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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 IIa and Class IIb Devices)

No. G10 037258 0012 Rev. 02

Manufacturer:

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

SRN Manufacturer - DE-MF-000009273

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.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 037258 0012 Rev. 02

Report No.:	713301230
Preceding Certificate No.:	G10 037258 0012 Rev. 01
Valid from:	2024-03-06
Valid until:	2026-03-09
Date of Initial Issuance:	2021-07-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-03-06

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 IIa
Device Group:	A010199 - NEEDLES FOR INFUSION AND COLLECTION - OTHER A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE A020108 - ENTERAL FEEDING SYRINGES A030101 - INFUSION CONTROLLERS A030103 - ENTERAL FEEDING CONTROLLERS A030201 - EXTENSIONS A040101 - ADMINISTRATION AND ASPIRATION FILTERS A060399 - FLUID COLLECTION BAGS AND SYSTEMS - OTHER A0799 - ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS - OTHER C010101 - PERIPHERAL I.V. CATHETERS C010299 - CENTRAL VENOUS CATHETERS - OTHER G020201 - NASOGASTRIC INTESTINAL TUBES V020380 - NEWBORN NUTRITION DEVICES - ACCESSORIES V020399 - NEWBORN NUTRITION DEVICES - OTHER Z120303 - INFUSION INSTRUMENTS Z121003 - ELECTROENCEPHALOGRAPHY INSTRUMENTS
Intended Purpose:	-

Classification:	Class IIb
Device Group:	Z120303 - INFUSION INSTRUMENTS
Intended Purpose:	Infusion Pumps and Accessories for Administration of Fluids.

Classification:	Class IIb
Device Group:	Z12030382 - INFUSION INSTRUMENTS - SOFTWARE ACCESSORIES
Intended Purpose:	Software for use with Fresenius Kabi infusion devices.

Classification:	Class IIb
Device Group:	G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHER
Intended Purpose:	Long-term intragastric or intestinal feeding and gastric decompression.

The validity of this certificate depends on conditions and/or is limited to the following:	.None.

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Revision History:

Rev.	Dated	Report	Description
00	2021-07-13	713186567	-
01	2023-01-27	713208304	-
02	2024-03-06	713301230	Amended: Other

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