

EC Certificate

Full Quality Assurance System

Certificate No.:
217392-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-538276-2016-MSL-IND

Valid Until:
21 May 2022

This is to certify that the quality system of:

Omni Lens Pvt. Ltd.

**5 - SAMRUDDHI, Opp. SAKAR III, Navarangpura, Ahmedabad, Gujarat,
India-380014**

For design, production and final product inspection/testing of:

Sterile Intra Ocular Lenses & Accessories

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, 18 September 2017



For:

DNV GL NEMKO PRESAFE AS

Tone Kolpus

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 om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replace the certificate 1238-2012-CE-IND-NA rev. 3 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) at recertification	2017-09-18

Products covered by this Certificate:

Product Name	Product Description	Class
Single piece PMMA Intraocular Lenses	(Raw material: PMMA, Yellow PMMA) Having combination of: <u>Diameter</u> : 12.00 mm to 13.50 mm (in 0.50 increment) <u>Optic Type & Size</u> (Spherical /Aspheric type optic with or without 360° square edge): 5.00 mm to 7.00 mm (in 0.25 increment) <u>Brands</u> : Omni, Intra, C-Thru, Innova, Innova Plus ,Techno Instrument Lens <u>Inner Packing</u> : Lens case or Lens tray <u>Outer packing</u> : Single Pack or Multiple packing in lens tray <u>Model/Design/Style</u> : AC131 UV, AC132 UV, AC133 UV, AC134 UV, CB111 UV, CB122 UV, CB191 UV, CB192 UV, CB132 UV, CB133 UV, CB143 UV, CB144 UV, CB132 UV2, CB133 UV2, CB143 UV2, CB144 UV2, CB11-33 UV, CB11-33 UV2, CB191 UVSQ, CB132 UV2SQ, CB191UVSC2, CB122 UVSC2, CB132UVSC2, CB133UVSC2, CB143UVSC2, CB144UVSC2, SQ525, SQ550, SQ600, SQ650, SQSC600, SQSC525, YSQSC600, YSQSC525, YSQ525, YSQ550, YSQ600, YSQ650, UVAC60-120, UVAC60-125, UVAC60-130, UVAC60-135, UVC50-120, UVC50-125, UVC55-125, UVC525-120, UVC525-125, UVC60-125, UVC60-130, UVC65-130, UVC65-135, UVHC60-125, UVHC60-130, UVHC65-130, UVHC65-135, UVC5/6 -130, UVHC5/6 -130, UVSQC525-120, UVSQHC60-125, UVC600-125SC2, UVC525-120SC2, SQ600ASP, YSQ600ASP	IIb

