

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: **GB5654025-214756**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

24/10/2025 - 23/10/2030

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: **GB5654025-214756**
Registration No.:

Tarikh Sah Pendaftaran:
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24/10/2025 -
23/10/2030

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

Nama Peranti Perubatan **OPHTHALMIC MICROSURGICAL KNIVES**
Medical Device Name

Kelas
Class

CLASS B

Jenama
Brand

ACUCUT

Kelompok
Group

FAMILY

Nama dan alamat
pembuat:
Name and address of
manufacturer

SHAH EYE CARE PRIVATE LIMITED
PLOT NO. 8 AND 9, KARUR INDUSTRIAL AREA, P.B. ROAD,
DAVANGERE-577006. KARNATAKA, INDIA.,
577006
INDIA

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	SP 15.0	SP 15.0	Different in angle of knife
2	SP 15.0-A-L	SP 15.0-A-L	Different in angle of knife
3	SP 15.0-A-R	SP 15.0-A-R	Different in angle of knife
4	SP 22.5	SP 22.5	Different in angle of knife
5	SP 22.5	SP 22.5	Different in angle of knife
6	SP 30.0	SP 30.0	Different in angle of knife
7	SP 45.0	SP 45.0	Different in angle of knife
8	CRU 20	CRU 20	Different in angle of knife
9	CRU 22	CRU 22	Different in angle of knife
10	CRU 25	CRU 25	Different in angle of knife
11	CRU 26	CRU 26	Different in angle of knife
12	CRD 22	CRD 22	Different in angle of knife
13	CRD 26	CRD 26	Different in angle of knife
14	CRS 20	CRS 20	Different in angle of knife
15	CRS 26	CRS 26	Different in angle of knife
16	KR 08	KR 08	Different in angle of knife
17	KR 10	KR 10	Different in angle of knife
18	KR 12	KR 12	Different in angle of knife



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
19	KR 14	KR 14	Different in angle of knife
20	KR 16	KR 16	Different in angle of knife
21	KR 18	KR 18	Different in angle of knife
22	KR 20	KR 20	Different in angle of knife
23	KR 22	KR 22	Different in angle of knife
24	KR 23	KR 23	Different in angle of knife
25	KR 24	KR 24	Different in angle of knife
26	KR 25	KR 25	Different in angle of knife
27	KR 26	KR 26	Different in angle of knife
28	KR 265	KR 265	Different in angle of knife
29	KR 275	KR 275	Different in angle of knife
30	KR 28	KR 28	Different in angle of knife
31	KR 285	KR 285	Different in angle of knife
32	KR 30	KR 30	Different in angle of knife
33	KR 32	KR 32	Different in angle of knife
34	KR 34	KR 34	Different in angle of knife
35	KR DB 08	KR DB 08	Different in angle of knife
36	KR DB 10	KR DB 10	Different in angle of knife
37	KR DB 12	KR DB 12	Different in angle of knife
38	KR DB 14	KR DB 14	Different in angle of knife
39	KR DB 16	KR DB 16	Different in angle of knife
40	KR DB 18	KR DB 18	Different in angle of knife
41	KR DB 20	KR DB 20	Different in angle of knife
42	KR DB 22	KR DB 22	Different in angle of knife
43	KR DB 24	KR DB 24	Different in angle of knife
44	KR DB 25	KR DB 25	Different in angle of knife
45	KR DB 26	KR DB 26	Different in angle of knife
46	KR DB 265	KR DB 265	Different in angle of knife
47	KR DB 275	KR DB 275	Different in angle of knife
48	KR DB 28	KR DB 28	Different in angle of knife
49	KR DB 285	KR DB 285	Different in angle of knife
50	KR DB 30	KR DB 30	Different in angle of knife



