

2.3 EC Declaration of conformity

We herewith declare on our sole responsibility, that the design, production, and packaging of the described product is compliant with the specific requirements of the Directive 93/42/EEC concerning medical devices, that the product has been classified according to the rules of classification of the Annex IX of the Directive 93/42/EEC and satisfied all requirements of the Annex II (without Section 4) of the Directive 93/42/EEC.

Product	gigasept PAA
Item code	195751
Manufacturer	BIOXAL SA – Route des Varennes - 71100 CHALON-SUR-SAONE - FRANCE
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 D-60433 Frankfurt am Main GERMANY Notified Body EC 0297
Class of the medical device (Directive 93/42/EEC, Annex IX, Rule 15)	IIb
Product group	Disinfectant, medical devices
Product category (EN ISO 15225)	Hospital hardware
Issued certificates	EN ISO 9001 _ Cert. Reg. No. 368588 QM15 EN ISO 13485 _ Cert. Reg. No. 368588 MP2016 Annex II _ Cert. Reg. No. 368588 MR2
Standards applied	Applied standards are listed in Sec. 2.4 of the technical documentation.

***I, the undersigned, declare that BIOXAL SA,
bears the sole responsibility for issuing this Declaration.***

Position of the responsible person General Manager

Name of the responsible person Sylvain LEMAIRE

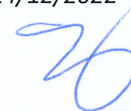
Location

Chalon-sur-Saône

Date of issue

14/12/2022

Signature



This Declaration is valid until an updated version has been issued, but not longer than 2024-05-26.

Localization of the technical documentation: Bioxal SA, Regulatory Affairs office.