

# 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

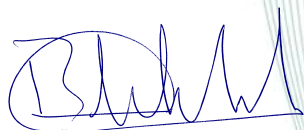
### Scope:

Design and development, manufacture and distribution of 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, umbilical clamps, tissue culture supplies, transport swabs, tube strippers, heat sealers, blood tube mixers, automated devices for handling blood tubes, pipettes and related accessories

Certificate expiry date: 2025-07-01  
Certificate effective date: 2023-07-01  
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.A. 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-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  
Facility Identifier F004391

Design and development, manufacture, and distribution of containers for venous blood collection, devices for ESR, containers for collection of samples from the human body, tissue culture supplies, and related accessories.

Design and development and distribution of needles, lancets, devices for capillary blood collection, adapters, umbilical clamps, pipettes, transport swabs, tube strippers, heat sealers, blood tube mixers, automated devices for handling blood tubes and related accessories.

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

Manufacture of needles, devices for capillary blood collection, adapters, sample containers for human specimens, general laboratory products, and related accessories.

Sarstedt AG & Co. KG  
Industriegelände 16  
51674 Wiehl  
Germany  
Facility Identifier F004391

Manufacture of IVD containers and related accessories

Sarstedt AG & Co. KG  
Boschstraße 15  
53359 Rheinbach  
Germany  
Facility Identifier F004392

Manufacture of sample containers for human specimens, general laboratory products, laboratory products suitable for in-vitro diagnostic procedures



# 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

Sarstedt AG & Co. KG  
Ernst-Stenner-Straße 15  
58675 Hemer  
Germany  
Facility Identifier F004477

Manufacture of IVD containers and related accessories.

Addendum expiry date: 2025-07-01  
Addendum effective date: 2023-07-01