

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.

Disinfectant wipes for the disinfection of non-invasive medical devices.

Trade name:	DENTIRO® Wipes
Intended purpose:	DENTIRO® Wipes are ready-to-use disinfectant wipes for the residue-free disinfection and cleaning of small surfaces of non-invasive medical devices such as operating tables, gurneys, IV poles, and dental chairs. The highly saturated wipes have a low alcohol content of less than 50%, which not only reduces the potential for allergies but also increases material compatibility. DENTIRO® Wipes are free of aldehydes.
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
955100144OF100013SWBV	CH-041079	Refill pouch with 120 disinfectant wipes (14.5 x 20 cm), classic scent
955100144OF100013SWBV	CH-041081	Refill pouch with 120 disinfectant wipes (14.5 x 20 cm), classic scent
955100144OF100013SWBV	CH-041083	Refill pouch with 120 disinfectant wipes (14.5 x 20 cm), floral scent
955100144OF100013SWBV	CH-041084	Refill pouch with 120 disinfectant wipes (14.5 x 20 cm), lemon scent
955100144OF100013SWBV	CH-041092	Refill pouch with 100 disinfectant wipes (14.5 x 40 cm), classic scent
955100144OF100013SWBV	CH-041097	Refill pouch with 100 disinfectant wipes (14.5 x 40 cm), lemon scent
955100144OF100013SWBV	CH-042080	Refill pouch with 250 disinfectant wipes (14.5 x 20 cm), lemon scent
955100144OF100013SWBV	CH-042084	Refill pouch with 120 disinfectant wipes (19.3 x 21 cm), lemon scent

Killing Germs
for a safer world

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Identification number:

2460

Certificate number:

10000400154-PA-NA-MYS, rev.1

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Lee Moi Wong
Chief Research Officer

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