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)

Percutaneous Tubes Replacement Sets 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 5.1, rule 5

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, 27.03.2024 Sandra Leipold
Sr. Manager RA

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S.Leipold
Signer Name: Sandra Leipold
Signing Reason: I approve this document
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Attachment to EU DECLARATION OF CONFORMITY

Percutaneous Tubes Replacement Sets and Accessories

Article Number	Product Name	Basic UDI-DI
7750921	Freka® Stoma Measuring Device	42502737NEN60221s000000RV

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Certificate Of Completion

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Envelope Sent	Hashed/Encrypted	3/27/2024 10:31:56 AM
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Signing Complete	Security Checked	3/27/2024 10:33:02 AM
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