EU Technical Documentation Assessment Certificate

Certificate no.:	Initial certification date:	Valid Until:
10000492112-PA-NoMA-IND Rev. 1.0	12 March 2022	12 March 2027

This is to certify that:

Intraocular lenses and Capsular Tension Rings

Manufactured by:

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

SRN: IN-MF-000008482

Has been assessed and found to comply with respect to:

Technical Documentation Assessment as described in Annex IX (Chapter II) of Regulation 2017/745 on Medical Devices

Place and date:
Høvik, 19 May 2022

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Palani Damodharan
Principal Assessor

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate		12 March 2022
1.0	Correction of BASIC-UDI-DI of Single Piece/Multipiece PMMA Intraocular Lenses		19 May 2022

Products covered by this Certificate:

Single Piece/Multipiece PMMA Intraocular Lenses	Class	EMDN code
Basic UDI-DI:89042346PMMAUF Single Piece PMMA Intraocular Lenses B60125C, B65135C, B60125S, B60130S, B50120C, B55125C, FSQ605C, SQ605C.	IIb	P030102090104
Basic UDI-DI:89042346PMMAUF PMMA Multipiece Intraocular Lenses 65135JM	IIb	P030102090104
Intended purpose of the Medical Device		
Single piece and multipiece PMMA Intraocular Lenses are intended to replace the human crystalline lens for surgical correction of the aphakia after intra or extra capsular extraction of the lens in patients with cataracts.		

Hydrophilic Intraocular Lenses	Class	EMDN code
BASIC UDI-DI:89042346HPFLDQU Hydrophilic Foldable Intraocular Lenses (Spherical, Mono focal, Single piece) 600, 4x4, 600ROH, S600MZ	IIb	P030102090102
BASIC UDI-DI:89042346HPFLDQU Hydrophilic Foldable Intraocular Lenses (Spherical, Mono focal, Multipiece) TP600, TP613	IIb	P030102090102
BASIC UDI-DI:89042346HPFLDQU Hydrophilic Foldable Intraocular Lenses (Aspheric, Mono focal, Single piece) AS600	IIb	P030102090202
BASIC UDI-DI:89042346HPFLDQU Surface Modified Hydrophilic Intraocular Lenses (Aspheric, Mono focal, Single piece) HSAS600, HSAS600ROH, HSAS4X4, YHSAS600, YHSAS4X4	IIb	P030102090202
BASIC UDI-DI:890602552HPFLDMFPQ Surface Modified Hydrophilic Intraocular Lenses (Diffractive-Refractive, Multifocal, Single piece) DIYHS600ROH	IIb	P030102100202
BASIC UDI-DI:8905286PHAKIC57 Phakic Hydrophilic Intraocular Lenses (Aspheric, Mono focal, Single piece) PKC120NH, PKC125NH, PKC130NH, PKC135NH, PKC140NH, PKC110NH, PKC115NH	IIb	P030101030202
BASIC UDI-DI:8905286PHAKIC57 Phakic Toric Hydrophilic Intraocular Lenses (Aspheric, Mono focal, Toric, Single piece) PC120T, PC125T, PC130T, PC135T, PC140T, PC110T, PC115T	IIb	P030101030302
Intended purpose of the Medical Device		
Hydrophilic & Surface Modified Monofocal Intraocular Lenses are intended to be implanted into the capsular bag in the posterior chamber of the eye for the visual correction of aphakia secondary to the removal of the crystalline lens in adult patients with cataracts. Surface Modified Multifocal Intraocular Lenses are intended for cataract patients with Presbyopia. Phakic Intraocular Lenses are indicated in Phakic adults for the correction or reduction of Refractive error (myopia/hyperopia) and Phakic Toric Intraocular Lenses are indicated in Phakic adults for the correction or reduction of Refractive error (myopia/hyperopia) and refractive error with astigmatism.		

