RR Mechatronics
Masters of Measurement

EU DECLARATION OF CONFORMITY

RR Mechatronics Manufacturing B.V.

P.O.Box 225

1620 AE HOORN

The Netherlands

De Corantijn 13

1689 AN ZWAAG

The Netherlands

T +31 229 291 129

www.rrmechatronics.com

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 Cleaning Solution:

Trade name/ Model: **Starrsed Disinfectant**

Variants:

Variant:	Product-ID (REF):	UDI-DI
Starrsed Disinfectant	**QRR010947**	**08719189137231**

Basic UDI-DI (BUDI-DI): 8719189137XR4TCPWB

EMDN-code: W0103010105 Cbc-reagents (cleaning-/diluting-/lysing-/sheat-fluids)

Classification IVDR: Class A

Intended purpose: Product for automatic disinfection of the waste system of Starrsed ESR analyzers

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)

RR Mechatronics
Masters of Measurement

The following harmonized standards have been applied:

EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
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
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 2012.

Place: Zwaag, The Netherlands

Date: May 14, 2024

Signature:

Stamp:

RR Mechatronics Manufacturing B.V. - RR Mechatronics International B.V. - RR 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.