

## EU DECLARATION OF CONFORMITY

RR Mechatronics Manufacturing B.V.

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

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The Netherlands

**RR Mechatronics Manufacturing B.V.**

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We declare that the:

The Semi-Automatic Erythrocyte Sedimentation Rate analyzer series:

Trade name/ Model: **Starrsed ST**

Variants:

Variant:	Product-ID (REF):	UDI-DI
<b>Starrsed ST 120V</b>	<b>A0026376</b>	<b>08719189137286</b>
<b>Starrsed ST 230V</b>	<b>BANG109000</b>	<b>08719189137026</b>

Basic UDI-DI (BUDI-DI): 8719189137CKJA7SL6

EMDN-code: W02029001 Erythrocyte sedimentation rate devices

Classification IVDR: Class A

Intended purpose: Semi-automated analyzer for in vitro determination of the Erythrocyte Sedimentation Rate (ESR) for 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:

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

The following harmonized standards have been applied:

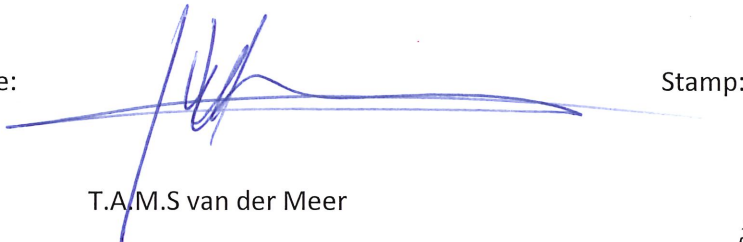
- |                         |   |
|-------------------------|---|
| EN ISO 13485:2016       | Medical devices – Quality management systems – Requirements for regulatory purposes   |
| EN ISO 14971:2012       | Medical devices – Application of risk management to medical devices   |
| EN-ISO 15223-1:2021     | 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: May 14, 2024

Signature:



Stamp:

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

Function title: CEO

RR Mechatronics Manufacturing B.V.

