EU Certificate

for the assessment of the quality management system

according to Medical Device Regulation (EU) 2017/745 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 Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo50650-00.

EU Certificate no.: 50650-60-00

Certificate valid from: 2023-04-24
Certificate valid to: 2026-09-23

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

Karin Leicht
DEKRA Certification GmbH, Stuttgart, 2023-04-24
Notified Body ID number: 0124

Annex to the EU Certificate no. 50650-60-00

valid from 2023-04-24 to 2026-09-23

Revision status of the annex: 1 dated 2023-09-18

Following devices/device categories are included in this certificate:

Class IIa

- Safety-Multifly®-Needles
- Multifly®-Needles
- S-Monovette® Needles
- S-Monovette® Safety-Needles
- Micro-Needles
- Safety-Lancets

Class Is

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.

- Umbilical clamp

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Karin Leicht
DEKRA Certification GmbH, Stuttgart, 2023-09-18
Notified Body ID-number: 0124