

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 5.3, rule 7

Class x 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

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Attachment to EU DECLARATION OF CONFORMITY

Cannula Systems

Basic UDI-DI: 42502737NIV51112a000000WQ

Article Number	Product Name	Intended purpose
8081211	Ambix Intrastick® Safe 19Gx14mm max 21 bar/300 psi-max 5ml/s	Safety cannula system for port puncture.
8081221	Ambix Intrastick® Safe 19Gx17mm max 21 bar/300 psi-max 5ml/s	
8081231	Ambix Intrastick® Safe 19Gx20mm max 21 bar/300 psi-max 5ml/s	
8081241	Ambix Intrastick® Safe 19Gx27mm max 21 bar/300 psi-max 5ml/s	
8081251	Ambix Intrastick® Safe 20Gx10mm max 21 bar/300 psi-max 4ml/s	
8081261	Ambix Intrastick® Safe 20Gx14mm max 21 bar/300 psi-max 4ml/s	
8081271	Ambix Intrastick® Safe 20Gx17mm max 21 bar/300 psi-max 4ml/s	
8081281	Ambix Intrastick® Safe 20Gx20mm max 21 bar/300 psi-max 4ml/s	
8081291	Ambix Intrastick® Safe 20Gx27mm max 21 bar/300 psi-max 4ml/s	
8081301	Ambix Intrastick® Safe 22Gx14mm max 21 bar/300 psi-max 1,5ml/s	
8081311	Ambix Intrastick® Safe 22Gx17mm max 21 bar/300 psi-max 1,5ml/s	
8081321	Ambix Intrastick® Safe 22Gx20mm max 21 bar/300 psi-max 1,5ml/s	
8081331	Ambix Intrastick® Safe 22Gx27mm max 21 bar/300 psi-max 1,5ml/s	
8084211	Ambix NONCORstick® Safe 19Gx14mm max 21 bar/300 psi-max 5ml/s	
8084221	Ambix NONCORstick® Safe 19Gx17mm max 21 bar/300 psi-max 5ml/s	
8084231	Ambix NONCORstick® Safe 19Gx20mm max 21 bar/300 psi-max 5ml/s	
8084241	Ambix NONCORstick® Safe 19Gx27mm max 21 bar/300 psi-max 5ml/s	
8084251	Ambix NONCORstick® Safe 19Gx35mm max 21 bar/300 psi-max 5ml/s	

Article Number	Product Name	Intended purpose
8084261	Ambix NONCORstick® Safe 20Gx14mm max 21 bar/300 psi-max 4ml/s	
8084265	Ambix NONCORstick® Safe 20Gx10mm max 21 bar/300 psi-max 4ml/s	
8084271	Ambix NONCORstick® Safe 20Gx17mm max 21 bar/300 psi-max 4ml/s	
8084281	Ambix NONCORstick® Safe 20Gx20mm max 21 bar/300 psi-max 4ml/s	
8084291	Ambix NONCORstick® Safe 20Gx27mm max 21 bar/300 psi-max 4ml/s	
8084295	Ambix NONCORstick® Safe 20Gx35mm max 21 bar/300 psi-max 4ml/s	
8084301	Ambix NONCORstick® Safe 22Gx14mm max 21 bar/300 psi-max 1,5ml/s	
8084311	Ambix NONCORstick® Safe 22Gx17mm max 21 bar/300 psi-max 1,5ml/s	
8084321	Ambix NONCORstick® Safe 22Gx20mm max 21 bar/300 psi-max 1,5ml/s	
8084331	Ambix NONCORstick® Safe 22Gx27mm max 21 bar/300 psi-max 1,5ml/s	
8084341	Ambix NONCORstick® Safe 22Gx35mm max 21 bar/300 psi-max 1,5ml/s	
M20830010	Ambix Intrastick® Safe 20G x 24mm max 21 bar/300 psi-max 4ml/s	
M20830015	Ambix Intrastick® Safe 19G x 24mm max 21 bar/300 psi-max 5ml/s	
M20830020	Ambix Intrastick® Safe 22G x 24mm max 21 bar/300 psi-max 1,5ml/s	
M20830025	Ambix NONCORstick® Safe 20Gx24mm max 21 bar/300 psi-max 4ml/s	
M20830030	Ambix NONCORstick® Safe 22Gx24mm max 21 bar/300 psi-max 1,5ml/s	
M20830035	Ambix NONCORstick® Safe 19Gx24mm max 21 bar/300 psi-max 5ml/s	

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