



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,
10.12.2025

Dr. Sandra Leipold
Director Regulatory Affairs

Signed by:

S. Leipold



Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 10-Dec-2025 | 12:46 PM 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

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	
2881011	Care-Lock® Adaptor	

Certificate Of Completion

Envelope Id: 83F582A5-928B-4E64-A27C-1FF090190D7D

Status: Completed

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Source Envelope:

Document Pages: 2

Signatures: 1

Envelope Originator:

Certificate Pages: 1

Initials: 0

Aleksandra Dzikowska

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Else-Kröner-Straße 1

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Signer Events

Sandra Leipold

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Dr.

Security Level: Email, Account Authentication (Required), Login with SSO

Signature

Signature Adoption: Uploaded Signature Image

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Editor Delivery Events

Status

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Agent Delivery Events

Status

Timestamp

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

12/10/2025 12:41:25 PM

Certified Delivered

Security Checked

12/10/2025 12:46:40 PM

Signing Complete

Security Checked

12/10/2025 12:46:56 PM

Completed

Security Checked

12/10/2025 12:46:56 PM

Payment Events

Status

Timestamps