



**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 TÜV SÜD Product Service
GmbH, Ridlerstr. 65, 80339 Munich, Germany, 0123)

KabiRinse, Eye 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.

Trond Frost
Place and date of issue/

Trond Frost 18 OCT 2019

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>
83 19 44	KabiRinse, Eye Irrigation Solution, Microspol ampoules 30 mL