
06.1C_SUMMARY OF SAFETY & CLINICAL PERFORMANCE (SSCP)

Multifocal Hydrophilic Acrylic Foldable IOL (BIOL, Avafold, Intra, I-Xpert, Revive, Trioptix, Ocuflex -TF, Smart 3 Lens FOCUS THREE)

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This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of clinical data and other information about safety and clinical performance of the medical device.

Note: This SSCP is not intended to replace the Instructions for Use or Implant Card, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

PART I

INFORMATION INTENDED FOR USERS/HEALTHCARE PROFESSIONALS

The following information is intended for users/ healthcare professionals.

1. IDENTIFICATION OF DEVICE AND MANUFACTURER

1.1 Device Trade Names/ Brand Names

Hydrophilic Multifocal Acrylic Intraocular Lens (IOLs) of the following brands are available:

- BIOL
- Avafold
- Intra
- I-Xpert,
- Revive
- Trioptix
- Ocuflex –TF
- Smart 3 Lens
- FOCUS THREE
- TriOptix

Multifocal Hydrophilic Acrylic Foldable IOLs are available in the following countries:

- Slovak republic
- Italy
- Chelyabinsk- Russia
- USA
- Bangkok
- Brazil
- Cambodia
- Indonesia
- Syria
- Belgium
- Turkey

- Bogota

1.2 Manufacturer's Name & Address

Omni Lens Pvt. Ltd.

Factory: A-69/A-70, Electronic Estate, GIDC, Sector-25, Gandhinagar-382016, Gujarat, India.

Reg. office: 5, Samruddhi, Opp. Sakar III, Navarangpura, Ahmedabad-380014, Gujarat, India.

1.3 Manufacturer's Single Registration Number (SRN)

IN-MF-000022124

1.4 Basic UDI-DI

Multifocal Hydrophilic Acrylic Foldable IOL: 8905449IOLPHILMULTJR

NOTE: GS1 is the issuing entity for Omni Lens Pvt. Ltd.

1.5 Medical Device Nomenclature Description/ Text

EMDN Code: P030102100202

Description for EMDN Code: IOLs, APHAKIC, MULTIFOCAL, ASPHERICAL, HYDROPHILIC ACRYLIC

1.6 Class of Device

Multifocal Hydrophilic Acrylic Foldable IOL is classified as class IIb devices as per Rule 8 of Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (EUMDR).

It falls under the category of surgically invasive, implantable device intended for long term use. It is intended to be implanted in the eye in place of natural lens during cataract surgery for better near, intermediate and distance vision and is intended for continuous use for more than 30 days.

1.7 Year When the First Certificate (CE) was Issued Covering the Device

2012.

1.8 Authorized Representative

EU Authorized Representative Name	Obelis S.A
EU Authorized Representative Address	Boulevard GénéralWahis, 53 1030 Brussels Belgium Tel: +32.2.732.59.54 Fax: +32.2.732.60.03 E-mail: mail@obelis.net

SRN Number	BE-AR-000000106
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1.9 Notified Body's (NB's) Name and the Notified Body's Single Identification Number (SIN)

Notified Body Name	DNV Product Assurance AS
Notified Body Identification Number	2460

2. INTENDED PURPOSE OF THE DEVICE INCLUDING INDICATIONS, CONTRAINDICATIONS AND TARGET POPULATION

2.1 Intended Purpose

Multifocal Hydrophilic Acrylic Foldable IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. Multifocal Hydrophilic Acrylic Foldable IOL is based on the principle of diffraction, whereby light slows down and changes direction when it encounters an obstacle and gets directed towards distant, intermediate and near focal points.

2.2 Indications

Multifocal Hydrophilic Acrylic Foldable IOL is indicated for the replacement of human crystalline lens to achieve visual correction of aphakia in patients when extracapsular cataract extraction or phacoemulsification is performed. Multifocal Hydrophilic Acrylic Foldable IOL is intended for placement in the capsular bag. In patients with the need for near, distant and/or intermediate vision.

2.3 Intended Population

Aphakic adult patients of age 18 years and above.

2.4 Intended User

Multifocal Hydrophilic Acrylic Foldable IOL should be used by ophthalmic surgeons only.

2.5 Contraindication or Limitation

These conditions are (non-exhaustive list):

- Choroidal hemorrhage
- Chronic severe uveitis
- Excessive vitreous loss
- Extremely shallow anterior chamber
- Medically uncontrolled glaucoma & Excessive vitreous pressure
- Microphthalmos
- Aniridia
- Posterior capsular rupture & Zonular separation (preventing fixation of IOL)
- Proliferative diabetic retinopathy (severe)

- Severe corneal dystrophy & optic atrophy
- Rubeosis iridis-Congenital bilateral cataract, recurrent anterior or posterior segment
- inflammation of unknown etiology, Rubella cataract
- Retinal detachment
- Iris atrophy
- Severe ametropia and aniseikonia
- IOL replacement or extraction
- Excessive intraoperative vitreous loss
- Hemorrhage

In above condition, IOL implantation can be done with judgement of Surgeon.

2.6 Claims

Compared to regular intraocular lenses (IOL), Multifocal Hydrophilic Acrylic Foldable IOL claims to correct near, intermediate and distance vision and thereby reduce the need for glasses for readers.

3. DEVICE DESCRIPTION

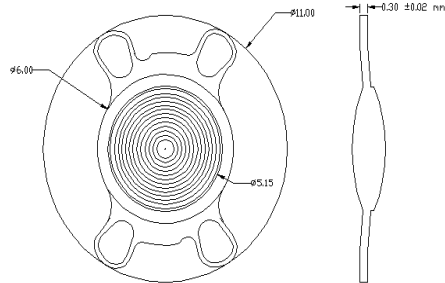
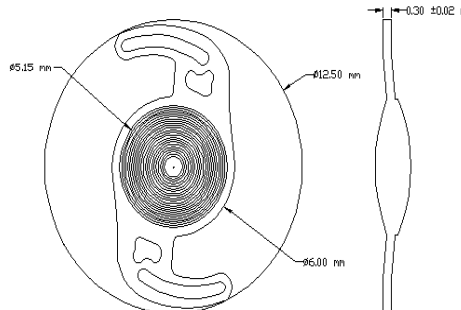
3.1 Description of the Device

Intraocular Lens (IOL) is an artificial lens that is implanted in the eye to replace the natural lens affected by cataract. The first IOL was implanted by Sir Harold Ridley in 1949 but the concept of IOL began to spread after the 1970s. Today, there are various types of materials and designs that exist for an IOL. Different material types include: polymethyl methacrylate (PMMA), silicone, acrylic materials such as hydrophobic and hydrophilic acrylic. Acrylic materials are the preferred choice for Ophthalmologists because of its flexible and foldable capacities with a lower rate of opacification compared to other materials. In addition to wide range of material types, IOLs are available in a variety of designs such as monofocal, multi-focal, accommodative and toric.

Intraocular Lens consists of two parts: 1) Optic, and 2) Haptic. Optic is the small center portion that acts as an artificial lens, and haptic is the side structure that holds the lens in place once implanted. This technical documentation covers in its scope various models of Multifocal Hydrophilic Acrylic Foldable IOLs with 25% water content. The models are available in Quadra and Flex loop haptic configuration.

The natural lens is protected against phototoxic UV light due to the filter properties of the cornea, aqueous humour, lens and retina. Hence, after cataract surgery, it becomes important to protect the eye from UV radiation through the artificial lens. Multifocal Hydrophilic Acrylic Foldable IOL material is made up of UV absorbing acrylic material (UV Cut off) that allows transmission of <10% of light of wavelength 360 nm or lower which ensures protection of the eye from UV radiation. The Multifocal Hydrophilic Acrylic Foldable IOLs are available in yellow optic tint which provides better contrast sensitivity by absorbing blue-light and possibly protecting the retina from damage and development of age-related macular degeneration (AMD).

The haptic configuration for Omni's Multifocal Hydrophilic Acrylic Foldable IOL includes flex and Quadra.

