



DET NORSKE VERITAS

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 81001-2010-CE-IND-NA
This Certificate consists of 5 pages

This is to certify that the Quality Management System of

Bio-Tech Vision Care Pvt. Ltd.

555-556-557, Near Subham Tex-O –Pack, Khatraj,
Dist. Gandhinagar, Gujarat, India

for design, production and final product inspection/testing of

Intraocular Lens and Devices for Intra-Ocular Surgery

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, 2 August 2010

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY



This Certificate is valid until:

14 March 2012

Eugenie Winger Husebye
Certification Manager



Notified Body No.:
0434

Angela Lanna
Technical Reviewer

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

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.: 81001-2010-CE-IND-NA
 Rev. No.:
 Project No.: PRJC-46105-2008-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 certificate (The following certificates merged into this certificate: 27149-2008-CE-NOR Rev 02, 2005-OSL-MDD-0272, 1864-2007-CE-NOR, 60619-2009-CE-IND-NA, 2005-OSL-MDD-0457, 67595-2009-CE-IND-NA Rev. 01)	2010-08-02

Products covered by this Certificate

Product Description	Product	Class
Intra ocular lenses	<p>PMMA Intra Ocular Lenses :</p> <ul style="list-style-type: none"> • Single Piece PMMA Lenses : B60120C, B60125C, B60130C, B65130C, B65135C, B60125S, B60130S, B65125C, B65135J, I60120C, I60125C, I60130C, I65130C, I65135C, I60125S, I60130S, I65125C, I65135J, B50120C, B525120C, B55125C, B50125C, B525125C, B55120C, B55125S, I50120C, I525120C, I55125 C, I50125C, I525125 C, I55120C, I55125S, FSQ525C, FSQ605C, FSQ613C, FSQ655C, FSQY605C, FSQY525C, FSQ555C, SQ605C, SQ613C, SQY605C, B525, K50C, K525, K55C, K60C, K60S, K60W, K61C, K61S, K6535C, K6535W, K65C, K65SF, K5225, K6525, K65, MF55, K6W, K61, K61SF, K61W, CL6530, CLE50, CLE55, CLE60, CLE60S, CLE60W, CLE61, CLE61W, CLE65C, CLE65W, CLE65JM, CLE615, 60CLE130, 55CLE125 • Scleral Fixation Lenses: BSF6513, BSF6025, BSF65 • Scleral fixation lenses with optic diameter 5.0-7.0mm and overall diameter between 12.0-13.5 mm <p>PMMA Multipiece Intraocular Lens:</p> <ul style="list-style-type: none"> • 60125CM, 60130CM, 65135CM, 55125CM, 50120CM, 65135JM, 60130JM, MULTI55, MULTI60125 <p>Hydrophilic Acrylic Foldable Intraocular Lenses:</p> <ul style="list-style-type: none"> • 600, 600-OH, 4x4, 600 ROHH, BCR600, BCR600OH, BTP600 • DuoAcryl 600, DuoAcryl MF 	IIB



	<ul style="list-style-type: none"> • Micro, Micro626, 600L, 600LMF, 4x4FIT, TP600, TP550, TP613 • 600ROH, ATF 575, ATF575MF, AS600, AS600ROH, ASTP613, AS4X4FIT, AS4X4, ASTP600, DI600, DI600ROH, DI4X4, DIMICRO, DIMICRO626, DI600L, S600MZ, AS600ROHMZ <p>Capsular Tension Rings (Clear as well as Blue):</p> <ul style="list-style-type: none"> • CTR11, CTR 11.5, CTR12, CTR12.5, CTR13, CTR 13.5, CTR 14, CTR 11B, CTR 11.5B, CTR12B, CTR12.5B, CTR13B, CTR 13.5B, CTR14B <p>Hydrophobic IOLs (Clear as well as Yellow):</p> <ul style="list-style-type: none"> • HF600, HF4X4, HF600ROH, HFTP600, ASHF600, ASHF4X4, DIHF600, DIHF600ROH, DIHF4X4 • HFY600, HFY4X4, HFY600ROH, HFYTP600, ASHFY4X4, ASHFY600, DIHFY600, DIHFY4X4, DIHFY600ROH <p>Surface modified Intra Ocular Lenses:</p> <ul style="list-style-type: none"> • HS600, HS600ROH, HSTP600, HS4X4, HS4X4FIT, HSMICRO, HSMICRO626, HSAS600, HSAS600ROH, HSAS4X4, HSASTP600, HSAS4X4FIT, HS600LMF, HSAS600MZ, HSAS600ROHMZ, DIHS600ROH, DIHS600, DIHS4X4, DIHS600L, DIHSMICRO, HSASATF575, HSATF575MF, FSQ605, FSQ525 • YHS600, YHS600ROH, YHSTP600, YHS4X4, YHS4X4FIT, YHSMICRO, YHSMICRO626, YHSAS600, YHSAS600ROH, YHSAS4X4, YHSASTP600, YHSAS4X4FIT, YHSAS600ROHMZ, YHSAS600MZ, DIYHS600, DIYHS600ROH, DIYHS4X4, DIYHSMICRO, DIYHS600L, YHSASATF575, YHSATF575MF, FSQY605, FSQY525 <p>Yellow Hydrophilic Acrylic Foldable IOLs:</p> <ul style="list-style-type: none"> • Y600, Y600OH, Y4X4, YMICRO, YMICRO626, Y600L, Y600LMF, Y4X4FIT, YTP600, YTP550, Y600ROH, YATF575, YATF575MF, YAS600, YAS600ROH, YAS4X4FIT, YAS4X4, YASTP600, DIY600, DIY600ROH, DIY4X4, DIYMICRO, DIYMICRO626, DIY600L 	
<p>Cartridges and Injectors for Ophthalmic surgery</p>	<p>Cartridges:</p> <ul style="list-style-type: none"> • Hydraulic Cartridges with Silicone stopper: <ul style="list-style-type: none"> ▪ Bio Hydro Cartridges-BHC 150, BHC 140, BHC 270 ▪ Bio Hydromini Cartridge- BHMC 145 • Mechanical Cartridge • Bio Meca Cartridge- BMC 180 <p>Injectors:</p> <ul style="list-style-type: none"> • Hydraulic injector - Bio Hydroject injector, Bioject V, Bioject D • Mechanical injector - Bio Mecaject injector 	<p>IIa</p>



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Iris Retractor	Iris Retractor	IIa
PVA spears, Cellulose spears, PVA cataract Kit	PVA Spears: <ul style="list-style-type: none">• Bio Spears-Sterile Cellulose Spears: <ul style="list-style-type: none">• Bio Cel-Sterile PVA cataract Kit: <ul style="list-style-type: none">• Biocare Cata Kit-Sterile	IIa
Ophthalmic Surgical Blades	<ul style="list-style-type: none">• Flat Stock Blades• Round Stock Blades	IIa
Ophthalmic Strips	<ul style="list-style-type: none">• Lissamine Green Ophthalmic Strips• Rose Bengal Ophthalmic Strips• Schirmer Strips	IIa

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

Sites covered by this certificate

Site Name	Address
Bio-Tech Vision Care Pvt. Ltd.	Plot No.555, 556, 557, Nr.Subham Tex-O-Pack, Dist. Gandhinagar, Khatraj, Gujarat, India

EU Representative: Mr. Siddharth Asnani, 17 Wellesley Road, Ilford, Essex IG14JT, United Kingdom



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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