Device Classification

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
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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 is a review of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning the classification of medical devices. **Article 51 Classification of Devices** was referred to classify the device taking into account the Intended Purpose of the device and is in accordance with the **Annex VIII Classification Rules** to determine the device classification of Device Name.

2. Device Description and Intended Purpose

2.1. Device Description

- *Device Name:* [Device Name]
- *Device Model/Version:* [Model/Version]
- *Primary Function:* [Describe the main function]
- *Technical Specifications:* [Brief technical specifications]

2.2. Intended Purpose

- The device is intended for [Intended Use] in [Healthcare, Clinical, etc.].
- It is used for [specific purpose, e.g., diagnosis, treatment, monitoring].

2. Reference Documents and guidelines

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
    - Article 51 Classification of devices
    - Annex VIII Classification Rules

- MDCG 2021-24 (https://health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf);

3. Classification Determination

Under **EU MDR (2017/745) Annex VIII**, medical devices are classified based on risk level, duration of use, and invasiveness. This section outlines the rules applied and rationale for classification.

3.1. Classification Rules Applied

Rule	Description	Applicability to Device

3.2. Classification Outcome

Based on the rules applied, the device is classified as **Class [I, IIa, IIb, or III].**

4. Justification of Classification

This section provides the reasoning behind the classification decision, in alignment with **Annex VIII** rules.

- [Detailed explanation justifying the device classification]
- [Refer to any design features, intended use, risk profile, or similar devices that informed the classification]

5. Risk Assessment summary

A brief summary of the risk assessment findings that support the classification:

- *Risk Type:* [E.g., biological, electrical]
- *Potential Hazards:* [List key hazards]
- *Risk Control Measures:* [Summary of risk mitigation measures applied]

Note: Refer to the device's Risk Management documentation for a complete analysis.

6. Conformity Assessment Route

Based on the classification (Class [I, IIa, IIb, or III]), the conformity assessment route selected is:

- [E.g., Annex IX, X, XI—describe the relevant annex for conformity assessment for this device class.]

Provide any further description or steps relevant to the conformity assessment.

7. Conclusion

The **Conclusion** section of the Device Classification Document summarizes the classification determination, including key justifications and the selected conformity assessment route. This section ensures clarity on the classification outcome and confirms alignment with regulatory requirements.