

## 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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We declare that:

The Erythrocyte Sedimentation Rate Control:

Trade name/ Model: **Starrsed Control**

Variants:

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

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)

