

Manufacturer Name

Product Name/ Model Name

Instructions For Use

[Insert Device Picture]

CE Mark

Date of issue: DD/MM/YYYY

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Please note that while every effort has been made to ensure that the data given in this document is accurate, the information, figures, illustrations, tables, specifications, and schematics contained herein are subject to change without notice.

Reference Documents

EU MDR 2017/745; ISO 14971; MEDDEV

Errors and Omission

If errors or omissions are found in this manual, please notify **Company Name**.

Warning

A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

Caution

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property.

Illustrations

Illustrations may show design models; production units may incorporate changes.

Trademarks

Trademark	Trademark Owner
Trademark Name	Manufacturer Name
Trademark Name	

Manufactured by:

Manufacturer's registered address

Authorised Representative:

Authorised Representative registered address

Revision Date	Revision	Revised By	Details
DD-MM-YYYY	01	In-charge Person	Revisions/ changes made

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1. Device overview

1.1. Device Description

Describe the device, its main components, accessories (if applicable), and any other relevant characteristics.

1.2. Technical Specifications

Includes detailed, measurable information about the device's design, performance characteristics, and operational parameters. This section provides essential data that ensures users understand the capabilities and limitations of the device.

2. Intended Purpose & users

Provide a brief description of the intended use of the device, including its target users and intended patient population.

3. Indications and Contraindications

3.1. Indications

Describe conditions or situations in which the device should be used.

3.2. Contraindications

Provide any conditions or situations in which the device should not be used.

4. Warnings and Precautions

List safety warnings, potential risks, and precautions to take when using the device. Include specific warnings related to the device's operation, such as electrical safety, handling sharp components, etc.

5. Instructions for Use

Step-by-step guidance on the proper use of the device, from setup to operation.

Example:

1. Unpack the device and verify all components.
2. Follow [procedure] to assemble the device as illustrated.
3. Apply [any other specific instructions related to usage].

6. Maintenance and Storage

Provide details on how to maintain and store the device to ensure its safety and longevity.

7. Disposable Instructions

Instructions on how to safely dispose of the device and its components in compliance with applicable regulations.

8. Symbols and Definitions

List and define any symbols used in the document, as per **ISO 15223-1** or other applicable standards.