



EC DECLARATION OF CONFORMITY

Annex II excluding (4) of Directive 93/42/EEC
according to EC-certificate No. G1 047402 0083
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstraße 65, 80339 Munich, Germany, CE0123

Irrigation Solution – Bottle (Flowfusor)
(Product name)

See attached list
(Article number)

Class IIa

We
Fresenius Kabi France
5 place du Marivel, 92316 Sèvres Cedex
France

On behalf of

Fresenius Kabi AG
D-61346 Bad Homburg
Germany

legal 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.

Place and date of issue/

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

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

Irrigation Solution – Bottle (Flowfusor)
(attachment to Declaration of conformity regarding medical devices)

Article number	Product name
FBP7255	Purisole Irrigation Solution, Flowfusor bottle, 2 000 mL
FBP7204	Sterile water for Irrigation, Flowfusor bottle, 1 000 mL
FBP7205	Sterile water for Irrigation, Flowfusor bottle, 2 000 mL
FBP7224	Glycine 1.5% Irrigation Solution, Flowfusor bottle, 1 000 mL
FBP7225	Glycine 1.5% Irrigation Solution, Flowfusor bottle, 2 000 mL
FBP7214	Sodium chloride 9 mg/mL Irrigation Solution, Flowfusor bottle, 1 000 mL
FBP7215	Sodium chloride 9 mg/mL Irrigation Solution, Flowfusor bottle, 2 000 mL