

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)

Percutaneous Tubes Replacement Sets 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:

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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

Percutaneous Tubes Replacement Sets and Accessories

Article Number	Product Name	Basic UDI-DI	Intended Purpose (include full text for intended purpose of the device)	Serial Number/Batch Number (add for batch specific DoCs)
7755648	Freka® GastroTube FR15, ENFit	42502737NEN60212b000000GQ	For long-term intragastric feeding and gastric decompression for use in a healed stoma tract.	n/a
7751241	Freka® Button FR 15, 1.1 cm		Percutaneous replacement system for long-term intragastric feeding, keeping stoma tract open. For use in a healed stoma tract.	
7751251	Freka® Button FR 15, 1.4 cm			
7751261	Freka® Button FR 15, 1.7 cm			
7751271	Freka® Button FR 15, 2.0 cm			
7751281	Freka® Button FR 15, 2.5 cm			
7751291	Freka® Button FR 15, 3.0 cm			
7751301	Freka® Button FR 15, 3.5 cm			
7751311	Freka® Button FR 15, 4.0 cm			
7751321	Freka® Button FR 15, 4.5 cm			