



# DET NORSKE VERITAS

## FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 67725-2009-CE-IND-NA Rev. 1.0  
This Certificate consists of 3 pages

*This is to certify that the Quality Management System of*

### **Tarun Enterprises**

8/8, Strachy Road, Allahabad-211001, U.P., India

*for 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 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, 27 June 2011

*This Certificate is valid until:*

**25 February 2015**

For DET NORSKE VERITAS CERTIFICATION AS  
NORWAY



*Cecilie Gudesen Torp*

Cecilie Gudesen Torp  
Certification Manager



Notified Body No.:  
0434

Mariann Jeremiassen  
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.



Cert. No.: 67725-2009-CE-IND-NA  
 Rev. No.: 1.0  
 Project No.: PRJC-180946-2009-PRC-IND

### 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
	Original certificates 2004-OSL-MDD-0259/0460/0461 and 2006-OSL-MDD-0289/0290/0291	2004-07-02 2006-07-20
	Recertification	2010-02-25
	<b>Cancellation of Ophthalmic Diagnostic Strip models</b>	<b>2011-06-27</b>

### Products covered by this Certificate

Product Description	Product	Class
Intraocular Lenses	PMMA Single Piece (PC and AC Lenses) – Models: OPS – 6535, 6530, 6025, 5525, 5225, 5020 OPAC – 6030 OPMC – 6535, 6530, 6025, 5525 OPMJ – 6535, 6530 Foldable Hydrophilic Acrylic Lenses (With or Without Injector and Cartage) – Models: OPF 6025, OPFS 6025, OPFP 5705	Class IIb
Ophthalmic Solutions	Trypan Blue, Hydroxypropyl Methylcellulose, Sodium Hyaluronate	Class IIb
Ophthalmic Diagnostic Strips	Schirmer Tear Test Strips (With or Without Blue Mark)	Class Is
Ophthalmic Disposable Devices	Surgical Drapes & Pads, Stainless Steel Speculums, Stainless Steel Needle Holders, Spears, Eye Shield (Clear and Coloured)	Class Is
Ophthalmic Surgical Instruments	Forceps, Scissors, Probes, Choppers, Ophthalmic Cannula, Bimanual, Iris Retractor, Endocapsular Tension Rings, Endocapsular Tension Rings Injector, Trephine/Suction Trephine	Class IIa



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Ophthalmic Microsurgical Knives	With or Without Polycarbonate Handle Implant – Tip Size 4.0, 5.0, 5.2, 5.5 mm Phaco Slit - Tip Size 1.2, 1.65, 1.8, 2.0, 2.2, 2.5, 2.6, 2.65, 2.8, 3.0, 3.2, 3.5 mm Crescent - Bevelled up, Bevelled down Stab Incision - 15/30/45 degree with restricted depth 3.0mm to 6.0mm in 15 degree and restricted depth 3.0mm to 3.5mm in 30 degree, MVR Angled and Straight in 19G, 20G & 23G	Class IIa
Ophthalmic Equipment	Keratometer	Class Im

The complete list of devices is filed with the Notified Body.

#### Sites covered by this certificate

Site Name	Address
Tarun Enterprises	8/8, Strachy Road, Allahabad-211001, U.P., India

**EU Representative:** M/s Konsultantz Ltd., 177, A, Percy Road, Whitton, TW2 6JS, U.K.

#### 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