

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 04 7402 0083  
ausgestellt durch die Benannte Stelle TÜV Süd Product Service GmbH,  
Ridlerstraße 65, 80339 München, Deutschland, CE0123

### **IV Extension Lines**

(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 Hersfeld, 21.06.2022  
Place and date of issue/  
Ort und Datum der Ausstellung

  
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 IV Extension Lines

Article Code	Article Name
2873112	Heidelberger Extension 30 cm
2873122	Heidelberger Extension 75 cm
2873132	Heidelberger Extension 75 cm, DEHP-free
2873142	Heidelberger Extension 100 cm
2873147	Heidelberger Extension 100 cm, DEHP-free
2873152	Extension with inject-connection piece
2873212	Heidelberger Extension 140 cm
2873222	Heidelberger Extension 140 cm, DEHP-free
2873232	Heidelberger Extension 140 cm, yellow, DEHP-free
2873302	Heidelberger Extension 190 cm
2873512	Extension 2-fold, LL
2873612	Extension 4-fold, LL
2873712	Extension 5-fold with Inj. Cap, LL
2888552	Extension 2-fold, 100 cm, LL
2888562	Heidelberger Extension 150 cm, with 3-way-stopcock
2888572	Injectomat Line PVC 300 cm
2888582	Injectomat Line PVC 150 cm, with reflux valve
2888592	Injectomat Line PVC 200 cm, with reflux valve
2888602	Injectomat Line PVC 45 cm
9000973	Injectomat Line PVC, 150 cm
9001515	Spiralleitung PE 6 m / 1 x 2 mm (MRT)
9001516	Spiralleitung PE 1.5 m / 1 x 2 mm (MRT)
9004112	Injectomat Line PE 50 cm
9004122	Injectomat Line PE 100 cm
9004132	Injectomat Line PE 150 cm
9004142	Injectomat Line PE 200 cm
9004149	Injectomat Line ASV PVC 200 cm
9004152	Injectomat Line PE 250 cm
9004155	Injectomat Line TIVA 180 Twin BCV, PVC 180 cm
9004162	Injectomat Line PE 300 cm
9004163	Injectomat Line TIVA 180 Twin Y BCV, PVC 180 cm
9004172	Injectomat Line PE 150 cm, light-protected, yellow
9004182	Injectomat Line PE 200 cm, light-protected, yellow
9004192	Injectomat Line PE 150 cm, light-protected, black
9004212	Injectomat Line PVC 150 cm, light-protected, yellow
9004222	Injectomat Line PVC 200 cm, light-protected, yellow
9004242	Injectomat Line PVC 150 cm

Article Code	Article Name
9004248	Injectomat line PVC 150 cm DEHP-free
9004312	Injectomat Line PE 150 cm, with back check valve
9004442	Injectomat Line PVC 250 cm
9014102	Injectomat Line PE 200 cm, light-protected, black
9014342	Injectomat Line PVC 200 cm
2873112AP	Heidelberger Extension 30 cm
2873112CB	Heidelberger Extension 30 cm
9004112AP	Injectomat Line PE 50 cm
9004132AP	Injectomat Line PE 150 cm
9004132CB	Injectomat Line PE 150 cm
9004142AP	Injectomat Line PE 200 cm
9004142CB	Injectomat Line PE 200 cm
9004152AP	Injectomat Line PE 250 cm
M76400245	Extension 2-fold, K-NECT, LLM, DEHP-free, Latex-free
M76400345	Extension 3-fold, K-NECT, BCV, LLM, DEHP-free, Latex-free
M77401845	Extension K-NECT, Y, LLM, DEHP-free, Latex-free
M78401045	Extension K-NECT, micro bore, DEHP-free, Latex-free
M78401046	Extension K-NECT MaxPlus
Z072016F	SE 1400 S
Z072025F	Extension Y BCV
Z072039F	Extension ASV Y BCV