UNITED DISINFECTANT MANUFACTURERS

Declaration of Conformity

MANUFACTURER

United Disinfectant Manufacturers AG
Allmendstrasse 21
8320 Fehraltorf
Switzerland

AUTHORIZED REPRESENTATIVE

United Disinfectant Manufacturers AG
Dr. Grass-Strasse 12
9490 Vaduz
Principality of Liechtenstein

IDENTIFICATION OF THE MEDICAL DEVICE

PROSEPT® Sonic (Liquid concentrate for the thorough cleaning of contaminated dental and surgical instruments in the ultrasonic cleaning device):

Basic UDI-DI	Item Code	Trade Name	Delivery Form
955100187OF100004ILHQ	OD-061050	PROSEPT® Sonic	1 litre bottle

CLASS OF THE MEDICAL DEVICE

Class I [according to the classification rules in Annex VIII of the Regulation (EU) 2017/745 on medical devices]

CONFORMITY ASSESSMENT PROCEDURE

Annex II, III, and IV of the Regulation (EU) 2017/745 on medical devices

STANDARDS APPLIED

EN ISO 13485:2016 + A11:2021, EN ISO 14971:2019 + A11:2021, EN 62366-1:2015 + A1:2020, EN ISO 10993-1:2020, EN ISO 21530:2004, EN ISO 20417:2021, EN ISO 15223-1:2021

NOTIFIED BODY

Not Applicable

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CE MARK AFFIXED

CE

AUTHORIZED SIGNATORY

This Declaration of Conformity is issued under the sole responsibility of United Disinfectant Manufacturers AG. We hereby declare that the above-mentioned device(s) meet the provisions of the Regulation (EU) 2017/745 on medical devices. Our quality management system is certified according to EN ISO 13485:2016. Our notified body is DNV Product Assurance AS (Notified Body number: 2460). All supporting documentation is retained at the premises of the manufacturer.

Lee Moi Wong
Chief Research Officer
Fehraltorf

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2023.04.04
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