



**FRESENIUS  
KABI**

## EC DECLARATION OF CONFORMITY

(Annex II.3 of Directive 93/42/EEC;  
according to EC-certificate No. G1 15 03 47402 048 issued by notified body TÜV SÜD Product Service  
GmbH, Ridlerstr. 65, 80339 Munich, Germany, CE0123)


**Chlorhexidine 0.2 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.

HALDEN Trond Frost 15 APR 2015   
Place and date of issue/ Name (printed letters) and signature of authorized person/

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



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

<u>Article number</u>	<u>Description</u>
92 13 18	Chlorhexidine 0.2 mg/mL Irrigation Solution, Irriflex ampoules 120 mL
86 15 34 (ESS 1534)	Chlorhexidine 0.2 mg/mL Irrigation Solution, Octavia bottles, 1000 mL