CERTIFICATE

Number: 2116853

The management system of:

Sanquin Reagents B.V.

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: 1 July 2023
Certified since: 1 July 2008

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Certification Manager

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra.nl Company registration 09085396