



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)

Infusion Sets Pressure

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.

Asbach, 22.04.2025

Place and date of issue/

SLipold

Sandra Leipold, Director Regulatory Affairs

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



Attachment to EU DECLARATION OF CONFORMITY

TF Infusion Sets Pressure
Generic Devices: Volumat Lines, MS-Sets, K-Zero,
Infudrop/VS Sets

Article Number	Product Name	Basic UDI-DI
M46441900Y	VL ST02	42502737NIV50112a000000VR
M46441980Y	VL ST02-ND	42502737NIV50112a000000VR
M46442500Y	VL ST22	42502737NIV50112a000000VR
M46442600Y	VL ST42	42502737NIV50112a000000VR
M46443400Y	VL SP62 PUR material	42502737NIV50112a000000VR
M46443600Y	VL SP92 PUR material, blue tubing	42502737NIV50112a000000VR
M46443900Y	VL ON11	42502737NIV50112a000000VR
M46444000Y	VL ON42 PUR material	42502737NIV50112a000000VR
M46444001Y	VL ON401 PUR material	42502737NIV50112a000000VR
M46444080Y	VL ON42 OP NF Light-protected, PUR material	42502737NIV50112a000000VR
M46444100Y	VL ON72 PUR material	42502737NIV50112a000000VR
M46444230Y	VL ON22 OP NF Light-protected, PUR material	42502737NIV50112a000000VR
M46444400Y	VL PN02	42502737NIV50112a000000VR
M46444901Y	VL ON91 Light-protected, PUR material	42502737NIV50112a000000VR
M46445200Y	VL PA92 Paediatric, burette set	42502737NIV50112a000000VR
M46445801Y	VL ON42 OP PUR material	42502737NIV50112a000000VR
M46446000Y	VL ON22 OP Light-protected, PUR material	42502737NIV50112a000000VR
M79400849Y	K-Zero®	42502737NIV50112a000000VR
M46443200Y	VL ST44	42502737NIV50112a000000VR
M46442200Y	VL PA02 Paediatric	42502737NIV50112a000000VR
M46444904	VL SP91-PE, PE-lined fluid path (Polyethylene)	42502737NIV50112a000000VR
M46444350	VL PN93 Light-protected	42502737NIV50112a000000VR
M46444815	VL ON17 PUR material	42502737NIV50112a000000VR

Article Number	Product Name	Basic UDI-DI
M46444200Y	VL ON22 PUR material	42502737NIV50112a000000VR
M46444235Y	VL ON22 OP NF Light-protected, PUR material	42502737NIV50112a000000VR
M46430550Y	MS 31	42502737NIV50112a000000VR
M46444051Y	VL ON42 FX PUR material, freeflex spike	42502737NIV50112a000000VR
M46444061Y	VL ON42 SC PUR material, 3-way-stopcock	42502737NIV50112a000000VR
M46444071Y	VL ON42 OP SC Light-protected, PUR material, 3-way-stopcock	42502737NIV50112a000000VR
M46444085Y	VL ON42 OP NF Light-protected, PUR material	42502737NIV50112a000000VR
M46444251Y	VL ON22 FX PUR material, freeflex spike	42502737NIV50112a000000VR
M46444700Y	VL ON21	42502737NIV50112a000000VR
M46444800Y	VL ON12 PUR material	42502737NIV50112a000000VR
M46444850Y	VL ON12 FX PUR material, freeflex spike	42502737NIV50112a000000VR
M46444904Y	VL SP91-PE PE-lined fluid path (Polyethylene)	42502737NIV50112a000000VR
M46441920Y	VL ST02 AirBlock	42502737NIV50112a000000VR
M46442520Y	VL ST22 AirBlock	42502737NIV50112a000000VR
M46442620Y	VL ST42 AirBlock	42502737NIV50112a000000VR
M46443800Y	VL PA93 Paediatric, burette set	42502737NIV50112a000000VR
M46443510	VL SP90 AirBlock PUR material	42502737NIV50112a000000VR
M46444084	VL ON42 OP NF AirBlock PUR material, light-protected	42502737NIV50112a000000VR
M46444210	VL ON22 AirBlock PUR material	42502737NIV50112a000000VR
M46444234	VL ON22 OP NF AirBlock PUR material, light-protected	42502737NIV50112a000000VR
M46444315	VL PN00 AirBlock 1.2 micron filter	42502737NIV50112a000000VR
M46444610	VL ON70 AirBlock PUR material, 0.2 micron filter	42502737NIV50112a000000VR
M46444810	VL ON72 AirBlock PUR material, 0,2 micron filter	42502737NIV50112a000000VR
M46444910	VL ON90 AirBlock PUR material, light-protected	42502737NIV50112a000000VR
M46445300Y	VL PA94 Paediatric, burette set	42502737NIV50112a000000VR
M46444370	VL PN95	42502737NIV50112a000000VR
M46444380	VL PN96	42502737NIV50112a000000VR
M46443500S	VL SP 90	42502737NIV50112a000000VR
Z072810F	MS 10 DEHP-FREE	42502737NIV50112a000000VR
M46441620	VL ST01 AirBlock	42502737NIV50112a000000VR
M46441320	VL ST10 AirBlock	42502737NIV50112a000000VR

