EU DECLARATION OF CONFORMITY

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MANUFACTURER according to Regulation 2017/745

BIOXAL SAS
ZI Sud - Secteur A - Route des Varennes, 71100 Chalon sur Saône
Registration Number acc. to Art. 31 2017/745 FR-MF-000000481

Basic UDI-DI

426070938BIOXAL-BUDI-04M9

MEDICAL DEVICE

Product name	terralin PAA
Code acc. to Art. 26 2017/745	D050103
Intended Purpose	For disinfection of surfaces with mechanical action in medical areas

Risk Class

According to Regulation 2017/745 IIa

Common specifications

NA

NOTIFIED BODY

DQS Medizinprodukte GmbH
August-Schanz-Str. 21, D-60433 Frankfurt am Main GERMANY
EC 0297

Certificates

EN ISO 13485_ Cert. Reg. No. 368588 MP2021
Regulation 2017/745_ Cert. Reg. No. 368588 MDR2017Q

Conformity Assessment Procedure according to Regulation 2017/745

Annex IX
Chapter I, III and section 4

Bioxal bears the sole responsibility for issuing this Declaration
Bioxal herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

BIOXAL, Chalon sur Saône - FRANCE
16/06/2026

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This Declaration is valid until an updated version has been issued, but not longer than 02/05/2029

8_EU DoC terralin PAA_EN

Final Audit Report 2026-06-16

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