



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)

Percutaneous Tubes Replacement Sets and Accessories

Refer to attachment
(Product name)

Refer to attachment
(Article number)

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

Class q IIa - x 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.

Ebersburg, 30.10.2025

Dr. Sandra Leipold
Director Regulatory Affairs

Signed by:

S. Leipold



Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 30-Oct-2025 | 11:38 AM CET

Place and date of issue/

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B0645EE7DA3E462B9FA14298C5C5ABFE

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



Attachment to EU DECLARATION OF CONFORMITY

TF Percutaneous Tubes Replacement Sets and Accessories

Article Number	Product Name	Basic UDI-DI
7755648	Freka® GastroTube FR15, ENFit	42502737NEN60212b000000GQ
7751241	Freka® Button FR 15, 1.1 cm	
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	

Certificate Of Completion

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Sandra Leipold

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Agent Delivery Events

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Intermediary Delivery Events

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Certified Delivery Events

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Status

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