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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 Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 037258 0025 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 drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result. Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment 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:G70 037258 0025 Rev. 02

Report No.:	713296589
Preceding Certificate No.:	G70 037258 0025 Rev. 01
Valid from:	2024-06-12
Valid until:	2027-05-16
Date of Initial Issuance:	2022-05-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-06-12

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	Class IIb
Device Group:	G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHER
Basic UDI-DI:	42502737NEN60112b00I000M3
Intended Purpose:	Percutaneous intragastric long-term feeding and gastric decompression / drainage by gravity.
Device(s):	Freka® PEG Freka® PEG Pro Set

Classification:	Class IIb
Device Group:	G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHER
Basic UDI-DI:	42502737NEN60132b00I000NH
Intended Purpose:	For long-term intestinal feeding after abdominal or laparoscopic procedures.
Device(s):	Freka® FCJ

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List of variants for Basic UDI-DI 42502737NEN60112b00I000M3 - Freka® PEG:

No.	Article number	Article name/description
1	7755642	Freka® PEG CH/FR9, ENFit
2	7755643	Freka® PEG CH/FR15, ENFit
3	7755644	Freka® PEG CH/FR20, ENFit

List of variants for Basic UDI-DI 42502737NEN60112b00I000M3 - Freka® PEG Pro Set:

No.	Article number	Article name/description
1	M90800346	Freka® PEG Pro Set FR 12
2	M90800347	Freka® PEG Pro Set FR 14
3	M90800348	Freka® PEG Pro Set FR 20
4	M90800349	Freka® PEG Pro Set FR 16

List of variants for Basic UDI-DI 42502737NEN60132b00I000NH - Freka® FCJ:

No.	Article number	Article name/description
1	7755645	Freka® FCJ FR 9, ENFit

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

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Revision History:

Rev.	Dated	Report	Description
00	2022-05-17	713193538	-
01	2023-11-16	713282784	Supplemented: Device(s)/group of device(s) added
02	2024-06-12	713296589	Supplemented: Device(s)/group of device(s) added

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