

# Declaration of Conformity

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## MANUFACTURER

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United Disinfectant Manufacturers AG  
Allmendstrasse 21  
8320 Fehraltorf  
Switzerland

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## AUTHORIZED REPRESENTATIVE

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

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## IDENTIFICATION OF THE MEDICAL DEVICE

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PROSEPT® Wipes (Ready-to-use wipes for the quick, comprehensive, and residue-free disinfection of non-invasive medical devices):

Basic UDI-DI	Item Code	Trade Name	Delivery Form
955100187OF100012SWK9	OD-041079	PROSEPT® Wipes	Refill pouch (14.5 x 20 cm), 120 pcs, classic scent
955100187OF100012SWK9	OD-041081	PROSEPT® Wipes	Refill pouch (14.5 x 20 cm), 120 pcs, classic scent
955100187OF100011SWK4	OD-041084	PROSEPT® Wipes	Refill pouch (14.5 x 20 cm), 120 pcs, lemon scent
955100187OF100012SWK9	OD-041092	PROSEPT® Wipes	Jumbo, Refill pouch (14.5 x 40 cm), 100 pcs, classic scent
955100187OF100011SWK4	OD-042080	PROSEPT® Wipes	Value, Refill pouch (14.5 x 20 cm), 250 pcs, lemon scent
955100187OF100011SWK4	OD-042084	PROSEPT® Wipes	Premium, Refill pouch (19.3 x 21 cm), 120 pcs, lemon scent

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## CLASS OF THE MEDICAL DEVICE

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

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## CONFORMITY ASSESSMENT PROCEDURE

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

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## STANDARDS APPLIED

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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

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## NOTIFIED BODY

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DNV Product Assurance AS  
Veritasveien 3  
1363 Høvik  
Norway

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## CE MARK AFFIXED

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## AUTHORIZED SIGNATORY

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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  
Date of Issue: 25.09.2022  
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