



EC DECLARATION OF CONFORMITY

Annex II excluding (4) of Directive 93/42/EEC
according to EC-certificate No. G1 047402 0083 Rev. 00 and Expiration Date 26 May
2024

issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

Sodium Chloride 0.9% for irrigation
Water for irrigation
Fisiosept
(Product name)

5600340530615; 5600340530622; 5600340530639; 5600340530646;
5600340530653; 5600340530660; 5600340530677; 5600340530684;
5600340530691; 5600340530707; 5600340530714; 5600340530721;
5600340530738; 5600340530745; 5600340530752; 5600340530769;
5600340530783
(article number)

Class IIa - IIb

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.

Bad Homburg, 08.11.2022

Patrick Stellmacher
Manager Regulatory Affairs
BU INS – Fresenius Kabi – MedTech

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