RR Mechatronics
Masters of Measurement

E.C. 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

We declare that:

the Automatic Reagent Preparation Unit:

Trade name: **RPU-2100**

Product models:

Model name:	Product-ID (REF):
RPU-2100R	**NARP109010**

GMDN-code: 15133 (Laboratory diluter)
Classification: General IVD

- Is in conformity with the requirements of the following EC directives:

98 / 79 / EC **In vitro diagnostic medical devices**
(conformity assessment according Annex III of directive 98/79/EC)

2011/65/EU **Restriction of the use of certain hazardous substances (RoHS 2)**
(conformity assessment according Article 7 of directive 2011/65/EU)

- The following harmonized standards have been applied:

EN 61010-2-101, Safety requirements for electrical equipment for measurement, control and laboratory use - Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 61326-2-6, Electrical equipment for measurement, control and laboratory use - EMC requirements - Particular requirements for in vitro diagnostic (IVD) medical equipment

EN ISO 18113-3, In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use

EN-ISO 15223-1, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

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

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

The CE mark was applied for the first time on this type of product in 2010.

Place: Zwaag, The Netherlands
Date: April 12, 2018

Signature:

Konstantin Artz

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

Function title: Manager Quality Assurance & Regulatory Affairs
RR Mechatronics Manufacturing B.V.