

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN



MEDICAL DEVICE
AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GC4311826-237907**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

24/07/2026 - 23/07/2031

Sijil ini adalah dengan ini diberi kepada: **RAINBOW OCULAR DEVICES SDN BHD**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

**78A, JALAN BP7/8 BANDAR BUKIT PUCHONG,
47120 PUCHONG, SELANGOR,
47120 PUCHONG
SELANGOR DARUL EHSAN**

Peranan establismen
Role of establishment

Wakil Diberi Kuasa
Authorized Representative

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.

to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.

This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.



MURALITHARAN PARAMASUA
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY



No. Pendaftaran: **GC4311826-237907**
Registration No.:

Tarikh Sah Pendaftaran: **24/07/2026 -**
Registration Validity Date: **23/07/2031**

Butir-butir peranti perubatan yang didaftarkan

Particulars of the registered medical device

Nama Peranti Perubatan **HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS**
Medical Device Name

Kelas **CLASS C** Jenama **OPTIMA**
Class Brand

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **EXCELLENT HI-CARE PRIVATE LIMITED**
Name and address of manufacturer **25/2 ANNA STREET, VENKATAKRISHNAN NAGAR, ARUMBAKKAM, CHENNAI, 6000106 TAMIL NADU, INDIA., 6000106 INDIA**

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Hydrphobic acrylic foldable Intraocular lens	HFS 6125SQ	Size and angle
2	Hydrphobic acrylic foldable Intraocular lens	HFS 6125SQY	Size and angle
3	Hydrphobic acrylic foldable Intraocular lens	HFS 6130SQ	Size and angle
4	Hydrphobic acrylic foldable Intraocular lens	HFS 6130SQY	Size and angle
5	Hydrophobic Toric Intraocular lens	MO-T-615 T1.50	Size and angle
6	Hydrophobic Toric Intraocular lens	MO-T-615 T2.25	Size and angle
7	Hydrophobic Toric Intraocular lens	MO-T-615 T3.00	Size and angle
8	Hydrophobic Toric Intraocular lens	MO-T-615 T3.75	Size and angle
9	Hydrophobic Toric Intraocular lens	MO-T-615 T4.50	Size and angle
10	Hydrophobic Toric Intraocular lens	MO-T-615 T5.25	Size and angle
11	Hydrophobic Toric Intraocular lens	MO-T-615 T6.00	Size and angle



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
12	Hydrophobic Trifocal Intraocular lens	TRI-FO-617	Size and angle
13	Hydrophobic enhanced depth of focus Intraocular lens	HFS EDOF6130	Size and angle
14	Hydrophobic multipiece acrylic foldable Intraocular lens	MPH 6130	Size and angle
15	Hydrophobic multipiece acrylic foldable Intraocular lens	MPH 6135	Size and angle
16	Hydrophobic multipiece acrylic foldable Intraocular lens	MPH 6140	Size and angle
17	Hydrophobic multipiece acrylic foldable Intraocular lens	MPH6130-Y	Size and angle
18	Hydrophobic multipiece acrylic foldable Intraocular lens	MPH6135-Y	Size and angle
19	Hydrophobic multipiece acrylic foldable Intraocular lens	MPH6140-Y	Size and angle
"End Of Product List"			

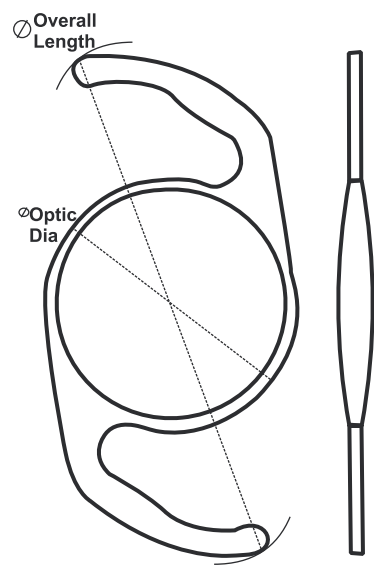


**Hydrophobic Acrylic Foldable
Intraocular lens**



**Hydrophobic Acrylic Foldable
Intraocular lens Yellow**

Model	HFS 6125SQ	HFS 6125SQY	HFS 6130SQ	HFS 6130SQY
Overall Diameter (mm)	12.50	12.50	13.00	13.00

