

EU DECLARATION OF CONFORMITY

RR Mechatronics Manufacturing B.V.

P.O.Box 225

This declaration of conformity is issued under the sole responsibility

1620 AE HOORN

of the manufacturer:

The Netherlands

De Corantijn 13

RR Mechatronics Manufacturing B.V.

1689 AN ZWAAG

The Netherlands

De Corantijn 13, 1689 AN Zwaag, The Netherlands

T+31 229 291 129

www.rrmechatronics.com

SRN: NL-MF-000023105

We declare that:

The Cleaning Solution:

Trade name/ Model:

Starrsed X-Clean

Variants:

Variant:	Product-ID (REF):	UDI-DI
Starrsed X-Clean	QRR010946	08719189137224

Basic UDI-DI (BUDI-DI): 8719189137H2C8FYCU

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 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)



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 14, 2024

Signature:

Stamp:

Name:

T.A.M.S van der Meer

Function title:

CEO

RR Mechatronics Manufacturing B.V.

