

# 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](http://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
<b>Ophthalmic Solutions</b>		
Hydroxy Propyl Methyl Cellulose Ophthalmic Solution USP 2% w/v, 2.4% w/v	<ol style="list-style-type: none"> <li>1. Eye Visc (3ml and 5ml vial)</li> <li>2. Eye Visc plus PFS (2ml)</li> <li>3. Eye Visc PFS 2.4% (2ml PFS)</li> <li>4. Metilon Plus PFS (2ml)</li> </ol>	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"> <li>1. Bio-Hyalur EV (18mg/ml) 1 ml, 1.6 ml</li> <li>2. Bio-Hyalur SV (30mg/ml) 1 ml, 1.6 ml</li> <li>3. Bio-Vial (2.0ml)</li> </ol>	IIb
<b>Silicone Oil</b>		
Silicone Oil 1000 cst	1. BIOSIL (10ml Vial)	IIb
Silicone Oil 5000 cst	1. BIOSIL-F (10ml Vial)	IIb
<b>Perfluoro-n-octane liquid</b>	1. BIO OCTANE (5ml Vial)	IIb
<b>Perfluorodecalin liquid</b>	1. BIO DECALIN (5ml and 7ml Vial)	IIb

The complete list of devices is filed with the Notified Body

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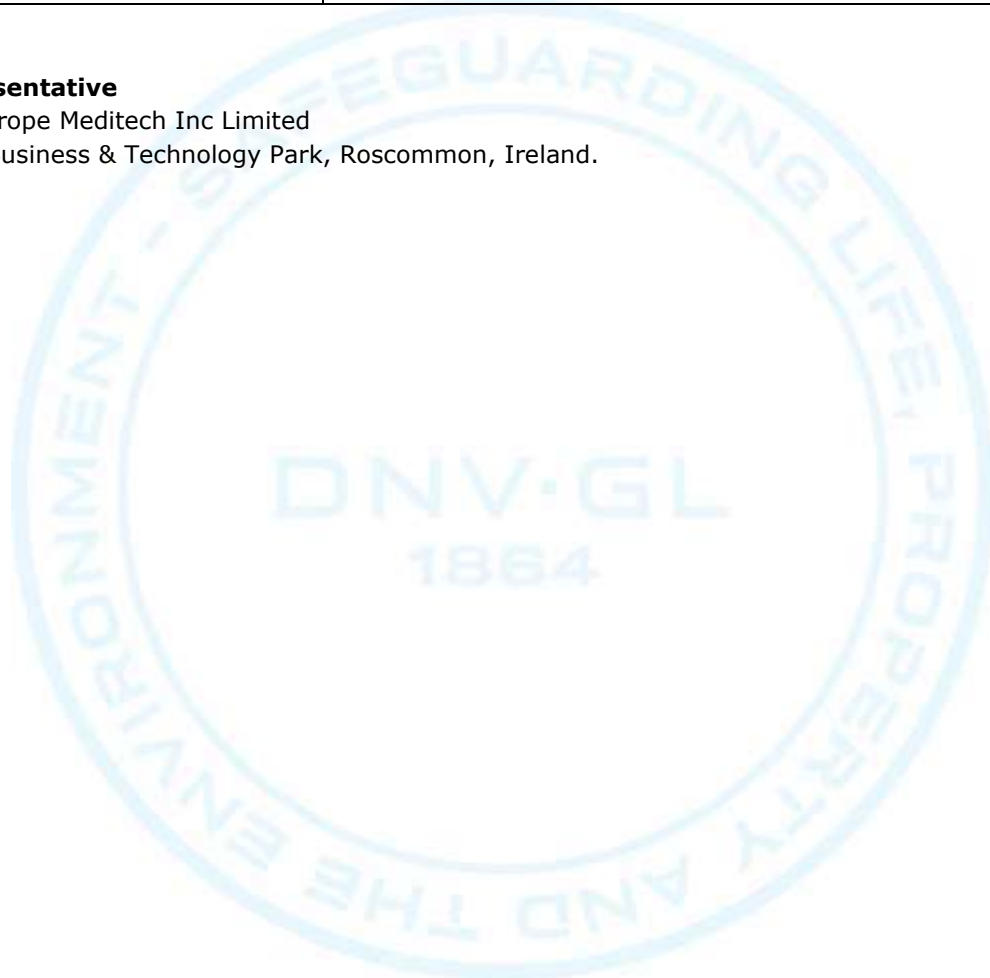
Valid Until:  
27 May 2024

**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.

Accredited Body: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

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



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Digitally signed by Pereteatco Alina  
Date: 2021.10.08 07:02:31 EEST



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VISION CARE

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# CATARACT SURGERY SOLUTIONS

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[www.biotechhealthcare.com](http://www.biotechhealthcare.com)

## Bio-Hyalur Range Sodium Hyaluronate Ophthalmic Solution

The best options for the protection & control you need in ophthalmic surgery

- Cataract Extraction
- Intraocular Lens (IOL) implantation
- Corneal transplantation surgery
- Glaucoma filtering surgery

### Advantages:

- Source - Bacterial fermentation
- Ideal for lubricating the cartridges of IOLs for implantation
- Excellent endothelial protection
- Easy to inject and remove from the eye
- High viscosity for further expansion of the anterior chamber & higher maintenance of spaces while doing ophthalmic surgery
- Latex free





## Specification: Bio-Hyalur Range

### Sodium Hyaluronate Ophthalmic Solution

Product Name	Bio-Hyalur	Bio-Hyalur Plus	Bio-Hyalur HV	Bio-Hyalur SV
Sodium Hyaluronate	1.0%	1.4%	2.4%	3.0%
Concentration	10mg/ml	14mg/ml	24mg/ml	30mg/ml
Origin	Bacterial Fermentation	Bacterial Fermentation	Bacterial Fermentation	Bacterial Fermentation
Molecular weight (Million Daltons)	2.8-3.2	2.8-3.2	2.8-3.2	2.8-3.2
Viscosity at Zero shear rate at 25° C ± 2° C	300,000 mPas	400,000 mPas	850,000 mPas	1,000,000 mPas
Osmolality	270-400 mOsmol/kg	270-400 mOsmol/kg	270-400 mOsmol/kg	270-400 mOsmol/kg
pH at 25° C ± 2° C	6.8 to 7.6	6.8 to 7.6	6.8 to 7.6	6.8 to 7.6
Storage	2°C to 25°C	2°C to 25°C	2°C to 25°C	2°C to 25°C
Volume	1.0ml	1.0ml	1.0ml	1.0ml
Cannula	27gauge	27gauge	27gauge	27gauge
Approval	CE mark	CE mark	CE mark	CE mark



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