

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: **GB1670126-240410**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

20/08/2026 - 19/08/2031

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 **SODIUM HYALURONATE**
Medical Device Name

Kelas **CLASS B**
Class

Jenama
Brand

CO VISC

Kelompok **FAMILY**
Group

Nama dan alamat
pembuat:
Name and address of
manufacturer

ALFA INSTRUMENTS S.R.L
VIA FRATELLI BANDIERA NCC, 80026 CASORIA (NA), ITALIA,
80026
ITALY

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	CO-VISC 1.4%	CO1.4	14 mg sodium hyaluronate/ml)
2	CO-VISC 1.6%	CO1.6	16 mg sodium hyaluronate/ml)
3	CO-VISC 1.8%	CO1.8	18 mg sodium hyaluronate/ml)
4	CO-VISC 2.0%	CO2.0	20 mg sodium hyaluronate/ml)
"End Of Product List"			

CO-VISC™



A line of **Sodium Hyaluronate** derived from **Bacterial Fermentation**
1.1 ml glass syringe **Cohesive & Dispersive**

CE 0425

CO-VISC™ is a sterile non-pyrogenic solution of highly purified sodium hyaluronate. It is supplied in a single use glass syringe with a Luer-Lock™ fitting and with a cannula of 27 gauge.

CO-VISC™ 2% VISCO-ADAPTATIVE: At rest, the OVD contains medium and short chains (low molecular weight).

CO-VISC™ 2% combines the advantages of the cohesive physical properties of the viscoelastic inactive and the dispersive physical properties of a low molecular weight.

Concentration	1%	1.4%	1.6%	1.8%	2%
Molecular Weight (Mill. Dalton)	1.1-1.5	1.1-2.0	1.2-2.0	2.0	3.0
Viscosity (mPas)	60 000	200 000	400 000	600 000	1 000 000

VISCO-ADAPTIVE

Osmolality (mOsm/kg) : 300 - 350

Storage: 2°C to 25°C

pH: 6.8 - 7.5

OVD

Features

1. Viscosity
2. Pseudoplasticity
3. Elasticity
4. Cohesiveness
5. Coatability
6. Dispersiveness

Functions

- Ease of use
- Endothelium Protection
- Chamber retention
- Capsulorhexis Control
- Bag inflation
- Easy Removal

Does NOT contain animal tissue
Medical Device: Class IIa



For more information, visit odc-industries.com

CE 0425