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:

Isotonic solution

Trade name/ Model: **RPI-Check**

Variants:

Variant:	Product-ID (REF):	UDI-DI
RPI-Check	**A0020487**	**08719189137538**

Basic UDI-DI (BUDI-DI): 8719189137SJ3ZFHS2

EMDN-code: W01030199 In vitro medical devices, reagents, heamatology / haemostasis, immunohaematology / histology / cytology, haematology reagents, haematology reagents - other

Classification IVDR: Class A

Intended purpose: RPI-Check is an isotonic solution that is used in the daily routine to monitor the operation of the measurement functions within the RPI. If a shift in performance is determined, it may indicate the RPI requires service

is in conformity with the requirements of the following EU legislation(s):

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

(conformity assessment according Article 48, §10 of this regulation)

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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 18113-1:2011	In vitro medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN ISO 23640:2015	In vitro medical devices – Evaluation of stability of in vitro diagnostic reagents

The CE mark was applied for the first time on this type of IVD reagent in 2021.

Place: Zwaag, The Netherlands

Date: May 14, 2024

Signature: Stamp:

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

Function title: CEO

RR Mechatronics Manufacturing B.V.

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