



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 024492 2491 Rev. 00

Manufacturer

Fresenius Medical Care AG & Co. KGaA

61346 Bad Homburg

GERMANY

Product Category(ies):

- Tubing systems and accessories for
haemodialysis, peritoneal dialysis and
apheresis therapies
- Rinsing solutions

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

713163830_2

Valid from:

2019-11-29

Valid until:

2024-05-26

Date,

2019-11-29

Christoph Dicks

Head of Certification/Notified Body



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Facility(ies):

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Str. 1, 61352 Bad Homburg,
GERMANY