Haptic Type	Final IOL Image	Drawing
Quadra		
Flex loop		

Multifocal Hydrophilic Acrylic IOL Brands:

Revive, Intra, TriOptix, BIOL, Smart 3 Lens FOCUS THREE, I- Xpert, Avafold

Parameters	Specifications
Dioptric Power	(+) 8 to (+) 32 D
Additional Power	1.75, 3.0, 3.5
MTF value	≥ 0.43
Optic Resolution	≥ 70%
Optic diameter	5.0mm-7.0mm (0.25 increments)
Overall diameter / Length	11mm – 13.50 mm (0.50 increments)
Haptic Angle	0° – 10°
Optic material	Hydrophilic Acrylic with 25% water content
Optic design	Diffraction multifocal, Bifocal, Trifocal with aspheric surface
Configuration	Bi-convex
Color	Yellow
Haptic configuration	Quadra & Flex loop
Ref.Index	1.45-1.50

- **Principle of Operation:**

Multifocal Hydrophilic Acrylic Foldable IOLs are intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. These IOLs are based on the principle of diffraction, whereby light slows down and changes direction when it encounters an obstacle and gets directed towards distant and near focal points. Because of the hydrophilic nature, the IOL is capable of being folded prior to insertion and takes its original unfolded shape after implantation.

Multifocal Hydrophilic Acrylic Foldable IOL material is made up of UV absorbing acrylic material (UV Cut off) that allows transmission of <10% of light of wavelength 360 nm or lower which ensures protection of the eye from UV radiation.

3.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

a. Legacy Device Details

Legacy Device Name:	Multifocal Hydrophilic Acrylic Foldable IOL
Brand/Proprietary Name:	BIOL, AvaFold, Intra, I-Xpert, Revive, Trioptix, OcuFlex -TF, Smart 3 Lens FOCUS THREE
Models/Variants:	YSQFL600DF/ HFL2125605NYD, YSQQ600DF/ MAY4, PBFY37MF/ HQL1110605NYD
EU Technical Documentation Assessment Certificate-	Management System Certificate (ISO 13485:2016/EN ISO 13485:2016) Certificate No.: 248937-2017-AQ-IND-NA-PS EU Technical Documentation Assessment Certificate (Regulation 2017/745)-C567415 EU Quality Management System Certificate (Regulation 2017/745)-10000501570-PA-NoMA-IND
Notified Body Details:	DNV Product Assurance AS
Is any significant difference between Legacy Device & Device Under Evaluation?	There is no significant difference between legacy device and subject device with respect to raw materials used in production, device description, intended purpose, medical indications, target user, target patient population, side-effects, and contraindications.

There are various models of Multifocal Hydrophilic Acrylic Foldable IOLs established (Refer ATCH09). The variations are as follows:

- Optic and haptic designs.
- The types of haptic configuration include Flex loop and Quadra loop.
- The optic configuration includes Bifocal and trifocal.
- On account to register the lens with same specification with different distributor in same country; the brand names and model numbers are kept in multiples for any one type of lens.
- The raw material used in Multifocal Hydrophilic Acrylic Foldable IOL comes from Benz.

- All our lenses are compatible for all our lens delivery system models covered under brand name "Aquaject Plus, LDS & X-Ject".

The clinical data from the post market clinical study of Multifocal Hydrophilic Acrylic Foldable IOLs variants PBFY37MF & YSQFL600DF supports the other variants performance and safety. These models are selected so that they cover most of the model variation and further these are the fast-moving models.

Hence all the device variants are considered as legacy devices.

3.3 Description of any accessories which are intended to be used in combination with the device

- **Accessories Included**

Multifocal Hydrophilic Acrylic Foldable IOLs do not contain any devices that can be considered accessory. One type of packaging contains a sterile injector and sterile cartridge but they are treated as separate medical devices.

- **Accessories Not Included But Necessary for Use**

The use of a lens delivery system is essential for the implantation of intraocular lens. It consists of cartridge, injector and cushion.

Packing configurations of IOL (regular/Single).

3.4 Description of any other devices and products which are intended to be used in combination with the device

Multifocal Hydrophilic Acrylic foldable IOL is intended to be used in combination with following medical devices and substances during cataract surgery:

Lens Delivery System: It is a sterile, single use injector and cartridge system used to deliver lens into the capsular bag.

Ophthalmic visco-surgical devices (OVDs) like Sodium Hyaluronate, HPMC are used for smooth lens implantation, protect intraocular tissues and maintain anterior chamber stability.

Balanced Salt Solution (BSS) used for irrigation of the anterior chamber during surgery to maintain physiological conditions and remove debris.

Others: Phacoemulsification machine & handpiece, surgical microscope, standard ophthalmic instruments like forceps, cannulas and topical ophthalmic medications such as anti-inflammatory and antibiotic eye drops (used preoperatively to control inflammation and prevent infection).

Packing configurations of IOL (regular/Single)

4. RISKS AND WARNINGS

4.1 Residual risks (based on overall assessment)

- IOL Dislocation,
- Allergic Reaction,
- Undesired vision correction,
- Inconvenience to patient,
- Environmental Contamination

4.2 Complication and Adverse Events

As with any surgical procedure, there is risk involved.

The quantitative/qualitative system is used for categorization of probability of occurrence of harm and severity of harm to the patient, operator, equipment, or environment.

- a. Severity - A measure of possible physical injury or damage to the health of people or damage to property or the environment as result of a hazard. Severity must be determined for each hazard.

Rating	Definition	Value
Catastrophic	Results in permanent impairment or life-threatening injury	S5
Critical	Results in major injury or impairment requiring professional medical intervention	S4
Serious	Results in minor injury or impairment requiring professional medical intervention	S3
Minor	Results in temporary injury or impairment not requiring professional medical intervention	S2
Negligible	Inconvenience or temporary discomfort	S1

Note: Product specific harms are identified as part of risk management report/file.

- b. Probability of Occurrence - The probability of harm results from occurrence of initiating event.

Definition	Description	Value
Frequent	Will undoubtedly happen or recur, possibly frequently	P5
Probable	Will probably happen or recur, but it is not a persisting issue / circumstance	P4
Occasional	Might happen or recur occasionally	P3
Remote	Do not expect it to happen or recur but it is possible it may do so	P2
Improbable	This will probably never happen or recur	P1

Risk Matrix is as follows:

Before implementation of Risk Control Measures

Probability of Occurrence	Severity				
	S1	S2	S3	S4	S5
P5	P5*S1(RC)	P5*S2(RC)	P5*S3(RC)	P5*S4(RC)	P5*S5(RC)
P4	P4*S1(RC)	P4*S2(RC)	P4*S3(RC)	P4*S4(RC)	P4*S5(RC)
P3	P3*S1(RB)	P3*S2(RB)	P3*S3(RC)	P3*S4(RC)	P3*S5(RC)

P2	P2*S1(RA)	P2*S2(RB)	P2*S3(RB)	P2*S4(RC)	P2*S5(RC)
P1	P1*S1(RA)	P1*S2(RA)	P1*S3(RB)	P1*S4(RB)	P1*S5(RB)

Not Acceptable Region (NA)	Acceptable region (A)
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Risk Acceptability before implementing risk control measures:

Risk index		Risk Classification	Acceptance guidelines
High	R C	Not Acceptable (NA)	Requires risk reduction by implementing necessary and/or possible control measures for reducing/moving the hazards from not acceptable region to acceptable region.
Medium	R B	Not Acceptable (NA)	Requires risk reduction by implementing necessary and/or possible control measures for reducing/moving the hazards from not acceptable region to acceptable region.
Low	R A	Acceptable (A)	Directly acceptable. However, all necessary and/or possible control measures are implemented to minimize probability of risk occurrence for reducing/moving the hazards from not acceptable region to acceptable region.

