

## **EC DECLARATION OF CONFORMITY**

Annex II excluding (4) of Directive 93/42/EEC  
according to EC-certificate No. G1 047402 0083 and Expiration Date 2024-05-26  
issued by Notified Body TÜV Süd Product Service GmbH,  
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

**Irrigation solutions**  
(Product name)

**Refer to attachment**  
(Article number)

Class IIa

We

**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.



Barcelona, 2021-06-15

Alfons Villagrasa Bot, Qualified person, QMR PU Vilassar  
(Quality Management Representative)

Place, date of issue

Name (printed letters), position and signature of authorized person (1)

(1) The representative signs the declaration on behalf of Fresenius Kabi AG according to the Fresenius Kabi global Global-SOP-QM-000003431 "Responsibilities of Medical Devices".

Valid starting with the original date of the document until product change.  
Expiry date of certificate: 2024-05-26

## Attachment to EC Declaration of Conformity

### Irrigation solutions

Article code	Description	GMDN	Physical manufacturer name and address
B316253	Sterile water irrigation solution Irriflex 120 ml	37207	(2)
B316263	Sodium Chloride 9 mg/ml irrigation solution Irriflex 120 ml	37207	(2)
B314791	Sodium Chloride 9 mg/ml irrigation solution KabiPac 100 ml	37207	(2)
B314801	Sodium Chloride 9 mg/ml irrigation solution KabiPac 500 ml	37207	(2)
2559041	Freka Drainjet Purisole SM verdünnt 60 ml	37207	(2)
B313763	Freka Drainjet Solutio R Plus 60 ml	37207	(2)
B311181	Drainjet Fisiológico para Irrigación 60 ml	37207	(2)
B311171	Drainjet Fisiológico para Irrigación 120 ml	37207	(2)
1313041	Freka Drainjet Isotonische Kochsalzlösung 60 ml	37207	(2)
1313121	Freka Drainjet Isotonische Kochsalzlösung 120 ml	37207	(2)
B312443	Flowfusor Bellows Pack 120 ml	37207	(2)
B313043	Drainjet Fisiológico para Irrigação Fresenius 60 ml	37207	(2)
B313053	Drainjet Fisiológico para Irrigação Fresenius 120 ml	37207	(2)

**(2) Physical Manufacturer name and address:**

Fresenius Kabi España, S.A.U.  
 Doctor Ferran, 12  
 08339 Vilassar de Dalt (Barcelona)  
 Spain