DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 67725-2009-CE-IND-NA 4.0
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 design, production and final product inspection/testing of

Sterile and non-sterile 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, 10 July 2015

For DNV GL BUSINESS ASSURANCE NORWAY AS

Eugenie Winger Husebye
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
25 February 2020

Aud Løken Eiklid
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

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
1.0	Cancellation of Ophthalmic Diagnostic Strip models	2011-06-27
2.0	Withdrawal of Hydroxypropyl Methylcellulose Ophthalmic Solution	2013-12-13
3.0	EU Representative corrected	2013-12-18
4.0	**Recertification and removal of IOLs from the scope**	**2015-07-10**

Products covered by this Certificate

Product Description	Product	Class
Ophthalmic Solutions	• Trypan Blue 0.6mg and 0.8mg • Sodium Hyaluronate1mg to 1.8mg • Hydroxypropyl Methyl Cellulose 1% to 2%	IIb
Ophthalmic Microsurgical Knives	With or Without Polycarbonate Handle • Implant – Tip Size 4.0, 5.0, 5.2, 5.5 mm • Phaco Slit/Clear Cornea - Tip Size 1mm to 3.5 mm • Crescent - Bevelled up, Bevelled down, Double Bevelled up, Double 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	IIa
Ophthalmic Surgical Instruments-Reusable and Disposable use (Stainless steel and Titanium)	Speculums, Depressors Speculums, Retractors, Retractors knives, Keratome, Knives, Spuds, Curettes, Probes, Spoons, Dialators, Dissectors, Clamps, Mallets Forceps, Nibbler, Punches, Trephine, Suction Trephine, Hooks, Cauterys, Loops, Spatula, Calipers Markers, Fixation Ring, Forceps, IOL Holder & Folder, IOL Manipulators, Hook, Nucleus Polisher, Choppers, Vietro Retinal Instruments (Micro & Macro), Scissors, Blade Breaker, Needle Holders, Ophthalmic Cannula with/without Handle, Bimanual sets, Iris Retractor, Capsule Hook, Endocapsular Tension Rings, Endocapsular Tension Rings Injector.	IIa

Ophthalmic Diagnostic Strips	• Schirmer Tear Test Strips Plain • Schirmer Tear Test Strips Mark Blu	Im
Ophthalmic Disposable Devices	Ophthalmic/Surgical Drapes & Pads, Face Mask, Caps, Gown, Apron, Shoe Cover, Bed Sheet and Pillow Cover, Spears, Eye Shield (Clear and Coloured)	Is
Ophthalmic Fluorescein Sodium Strips U.S.P. (Used for contact lens fitting)	Fluorescein Sodium Strips U.S.P. 0.6 and 1mg Box of 10, 20, 50, 100, 300, 500 Strips	Is
Ophthalmic Equipment	Keratometer	Im

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

Sites covered by this certificate: 8/8, Strachy Road, Allahabad – 211001, U.P., India.

EU Representative: Med Devices Lifesciences Ltd., The Black Church, St. Mary's Place,
Dublin 7, Ireland.
Telephone: +353 766801106
Web Site: www.meddevices.net

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