EC Certificate
Full Quality Assurance System

Certificate No.:
242532-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-534687-2015-MSL-IND

Valid Until:
12 April 2020

This is to certify that the quality system of:

BioTech Ophthalmics Pvt. Ltd.
Plot no. 555, 556, 557 Khatraj-Vadsar Road, Opp. Shubham Tex-O-Pack, Village 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 Article 11.3.a and Annex II excluding section 4 (Module H2) 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, 17 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

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.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replace the certificate 74818-2010-CE-IND-NA Rev. 5.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) and change in the EC Representative	2017-11-17

Products covered by this Certificate:

Product Description	Product Name	Class
Hydroxy Propyl Methyl Cellulose Ophthalmic Solution USP 2% w/v, 2.4% w/v	Eye Visc • 3 ml and 5 ml vial • Eye Visc PFS 2 ml, 2.5 ml and 3ml • Eye Visc plus PFS 2ml • Eye Visc PFS 2.4% (2ml PFS) Metilon 20 PFS 2ml Metilon Plus PFS 2 ml	IIb
Trypan blue (0.06% w/v) Ophthalmic solution	Bio-Blue • 1 ml vial and Pack of 5 or 10 vials • 1 ml PFS and Pack of 5 or 10 PFS	IIb
Trypan Blue(0.15% w/v) ophthalmic solution	Bio-Blue Plus • 1 ml vial and Pack of 5 or 10 vials • 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 vial and Pack of 5 or 10 vials • 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

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Sodium Hyaluronate Ophthalmic Solution	Bio-Hyalur PLUS (14 mg/ml), • 1.0 ml, 1.6 ml Bio-Hyalur (10 mg/ml), • 1.0 ml, 1.6 ml Bio-Hyalur DUO • 1.0 ml Bio-Hyalur MV (16 mg/ml) • 1.6 ml Bio-Hyalur EV (18 mg/ml) • 1.0 ml, 1.6 ml Bio-Hyalur HV (24mg/ml) • 0.5 ml, 0.8 ml, 1.0 ml, 1.6 ml Bio-Hyalur 1.2% • 1.0 ml, 1.6 ml Bio Hyalur SV (30mg/ml) • 1.0 ml, 1.6 ml Bio-Vial • 2.0 ml	IIb
Silicone Oil 1000cst	BIOSIL 10 ml vial and PFS	IIb
Silicone Oil 5000cst	BIOSIL-F 10 ml vial and PFS	IIb
Perfluoro-n-octane liquid	BIO OCTANE 5 ml and 7 ml vial and PFS	IIb
Perfluorodecalin liquid	BIO DECALIN 5 ml and 7 ml vial and PFS	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
BioTech Ophthalmics Pvt. Ltd.	Plot no. 555, 556, 557 Khatraj-Vadsar Road, Opp. Shubham Tex-O-Pack, Village Khatraj, Taluka Kalol, Dist. Gandhinagar, Gujarat, India

EU Representative

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

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A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
242532-2017-CE-IND-NA-PS Rev. 0.0	**PRJC-534687-2015-MSL-IND**	**12 April 2020**

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

"LENSES GRUP" S.R.L.