

Management System Certificate

Certificate No.:
243094-2017-AQ-IND-NA-PS Rev. 2.0

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

Initial Certification Date:
09 September 2011

Valid Until:
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 and Dermal use

Place and Date:
Høvik, 21 January 2019

For:
DNV GL PRESAFE AS



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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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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	<p>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.</p> <p>Design, Manufacture, Supply, Installation and Servicing of Non-sterile Phacoemulsificator & Sterile/Non-sterile accessories.</p>
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.)	Design, manufacture, sales and distribution of sterile solutions for Ophthalmic, Osteoarthritis and Dermal use.

End of Certificate