After implementing Risk Control Measures

Probability of Occurrence	Severity				
	S1	S2	S3	S4	S5
P5	P5*S1(RC)	P5*S2(RC)	P5*S3(RC)	P5*S4(RC)	P5*S5(RC)
P4	P4*S1(RC)	P4*S2(RC)	P4*S3(RC)	P4*S4(RC)	P4*S5(RC)
P3	P3*S1(RB)	P3*S2(RB)	P3*S3(RC)	P3*S4(RC)	P3*S5(RC)
P2	P2*S1(RA)	P2*S2(RB)	P2*S3(RB)	P2*S4(RC)	P2*S5(RC)
P1	P1*S1(RA)	P1*S2(RA)	P1*S3(RB)	P1*S4(RB)	P1*S5(RB)

Not Acceptable Region (NA)	Acceptable after Benefit Risk Analysis(CA)	Acceptable region (A)
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Risk Acceptability after implementing risk control measures:

Risk index		Risk Classification	Acceptance guidelines
High	R C	Not Acceptable (NA)	Requires risk reduction by implementing necessary and/or possible control measures for reducing/moving the hazards from not acceptable region to acceptable region.
Medium	R B	Will be conditionally Acceptable based on Benefit-Risk Analysis (CA)	All necessary and/or possible control measures are implemented to minimize probability of risk occurrence for reducing/moving the hazards from not acceptable region to acceptable region. Based on the benefit/risk analysis all the residual risks are disclosed by providing information on safety in the form of symbol, precaution, warnings and cautions in IFU & Label.

Risk index		Risk Classification	Acceptance guidelines
Low	R A	Acceptable (A)	Directly acceptable. However, all necessary and/or possible control measures are implemented to minimize probability of risk occurrence for reducing/moving the hazards from not acceptable region to acceptable region.

After Evaluation of Benefit-Risk Analysis

Probability of Occurrence	Severity				
	S1	S2	S3	S4	S5
P5	P5*S1(RC)	P5*S2(RC)	P5*S3(RC)	P5*S4(RC)	P5*S5(RC)
P4	P4*S1(RC)	P4*S2(RC)	P4*S3(RC)	P4*S4(RC)	P4*S5(RC)
P3	P3*S1(RB)	P3*S2(RB)	P3*S3(RC)	P3*S4(RC)	P3*S5(RC)
P2	P2*S1(RA)	P2*S2(RB)	P2*S3(RB)	P2*S4(RC)	P2*S5(RC)
P1	P1*S1(RA)	P1*S2(RA)	P1*S3(RB)	P1*S4(RB)	P1*S5(RB)

Not Acceptable Region (NA)	Acceptable region (A)
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Risk Acceptability after evaluating benefit-risk analysis :

Risk index		Risk Classification	Acceptance guidelines
High	RC	Not Acceptable (NA)	Requires risk reduction by implementing necessary and/or possible control measures for reducing/moving the hazards from not acceptable region to acceptable region.
Medium	RB	Conditionally Acceptable based on Benefit-Risk Analysis (CA)	All necessary and/or possible control measures are implemented to minimize probability of risk occurrence for reducing/moving the hazards from not acceptable region to acceptable region. Based on the benefit/risk analysis all the residual risks are disclosed by providing information on safety in the form of symbol, precaution, warnings and cautions in IFU & Label.
Low	RA	Acceptable (A)	Directly acceptable. However, all necessary and/or possible control measures are implemented to minimize probability of risk occurrence for reducing/moving the hazards from not acceptable region to acceptable region.

Risk Assessment related to clinical surgery stages with its residual risk:

Clinical Surgery Stages	Risk detail	Probability	Severity	Risk Index(before risk control)	Mitigation of risk	Probability	Severity	Risk Index(after risk control)	Risk Index (after risk benefit)
Pre-operative & Operative	IOL breakage during implantation	P2	S2	NA	Surgical Training (Handling of IOL)	P1	S2	A	
	Incorrect lens power on labels (H26)	P2	S2	NA	Biometry & Barcode check	P1	S2	A	
	Overtime storage of the device (H7)	P2	S2	NA	Refer Information on the label and IFU	P1	S2	A	
	Insufficient sterilization(H14)	P2	S2	NA	Packaging (Sterile)	P1	S2	A	
	Delay in Procedure (H24,H25)	P2	S2	NA	Sufficient information in IFU	P1	S2	A	
	Transcription error (H31 - H36)	P2	S4	NA	Proper attention during implantation & selection of IOL based on the biometry	P1	S4	A(Require risk benefit)	A
	Perception error(H37-H38,H40,H42-H45)	P2	S4	NA	Informative Instructions Leaflet	P1	S4	A(Require risk benefit)	A
	Cognition error(H39,H41,H46-H65)	P2	S3	NA	Manage rule based knowledge ,proper attention during implantation procedure	P1	S3	A(Require risk benefit)	A
	Forseeable Misuse(H66- H69)	P2	S3	NA	Instruction on IFU	P1	S3	A(Require	A

								risk benefit)	
	Packing Hazard(H73-H86)	P2	S2	NA	Proper checking and verification before implantation	P1	S2	A	
Immediate Post Op	Endophthalmitis	P2	S2	NA	Povidone-Iodine, Antibiotics	P1	S2	A	
	Inflammation (uveitis)	P3	S2	NA	Steroid drops , material biocompatibility tests	P1	S2	A	
	Lens decentration/tilt(H15)	P2	S3	NA	Improvement in haptic design	P1	S3	A(Require risk benefit)	A
	Refractive (Knowledge based formula) H30	P2	S4	NA	Better calculation formula	P1	S4	A(Require risk benefit)	A
Late Post op	Posterior capsular opacification / undesired vision correction(H20, H21, H27-H30, H32-H36, H38, H40, H42-H63, H67, H72)	P4	S3	NA	Edge design optimization	P2	S3	A(Require risk benefit)	A
	IOL dislocation (H15,H16,H64,H65)	P2	S3	NA	Haptic design stability & capsular bag integrity	P1	S3	A(Require risk benefit)	A
	Glistenings/Glare & Halos (H17-19,22,23,39,41,66,68, 69)	P3	S3	NA	Rubbing avoidance after surgery	P1	S3	A(Require risk benefit)	A
	Cystoid macular edema/corneal edema	P2	S2	NA	NSAIDS, Additional follow up	P1	S2	A	

	Pupillary block	P2	S2	NA	Medications- Eyedrops, reducing IOP, Regular Follow-Up Examinations, Lifestyle Modifications	P1	S2	A	
	Prolonged Eye Irritation (H1-H14)	P2	S2	NA	Medications- Eyedrops, Regular Follow-Up Examinations	P1	S2	A	
Inconvenience to patient	Depletion of IOL stock leading to rescheduling the surgery or wrong IOL implantation(H31)	P2	S3	NA	Proper scheduling on basis of iol stock	P1	S3	A(Require risk benefit	A
Environmental situation	Improper disposal of the device(H71)	P2	S3	NA	Instruction on IFU	P1	S3	A(Require risk benefit	A

Residual Risk & Risk Benefit Analysis:

#	Residual Risk with the product	Associated Hazard Id's	Literature outcomes	Medical Benefits	Conclusion
1.	IOL Dislocation	H15, H16, H64, H65	The mechanism of the posterior capsule tear could have been focal digital pressure on the eye that displaced the IOL vertically, causing the sharp edge of the haptic to rupture the posterior capsule. Other case reports describing isolated posterior capsule rupture from mechanical pressure were in eyes with natural crystalline lenses and not in pseudophakic eyes with causative factors that included trauma, hypermature cataract, polar cataract, and pseudoexfoliation	This is the first case of excessive eye rubbing leading to bilateral rupture of the posterior capsule in pseudophakic eyes and in-the-bag IOL dislocation. Correlation with the IOL type, particularly in reference to haptic tips and the described complication, cannot be ascertained conclusively but could be an implicating factor	Accepted based on Benefit-Risk Analysis. <u>However, it will be effectively monitored through the PMS Studies.</u>
2.	Allergic Reaction (Glistening /Glare & Halos)	H17, H18, H19, H22, H23, H39, H41, H66, H68, H69	Chronic eye rubbing in allergic eye diseases can lead to progression of keratoconus, and to other rare anterior and posterior segment complications. Strategies eliminating eye rubbing and its consequences are vital, mainly among at-risk populations, such as young children and individuals with allergic ocular disorders or corneal transplant	Rubbing avoidance may reduce the incidence of adverse responses following any form of invasives procedure, such as corneal surgery. In 2009, McMonnies suggested a strategy for preventing chronic behavior of eye rubbing. The approach for the habit modification that was suggested consists of four stages: stage 1: rubbing habit awareness; stage 2: competing responses, stage 3: developing high motivation	Accepted based on Benefit-Risk Analysis. <u>However, it will be effectively monitored through the PMS Studies.</u>

