

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.

Powerful disinfectant concentrate for medical and dental instruments.

Trade name:	OROLIN® Multisept Plus
Intended purpose:	OROLIN® Multisept Plus is a powerful concentrate for the manual disinfection and cleaning of medical and dental instruments made of stainless steel, tungsten carbide, diamond grit, titanium, silicon carbide, and silicone. Also suitable for alcohol-sensitive rotary instruments. OROLIN® Multisept Plus is free of aldehydes, phenols, and chlorine.
Classification:	Class IIb 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
955100144OF100008ILAT	CH-060005	250 ml bottle
955100144OF100008ILAT	CH-060016	1 litre bottle
955100144OF100008ILAT	CH-060020	2 litre bottle
955100144OF100008ILAT	CH-060025	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
Expires:	27.05.2024

Lee Moi Wong
Chief Research Officer
Fehraltorf
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This signed document is valid for all translations attached.

Killing Germs
for a safer world

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