

## **EU DECLARATION OF CONFORMITY**

Annex IX, chapter I and III of Regulation 2017/745 according to  
EC-certificate No. G10 037258 0012 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

IV Extension Lines

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.

Signed by:

*S. Leipold*



Signer Name: Sandra Leipold  
Signing Reason: I approve this document  
Signing Time: 26-Nov-2025 | 2:40 PM CET

B9645EE7DA3E453B9FA14298C5C5ABFE

Bad Hersfeld

Place and date of issue/

Dr. Sandra Leipold, Director Regulatory Affairs

Valid starting with the original date of the document until product change

**Attachment to EU DECLARATION OF CONFORMITY**

**IV Extension Lines**

**Generic Device Group: Extensions**

Article Number	Product Name	Basic UDI-DI
M78401045Y	K-Zero Extension	42502737NIV50212a000000WN
M78415240	Infusion Set PE	
9004172	Injectomat Line PE, 150 cm, light-protected, yellow	
9004192	Injectomat Line PE, 150 cm, light-protected, black	
9004112	Injectomat Line PE, 50 cm	
9004132	Injectomat Line PE, 150 cm	
9004142	Injectomat Line PE, 200 cm	
9004152	Injectomat Line PE, 250 cm	
9004162	Injectomat Line PE, 300 cm	
9004242	Injectomat Line PVC, 150 cm	
9004442	Injectomat Line PVC 250cm	
9014342	Injectomat Line PVC, 200 cm	
Z072039F	Extension ASV Y BCV	
9004182	PE, 100 cmPE, 200 cm, light-protected, yellow	
9004222	Injectomat Line PVC, 200 cm, light-protected, yellow	
9004212	Injectomat Line PVC, 150 cm, light-protected, yellow	
9000973	Injectomat Line PVC, 150 cm, Fine Dosing	

Article Number	Product Name	Basic UDI-DI
9004122	Injectomat Line PE, 100 cm	42502737NIV50212a000000WN
9004312	Injectomat-Line PE, Back Check Valve, 150cm	
9004149	Injectomat Line PVC, 200 cm, Anti Siphon Valve	
9004155	Injectomat Line TIVA Twin ASV	
9004163	Injectomat Line TIVA Twin Y BCV, ASV	
9001515	Spiral Line PE 600 cm LLm/f	
9001516	Spiral Line PE 150 cm LLm/f	
Z072025F	Extension Y BCV	