EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
240125-2017-CE-ITA-NA-PS Rev. 0.0	**PRJC-79069-2008-MSL-ITA**	**22 September 2018**

This is to certify that the quality system of:

OPTIKON 2000 S.P.A.
Via del Casale di Settebagni, 13
00138 ROMA
Italy

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

Ophthalmic Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) 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, 9 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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 for Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the Certificate Certificate No. 32034-2008-CE-NOR rev.11 (NB 0434), following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	2017-11-09

Products covered by this Certificate:

Product Description	Product Name	Class
Ophthalmic Surgical Equipment	Equipment for the surgery of the anterior and posterior segment of the eye, having the following functions, grouped in any combination - Irrigation and Aspiration - Phacoemulsification - Vitrectomy - Diathermy - Endoillumination - Fluids Exchange - Cryosurgery - Photocoagulation	IIb
Ophthalmic Diagnostic Equipment	Corneal Topography And Aberrometry	IIa
	Ultrasound Diagnostic Equipment	IIa
Ophthalmic Diagnostic Accessories	A-Scan Probes	IIa
	B-Scan Probes	IIa
	Pachimetry Probes	IIa

Ophthalmic Surgical Accessories – Reusable	Channelling Devices	IIa
	Contact Lens For Surgery	IIa
	Cryosurgery Probes	IIb
	Diathermy Accessories	IIb
	I/A Accessories	IIa
	Phacoemulsification Handpieces	IIb
	Phacoemulsification Tips	IIa
	Sleeves	IIa
	Vitrectomy Accessories	IIb
Ophthalmic Surgical Accessories - Single-Use	Single Use Actuating Kits	Is
	Single Use Air Injection Tubes	IIa
	Single Use Anterior Vitrectomy Probes	IIb
	Single Use Aspiration Cannulae	IIa
	Single Use Backflush Handles	IIa
	Single Use Cassettes	IIa
	Single Use Connectors	IIa
	Single Use Controlled Irrigation Kits	IIa
	Single Use Diathermy Probes	IIb
	Single Use Drapes And Covers	Is
	Single Use Fiber Optic Illumination Probes	IIb
	Single Use Fluid Removal Kits	IIb
	Single Use I/A Tubing Sets And Cassettes	IIb
	Single Use Illumination Chandeliers	IIb
	Single Use Infusion Kits	IIb
	Single Use Sensors	Im/ Is
	Single Use Irrigation Administration Sets	IIa
	Single Use Phaco Tips	IIa
	Single Use Posterior Vitrectomy Probes	IIb
	Single Use Stopcocks	IIa
	Single Use Surge Suppressors	IIa

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	Single Use Surgical Knives	IIa
	Single Use Trocar Kits	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
OPTIKON 2000 S.p.A. Head Office and Operating site	Via del Casale di Settebagni, 13 00138 Roma Italy

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate