EU Quality Management System Certificate

Certificate no.:
C528629

Initial certification date:
12 March 2022

Valid Until:
12 March 2027

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.

SRN: IN-MF-000008482

For design, production and final product inspection/testing of:

Intraocular lens, Devices for Intraocular Surgery, Capsular Tension Ring, Iris Retractors & Ophthalmic Strips

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 12 March 2022

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Alessandra Rinna
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate		12 March 2022

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
Single Piece PMMA Intraocular Lenses Single piece PMMA Intraocular Lenses are intended to replace the human crystalline lens for surgical correction of the aphakia after intra or extra capsular extraction of the lens in patients with cataracts.	B60125C, B65135C, B60125S, B60130S, B50120C, B55125C, FSQ605C, SQ605C	IIb
PMMA Multipiece Intraocular Lenses Multipiece PMMA Intraocular Lenses are intended to replace the human crystalline lens for surgical correction of the aphakia after intra or extra capsular extraction of the lens in patients with cataracts.	65135JM	IIb
Hydrophilic Acrylic Foldable Intraocular Lenses Hydrophilic Single piece and Multi-piece Intraocular Lenses are intended to be implanted into the capsular bag in the posterior chamber of the eye for the visual correction of aphakia secondary to the removal of the crystalline lens in adult patients with cataracts.	600, 4x4, TP600, TP613, 600ROH, AS600, S600MZ	IIb
Surface Modified Hydrophilic Intraocular Lenses Hydrophilic Surface Modified Intraocular Lenses are intended to be implanted into the capsular	HSAS600, HSAS600ROH, HSAS4X4, YHSAS600, YHSAS4X4, DIYHS600ROH	IIb

bag in the posterior chamber of the eye for the visual correction of aphakia secondary to the removal of the crystalline lens in adult patients with cataracts. Surface Modified Multifocal Intraocular Lenses are intended for cataract patients with Presbyopia.		
Phakic Hydrophilic Intraocular Lenses Phakic Intraocular Lenses are indicated in Phakic adults for the correction or reduction of Refractive error (myopia/ hyperopia).	PKC120NH, PKC125NH, PKC130NH, PKC135NH, PKC140NH, PKC110NH, PKC115NH	IIb
Phakic Toric Hydrophilic Intraocular Lenses Phakic Toric Intraocular Lenses are indicated in Phakic adults for the correction or reduction of Refractive error (myopia/hyperopia) and refractive error with astigmatism.	PC120T, PC125T, PC130T, PC135T, PC140T, PC110T, PC115T	IIb
Hydrophobic Intraocular Lenses Hydrophobic acrylic Intraocular Lenses are intended to be implanted into the capsular bag in the posterior chamber of the eye for the visual correction of aphakia secondary to the removal of the crystalline lens in patients with cataracts. Hydrophobic acrylic multifocal, multifocal Toric, EDOF & EDOF Toric Intraocular Lenses are also indicated for presbyopic patients who seeks greater independence from glasses for intermediate and/or near vision in addition to far vision with or without corneal astigmatism.	HF600, ASHF600, HFY600, ASHFY600, DIHFY600, ASHFY6002, TRHFY600, TRHFY600T, HFY600T, ASHFY600D	IIb
Hydrophobic Toric Intraocular Lenses Hydrophobic acrylic Toric Intraocular Lenses are intended to be implanted into the capsular bag in the posterior chamber of	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	IIb

the eye for the visual correction of aphakia secondary to the removal of the crystalline lens in patients with cataracts with regular corneal astigmatism. Hydrophobic acrylic multifocal Toric Intraocular Lenses are also indicated for presbyopic patients who seeks greater independence from glasses for near vision in addition to far vision with corneal astigmatism.		
Preloaded Delivery System with Hydrophobic Intraocular Lenses Preloaded Hydrophobic acrylic Intraocular Lenses are intended to be implanted into the capsular bag in the posterior chamber of the eye for the visual correction of aphakia secondary to the removal of the crystalline lens in patients with cataracts. Preloaded Hydrophobic acrylic multifocal, multifocal Toric, EDOF & EDOF Toric Intraocular Lenses are indicated for presbyopic patients who seeks greater independence from glasses for intermediate and/or near vision in addition to far vision with or without corneal astigmatism.	PAHFY600F, PLHF-10, PLHF-20, PLHF-30, PLHFD-10, PLHFD-20, PLHFD-30, PLHF2, PLHFD6, PLHF-05, PLHFD-05, PLHFD6T, PLHF2E, PLHF2ET	IIb
Capsular Tension Ring CTR is indicated for the stabilization of weakened, broken, or missing zonules that are suspected or observed during cataract extraction using phacoemulsification and continuous curvilinear capsulorhexis techniques.	CTR11, CTR12, CTR13, CTR14, CTR11B, CTR12B, CTR13B, CTR14B	IIb
Intraocular Lens delivery system IOL delivery system is indicated for implantation of intraocular lens into the eye.	Bio Hydroject: BHSET 150, BHSET 140, BHSET 150P Bio Mecaject: BMSET 180 Bioject: Bioject-P220, Bioject-P260, Bioject-P300 IC-8: IC-8-350, IC-8-380	IIa

Iris Retractor The flexible Iris Retractor enables the mechanical dilation of the pupil where dilation cannot be achieved pharmacologically. It 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.	IRIS RETRACTOR	IIa
Ophthalmic Strips Schirmer Strips Bio Schirmer Ophthalmic Strip is indicated for the measurement of production of tear and its volume for a dry eye test.	BIO SCHIRMER	Is
Ophthalmic Strips Fluorescein Sodium Strips Bio Fluoro Ophthalmic Strip is indicated for staining the anterior segment of the eye when fitting contact lenses, in disclosing corneal injury and in applanation tonometry.	BIO FLUORO	Is

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: 10000492112-PA-NoMA-IND

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 the Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.