DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000368344-PA-NA-IND	PRJC-556142-2016-MSL-IND	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

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	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	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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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