RR Mechatronics
Masters of Measurement

EU DECLARATION OF CONFORMITY

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

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:

The Automatic Erythrocyte Sedimentation Rate analyzer series:

Trade name/ Model: **Interrliner**

Variants: see table on page 3

Basic UDI-DI (BUDI-DI): 8719189137PH257CGN

EMDN-code: W02029001 Erythrocyte sedimentation rate devices

Classification IVDR: Class A

Intended purpose: Automated analyzer for in vitro determination of the Erythrocyte Sedimentation Rate (ESR) of human blood samples in conformity with the Westergren standard.

For professional use in medical laboratories only. To be used for all patient populations, not restricted by age or any other anatomical or physiological particulars.

is in conformity with the requirements of the following EU legislations:

Regulation (EU) 2017/746 **In vitro diagnostic medical devices**

(conformity assessment according Article 48 of this regulation)

RR Mechatronics
Masters of Measurement

Directive 2011/65/EU **Restriction of the use of certain hazardous substances**

Including the amendment of Annex II; 2015/863

(conformity assessment according Article 7 of this directive)

The following (harmonized) standards have been applied:

EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN-ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 18113-3:2011	In vitro medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN IEC 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN IEC 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
EN IEC 62366-1:2008	Medical devices – Application of usability engineering to medical devices

The CE mark was applied for the first time on this type of IVD device in 2000.

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.

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

RR Mechatronics
Masters of Measurement

EU DECLARATION OF CONFORMITY

This declaration is applicable to the following system models:

Variants:	Product-ID (REF):	UDI-DI
Interrliner XN1 FRL 120V	A0026349	08719189137729
Interrliner XN1 FRL 230V	EHST109621	08719189137088
Interrliner XN1 230V	EHST109421	08719189137057
Interrliner XN2 FRL 120V	A0026350	08719189137736
Interrliner XN2 FRL 230V	EHST109622	08719189137095
Interrliner XN2, 230V	EHST109422	08719189137064
Interrliner XN3 FRL 120V	A0026351	08719189137743
Interrliner XN3 FRL 230V	EHST109623	08719189137101
Interrliner XN3 230V	EHST109423	08719189137071