

# E C C E R T I F I C A T E

## 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)



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.  
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

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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>Eye Visc (3ml and 5ml vial)</li> <li>Eye Visc plus PFS (2ml)</li> <li>Eye Visc PFS 2.4% (2ml PFS)</li> <li>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>Bio-Hyalur EV (18mg/ml) 1 ml, 1.6 ml</li> <li>Bio-Hyalur SV (30mg/ml) 1 ml, 1.6 ml</li> <li>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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**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

# APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:  
10000368344-PA-NA-IND

Valid Until:  
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:  
**BIO-TECH VISION CARE PVT. LTD.**

originally issued in compliance with:  
**the Council Directive 93/42/EEC on Medical Devices, as amended**

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

#### Site covered by certificate

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

Place and date:  
Høvik, 21 September 2021



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



**Hazem Tinawi**  
Technical Reviewer

The name or identifier of a device already covered by the certification, has been revised.

<b>Products covered by this Certificate (replaces information on certificate): 10000368344-PA-NA-IND</b>		
<b>Product Description</b>	<b>Product Name</b>	<b>Class</b>
<b>Ophthalmic Solutions</b>		
Hydroxy Propyl Methyl Cellulose Ophthalmic Solution USP 2% w/v	<ul style="list-style-type: none"> <li>Eye Visc (3ml and 5ml vial)</li> </ul>	IIb
Trypan Blue (0.06% w/v) Ophthalmic Solution	<ul style="list-style-type: none"> <li>Bio-Blue - 1 ml vial and Pack of 5 or 10 vials</li> </ul>	IIb
Trypan Blue (0.15% w/v) Ophthalmic Solution	<ul style="list-style-type: none"> <li>Bio-Blue Plus - 1 ml vial and Pack of 5 or 10 vials</li> </ul>	IIb
Sodium Hyaluronate Ophthalmic Solution	<ul style="list-style-type: none"> <li>Bio-Vial (2.0ml)</li> </ul>	IIb
<b>Silicone Oil</b>		
Silicone Oil 1000 cst	<ul style="list-style-type: none"> <li>BIOSIL (10ml Vial)</li> </ul>	IIb
Silicone Oil 5000 cst	<ul style="list-style-type: none"> <li>BIOSIL-F (10ml Vial)</li> </ul>	IIb
<b>Perfluoro-n-octane liquid</b>	<ul style="list-style-type: none"> <li>BIO OCTANE (5ml Vial)</li> </ul>	IIb
<b>Perfluorodecalin liquid</b>	<ul style="list-style-type: none"> <li>BIO DECALIN (5ml and 7ml Vial)</li> </ul>	IIb

<b>Appendix History -</b>		
<b>Revision</b>	<b>Description</b>	<b>Issued Date</b>
0.0	Original Appendix- Product transfer to BIO-TECH VISION CARE PVT. LTD. (Unit 2) EC certificate #277565-2018-CE-IND-NA-PS List of products: 1. Eye Visc plus PFS (2ml) 2. Eye Visc PFS 2.4% (2ml PFS) 3. Metilon Plus PFS (2ml) 4. Bio-Hyalur EV (18mg/ml) 1 ml, 1.6 ml 5. Bio-Hyalur SV (30mg/ml) 1 ml, 1.6 ml	16 September 2021
1.0	Correct clerical errors.	21 September 2021