FRESENIUS KABI

EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EU certificate No. G10 0372580012 Rev. 02 and Expiration Date 2026-03-09 issued by Notified Body TÜV Süd Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

Subcutaneous Cannulas

Refer to attachment
(Product name)

Refer to attachment
(article number)

Device classification according to Annex VIII, clause 5.3, rule 7

Class ☒ IIa - ☐ 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.

Bad Hersfeld,
25.08.2025

Dr. Sandra Leipold
Director Regulatory Affairs

Signed by:
S.Gipold
Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 26-Aug-2025 | 9:50 AM CEST
B9645EE7DA3F453B9FA14298C5C5ABFE

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

Subcutaneous Cannulas

Article Number	Product Name	Basic UDI-DI
8088041	Therastick® 28G * 12 mm, 60 cm	42502737NIV51312a000000YJ
8088051	Therastick® 28G * 12 mm, 80 cm	
8088071	Therastick® 28G * 8 mm, 80 cm	
8088061	Therastick® 28G * 12 mm, 110 cm	

Certificate Of Completion

Envelope Id: 198DB468-6E19-4877-90F0-AF7236AC2A45
Status: Completed
Subject: Complete with Docusign: 513_TF Subcutaneous Cannulas_EU DoC_25.08.2025.docx
Source Envelope:
Document Pages: 2
Signatures: 1
Envelope Originator:
Certificate Pages: 1
Initials: 0
Aleksandra Dzikowska
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Else-Kröner-Straße 1
EnvelopeId Stamping: Disabled
Bad Homburg v.d.H, Hessen 61352
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Aleksandra.Dzikowska@fresenius-kabi.com
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8/25/2025 10:38:20 AM
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Aleksandra.Dzikowska@fresenius-kabi.com
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Signer Events	Signature	Timestamp
Sandra Leipold Sandra.Leipold@fresenius-kabi.com Dr. Security Level: Email, Account Authentication (Required)	 Signature Adoption: Uploaded Signature Image Signature ID: B9645EE7-DA3E-453B-9FA1-4298C5C5ABFE Using IP Address: 165.85.22.142 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 8/25/2025 10:44:42 AM Viewed: 8/25/2025 1:14:41 PM Signed: 8/26/2025 9:51:06 AM

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Editor Delivery Events	Status	Timestamp

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Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

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Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	8/25/2025 10:44:42 AM
Certified Delivered	Security Checked	8/25/2025 1:14:41 PM
Signing Complete	Security Checked	8/26/2025 9:51:06 AM
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