DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
277565-2018-CE-IND-NA-PS Rev. 1.0	PRJC-556142-2016-MSL-IND	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.

Digitally signed by Iarovoi Petru
Date: 2020.04.24 17:38:19 EEST
Reason: MoldSign Signature
Location: Moldova

Place and date:
Høvik, 04 March 2020

NORWEGIAN ACCREDITATION

PROD 021

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

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

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
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	IIb

	(5 ml & 7ml PFS)	
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, Gujarat, India

EU Representative

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

Certificate No.:	Project No.:	Valid Until:
277565-2018-CE-IND-NA-PS Rev. 1.0	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

Presafe®
A DNV GL & NEMKO COMPANY

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
243116-2017-CE-IND-NA-PS	**PRJC-556142-2016-MSL-IND**	**14 March 2022**

This is to certify that the quality system of:

Bio-Tech Vision Care Pvt. Ltd.
555-556-557, Near Subham Tex-O-Pack, Khatraj, Dist. Gandhinagar, Gujarat, India

For design, production and final product inspection/testing of:

Ophthalmic Strips

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, 04 July 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Bjørg Synnøve Nesgård

Bjørg Synnøve Nesgård

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.

Presafe®
A DNV GL & NEMKO COMPANY

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
243116-2017-CE-IND-NA-PS	**PRJC-556142-2016-MSL-IND**	**14 March 2022**

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	Supersedes DNVGL (NB0434) certificate no 81001-2010-CE-IND-NA Rev. 7.0 following transfer of notified body functions to DNV GL Nemko Presafe AS (NB2460)	2017-07-04

Products covered by this Certificate:

Product Description	Product Name	Class
Ophthalmic Strips	• Schirmer Strips • Fluorescein Sodium Strips for contact lens fitting	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Bio-Tech Vision Care Pvt. Ltd., 555-556-557, Near Subham Tex-O-Pack, Khatraj, Dist. Gandhinagar, Gujarat, India

EU Representative

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

Presafe®
A DNV GL & NEMKO COMPANY

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
243116-2017-CE-IND-NA-PS	**PRJC-556142-2016-MSL-IND**	**14 March 2022**

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.

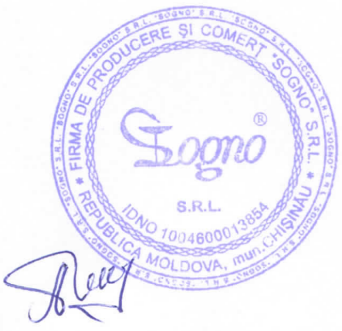
The following may render this Certificate invalid:

- 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



Presafe®
A DNV GL & NEMKO COMPANY

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid until:
215570-2017-CE-IND-NA-PS Rev 0.0	PRJC-556142-2016-MSL-IND	14 March 2022

This is to certify that the quality system of:

Bio-Tech Vision Care Pvt. Ltd.

555-556-557, Near Subham Tex-O-Pack, Khatraj, Dist. Gandhinagar, Gujarat, India

For design, production and final product inspection/testing of:

Intraocular Lens and Devices for Intra-Ocular Surgery

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) 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, 07April 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alexey Shiryaev
Certification Manager

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

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid until:
215570-2017-CE-IND-NA-PS Rev 0.0	PRJC-556142-2016-MSL-IND	14 March 2022

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	Supercedes DNVGL (NB0434) certificate no 215570-2017-CE-IND-NA following transfer of notified body functions to DNV GL Nemko Presafe AS (NB2460)	**2017-04-07**

Products covered by this Certificate:

Product Description	Product	Class
Intra ocular lenses	PMMA Intra Ocular Lenses : • Single Piece PMMA Lenses : B60125C, B65135C, B60125S, B60130S, B50120C, B55125C, I55120C, I55125S, FSQ525C, FSQ605C, FSQ613C, FSQ655C, SQ605C • PMMA Multipiece Intraocular Lens: 65135JM Hydrophilic Acrylic Foldable Intraocular Lenses: • 600, 4x4 • TP600, TP613 • 600ROH, AS600, S600MZ Hydrophobic IOLs (Clear as well as Yellow): • HF600, ASHF600 • HFY600, ASHFY600, DIHFY600, ASHFY6002, TRHFY600 Surface modified Intra Ocular Lenses: • HSAS600, HSAS600ROH, HSAS4X4 • YHSAS600, YHSAS4X4, DIYHS600ROH Hydrophobic Toric IOLs: • HFY-10, HFY-20, HFY-30, HFYD-10, HFYD-20, HFYD-30, HFY-35, HFY-40, HFY-50, HFY-60, HFYD-35, HFYD-40, HFYD-50, HFYD-60, HFY-05, HFYD-05.	IIb