Optic	6.00 mm			Specification: 
Optic Design	Aberration Neutral, Negative Aspheric Biconvex			
Haptic Design	Step Vaulted ``C``Design, 0 Angulation			
PCO Protection	360° Perfect Square edge around the optic edge			
Delivery system	Preloaded / Non preloaded			
Power Range	-10.00 D to +40.0 D (increments 0.50 D)			
Material	Hydrophobic, Refractive index : 1.4933+0.002			
A.Constant		Ultrasound	Optical Biometry	
	SRK/T	118.4	118.7	
	SRK/II	118.6	118.9	



Scan to view
loading procedure

OPTIMA JET **Preloaded Injector System** is specially designed for smoother and safer delivery of Hydrophobic IOL

OPTIMA JET **Non-Preloaded Injector System** is smoother and safer delivery of Hydrophobic IOL

OPTIMA JET injector system deliver the IOL from **1.80 mm to 2.60 mm Incision** with various cartridges

Click-lock mechanism thereby securing the lens in the exact position for a perfect lens delivery into the eye

Lens insertion is gentle and without the lens wedging or twisting ensure a controlled release, and consequently a precise positioning in the eye



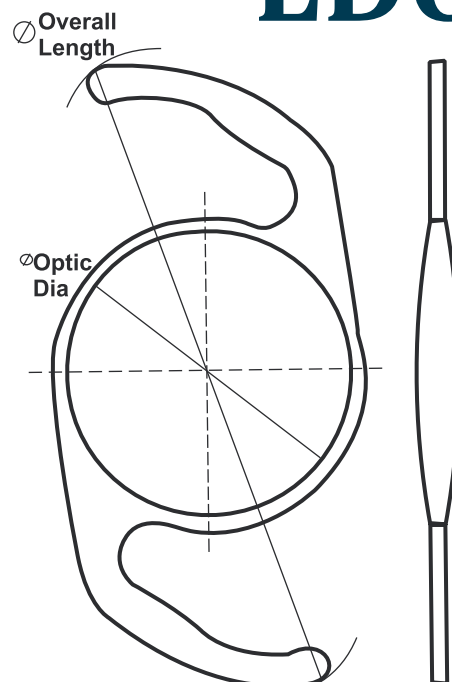
Standard Aspheric optics vision performance under low light



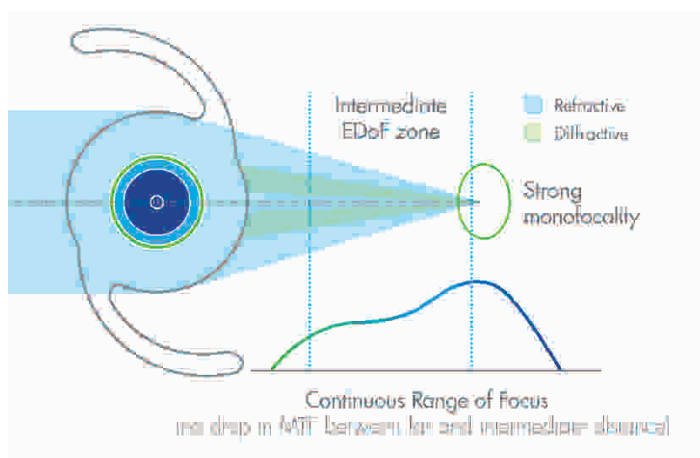
Aberration neutral **Optima VUE** Hydrophobic aspheric Foldable excellent visual performance under low light

Model	HFS EDOF 6130		
Optic Diameter	6.00 mm		
Overall Length	13.00 mm		
Optic Design	Aberration Neutral, Negative Aspheric Biconvex		
Haptic Design	Step Vaulted ``C``Design, 0°Angulation		
PCO Protection	360° Perfect Square edge around the optic edge		
Delivery system	Preloaded / Non preloaded (2.40mm nozzle for sub 2.6 mm incision)		
Power Range	0.0 D to +30.0 D (increments 0.50 D)		
IOL Plane	Purely Refractive with +3.00 D and +3.25 D Additional Power		
Material	Hydrophobic, Refractive index : 1.4933+0.002		
A.Constant		Ultrasound	Optical Biometry
	SRK/T	118.4	118.7
	SRK/II	118.6	118.9