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<p>Hydrophilic Acrylic Foldable Intraocular Lenses</p>	<p>(Raw materials: HA 25% & HA 26% (Clear & Natural/Extended Yellow)) Having combination of: <u>Diameter:</u> 11.00 mm to 13.50 mm (in 0.50 increment) <u>Optic Type & Size:</u> (Spherical /Aspheric, Multifocal/ Diffractive Multifocal, Toric / Diffractive Toric type optic with or without 360° square edge): 5.00 mm to 7.00 mm (in 0.25 increment) <u>Brands:</u> Omni, Intra, C-Thru, Aquafold, Innova, Innova Plus, Innova Asp, GenNext, Revive, Axis, BIOL, Techno Instrument Lens <u>Inner Packing:</u> Vial, Blister, Holster, Semi preloaded, Preloaded or Multiple <u>Outer packing:</u> Single Pack, Combo pack <u>Model/Design/Style:</u> CBF31UVFL,CBF32FLEX,CBF32MFFLEX,CBF32UV,CBF32UVA,CBF32UVQ,CBF32UVFL,CBF32MFFL,CBF32UVASP,CBF32UVDF, CBF32UVFLASP,CBF32MFFL,CBF32UVASP,CBF32UVDF, CBF33UV,CBF33UVA,CBF33UVQ,CBF33UVFL,CBF33MFFL,CBF33UVASP,CBF33UVDF, CBF33UVFL,CBF33MFFL,CBF33UVASP,CBF33UVDF, CBF81UV,CBF81UVA,CBF81UVQ,CBF81UVFL,CBF81MFFL,CBF81UVASP,CBF81UVDF, CBF81UVFL,CBF81MFFL,CBF81UVASP,CBF81UVDF, CBF82UVA,CBF82UVASP,CBF37UV,CBF37UVA,CBF37UVQ,CBF37UVFL,CBF37MFFL,CBF37UVASP,CBF37UVDF, CBF37UVFL,CBF37MFFL,CBF37UVASP,CBF37UVDF, CBFY37UV,CBFY37UVA,CBFY37UVQ,CBFY37UVFL,CBFY37MFFL,CBFY37UVASP,CBFY37UVDF, CBF33 SUVASP+, CBFY33SUVASP+, CBF32UVMCR,CBF33UVMCR,CBFY32UVMCR,CBFY33UVMCR, LBF33UVDF, PBF37UV,PBF37UVA,PBF37UVAQ,PBF37UVQ, PBF37UVFL,PBF37MFFL,PBF37UVASP,PBF37UVDF,PBFY37UV,PBFY37UVA,PBFY37UVQ,PBFY37UVFL,PBFY37MFFL,PBFY37UVASP,PBFY37UVDF, SQ600,SQA600,SQFL600,SQQ600, SQMFFL600,SQA600DF,SQA600MCR,YSQ600,YSQA600,YSQFL600,YSQQ600,YSQMFFL600,YSQA600DF,YSQA600MCR, SQA575, SQFL575, SQQ575, SQMFFL575, YSQA575, YSQFL575, YSQQ575, YSQMFFL575, SQFL600ASP, SQA600ASP, SQQ600ASP,SQMFFL600ASP, YSQFL600ASP, YSQA600ASP, YSQQ600ASP,YSQMFFL600ASP, SQA600DF, SQFL600DF, SQQ600DF, YSQA600DF, YSQFL600DF, YSQQ600DF, SQA600MCR, YSQA600MCR, AY4, UVF575-120, UVF575-120FL, UVF575-120Q, UVF575-120MFFL, UVF575-125, UVF575-125FL, UVF575-125Q, UVF575-125MFFL, UVF600-110Q, UVF600-125A, UVF600-125FL, UVF600-125Q, UVF600-125MFFL, UVF600-130A, UVF600-130FL, UVF600-130Q, UVSQF600-125A, UVSQF600-125FL, UVSQF600-110Q, UVF600-130DFFL, UVF600-130DFA, UVF600-110DFQ,</p>	<p>IIb</p>
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	<p>UVF600-125DFFL, UVSQF600-125MCR CBF33UVT, CBF33UVT1 to CBF33UVT9, CBFY33UVT, CBFY33UVT1 to CBFY33UVT9, PBF37UVQT, PBF37UVQT1 to PBF37UVQT9, PBFY37UVQT, PBFY37UVQT1 TO PBFY37UVQT9, SQFL600T, SQFL600T1 to SQFL600T9, YSQFL600T, YSQFL600T1 to YSQFL600T9, SQQ600UVT, SQQ600UVT1 to SQQ600UVT9, YSQQ600UVT, YSQQ600UVT1 to YSQQ600UVT9, CBF32UVASP*+, PBF37UVASP*+, SQQ600MCR*+, YSQQ600MCR*+, TAY4, HAY4, M AY4, LDS AY4, CBF33SUVASP+, CBF35UVFL, SQQ600ASP*, CBF32UVFLASP*., LBF33UVDF, PBF31UVQ, PBF 33UVQ, PBF35UVQ, PBF37UVAQ (EU), ASPHI6108, PBF41UVQ, PBF43UVQ, PBF45UVQ, PBF37UVQDFT#, CBF32UV26, CBF31UVFLASP*. (* is added for HA26% material after each model)</p>	
<p>Hydrophobic Acrylic Foldable Intraocular Lenses</p>	<p>(Raw material: Hydrophobic Acrylic - Clear & Natural Yellow) Having combination of: <u>Diameter:</u> 11.00 mm to 13.50 mm (in 0.50 increment) <u>Optic Type & Size:</u> (Spherical /Aspheric, Multifocal / Diffractive Multifocal, Toric / diffractive toric type optic with or without 360° square edge): 5.00 mm to 7.00 mm (in 0.25 increment) <u>Brands:</u> Acrivue, OMNI, Intra, C-Thru, Aquafold, Innova, Innova Plus, Innova Asp, GenNext, Revive, Axis, BIOL, Techno Instrument Lens <u>Inner Packing:</u> Lens case, Semi preloaded, Preloaded <u>Outer packing:</u> Single Pack, Combo pack <u>Model/Design/Style:</u> LBHF32 UV, LBHF33 UV, LBHF37 UV, LBHF38 UV, LBHY32 UV, LBHY33 UV, LBHY37 UV, LBHY38 UV, LBHF32 UVASP, LBHF33 UVASP, LBHF37 UVASP, LBHF38 UVASP, LBHY32 UVASP, LBHYO32UVASP, LBHY33 UVASP, LBHY37 UVASP, LBHYO37UVASP, LBHY38 UVASP, CBHF32 UVASP, CBHF33 UVASP, CLBHF37 UVASP, CBHF38 UVASP, CLBHY32 UVASP, CLBHY33 UVASP, CBHY37 UVASP, CLBHY38 UVASP, CLBHF32 UVASP, CLBHF33 UVASP, CBHF37 UVASP, CBHF38 UVASP, CBHY32 UVASP, CBHY33 UVASP, CBHY37 UVASP, CBHY38 UVASP, PBHF33UVASP, PBHF37UVASP, PBHY37UVASP, PBHF32UVASP, PBHY32UVASP, PBHYO32UVA SP, PBHYO37UVASP, LBHF32UVDF, LBHY32UVDF, LBHYO32UVDF, PBHF37UVDF, PBHY37UVDF, PBHYO37UVDF, FLHF32UVDF, FLHY32UVDF, HBHYO37UVASP, FLHF32UVASP, FLHY32UVASP, HAY4 H ANY4, MH ANY4. LBHY32UVT, LBHY32UVT1 TO LBHY32UVT9, LBHF32UVT, LBHF32UVT1 To LBHF32UVT9, BHY37UVQT, PBHY37UVQT1 TO PBHY37UVQT9, PBHF37UVQT, PBHF37UVQT1 to PBHF37UVQT9, TH ANY4, CBHF33UVT1 TO CBHF33UVT9, CSQHF60125L1,</p>	<p>IIb</p>

