

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® Sensi (Alcohol-free, ready-to-use solution for the quick and comprehensive disinfection of non-invasive medical devices):

Basic UDI-DI	Item Code	Trade Name	Delivery Form
955100187OF100020SLJG	OD-011004	PROSEPT® Sensi	200 ml foamer bottle
955100187OF100020SLJG	OD-011100	PROSEPT® Sensi	1 litre bottle
955100187OF100020SLJG	OD-011104	PROSEPT® Sensi	5 litre canister

CLASS OF THE MEDICAL DEVICE

Class IIa (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

CE MARK AFFIXED



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.

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