

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 Erythrocyte Sedimentation Rate Control:

Trade name/ Model:

Starrsed Control

Variants:

Variant:	Product-ID (REF):	UDI-DI
Starrsed Control Level N	QRR049001	08719189137118
Starrsed Control Level A	QRR049002	08719189137125

Basic UDI-DI (BUDI-DI): 8719189137E4TB8YG8

EMDN-code:

Starrsed Control Level N: W0103010502 abnormal blood controls

Starrsed Control Level A: W0103010501 normal blood controls

Classification IVDR:

Class A

Intended purpose:

In-vitro diagnostic quality control material to monitor the precision of Starrsed

Erythrocyte Sedimentation Rate (ESR) instruments and procedures

is in conformity with the requirements of the following EU legislation(s):

Regulation (EU) 2017/746

In vitro diagnostic medical devices

(conformity assessment according Article 48, §10 of this regulation)

DOC-2078 F4401 DoC Starrsed Controls.v2

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Conditions: By the ORGALIME GENERAL CONDITIONS S2012 of March 2012. Any other conditions are herewith explicitly rejected by us. VAT number: NL 8557 65 392 B01 CoC Number 64657353



The following harmonized standards have been applied:

EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
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 18113-1:2011	In vitro medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN ISO 23640:2015	In vitro medical devices – Evaluation of stability of in vitro diagnostic reagents

The CE mark was applied for the first time on this type of IVD control in 2013.

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.

