



## 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 1

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:  
  
Signer Name: Sandra Leipold  
Signing Reason: I approve this document  
Signing Time: 10-Dec-2025 | 12:47 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              |
|----------------|--------------------------|---------------------------|
| 2843501        | Nephrostomy Drainage Bag | 42502737NUR70121s000000LU |
| 2890951        | Endoscopy Drainage Tube  |                           |
| 2885501        | Perineal Drape           |                           |

## Certificate Of Completion

Envelope Id: 0DC0449F-2F81-4488-9B85-62C60A3177FE

Status: Completed

Subject: Complete with Docusign: 701\_TF Urology\_EU DoC\_Is\_r1\_10.12.2025.docx

Source Envelope:

Document Pages: 2

Signatures: 1

Envelope Originator:

Certificate Pages: 1

Initials: 0

Aleksandra Dzikowska

AutoNav: Enabled

Else-Kröner-Straße 1

Envelopeld 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: 165.85.22.142

## Record Tracking

Status: Original

Holder: Aleksandra Dzikowska

Location: DocuSign

12/10/2025 12:37:53 PM

Aleksandra.Dzikowska@fresenius-kabi.com

## Signer Events

Sandra Leipold

Sandra.Leipold@fresenius-kabi.com

Dr.

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

## Signature

Signature Adoption: Uploaded Signature Image

Signature ID:

B9645EE7-DA3E-453B-9FA1-4298C5C5ABFE

Using IP Address: 165.85.22.142

With Signing Authentication via Docusign password

With Signing Reasons (on each tab):

I approve this document

## Timestamp

Sent: 12/10/2025 12:40:00 PM

Viewed: 12/10/2025 12:47:08 PM

Signed: 12/10/2025 12:47:22 PM

## Electronic Record and Signature Disclosure:

Not Offered via Docusign

## In Person Signer Events

## Signature

## Timestamp

## Editor Delivery Events

## Status

## Timestamp

## 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 12:40:00 PM

Certified Delivered

Security Checked

12/10/2025 12:47:08 PM

Signing Complete

Security Checked

12/10/2025 12:47:22 PM

Completed

Security Checked

12/10/2025 12:47:22 PM

## Payment Events

## Status

## Timestamps