				4: social support in which the responsibility for avoiding eye rubbing widens to include all family members	
3.	PCO/Undesired vision correction/ Knowledge based formula	H20, H21, H27, H28, H29, H30, H32, H33, H34, H35, H36, H38, H40, H42, H43, H44, H45, H46, H47, H48, H49, H50, H51, H52, H53, H54, H55, H56, H57, H58, H59, H60, H61, H62, H63, H67, H72	Intraocular lenses designed solely for the capsular bag should not be placed in the ciliary sulcus. Backup IOLs in appropriate powers, sizes, and designs should be available for every cataract procedure. The development, investigation, and supply of IOLs specifically designed for placement in eyes that lack adequate capsule support represent clinically important endeavors for ophthalmology and the ophthalmic industry.	This is the first case of excessive eye rubbing leading to bilateral rupture of the posterior capsule in pseudophakic eyes and in-the-bag IOL dislocation. Correlation with the IOL type, particularly in reference to haptic tips and the described complication, cannot be ascertained conclusively but could be an implicating factor	Accepted based on Benefit-Risk Analysis. <u>However, it will be effectively monitored through the PMS Studies.</u>
4.	Inconvenience to patient	H31	Intraocular lens development is driven by higher patient expectations for ideal visual outcomes. The recently US Food and Drug Administration-approved Softec HD™ lens is an aspheric, hydrophilic acrylic intraocular lens (IOL). The hydrophilic design of the lens is optimized to address dysphotopsia while maintaining biocompatibility, optical clarity, resistance to damage, and resistance to biocontamination. Aspheric lenses decrease postoperative spherical aberration. The addition of the	Despite a decade of popularity elsewhere, hydrophilic acrylic IOLs have not gained popularity in the US due to several early reports of calcification and opacification. ²⁻⁹ Recently, a new generation of hydrophilic acrylic IOLs has been approved by the FDA and is now available for clinical use in the US. Hydrophilic acrylics offer physical, biological, and optical qualities that make them suitable for use in foldable IOLs. These	Accepted based on Benefit-Risk Analysis. <u>However, it will be effectively monitored through the PMS Studies.</u>

			Softec lens provides clinicians with another option for IOL placement; however, randomized comparative studies of this lens to others already on the market remain to be completed.	characteristics include the following: Less dysphotopsia: Good biocompatibility: Good optical clarity: Resistance to damage during insertion: Less susceptibility to biocontamination:	
5.	Environmental Contamination	H71	The surgeon may need to remove an IOL at the time of primary implantation if it is damaged during insertion, if it is discovered to be the incorrect power, or if damage to the ocular tissues occurs during insertion, rendering the primary IOL unstable in the eye. Damage to an IOL can occur to a haptic or the optic. Haptic damage includes a bent or avulsed haptic, in the case of a looped or three-piece IOL, or a torn or avulsed portion of a plate-haptic in the case of a single-piece silicone (Figure 1) or Collamer (Staar, Monrovia, Calif.) IOL. If it is determined that the haptic damage renders the IOL unstable or decentered, the surgeon should remove and replace the IOL. Damage to the capsule, particularly a posterior tear that occurs during primary IOL implantation, may require primary IOL	The replacement IOL implantation method and location are both dependent on the status of the ocular anatomy following IOL removal. If all is normal and there is an intact capsular bag, then the secondary implantation procedure is no different from the first; the IOL goes in the same location, usually the capsular bag	Accepted based on Benefit-Risk Analysis. <u>However, it will be effectively monitored through the PMS Studies.</u>

			removal and replacement with an IOL in a different location.		
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Reference: OLPL/TMF/02B (Risk Management Report)

The possible adverse effects and complications accompanying a cataract surgery may be the following (non-exhaustive list):

- Posterior capsule opacification
- Cystoid Macular edema
- Corneal edema
- Pupillary block
- Iridocyclitis
- Hyalites
- Endophthalmitis and Panophthalmitis
- Recurrent anterior or posterior segment inflammation of unknown etiology
- IOL precipitates
- IOL Decentration
- IOL dislocation and subluxation
- TASS (Toxic anterior segment syndrome)
- There may be short-term interferences with diagnostic tools such as optical torch or MRI; risks related to this have been captured in risk management and residual risks are acceptable because of the low probability of occurrence of harm. The user is informed about such risks via IFU.
- Iritis
- Recurrent anterior or posterior segment inflammation of unknown etiology
- IOL precipitates
- IOL Decentration
- IOL dislocation and subluxation
- TASS (Toxic anterior segment syndrome)
- There may be short-term interferences with diagnostic tools such as optical torch or MRI; risks related to this have been captured in risk management and residual risks are acceptable because of the low probability of occurrence of harm. The user is informed about such risks via IFU.

4.3 Warnings and Precautions

- Do not re-sterilize these Intraocular Lenses by any methods. If re-sterilized, the lens may lose its functionality and may lead to infection.
- Use only sterile intraocular irrigating solution to rinse and/or soak IOLs to retain sterile condition and avoid contamination.
- Once packaging has been opened, the intraocular lens must be used immediately. The IOLs of Hydrophilic nature can cause the IOL to absorb substances with which it comes into contact, such as disinfectants, medicines, blood cells, etc. This may cause a "Toxic IOL Syndrome". Rinse the IOL carefully before implantations with sterile balance salt solution or balanced saline solution.
- Do not re-use the IOL. If IOL is reused, it can cause loss of vision/serious complication.
- Do not use the intraocular lens after the expiration date shown on the outside package label. After

- expiry, sterility is not retained and can cause infection.
- Handle the intraocular lens carefully. Rough handling or excessive handling may damage the IOL.
- A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and /or assisted in numerous surgical implantations and successfully completed one or more courses on intraocular lenses prior to attempting to implant IOLs.
- The surgeon must be aware of the risk of opacification of the intraocular lens, which may necessitate IOL removal.
- All cases of IOL removal must be reported to Omni Lens.
- In case of any adverse event noted, contact manufacturer (Omni Lens Pvt. Ltd) or authorized representative and competent authority of the member state where user / patient is established without any delay or within 24 hrs. A report describing the adverse event, therapy adopted, traceability detail of the lens used will be requested.
- When the preloaded system is used improperly, the haptics of the IOL, may become broken, please refer to the specific "Instruction for use of Preloaded system", provided with this IOL Pack.
- Omni will not be responsible for any damage occurred to patient due to not following above listed warnings. The risks associated are: decentration of IOL, contamination, infection or loss of vision in operated eye.
- To successfully implant intraocular lens, choose right lens delivery system.

For the Multifocal intra ocular lenses additional warnings are:

- The physician should consider the following points that are unique to the Multifocal IOL.
- It is recommended emmetropia be targeted for optimum visual performance.
- Patients with significant pre-operative astigmatism or expected to get post-operative astigmatism > 1.0 D may not achieve optimal visual outcomes.
- Care should be taken to achieve Multifocal centration, as lens decentration may result in patient experiencing decrease of visual quality under certain lighting conditions.
- As it is the case for all Multifocal IOLs with simultaneous vision, some patients may experience a reduction of contrast sensitivity compared to monofocal lens (IOL) that may be more important in low lighting conditions.
- Some patients may experience some visual effects due to the superposition of focused and unfocused multiple images at different foci. These visual effects may be perceptions of halos and radial lines around point source of light under night time conditions.

IOL is void of all warranties expressed or implied if

- IOL is re sterilized by any one.
- IOL is repackaged by anyone.
- IOL is altered in any manner.

4.4 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN), if applicable

No Field Safety Corrective Action (FSCA) taken and no Field Safety Notices (FSN) issued for Multifocal

Hydrophilic Acrylic Foldable IOL till date.

5. SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

5.1 Summary of clinical data related to equivalent device, if applicable

The Multifocal Hydrophilic Acrylic Foldable IOL clinical evaluation is based on the sufficient clinical evidence related to legacy device and well-established technology as per the guidance document MDCG 2020-6:2020 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC.

