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

Urology

Refer to attachment
(Product name)

Refer to attachment
(article number)

Device classification according to Annex VIII, clause 4.2, rule 2

Class ☒ 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.

Bad Hersfeld,
07.05.2025

Dr. Sandra Leipold
Director Regulatory Affairs

Signed by:
S. Leipold
Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 08-May-2025 | 10:47 AM CEST
B9645EE7DA3E453B9FA14298C5C5ABFE

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

Urology

Article Number	Product Name	Basic UDI-DI
2841001	Bladder Syringe Filling Set	42502737NUR70121s000000LU
2884021	Transfer Set 5 D	
2884091	Transfer Set 4 D	
2881061	Spike Adaptor	42502737NUR70211s000000M2
2881501	Care-Lock® Injection-site Adaptor	

Certificate Of Completion

Envelope Id: BB97D7B4-65CD-40C3-93AE-3D8938D4E245
Status: Completed
Subject: Complete with Docusign: 701_TF Urology_EU DoC_Is_r2_07.05.2025.docx
Source Envelope:
Document Pages: 2
Signatures: 1
Envelope Originator:
Certificate Pages: 5
Initials: 0
Aleksandra Dzikowska
AutoNav: Enabled
Else-Kröner-Straße 1
EnvelopeId Stamping: Disabled
Bad Homburg v.d.H, Hessen 61352
Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna
Aleksandra.Dzikowska@fresenius-kabi.com
IP Address: 10.111.40.7

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Aleksandra.Dzikowska@fresenius-kabi.com
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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: 137.83.243.76 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 5/7/2025 8:30:48 AM Viewed: 5/8/2025 10:46:54 AM Signed: 5/8/2025 10:47:10 AM

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ID: 01110a25-22b3-471c-8f97-db5299a15ab8

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Intermediary Delivery Events	Status	Timestamp

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	5/7/2025 8:30:48 AM
Certified Delivered	Security Checked	5/8/2025 10:46:54 AM
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