OCC Switzerland

Declaration of Conformity

MANUFACTURER

Oro Clean Chemie AG
Allmendstrasse 21
8320 Fehraltorf
Switzerland

AUTHORIZED REPRESENTATIVE

Oro Clean Chemie s.r.o.
Vinohradská 2828/151
Žižkov
130 00 Praha 3
Czech Republic

IDENTIFICATION OF THE MEDICAL DEVICE

DENTIRO® Light (Ready-to-use surface disinfectant for the rapid and residue-free disinfection of non-invasive medical devices. Perfume-free):

Basic UDI-DI	Item Code	Trade Name	Delivery Form
955100144OF100010SLAQ	CH-031005	DENTIRO® Light	250 ml bottle
955100144OF100010SLAQ	CH-031013	DENTIRO® Light	1 litre bottle
955100144OF100010SLAQ	CH-031025	DENTIRO® Light	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

OCC Switzerland

CE MARK AFFIXED

CE
2460

AUTHORIZED SIGNATORY

This Declaration of Conformity is issued under the sole responsibility of Oro Clean Chemie 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
2022.06.29
23:00:03 +02'00'

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