

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: **GC5994826-232843**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

22/05/2026 - 21/05/2031

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



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Registration No.:

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Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan **HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENS SYSTEM**
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	Clear Hydrophilic Acrylic Foldable IOL	SAF6125SQ-R	Clear Lens, Optic Size & Diameter
2	Clear Hydrophilic Acrylic Foldable IOL	SAF 6125SQ,	Clear Lens, Optic Size & Diameter
3	Clear Hydrophilic Acrylic Foldable IOL	SAF 6011SQ	Clear Lens, Optic Size & Diameter
4	Clear Hydrophilic Acrylic Foldable IOL	SAF 6016SQ	Clear Lens, Optic Size & Diameter
5	Yellow Hydrophilic Acrylic Foldable IOL	SAF6125SQY-R	Yellow Lens, Optic Size & Diameter
6	Yellow Hydrophilic Acrylic Foldable IOL	SAF 6125SQY,	yellowLens, Optic Size & Diameter
7	Yellow Hydrophilic Acrylic Foldable IOL	SAF 6011SQY	Yellow Lens, Optic Size & Diameter
8	Yellow Hydrophilic Acrylic Foldable IOL	SAF 6016SQY	Yellow Lens, Optic Size & Diameter
9	Hydrophilic Acrylic Foldable IOL	SAF5120	Shape, Optic Size & Diameter
10	Hydrophilic Acrylic Foldable IOL	SAF6125-R	Shape, Optic Size & Diameter
11	Hydrophilic Acrylic Foldable IOL	SAF6125	Shape, Optic Size & Diameter
12	Hydrophilic Acrylic Foldable IOL	SAF6010	Shape, Optic Size & Diameter
13	Hydrophilic Acrylic Foldable IOL	SAF6011	Shape, Optic Size & Diameter



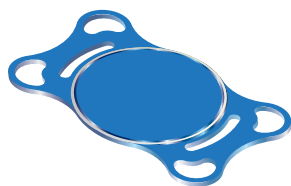
NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
14	Hydrophilic Acrylic Foldable IOL Phaki Lens	IMPCL 619	Shape, Optic Size & Diameter
15	Hydrophilic Acrylic Foldable IOL Phaki Lens	IMPCL 621	Shape, Optic Size & Diameter
16	Hydrophilic Acrylic Foldable IOL Phaki Lens	IMPCL 622	Shape, Optic Size & Diameter
17	Hydrophilic Acrylic Foldable IOL Phaki Lens	IMPCL 302	Shape, Optic Size & Diameter
18	Hydrophilic Acrylic Foldable IOL Phaki Lens	IMPCL 603	Shape, Optic Size & Diameter
19	Hydrophilic Acrylic Foldable IOL Phaki Toric Lens	PT554	Shape, Optic Size & Diameter
20	Hydrophilic Acrylic Foldable IOL Phaki Toric Lens	PT553	Shape, Optic Size & Diameter
21	Hydrophilic Acrylic Foldable IOL Phaki Toric Lens	PT552	Shape, Optic Size & Diameter
22	Hydrophilic Acrylic Foldable IOL Phaki Toric Lens	PT551	Shape, Optic Size & Diameter
23	Hydrophilic Acrylic Foldable IOL Phaki Toric Lens	PT550	Shape, Optic Size & Diameter
"End Of Product List"			



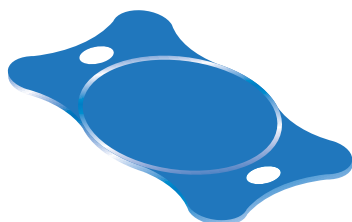
Model	SAF6125SQ-R	SAF6125SQY-R
Optic Diameter	6.00 mm	
Overall Diameter	12.50 mm	
Optic Design	Aberration Neutral, Negative Aspheric Biconvex	
Haptic Design	Double Haptics , 5° Angulation	
PCO Protection	360° perfect Square edge around the optic edge	
Suggested A. Constant	+ve power Range: 118, -ve Power Range : 117.4	



