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 x 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.

DocuSigned by:
S. Gipold
B9645EE7DA3E453...

Ebersburg, 09.09.2025

Place and date of issue/ Dr. Sandra Leipold, Director Regulatory Affairs

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

FRESENIUS KABI

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	