UNITED DISINFECTANT MANUFACTURERS

Digitally signed by Smîntînă Alexandru
Date: 2024.10.21 11:15:45 EEST
Reason: MoldSign Signature
Location: Moldova

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® Jet Forte (Liquid concentrate for the thorough cleaning of dental suction units):

Basic UDI-DI	Item Code	Trade Name	Delivery Form
955100187OF100015ALHC	OD-071005	PROSEPT® Jet Forte	250 ml bottle
955100187OF100015ALHC	OD-071120	PROSEPT® Jet Forte	2 litre bottle
955100187OF100015ALHC	OD-071125	PROSEPT® Jet Forte	5 litre canister

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

UNITED DISINFECTANT MANUFACTURERS

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

Lee Moi Wong
2023.04.04
05:58:34 +02'00'

Name: Lee Moi Wong
Designation: Chief Research Officer
Place of Issue: Fehraltorf, Switzerland
Date of Issue: 04.04.2023
Document Version: A3ADP7