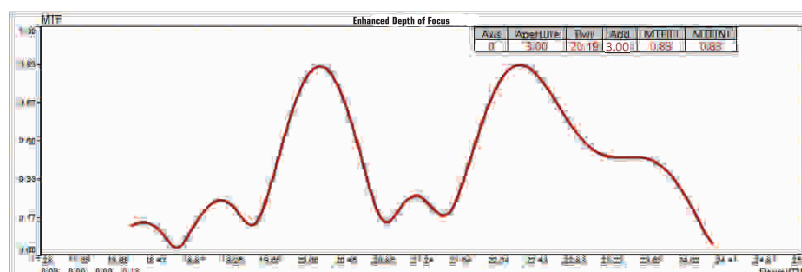
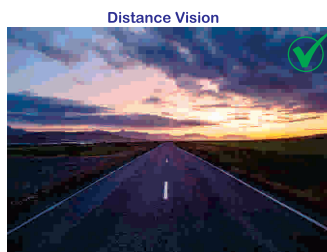
Specification:



Refractive Enhanced Depth of Focus



- ✓ Lens offers excellent distance as well as intermediate vision
- ✓ EDOF is a new technology that has recently emerged in the treatment of **Presbyopia -Correcting IOLs**
- ✓ Designed to enable safe and ease of implantation in the eye
- ✓ EDOF Lenses work by creating a single elongated focal point to enhance "Depth Of Focus".



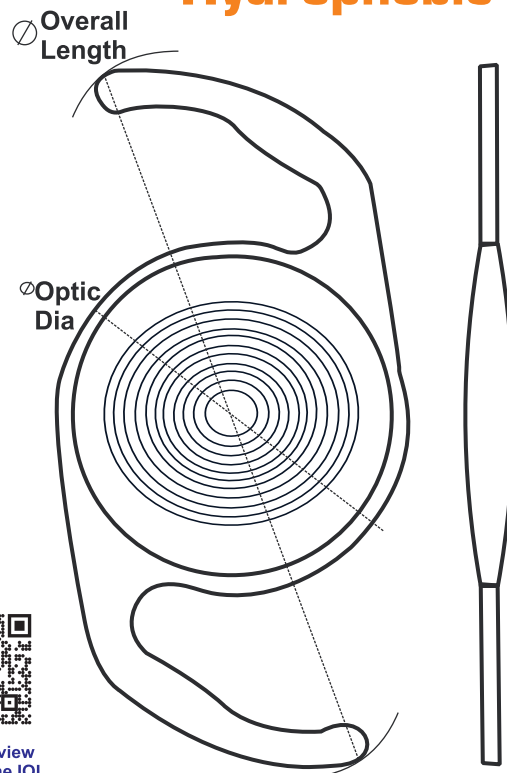
Optima[®] VUE TRIFOCAL-EF

Trifocal Enhanced Depth of Focus Glistening Free IOL

Model	TRI-FO-617		
Optic Diameter	6.00 mm		
Overall Length	13.00 mm		
Optic Design	Aberration Neutral, Negative Aspheric Biconvex		
Haptic Design	Step Vaulted ``C``Design, 0 Angulation		
PCO Protection	360 Perfect Square edge around the optic edge		
Delivery system	Preloaded / Non preloaded (2.20mm nozzle for sub 2.4 mm incision)		
Power Range	0.0 D to +30.0 D (increments 0.50 D)		
IOL Plane	Trifocal,Diffractive, +3.50 D near add and +1.75 D intermediate add at the IOL plane		
Material	Hydrophobic, Refractive index : 1.4933+0.002		
A.Constant		Ultrasound	Optical Biometry
	SRK/T	118.4	118.7
	SRK/II	118.6	118.9

Specification:

Trifocal Hydrophobic



Scan to view
Implant the IOL

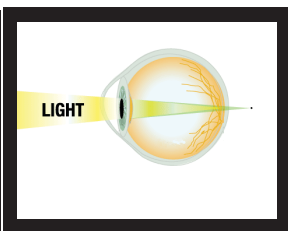
CATARACT



Signs of Cataracts

Clouded Blurred or dim vision
Increasing difficulty with vision at night
Sensitivity to light and glare
Seeing "halos" around lights
Fading or yellowing of colors

PRESBYOPIA



Signs of Presbyopia

Having eyestrain or headaches after reading or doing close work.
Having difficulty reading small print.
Having fatigue from doing close work.
Squinting

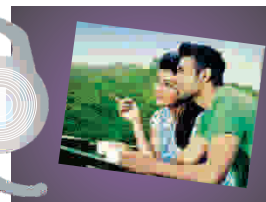


Optima[®] VUE TRIFOCAL-EF

IOLs have three features to personalize your Visions.

