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.

: C1 : 2% , C2 : 1.50%, C3 : 1.25% (cible), C4 :1.20% , C5 : 1.00%