



DET NORSKE VERITAS

FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 32034-2008-CE-NOR
This Certificate consists of 4 pages

This is to certify that the Quality Management System of

OPTIKON 2000 S.P.A.

Roma, Italy

for production and final product inspection/testing of

Ophthalmic Devices

has been assessed with respect to

the conformity assessment procedure described in Articles 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 22 September 2009

This Certificate is valid until:

22 September 2013

For DET NORSKE VERITAS CERTIFICATION AS
Norway

Marianne Spæren
Certification Manager

Notified Body No.:
0434

Cecilie Gudesen Torp
Technical Reviewer

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300 000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



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 Rev. 2.0
 Project No.: PRJC-79069-2008-MSL-ITA

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	Original Certificate	2003-09-22
1.0	Re-Certification	2008-09-12
2.0	Re-Certification	2009-09-22

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 function, grouped in any combination <ul style="list-style-type: none"> • Irrigation and Aspiration • Phacoemulsification • Vitrectomy • Diathermy • Endoillumination • Fluids Exchange • Cryosurgery 	Class IIb
Ophthalmic Diagnostical Equipment	Corneal Topography System Ultrasonic Diagnostical Equipment: <ul style="list-style-type: none"> • Pachimeters • A-mode Scanning systems • A/B-mode Scanning systems 	Class IIa
Ophthalmic Diagnostical Accessories	Diagnostic Ultrasound Probes <ul style="list-style-type: none"> • A mode Scanning Probes • B Mode Scanning probes • Pachymeter Probes 	Class IIa



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<p>Ophthalmic Surgical Accessories</p>	<p>I/A Accessories</p> <ul style="list-style-type: none"> • Sleeves • I/A Cannulae • Infusion Cannulae • Aspiration Cannulae <p>Accessories for channelling liquid or gas</p> <ul style="list-style-type: none"> • Tubes for irrigation and aspiration • Tubes for air injection • Stopcocks • Hand-Pieces for irrigation and aspiration <p>Contact Lenses for surgery</p> <p>Fiber optic Illumination Probes</p>	<p>Class IIa</p>
<p>Ophthalmic Surgical Accessories</p>	<p>Phacoemulsification accessories</p> <ul style="list-style-type: none"> • Phacoemulsification Handpieces • Phacoemulsification Tips <p>Vitrectomy accessories</p> <ul style="list-style-type: none"> • Vitrectomy Probes • Blades for vitreous cutters • Microscissors <p>Diathermy Accessories</p> <ul style="list-style-type: none"> • Bipolar diathermy probes • Monopolar diathermy probes • Cautery Electrodes <p>Cryosurgery accessories</p> <ul style="list-style-type: none"> • Cryosurgery Probes 	<p>Class IIb</p>

The complete list of devices is filed with the Notified Body, ref.: project no. PRJC-79069-2008-MSL-ITA

Sites covered by this certificate

Via del Casale di Settebagni, 13 - 00138 Roma, Italy



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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 the local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE