



**EU DECLARATION OF CONFORMITY**

Annex IX, chapter I and III of Regulation 2017/745 according to EU certificate No. G10  
037258 0012 Rev. 02 and Expiration Date 2026-03-09  
issued by Notified Body (e.g. 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)

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, 15.01.2025

Dr. Sandra Leipold,  
Sr. Manager RA

Signed by:



Signer Name: Sandra Leipold

Signing Reason: I approve this document

Signature Title: Sandra Leipold

Signature Date: 15.01.2025 11:39 PM CET

Signature Hash: B9645EE7DA3E453B9FA14298C5C5ABFE

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



**Attachment to EU DECLARATION OF CONFORMITY**

**Enteral Feeding Tubes Percutaneous and Accessories**

<b>Article Number</b>	<b>Product Name</b>	<b>Basic UDI-DI</b>
M90800350	Freka® Intestinal Tube FR 12 for Freka® PEG FR 20	42502737NEN60122b000000GJ
M90800351	Freka® Intestinal Tube FR 9 for Freka® PEG FR 15	
M90800373	Freka® Intestinal Tube FR 9 for Freka® PEG FR 16	

## Certificate Of Completion

Envelope Id: 538B7622-608D-4323-8AC0-A96BE7ECF23F	Status: Completed
Subject: Complete with Docusign: 601_TF Enteral Feeding Tubes Percutaneous and Accessories_Ilb_EU DoC_NE...	
Source Envelope:	
Document Pages: 2	Signatures: 1
Certificate Pages: 5	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelopeld Stamping: Disabled	Aleksandra Dzikowska
Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna	Else-Kröner-Straße 1
	Bad Homburg v.d.H, Hessen 61352
	Aleksandra.Dzikowska@fresenius-kabi.com
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Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	1/15/2025 1:38:51 PM
Certified Delivered	Security Checked	1/15/2025 1:39:42 PM
Signing Complete	Security Checked	1/15/2025 1:39:57 PM
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