



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.

Ebersburg, 15.04.2024

Dr. Sandra Leipold,
Sr. Manager RA

DocuSigned by:

S. Leipold

Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 15-Apr-2024 | 1:19 PM CEST

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

Certificate Of Completion

Envelope Id: 2240078A5178445B998753D47FA75A28	Status: Completed
Subject: Complete with DocuSign: 600_TF enteral class I_EU DoC_NEN60011_27Mar2024_DRAFT.docx, 601_TF Ent...	
Source Envelope:	
Document Pages: 7	Signatures: 3
Certificate Pages: 5	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelopeld 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
	IP Address: 130.41.105.191

Record Tracking

Status: Original	Holder: Sandra Leipold	Location: DocuSign
4/15/2024 1:15:45 PM	Sandra.Leipold@fresenius-kabi.com	

Signer Events

Signature	Timestamp
<p>Sandra Leipold sandra.leipold@fresenius-kabi.com Dr.</p> <p>Security Level: Email, Account Authentication (Required), Login with SSO</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 I approve this document I approve this document</p>	<p>Sent: 4/15/2024 1:18:04 PM Viewed: 4/15/2024 1:18:55 PM Signed: 4/15/2024 1:19:30 PM</p>

Electronic Record and Signature Disclosure:
Accepted: 5/16/2023 2:26:44 PM
ID: 01110a25-22b3-471c-8f97-db5299a15ab8

In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
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	4/15/2024 1:18:04 PM
Certified Delivered	Security Checked	4/15/2024 1:18:55 PM
Signing Complete	Security Checked	4/15/2024 1:19:30 PM
Completed	Security Checked	4/15/2024 1:19:30 PM

Payment Events

Status

Timestamps

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, Fresenius Kabi Deutschland GmbH (CFR Part 11) (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a \$0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Fresenius Kabi Deutschland GmbH (CFR Part 11):

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: docusign.globaladmin@fresenius-kabi.com

To advise Fresenius Kabi Deutschland GmbH (CFR Part 11) of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at docusign.globaladmin@fresenius-kabi.com and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Fresenius Kabi Deutschland GmbH (CFR Part 11)

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to docusign.globaladmin@fresenius-kabi.com and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with Fresenius Kabi Deutschland GmbH (CFR Part 11)

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

- i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;
- ii. send us an email to docusign.globaladmin@fresenius-kabi.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: <https://support.docusign.com/guides/signer-guide-signing-system-requirements>.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Fresenius Kabi Deutschland GmbH (CFR Part 11) as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Fresenius Kabi Deutschland GmbH (CFR Part 11) during the course of your relationship with Fresenius Kabi Deutschland GmbH (CFR Part 11).