

## 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® WD4200   | as of serial number 502-000009 |
| Wassenburg® WD440    | as of serial number 203-559    |
| Wassenburg® WD440 PT | as of serial number 303-363    |
| Wassenburg® WD415    | as of serial number 402-257    |

See Appendix I 'List of accessories' for the accessories to the WD4200, WD440, WD440 PT and WD415.

***Basic UDI-DI (GTIN)***

The basic UDI-DI for above mentioned medical devices is: 8719324979WD01EU

***Single Registration Number (SRN)***

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

***Risk Classification:***

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

Medical Device Directive (93/42/EEC), Annex IX (Classification Criteria), Chapter III (Classification), part 4 (Special Rules), point 4.3 (Rule 15):

'All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb.'

'All devices intended specifically to be used for disinfecting medical devices are in Class IIa. ► **M5** Unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb. ◀'

'This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.'

Based on the intended use of the Washer Disinfector the product complies with the description given in rule 15. No other rules are considered to be applicable. Therefore the Washer Disinfector is classified according rule 15 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 - Full Quality Assurance System, with certificate number CE 635727 issued by BSI Group The Netherlands B.V., The Netherlands (Identification number: 2797).

CE assessment route: Directive 93/42/EEC on Medical Devices, Annex II, excluding Section 4.

**Standards Applied:**

A list of Harmonized 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 Essential Requirements as laid out in the Medical Devices Directive 93/42/EEC. An application for the concerned products is not lodged to any other Notified Body than mentioned in this Declaration of Conformity.

**Authorised Signatory:**

Place:

Dodewaard, the Netherlands

30-9-2021

**X** Alexander Vermeulen

Alexander Vermeulen  
Manager RA, PRRC

Ondertekend door: avermeulen.wassenburgmedical.nl

01/10/2021

**X** Ronald Wassenburg

Ronald Wassenburg  
Managing Director

Ondertekend door: Ronald Wassenburg

## Appendix I

List of accessories

**Connection set**

**TOE Probe Case (only applicable for WD440PT)**

## Appendix II

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

**EN 1041:2008+A1:2013** Information supplied by the manufacturer of medical devices

**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 15883-1:2009** Washer-disinfectors — Part 1: General requirements, terms and definitions and tests

**EN ISO 15883-4:2019** Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

**EN 62304:2006** Medical device software — Software life-cycle processes

**EN 62366-1:2015** Medical devices — Application of usability engineering to medical devices