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
51	KR DB 32	KR DB 32	Different in angle of knife
52	KR DB 34	KR DB 34	Different in angle of knife
53	CC 08	CC 08	Different in angle of knife
54	CC 10	CC 10	Different in angle of knife
55	CC 12	CC 12	Different in angle of knife
56	CC 14	CC 14	Different in angle of knife
57	CC 16	CC 16	Different in angle of knife
58	CC 18	CC 18	Different in angle of knife
59	CC 20	CC 20	Different in angle of knife
60	CC 22	CC 22	Different in angle of knife
61	CC 24	CC 24	Different in angle of knife
62	CC 25	CC 25	Different in angle of knife
63	CC 26	CC 26	Different in angle of knife
64	CC 265	CC 265	Different in angle of knife
65	CC 275	CC 275	Different in angle of knife
66	CC 28	CC 28	Different in angle of knife
67	CC 285	CC 285	Different in angle of knife
68	CC 30	CC 30	Different in angle of knife
69	CC 32	CC 32	Different in angle of knife
70	CC 34	CC 34	Different in angle of knife
71	EXT 52	EXT 52	Different in angle of knife
72	EXT 55	EXT 55	Different in angle of knife
73	MVR 19	MVR 19	Different in angle of knife
74	MVR 20	MVR 20	Different in angle of knife
75	MVR 21	MVR 21	Different in angle of knife
76	MVR 23	MVR 23	Different in angle of knife
77	MVR 24	MVR 24	Different in angle of knife
78	MVR 25	MVR 25	Different in angle of knife
79	MVR 19A	MVR 19A	Different in angle of knife
80	MVR 20A	MVR 20A	Different in angle of knife
81	MVR 21A	MVR 21A	Different in angle of knife
82	MVR 23A	MVR 23A	Different in angle of knife



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
83	MVR 24A	MVR 24A	Different in angle of knife
84	MVR 25A	MVR 25A	Different in angle of knife
85	CC DB 08	CC DB 08	Different in angle of knife
86	CC DB 10	CC DB 10	Different in angle of knife
87	CC DB 12	CC DB 12	Different in angle of knife
88	CC DB 014	CC DB 014	Different in angle of knife
89	CC DB 16	CC DB 16	Different in angle of knife
90	CC DB 18	CC DB 18	Different in angle of knife
91	CC DB 20	CC DB 20	Different in angle of knife
92	CC DB 22	CC DB 22	Different in angle of knife
93	CC DB 24	CC DB 24	Different in angle of knife
94	CC DB 25	CC DB 25	Different in angle of knife
95	CC DB 26	CC DB 26	Different in angle of knife
96	CC DB 265	CC DB 265	Different in angle of knife
97	CC DB 275	CC DB 275	Different in angle of knife
98	CC DB 28	CC DB 28	Different in angle of knife
99	CC DB 285	CC DB 285	Different in angle of knife
100	CC DB 30	CC DB 30	Different in angle of knife
101	CC DB 32	CC DB 32	Different in angle of knife
102	CC DB 34	CC DB 34	Different in angle of knife
"End Of Product List"			

CE
2803

Manufactured By....

Shah
Eye Care (P) Ltd
the winds of change...

ACCURATE

HIGH PERFORMANCE

ULTRA SHARP

DIMENSIONALLY PRECISE

CUTTING EDGE

TECHNOLOGY



acucut

Redefining Accuracy

DISPOSABLE OPHTHALMIC MICRO SURGICAL KNIVES





Ophthalmologist worldwide know that minimizing risks and meeting patient performance demand are the most important issues to consider when choosing the right surgical knives.

Shah Eye Care Pvt. Ltd.

offers a line of **ACUCUT** OPTHALMIC MICRO SURGICAL KNIVES that consistently provide both the quality and high Performance necessary to achieve these goals.

Shah Eye Care Pvt. Ltd is certified ISO 13485 : 2016 for quality management system and following the CGMP (current good manufacturing practices) as per FDA guidelines.

Acucut disposable micro surgical ophthalmic knives are supplied with CE marking.

