Management System Certificate

Certificate No.:	Initial Certification Date:	Valid Until
243094-2017-AQ-IND-NA-PS	09 September 2011	08 September 2021 – 09 September 2024

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.

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016/EN ISO 13485:2016

This certificate is valid for the following scope:

Design, Manufacturing and Supply of Sterile Single piece and Multi piece PMMA Intra Ocular Lenses (Clear and Yellow), Single Piece and Multi- piece (3 Pieces) Hydrophilic Foldable Acrylic Intra Ocular lenses (Clear and Yellow), Scleral Fixation Lenses, Single piece and Multi piece Hydrophobic Intra Ocular Lenses (Clear and Yellow), Surface Modified Intra Ocular Lenses (Clear and Yellow), Iris Retractors, Preloaded Delivery System with Hydrophobic IOLs, Multifocal Intraocular lenses, Hydrophobic and Hydrophilic Toric IOLs, Phakic IOLs, Phakic Toric IOLs, Intrastromal Corneal Rings, Ophthalmic Surgical Blades, Capsular Tension Rings (Clear and Blue), Cartridges and Injectors, Ophthalmic strips, PVA spears.

Design, Manufacture, Supply, Installation and Servicing of Non-sterile Phacoemulsificator & Sterile/Non-sterile accessories.

Design, Manufacture, Sales and Distribution of Sterile solutions for Ophthalmic, Osteoarthritis, Dermal and Urology use.

Digitally signed by Pereteatco Alina
Date: 2021.10.08 07:21:35 EEST

Place and date:
Høvik, 06 September 2021

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

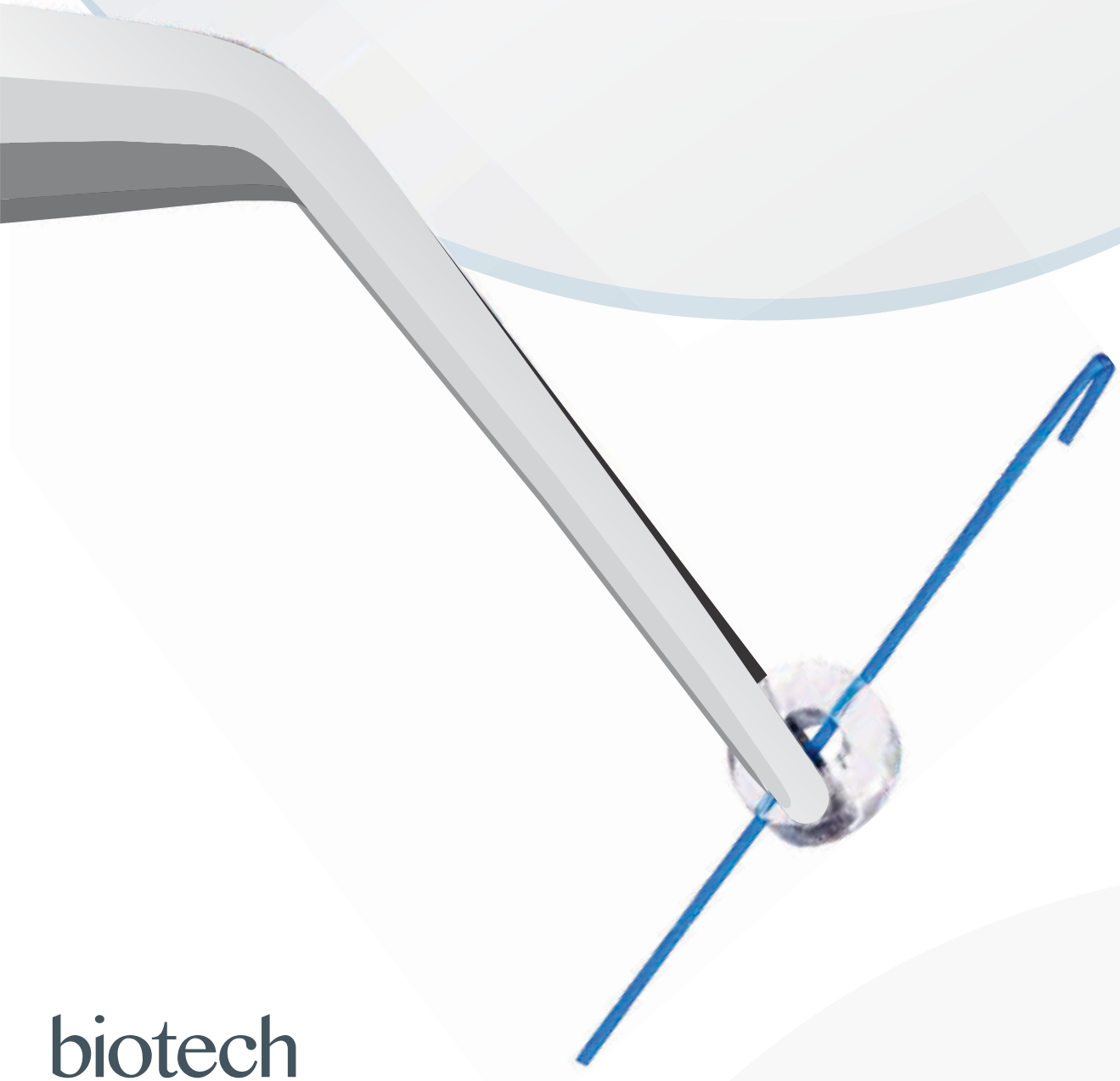
Digitally signed by Pereteatco Alina
Date: 2021.10.08 12:39:41 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate No.: 243094-2017-AQ-IND-NA-PS
Place and date: Høvik, 06 September 2021

