

CERTIFICATE

Number: 2247783

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

Sarstedt AG & Co. KG

Sarstedtstraße 1
51588 Nümbrecht
Germany

Manufacturer DUNS 388000270

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure, Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 4 - Production Quality Assurance Procedure
Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

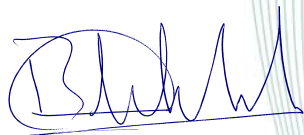
Scope:

Design and development, manufacturing and distribution of needles, lancets, containers for venous blood collection, devices for ESR, devices for capillary blood collection, containers for collection of samples from the human body, adapters, tourniquets, umbilical clamps, tissue culture supplies, transport swabs, tube strippers, heat sealers, blood tube mixers, automated devices for handling blood tubes, pipettes.

Certificate expiry date: 2023-07-01
Certificate effective date: 2020-07-15
Certified since: 2020-07-15

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.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: 2247783

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

Sarstedt AG & Co. KG

Sarstedtstraße 1
51588 Nümbrecht
Germany

Certified organization(s) and/or locations:

Different scope

Sarstedt AG & Co. KG
Sarstedtstraße 1
51588 Nümbrecht
Germany
DUNS: 388000270

Design and development, manufacturing and distribution of needles, lancets, and related accessories.

Sarstedt AG & Co. KG
Winterborner Straße
51588 Nümbrecht
Germany
DUNS: 341806855

Manufacturing of needles, lancets, and related accessories.

Sarstedt AG & Co. KG
Industriegelände 16
51674 Wiehl
Germany
DUNS: 315252492

Manufacturing of IVD containers and related accessories.

Sarstedt AG & Co. KG
Boschstraße
53359 Rheinbach
Germany
DUNS: 340202394

Manufacturing, packaging, labelling of IVD and laboratory products

Sarstedt AG & Co. KG
Ernst-Stenner-Straße 15
58675 Hemer
Germany
DUNS: 331465976

Manufacturing of IVD containers and related accessories.

Addendum expiry date: 2023-07-01

Addendum effective date: 2020-07-15