

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 – Ringer

(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 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.

Seurs 24th January 2022 BERTHOV-TAIAB Sylvic Grapon vible Pharmon's L. 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

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IRRIGATION SOLUTIONS (BOTTLE PACKAGING) - RINGER (attachement to Declaration of conformity regarding medical devices)

Category	Volume	Article number	Commercial name
Products with non-perforable caps			
Ringer	500 mL	B231552	Ringer Fresenius Spüllösung 500 mL
		B231551	Ringer Fresenius 500 mL
	1 000 mL	B231553	Ringer Fresenius Spüllösung 1 000 mL
Ringer lactate	500 mL	B207032	Ringer Lactate Fresenius
Products with perforable caps			
Ringer	250 mL	B231550	Ringer 250 mL
	500 mL	B231556	Ringer 500 mL
	1 000 mL	B231558	Ringer 1 000 mL