



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745
according to EU certificate No. G11 037258 0015 Rev. 01 and Expiration Date 2027-07-31
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 4.2, rule 2

Class **X** Is Im Ir


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.

Asbach, 18.08.2024

Sandra Leipold, Sr. Manager 

Signed by:

S. Leipold

Signer Name: Sandra Leipold

Signing Reason: I approve this document

Signing Time: 19. Aug. 2024 18:31 PM CEST

Signature of authorized person/
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

Article Number	Product Name	Basic UDI-DI
M90800353	Freka® Y Connector for PEG FR 20/9, 2xENFit	42502737NEN60131s000000RP
7901081	Hermann Gastrostomy Dressing Set	
7981941	Erlanger Dressing Set	

Certificate Of Completion

Envelope Id: 335F205CB7274ABABE41A862831B05DE	Status: Completed
Subject: Complete with DocuSign: 601_TF Enteral Feeding Tubes Percutaneous and Accessories_Is_EU DoC_NEN...	
Source Envelope:	
Document Pages: 2	Signatures: 1
Certificate Pages: 5	Initials: 0
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Enveloped Stamping: Disabled	Sandra Leipold
Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna	Else-Kröner-Straße 1
	Bad Homburg v.d.H, Hessen 61352
	Sandra.Leipold@fresenius-kabi.com
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8/19/2024 8:31:11 PM	Sandra.Leipold@fresenius-kabi.com	

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<p>Sandra Leipold sandra.leipold@fresenius-kabi.com Dr.</p> <p>Security Level: Email, Account Authentication (Required)</p> <p>Signature Adoption: Uploaded Signature Image Signature ID: B9645EE7-DA3E-453B-9FA1-4298C5C5ABFE Using IP Address: 130.41.105.191</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document</p>	<p>Sent: 8/19/2024 8:31:26 PM Viewed: 8/19/2024 8:31:45 PM Signed: 8/19/2024 8:32:10 PM</p>

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Status	Timestamps
Envelope Sent	8/19/2024 8:31:26 PM
Certified Delivered	8/19/2024 8:31:45 PM
Signing Complete	8/19/2024 8:32:10 PM
Completed	8/19/2024 8:32:10 PM

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