

Management System Certificate

Certificate No.:
243094-2017-AQ-IND-NA-PS

Initial Certification Date:
09 September 2011

Valid Until
08 September 2021 – 09 September 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.

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016/EN ISO 13485:2016

This 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.

Digitally signed by Pereteatco Alma

Date: 2021.10.08 07:21:35 EEST



Place and date:
Høvik, 06 September 2021



MSYS 018

For the issuing office:
DNV Product Assurance AS

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative



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

Accredited Body: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Site name	Site address	Site specific 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

EC Certificate

Full Quality Assurance System

Certificate No.:
243116-2017-CE-IND-NA-PS

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

Valid Until:
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



For:
DNV GL NEMKO PRESAFE AS



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.

EC Certificate

Full Quality Assurance System

Certificate No.:
243116-2017-CE-IND-NA-PS

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

Valid Until:
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	<ul style="list-style-type: none">Schirmer StripsFluorescein 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

EC Certificate

Full Quality Assurance System

Certificate No.:
243116-2017-CE-IND-NA-PS

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

Valid Until:
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



OPHTHALMIC DIAGNOSTIC STRIPS

In Medical Grade Tyvek Pouches

Schirmer Strips

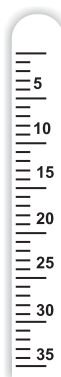
CE
2460



Sterile Ophthalmic strips for Dry Eye test

Packaging:

Each box contains 100 sterile strips.



Indications:

- Used for measurement of tear production
- Gauged for easy reading

Fluorescein Sodium Ophthalmic Strips

CE
2460

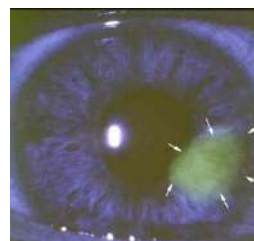


Composition (per strip):

Each strip is impregnated with 1.0 mg of Fluorescein Sodium

Packaging:

Each box contains 100 sterile strips.



Indications:

- For Applanation Tonometry
- For evaluating Contact Lens fitting

High Molecular Fluorescein Sodium Ophthalmic Strips

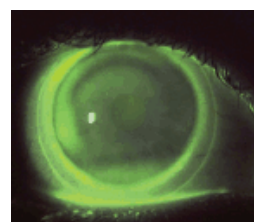


Composition (per strip):

Each strip is impregnated with 0.5 mg of high molecular Fluorescein Sodium

Packaging:

Each box contains 100 sterile strips.



Indications:

- For Applanation Tonometry
- For evaluating Contact Lens fitting

Lissamine Green Ophthalmic Strips

**Composition (per strip):**

Each strip is impregnated with 1.5 mg of Lissamine Green

Packaging:

Each box contains 100 sterile strips.

**Indications:**

- To stain preferentially damaged or devitalized cells
- To indicate any dry patches, as well as any mucus-deficient or damaged Corneal Epithelial cells
- It does not stain healthy, proliferating Ocular surface cells and has minimal effect on cell viability

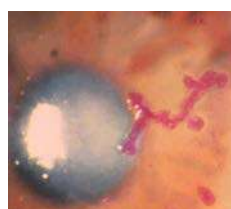
Rose Bengal Ophthalmic Strips

**Composition (per strip):**

Each strip is impregnated with 1.5 mg of Rose Bengal

Packaging:

Each box contains 100 sterile strips.

**Indication:**

- It stains dead or degenerated Epithelial cells of Cornea & Conjunctiva.



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