

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
217392-2017-CE-IND-NA-PS Rev. 2.0

Valid Until:
21 May 2022

This is an Appendix issued to EC Certificate issued for manufacturer:

Omni Lens Pvt. Ltd.

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

originally issued in compliance with:

the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment and/or audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established:

The name or identifier of a device already covered by the certification, has been revised.

Place and date:
Høvik, 17 August 2021

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



Mariann Jeremiassen
Principal Assessor

Products covered by this Certificate (replaces information on certificate):		
Product Description	Product Name	Class
PMMA Intraocular Lenses	(Raw material: PMMA, Yellow PMMA) Having combination of: Diameter: 12.00 mm to 13.50 mm (in 0.50 increment) Optic Type & Size (Spherical /Aspheric type optic with or without 360° square edge): 5.00 mm to 7.00 mm (in 0.25 increment) Brands: Omni, Intra, C-Thru, Innova, Innova Plus, Techno Instrument Lens Inner Packing: Lens case or Lens tray Outer packing: Single Pack or Multiple packing in lens tray Model/Design/Style: 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
Hydrophilic Acrylic Foldable Intraocular Lenses	(Raw materials: HA 25% & HA 26% (Clear & Natural/Extended Yellow)) Having combination of: Diameter: 11.00 mm to 13.50 mm (in 0.50 increment) Optic Type & Size: (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) Brands: Omni, Intra, C-Thru, Aquafold, Innova, Innova Plus, Innova Asp, GenNext, Revive, Axis, BIOL, Techno Instrument Lens, Inner Packing: Vial, Blister, Holster, Semi preloaded, Preloaded or Multiple Outer packing: Single Pack, Combo pack Model/Design/Style: CBF31UVFL, CBF32FLEX, CBF32MFFLEX, CBF32UV, CBF32UVA, CBF32UVQ, CBF32UVFL, CBF32MFFL, CBF32UVASP, CBF32UVDF, CBFY32UV, CBFY32UVA, CBFY32UVQ, CBFY32UVFL, CBF32UVFLASP, CBFY32MFFL, CBFY32UVASP,	IIb

	CBFY32UVDFA, CBF33UV, CBF33UVA, CBF33UVQ, CBF33UVFL, CBF33MFFL, CBF33UVASP, CBF33UVDFA, CBFY33UV, CBFY33UVA, CBFY33UVQ, CBFY33UVFL, CBFY33MFFL, CBFY33UVASP, CBFY33UVDFA, CBF81UV, CBF81UVA, CBF81UVQ, CBF81UVFL, CBF81MFFL, CBF81UVASP, CBF81UVDFA, CBFY81UV, CBFY81UVA, CBFY81UVQ, CBFY81UVFL, CBFY81MFFL, CBFY81UVASP, CBFY81UVDFA, CBF82UVA, CBF82UVASP, CBF37UV, CBF37UVA, CBF37UVQ, CBF37UVFL, CBF37MFFL, CBF37UVASP, CBF37UVDFA, CBFY37UV, CBFY37UVA, CBFY37UVQ, CBFY37UVFL, CBFY37MFFL, CBFY37UVASP, CBFY37UVDFA, CBF33 SUVASP+, CBFY33SUVASP+, CBF32UVMCR, CBF33UVMCR, CBFY32UVMCR, CBFY33UVMCR, LBF33UVDF, PBF37UV, PBF37UVA, PBF37UVAQ, PBF37UVQ, PBF37UVFL, PBF37MF, PBF37UVASP, PBF37UVDFA, PBFY37UV, PBFY37UVA, PBFY37UVQ, PBFY37UVFL, PBFY37MF, PBFY37UVASP, PBFY37UVDFA, 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, 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*+, SQQ600MCR*+, TAY4, HAY4, M AY4, LDS AY4, CBF33SUVASP+, CBF35UVFL, SQQ600ASP*, CBF32UVFLASP*., LBF33UVDF, PBF31UVQ, PBF33UVQ, PBF35UVQ, PBF37UVAQ (EU), ASPHI6108, PBF41UVQ, PBF43UVQ, PBF45UVQ, PBF37UVQDFT#, CBF32UV26, CBF31UVFLASP*. (* is added for HA26% material after each model) Polylens A20, Polylens AS66, Polylens AS 62, Polylens AS 64, Polylens AS 66*, Polylens AS 66-Y, Polylens AS 68, Polylens AS 68-Y	
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Hydrophobic Acrylic Foldable Intraocular Lenses	(Raw material: Hydrophobic Acrylic - Clear & Natural Yellow) Having combination of: Diameter: 11.00 mm to 13.50 mm (in 0.50 increment) Optic Type & Size: (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) Brands: Acrivue, OMNI, Intra, C-Thru, Aquafold, Innova, Innova Plus, Innova Asp, GenNext, Revive, Axis, BIOL, Techno Instrument Lens Inner Packing: Lens case, Semi preloaded, Preloaded Outer packing: Single Pack, Combo pack Model/Design/Style: 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, LBHYO32 UVASP, LBHY33 UVASP, LBHY37 UVASP, LBHYO37 UVASP, 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, PBHYO32UVASP, 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, CSQHF60125L1AP, YSQHF60125L1, YSQHF60125L1AP, YSQHF60125L1DF, CSQHF60125L1DF, YSQHF60110Q4AP, CSQHF60110Q4AP, YSQHF60110Q2AP, CSQHF60110Q2AP, YSQHF60125L1TR*, SQHF60125L1TR*, YSQHF60110Q2TR*, CSQHF60110Q2TR*, CSQHF60120Q4AP, CSQHF60130Q4AP, CSQHF60130C1AP.	Iib
Capsular Tension Ring	Raw material: PMMA, BLUE PMMA Brand Names: Omni, Intra Inner Packing: Lens case Outer packing: Single Pack Models: 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	Iib

Lens Delivery System	Brand Names: Aquaject (Cartridge & Cushion), Aquaject Plus (Cartridge, Cushion & Injector or Cartridge, Cushion, Injector and Lens Rolling System Part-2), LDS Inner Packing: Paper Pouch, Blister Pack Outer packing: Single Pack, Combo Pack Models: 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	Ila
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Appendix History -		
Revision	Description	Issued Date
0.0	To remove the term "Single piece" from "Single piece PMMA Intraocular Lenses" and to correct to "PMMA Intraocular Lenses"	17 August 2021