

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: **GA10405726-231587**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

29/04/2026 - 28/04/2031

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

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

Nama Peranti Perubatan **Scleral Marker**
Medical Device Name

Kelas **CLASS A**
Class

Jenama **Uzeonce**
Brand

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **WIZCURE MEDICAL DEVICES PVT. LTD.**
Name and address of manufacturer
G-1034, PHASE - 3, RIICO INDUSTRIAL AREA BHIWADI - 301019, RAJASTHAN. INDIA. 301019, INDIA

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Scleral Marker Double Ended 3.0 & 3.5mm	3L016	Length of Marker
2	Scleral Marker Double Ended 3.5 & 4.0mm	3L017	Length of Marker
3	Scleral Marker Double Ended 4.0 & 4.5mm	3L018	Length of Marker
4	Scleral Marker Double Ended (size)	3L019 (S)	Length of Marker
"End Of Product List"			

SCLERAL MARKER

CAT#	DESCRIPTION	PACKING
3L016	Scleral Marker Double Ended 3.0 & 3.5mm	Box of 10
3L017	Scleral Marker Double Ended 3.5 & 4.0mm	Box of 10
3L018	Scleral Marker Double Ended 4.0 & 4.5mm	Box of 10
3L019	Scleral Marker Double Ended (custom size)	Box of 10

Key Features -

- Constructed from highly quality plastic polymer.
- Made from Biocompatible material.
- Supplied sterile, single use only, with shelf-life of 5-years.
- 10 units /Box

Intended Use -

The Scleral Marker is a hand held instrument having two pointed tips maintained at a fixed distance. The pointed tips leave two temporary indent mark on the tissues at the predetermined fixed distance. The device is double ended, with the pointed tips at different distance at each end.

WIZCURE MEDICAL DEVICES PVT. LTD.

G-1034, Phase III, RIICO Industrial Area, Bhiwadi,
Rajasthan - 301019, India

UzeOnce™

Single Use
Surgical
Products

Scleral Markers

CE
2862



10 PCS

STERILE EO



UDI



(01)89061034507009(10)UZM011712608530

STERILE:

Until indicated expiration date,
unless package is opened
or damaged. Verify the integrity of
the sterile package before use.

↓ PEEL HERE ↓

Blue to Brown
in ETO

