FRESENIUS KABI

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 (e.g. TÜV Süd Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123)

Transfusion Sets

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.

19-Mar-2024

DocuSigned by:
S. Gipold
B9645EE7DA3E453...

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

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

FRESENIUS KABI

Attachment to EU DECLARATION OF CONFORMITY

TF Transfusion Sets
Generic Devices: Volumat Lines, MS-Sets

Article Number	Product Name	Basic UDI-DI
M46442700Y	VL TR12 Transfusion	42502737NIV50312a000000XK
M46442900Y	VL TR42 Transfusion	42502737NIV50312a000000XK
M46443000Y	VL TR22 Transfusion	42502737NIV50312a000000XK
M46443100Y	VL SP22 2 Spikes	42502737NIV50312a000000XK
M46444500Y	VL TR43 Transfusion	42502737NIV50312a000000XK
M46446200Y	VL TR21 Transfusion	42502737NIV50312a000000XK