The demonstration of similarities fulfilled by comparing the regulatory, clinical, technical and biological characteristics. The identified differences are fully disclosed, evaluated and justified thorough preclinical data, risk analysis, usability verification, PMS data, PMCF data and literature data.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

We don't use any new technology or materials, no new clinical applications, and no additional incremental functionality implemented for "Multifocal Hydrophilic Acrylic Foldable IOL". The technology used for Multifocal Hydrophilic Acrylic Foldable IOL is already present in several other similar devices currently used in the market. Additionally, no general safety and performance is claimed that goes beyond the standard requirements and no risk is identified that would require additional clinical study.

- a. General Safety & Performance conformity assessment as per MDCG 2020-6:2020 – Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC and Appendix 7 of MEDDEV 2.7.1 Rev.4 - Clinical Evaluation - A Guide for Manufacturers and Notified Bodies.
- b. Use of Data from Similar devices as per MDCG 2020-6 - Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC.
- c. Clinical Citations study as per Appendix A4, A5 & A6 of MEDDEV 2.7.1 Rev.4 - Clinical Evaluation - A Guide for Manufacturers and Notified Bodies.
- d. Post market Clinical data's as per Regulation (EU) 2017/745 Article 61 & Annex XIV Part B guidelines.
- e. Post Market Surveillance study as per Regulation (EU) 2017/745 Article 82, 83, 84, 85 & 86 & Annex XIV Part B and NB-MED 2.12-1 Rev 11 guidelines.

The outcomes of Clinical evaluation support and encourage the use of Multifocal Hydrophilic Acrylic Foldable IOL and indicate the absence of significant safety and performance risks associated with.

Clinical evaluation through sufficient clinical data related to legacy device, similar devices and non-clinical data related to legacy device by demonstrating the conformity with applicable General Safety and Performance Requirements indicates that our Multifocal Hydrophilic Acrylic Foldable IOL leverages existing Well-Established Technology, and large amount of data confirms its clinical safety and efficacy.

Therefore, we conclude that there is no requirement of conducting formal clinical investigation as per ISO 14155 requirements for our Multifocal Hydrophilic Acrylic Foldable IOL.

5.3 Summary of clinical data from other sources, if applicable

Post-market surveillance data collected after the initial CE marking of the device as per the European Medical Device Directive constitute other sources of clinical data. Such PMS data was collected from a PMCF study, the internal vigilance database (complaints, adverse event reporting, market surveillance), product feedback and surveys, and external adverse event databases.

Post Market Surveillance (PMS) data is also considered as clinical data. Hence, data from a PMCF study, market complaints, and vigilance is also given below:

- **PMCF study**

The Intra Ocular Lenses from Omni lens pvt ltd has reached all the safety and performance requirements with respect to the intended use of the device from the clinical investigation.

Based on the result of 52 subjects.

The Uncorrected Distance Visual acuity from Pre-operative mean value is 70.00 and after the surgery log mar value has gradually achieved stabilization of mean value of 100 which is normal range.

After surgery the Uncorrected Intermediate Visual Acuity has increased from 75.00 mean value after the surgery log mar value has gradually achieved stabilization of mean value of 100 which is normal range.

After surgery the Uncorrected Near Visual Acuity has increased from 70.00 after the surgery log mar value has gradually achieved stabilization of mean value of 100 which is normal range.

On the other hand, the Best Corrected Distance Visual Acuity from preoperative log mar mean value is 0.721 and after the surgery Log Mar value has gradually achieved stabilization of log mar mean 0 which is the normal range. After surgery, Distance corrected Intermediate Visual acuity & Distance corrected near visual acuity log mar is 0 has gradually achieved stabilization on last day of follow up which is the normal range.

Hence it proves very good performance of OMNI'S IOL.

IOL Decentration, IOL tilt, IOL dislocation, IOL discoloration, IOL opacity and glistening in IOL were not observed in any of the subject participated during the study period.

There were no new risks identified from the clinical investigation for the products hence there was no addition to the residual risks which we have already identified in the Risk Management Report and that is been mitigated and are acceptable when weighed against the benefits to the patient. None of the subject had reported safety related issues and there were no adverse events reported.

- **Complaints**

The manufacturer has not received any complaints for Multifocal Hydrophilic Acrylic Foldable IOL.

- **Adverse Events Reporting**

No adverse events have been reported for this device to any regulatory agency.

5.4 An overall summary of the clinical performance and safety

Clinical safety and performance of Multifocal Hydrophilic Acrylic Foldable IOL is evaluated by analyzing post-market surveillance (PMS) data of the subject device, Post Market Clinical Follow-up (PMCF) data of patients undergoing implantation of the Multifocal Hydrophilic Acrylic Foldable IOL in real-world scenario and comparing the same with the safety and performance endpoint (SPE) data provided in ISO 11979-7:2024 (E). EN ISO 11979-7:2024: Clinical investigations of intra ocular lenses for the correction of aphakia provide safety and performance endpoints (SPE) rates which are the historical data derived from weighted averages of the data from large clinical investigations of anterior and posterior chamber IOLs. The results of the present trial are compared with the SPE rate of posterior chamber IOL (Table E.2) from EN ISO 11979-7:2024 for the demonstration of visual performance and safety of study device.

Posterior chamber IOL adverse event rates:

Adverse events	SPE rate %
Cumulative:	
Cystoid macular oedema	3.0%
Hypopyon	0.3%
Endophthalmitis	0.1%
Lens dislocated from posterior chamber	0.1%
Pupillary block	0.1%
Retinal detachment	0.3%
Secondary surgical intervention	0.8%
Persistent:	
Corneal stroma oedema	0.3%
Cystoid macular oedema	0.5%
Iritis	0.3%
Raised IOP requiring treatment	0.4%

The Intra Ocular Lenses from Omni lens pvt ltd has reached all the safety and performance requirements with respect to the intended use of the device from the clinical investigation.

Based on the result of 52 subjects.

The Uncorrected Distance Visual acuity from Pre-operative mean value is 70.00 and after the surgery log mar value has gradually achieved stabilization of mean value of 100 which is normal range.

After surgery the Uncorrected Intermediate Visual Acuity has increased from 75.00 mean value after the surgery log mar value has gradually achieved stabilization of mean value of 100 which is normal range.

After surgery the Uncorrected Near Visual Acuity has increased from 70.00 after the surgery log mar value has gradually achieved stabilization of mean value of 100 which is normal range.

On the other hand, the Best Corrected Distance Visual Acuity from preoperative log mar mean value is 0.721 and after the surgery Log Mar value has gradually achieved stabilization of log mar mean 0 which is the normal range. After surgery, Distance corrected Intermediate Visual acuity & Distance corrected near visual acuity log mar is 0 has gradually achieved stabilization on last day of follow up which is the normal range.

Hence it proves very good performance of OMNI'S IOL.

There were no new risks identified from the clinical investigation for the products hence there was no addition to the residual risks which we have already identified in the Risk Management Report and that is been mitigated and are acceptable when weighed against the benefits to the patient. None of the subject had reported safety related issues and there were no adverse events reported.

5.5 Ongoing or planned post-market clinical follow-up

The PMCF plan for the period from April 2025 to March 2026 includes the collection of patient data from surgeries performed during this timeframe. Post-operative follow-up is conducted for up to six months, after which data analysis is performed, and a report is prepared.

The study completed for the above-mentioned period demonstrated improved visual acuity in all patients. No cases of IOL decentration, IOL tilt, IOL dislocation, IOL discoloration, IOL opacity, or glistening were observed in any of the subjects. Additionally, no other complications or device failures were reported.

The next report will be made available in August/September of next year. It will include patient data from devices dispatched and surgeries performed between April 2026 and March 2027, with the six-month follow-up and data analysis completed by September. Until now, no adverse events have been reported. PMCF report summary is seen under Section 5.4.

6. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

There are several alternatives available to Multifocal Hydrophilic Acrylic Foldable IOL implantation for cataract management. These are:

- Lifestyle modifications
- Therapeutic treatment with anti-cataract drugs
- Aphakic contact lenses
- Surgeries with IOL implantation or where no IOL implanted, aphakic glasses or contact lenses used
- Hydrophobic monofocal IOLs: These are made from low water content acrylic materials. Associated with a lower incidence of posterior capsule opacification (PCO) and better long-term capsular bag stability. On the other hand, they may also exhibit slightly less flexibility, and some designs have been associated with glistening formation over time.
- Other Intraocular lens including premium IOL hydrophilic or hydrophobic (Multifocal IOL, Toric IOL , accommodating IOL , EDOF extended depth of focus IOL)

7. SUGGESTED PROFILE AND TRAINING FOR USERS

There is no specific training requirement for IOL implantation as it is intended to be used by trained and experienced ophthalmic surgeons only.

