

## 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 disinfectant wipes for the rapid disinfection and cleaning of non-invasive medical devices.

<b>Trade name:</b>	DENTIRO® Sensitive Wipes
<b>Intended purpose:</b>	DENTIRO® Sensitive Wipes are ready-to-use disinfectant wipes based on alcohols and quaternary ammonium compounds. The disinfectant wipes are ideal for the rapid disinfection and cleaning of non-invasive medical devices such as operating tables, gurneys, IV poles, and dental chairs. The low alcohol content of less than 50% ensures high material compatibility and reduces the potential for allergies and skin irritation. DENTIRO® Sensitive Wipes have a discrete lemon fragrance.
<b>Classification:</b>	Class IIa according to Annex IX of Council Directive 93/42/EEC (Rule 15)
<b>Conformity assessment procedure:</b>	Annex II excluding section 4
<b>Applied standards:</b>	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
955100144OF100021SWBS	CH-043054	Refill pouch with 120 disinfectant wipes (19.3 x 21 cm), classic scent

**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

This signed document is valid for all translations attached.

**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