RR Mechatronics
Masters of Measurement

EU DECLARATION OF CONFORMITY

RR Mechatronics Manufacturing B.V.

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This declaration of conformity is issued under the sole responsibility of the manufacturer:

RR Mechatronics Manufacturing B.V.

De Corantijn 13, 1689 AN Zwaag, The Netherlands

SRN: NL-MF-000023105

We declare that the:

Product for general laboratory use:

Trade name/ Model: **RPI**

Variants:

Variants:	Product-ID (REF):	UDI-DI
RPI-ECO21 120V	**A0021587**	**08719189137347**
RPI-ECO21 230V	**A0021595**	**08719189137484**

Basic UDI-DI (BUDI-DI): 8719189137XH61THP4

EMDN-code: W02079002 In vitro medical device, IVD Instruments, general purpose IVD Instruments, various general purpose IVD Instruments, diluters

Classification IVDR: Class A

Intended purpose: The RPI is a general purpose instrument intended to dilute a concentrated reagent to a usable fluid for in vitro laboratory testing.

is in conformity with the requirements of the following EU legislations:

Regulation (EU) 2017/746 **In vitro diagnostic medical devices**

(conformity assessment according Article 48 of this regulation)

Directive 2011/65/EU **Restriction of the use of certain hazardous substances**

Including the amendment of Annex II; 2015/863

(conformity assessment according Article 7 of this directive)

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The following (harmonized) standards have been applied:

EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN-ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 18113-3:2011	In vitro medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN IEC 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN IEC 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
EN IEC 62304:2006	Medical device software – Software life-cycle processes
EN IEC 62366-1:2008	Medical devices – Application of usability engineering to medical devices
NEN-EN-IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

The CE mark was applied for the first time on this type of IVD device in 20yy.

Place: Zwaag, The Netherlands

Date: May 15, 2024

Signature:

Stamp: RR Mechatronics Manufacturing B.V. • RR Mechatronics International B.V. • Mechatronics Instruments B.V. • RR Mechatronics De Corantijn 13 1689 AN Zwaag The Netherlands

Name: T.A.M.S van der Meer

Function title: CEO

RR Mechatronics Manufacturing B.V.