



**FRESENIUS  
KABI**

## EC DECLARATION OF CONFORMITY

(Annex II of Directive 93/42/EEC,  
according to EC-certificate No G1 047402 0078 Rev. 00 issued by notified body TUV SÜD Product Service  
GmbH, Ridlerstr. 65, 80339 Munich, Germany, 0123)

**Sodium chloride 9 mg/mL Irrigation Solution**  
(Product name)

See attachment  
(Article number)

Class  IIa -  IIb

We  
**Fresenius Kabi AG**  
**D - 61346 Bad Homburg, Germany**

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 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.

11/2019  
Place and date of issue/

Trond Frost 18 OCT 2019

[Signature]  
Name (printed letters) and signature of authorized person/

Valid starting with the original date of the document until product change

**Attachment to declaration of conformity regarding medical devices**

<u>Article number</u>	<u>Description</u>
93 69 08	Sodium chloride 9 mg/mL Irrigation Solution, Microspol ampoules 30 mL