

# EU Certificate

for the assessment of the  
quality management system



## according to Regulation on In-vitro Diagnostic Medical Devices (EU) 2017/746 Annex IX Chapter I+III

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the manufacturer

**SARSTEDT AG & Co. KG**

**Single Registration Number (SRN): DE-MF-000005649**

Sarstedtstraße 1, 51588 Nümbrecht, Germany

applies a quality management system according to Annex IX Chapter I+III of the regulation on in-vitro diagnostic medical devices (EU) 2017/746 for the devices listed in the annex. This certificate is based on the assessments listed in CNo50650-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 50650-70-00-00

Certificate valid from: 2024-12-12

Certificate valid to: 2026-09-23



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)

BS-IVDR-100

DEKRA Certification GmbH, Stuttgart  
Notified Body ID: 0124

# Annex to the EU Certificate no. 50650-70-00-00

Following devices/device categories are included in this certificate:

## Class A sterile

For the devices listed below, the review of the quality management system refers exclusively to the aspects relating to establishing, securing and maintaining sterile conditions.

### Product group IVR 0803:

Sample containers for human specimens  
W0501 - SAMPLE COLLECTION DEVICES

Intended use: Sample containers for human specimens for in-vitro diagnostic procedures, and related accessories

- S-Monovette®  
Basic UDI-DI: 4038917SARTD00100S4S
- S-Sedivette®:  
Basic UDI-DI: 4038917SARTD00101S4V
- Monovette®  
Basic UDI-DI: 4038917SARTD00102S4Y
- Blood-gas Monovette®  
Basic UDI-DI: 4038917SARTD00103S53
- V-Monovette® Urine  
Basic UDI-DI: 4038917SARTD01001S4Z
- V-Monovette®  
Basic UDI-DI: 4038917SARTD00900S6J

### Product group IVR 0801:

Products for general laboratory use (Liquid Handling)  
W0503 - DEVICES FOR SAMPLES ANALYSES

Intended use: Transfer of human samples or diagnostic reagents for in-vitro diagnostic procedures

- Transfer pipette  
Basic UDI-DI: 4038917SARTD09000U7S

Change(s) to previous certificate: n.a.