Device Description

Device Name/ Model Name

Document Authorisation

Task	Name	Signature	Date
Document Prepared By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Reviewed By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Approved By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY

Revision History

Version	Release Date	Change History
Version Number	DD-MM-YYYY	Changes made on the particular release date mentioned in previous column.

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1. Purpose

This document has been created in order to fulfil the requirements of Regulations (EU) 2017/745. This document will serve the purpose of identifying the device which is subject to the evaluation along with its previous generation (if any) as well as the general overview of the identified similar devices, equivalent device (only if equivalence is claimed).

2. References Documents and guidelines

- Regulation (EU) 2017/745
- MEDDEV 2.7/1 revision 4

3. Device information

State the intended use, indications, and intended users, as specified in the device's instructions for use (IFU) and labelling.

4. Device Clinical information

4.1. Intended purpose & users

Summarize the medical purpose for which the device is intended, as per EU MDR definition.

4.2. Indications for Use

Detail the specific conditions or symptoms the device is intended to treat, diagnose, or monitor.

4.3. Contraindications/ Warnings/ Precautions

List any known contraindications where the device should not be used.

4.4. Technical specifications

List specifications such as dimensions, weight, performance parameters, and operating conditions.

4.5. General Descriptions

Briefly describe the device, including its type and main components. Describe the purpose, key features, and any distinctive characteristics.

4.6. List of Components & Accessories

List all key components of the device, including materials and any active elements, if applicable. List any accessories intended to be used in conjunction with the device and clarify their role or purpose.

4.7. Principle of Operation

Briefly describe how the device operates, the principles behind its mechanism, and how it achieves its intended purpose.

4.8. Rationale for the Qualification of the product as a device and Risk Class of Device

State the classification (e.g., Class I, IIa, IIb, III) based on the intended purpose, risk level, and rules applied under MDR Annex VIII. Provide a clear rationale for the device's classification, referencing MDR Annex VIII rules and justifying any particular rule choice.

4.9. Explanation of any Novel features

Include a description of any unique or innovative aspects of the device that differentiate it from other similar devices on the market. This section should address features or functionalities that are new, groundbreaking, or significantly improve upon existing technologies or methods.

5. Clinical performance and benefits

List the intended clinical benefits the device is expected to provide, referencing any supporting data if available.

6. Market History

Provide an overview of the device's history in the market, both in the EU and internationally, to demonstrate the device's track record, any regulatory approvals obtained, and performance in real-world settings.

7. Equivalent/ similar Device or previous generation devices

Provide details on any similar or equivalent devices on the market or previous generations of the device. The aim is to establish any design or functional continuity and to show how past device iterations or similar models have influenced the current version.

8. Packaging and labelling information

Summarize the labelling, including warnings, instructions for use, and symbols used on the label in compliance with MDR requirements. Describe the packaging material, protective features, and any special handling instructions required to maintain device integrity.