


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	dialog active 5KG
Item code	104149
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	Alexandre MORAINVILLE
Location	Chalon-sur-Saône
Date of issue	20 th of May 2021
Signature	

*This Declaration is valid until an updated version has been issued, but not longer than 2022-12-26.
Localization of the technical documentation: Bioxal SA, Regulatory Affairs office.*