

SQS as a conformity assessment body identification number 1250 herewith certifies the company

Oro Clean Chemie AG
Allmendstrasse 21
8320 Fehraltorf
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II

Directive 93/42/EEC (without section 4)

This approval is based on the result of the audit documented in the report dated April 23, 2018.

The scope of validity covers the products

Cleaning, disinfection and hygiene products for medical and dental markets

The following CE label can be applied to the products mentioned in the Appendix of this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Validity 02.05.2018–01.05.2021
 Issue 02.05.2018

Reg. no. 31727
 Approved Medical Responsible
 02.05.2018



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



sqs.ch

ANNEX II

Directive 93/42/EEC (without section 4)

This Appendix is valid only in connection with the following certificate:

Registration Number 31727

Validity from May 2, 2018 up to and including May 1, 2021

This approval includes the following Medical Devices:

OROCLEAN Products

Disinfectants for surfaces of medical devices
(medical equipment, installations and instruments)

Class IIa

DENTIRO® Foam
DENTIRO® Zero
ISORAPID® Floor
ISORAPID® OP-Forte AF
OROLIN® OP-Forte AF

Class IIb

DENTIRO® Light
DENTIRO® Sensitive
DENTIRO® Mikro
DENTIRO® Wipes
DENTIRO® Jumbo Wipes
ISORAPID® Liquid
ISORAPID® Spray

Disinfectants for medical and dental instruments

Class IIa

TURBOCIDOL®
OROLIN® Intra

Class IIb

OROLIN® Burbath
OROLIN® Multisept Plus
OROCID-MULTISEPT® Plus
OROLIN® Perasept

Disinfectants for dental aspirating units
and amalgam separators

Class IIa

ORO CLEAN® Plus

Disinfectants for dental impression materials

Class IIa

ASEPTOPRINT® Liquid
ASEPTOPRINT® Spray

Appendix issue date: May 2, 2018



sqs.ch