Site name	Site address	Site specific scope
Bio-Tech Vision Care Pvt. Ltd.	Unit 1: Plot No. 555-556-557, Opp. Subham Tex-O-Pack, Khatraj-Vadsar Road, P.O.: Khatraj, Taluka, Kalol, Dist. Gandhinagar, Gujarat, India.	Design, Manufacturing and Supply of Sterile Single piece and Multi piece PMMA Intra Ocular Lenses (Clear and Yellow), Single Piece and Multi- piece (3 Pieces) Hydrophilic Foldable Acrylic Intra Ocular lenses (Clear and Yellow), Scleral Fixation Lenses, Single piece and Multi piece Hydrophobic Intra Ocular Lenses (Clear and Yellow), Surface Modified Intra Ocular Lenses (Clear and Yellow), Iris Retractors, Preloaded Delivery System with Hydrophobic IOLs, Multifocal Intraocular lenses, Hydrophobic and Hydrophilic Toric IOLs, Phakic IOLs, Phakic Toric IOLs, Intrastromal Corneal Rings, Ophthalmic Surgical Blades, Capsular Tension Rings (Clear and Blue), Cartridges and Injectors, Ophthalmic strips, PVA spears. Design, Manufacture, Supply, Installation and Servicing of Non-sterile Phacoemulsificator & Sterile/Non-sterile accessories.
Bio-Tech Vision Care Pvt. Ltd.	Unit 2: Plot No. 4, PHARMEZ, Sarkhej-Bavla N.H. 8A, Village: Matoda, Taluka: Sanand, Dist.: Ahmedabad- 382213, Gujarat, India.	Design, Manufacture, Sales and Distribution of Sterile solutions for Ophthalmic, Osteoarthritis and Dermal use
Bio-Tech Vision Care Pvt. Ltd.	Unit 3: Plot no. 555, 556, 557 Khatraj-Vadsar Road, Opp. Shubham Tex-O-Pack, Village Khatraj, Taluka Kalol, Dist. Gandhinagar, Gujarat, India.	Design, Manufacture, Sales and Distribution of Sterile solutions for Ophthalmic and Urology use

CE
2460

IRIS RETRACTORS



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www.biotechhealthcare.com

IRIS RETRACTORS

Description:

Iris Retractor consists of a flexible hook made of bright blue polypropylene monofilament and adjustable silicone stopper which safely enables the mechanical dilation of the pupil.

Packaging:

Each storage case contains 5 disposable e iris retractors. Typically, four(4) iris retractors are required to obtain adequate iris dilataion. It is supplied sterile(ethylene oxide sterilized).

Indication:

The flexible Iris Retractor enables the mechanical dilation of the pupil where dilation cannot be achieved pharmacologically. It is a simple, safe & fast alternative to reduce the surgical time. The flexible Iris Retractor gently stretches and retains the Iris for maximum visibility during surgical procedures like phacoemulsification, retina & vitreous surgery. It can be safely used in aphakic, pseudophakic and phakic eyes.

Directions for Use:

- The Iris Retractor must be opened in a sterile environment and used as soon as possible after opening the box.
- Check the integrity of the sterile packaging before use.
- Examine the label on the unopened package for manufacturing and expiration date.
- Make four small and self-sealing incisions, equidistance from each other and as close as possible to the limbus using 0.5 mm wide spatula shaped knife.
- Hold the Iris Retractor gently with the help of forceps at silicone lock, introduce the retractor into the eye through the incision. Surgery must be performed using non-toothed, polished instruments.
- Insert the hooked end of the retractor into the incision and then move the hook over the Iris. Retracting the device dilates the pupil. The tension of the hook is adjusted by sliding the silicone stopper along the shaft of the retractor. When all four retractors are in place, the pupil is enlarged as a square. The dilation is maintained by the silicone stoppers at the incision site. The tension of the hook is adjusted by sliding the silicone stopper along the shaft of the retractor.

Removal of Iris Retractor:

- Slide the silicone stopper away from the cornea to release the Iris.
- Unlock the retractor from the Iris.
- Slowly, withdraw the retractor from the eye. The hooked end will straighten and slip through the self-sealing incision.

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BIOTECH VISION CARE PVT LTD | Block 1, Abhishree Corporate Park, Opp. Swagat Bunglow BRTS Stop
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MKT1014 | REV03 | 08-2021

DNV·GL

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

Cathrine Wisbech

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

Certificate No.:
215570-2017-CE-IND-NA-PS Rev 1.0

Project No.:
PRJC-556142-2016-MSL-IND

Valid Until:
14 March 2022

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