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:

The Automatic Erythrocyte Sedimentation Rate analyzer series:

Trade name: **Starrsed TL**

Product models:

Model name:	Product-ID (REF):	Basic UDI-DI
Starrsed TL 120V	A0026352	08719189137750
Starrsed TL 230V	TLAX109100	08719189137330

EMDN-code: W02029001 Erythrocyte sedimentation rate devices
Classification IVDR: Class A

Intended purpose: Automated analyzer for 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 for all patient populations, not restricted by age or any other anatomical or physiological particulars.

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 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 18113-3:2011	In vitro medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN IEC 61010-2-101:2002	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 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
EN IEC 62366-1:2008	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 2015.

Place: Zwaag, The Netherlands
Date: October 13, 2022

Signature:

Stamp:

Name: Jan Buis

Function title: CEO
RR Mechatronics Manufacturing B.V.