

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: **GA9763725-210117**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

29/08/2025 - 28/08/2030

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
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This certificate is hereby issued to:

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

Nama Peranti Perubatan **STERILE OPHTALAMIC DRAPE SINGLE POUCH**
Medical Device Name

Kelas **CLASS A** Jenama **biotex**
Class Brand

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **BIOTEX MEDICAL TEKSTIL ITHALAT IHRACAT SAN.VE TIC A.S**
Name and address of manufacturer **ISLAMPASA MH.2 NOLU SEHITLER CD. NP41/G MERKEZ-53020RIZE-TURKIYE 53020, TURKEY**

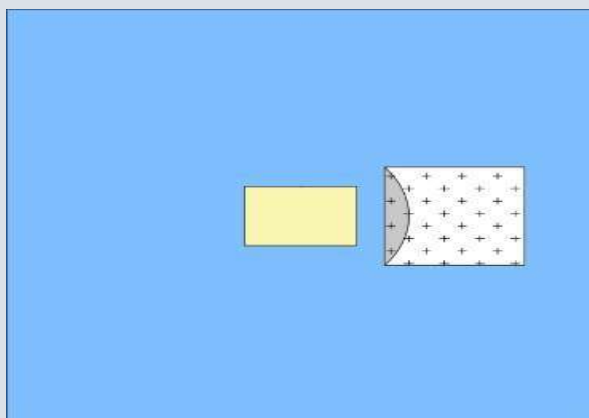
APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	STERILE OPHTALAMIC DRAPE SINGLE POUCH 100 x 130cm	ROD 338-1	STERILE OPHTALAMIC DRAPE SINGLE POUCH 100 x 130cm
2	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 100 x 150cm	ROD 338-2	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 100 x 150cm
3	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 130 x 130cm	ROD 338-3	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 130 x 130cm
4	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 150 x 160cm	ROD 338-4	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 150 x 160cm
5	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 120 X120cm	ROD 338-5	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 120 x 120cm
6	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 60 X60cm	ROD 338-6	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 60 x 60cm
7	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 50x50cm	ROD 338-7	STERILE OPHTALAMIC DRAPE SINGLEPOUCH 50x 50cm
"End Of Product List"			

PRODUCT : STERILE OPHTHALMIC DRAPE SINGLE POUCH

Description Of Medical Device: A sterile, single-use protective covering designed specifically for use during ophthalmic (eye) surgical procedures. It is intended to Maintain a sterile field around the surgical site.

Intended Use Of Medical Device: This set can be used during the surgery operations. This product is disposable and it prevents the bacterial transfer between the medical team and the patient, reduces the occurring of possible contamination and infection between the patient and the medical team.



Product Name	Dimensions	Piece	Fabric Type
STERILE OPHTHALMIC DRAPE SINGLEPOUCH/ ROD- 338	40*50 CM	1	40gr SMS
STERILE OPHTHALMIC DRAPE SINGLEPOUCH / ROD-338-1	100*130 CM	1	40gr SMS
STERILE OPHTHALMIC DRAPE SINGLEPOUCH / ROD-338-2	100*150 CM	1	40gr SMS
STERILE OPHTHALMIC DRAPE SINGLEPOUCH / ROD-338-3	130*130 CM	1	40gr SMS
STERILE OPHTHALMIC DRAPE SINGLEPOUCH / ROD-338-4	150*160 CM	1	40gr SMS
STERILE OPHTHALMIC DRAPE SINGLEPOUCH / ROD-338-5	120*120CM	1	40gr SMS
STERILE OPHTHALMIC DRAPE SINGLEPOUCH / ROD-338-6	60*60 CM	1	40gr SMS
STERILE OPHTHALMIC DRAPE SINGLEPOUCH / ROD-338-7	50*50CM	1	40gr SMS