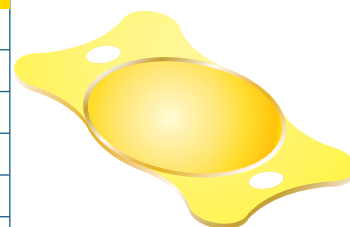
Model	SAF 6125SQ	SAF6125 SQY
Optic Diameter	6.00 mm	
Overall Diameter	12.50 mm	
Optic Design	Aberration Neutral, Negative Aspheric Biconvex	
Haptic Design	Lens Factors: 1.36" C" design, 5° Angulation	
PCO Protection	360° perfect Square edge around the optic edge	
Suggested A.Constant	+ve power Range: 118, -ve Power Range : 117.4	



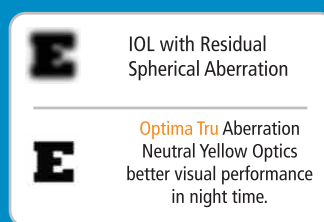
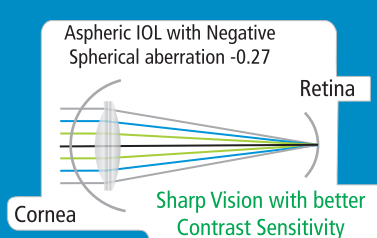
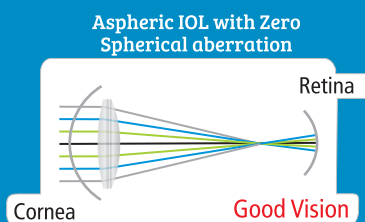
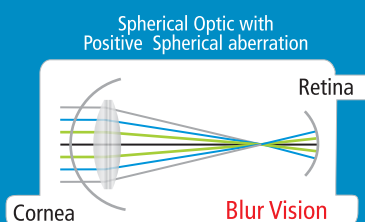
Model	SAF 6011SQ	SAF 6011SQY
Optic Diameter	6.00 mm	
Overall Diameter	11.00 mm	
Optic Design	Aberration Neutral, Negative Aspheric Biconvex	
Haptic Design	4-Point Fixation, 5° Angulation	
PCO Protection	360° perfect Square edge around the optic edge	
Suggested A.Constant	+ve power Range: 118, -ve Power Range : 117.4	



Model	SAF 6016SQ	SAF 6016SQY
Optic Diameter	6.00 mm	
Overall Diameter	10.60 mm	
Optic Design	Aberration Neutral, Negative Aspheric Biconvex	
Haptic Design	Plate Haptics , 5° Angulation	
PCO Protection	360° perfect Square edge around the optic edge	
Suggested A.Constant	+ve power Range: 118, -ve Power Range : 117.4	



SPHERICAL ABERRATION OF MONOFOCAL IOL



Optima Tru / Optima Clear

- ✓ Natural Yellow Hydrophilic Acrylic, 26% Water Content with UV filter
 - ✓ UA-A(Violet light and dark blue light) filter and allowing healthy blue spectrum light in
 - ✓ Powers Available : - 10.0 D to +40.0 D
 - ✓ Better visual acuity and Enhanced contrast even at night mode.
- (+10.0 D to +30.0 D in 0.5 D steps -10.0 D to +9.0 D and +31.0 to +40.0 D in 1.0 D Steps)

Fold Lenses



PRODUCT INFORMATION

The first injector within the family, **ErgoTouch FLY** is ergonomically designed to work with all injection types, including mono or bi-manual injection. Its sturdy, crystal-clear body, practical soft-touch grip and familiar butterfly cartridge lock design provide an injector system that accommodates different surgical preferences and techniques.

- Perfect for mono manual and bi-manual injection procedures
- Device stability for better control
- Soft-touch anti-slip grip for safety
- Butterfly cartridges for secure, safe and efficient loading of IOL lenses

Product Details:

Shelf life: 3 years

Storage: From 5°C to 45°C

IOL Type Compatibility: Hydrophilic and Hydrophobic lenses

IOL Lens Compatibility: One Piece IOL

OVD Compatibility: Recommended viscoelastic Sodium ha 1.0 to 2.0% and other viscoelastic concentration (up to 3%)
Also compatible with HPMC 2%

Packaging Options:



ErgoTouch FLY Pouch

- 1x Pouch contains 1x injector and 1x cartridge
- A pouch: 10cm width, 1.5cm height* and 30cm depth
- Injector and cartridge sealed separately in pouch for safety
- Flexible packaging makes the pouch option ideal for fitting into a manufacturer's own intraocular lens packaging



ErgoTouch FLY Blister

- 1x Dispenser box contains 10x blister packs
- 1x Blister pack contains 1x injector and 1x cartridge
- Dispenser box: 8.9cm width, 22.2cm height and 20.4cm depth
- Blister packs: 8.6cm width, 2.3cm height and 20.2cm depth
- Blister packs and dispenser boxes provide extra safety for both the injector and the cartridge, due to the rigid and strong packaging



*Height of pouch is conducive of the height of injector

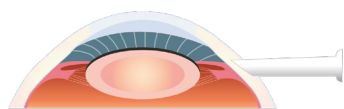
Item Code	Product Name	Incision Size (mm)*		
		Wound Assisted	Into the Wound	Into the Bag

ErgoTouch FLY under Pouch & Cartridge GMS

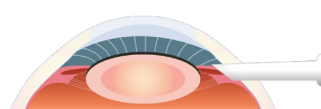
ET1-P-GMS-18-CE	ErgoTouch FLY under Pouch with cartridge GMS 1.8 – CE Mark	1.8	2.0	2.2
ET1-P-GMS-20-CE	ErgoTouch FLY under Pouch with cartridge GMS 2.0 – CE Mark	2.0	2.2	2.4
ET1-P-GMS-22-CE	ErgoTouch FLY under Pouch with cartridge GMS 2.2 – CE Mark	2.2	2.4	2.6
ET1-P-GMS-24-CE	ErgoTouch FLY under Pouch with cartridge GMS 2.4 – CE Mark	2.4	2.6	2.8
ET1-P-GMS-26-CE	ErgoTouch FLY under Pouch with cartridge GMS 2.6 – CE Mark	2.6	2.8	3.0

ErgoTouch FLY under Blister & Cartridge GMS

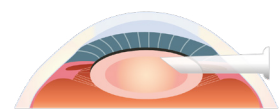
ET1-B-GMS-18-CE	ErgoTouch FLY under Blister with cartridge GMS 1.8 – CE Mark	1.8	2.0	2.2
ET1-B-GMS-20-CE	ErgoTouch FLY under Blister with cartridge GMS 2.0 – CE Mark	2.0	2.2	2.4
ET1-B-GMS-22-CE	ErgoTouch FLY under Blister with cartridge GMS 2.2 – CE Mark	2.2	2.4	2.6
ET1-B-GMS-24-CE	ErgoTouch FLY under Blister with cartridge GMS 2.4 – CE Mark	2.4	2.6	2.8
ET1-B-GMS-26-CE	ErgoTouch FLY under Blister with cartridge GMS 2.6 – CE Mark	2.6	2.8	3.0



Wound-assisted technique



Into-the-wound-assisted technique



Into-bag-assisted technique

*Suggested minimum incision. The incision size depends on the ophthalmic surgeon technique

OPTIMA IOL's

A-CONSTANT REFERENCE

Hydrophilic acrylic foldable intraocular lenses



HYDROPHILIC

BIOMETRY CONSTANTS

Refractive index 1.457

PARAMETER	ULTRASOUND	OPTICAL BIOMETRY
AC Depth	5.02	4.80
A Constant Nominal (SRK/T)	117.8	117.88
A Constant Nominal (SRK/II)	118.1	118.0
A CONSTANT - IOL MASTER		
Haigis (a0)	1.34	0.568
Haigis (a1)	0.40	0.40
Haigis (a2)	0.10	0.10
Holladay (1 Const sf)	1.28	1.02

REGISTERED MODELS

MDA REGISTRATION GC5994826-232843

SAF6125SQ-R	SAF 6125SQ	SAF 6011SQ
SAF 6016SQ	SAF6125SQY-R	SAF 6125SQY
SAF 6011SQY	SAF 6016SQY	SAF5120
SAF6125-R	SAF6125	SAF6010
SAF6011	IMPCL 619	IMPCL 621
IMPCL 622	IMPCL 302	IMPCL 603
PT554	PT553	PT552
PT551	PT550	

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