

**EC DECLARATION OF CONFORMITY
PHYSIOLOGICA / SODIUM CHLORIDE 0.9%**



Version 1.3-1

<i>Product Name(s)</i>	Physiologica / Sérum Physiologique / Sodium chloride 0.9% and other trade names
<i>Legal manufacturer's name</i>	Gifrer Barbezat
<i>Business address</i>	8-10 rue Paul Bert 69150 DECINES-CHARPIEU FRANCE
<i>Identification of the devices</i>	Table 1 of ListOfReferences_SerumPhy – 2020.10.02
<i>Classification</i>	Class Is
<i>Intended Use</i>	Nasal and ophthalmic isotonic sterile cleansing solution
<i>GMDN code</i>	44844 : Nasal irrigation saline solution, sterile 60756: Eye irrigation solution
<i>Technical dossier ref.</i>	Physiologica / Sérum physiologique
<i>Conformity Assessment Procedure</i>	Annex V: EC declaration of Conformity - Production Quality Assurance Annex VII : EC declaration of Conformity
<i>Conformity Assessment Standards applied</i>	NF EN ISO 13485 : 2016 Other standards : see part III.2 in the technical dossier
<i>CE Certificate</i>	N° 10301 – rev.23
<i>Name and address of notified body</i>	GMED (N°CE 0459) – 1, rue Gaston Boissier 75015 Paris France

We state that the medical device complies with the applicable Essential Requirements for safety and performance, is classified according to the classification rules and meet all the applicable conformity assessments elements according to the council directive 93/42/CEE dated on 14 June 1993 (DDM) and with its national law transposition, and the council directive 2007/47/CE dated on 5 September 2007, mainly with the requirements of "LIVRE Vbis" of the "Code de la Santé Publique".

Issued in Décines on	2021.04.15
Merita KACI Regulatory affairs Manager, Gifrer Barbezat	