

EG-Konformitätserklärung

EC DECLARATION OF CONFORMITY

Annex II excluding (4) of Directive 93/42/EEC
according to EC-certificate No. G1 04 7402 0083
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, CE0123

Anhang II ausschließlich (4) der Richtlinie 93/42/EWG
entsprechend EG-Zertifikat Nr. G1 047402 0083
ausgestellt durch die Benannte Stelle TÜV Süd Product Service GmbH,
Ridlerstraße 65, 80339 München, Deutschland, CE0123

Infusion Sets Pressure

(Product name / Produktname)

See attached list / siehe beigefügte Liste
(Article number / Artikelnummer)

Class / Klasse IIa - IIb

We / Wir

Fresenius Kabi AG
61346 Bad Homburg, Germany

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 Directive 93/42/EEC, as amended by 2007/47/EC, and its transposition into national laws. The products comply with the essential 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.

Hersteller der oben genannten Produkte, erklären hiermit in unserer alleinigen Verantwortung für diese Konformitätserklärung, dass die oben aufgeführten Produkte mit allen relevanten Anforderungen der Direktive 93/42/EWG, geändert durch 2007/47/EG und deren Umsetzung in nationale Gesetze übereinstimmen. Die Produkte erfüllen die Anforderungen des Anhangs I sowie die Anforderungen der weiteren anwendbaren Standards und normativen Dokumente, wie in der anwendbaren technischen Dokumentation aufgeführt. Alle unterstützenden Dokumente werden in den Räumlichkeiten des Herstellers aufbewahrt.

Bad Homburg 01.02.2023

Place and date of issue/
Ort und Datum der Ausstellung

S. Leipold

Dr. Sandra Leipold, Senior Manager Regulatory Affairs
Name (printed letters), position and signature of authorized person/
Name (Blockschrift), Position und Unterschrift der autorisierten Person

Valid starting with the original date of the document until product change
Gültig ab Ausstellungsdatum bis Produktänderung
Expiry date of Certificate: 26. May 2024

List of Infusion Sets Pressure

Article Code	Article Name
2886100	Infudrop FX-P
2886200	Infudrop FX-P S Y
2886262	Infudrop Air matic P, 200 cm
2886300	Infudrop FX-P S
2886312	Infudrop Air Matic P
2886331	Infudrop Air matic P-RS, 240cm
2886342	Infudrop Air matic P-RS, with reflux valve
2886342AP	Infudrop Air matic P-RS, with reflux valve
2886342CB	Infudrop Air matic P-RS, with reflux valve
2886362	Infudrop Air M-P, 175 cm
2886363	Infudrop Air 18 M-P, 175 cm
2886372	Infudrop Air M-P, 150 cm
2886382	Infudrop Air M-P, 230 cm
2886402	Infudrop Air M-P, 175 cm
2886432	Infudrop Air-Nitro P, DEHP-free, light-protect.w/o inject.
2886442	Infudrop 18V92 Luer Lock
2886462	Infudrop Air M-P, PVC-free, 150 cm
2886472	Infudrop Air M-P, PVC-free, 240 cm
2886512	Infudrop Air M-P RS-DWH + 10 cm
2886522	Infudrop Air M-PY, with Y-injection port
2886532	Infudrop Air 21 P
2886532AP	Infudrop Air 21 P
2886542	Infudrop Air 21 P, 230 cm
2886542AP	Infudrop Air 21 P, 230 cm
2886544	Infudrop Air P P
2886552	Infudrop Air 21 P-RS, with reflux valve
2886562	Infudrop Air 21 P-Y LLM
2886572	Infudrop Air 21 P LLM
2886582	Infudrop Air 21 P 3V LLM
2886592	Infudrop Air 21 P-Y 3V LLM
2886600	Infudrop FX-P PVC-free
2886700	Infudrop FX-P compact
2886800	Infudrop FX-P S compact
2886900	Infudrop FX-P S compact PVC free
2892098	Ambix activ Set stationary
2892100	Ambix activ set ambulatory SF
8590982	TIVA-Drop Air matic P
8590982CB	TIVA-Drop Air matic P
9001371	Intradrop Air VS, 250cm
9001381	Intradrop-Air VSY
9801371	Intradrop-Air VS Lipid
M46441000	Infusion Set VL ST 00
M46441000S	Infusion Set VL ST 00
M46441000SAP	Infusion Set VL ST 00
M46441000SCB	Infusion Set VL ST 00
M46441300S	Infusion Set VL ST 10
M46441360	Infusion Set VL ST 10-0 (USA)

