

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: **GB10282926-229547**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

25/03/2026 - 24/03/2031

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

Nama Peranti Perubatan **IRIS RETRACTORS**
Medical Device Name

Kelas
Class

CLASS B

Jenama
Brand

IRIS CARE

Kelompok
Group

FAMILY

Nama dan alamat
pembuat:
Name and address of
manufacturer

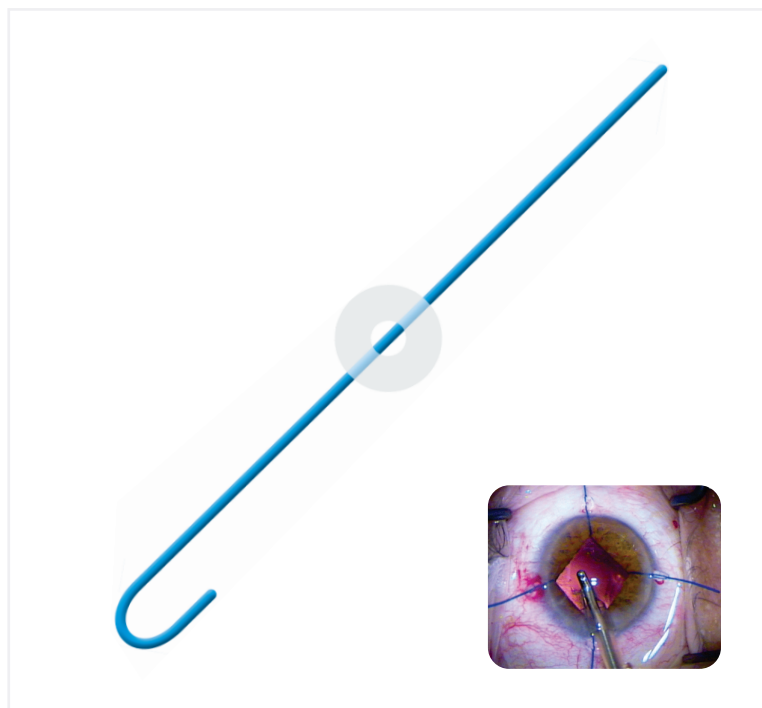
MADHU INSTRUMENTS PVT. LTD
UNIT 1-F90/3D OKHLA INDUSTRIAL AREA, PHASE-1 NEW DELHI -11020
INDIA,
110020
INDIA

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Iris Retractor Flat	MIPL/DI/ZZ-01	Flat Shape
2	Iris Retractor Regular	MIPL/DI/ZZ-02	Regulator Shape
3	Iris Retractor 0.15mm	MIPL/DI/ZZ-03	Size 0.15mm Size
4	Iris Retractor Black	MIPL/DI/ZZ-04	black color
"End Of Product List"			

Iris Retractors

Iris retractors are used for temporary retraction (pupil enlargement) of the iris where dilation cannot be achieved pharmacologically.



Product Description

Product Code	Description	Qty. per box
MIPL/D1	Iris Retractors	5 Pcs. (Sterile)

Features

- Flexible retractors made of bright blue PP (Polypropylene)
- Stretches and stabilizes the Iris during the cataract surgery
- An adjustable silicon stopper provides a superior grip and allows adjustment of the pupil size
- Easy to insert and remove
- CE certified

Instructions for Use

The instructions for use and surgical technique are supplied in the form of a leaflet with instructions given in diagram form where appropriate . The international symbols used on the packaging are also explained.

Sterilization

Products are sterilized through Ethylene Oxide (EO) according to a validated cycle.



MADHU INSTRUMENTS PVT LTD

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