

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 disinfection and cleaning of non-invasive medical devices.

Trade name: DENTIRO® Maxx
Intended purpose: DENTIRO® Maxx is a surface disinfectant and cleaner with a high alcohol content supplemented by quaternary ammonium compounds. The disinfectant is ideal for the rapid 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
955100144OF100007SLBL	CH-034013	250 ml bottle
955100144OF100007SLBL	CH-034016	1 litre bottle
955100144OF100007SLBL	CH-034020	2 litre bottle
955100144OF100007SLBL	CH-034025	5 litre canister

Authorized representative in the EU: Oro Clean Chemie s.r.o.
Vinohradská 2828/151
Žižkov
130 00 Praha 3
Czech Republic

Notified body: DNV Product Assurance AS
Veritasveien 1
1363 Høvik
Norway

Identification number: 2460
Certificate number: 10000400154-PA-NA-MYS, rev.1
Issued: Høvik, 30.03.2021
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Lee Moi Wong
Chief Research Officer

This signed document is valid for all translations attached.