However, following instructions needs to be followed while removing IOL from the container and for its proper use.

INSTRUCTION FOR THE REMOVAL OF IOL FROM CONTAINER:

- Remove IOL vial from peelable pouch. Firmly hold vial in one hand and unscrew the cap with your fingers. Remove the rubber stopper and remove the IOL from the vial.
- In case vial is having Holder device then take out the Holder on which IOL is mounted, open the Holder

carefully and take out the IOL.

- In case vial is having Holder Folder device then take out the Holder Folder on which IOL is mounted and fold the IOL with the device.
- If IOL packed in Blister, remove IOL blister from peelable pouch, firmly hold blister in one hand and pull the aluminium lid carefully and take out the IOL.
- In case Blister is having Holder device then take out the Holder on which IOL is mounted, open the Holder carefully and take out the IOL.
- In case of IOL packed in preloaded system, a leaflet containing diagrammatic representation for handling of preloaded system has been provided separately.
- Exercise caution when removing the IOL as the IOL can be easily damaged. Inspect IOL for debris and damage. The IOL should be handled by the haptic portion only.

INSTRUCTION FOR USE:

In order to avoid temporary opaqueness at the time of implantation of the only current method recommended is to equilibrate the IOL at 25° C prior to implantation for a minimum of 60 minutes.

- Grasp the IOL by the haptic and rinse in a balanced saline solution prior to implantation into the eye. Use the IOL immediately. Do not leave the IOL exposed to air for too long as it will dehydrate.
- It is imperative that the IOL be placed in the capsular bag and highly recommended that an extracapsular cataract extraction/Phacoemulsification procedure be used.

8. REFERENCE TO STANDARDS AND COMMON SPECIFICATION (CS) APPLIED

8.1 The following harmonized CEN standards are used in the design, testing and manufacturing of the Multifocal Hydrophilic Acrylic Foldable IOL

Harmonized Standard No.	Harmonized Standard Title
EN ISO 13485:2016 EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11: 2021	Medical devices – quality management systems – requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019, EN ISO 14971:2019/A11:2021	Medical devices – application of risk management to medical devices (ISO 14971:2019)
EN ISO 15223 -1:2021	Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – Part 1: general requirements (ISO 15223 -1:2021)
EN ISO 11607-1:2020, EN ISO 11607- 1:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 11607-2:2020, EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
EN ISO 11737-1:2018, EN ISO 11737- 1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)

Harmonized Standard No.	Harmonized Standard Title
EN ISO 10993-1:2025	Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process (ISO 10993-1:2025)
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017) EN ISO 10993-4:2017/A1:2025
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009) EN ISO 10993-5:2009/A11:2025
EN ISO 10993-9:2021	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)
EN ISO 10993-18:2020 EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
EN 556-1: 2024	Sterilization of medical devices – Requirements for medical devices to be designated “sterile” – Part 1: Requirements for terminally sterilized medical devices
EN ISO 17665:2024	Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)
EN ISO 14155:2020 EN ISO 14155:2020/A11: 2024	Clinical investigation of medical devices for human subjects - Good clinical practice

8.2 List of Standards:

Standard No.	Standard Title
ISO 13485:2016	Medical devices – quality management systems – requirements for regulatory purposes
EN ISO 13485:2016/AC:2018	
EN ISO 13485:2016/A11: 2021	
ISO 14971:2019	Medical devices – application of risk management to medical devices
EN ISO 14971:2019/A11: 2021	
ISO/ TR 24971: 2020	Medical devices – guidance on the application of ISO 14971
ISO 15223 -1:2021/Amd 1 :2025	Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – Part 1: general requirements
EN ISO 15223 -1:2021	
ISO 15223-2:2010	Medical devices - symbols to be used with medical device labels, labeling, and information to be supplied - Part 2: Symbol development, selection and validation
ISO 20417: 2026	Medical Devices - Information supplied by the manufacturer of medical

	devices
ISO 11607-1:2019	Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-1:2020/A1:2023	
ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: validation requirements for forming, sealing and assembly processes
EN ISO 11607-2:2020/A1:2023	
ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-1:2018/A1: 2021	
ISO 11737-2:2019	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11737-2:2020	
ISO 10993-1:2025	Biological evaluation of medical devices – Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process
ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2026	Biological evaluation of medical devices - part-6: Tests for local effects after implantation
ISO 10993-9:2019	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
EN ISO 10993-9:2021	
ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
EN ISO 10993-10:2023	
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
ISO 10993-12:2021/Amd 1:2025	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-12:2021	
ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents
EN ISO 10993-17:2023	
ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-18:2020	
EN ISO 10993-18:2020 /A1:2023	
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
EN ISO 10993-23:2021	
ISO 17665:2024	Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices
EN 556-1: 2024	Sterilization of medical devices – Requirements for medical devices to be designated “sterile” – Part 1: Requirements for terminally sterilized medical devices
ISO 11979-2:2024	Ophthalmic Implants – Intraocular lenses – Part 2: Optical properties and test methods
ISO 11979-3:2012	Ophthalmic Implants – Intraocular lenses – Part 3: Mechanical properties and test methods
ISO 11979-4:2026	Ophthalmic Implants – Intraocular lenses – Part 4: Labeling and Information
ISO 11979-5:2020	Ophthalmic Implants – Intraocular lenses – Part 5: Biocompatibility
ISO 11979-6:2014	Ophthalmic Implants – Intraocular lenses – Part 6: Shelf-life and transport

	stability
ISO 11979-7:2024	Ophthalmic Implants – Intraocular lenses – Part 7: Clinical Investigations of intraocular lenses for the correction of aphakia
ISO 11979-8:2017	Ophthalmic Implants – Intraocular lenses – Part 8: Fundamental requirements
ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISO 14644-3:2019	Cleanrooms and associated controlled environments – Part 3: Test methods
ISO 14644-4:2022	Cleanrooms and associated controlled environments – Part 4: Design, construction and start-up
ISO 14698-1:2003	Cleanrooms and associated controlled environments – Bio contamination control – Part 1: General principles and methods
ISO 14698-2:2003	Cleanrooms and associated controlled environments – Bio contamination control – Part 2: Evaluation and interpretation of bio contamination data
IEC 62366-1:2015/Amd 1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
ASTM D4169 – 23E01	Standard practice for performance testing of shipping containers and systems
ASTM D6198-18R24	Standard Guide for Transport Packaging Design
ASTM F1929 – 23	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F88/F88M – 23	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886/F1866M-25	Standard Test Method for determining integrity of primary packaging by visual inspection
ISO/ TR 20416: 2020	Medical devices – Post market surveillance for manufacturers
ISO 14155:2026	Clinical Investigation of medical devices for human subjects-Good Clinical Practice

8.3 Regulations & Guidelines

#	Regulation and Guidelines	Title
1.	REGULATION (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and Of The Council of 5 April 2017on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2.	MDCG 2018-1 Rev.4	Guidance on BASIC UDI-DI and changes to UDI-DI
3.	MDCG 2018-4	Annex: UDI database Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs
4.	MDCG 2019-1	MDCG guiding principles for issuing entities rules on Basic UDI-DI
5.	MDCG 2019-4	Timelines for registration of device data elements in EUDAMED
6.	MDCG 2019-5	Registration of legacy devices in EUDAMED
7.	MDCG 2019-7-Rev 1	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)
8.	MDCG 2019-8 v2	Guidance Document - Implant Card relating to the application of Article 18

