EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

BIOXAL SA

Route des Varennes
71100 Chalon sur Saône
France

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Disinfectants for medical devices, according to the annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	368588 MR2
Certificate unique ID	170776237
Effective date	2021-05-22
Expiry date	2024-05-26
Frankfurt am Main	2021-05-22

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
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Device family	Device	Class
Disinfectants for medical devices, peracetic acid	BIOXAL M	IIb
	GIGASEPT PAA	IIb
	GIGASEPT PAA CONCENTRATE	IIb
	TERRALIN PAA	IIa
	TPH 5358 BASE	IIb
	THERMOSEPT PAA BASE	IIb
	DIALOX	IIb
	GIGASEPT AER	IIa
	DIALOX ACTIVE	IIb
	THERMOSEPT PAA BASE (adapter)	IIb