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® Fortis (Powerful concentrate for the disinfection and cleaning of medical instruments through manual reprocessing):

Basic UDI-DI	Item Code	Trade Name	Delivery Form
955100187OF100008ILJC	OD-060013	PROSEPT® Fortis	250 ml bottle
955100187OF100008ILJC	OD-060016	PROSEPT® Fortis	1 litre bottle
955100187OF100008ILJC	OD-060020	PROSEPT® Fortis	2 litre bottle
955100187OF100008ILJC	OD-060025	PROSEPT® Fortis	5 litre canister

CLASS OF THE MEDICAL DEVICE

Class IIb (according to the classification rules in Annex IX of the Council Directive 93/42/EEC concerning medical devices)

CONFORMITY ASSESSMENT PROCEDURE

Annex II (excluding Section 4) of the Council Directive 93/42/EEC concerning medical devices

STANDARDS APPLIED

EN ISO 13485:2016 + A11:2021, EN ISO 14971:2019 + A11:2021, EN 62366-1:2015 + A1:2020, EN 14885:2018, EN ISO 10993-1:2020, EN ISO 21530:2004, EN ISO 20417:2021, EN ISO 15223-1:2021

NOTIFIED BODY

DNV Product Assurance AS
Veritasveien 3
1363 Høvik
Norway

UNITED DISINFECTANT MANUFACTURERS

CE MARK AFFIXED

CE
2460

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 Council Directive 93/42/EEC concerning 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.

Juerg Suter
Chief Executive Officer
Fehraltorf

Juerg Suter
2022.09.25
19:30:20 +02'00'

Name: Juerg Suter
Designation: Chief Executive Officer
Place of Issue: Fehraltorf, Switzerland
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