#	Regulation and Guidelines	Title
		Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
9.	MDCG 2019-9 Rev.1	Summary of safety and clinical performance (A guide for manufacturers and notified bodies)
10.	MDCG 2020-5	Guidance on clinical evaluation-Equivalence
11.	MDCG 2020-6	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC
12.	MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
13.	MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template: A guide for manufacturers and notified bodies
14.	MDCG 2020-10/1 Rev 1	Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745
15.	MDCG 2020-13	Clinical evaluation assessment report template
16.	MDCG 2021-1 Rev.1	Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional
17.	MDCG 2021-5 Rev.1	Guidance on standardisation for medical devices
18.	MDCG 2021-08	Clinical Investigation application/notification documents
19.	MDCG 2021-12 Rev.1	FAQ on the European Medical Device Nomenclature (EMDN)
20.	MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system
21.	MDCG 2021-24 Rev.1	Guidance on classification of medical devices
22.	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745
23.	MDCG 2021-25 Rev.1	Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
24.	MDCG 2024-2 Rev.1	Procedures for the updates of the European Medical Device Nomenclature
25.	MDCG 2024-3	Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices
26.	MDCG 2024-5	Guidance on content of the Investigator's Brochure for clinical investigations of medical devices
27.	MDCG 2024-15	Guidance on the publication of the clinical investigation reports and their summaries in the absence of EUDAMED
28.	MDCG 2025-10	Guidance on post-market surveillance of medical devices and in vitro diagnostic medical devices
29.	MDCG 2026-3	2026 EMDN Version History
30.	MDCG 2026-4	MDCG Position Paper: Management of SS(C)P in EUDAMED after mandatory use

8.4 MEDICAL DEVICE DIRECTIVE:

Sr.No.	Code	Title
1.	MEDDEV 2.7/1 rev 4	Clinical evaluation: A guide for manufacturers and notified bodies

2.	MEDDEV 2.7/4	Guidelines on clinical investigations : A guide for manufacturers and notified bodies
3.	MEDDEV 2.12/1 Rev 8	Guidelines on a Medical Devices Vigilance System
4.	MEDDEV 2.12/2 Rev 2	Guidelines on post-market clinical follow-up
5.	MEDDEV 2.5/5 Rev 3	Translation procedure

9. CONFORMITY ASSESSMENT :

Conformity assessment (Annex IX) based on a quality management system (Chapter I) and on assessment of technical documentation (Chapter II).

The manufacturer shall establish, document and implement a quality management system as described in Article 10(9) and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall lodge an application for assessment of its quality management system with a notified body.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annexes II and III of MDR.

The SSCP shall be prepared, reviewed, validated by the notified body and uploaded whenever there is any update in clinical and/or safety information or at least annually. When updating the SSCP, all sections of the document shall be updated if needed so that they are in alignment with the most current version of the relevant parts of the technical documents of the device.

The SSCP report shall be reviewed by the Notified Body. The notified body shall validate the prepared SSCP report during certification, periodic Surveillance and Renewal audits.

- (i) OLPL shall submit the SSCP as a part of other technical documents submitted during the conformity assessment before issuing the certificate.
- (ii) During Certification renewal, OLPL shall submit a draft SSCP which has been updated within the previous 12 months, regardless of whether there are new data or conclusion. The Notified body shall apply the same principle followed for the validation of SSCP documents during the initial certification.

The SSCP shall be Uploaded and managed in EUDAMED by the notified body. The Timelines for Uploading of SSCP documents in EUDAMED is as follows,

- (i) The Notified body shall upload the SSCP validated in conjunction with an initial conformity assessment while it uploads the Issued certificate.
- (ii) The Notified body shall upload a SSCP whenever it has been validated against relevant technical documents and thus replacing the SSCP uploaded at the initial certification with the currently validated revision.
- (iii) When the Initial SSCP document (English) is translated to other languages depending on the member states on which we plan to place the product on the market. The Translated SSCP document shall be uploaded in EUDAMED within 15 days of receiving them.

When the initial SSCP document is not in English, OLPL shall provide a translated SSCP document in English within 90 days of the initial publication of the SSCP in EUDAMED and the same shall be uploaded by the notified body within 15 days of receiving them.

10. REVISION HISTORY

SSCP revision number	Date issued	Change description
00	25/01/2022	Initial release: Transition from MDD 93/42/EEC to EU MDR Medical Device Regulation 2017/745
01	05/09/2022	Updated as per TR comments
02	21/10/2023	Updated PMCF summary
03	14/09/2024	Updated Certificate details, PMCF Summary, Updated Standards.
04	03/09/2025	Updated PMCF Summary
05	03/10/2025	Updated as per Audit (P3 Clinical Assessment) comments : 1. Broaded Section 3.3 2. Added risk quantification (probability & severity) with risk assessment of clinical surgery stages. 3. Updated section 5.5 with PMCF Plan summary. 4. Updated Section 6 5. Updated section 8 with harmonized standards & regulation. 6. Updated section of conformity assessment.
06	29/09/2026	Updated as per financial year April 2025 to March 2026

PART II

INFORMATION INTENDED FOR PATIENTS

The following information is intended for patients or lay persons. A more extensive summary of device's safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

Note: This SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.

1. IDENTIFICATION OF DEVICE AND GENERAL INFORMATION

1.1 Device Trade Names/ Brand Names

Hydrophilic Multifocal Acrylic Intraocular Lens (IOLs) of the following brands are available:

- BIOL
- Avafold
- Intra
- I-Xpert,

- Revive
- Trioptix
- Ocuflex –TF
- Smart 3 Lens
- FOCUS THREE
- TriOptix

Multifocal Hydrophilic Acrylic Foldable IOLs are available in the following countries:

- Slovak republic
- Italy
- Chelyabinsk- Russia
- USA
- Bangkok
- Brazil
- Cambodia
- Indonesia
- Syria
- Belgium
- Turkey
- Bogota

1.2 Manufacturer's Name & Address

Omni Lens Pvt. Ltd.

Factory: A-69/A-70, Electronic Estate, GIDC, Sector-25, Gandhinagar-382016, Gujarat, India.

Reg. Office: 5, Samruddhi, Opp. Sakar III, Navarangpura, Ahmedabad-380014, Gujarat, India.

1.3 Basic UDI-DI

Multifocal Hydrophilic Acrylic Foldable IOL: 8905449IOLPHILMULTJR

NOTE: GS1 is the issuing entity for Omni Lens Pvt. Ltd.

1.4 Year When the device was first CE-marked

2012

2. INTENDED USE OF THE DEVICE

2.1 Intended Purpose

Multifocal Hydrophilic Acrylic Foldable IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. Multifocal Hydrophilic Acrylic Foldable IOL is based on

the principle of diffraction, whereby light slows down and changes direction when it encounters an obstacle and gets directed towards distant, intermediate and near focal points.

2.2 Indications

Multifocal Hydrophilic Acrylic Foldable IOL is indicated for the replacement of human crystalline lens to achieve visual correction of aphakia in patients when extracapsular cataract extraction or phacoemulsification is performed. Multifocal Hydrophilic Acrylic Foldable IOL is intended for placement in the capsular bag. In patients with the need for near, distant and/or intermediate vision.

2.3 Intended patient groups

Aphakic adult patients of age 18 years and above.

2.4 Contraindications

These conditions are (non-exhaustive list):

- Choroidal hemorrhage
- Chronic severe uveitis
- Excessive vitreous loss
- Extremely shallow anterior chamber
- Medically uncontrolled glaucoma & Excessive vitreous pressure
- Microphthalmos
- Aniridia
- Posterior capsular rupture & Zonular separation (preventing fixation of IOL)
- Proliferative diabetic retinopathy (severe)
- Severe corneal dystrophy & optic atrophy
- Rubeosis iridis-Congenital bilateral cataract, recurrent anterior or posterior segment
- inflammation of unknown etiology, Rubella cataract
- Retinal detachment
- Iris atrophy
- Severe ametropia and aniseikonia
- IOL replacement or extraction
- Excessive intraoperative vitreous loss
- Hemorrhage

In above condition, IOL implantation can be done with judgement of Surgeon.

