

**EU DECLARATION OF CONFORMITY**

Annex IX, chapter I and III of Regulation 2017/745 according to EU certificate  
No. G10 0372580012 Rev. 02 and Expiration Date 2026-03-09  
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, 15.10.2024

Dr. Sandra Leipold  
Senior Manager Regulatory Affairs

Place and date of issue/

Name (printed letters), position and signature of authorized person/

Signed by:



Signer Name: Sandra Leipold

Signing Reason: I approve this document

Signing Time: 15 Oct 2024 | 3:46 PM CEST

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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
2848011	Twin Transfer Set 2 D/X - double sterile	42502737NUR70112a000000B6
2848021	Transfer Set 4 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	
2883111	Transfer Set 9 D	
2883131	Cystoscopy Transfer Set	
2883401	Transfer Set 3 D	
2883711	Transfer Set 10 CL/X - double sterile	
2884201	Transfer Set 6 D	
2890101	Twin Transfer Set 2 D	
2890111	Twin Transfer Set 2a CL	
2890401	Twin Transfer Set 6 D	
2890701	Twin Transfer Set 9 D	