



**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,  
13.03.2025

Dr. Sandra Leipold  
Director  
Regulatory Affairs

Signed by:



Signer Name: Sandra Leipold  
Signing Reason: I approve this document  
Signing Time: 13-Mar-2025 | 9:19 AM CET

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**

<b>Article Number</b>	<b>Product Name</b>	<b>Basic UDI-DI</b>
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: AC0AC8AB-A6C0-4A14-B42D-1D3E975B085D	Status: Completed
Subject: Complete with Docusign: 701_TF Urology_EU DoC_Is_r2_13.03.2025.docx	
Source Envelope:	
Document Pages: 2	Signatures: 1
Certificate Pages: 5	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
	IP Address: 165.85.22.142

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Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/13/2025 9:16:43 AM
Certified Delivered	Security Checked	3/13/2025 9:19:31 AM
Signing Complete	Security Checked	3/13/2025 9:22:20 AM
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