[illegible]	
[illegible]	
[illegible]	
[illegible]	

Commented [AES20]: Write in the name and address of the [illegible]

Commented [AES21]: Write in risk class of the device in [illegible]

Commented [AES22]: State here under which conformity [illegible]

We herewith declare that the abovementioned products meet the provisions of the following EC Council Medical Device Regulation 2017/745 and its implementation in national law. All supporting documentation is retained on the premises of the manufacturer.	
Applicable standards	
[illegible]	
[illegible]	
[illegible]	
[illegible]	

3. European representative

EU representative's name and address	
[illegible]	

4. General safety and performance requirements

GSPR document	

5. List of applicable standards

Name of the standard	[illegible]	[illegible]

6. Requirements regarding design and manufacturing

Description of the production process

List of critical suppliers and subcontractors		
Supplier/Subcontractor	[illegible]	[illegible]

Commented [AES23]: Include the list of applicable harmonized [illegible]

Commented [AES24]: Include the name and identification [illegible]

Commented [AES25]: Include the place and date of issuing as [illegible]

Commented [AES26]: Check if the signature of the authorized [illegible]

Commented [AES27]: This applies to all companies that are not registered in EU.

Commented [AES28]: Include information related to the [illegible]

Commented [AES29]: This document is prepared by Notified [illegible]

Commented [AES30]: If you are using the ISO 13485 & MDR Integrated Toolkit, you can delete a table and write: "The list of applicable standards is defined in document Appendix 2 – List of External Documents." in this section instead.

Commented [AES31]: List all standards used in the [illegible]

Commented [AES32]: List whether the standards is harmonized or not.

Commented [AES33]: Include justification for why you have [illegible]

Commented [AES34]: Include a description of the [illegible]

Commented [AES35]: You need to have signed quality [illegible]

Commented [AES36]: Include the full name and address of the [illegible]

Commented [AES37]: List the process or critical material that [illegible]

Commented [AES38]: Include information about the [illegible]

7. Material properties – chemical, physical and biological

Part/Component	Material (including any specific treatment)	[illegible]	[illegible]	[illegible]

8. Benefit-risk analysis and risk management

Document name	[illegible]	[illegible]

9. Biocompatibility

Biocompatibility report details				
Name of the report				
Date of the report				
Version				
Laboratory name	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]				

10. Pre-clinical data

Commented [AES39]: If your medical device is not implantable, and does not contain medicinal substance, animal tissue or human blood derivative, you can delete this section.

This section is to:
•Include additional data above what's already required under preclinical data, etc.
[illegible]

Provide a detailed description of all the materials used in the device, including coatings if relevant. Include the grade of the material and if it is intended for medical applications. If not, a justification for why the assessor accepts the material used must be provided (complete chemical, biological and physical characterization).

[illegible]

Commented [AES40]: E.g., surface treatment of an implant device

Commented [AES41]: Include the Risk Management Plan, Risk Management Report, and any other documents related to risk management.

[illegible]

Commented [AES42]: If your medical device does not require [illegible]

Commented [AES43]: Name the laboratory in which [illegible]

Commented [AES44]: If you have used non-accredited [illegible]

Commented [AES45]: E.g., studies in technical performance [illegible]

Test	Document with test result		Date	Version
Laboratory name	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]				

Commented [AES46]: Name the laboratory in which testing

Commented [AES47]: If you have used non-accredited

11.Stability

Stability report details				
Name of the report				
Date of the report				
Version				
Laboratory name	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]				

Commented [AES48]: Name the laboratory in which

Commented [AES49]: If you have used non-accredited

12.Sterilization and sterilization validation

Document name			Date	Version
Laboratory name	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]				

Commented [AES50]: Name the laboratory in which

Commented [AES51]: If you have used non-accredited

13. Radiation/electrical safety

Radiation/electrical safety report details				
Name of the report				
Date of the report				
Version				
Laboratory name	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]				

Commented [AES52]: If your medical device is class I or class [illegible]

Commented [AES53]: Name the laboratory in which testing [illegible]

Commented [AES54]: If you have used non-accredited [illegible]

14. Software and software validation

Document name	Date	Version

Commented [AES55]: You can delete this section:
• if your medical device does not have software [illegible]

15. Usability

Usability report details	
Name of the report	
Date of the report	
Version	
[illegible]	

Commented [AES56]: If there is no need for the usability (e.g. [illegible]

Commented [AES57]: If no usability study was performed, you [illegible]

Commented [AES58]: Provide justification for why you have [illegible]

16. Labeling

Label type	[illegible]	[illegible]

Commented [AES59]: List all types of labels.

17. Instructions for use (IFU)

Instructions for use details	
Name of the document	
Date of the document	
Version	
[illegible]	

Commented [AES60]: Instructions for use are not required for class I and class IIa devices if such devices can be used safely [illegible]

Commented [AES61]: If you do not have instructions for use [illegible]

Commented [AES62]: Provide justification for why you have [illegible]

18. Clinical evaluation

Document name	[illegible]	[illegible]

Commented [AES63]: Include the Clinical Evaluation Plan, [illegible]

19. Post-market surveillance

Document name	[illegible]	[illegible]

Commented [AES64]: Include the PMS Plan, PSUR report, and [illegible]