Article Number	Product Name	Basic UDI-DI
M46441020	VL ST00 AirBlock	42502737NIV50112a000000VR
M46445665	VL PR42-11	42502737NIV50112a000000VR
M46445695	VL PR42-12	42502737NIV50112a000000VR
M46445865	VL PR72-11, 0.2 micron filter	42502737NIV50112a000000VR
M46441300S	VL ST10	42502737NIV50112a000000VR
M46441395	VL SP10-PE PE-lined fluid path (Polyethylene)	42502737NIV50112a000000VR
M46441995	VL SP02-PE PE-lined fluid path (Polyethylene)	42502737NIV50112a000000VR
M46444495	VL SP42-PE PE-lined fluid path (Polyethylene)	42502737NIV50112a000000VR
M46445495	VL SP40-11-PE PE-lined fluid path (Polyethylene)	42502737NIV50112a000000VR
M46441000S	VL ST00 standard	42502737NIV50112a000000VR
M46444600S	VL ON70 Oncology, PP material	42502737NIV50112a000000VR
M46444900S	VL ON90 Light-protected	42502737NIV50112a000000VR
M46441960	VL ST 02-0	42502737NIV50112a000000VR
M46441985	VL ST 02-X0, non-siliconized spike	42502737NIV50112a000000VR
M46442460	VL PN02-1, 1.2 micron filter	42502737NIV50112a000000VR
M46443450	VL SP 62-1, PUR material	42502737NIV50112a000000VR
M46444160	VL ON 72-1, PUR material, 0.2 micron filter	42502737NIV50112a000000VR
M46444175	VL ON 72-X1, PUR material, 0.2 micron filter	42502737NIV50112a000000VR
M46445260	VL PA 92-1, paediatric, burette set	42502737NIV50112a000000VR
M46445270	VL PA 92-2, paediatric, burette set	42502737NIV50112a000000VR
M46445475	VL SP 40-11, PUR material	42502737NIV50112a000000VR
M46445660	VL PR 42-11	42502737NIV50112a000000VR
M46445670	VL PR 42-21	42502737NIV50112a000000VR
M46445690	VL PR 42-12	42502737NIV50112a000000VR
M46445780	VL PR 44-12	42502737NIV50112a000000VR
M46445860	VL PR 72-11	42502737NIV50112a000000VR
M46444083	VL ON42 OP NF PE Light-protected, PE-lined fluid path (Polyethylene)	42502737NIV50112a000000VR
M46444233	VL ON22 OP NF PE Light-protected, PE-lined fluid path (Polyethylene)	42502737NIV50112a000000VR
2886300	Infudrop FX-P S	42502737NIV50112a000000VR