



EC Certificate

Full Quality Assurance System

Certificate No.:
215570-2017-CE-IND-NA-PS Rev 0.0

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:

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, 07 April 2017



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.

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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	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	<p>PMMA Intra Ocular Lenses :</p> <ul style="list-style-type: none"> Single Piece PMMA Lenses : B60125C, B65135C, B60125S, B60130S, B50120C, B55125C, I55120C, I55125S, FSQ525C, FSQ605C, FSQ613C, FSQ655C, SQ605C PMMA Multipiece Intraocular Lens: 65135JM <p>Hydrophilic Acrylic Foldable Intraocular Lenses:</p> <ul style="list-style-type: none"> 600, 4x4 TP600, TP613 600ROH, AS600, S600MZ <p>Hydrophobic IOLs (Clear as well as Yellow):</p> <ul style="list-style-type: none"> HF600, ASHF600 HFY600, ASHFY600, DIHFY600, ASHFY6002, TRHFY600 <p>Surface modified Intra Ocular Lenses:</p> <ul style="list-style-type: none"> HSAS600, HSAS600ROH, HSAS4X4 YHSAS600, YHSAS4X4, DIYHS600ROH <p>Hydrophobic Toric IOLs:</p> <ul style="list-style-type: none"> 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

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	<p>Phakic IOLs:</p> <ul style="list-style-type: none"> • PKC120NH, PKC125NH, PKC130NH <p>Phakic Toric IOLs:</p> <ul style="list-style-type: none"> • PC120T, PC125T, PC130T <p>Preloaded Delivery System with Hydrophobic IOLs:</p> <ul style="list-style-type: none"> • PAHFY600F, PLHF-10, PLHF-20, PLHF-30, PLHFD-10, PLHFD-20, PLHFD-30, PLHF2, PLHFD6, PLHF-05, PLHFD-05 	
Capsular Tension Rings	<p>Clear as well as Blue:</p> <ul style="list-style-type: none"> • CTR11, CTR12, CTR13, CTR14, CTR11B, CTR12B, CTR13B, CTR14B. 	IIb
Cartridges and Injectors for Ophthalmic surgery	<p>Cartridges:</p> <ul style="list-style-type: none"> • Hydraulic Cartridges with Silicone stopper: <ul style="list-style-type: none"> • Bio Hydro Cartridges- BHC 150, BHC 140 • Mechanical Cartridge • Bio Meca Cartridge- BMC 180 <p>Injectors:</p> <ul style="list-style-type: none"> • Hydraulic injector - Bio Hydroject Injector • Mechanical injector - Bio Mecaject Injector <p>Pre-loaded Delivery System:</p> <ul style="list-style-type: none"> • Bioject-P260, Bioject-P220, Bioject-P300, IC- 8-350, IC- 8-380 	IIa
Iris Retractor	Iris Retractor	IIa
PVA spears	<p>PVA Spears:</p> <ul style="list-style-type: none"> • 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

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



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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