

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: **GB6542425-216269**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

11/11/2025 - 10/11/2030

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

Nama Peranti Perubatan **TRYPAN BLUE STERILE SOLUTION**
Medical Device Name

Kelas **CLASS B**
Class

Jenama
Brand

**VEU BLUE TRYPAN
BLUE STERILE
SOLUTION**

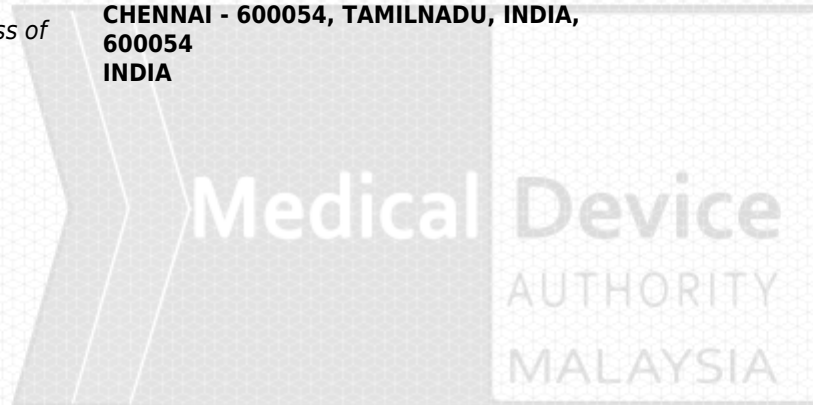
Kelompok **SINGLE**
Group

Produk Identifikasi
Product Identifier

VEU BLUE

Nama dan alamat
pembuat:
*Name and address of
manufacturer*

**SILOAM OPHTHALMICS
NO.23, FIRST FLOOR, PERIYAR STREET, KANNIGAPURAM, AVADI,
CHENNAI - 600054, TAMILNADU, INDIA,
600054
INDIA**



VEU-BLUE 1ML TRYPAN BLUE STERILE SOLUTION



PRODUCT DESCRIPTION

VUE-BLUE 1ML Trypan Blue Ophthalmic Solution is a vital dye, used to visualize the Capsulorhexis during cataract surgery in the absence of red fundus reflex. It stains the anterior Lens capsule offering excellent visualization in eyes with mature cataract. VUE-Blue is a sterile preparation of Trypan Blue in an isotonic, buffered vehicle.

- Active Ingredient: Trypan Blue 0.8 mg/mL
- Concentration: 0.08% w/v
- Packaging: 1ml. Vial, single use unit dose
- Box Packaging: 10 vials in a box

Composition

Each ml Contains:
Trypan Blue :0.8mg
Sodium Chloride I.P: 8.2mg

Packaging:

A glass vial packed in paper pouch and 10 vials packed in a unit carton.

Shelf Life

24 months from the date of manufacturing

Storage:

Store between 15°C-25°C
Keep in a cool dry place,
protect from light.



Administration

To use VEU-BLUE, the first step is to inject air into the anterior chamber using a 26 gauge needle in the area where the second site is made. This prevents water-like dilution of the trypan blue. Then the VEU-BLUE is withdrawn from the ampoule into the tuberculin syringe. Which is then injected by the needle into the anterior chamber between the air bubble and the lens capsule. Use the bevel down of the needle and see to it that the injection is made in a drop format so that the whole capsule gets stained. If some is left unstained, inject a drop in that area till it gets stained. It is kept like that for a minute for staining of the anterior capsule chamber. Now use a straight forceps to stabilize the eye with left hand and with the right hand make a clear corneal incision or scleral incision. Inject viscoelastic inside the eye to remove the air bubble and trypan blue. We can see the stained anterior capsule lying in the anterior chamber.

Indication

- Used as an aid in ophthalmic surgery
- Used as a staining agent
- Detects PC rupture
- Anterior/Posterior Capsulotomy
- Phacoemulsification
- Non Phaco SI Cataract Surgery

Supply

A glass vial packed in paper pouch and 10 vials packed in a unit carton.