

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



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

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

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

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

Revision status of the annex: 0 dated 2018-11-27

Devices/device categories included in the certificate:

Class I m / Is:

For the products listed below, the review of the Quality System refers exclusively to the manufacturing steps associated with product conformity concerning metrological requirements and aspect of manufacture concerned with securing and maintaining sterile conditions.

- Urine Measuring System UM 500

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
- Enclosed 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
- Safety-Heel®



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