RR Mechatronics
Masters of Measurement

UK 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

UK responsible Person:

Qserve Group UK Ltd.

282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom

I declare that the:

The Automatic Erythrocyte Sedimentation Rate analyzer series

Trade name/ Model: **Starrsed NSTA**

Variants:

Variant:	Product-ID (REF):	UDI-DI
Starrsed NSTA230V/ 240V	**A0030113**	**08719189137798**

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

GMDN-code: 56691 Erythrocyte sedimentation rate (ESR) analyser IVD

Classification UK MDR 2002: IVD other / Class I

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.

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is in conformity with the requirements of the Regulations:

Medical Devices Regulations 2002

The following designated 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

UK Marking in accordance with regulation 36 of the Regulations.

The UKCA mark was applied for the first time on this type of IVD instrument in 2025.

Place: Zwaag, The Netherlands

Date: June 26, 2024

Signature:

RR Mechatronics Manufacturing B.V. - RR Mechatronics International B.V. - RR Mechatronics Instruments B.V. - RR Mechatronics De Corantijn 13 1689 AM Zwaag The Netherlands

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

Function title: CEO

RR Mechatronics Manufacturing B.V.