EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex II excluding section (4)

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

SARSTEDT AG & Co. KG

Sarstedtstraße 1, 51588 Nümbrecht, Germany

Certified location:

Sarstedtstraße 1, 51588 Nümbrecht, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50650-Z5-00, the decision dated 2018-11-27 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-11-27 to 2023-09-27

Registration No.: 50650-16-02

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15 DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-11-27
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

84460

Annex to the EC Certificate No. 50650-16-02

Valid from 2018-11-27 to 2023-09-27

Revision status of the annex: 2 dated 2021-04-01

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Urine and secretion bag - sterile
- Urine Drainage-Systems - sterile
- Navel clamp - sterile

Class II a:

Blood Collection Needles:

- S-Monovette®-Needle, Safety-Needle
- Multifly®-Needle, Safety-Multifly®-Needle
- Micro-Needle

Safety Lancets:

- Safety-Lancet

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-03-05
Notified Body ID-number: 0124