RR Mechatronics
Masters of Measurement

RR Mechatronics Manufacturing B.V.

P.O.Box 225
1620 AE HOORN
The Netherlands

De Corantijn 13
1689 AN ZWAAG
The Netherlands

T +31 229 291 129
www.rrmechatronics.com

E.C. 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

We declare that:

the Automatic Erythrocyte Sedimentation Rate Analyser:

Trade name: **Starrsed RS**

Product models:

Model name:	Product-ID (REF):
Starrsed RS	**VERA109900**
Starrsed RS-LS	**VERA109910**

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: Jan Buis

Stamp: RR Mechatronics Manufacturing B.V. - Mechatronics Instruments B.V. - R&R Mechatronics International B.V. - RR Mechatronics De Corantijn 13 1689 AN Zwaag The Netherlands

Function title: CEO
RR Mechatronics Manufacturing B.V.