



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EU certificate
No. G10 0372580012 Rev. 03 and Expiration Date 2031-03-09
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 IIa - IIb

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,
10.03.2026

Dr. Sandra Leipold
Director Regulatory Affairs

Signed by:
S. Leipold
 Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 12-Mar-2026 | 9:53 AM CET
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Place and date of issue/

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Attachment to EU DECLARATION OF CONFORMITY

Urology

Basic UDI-DI: 42502737NUR70112a000000B6

Article Number	Product Name	Intended purpose
2847001	Setback valve	For flow control of irrigation solution
2848011	Twin Transfer Set 2 D/X - double sterile	Set for transfer of irrigation solution
2848021	Transfer Set 4 D/X - double sterile	
2877001	Twin Transfer Set 1 D/X - double sterile	
2877101	Transfer Set 1 D/X - double sterile	
2877201	Transfer Set 2 D/X - double sterile	
2877501	Transfer Set 2 CL/X - double sterile	
2877621	Twin Transfer Set 2 CL/X - double sterile	
2877651	Twin Transfer Set 3 CL/X - double sterile	
2877701	Transfer Set 1 CL/X - double sterile	
2881001	Transfer Set 1 CL	
2881021	Transfer Set 5 CL	
2881081	Transfer Set 2 CL	
2881101	Twin Transfer Set 1 CL	
2883101	Transfer Set 1 D	
2881131	Twin Transfer Set 4 CL	
2881201	Twin Transfer Set 2 CL	
2881301	Twin Transfer Set 3 CL	
2883111	Transfer Set 9 D	
2883131	Cystoscopy Transfer Set	
2883401	Transfer Set 3 D	
2883711	Transfer Set 10 CL/X - double sterile	
2884101	Twin Transfer Set 3 D	
2884201	Transfer Set 6 D	

Article Number	Product Name	Intended purpose
2890101	Twin Transfer Set 2 D	
2890111	Twin Transfer Set 2a CL	
2890401	Twin Transfer Set 6 D	
2890601	Twin Transfer Set 8 D	
2890701	Twin Transfer Set 9 D	
2894201	Twin Transfer Set 1 D	

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Envelope Sent	Hashed/Encrypted	3/10/2026 6:45:36 PM
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