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:

The Automatic Erythrocyte Sedimentation Rate analyzer series

Trade name/ Model: **Starrsed NSTA**

Variants:

Variants:	Product-ID (REF):	UDI-DI
Starrsed NSTA 120V	**A0030112**	**08719189137781**
Starrsed NSTA 230V/ 240V	**A0030113**	**08719189137798**

Basic UDI-DI (BUDI-DI): 8719189137HDA8BCGH

EMDN-code: W02029001 Erythrocyte sedimentation rate devices

Classification IVDR: Class A

Intended purpose: Automated analyzer for the qualitative in vitro determination of the Erythrocyte Sedimentation Rate (ESR) of human blood samples in conformity with the Westergren standard.

For professional use in medical laboratories only. To be used as aid to diagnosis for all patient populations, not restricted by age or any other anatomical or physiological particulars.

RR Mechatronics
Masters of Measurement

is in conformity with the requirements of the following EU legislations:

Regulation (EU) 2017/746	**In vitro diagnostic medical devices**
	(conformity assessment according Article 48 of this regulation)
Directive 2011/65/EU	**Restriction of the use of certain hazardous substances**
	Including the amendment of Annex II; 2015/863
	(conformity assessment according Article 7 of this directive)

The following harmonized standards have been applied:

EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2003	Performance evaluation of in vitro diagnostic medical devices
EN ISO 14971:2019	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 18113-3:2022	In vitro medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN IEC 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
EN IEC 62304:2006/Amd 1:2015	Medical device software – Software life-cycle processes
EN IEC 62366-1:2015	Medical devices – Application of usability engineering to medical devices

The CE mark was applied for the first time on this type of IVD device in 2024.

Place: Zwaag, The Netherlands

Date: June 26, 2024

Signature:

Stamp: RR Mechatronics Manufacturing B.V. - Mechatronics Instruments B.V. - R&R Mechatronics International 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.