



EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 10000400154-PA-NA-MYS, rev.1

Project No.: PRJN-195868-2020-PA-MYS

Valid Until: 27 May 2024

This is to certify that the quality system of:

Oro Clean Chemie AG

Allmendstrasse 21, 8320 Fehraltorf, Switzerland

For design, production and final product inspection/testing of:

DISINFECTANTS, CLEANERS, DECONTAMINATION AGENTS FOR INVASIVE AND NON-INVASIVE MEDICAL DEVICES

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 30 March 2021



For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Mariann Jeremiassen
Principal Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f2, rev.0

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	10 November 2020
1.0	Scope reduction and Products addition within MDD IA assessment (in Bold)	01 April 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Surface Disinfectants	CLEANSEPT® 22+ DENTIRO® Jumbo Wipes DENTIRO® Light DENTIRO® Maxx DENTIRO® Omni DENTIRO® Omni Wipes DENTIRO® Opti DENTIRO® Sensitive DENTIRO® Sensitive Wipes DENTIRO® Wipes DENTIRO® Zero ISORAPID® OP-Forte AF ISORAPID® Spray	IIa
Surgical Instrument Disinfectants	OROLIN® Burbath OROLIN® Multisept OROLIN® Multisept Plus	IIb
Dental Impression Disinfectants	ASEPTOPRINT® Liquid ASEPTOPRINT® Spray	IIa
Aspirating Unit Disinfectant	ORO CLEAN® Plus	IIa

The complete list of devices is filed with the Notified Body