

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:

CLEANSEPT Products
(Semiprivate Label Products for CLEANSEPT AG)

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

Class IIa
CLEANSEPT® 25+
CLEANSEPT® 27+
CLEANSEPT® 28+

Class IIb
CLEANSEPT® 20+
CLEANSEPT® 22+

Disinfectants for medical and dental instruments

Class IIa
CLEANSEPT® 39+

Class IIb
CLEANSEPT® 30+
CLEANSEPT® 33+
CLEANSEPT® 34+
CLEANSEPT® 37+

Disinfectants for dental aspirating units
and amalgam separators

Class IIa
CLEANSEPT® 40+

Disinfectants for dental impression materials

Class IIa
CLEANSEPT® 55+
CLEANSEPT® 50+

Appendix issue date: May 2, 2018

