



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EU certificate
No. G10 0372580012 Rev. 03 and Expiration Date 2031-03-09
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,
10.03.2026

Dr. Sandra Leipold
Director Regulatory Affairs

Signed by:

S. Leipold



Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 12-Mar-2026 | 9:53 AM CET

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Place and date of issue/

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Attachment to EU DECLARATION OF CONFORMITY

Subcutaneous Cannulas

Basic UDI-DI: 42502737NIV51312a000000YJ

Article Number	Product Name	Intended purpose
8088041	Therastick® 28G * 12 mm, 60 cm	Set for subcutaneous infusion
8088051	Therastick® 28G * 12 mm, 80 cm	
8088071	Therastick® 28G * 8 mm, 80 cm	
8088061	Therastick® 28G * 12 mm, 110 cm	

Certificate Of Completion

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	Bad Homburg v.d.H, Hessen 61352
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Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/10/2026 6:46:34 PM
Certified Delivered	Security Checked	3/12/2026 9:53:15 AM
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