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 - **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, 15.04.2024 Dr. Sandra Leipold, Sr. Manager RA

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FRESENIUS KABI

Attachment to EU DECLARATION OF CONFORMITY

Enteral Feeding Tubes Percutaneous and Accessories

Article Number	Product Name	Basic UDI-DI
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	

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