

# 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.**

Place and date:  
Høvik, 06 September 2021



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](http://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.<br>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   |