

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

Cannula Systems

Refer to attachment
(Product name)

Refer to attachment
(article number)

Device classification according to Annex VIII, clause 5.2, rule 6

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 | 9:52 AM CET

Place and date of issue/

Name (printed letters), position and signature of authorized person/
B9645EE7DA3E453B9FA14298C5C5A8FE

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

Attachment to EU DECLARATION OF CONFORMITY

Cannula Systems

Basic UDI-DI: 42502737NIV51122a000000XF

Article Number	Product Name	Intended purpose
5036711	Ambix Safe-Can® 22G x 25mm	Special cannula for port puncture.
5036721	Ambix Safe-Can® 22G x 37mm	
5036741	Ambix Safe-Can® 20G x 37mm	
5036761	Ambix Safe-Can® 20G x 25mm 90°	
5036771	Ambix Safe-Can® 20G x 37mm 90°	
5036781	Ambix Safe-Can® 22G x 25mm 90°	
5036791	Ambix Safe-Can® 22G x 37mm 90°	
5036801	Ambix Safe-Can® 22G x 60mm	

Certificate Of Completion

Envelope Id: 75AA04DE-7973-49C0-A167-9D7BC80D3E87	Status: Completed
Subject: Complete with Docusign: 511_TF CannulaSystems_EU DoC_r6_10.03.2026.docx	
Source Envelope:	
Document Pages: 2	Signatures: 1
Certificate Pages: 4	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelopeld Stamping: Disabled	Aleksandra Dzikowska
Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna	Else-Kröner-Straße 1
	Bad Homburg v.d.H, Hessen 61352
	Aleksandra.Dzikowska@fresenius-kabi.com
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Fresenius Kabi
 Security Level: Email, Account Authentication (Required), Login with SSO

Signature Adoption: Uploaded Signature Image
 Signature ID:
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 Accepted: 1/7/2026 1:24:10 PM
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Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/10/2026 6:49:06 PM
Certified Delivered	Security Checked	3/12/2026 9:52:50 AM
Signing Complete	Security Checked	3/12/2026 9:53:03 AM
Completed	Security Checked	3/12/2026 9:53:03 AM
Payment Events	Status	Timestamps

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