Each Type of IOLs have Outstanding vision to meet your specific needs. We can look forward to seek objects close, in-between and far into the distances.

+3.00



THE EXCELLENT LENS FOR YOUR LIFESTYLE

You have more comfort while reading a book, and more confidence while viewing the screen on your smart phone and TV and excellent vision to find your things on the Far Distance . Optima Binary Multifocal IOLs have a Unique solution for Excellent for your active lifestyle.

+3.50

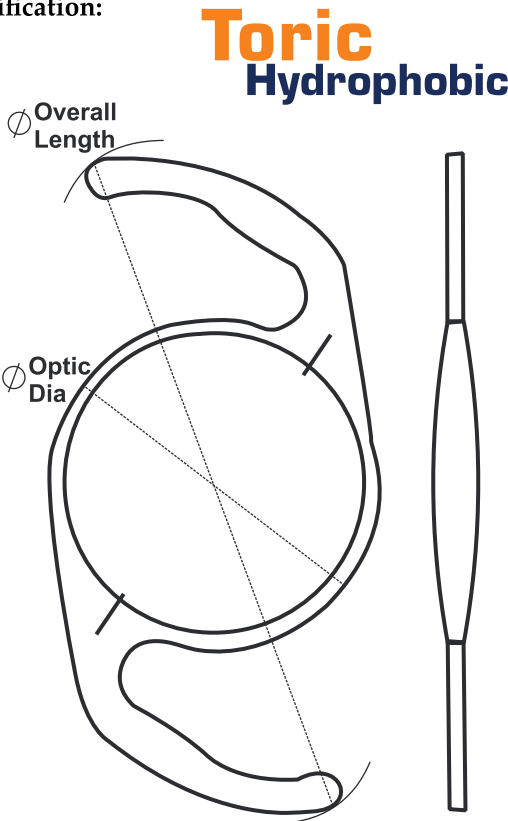


CONCLUSION:

Patients with age-related vision loss can look forward to regain their younger vision and reducing their dependence on glasses. Our Clinical studies indicates that 90 out of 100 patients said that they are satisfied with Binary Multifocal IOLs of Optima Family.

+4.00



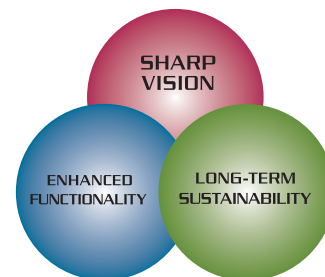
Optic Size	6.00mm	Specification: 								
Haptic Size	12.50mm & 13.00mm									
Optic	Biconvex, Anterior Toric Aspheric Surface									
Edge Design	Continuous 360 Posterior square edge									
Haptic Design	Single Haptic									
Haptic Angle	0°									
AC Depth	5.28 mm									
Incision	2.4mm & 2.2 mm									
Diopter Range	cylinder Power 1.5 D to 6.5D in 0.75 Increments									
Refractive Index	1.4933±0.002									
A.Constant	<table border="1"> <thead> <tr> <th></th><th>Ultrasound</th><th>Optical Biometry*</th></tr> </thead> <tbody> <tr> <td>SRK/T</td><td>118.4</td><td>118.7</td></tr> <tr> <td>SRK/II</td><td>118.6</td><td>118.9</td></tr> </tbody> </table>			Ultrasound	Optical Biometry*	SRK/T	118.4	118.7	SRK/II	118.6
	Ultrasound	Optical Biometry*								
SRK/T	118.4	118.7								
SRK/II	118.6	118.9								

*The Values are of estimates only. It is recommended that the surgeon derive his/her own values based on data of the eye to be operated upon & characteristic of IOL