PRECISION YOU CAN SEE

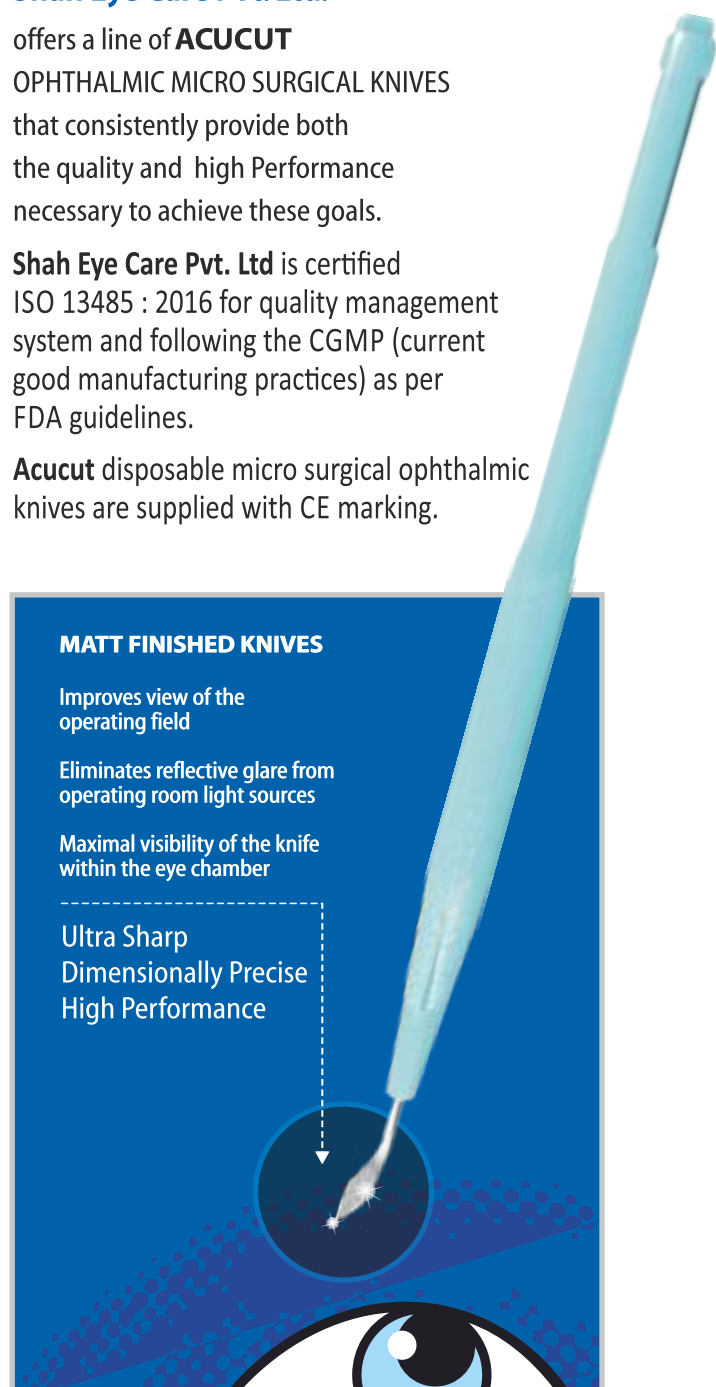
- **Ultra Sharp**
- Excellent tactile response with minimal drag
- Exact Sharpness & Consistency
- Dimensionally Precise
- Flawless cutting edge
- Superior wound architecture
- Minimal wound leakage

QUALITY YOU CAN FEEL

- High Performance
- Effortless tissue penetration
- Improved Surface Finish
- Our vacuum-purified double melt, hardened and tempered stainless steel technology produces a uniform strength and ductility that is critical to creating our precise cutting edge for smooth, uniform incisions
- Color Coding

PERFORMANCE YOU CAN TRUST

- Accurate, well controlled incisions
- Tightly sealing incisions
- Meet Patient Performance demand
- Rapid wound healing
- Reduced potential for infection



MATT FINISHED KNIVES

Improves view of the operating field

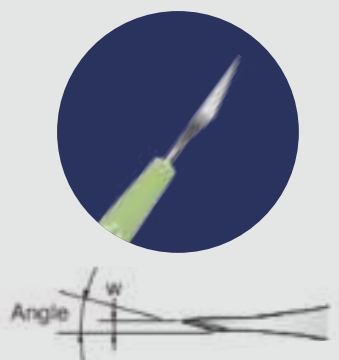
Eliminates reflective glare from operating room light sources

Maximal visibility of the knife within the eye chamber

Ultra Sharp
Dimensionally Precise
High Performance

SIDE PORT / STAB KNIVES

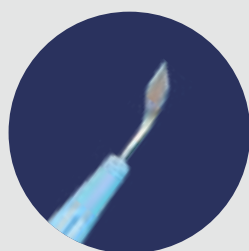
ACUCUT Side Port/Stab Knives are color coded for simple and accurate identification. Offered in a wide range of sizes, designed to create precise, consistent and fluid tight stab incisions.



MODEL	SHAPE	ANGLE	DIMENSION WIDTH (W)
SP 15.0	STRAIGHT	15°	1.5 mm
SP 15.0-A-L	ANGLED LEFT	15°	1.5 mm
SP 15.0-A-R	ANGLED RIGHT	15°	1.5 mm
SP 22.5	STRAIGHT	22.5°	1.5 mm
SP 30.0	STRAIGHT	30°	1.5 mm
SP 45.0	STRAIGHT	45°	1.5 mm

SLIT (KERATOME) SINGLE BEVEL KNIVES

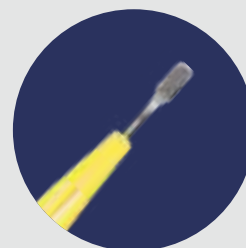
ACUCUT Slit Knives used for sclerocornea centesis incision during cataract surgery. Many sizes available to ensure the exact incision for your choice of Phaco tip and operating access along with standard angled bevel up model.