Article Code	Article Name
M46441375	Infusion Set VL ST10-X0 (NAM)
M46441600	Infusion Set VL ST 01
M46441600S	Infusion Set VL ST 01
M46441900	Infusion Set VL ST 02
M46441900S	Infusion Set VL ST 02
M46441900SAP	Infusion Set VL ST 02
M46441950	Infusion Set VL ST 02 (Taiwan)
M46441960	Infusion Set VL ST 02-0 (USA)
M46441980	Infusion Set VL ST 02 ND
M46441980AP	Infusion Set VL ST 02 ND
M46441985	Infusion Set VL ST02-X0 (NAM)
M46442200S	Infusion Set VL PA 02
M46442300S	Infusion Set VL PN00 FX
M46442460	Infusion Set VL PN 02-1 (USA)
M46442500S	Infusion Set VL ST 22
M46442600S	Infusion Set VL ST 42
M46442600SAP	Infusion Set VL ST 42
M46443200	Infusion Set VL ST 44
M46443400	Infusion Set VL SP 62
M46443400S	Infusion Set VL SP62
M46443450	Infusion Set VL SP 62-1 (USA)
M46443500S	Infusion Set VL SP 90
M46443600S	Infusion Set VL SP 92
M46443600SAP	Infusion Set VL SP 92
M46443650	Infusion Set VL SP 92 (Taiwan)
M46443700S	Infusion Set VL PN20
M46443800S	Infusion Set VL PA 93
M46443900	Infusion Set VL ON 11
M46443900S	Infusion Set VL ON 11
M46444000	Infusion Set VL ON 42
M46444000S	Infusion Set VL ON 42
M46444001	Infusion Set VL ON 401
M46444051	Infusion Set VL ON 42 FX
M46444061	Infusion Set VL ON 42 SC
M46444071	Infusion Set VL ON 42 OP SC
M46444080S	Infusion Set VL ON 42 OP NF
M46444085	VL ON42 OP NF
M46444100S	Infusion Set VL ON 72
M46444160	Oncology Set VL ON 72-1 (USA)
M46444175	Infusion Set VL ON72-X1 (NAM)
M46444200	Infusion Set VL ON 22
M46444200S	Infusion Set VL ON 22
M46444230S	Infusion Set VL ON 22 OP NF
M46444235	VL ON22 OP NF
M46444251	Infusion Set VL ON 22 FX
M46444300S	Infusion Set VL PN 00
M46444300SAP	Infusion Set VL PN 00
M46444300SCB	Infusion Set VL PN 00
M46444370	Infusion Set VL PN95