Model: MO-T-615	T1.50	T2.25	T3.00	T3.75	T4.50	T5.25	T6.00
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- ✓ The Toric IOL tailored to preserve the eye's natural spherical aberration - delivering stable outcomes with exceptional rotational stability.
- ✓ Uniform in power from center to edge across the principle meridian.
- ✓ Aspheric Optical Profile and Excellent Rotational Stability.
- ✓ Reduced PCO with Advanced Square Edge
- ✓ Predictable Astigmatic Correction
- ✓ Manufactured with state of art machining technology with latest advance machines which ensures predictable outcomes

Select Astig Toric IOL For:



General	Hydrophobic, Acrylic Aspheric Foldable Multipiece	Specification:  • Monofocal, Spherical with PVDF Haptics designed for better capsular stability • Suitable IOL for sulcus implantation.								
Optic	Bi-Convex									
Edge Design	Continuous 360° Posterior edge									
Haptic Design	Modified 'C' loop, PVDF (Polyvinylidene fluoride Monofilament)									
Haptic Angle	0° Angulation									
Ac Depth	5.00 mm									
Incision size	2.80 mm									
Optic Size	6.00 mm									
Power Range	+10.00 D to +30.0 D (increments 0.50 D)									
Material	Hydrophobic, Refractive index : 1.4933±0.002									
A.Constant	<table border="1"> <thead> <tr> <th></th><th>Ultrasound</th><th>Optical Biometry</th></tr> </thead> <tbody> <tr> <td>SRK/T</td><td>118.4</td><td>118.7</td></tr> <tr> <td>SRK/II</td><td>118.6</td><td>118.9</td></tr> </tbody> </table>			Ultrasound	Optical Biometry	SRK/T	118.4	118.7	SRK/II	118.6
	Ultrasound	Optical Biometry								
SRK/T	118.4	118.7								
SRK/II	118.6	118.9								

Model	MPH6130	MPH6135	MPH6140	MPH6130-Y	MPH6135-Y	MPH6140-Y
Haptic Size (mm)	13.00	13.50	14.00	13.00	13.50	14.00



why use us?

- Optima³Piece have haptics of a much more rigid material, such as PVDF (Polyvinylidene fluoride Monofilament)
- 3-piece lens for Bag/Sulcus and alternative fixation, alternative fixation(Sulcus), specially designed for alternative fixation (sulcus,Sulcus Sclera)
- The Haptics are much thinner and are much better tolerated in the sulcus than the bulky, single-piece haptics.

Original IOL Power	Adjustment IOL POWER for sulcus placement
0.0 to 8.50	None
9.50 to 17.50	-0.5D
18.00 to 26.50	-1.0D
27.00 to higher	-1.5D



Optima³Piece can be delivered through an incision as well as 2.80 mm with optima jet implantation system.

It is a Reusable Titanium injector, Designed specifically for optima 3 piece and Excellent Hi-Crea Cartridge.

Click-lock mechanism thereby securing the lens in the exact position for a perfect lens delivery into the eye.

Lens insertion is gentle and without the lens wedging or twisting ensures a controlled release, and consequently a precise positioning in the eye .



OPTIMA IOL's

A-CONSTANT REFERENCE

Hydrophobic acrylic foldable intraocular lenses



HYDROPHOBIC

BIOMETRY CONSTANTS

Refractive index 1.4933

PARAMETER	ULTRASOUND	OPTICAL BIOMETRY
AC Depth	5.02	5.61
A Constant Nominal (SRK/T)	118.4	118.7
A Constant Nominal (SRK/II)	118.6	118.9
A CONSTANT - IOL MASTER		
Haigis (a0)	1.34	1.96
Haigis (a1)	0.40	0.40
Haigis (a2)	0.10	0.10
Holladay (1 Const sf)	1.28	1.85

REGISTERED MODELS

MDA REGISTRATION GC4311826-237907

HFS 6125SQ	HFS 6125SQY	HFS 6130SQ
HFS 6130SQY	MO-T-615 T1.50	MO-T-615 T2.25
MO-T-615 T3.00	MO-T-615 T3.75	MO-T-615 T4.50
MO-T-615 T5.25	MO-T-615 T6.00	TRI-FO-617
HFS EDOF6130	MPH 6130	MPH 6135
MPH 6140	MPH6130-Y	MPH6135-Y
MPH6140-Y		

Suggested constants only. Surgeons should optimise values using their own clinical outcomes and biometry system.