



## **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 ☒ 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:

A handwritten signature in blue ink, appearing to read 'S. Leipold', is written over a blue curved line that connects to the 'Signed by:' text.



Signer Name: Sandra Leipold  
Signing Reason: I approve this document  
Signing Time: 18-Dec-2025 | 9:11 AM CET

Ebersburg, 18.12.2025

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Place and date of issue/

Sandra Leipold, Director Regulatory Affairs

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



**Attachment to EU DECLARATION OF CONFORMITY**

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

Article Number	Product Name	Basic UDI-DI
M46442700Y	VL TR 12 Transfusion	42502737NIV50312a000000XK
M46442900Y	VL TR 42 Transfusion	42502737NIV50312a000000XK
M46443000Y	VL TR 22 Transfusion	42502737NIV50312a000000XK
M46443100Y	VL SP 22 Transfusion, 2 Spikes	42502737NIV50312a000000XK
M46444500Y	VL TR 43 Transfusion	42502737NIV50312a000000XK
M46446200Y	VL TR 21 Transfusion	42502737NIV50312a000000XK
M46442800S	VL TR 00 Transfusion	42502737NIV50312a000000XK
M46443160	VL SP 22-0 Transfusion, 2 Spikes	42502737NIV50312a000000XK
Z072850F	MS 50 T Transfusion	42502737NIV50312a000000XK
M46443165	VL SP 22-00, 2 spikes	42502737NIV50312a000000XK
M46442860	VL TR 00-0 Transfusion	42502737NIV50312a000000XK