MODEL	DIMENSION WIDTH (W)	MODEL	DIMENSION WIDTH (W)
KR 10	1.0 mm	KR 25	2.5 mm
KR 12	1.2 mm	KR 26	2.6 mm
KR 14	1.4 mm	KR 265	2.65 mm
KR 16	1.6 mm	KR 275	2.75 mm
KR 18	1.8 mm	KR 28	2.8 mm
KR 20	2.0 mm	KR 285	2.85 mm
KR 22	2.2 mm	KR 30	3.0 mm
KR 24	2.4 mm	KR 32	3.2 mm

CRESCENT KNIVES

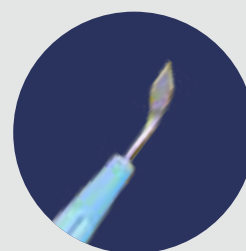
ACUCUT Crescent Knives, features straight sides and round tip and is optimum for creating scleral tunnel flaps. These knives available in bi-bevel, bevel-up and bevel-down.



MODEL	SHAPE	DIMENSION WIDTH (W)
CRU 20	Bevel up	2.0 mm
CRU 22	Bevel up	2.2 mm
CRU 26	Bevel up	2.6 mm
CRD 22	Bevel down	2.2 mm
CRD 26	Bevel down	2.6 mm
CRS 26	Straight	2.6 mm

SLIT (KERATOME) DOUBLE BEVEL KNIVES

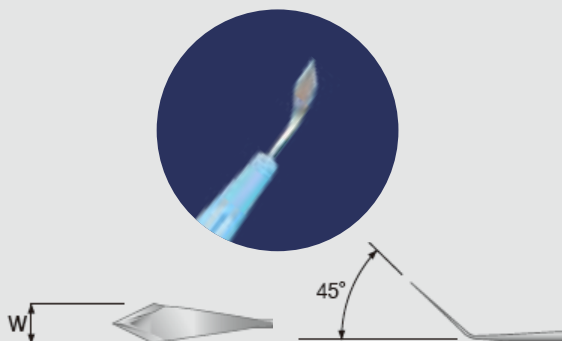
ACUCUT Slit Knives used for sclerocornea centesis incision during cataract surgery. Many sizes available to ensure the exact incision for your choice of Phaco tip and operating access along with standard angled bevel up model.



MODEL	DIMENSION WIDTH (W)	MODEL	DIMENSION WIDTH (W)
KR DB 18	1.8 mm	KR DB 265	2.65 mm
KR DB 20	2.0 mm	KR DB 275	2.75 mm
KR DB 22	2.2 mm	KR DB 28	2.8 mm
KR DB 24	2.4 mm	KR DB 285	2.85 mm
KR DB 25	2.5 mm	KR DB 30	3.0 mm
KR DB 26	2.6 mm	KR DB 32	3.2 mm

CLEAR CORNEA SINGLE BEVEL KNIVES

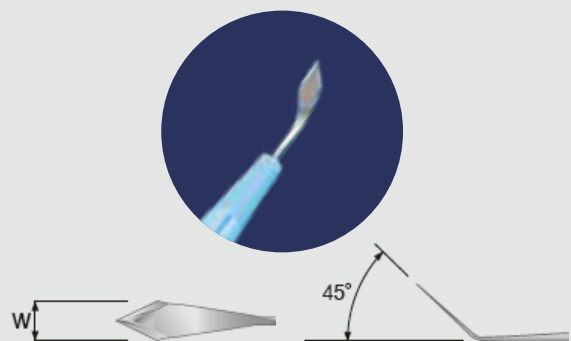
ACUCUT Clear Cornea single bevel knives manufactured by chemical etching process which creates ultra sharp blade, producing a single bevel perfectly suited to clear cornea incisions the new geometry allows high maneuverability for crafting the phaco self-sealing corneal tunnel



MODEL	DIMENSION WIDTH (W)	MODEL	DIMENSION WIDTH (W)
CC 10	1.0 mm	CC 25	2.5 mm
CC 12	1.2 mm	CC 26	2.6 mm
CC 14	1.4 mm	CC 265	2.65 mm
CC 16	1.6 mm	CC 275	2.75 mm
CC 18	1.8 mm	CC 28	2.8 mm
CC 20	2.0 mm	CC 285	2.85 mm
CC 22	2.2 mm	CC 30	3.0 mm
CC 24	2.4 mm	CC 32	3.2 mm

CLEAR CORNEA DOUBLE BEVEL KNIVES

ACUCUT Clear Cornea Double Bevel Knives manufactured by chemical etching process creates ultra-sharp knives, producing a double bevel perfectly suited to clear cornea incision the new geometry allows high maneuverability for crafting the phaco self-sealing corneal tunnel.



