

EU Declaration of Conformity



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EU certificate No. G10
037258 0012 Rev. 03 and Expiration Date 2031-03-09
issued by Notified Body (TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123)

Enteral Feeding Tubes Percutaneous and Accessories

Refer to attachment
(Product name)

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

Device classification according to Annex VIII, clause 5.1, rule 5

Class IIa - IIb

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 Hersfeld, 11.03.2026

Dr. Sandra Leipold,
Director Regulatory Affairs

DocuSigned by:
S. Leipold
B9645EE7DA3E453...

Place and date of issue/

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

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

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Attachment to EU DECLARATION OF CONFORMITY

**Enteral Feeding Tubes Percutaneous and Accessories
Intestinal Tubes**

Article Number	Product Name	Basic UDI-DI	Intended Purpose (include full text intended purpose of the device)	Serial Number/Batch Number (add for batch specific DoCs)
M90800350	Freka® Intestinal Tube FR 12 for Freka® PEG FR 20	42502737NEN60122b00000 0GJ	Long-term intestinal feeding or gastric decompression	n/a
M90800351	Freka® Intestinal Tube FR 9 for Freka® PEG FR 15			
M90800373	Freka® Intestinal Tube FR 9 for Freka® PEG FR 16			