EU DECLARATION OF CONFORMITY

Name and Address of Product Owner:

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

Manufacturing Site:

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

Medical Device(s):

Wassenburg® WD440	
BUDI-DI	8719324979WD01EU
Wassenburg® WD440 PT	
BUDI-DI	8719324979WD01EU
Wassenburg® WD4200	
BUDI-DI	8719324979WD01EU

See Appendix I for the accessories to the WD440, WD440 PT, WD4200

Intended purpose:

The Washer Disinfector is intended for washing and disinfection of flexible endoscopes and other re-usable thermolabile medical devices in the health care sector.

Single Registration Number (SRN)

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

Risk Classification:

WASSENBURG® Washer Disinfector (WD) is classified according to the MDR (EU) 2017/745. Based on the intended use of the Washer Disinfector, the product complies with the description given in rule 16. Therefore the Washer Disinfector is classified according to rule 16 as a class IIb medical device.

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).

Conformity assessment route:

According to the BSI CE Certificate the conformity assessment procedure is done according to Annex IX, chapter I and III of the Medical Device Regulation (EU) 2017/745.

Standards Applied:

A list of Applicable Standards from the Official Journal of the European Union is attached as Appendix II 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

25-3-2025

X Henk Jansen van Galen

Henk Jansen van Galen
Manager Quality Assurance

25/03/2025

X Ronald Wassenburg

Ronald Wassenburg
President, MD

Appendix I

List of accessories for WD440, WD440 PT, WD4200

Wassenburg® Connection Material WD

Appendix II

Applicable standards

Standard	Title
NEN-EN-ISO 13485:2016/A11:2021 ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
NEN-EN-ISO 14971:2019/A11:2021	Medical devices — Application of risk management to medical devices
NEN-EN-ISO 15883-1:2009/A1:2014	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests Part 4, except for 4.1.8, 4.2.3, 4.3.1, 4.3.3, 4.5 Part 5, except for 5.1.9, 5.1.10, 5.3.2, 5.4.2, 5.4.4, 5.4.5, 5.5.1.3, 5.6.3, 5.6.4, 5.6.6, 5.8.4, 5.11.4, 5.17,1, 5.17.2.1, 5.17.2.4, 5.18.7, 5.18.9, 5.19.2, 5.24.2, 5.24.3, 5.26, 5.27.1, 5.27.3 – 5.27.8, 5.28 Part 6, except for 6.1.2, 6.5.4, 6.5.6, 6.5.7, 6.7, 6.8.1 – 6.8.4, 6.9.1.1.3, 6.10.1, 6.10.2, 6.11, 6.12 Part 7 to 10
NEN-EN-ISO 15883-4: 2019	Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes Part 4, except for 4.1.10, 4.4.2.4.1, 4.4.5.2, 4.5.3, 4.7.2, 4.7.3, 4.8.2, 4.9.2.5 Part 5, except for 5.1.2, 5.2.2.4, 5.4.4, 5.7 Part 6, except for 6.2, 6.4.1.2, 6.4.2, 6.4.3, 6.8, 6.9.2, 6.10, 6.12.2.2.2, 6.12.2.3.5 Part 7 to 10
NEN-EN-ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
NEN-EN-IEC 62304:2006/C11:2008/A1:2015	Medical device software — Software life-cycle processes
NEN-EN-ISO 20417:2021 (cor. 2022-04)	Medical devices - Information to be provided by the manufacturer
NEN-EN-ISO 10993-1:2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
NEN-EN-IEC 62366-1:2015/C11:2016/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
NEN-EN-ISO 14155:2020/A11:2025	Clinical investigation of medical devices for human subjects – good clinical practices

NEN-EN-IEC 61326-1:2021 (industrial requirements)	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
NEN-EN-IEC 80001-1:2021	Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities.
NEN-EN-IEC 61010-1:2010/C1:2011/A1:2019/C1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
NEN-EN-IEC 61010-2-040:2021	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
NEN-EN 50419:2022	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
NEN-EN-ISO/IEC 27001:2023	Information security, cybersecurity and privacy protection - Information security management systems - Requirements