

# CERTIFICATE

Number: 2078320

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## RR Mechatronics Manufacturing B.V.

De Corantijn 13  
1689 AN Zwaag  
The Netherlands

including the implementation meets the requirements of the standard:

## EN ISO 13485:2016

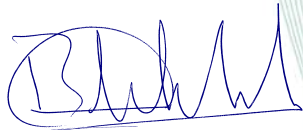
### Scope:

The design and development, manufacture and storage of in-vitro diagnostic medical devices and invitro diagnostic reagents, diluents, cleaners and controls used for the measurement of the Erythrocyte Sedimentation Rate, the measurement of erythrocyte aggregation and deformability, the detection of blood components, the preparation of IVD reagents, diluents and cleaners and the automation of specimen handling for the before mentioned device groups.

Certificate expiry date: 1 April 2026  
Certificate effective date: 28 February 2024  
Certified since: 1 February 2005

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.M. McKenzie  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed





# ADDENDUM

To certificate: 2078320

The management system of the organization(s) and/or location(s) of:

## RR Mechatronics Manufacturing B.V.

De Corantijn 13  
1689 AN Zwaag  
The Netherlands

Certified organization(s) and/or locations:

Different scope

RR Mechatronics Manufacturing B.V.  
Corantijn 23a  
1689 AN Zwaag  
The Netherlands

The storage of in-vitro diagnostic medical devices and in-vitro diagnostic reagents, diluents, cleaners and controls.

Addendum expiry date: 1 April 2026  
Addendum effective date: 28 February 2024