

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
277565-2018-CE-IND-NA-PS Rev. 2.0

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

Valid Until:  
18 May 2023

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:  
**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, 11 November 2020**

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



**Mariann Jeremiassen**

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	This certificate is traceable to the certificate no. 253881-2018-CE-IND-NA-PS Rev. 0.0 and Reissued with Merger of sites	2019-02-12
1.0	EC Representative Change	2020-03-04
<b>2.0</b>	<b>Product removal (OPTIFLEX (0.85 ml, 0.55 ml, 1.0 ml PFS) and OPTIFLEX 1.4% (0.85 ml, 0.55 ml, 1.0 ml PFS)</b>	<b>2020-11-11</b>

## Products covered by this Certificate:

Product Description	Product Name	Class
Hydroxy Propyl Methyl Cellulose Ophthalmic Solution USP 2% w/v	<ul style="list-style-type: none"> <li>Eye Visc PFS (2ml, 2.5ml &amp; 3ml PFS)</li> <li>Metilon 20 PFS (2ml)</li> </ul>	IIb
Sodium Hyaluronate Ophthalmic Solution	<ul style="list-style-type: none"> <li>Bio-Hyalur HV (24mg/ml) (0.5 ml, 0.8 ml, 1.0 ml, 1.6ml, 1.8ml &amp; 2.0ml PFS)</li> <li>Bio-Hyalur 1.2% (1.0 ml, 1.6 ml, 1.8 ml, 2.0 ml PFS)</li> <li>Bio-Hyalur DUO (1.0 ml, 1.8 ml, 2.0 ml PFS)</li> <li>Bio-Hyalur (10 mg/ml) (1.0 ml, 1.6 ml, 1.8 ml, 2.0 ml PFS)</li> <li>Bio-Hyalur Plus (14 mg/ml) (1.0 ml, 1.6 ml, 1.8 ml, 2.0 ml PFS)</li> </ul>	IIb
Trypan blue Ophthalmic solution	<ul style="list-style-type: none"> <li>Bio-Blue (1 ml PFS and Pack of 5 or 10 PFS)</li> <li>Bio-Blue Plus (1 ml PFS and Pack of 5 or 10 PFS)</li> </ul>	IIb
Brilliant Blue G or Acid Blue 90 Ophthalmic Solution	<ul style="list-style-type: none"> <li>Bio Blue 90 (0.5 ml and 1 ml PFS)</li> <li>Bio Blue 90 Plus (0.5 ml and 1 ml PFS)</li> </ul>	IIb
Combination of Brilliant Blue G or Acid Blue 90 and Trypan Blue Ophthalmic Solution	<ul style="list-style-type: none"> <li>Bio Blue Duo (0.5 ml and 1 ml PFS)</li> </ul>	IIb
Silicone Oil 1000cst/5000 cst	<ul style="list-style-type: none"> <li>BIOSIL (10ml PFS)</li> <li>BIOSIL-F (10ml PFS)</li> </ul>	IIb
Perfluoro-n-octane liquid	<ul style="list-style-type: none"> <li>BIO OCTANE (5 ml &amp; 7ml PFS)</li> </ul>	IIb

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Perfluoro decalin liquid	<ul style="list-style-type: none"> <li>BIO DECALIN (5 ml &amp; 7ml PFS)</li> </ul>	IIb
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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. (Unit 2)	Plot No. 4, PHARMEZ, Sarkhej-Bavla N.H. 8A, Village: Matoda, Taluka: Sanand, Dist.: Ahmedabad- 382213, Gujarat, India

#### EU Representative

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

Certificate No.:  
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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.:  
277565-2018-CE-IND-NA-PS Rev. 2.0

Valid Until:  
18 May 2023

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 2)  
Plot No. 4, PHARMEZ, Sarkhej-Bavla N.H. 8A, Village: Matoda, Taluka: Sanand,  
Dist.: Ahmedabad- 382213, 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

<b>Products covered by this Certificate (replaces information on certificate): 277565-2018-CE-IND-NA-PS Rev. 2.0</b>		
<b>Product Description</b>	<b>Product Name</b>	<b>Class</b>
Hydroxy Propyl Methyl Cellulose Ophthalmic Solution USP 2% w/v, <b>2.4% w/v</b>	<ul style="list-style-type: none"> <li>• Eye Visc PFS (2ml, 2.5ml &amp; 3ml PFS)</li> <li>• Metilon 20 PFS (2ml)</li> <li>• <b>Eye Visc plus PFS (2ml)</b></li> <li>• <b>Eye Visc PFS 2.4% (2ml PFS)</b></li> <li>• <b>Metilon Plus PFS (2ml)</b></li> </ul>	IIb
Sodium Hyaluronate Ophthalmic Solution	<ul style="list-style-type: none"> <li>• Bio-Hyalur HV (24mg/ml) (0.5 ml, 0.8 ml, 1.0 ml, 1.6ml, 1.8ml &amp; 2.0ml PFS)</li> <li>• Bio-Hyalur 1.2% (1 ml, 1.6 ml, 1.8 ml, 2.0 ml PFS)</li> <li>• Bio-Hyalur DUO (1 ml, 1.8 ml, 2.0 ml PFS)</li> <li>• Bio-Hyalur (10 mg/ml) (1 ml, 1.6 ml, 1.8 ml, 2.0 ml PFS)</li> <li>• Bio-Hyalur Plus (14 mg/ml) (1.0 ml, 1.6 ml, 1.8 ml, 2.0 ml PFS)</li> <li>• <b>Bio-Hyalur EV (18mg/ml) 1 ml, 1.6 ml</b></li> <li>• <b>Bio-Hyalur SV (30mg/ml) 1 ml, 1.6 ml</b></li> </ul>	IIb
Trypan blue Ophthalmic solution	<ul style="list-style-type: none"> <li>• Bio-Blue (1 ml PFS and Pack of 5 or 10 PFS)</li> <li>• Bio-Blue Plus (1 ml PFS and Pack of 5 or 10 PFS)</li> </ul>	IIb
Brilliant Blue G or Acid Blue 90 Ophthalmic Solution	<ul style="list-style-type: none"> <li>• Bio Blue 90 (0.5 ml and 1 ml PFS)</li> <li>• Bio Blue 90 Plus (0.5 ml and 1 ml PFS)</li> </ul>	IIb
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Silicone Oil 1000cst/5000 cst	<ul style="list-style-type: none"> <li>• BIOSIL (10ml PFS)</li> <li>• BIOSIL-F (10ml PFS)</li> </ul>	IIb
Perfluoro-n-octane liquid	<ul style="list-style-type: none"> <li>• BIO OCTANE (5 ml &amp; 7ml PFS)</li> </ul>	IIb
Perfluoro decalin liquid	<ul style="list-style-type: none"> <li>• BIO DECALIN (5 ml &amp; 7ml PFS)</li> </ul>	IIb

Appendix History -		
Revision	Description	Issued Date
0.0	Original Appendix- Change of manufacturing site of CE marked PFS (Prefilled syringe) products from Biotech Vision Care (Unit-3) (EC certificate # 10000368344-PA-NA-IND) to Biotech Vision Care (Unit-2).	16 September 2021
1.0	Correct clerical errors	21 September 2021