	Phakic IOLs: • PKC120NH, PKC125NH, PKC130NH Phakic Toric IOLs: • PC120T, PC125T, PC130T Preloaded Delivery System with Hydrophobic IOLs: • PAHFY600F, PLHF-10, PLHF-20, PLHF-30, PLHFD-10, PLHFD-20, PLHFD-30, PLHF2, PLHFD6, PLHF-05, PLHFD-05	
Capsular Tension Rings	Clear as well as Blue: • CTR11, CTR12, CTR13, CTR14, CTR11B, CTR12B, CTR13B, CTR14B.	IIb
Cartridges and Injectors for Ophthalmic surgery	Cartridges: • Hydraulic Cartridges with Silicone stopper: • Bio Hydro Cartridges- BHC 150, BHC 140 Mechanical Cartridge • Bio Meca Cartridge- BMC 180 Injectors: • Hydraulic injector - Bio Hydroject Injector • Mechanical injector - Bio Mecaject Injector Pre-loaded Delivery System: • Bioject-P260, Bioject-P220, Bioject-P300, IC- 8-350, IC- 8-380	IIa
Iris Retractor	Iris Retractor	IIa
PVA spears	PVA Spears: • Bio Spears-Sterile	IIa

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Bio-Tech Vision Care Pvt. Ltd., Plot No.555, 556, 557, Nr. Subham Tex-O-Pack, Dist. Gandhinagar, Khatraj, Gujarat, India

EU Representative

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

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid until:
215570-2017-CE-IND-NA-PS Rev 0.0	PRJC-556142-2016-MSL-IND	14 March 2022

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

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
243094-2017-AQ-IND-NA-PS Rev. 3.0	PRJC-556142-2016-MSL-IND	09 September 2011	09 September 2021

This is to certify that the management 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

With sites as listed overleaf.

Complies with the requirements of:
ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:
Design, Manufacturing and Supply of Sterile Single piece and Multi piece PMMA Intra Ocular Lenses (Clear and Yellow), Single Piece and Multi- piece (3 Pieces) Hydrophilic Foldable Acrylic Intra Ocular lenses (Clear and Yellow), Scleral Fixation Lenses, Single piece and Multi piece Hydrophobic Intra Ocular Lenses (Clear and Yellow), Surface Modified Intra Ocular Lenses (Clear and Yellow), Iris Retractors, Preloaded Delivery System with Hydrophobic IOLs, Multifocal Intraocular lenses, Hydrophobic and Hydrophilic Toric IOLs, Phakic IOLs, Phakic Toric IOLs, Intrastromal Corneal Rings, Ophthalmic Surgical Blades, Capsular Tension Rings (Clear and Blue), Cartridges and Injectors, Ophthalmic strips, PVA spears.
Design, Manufacture, Supply, Installation and Servicing of Non-sterile Phacoemulsificator & Sterile/Non-sterile accessories.
Design, Manufacture, Sales and Distribution of Sterile solutions for Ophthalmic, Osteoarthritis, Dermal and Urology use

Place and date:
Høvik, 06 March 2020

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
243094-2017-AQ-IND-NA-PS Rev. 3.0	PRJC-556142-2016-MSL-IND	09 September 2011	09 September 2021

Site Name	Address	Site Scope
Bio-Tech Vision Care Pvt. Ltd.	Unit 1: Plot No. 555-556-557, Opp. Subham Tex-O-Pack,Khatraj-Vadsar Road, P.O.: Khatraj, Taluka, Kalol, Dist. Gandhinagar, Gujarat, India	Design, Manufacturing and Supply of Sterile Single piece and Multi piece PMMA Intra Ocular Lenses (Clear and Yellow), Single Piece and Multi- piece (3 Pieces) Hydrophilic Foldable Acrylic Intra Ocular lenses (Clear and Yellow), Scleral Fixation Lenses, Single piece and Multi piece Hydrophobic Intra Ocular Lenses (Clear and Yellow), Surface Modified Intra Ocular Lenses (Clear and Yellow), Iris Retractors, Preloaded Delivery System with Hydrophobic IOLs, Multifocal Intraocular lenses, Hydrophobic and Hydrophilic Toric IOLs, Phakic IOLs, Phakic Toric IOLs, Intrastromal Corneal Rings, Ophthalmic Surgical Blades, Capsular Tension Rings (Clear and Blue), Cartridges and Injectors, Ophthalmic strips, PVA spears. Design, Manufacture, Supply, Installation and Servicing of Non-sterile Phacoemulsificator & Sterile/Non-sterile accessories.
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.	Design, Manufacture, Sales and Distribution of Sterile Solutions for Ophthalmic, Osteoarthritis and Dermal use
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	Design, Manufacture, Sales and Distribution of Sterile solutions for Ophthalmic and Urology use

End of Certificate