FOR AFR 013 / 02

Version 02

EU DECLARATION OF CONFORMITY

Class I

EU DECLARATION OF CONFORMITY

MANUFACTURER according to Regulation 2017/745

BIOXAL

Route des Varennes, 71100 Chalon sur Saône

Registration Number acc. to Art. 31 2017/745 FR-MF-000000481

Basic UDI-DI

426070938BIOXAL-BUDI-03M7

MEDICAL DEVICE

Product name	thermosept PAA additive
Code acc. to Art. 26 2017/745	125802
Intended purpose	instrument processing

RISK CLASS

According to Regulation 2017/745 - Annex VIII I

STANDARDS APPLIED

additional standards see technical documentation

CERTIFICATE

EN ISO 9001 _ Cert. Reg. No. 368588 QM15

EN ISO 13485_ Cert. Reg. No. 368588 MP2016

BIOXAL herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices

BIOXAL bears the sole responsibility for issuing this Declaration

Chalon sur Saône - FRANCE
13/12/2022

Sylvain LEMAIRE
General Manager Bioxal

Sophie RANGA
Regulatory Affairs & Microbiology Manager Bioxal
Person Responsible for Regulatory Compliance

This Declaration is valid until an updated version has been issued, but not longer than 26/12/2025