

# DECLARATION OF CONFORMITY

COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

We, Oro Clean Chemie AG, Allmendstrasse 21, 8320 Fehraltorf, Switzerland, declare under our sole responsibility that the products conform to the requirements of Council Directive 93/42/EEC and meet the relevant essential requirements of Annex I.

## Ready-to-use surface disinfectant with a high alcohol content for the rapid and residue-free disinfection and cleaning of non-invasive medical devices.

**Trade name:** DENTIRO® Opti  
**Intended purpose:** DENTIRO® Opti is a surface disinfectant and cleaner with a high alcohol content. The disinfectant is ideal for the rapid and residue-free disinfection and cleaning of alcohol-resistant surfaces of non-invasive medical devices such as operating tables and IV poles.  
**Classification:** Class IIa according to Annex IX of Council Directive 93/42/EEC (Rule 15)  
**Conformity assessment procedure:** Annex II excluding section 4  
**Applied standards:** EN ISO 13485:2016 + A11:2021, EN ISO 14971:2019 + A11:2021, EN 62366-1:2015 + A1:2020, EN 14885:2022, EN ISO 10993-1:2020, EN ISO 21530:2004, EN ISO 20417:2021, EN ISO 15223-1:2021

Basic UDI-DI	REF	Sizes
955100144OF100006SLBF	CH-033013	250 ml bottle
955100144OF100006SLBF	CH-033016	1 litre bottle
955100144OF100006SLBF	CH-033020	2 litre bottle
955100144OF100006SLBF	CH-033025	5 litre canister

**Authorized representative in the EU:** Oro Clean Chemie s.r.o.  
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**Notified body:** DNV Product Assurance AS  
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1363 Høvik  
Norway

**Identification number:** 2460  
**Certificate number:** 10000400154-PA-NA-MYS, rev.1  
**Issued:** Høvik, 30.03.2021  
**Expires:** 27.05.2024

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**Lee Moi Wong**  
Chief Research Officer

This signed document is valid for all translations attached.