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 RS**

Variants: See table on page 3

Basic UDI-DI (BUDI-DI): 8719189137YLN25BSV

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)

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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 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: Terms, definitions and general requirements
EN ISO 18113-3:2011	In vitro medical devices – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use
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: May 14, 2024

Signature: Stamp:

Name: T.A.M.S van der Meer

Function title: CEO

RR Mechatronics Manufacturing B.V.

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This declaration is applicable to the following system models:

Variants:	Product-ID (REF):	UDI-DI
Starrsed RS 120V Sysmex Low profile with inserts	A0026353	08719189137767
Starrsed RS 120V Coulter LH750	A0026453	08719189137361
Starrsed RS 120V Abbot long, black	A0026460	08719189137378
Starrsed RS 120V Bayer (Advia)	A0026464	08719189137385
Starrsed RS 120V Beckman Coulter DXH-800	A0026457	08719189137392
Starrsed RS 230V Coulter LH750	A0026454	08719189137408
Starrsed RS 230V Abbot long, black	A0026462	08719189137415
Starrsed RS 230V Bayer (Advia)	A0026466	08719189137422
Starrsed RS 230V Beckman Coulter DXH-800	A0026458	08719189137439
Starrsed RS 230V Sysmex Low profile with inserts	VERA109900	08719189137033
Starrsed RS LS 120V Sysmex Low profile with inserts	A0026354	08719189137774
Starrsed RS LS 120V Coulter LH750	A0026452	08719189137446
Starrsed RS LS 120V Abbot long, black	A0026461	08719189137453
Starrsed RS LS 120V Bayer (Advia)	A0026467	08719189137460
Starrsed RS LS 120V Beckman Coulter DXH-800	A0026456	08719189137293
Starrsed RS LS 230V Coulter LH750	A0026455	08719189137309
Starrsed RS LS 230V Abbot long, black	A0026463	08719189137316
Starrsed RS LS 230V Bayer (Advia)	A0026465	08719189137156
Starrsed RS LS 230V Beckman Coulter DXH-800	A0026459	08719189137163
Starrsed RS LS 230V Sysmex Low profile with inserts	VERA109910	08719189137040