EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
215570-2017-CE-IND-NA-PS Rev 1.0	PRJC-556142-2016-MSL-IND	14 March 2022

This is to certify that the quality system of:

BIO-TECH VISION CARE PVT. LTD.

Plot No. 555-556-557, Opp. Subham Tex-O-Pack,Khatraj-Vadsar Road, P.O.: Khatraj, Taluka, Kalol, 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 ANNEX II EXCLUDING SECTION 4 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, 05 March 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

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The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supercedes DNVGL (NB0434) certificate no 215570-2017-CE-IND-NA following transfer of notified body functions to DNV GL Nemko Presafe AS (NB2460)	2017-04-07
1.0	EC Representative Change	2020-03-05

Products covered by this Certificate:

Product Description	Product Name	Class
Intra ocular lenses	PMMA Intra Ocular Lenses : • Single Piece PMMA Lenses : B60125C, B65135C, B60125S, B60130S, B50120C, B55125C, I55120C, I55125S, FSQ525C, FSQ605C, FSQ613C, FSQ655C, SQ605C • PMMA Multipiece Intraocular Lens: 65135JM Hydrophilic Acrylic Foldable Intraocular Lenses: • 600, 4x4 • TP600, TP613 • 600ROH, AS600, S600MZ Hydrophobic IOLs (Clear as well as Yellow): • HF600, ASHF600 • HFY600, ASHFY600, DIHFY600, ASHFY6002, TRHFY600 Surface modified Intra Ocular Lenses: • HSAS600, HSAS600ROH, HSAS4X4 • YHSAS600, YHSAS4X4, DIYHS600ROH Hydrophobic Toric IOLs: • HFY-10, HFY-20, HFY-30, HFYD-10, HFYD-20, • HFYD-30, HFY-35, HFY-40, HFY-50, HFY-60, HFYD-35, HFYD-40, HFYD-50, HFYD-60, HFY-05, HFYD-05. Phakic IOLs: • PKC120NH, PKC125NH, PKC130NH Phakic Toric IOLs: • PC120T, PC125T, PC130T	IIb

	Preloaded Delivery System with Hydrophobic IOLs: • PAHFY600F, PLHF-10, PLHF-20, PLHF-30, PLHFD-10, PLHFD-20, PLHFD-30, PLHF2, PLHFD6, PLHF-05, PLHFD-05	
Capsular Tension Rings	Clear as well as Blue: • CTR11, CTR12, CTR13, CTR14, CTR11B, CTR12B, CTR13B, CTR14B.	IIb
Cartridges and Injectors for Ophthalmic surgery	Cartridges: • Hydraulic Cartridges with Silicone stopper: • Bio Hydro Cartridges- BHC 150, BHC 140 Mechanical Cartridge • Bio Meca Cartridge- BMC 180 Injectors: • Hydraulic injector - Bio Hydroject Injector • Mechanical injector - Bio Mecaject Injector Pre-loaded Delivery System: • Bioject-P260, Bioject-P220, Bioject-P300, IC-8-350, IC- 8-380	IIa
Iris Retractor	Iris Retractor	IIa
PVA spears	PVA Spears: • Bio Spears-Sterile	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, Opp. Subham Tex-O-Pack,Khatraj-Vadsar Road, P.O.: Khatraj, Taluka, Kalol, Dist. Gandhinagar, Gujarat, India

EU Representative
Biotech Europe Meditech Inc Limited
AF2, IDA Business & Technology Park,
Roscommon, Ireland

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