

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 10000400164-PA-NA-MYS, rev.1

Project No.: PRJN-195871-2020-PA-MYS

Valid Until: 27 May 2024

This is to certify that the quality system of:

Hygiene360 AG

Büelstrasse 17, 8330 Pfäffikon ZH, Switzerland

For design, production and final product inspection/testing of:

DISINFECTANTS, CLEANERS, DECONTAMINATION AGENTS FOR INVASIVE AND NON-INVASIVE MEDICAL DEVICES

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 30 March 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS



Mariann Jeremiassen
Principal assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	10 November 2020
1.0	Scope reduction and Products addition (in Bold)	01 April 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Surface Disinfectants	PROSEPT® Activa PROSEPT® Blaze PROSEPT® Floor PROSEPT® Jumbo Wipes PROSEPT® Sensi PROSEPT® Spray PROSEPT® Swipes PROSEPT® Ultima PROSEPT® Ultima Wipes PROSEPT® Wipes	IIa
Surgical Instrument Disinfectants	PROSEPT® Burs PROSEPT® Fortis PROSEPT® Instru	IIb
Dental Impression Disinfectant	PROSEPT® Impression S	IIa
Aspirating Unit Disinfectant	PROSEPT® Jet D	IIa

The complete list of devices is filed with the Notified Body