Hydrophobic Intraocular Lenses	Class	EMDN code
BASIC UDI-DI:8905286HFWTAM Hydrophobic Intraocular Lenses (Spheric, Mono focal) HF600	IIb	P030102090101
BASIC UDI-DI:8905286HFWTAM Hydrophobic Intraocular Lenses (Aspheric, Mono focal) ASHF600, ASHFY600, ASHFY6002, ASHFY600D	IIb	P030102090201
BASIC UDI-DI:89043265HFWTMFTG Hydrophobic Intraocular Lenses (Aspheric, Multifocal) DIHFY600, (Aspheric, Trifocal) TRHFY600	IIb	P030102100201
BASIC UDI-DI:89043265HFWTMFTG Hydrophobic Intraocular Lenses (Aspheric, EDOF) HFY600	IIb	P030102100201
BASIC UDI-DI:89043265HFWTMFTG Hydrophobic Intraocular Lenses (Aspheric, EDOF Toric) HFY600T	IIb	P030102100301
BASIC UDI-DI:89043265HFWTMFTG Hydrophobic Intraocular Lenses (Aspheric, Trifocal Toric) TRHFY600T	IIb	P030102100301
BASIC UDI-DI:8905286HFWTAM Hydrophobic Toric Intraocular Lenses (Aspheric, Toric, Mono focal) HFY-05, HFY-10, HFY-20, HFY-30, HFY-35, HFY-40, HFY-50, HFY-60	IIb	P030102090301
BASIC UDI-DI: 89043265HFWTMFTG Hydrophobic Toric Intraocular Lenses (Aspheric, Toric, Diffractive Refractive, Multi focal) HFYD-05, HFYD-10, HFYD-20, HFYD-30, HFYD-35, HFYD-40, HFYD-50, HFYD-60	IIb	P030102100301
BASIC UDI-DI: 8905286HFDR8Q Preloaded Hydrophobic Intraocular Lenses (Aspheric, Mono focal) PAHFY600F, PLHF2	IIb	P030102090201
BASIC UDI-DI: 8905286HFDR8Q Preloaded Hydrophobic Intraocular Lenses (Aspheric, Mono focal, Toric) PLHF-05, PLHF-10, PLHF-20,PLHF-30	IIb	P030102090301

Hydrophobic Intraocular Lenses	Class	EMDN code
BASIC UDI-DI: 89043265HFDRMFNZ Preloaded Hydrophobic Intraocular Lenses (Aspheric, Multifocal, Toric) PLHFD-05, PLHFD-10, PLHFD-20, PLHFD-30	IIb	P030102100301
BASIC UDI-DI: 8905286HFDR8Q Preloaded Hydrophobic Intraocular Lenses (Aspheric, EDOF) PLHFD6, PLHF2E	IIb	P030102100201
BASIC UDI-DI: 8905286HFDR8Q Preloaded Hydrophobic Intraocular Lenses (Aspheric, EDOF Toric) PLHFD6T, PLHF2ET	IIb	P030102100301
Intended purpose of the Medical Device		
Hydrophobic acrylic Intraocular Lenses (including Preloaded) are intended to be implanted into the capsular bag in the posterior chamber of the eye for the visual correction of aphakia secondary to the removal of the crystalline lens in patients with cataracts. Hydrophobic acrylic multifocal, multifocal Toric, EDOF & EDOF Toric Intraocular Lenses are indicated for presbyopic patients who seek greater independence from glasses for intermediate and/or near vision in addition to far vision with or without regular corneal astigmatism.		

Capsular Tension Ring	Class	EMDN code
Basic UDI-DI: 8905286CTRL2 CTR11, CTR12, CTR13, CTR14, CTR11B, CTR12B, CTR13B, CTR14B	IIb	Q0299
Intended purpose of the Medical Device		
CTR is indicated for the stabilization of weakened, broken, or missing zonules that are suspected or observed during cataract extraction using phacoemulsification and continuous curvilinear capsulorhexis techniques.		

Conformity Assessment for devices listed is covered by separate EU Quality Management System Certificate No.: C528629

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

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 inform the Notified Body of any intended change of the products detailed above and the Notified Body will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EU Quality Management System Certificate.

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.