DECLARATION OF CONFORMITY

Name and Address of Product Owner:

Wassenburg Medical B.V.
Edisonring 9
6669 NA Dodewaard
The Netherlands

We, Wassenburg Medical B.V., hereby declare that the Declaration of Conformity is issued under our sole responsibility.

Manufacturing Site:

Wassenburg Medical B.V.
Edisonring 9
6669 NA Dodewaard
The Netherlands

Medical Device(s):

Wassenburg® Connection Material WD

Intended purpose:

WASSENBURG® Connection Material WD is an accessory to the WASSENBURG® endoscope washer-disinfector (WD) for the connection of, and/or direction of flow through of, the thermolabile medical device in the WD for the washing and disinfection of flexible endoscopes and other reusable thermolabile medical devices in the healthcare sector.

Basic UDI-DI (GTIN)

The basic UDI-DI for above mentioned medical devices is: 8719324979CM01BV

Single Registration Number (SRN)

The Single Registration Number of Wassenburg Medical B.V. is: NL-MF-000000244

Risk Classification:

WASSENBURG® Connection Material WD is classified according to the MDR. Based on the Definitions in section 3.1, it is deemed an accessory to Washer Disinfector for connection the load (endoscopes and other thermolabile devices) to the WD. Since the Washer Disinfector is a Medical Device, the WASSENBURG® Connection Material WD CM is classified as a Class I Medical Device, based on the current regulation (EU) 2017/745 rule 1 for non-invasive devices.

Quality Management System Certificate:

Certificate of Registration - Quality Management System according to the harmonized standards ISO 13485:2016 & EN ISO 13485:2016, certificate number MD 635728 issued by BSI Group, Milton Keynes, United Kingdom.

CE Certificate - EU Quality Management System, with certificate number MDR 754529 R000 issued by BSI Group The Netherlands B.V., The Netherlands (Identification number: 2797).

Standards Applied:

A list of Harmonized Standards from the Official Journal of the European Union is attached as Appendix I to this document.

We, Wassenburg Medical B.V., hereby declare under our sole responsibility that the below mentioned devices have been classified according to the classification rules and conform to the General Safety and Performance Requirements as laid out in the Medical Devices Regulation (EU) 2017/745.

Authorised Signatory:

Place:
Dodewaard, the Netherlands

25-4-2024

X Alexander Vermeulen

Alexander Vermeulen
Director Medical Compliance, PRRC

26/04/2024

X Ronald Wassenburg

Ronald Wassenburg
President, MD

Appendix I:

List of Harmonized Standards from the Official Journal of the European Union

EN ISO 13485:2016 Medical devices - Quality management systems-Requirements for regulatory purposes

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements