FRESENIUS KABI

EC DECLARATION OF CONFORMITY

Annex VII and Annex V 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

(Product name)

See attached list
(Article number)

Class IIa
(Annex IX, Rule 7)

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 that the referenced products comply with all relevant provisions of Directive 93/42/EEC, as amended by Directive 2007/47/EEC, 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.

1er Octobre 2020 BERTHOU-TAIAR Sylvie Responsible Pharmacovigilance

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 SOLUTIONS (BOTTLE PACKAGING)

(attachment to Declaration of conformity regarding medical devices)

Category	Volume	Article number	Commercial name
Products with non-perforable caps			
NaCl 0.9%	250 mL	B230541	Versylene — Sodium chloride 0.9% Bottle of 250 mL
		B230542	NaCl 0.9% for irrigation 250 mL
		B230543	Versylene NaCl 0.9% 250 mL
	500 mL	B230551	Versylene — Sodium chloride 0.9% Bottle of 500 mL
		B230422	NaCl 0.9% Fresenius Ampuwa Spüllösung 500 mL Plastipur
		B230552	NaCl 0.9% for irrigation 500 mL
		B230553	Versylene NaCl 0.9% 500 mL
	1 000 mL	B230561	Versylene — Sodium chloride 0.9% Bottle of 1 000 mL
		B230423	NaCl 0.9% Fresenius Ampuwa Spüllösung 1 000 mL Plastipur
		3158736	0.9% w/v Sodium chloride for irrigation 1 L
		B230562	NaCl 0.9% for irrigation 1 000 mL
		B230563	Versylene NaCl 0.9% 1 000 mL
Sterile water	250 mL	B230511	Versylene — Sterile water Bottle of 250 mL
		B230512	Sterile water for irrigation 250 mL
	500 mL	B230521	Versylene — Sterile water Bottle of 500 mL
		B230672	Ampuwa Spüllösung 500 mL Plastipur
		3158591	Sterile water for irrigation 500 mL
		B230522	Sterile water for irrigation 500 mL
		B230523	Versylene Sterile water 500 mL
	1 000 mL	B230531	Versylene — Sterile water Bottle of 1 000 mL
		B230673	Ampuwa Spüllösung 1 000 mL Plastipur
		3158589	Sterile water for irrigation 1 L
		B230532	Sterile water for irrigation 1 000 mL
		B230534	Versylene Sterile water 1 000 mL
Products with perforable caps			
NaCl 0.9%	500 mL	B230554	Sodiumcloride 9mg/mL
	1 000 mL	B230564	Sodiumcloride 9mg/mL
Sterile water	1 000 mL	B230535	Sterile water