

## 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 solution for the disinfection and cleaning of dental rotary instruments.

**Trade name:** OROLIN® Burbath

**Intended purpose:** OROLIN® Burbath is a ready-to-use solution for the disinfection and cleaning of rotary dental and surgical instruments made of stainless steel, tungsten carbide, diamond grit, ceramic, polymer and silicone. OROLIN® Burbath has a very broad effective spectrum and is fast acting. OROLIN® Burbath is easily biodegradable.

**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
955100144OF100003ILA2	CH-061005	250 ml bottle
955100144OF100003ILA2	CH-061065	1 litre bottle
955100144OF100003ILA2	CH-061070	2 litre bottle
955100144OF100003ILA2	CH-061075	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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**Lee Moi Wong**  
Chief Research Officer

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**Killing Germs**  
for a safer world

Oro Clean Chemie (Distribution) AG • Allmendstrasse 21 • 8320 Fehraltorf • Switzerland  
Tel. + 41 (0)44 226 44 44 • info@oroclean.com • www.oroclean.com  
MWST-Nr.: CHE-107.890.761 • ZAZ Nr.: 3265-3 • VOC-Bew.: 20219