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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 077174 0007 Rev. 02

Manufacturer:

Fresenius Medical Care AG
Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY

SRN Manufacturer - DE-MF-000008193

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 077174 0007 Rev. 02

Report No.: 713315153

Preceding Certificate No.: G11 077174 0007 Rev. 01

Valid from: 2023-12-01
Valid until: 2026-12-01

Date of Initial Issuance: 2021-12-02

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-11-30

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class I
Device Group:	B0380 - APHERESIS DEVICES - ACCESSORIES
Device Properties:	MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	F900199 - PERITONAEAL DIALYSIS - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	F90040101 - HAEMODIALYSATE COLLECTION BAGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.2 - Sterilisation by irradiation

Classification:	Class I
Device Group:	F90040102 - PERITONAEAL DIALYSATE COLLECTION BAGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	V0599 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

The validity of this certificate depends on conditions and/or is limited to the following: -/-

Revision History:

Rev.	Dated	Report	Description
00	2021-12-02	713192272	-
01	2023-05-04	713264248	Supplemented: Device(s)/group of device(s) added
02	2023-12-01	713315153	Supplemented: Other

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