

## EU DECLARATION OF CONFORMITY

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

RR Mechatronics Manufacturing B.V.

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We declare that:

The Erythrocyte Sedimentation Rate Control:

Trade name: **Starrsed Control**

Product models: see table on page 2

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)

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: March 06, 2023

Signature:

Name: Thijs van der Meer

Function title: CEO

RR Mechatronics Manufacturing B.V.

Stamp:



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This declaration is applicable to the following models:

Model name:	Product-ID (REF):	Basic UDI-DI
<b>Starrsed Control Level N tube</b>	<b>QRR049001</b>	<b>08719189137118</b>
<b>Starrsed Control Level N Blister (6*QRR049001)</b>	<b>A0026577</b>	<b>08719189137149</b>
<b>Starrsed Control Level A tube</b>	<b>QRR049002</b>	<b>08719189137125</b>
<b>Starrsed Control Level A Blister (6*QRR049002)</b>	<b>A0026578</b>	<b>08719189137170</b>

