

CERTIFICATE

Number: 2116853

The management system of:

Sanquin Reagents B.V. Also trading as Essange Reagents

Plesmanlaan 125
1066 CX Amsterdam
The Netherlands

including the implementation meets the requirements of the standard:

ISO 13485:2016 EN ISO 13485:2016

Scope:

Design and development, manufacture, and distribution of in-vitro diagnostic devices intended to be used to determine markers of specific blood grouping systems.

Design and development, manufacture and distribution of in-vitro diagnostic devices intended to be used for the screening, confirmation, identification of infectious agents or determination of immune status.

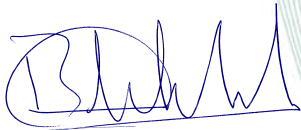
Design and development, manufacture and distribution of in-vitro diagnostic devices intended to be used for monitoring of levels of medicinal products, substances or biological components.

Provision of development services and contract manufacture of in-vitro diagnostic device reagents.

Design, development, manufacture and distribution of research use only IVD reagents.

Certificate expiry date: 1 July 2026
Certificate effective date: 19 January 2024
Certified since: 1 July 2008

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

