



EU DECLARATION OF CONFORMITY

Annex IX of Regulation 2017/745
according to EU certificate No. G70 037258 0025 Rev.01 and Expiration Date 2027-05-16
and EU certificate No. G12 037258 0016 Rev. 00 and Expiration Date 2027-08-08
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

Enteral Feeding Tubes Percutaneous and Accessories, Freka® PEG

Refer to attachment
(Product name)

Refer to attachment
(article number, serial number/batch number – if applicable)

Device classification according to Annex VIII, clause 5.4, rule 8

Class III - I Ib

We
Fresenius Kabi AG, Else-Kröner-Str. 1
61352 Bad Homburg, Germany
Single Registration Number (SRN): DE-MF-000009273

manufacturer of the above products, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of the Medical Device Regulation 2017/745 and any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The products comply with the general safety and performance requirements of Annex I, further applicable standards and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

Bad Homburg,
23.11.2023

Dr. Sandra Leipold,
Sr. Manager Regulatory Affairs

Place and date of issue/

Name (printed letters), position and signature of authorized person

DocuSigned by:

Signer Name: Sandra Leipold
Signing Reason: Approve this document
Signing Time: 23-Nov-2023 | 9:15 AM CET

B9645EE7DA3E453B9FA14298C5C5ABFE

Valid starting with the original date of the document until product change



Attachment to EU DECLARATION OF CONFORMITY

**Enteral Feeding Tubes Percutaneous and Accessories
Freka® PEG**

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	Serial Number/Batch Number
M90800346	Freka® PEG Pro Set FR 12	42502737NEN60112b0 0I000M3	G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHERS	Percutaneous intragastric long-term feeding and gastric decompression / drainage by gravity.	n/a
M90800347	Freka® PEG Pro Set FR 14				
M90800348	Freka® PEG Pro Set FR 20				
M90800349	Freka® PEG Pro Set FR 16				