

EU DECLARATION OF CONFORMITY

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

RR Mechatronics Manufacturing B.V.
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We declare that:

The Cleaning Solution:

Trade name: **Starrsed X-Clean**

Product models:

| Model name: | Product-ID (REF): | Basic UDI-DI |
|-------------------------|-------------------|-----------------------|
| Starrsed X-Clean | QRR010946 | 08719189137224 |

EMDN-code: W0103010105 Cbc-reagents (cleaning-/diluting-/lysing-/sheat-fluids)
 Classification IVDR: Class A

Intended purpose: Product for the automatic cleaning of the Westergren pipettes in Starrsed ST

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)

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 1998.

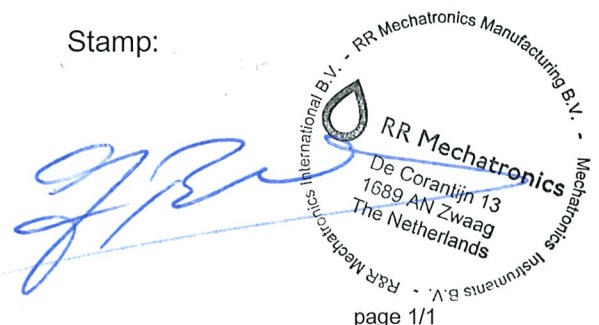
Place: Zwaag, The Netherlands
 Date: May 12, 2022

Signature:

Name: Jan Buis

Function title: CEO
 RR Mechatronics Manufacturing B.V.

Stamp:



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