3. DEVICE DESCRIPTION

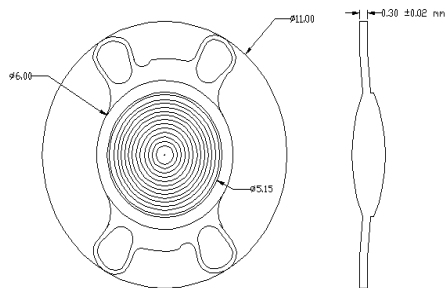
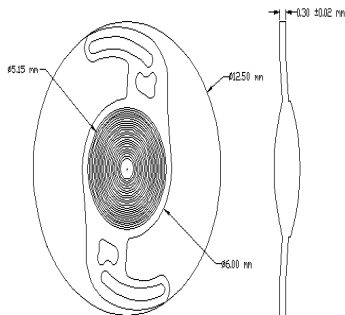
Intraocular Lens (IOL) is an artificial lens that is implanted in the eye to replace the natural lens affected by cataract. The first IOL was implanted by Sir Harold Ridley in 1949 but the concept of IOL began to spread after the 1970s. Today, there are various types of materials and designs that exist for an IOL. Different material types include: polymethyl methacrylate (PMMA), silicone, acrylic

materials such as hydrophobic and hydrophilic acrylic. Acrylic materials are the preferred choice for Ophthalmologists because of its flexible and foldable capacities with a lower rate of Opacification compared to other materials. In addition to wide range of material types, IOLs are available in a variety of designs such as monofocal, multi-focal, accommodative and toric.

Intraocular Lens consists of two parts: 1) Optic, and 2) Haptic. Optic is the small center portion that acts as an artificial lens, and haptic is the side structure that holds the lens in place once implanted. This technical documentation covers in its scope various models of Multifocal Hydrophilic Acrylic Foldable IOLs with 25% water content. The models are available in Quadra and Flex loop haptic configuration.

The natural lens is protected against phototoxic UV light due to the filter properties of the cornea, aqueous humor, lens and retina. Hence, after cataract surgery, it becomes important to protect the eye from UV radiation through the artificial lens. Multifocal Hydrophilic Acrylic Foldable IOL material is made up of UV absorbing acrylic material (UV Cut off) that allows transmission of <10% of light of wavelength 360 nm or lower which ensures protection of the eye from UV radiation. The Multifocal Hydrophilic Acrylic Foldable IOLs are available in yellow optic tint which provides better contrast sensitivity by absorbing blue-light and possibly protecting the retina from damage and development of age-related macular degeneration (AMD).

The haptic configuration for Omni's Multifocal Hydrophilic Acrylic Foldable IOL includes flex and Quadra.

Haptic Type	Final IOL Image	Drawing
Quadra		
Flex loop		

3.1 Description of the device and material/substances in contact with patient tissues

Multifocal Hydrophilic Acrylic Foldable IOL made up of hydrophilic chains that are able to absorb water, thus also called as hydrogels.

3.2 Information about medicinal substances in the device, if any

Multifocal Hydrophilic Intraocular Lens (IOL) does not contain medicinal substances or any constituents of human or animal origin.

3.3 Description of how the device is achieving its intended mode of action

Multifocal Hydrophilic Acrylic Foldable IOLs are intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. These IOLs are based on the principle of diffraction, whereby light slows down and changes direction when it encounters an obstacle and gets directed towards distant and near focal points. Because of the hydrophilic nature, the IOL is capable of being folded prior to insertion and takes its original unfolded shape after implantation.

Multifocal Hydrophilic Acrylic Foldable IOL material is made up of UV absorbing acrylic material (UV Cut off) that allows transmission of <10% of light of wavelength 360 nm or lower which ensures protection of the eye from UV radiation.

3.4 Description of accessories, if any

Accessories Included

Multifocal Hydrophilic Acrylic Foldable IOLs do not contain any devices that can be considered accessory. One type of packaging contains a sterile injector and sterile cartridge but they are treated as separate medical devices.

Accessories Not Included but Necessary for Use

The use of a lens delivery system is essential for the implantation of intraocular lens. It consists of cartridge, injector and cushion.

Packing configurations of IOL (regular/Single).

4. RISKS AND WARNINGS

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device i.e. Multifocal Hydrophilic Acrylic Foldable IOL or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1 How potential risks have been controlled or managed

For all the possible risks, effective risk control measures were applied to reduce them to "AS LOW AS POSSIBLE" (safe design, protective measures during manufacturing process, information for

safety in instruction for use- IFU). The risks were estimated based on rate of occurrence of harm and severity of harm. Each individual risk was deemed acceptable only if the benefit of the device outweighs the risk associated with the use of a device. From the results of the risk assessment, real-world clinical data from scientific literature and post market surveillance (PMS) show that nearly 100% of patients get the desired benefit of vision improvement from any distance (near, intermediate, far) from the Multifocal Hydrophilic Acrylic Foldable IOL implantation. The safety concerns are short-lived and do not cause irreparable harm to the patient. The residual risks have been listed in Instruction for Use (IFU) in the form of warnings, precautions and contraindications.

4.2 Residual Risks

- IOL Dislocation,
- Allergic Reaction,
- Undesired vision correction,
- Inconvenience to patient,
- Environmental Contamination

4.3 Complication and Adverse Events

As with any surgical procedure, there is risk involved. The possible adverse effects and complications accompanying a cataract surgery may be the following (non-exhaustive list):

- Posterior capsule opacification
- Cystoid Macular edema
- Corneal edema
- Pupillary block
- Iridocyclitis
- Hyalites
- Endophthemia and Panophthalmia
- Iritis
- Recurrent anterior or posterior segment inflammation of unknown etiology
- IOL precipitates
- IOL Decentration
- IOL dislocation and subluxation
- TASS (Toxic anterior segment syndrome)
- There may be short-term interferences with diagnostic tools such as optical torch or MRI; risks related to this have been captured in risk management and residual risks are acceptable because of the low probability of occurrence of harm. The user is informed about such risks via IFU.

4.4 Summary of any field safety corrective action (FSCA including FSN), if applicable

No Field Safety Corrective Action (FSCA) taken and no Field Safety Notices (FSN) issued for Multifocal Hydrophilic Acrylic Foldable IOL till date.

5. SUMMARY OF CLINICAL DATA AND SAFETY

The Intra Ocular Lenses from Omni lens pvt ltd has reached all the safety and performance requirements with respect to the intended use of the device from the clinical investigation.

Based on the result of 52 subjects.

The Uncorrected Distance Visual acuity from Pre-operative mean value is 70.00 and after the surgery log mar value has gradually achieved stabilization of mean value of 100 which is normal range.

After surgery the Uncorrected Intermediate Visual Acuity has increased from 75.00 mean value after the surgery log mar value has gradually achieved stabilization of mean value of 100 which is normal range.

After surgery the Uncorrected Near Visual Acuity has increased from 70.00 after the surgery log mar value has gradually achieved stabilization of mean value of 100 which is normal range.

On the other hand, the Best Corrected Distance Visual Acuity from preoperative log mar mean value is 0.721 and after the surgery Log Mar value has gradually achieved stabilization of log mar mean 0 which is the normal range. After surgery, Distance corrected Intermediate Visual acuity & Distance corrected near visual acuity log mar is 0 has gradually achieved stabilization on last day of follow up which is the normal range.

Hence it proves very good performance of OMNI'S IOL.

There were no new risks identified from the clinical investigation for the products hence there was no addition to the residual risks which we have already identified in the Risk Management Report and that is been mitigated and are acceptable when weighed against the benefits to the patient. None of the subject had reported safety related issues and there were no adverse events reported.

6. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

There are several alternatives available to Multifocal Hydrophilic Acrylic Foldable IOL implantation for medical condition in which the lens of the eye becomes cloudy, resulting in blurred vision (cataract) management. Some of them are listed below:

- Lifestyle modifications
- Therapeutic treatment with anti-cataract drugs
- Aphakic contact lenses
- Surgeries with IOL implantation or where no IOL implanted, aphakic glasses or contact lenses used.

- Hydrophobic monofocal IOLs: These are made from low water content acrylic materials. Associated with a lower incidence of posterior capsule opacification (PCO) and better long-term capsular bag stability. On the other hand, they may also exhibit slightly less flexibility, and some designs have been associated with glistening formation over time.
- Other Intraocular lens including premium IOL hydrophilic or hydrophobic (Multifocal IOL, Toric IOL , accommodating IOL , EDOF extended depth of focus IOL)

7. SUGGESTED TRAINING FOR USERS

There is no specific training requirement for IOL implantation as it is intended to be used by trained and experienced eye (Ophthalmic) surgeons only.