

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10000368344-PA-NA-IND

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

Valid Until:
27 May 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.

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

STERILE SOLUTIONS FOR OPHTHALMIC USE

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, 22 October 2020

For:
DNV GL PRESAFE AS
Notified Body No.: 2460



Palani Damodharan

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	Initial certificate	22 October 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Ophthalmic Solutions		
Hydroxy Propyl Methyl Cellulose Ophthalmic Solution USP 2% w/v, 2.4% w/v	<ol style="list-style-type: none"> 1. Eye Visc (3ml and 5ml vial) 2. Eye Visc plus PFS (2ml) 3. Eye Visc PFS 2.4% (2ml PFS) 4. Metilon Plus PFS (2ml) 	IIb
Trypan Blue (0.06% w/v) Ophthalmic Solution	1. Bio-Blue - 1 ml vial and Pack of 5 or 10 vials	IIb
Trypan Blue (0.15% w/v) Ophthalmic Solution	1. Bio-Blue Plus - 1 ml vial and Pack of 5 or 10 vials	IIb
Sodium Hyaluronate Ophthalmic Solution	<ol style="list-style-type: none"> 1. Bio-Hyalur EV (18mg/ml) 1 ml, 1.6 ml 2. Bio-Hyalur SV (30mg/ml) 1 ml, 1.6 ml 3. Bio-Vial (2.0ml) 	IIb
Silicone Oil		
Silicone Oil 1000 cst	1. BIOSIL (10ml Vial)	IIb
Silicone Oil 5000 cst	1. BIOSIL-F (10ml Vial)	IIb
Perfluoro-n-octane liquid	1. BIO OCTANE (5ml Vial)	IIb
Perfluorodecalin liquid	1. BIO DECALIN (5ml and 7ml Vial)	IIb

The complete list of devices is filed with the Notified Body

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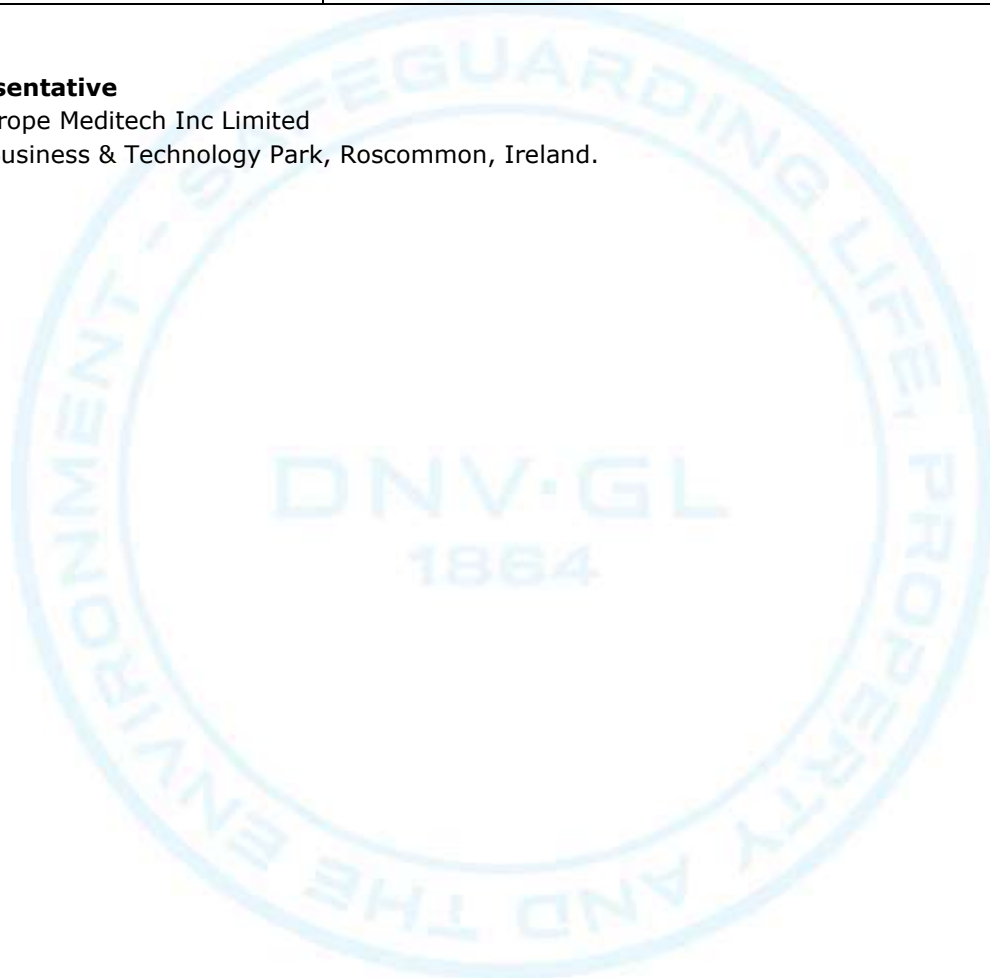
Valid Until:
27 May 2024

Sites covered by this certificate

Site Name	Address
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

EU Representative

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



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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 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

Management System Certificate

Certificate No.:
243094-2017-AQ-IND-NA-PS

Initial Certification Date:
09 September 2011

Valid Until
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 Alma
Date: 2021.10.08 07:21:35 EEST



Place and date:
Høvik, 06 September 2021



For the issuing office:
DNV Product Assurance AS

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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

Digitally signed by Pereteatco Alma
Date: 2021.10.08 07:03:04 EEST



biotech

VISIONCARE

CATARACT SURGERY SOLUTIONS

www.biotechhealthcare.com

Bio-Blue

Trypan Blue Ophthalmic Solution 0.06 % W/V for Intraocular use as an adjunct to Cataract and Ophthalmic Surgery

Bio-Blue is used as a stain for performing capsulorhexis during cataract surgery.

Description:

Bio-Blue is a sterile solution of Trypan Blue, a biocompatible intraocular solution used during ophthalmic surgery. It is frequently used in eyes with mature cataracts, poor red fundus reflex or narrow pupils.

Indications:

- Phacoemulsification
- Small Incision Cataract Surgery
- Extra Capsular Cataract Surgery
- Incomplete Capsulorhexis
- Anterior/Posterior Capsulotomy
- Membrane peeling
- Improved visualization



Packaging:

- Bio-Blue™ (Trypan Blue Ophthalmic Solution 0.06 % W/V) 1.0ml in sterile glass vial
- Bio-Blue™ (Trypan Blue Ophthalmic Solution 0.06 % W/V) 1.0ml in sterile PFS



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VISION CARE

BIOTECH VISION CARE PVT LTD | Block 1, Abhishree Corporate Park, Opp. Swagat Bunglow BRTS Stop
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