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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 (Implantable Class IIb Devices and Class III Devices)

No. G12 037258 0016 Rev. 01

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 certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. 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:G12 037258 0016 Rev. 01

Report No.: 713332704

Preceding Certificate No.: G12 037258 0016 Rev. 00

Valid from: 2024-07-11
Valid until: 2027-08-08

Date of Initial Issuance: 2022-08-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-07-11

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 IIb
Device Group:	G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHER
Intended Purpose:	For long-term intestinal feeding after abdominal or laparoscopic procedures

Classification:	Class IIb
Device Group:	G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHER
Intended Purpose:	Percutaneous intragastric long-term feeding and gastric decompression / drainage by gravity

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

Revision History:

Rev.	Dated	Report	Description
00	2022-08-09	713193538	-
01	2024-07-11	713332704	Supplemented: Other

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