



EC DECLARATION OF CONFORMITY

Annexes V and VII of European Directive 93/42/EEC

Sodium Bicarbonate 1.4%

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Oral irrigation solution

(Product name)

See attached list

(Article number)

Class I (rule 5)

We

**Fresenius Kabi AG
D-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.

Since 24th August 2020 **BERTHOV-TAIAB** *(Responsible Pharmacist, FKF)*
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

SODIUM BICARBONATE 1.4%
(attachement to Declaration of conformity regarding medical devices)

Article number	Product name
B230161	Sodium bicarbonate 1.4% – 250 mL
B230151	Sodium bicarbonate 1.4% – 500 mL
B230131	Sodium bicarbonate 1.4% – 250 mL in a 500 mL bottle