



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,
18.12.2024

Nicole Biehl
Director Regulatory Affairs & Post
Market Surveillance

Signed by:

Signer Name: Nicole Biehl

Signing Reason: I approve this document

Signing Time: 19-Dez-2024 | 10:00 AM

601E0895EFE8489FADCF7042853A

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