



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EU certificate No. G10
0372580012 Rev. 03 and Expiration Date 2031-03-09
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.

Bad Hersfeld, 12.03.2026

Place and date of issue/



Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 12-Mar-2026 | 11:25 AM CET

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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
Intended Purpose: IV administration set for infusion
pumps
Basic UDI-D: 42502737NIV50112a000000VR

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

Article Number	Product Name
M46444350	VL PN93 Light-protected
M46444815	VL ON17 PUR material
M46444200Y	VL ON22 PUR material
M46444235Y	VL ON22 OP NF Light-protected, PUR material
M46430550Y	MS 31
M46444051Y	VL ON42 FX PUR material, freeflex spike
M46444061Y	VL ON42 SC PUR material, 3-way-stopcock
M46444071Y	VL ON42 OP SC Light-protected, PUR material, 3-way-stopcock
M46444085Y	VL ON42 OP NF Light-protected, PUR material
M46444251Y	VL ON22 FX PUR material, freeflex spike
M46444700Y	VL ON21
M46444800Y	VL ON12 PUR material
M46444850Y	VL ON12 FX PUR material, freeflex spike
M46444904Y	VL SP91-PE Light-protected, PE-lined fluid path (Polyethylene)
M46441920Y	VL ST02 AirBlock
M46442520Y	VL ST22 AirBlock
M46442620Y	VL ST42 AirBlock
M46443800Y	VL PA93 Paediatric, burette set
M46443510	VL SP90 AirBlock PUR material
M46444084	VL ON42 OP NF AirBlock PUR material, light-protected
M46444210	VL ON22 AirBlock PUR material
M46444234	VL ON22 OP NF AirBlock PUR material, light-protected
M46444315	VL PN00 AirBlock 1.2 micron filter
M46444610	VL ON70 AirBlock PUR material, 0.2 micron filter
M46444810	VL ON72 AirBlock PUR material, 0,2 micron filter
M46444910	VL ON90 AirBlock PUR material, light-protected
M46445300Y	VL PA94 Paediatric, burette set
M46444370	VL PN95 Light-protected
M46444380	VL PN96 Light-protected
M46443500S	VL SP 90
Z072810F	MS 10 DEHP-FREE
M46441620	VL ST01 AirBlock

Article Number	Product Name
M46441320	VL ST10 AirBlock
M46441020	VL ST00 AirBlock
M46445665	VL PR42-11
M46445695	VL PR42-12
M46445865	VL PR72-11, 0.2 micron filter
M46441300S	VL ST10
M46441395	VL SP10-PE PE-lined fluid path (Polyethylene)
M46441995	VL SP02-PE PE-lined fluid path (Polyethylene)
M46444495	VL SP42-PE PE-lined fluid path (Polyethylene)
M46445495	VL SP40-11-PE PE-lined fluid path (Polyethylene)
M46441000S	VL ST00 standard
M46444600S	VL ON70 Oncology, PP material
M46444900S	VL ON90 Light-protected
M46441960	VL ST 02-0
M46441985	VL ST 02-X0, non-siliconized spike
M46442460	VL PN02-1, 1.2 micron filter
M46443450	VL SP 62-1, PUR material
M46444160	VL ON 72-1, PUR material, 0.2 micron filter
M46444175	VL ON 72-X1, PUR material, 0.2 micron filter
M46445260	VL PA 92-1, paediatric, burette set
M46445270	VL PA 92-2, paediatric, burette set
M46445475	VL SP 40-11, PUR material
M46445660	VL PR 42-11
M46445670	VL PR 42-21
M46445690	VL PR 42-12
M46445780	VL PR 44-12
M46445860	VL PR 72-11
M46444083	VL ON42 OP NF PE Light-protected, PE-lined fluid path (Polyethylene)
M46444233	VL ON22 OP NF PE Light-protected, PE-lined fluid path (Polyethylene)
2886300	Infudrop FX-P S
Z072890F	OP MS Light-protected

Article Number	Product Name
8590982	TIVA-Drop P