MODEL	DIMENSION WIDTH (W)	MODEL	DIMENSION WIDTH (W)
CC DB 18	1.8 mm	CC DB 265	2.65 mm
CC DB 20	2.0 mm	CC DB 275	2.75 mm
CC DB 22	2.2 mm	CC DB 28	2.8 mm
CC DB 24	2.4 mm	CC DB 285	2.85 mm
CC DB 25	2.5 mm	CC DB 30	3.0 mm
CC DB 26	2.6 mm	CC DB 32	3.2 mm

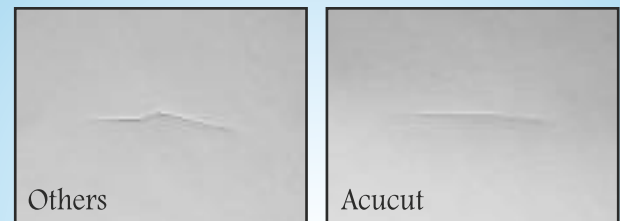
MVR KNIVES

ACUCUT MVR Knives specially designed for very precise vitrectomy surgery, available in both straight & angled styles. These knives are used for centesis incision into sclera during vitreous body surgery. It is also used to create side ports during cataract surgery

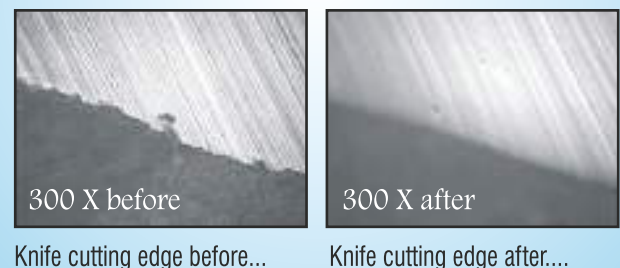


MODEL STRAIGHT	GAUGE	DIMENSION WIDTH (W) Tol : +/- 0.1 mm	MODEL ANGLED	GAUGE	DIMENSION WIDTH (W) Tol : +/- 0.1 mm
MVR 19	19G	1.4 mm	MVR 19 A	19A	1.4 mm
MVR 20	20G	1.2 mm	MVR 20 A	20A	1.2 mm
MVR 23	23G	1.0 mm	MVR 23 A	23A	1.0 mm
MVR 24	24G	0.8 mm	MVR 24 A	24A	0.8 mm
MVR 25	25G	0.6mm	MVR 25 A	25A	0.6mm

CUTTING COMPARISON



ADVANTAGE OF ELECTROPOLISHING



Manufactured By...

Shah
Eye Care (P) Ltd
the winds of change...



GLOBAL PRESENCE

"ACUCUT is globally accepted product in the medical device industry. It has authorized distributors/dealers in all states of India and more than 60 countries across the globe namely USA, Brazil, France, Germany, Italy, Norway, Spain, Portugal, Greece, Lithuania, Ukraine, Latvia, Poland, Czech Republic, Albania, Bulgaria, Romania, Turkey, Jordan, Morocco, Srilanka, Austria, Israel, Lebanon, Iran, Dubai, Kuwait, Kenya, Sudan, Pakistan, Philippines, Singapore, Hong kong, Thailand, Vietnam, Indonesia, Malaysia etc

ACUCUT SHARPNESS

The ELETRO ETCHING technology non-grinding sharpening process begins by obtaining a high quality stainless steel that is hardened and tempered to a uniform tensile strength and toughness. This process produces a structure that can be finished to ensure a consistently sharp, precise cutting edge, High performance. In addition to minimizing tissue damage during incisions, the ultra cutting quality makes it possible to produce an accurate incision size at all times.

ACUCUT CONSISTENCY

ELETRO ETCHING technology virtually assures that the 100th blade or needle is as sharp and dimensionally consistent as the first. The ELECTRO ETCHING technology is fully automated manufacturing minimizes operator handling to produce unparalleled consistency.

Manufactured By....



Factory

Plot No.8 & 9, Karur Industrial Area, P. B. Road,
Davangere - 577 006, Karnataka (state), India.

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Business Whatsapp +91 - 7619550444

Email - sales@shaheycare.com,

Web - www.shaheycare.com

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