

## E.C. 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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**RR Mechatronics Manufacturing B.V.**  
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We declare that:

the Automatic Erythrocyte Sedimentation Rate Analyser:

Trade name: **Starrsed TL**

Product models:

Model name:	Product-ID (REF):
<b>Starrsed TL</b>	<b>TLAX109100</b>

GMDN-code: 56691 (Erythrocyte sedimentation rate (ESR) analyser IVD, automated)  
Classification: General IVD

- Is in conformity with the requirements of the following EC directives:

**98 / 79 / EC**

**In vitro diagnostic medical devices**

(conformity assessment according Annex III of directive 98/79/EC)

**2011/65/EU**

**Restriction of the use of certain hazardous substances (RoHS 2)**

(conformity assessment according Article 7 of directive 2011/65/EU)

- The following harmonized standards have been applied:

EN 61010-2-101,	Safety requirements for electrical equipment for measurement, control and laboratory use - Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61326-2-6,	Electrical equipment for measurement, control and laboratory use - EMC requirements - Particular requirements for in vitro diagnostic (IVD) medical equipment
EN ISO 18113-3,	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
EN-ISO 15223-1,	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971,	Medical devices - Application of risk management to medical devices
EN ISO 13485,	Medical devices - Quality management systems - Requirements for regulatory purposes

The CE mark was applied for the first time on this type of product in 2015.

Place: Zwaag, The Netherlands

Date: April 12, 2018

Signature:



Konstantin Artz

Stamp:



Function title: **Manager Quality Assurance & Regulatory Affairs**  
**RR Mechatronics Manufacturing B.V.**