

CERTIFICATE

Number: 2116853

The management system of:

Sanquin Reagents B.V.
Also trading as Essange Reagents

Plesmanlaan 125
1066 CX Amsterdam
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.

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

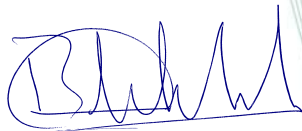
Design, development, manufacture and distribution of research use only IVD reagents

Certificate expiry date: 1 July 2029

Certificate effective date: 1 July 2026

Certified since: 1 July 2008

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



F. Godeke
Certification Manager

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