

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 Facility Identifier F004391

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 665/2022, 551/2021 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

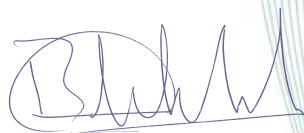
Scope:

Design and development, manufacture and distribution of blood collection needles, lancets and umbilical clamps, as well as IVD sample containers for venous and capillary blood collection and other human specimens, devices for ESR, adapters, tissue culture supplies, transport swabs, tube strippers, blood tube mixers, automated devices for handling blood tubes, and pipettes.

Certificate expiry date: 2028-07-01
Certificate effective date: 2025-07-01
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.M. McKenzie
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-checkme.com/org>

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:

Sarstedt AG & Co. KG
Sarstedtstraße 1
51588 Nümbrecht
Germany
Facility Identifier F004391

Different scope

Design and development and distribution of blood collection needles, lancets as well as umbilical clamps.

Design and development and distribution of IVD sample containers for capillary blood collection, adapters, transport swabs, tube strippers, blood tube mixers, automated devices for handling blood tubes, and pipettes.

Design and development, manufacture and distribution of IVD sample containers for venous blood collection, devices for ESR, and tissue culture supplies.

Sarstedt AG & Co. KG
Winterborner Straße
51588 Nümbrecht
Germany
Facility Identifier F004391

Manufacture of blood collection needles, IVD sample containers for capillary blood collection, and adapters for venous blood collection.

Addendum expiry date: 2028-07-01

Addendum effective date: 2025-07-01