Article Code	Article Name
M46444380	Infusion Set VL PN96
M46444400S	Infusion Set VL PN 02
M46444600	Infusion Set VL ON 70
M46444600S	Infusion Set VL ON 70
M46444600SAP	Infusion Set VL ON 70
M46444700	Infusion Set VL ON 21
M46444700S	Infusion Set VL ON 21
M46444800	Infusion Set VL ON 12
M46444800S	Infusion Set VL ON 12
M46444850	Infusion Set VL ON 12 FX
M46444850S	Infusion Set VL ON 12 FX
M46444900	Infusion Set VL ON 90
M46444900S	Infusion Set VL ON 90
M46444900SAP	Infusion Set VL ON 90
M46444901	Infusion Set VL ON 91
M46444960S	Infusion Set VL ON 90 FX
M46445100	Infusion Set VL ON 40
M46445100S	Infusion Set VL ON40
M46445200	Infusion Set VL PA 92
M46445200S	Infusion Set VL PA 92
M46445200SAP	Infusion Set VL PA 92
M46445260	Infusion Set VL PA 92-1 (USA)
M46445270	Infusion Set VL PA 92-2 (USA)
M46445300S	Infusion Set VL PA 94
M46445465	Infusion Set VL PR40-11 (NAM)
M46445475	Infusion Set VL SP40-11
M46445500S	Infusion Set VL ON10
M46445660	Infusion Set VL PR 42-11 (USA)
M46445665	Infusion Set VL PR42-11
M46445670	Infusion Set VL PR 42-21 (USA)
M46445690	Infusion Set VL PR 42-12 (USA)
M46445695	Infusion Set VL PR42-12
M46445700S	Infusion Set VL ON20
M46445780	Infusion Set VL PR44-12 (NAM)
M46445801	Infusion Set VL ON 42 OP
M46445860	Infusion Set VL PR 72-11 (USA)
M46445865	Infusion Set VL PR72-11
M46445900S	Infusion Set VL ON30
M46446000S	Infusion Set VL ON22 OP
M46446100S	Infusion set VL PR 21
M46446600	Infusion Set VL ON 15
M46446700	Infusion Set VL ON 45
M46446800	Infusion Set VL ST 30
M48403410	Infudrop P 230
M48403420	Infudrop® AirBlock P 230 cm, vol~23ml
M48403520	Infudrop P 180
M48403530	Infudrop AirBlock P180cm
M48403570	Infudrop matic P K-Nect 180 cm
M48403579	Infudrop P INJ 230 cm

Article Code	Article Name
M48403580	Infudrop P 3W 230 cm
M48403581	Infudrop P BCV 180 cm
M48403582	Infudrop P BCV 3W 180 cm
M48403584	Infudrop P BCV 3W 180 cm PE+10
M48403597	Infudrop AirBlock P BCV 180 cm, vol~19ml
M48403598	Infudrop AirBlock P BCV 3W 180 cm
M48413545	Infudrop Air 21 K-NECT, Y, LLM, DEHP-free, Latex-free
M48413645	Infudrop Air 21 K-NECT, 2Y, BCV, LLM, DEHP-free, Latex-free
M48441617	Infudrop matic P 240 cm
M48451520	Infudrop matic P 180 cm
M48451535	Infudrop matic P BCV 240 cm
M48454520	Infudrop matic P BCV 180 cm
Z072610F	VS 10 DEHP-FREE
Z072710F	VS 10
Z072710FAP	VS 10
Z072710FCB	VS 10
Z072733F	VS 33
Z072760F	VS 60
Z072770F	VS 70
Z072790F	OP VS
Z072810F	MS 10 DEHP-FREE
Z072820F	MS 20 DEHP-FREE
Z072830F	MS 30 DEHP-FREE
Z072831F	MS 31 DEHP-FREE
Z072835F	MS 35 DEHP-FREE
Z072890F	OP MS DEHP-FREE
Z072905F	MS 05
Z072910F	MS 10
Z072920F	MS 20
Z072930F	MS 30
Z072931F	MS 31
Z072933F	MS 33
Z072934F	MS 34
Z072960F	MS 60
Z072965F	MS 65
Z072970F	MS 70
Z072981F	MS 81
Z072982F	MS 82
Z072990F	OP MS
Z072995F	MS 95
Z072997F	MS 97
M46441020	VL ST00 AirBlock
M46441320	VL ST10 AirBlock
M46441620	VL ST01 AirBlock
M46441920	VL ST02 AirBlock
M46442520	VL ST22 AirBlock
M46442620	VL ST42 AirBlock
Z072730F	VS 30
M46446100Y	Infusion Set VL PR21