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	CSQHF60125L1AP, YSQHF60125L1, YSQHF60125L1AP, YSQHF60125L1DF, CSQHF60125L1DF, YSQHF60110Q4AP, CSQHF60110Q4AP, YSQHF60110Q2AP, CSQHF60110Q2AP, YSQHF60125L1TR*, SQHF60125L1TR*, YSQHF60110Q2TR*, CSQHF60110Q2TR*, CSQHF60120Q4AP, CSQHF60130Q4AP, CSQHF60130C1AP,	
Capsular Tension Ring	<p><u>Raw material:</u> PMMA, BLUE PMMA</p> <p><u>Brand Names:</u> Omni, Intra</p> <p><u>Inner Packing:</u> Lens case</p> <p><u>Outer packing:</u> Single Pack</p> <p><u>Models:</u> CTR 100, CTR 110, CTR 120, CTR 130, CTR 140, CTR150, CTR160, CTR 100BL, CTR 110BL, CTR 120BL, CTR 130BL, CTR 140BL, CTR150BL, CTR160BL IRING 10, IRING 11, IRING 12, IRING 13, IRING 14, IRING 15. IRING 16, IRING 10BL, IRING 11BL, IRING 12BL, IRING 13BL, IRING 14BL, IRING 15BL, IRING 16BL</p>	IIb
Lens Delivery System	<p><u>Brand Names:</u> Aquaject (Cartridge & Cushion), Aquaject Plus (Cartridge, Cushion & Injector or Cartridge, Cushion, Injector and Lens Rolling System Part-2)</p> <p><u>Inner Packing:</u> Paper Pouch, Blister Pack</p> <p><u>Outer packing:</u> Single Pack, Combo Pack</p> <p><u>Models:</u> Flyglide, Mini, Micro, Small, Monoglide, IM-WS-Y-Small, IM-WS-Y-Mini, IM-WS-Y-Flyglide, IM-WS-W-Micro, AQ-S-B-Small, AQ-S-B-Mini, AQ-S-B-Flyglide, SA-WS-B-Small. SA-WS-B-Mini, SA-WS-B-Flyglide, IM-WS-Y Monoglide, IM-WS-W-Mini, SA-S-B-Flyglide, SA-S-B-Small, AQ-S-B-Monoglide, AQ-S-B-Micro, SA-S-B-Small, SA-S-B-mini. AQ-S-W-Micro, AQ-S-B-MJ18, AQ-S-B-MJ20, AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-MJ26, AQ-S-B-MJ28, AQ-S-B-RET20, AQ-S-B-RET22, AQ-S-B-RET24, AQ-S-B-RET26, AQ-S-B-CON18, AQ-S-B-CON20, AQ-S-B-CON22, AQ-S-B-CON24, AQ-S-B-CON26</p>	IIa

The complete list of devices is filed with the Notified Body

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Sites covered by this certificate

Site Name	Address
Omni Lens Pvt. Ltd.	Registered office: 5 - SAMRUDDHI, Opp. SAKAR III, Navarangpura, Ahmedabad, Gujarat, India-380014 Factory: A-69 / A-70, Electronics Estate, GIDC, Sector 25, Gandhinagar, Gujarat, India

EU Representative:

Obelis S.A, Boulevard General Wahis 53, 1030 Brussels, BELGIUM. Email: mail@obelis.net

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