EC Certificate
Full Quality Assurance System

Certificate No.:
277565-2018-CE-IND-NA-PS Rev. 0.0

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, 12 February 2019

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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

EC Certificate
Full Quality Assurance System

Certificate No.:
277565-2018-CE-IND-NA-PS Rev. 0.0

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

Valid Until:
18 May 2023

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

Products covered by this Certificate:

Product Description	Product Name	Class
Hydroxy Propyl Methyl Cellulose Ophthalmic Solution USP 2% w/v	• Eye Visc PFS (2ml, 2.5ml & 3ml PFS) • Metilon 20 PFS (2ml)	IIb
Sodium Hyaluronate Ophthalmic Solution	• Bio-Hyalur HV (24mg/ml) (0.5 ml, 0.8 ml, 1.0 ml, 1.6ml, 1.8ml & 2.0ml PFS) • Bio-Hyalur 1.2% (1.0 ml, 1.6 ml, 1.8 ml, 2.0 ml PFS) • Bio-Hyalur DUO (1.0 ml, 1.8 ml, 2.0 ml PFS) • Bio-Hyalur (10 mg/ml) (1.0 ml, 1.6 ml, 1.8 ml, 2.0 ml PFS) • Bio-Hyalur Plus (14 mg/ml) (1.0 ml, 1.6 ml, 1.8 ml, 2.0 ml PFS) • OPTIFLEX (0.85 ml, 0.55 ml, 1.0 ml PFS) • OPTIFLEX 1.4% (0.85 ml, 0.55 ml, 1.0 ml PFS)	IIb

EC Certificate
Full Quality Assurance System

Certificate No.: **277565-2018-CE-IND-NA-PS Rev. 0.0**
Project No.: **PRJC-556142-2016-MSL-IND**
Valid Until: **18 May 2023**

Trypan blue Ophthalmic solution	• Bio-Blue (1 ml PFS and Pack of 5 or 10 PFS) • Bio-Blue Plus (1 ml PFS and Pack of 5 or 10 PFS)	IIb
Brilliant Blue G or Acid Blue 90 Ophthalmic Solution	• Bio Blue 90 (0.5 ml and 1 ml PFS) • Bio Blue 90 Plus (0.5 ml and 1 ml PFS)	IIb
Combination of Brilliant Blue G or Acid Blue 90 and Trypan Blue Ophthalmic Solution	• Bio Blue Duo (0.5 ml and 1 ml PFS)	IIb
Silicone Oil 1000cst/5000 cst	• BIOSIL (10ml PFS) • BIOSIL-F (10ml PFS)	IIb
Perfluoro-n-octane liquid	• BIO OCTANE (5 ml & 7ml PFS)	IIb
Perfluoro decalin liquid	• BIO DECALIN (5 ml & 7ml PFS)	IIb

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 (Guj.)

EU Representative

Neuvida Medical Device Inc Limited, 136-137 Churchill House, Stirling Way, Borehamwood, WD6 2HP, England

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
277565-2018-CE-IND-NA-PS Rev. 0.0	**PRJC-556142-2016-MSL-IND**	**18 May 2023**

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