

# 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® Jet D (Powerful liquid concentrate for the disinfection and cleaning of dental suction units):

Basic UDI-DI	Item Code	Trade Name	Delivery Form
955100187OF100014ALH7	OD-071020	PROSEPT® Jet D	2 litre bottle
955100187OF100014ALH7	OD-071025	PROSEPT® Jet D	5 litre canister

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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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