

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: **GC2745423-116250**
Registration No.:

Tarikh Sah Pendaftaran: **18/01/2023 - 17/01/2028**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada:
This certificate is hereby issued to:

KOVWA SDN BHD

yang beralamat di:
which is located at:

**35, JALAN BRP 6/13, BUKIT RAHMAN PUTRA,
40160
SHAH ALAM SELANGOR DARUL EHSAN**

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.



AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
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No. Pendaftaran: **GC2745423-116250**
Registration No.:

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

Nama Peranti Perubatan **SECORIM ABO COLUMN**
Medical Device Name

Kelas **CLASS C** Jenama **VITROSORB**
Class Brand

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **VITROSORB AB**
Name and address of **MEDEON SCIENCE PARK, MALMO, SWEDEN,**
manufacturer **20512**
SWEDEN

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	SECORIM ABO A-Column	A-100	The SECORIM ABO-column is intended for specific adsorption of anti-A and anti-B-antibodies from plasma, which lowers the antibody level to allow for transplantation from a donor with ABO-incompatible (ABOi) blood group. The efficacy of the treatment shall always be confirmed by measuring the antibody level.
2	SECORIM ABO B-Column	B-100	The SECORIM ABO-column is intended for specific adsorption of anti-A and anti-B-antibodies from plasma, which lowers the antibody level to allow for transplantation from a donor with ABO-incompatible (ABOi) blood group. The efficacy of the treatment shall always be confirmed by measuring the antibody level.



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
3	SECORIM ABO AB-Column	AB-100	The SECORIM ABO-column is intended for specific adsorption of anti-A and anti-B-antibodies from plasma, which lowers the antibody level to allow for transplantation from a donor with ABO-incompatible (ABOi) blood group. The efficacy of the treatment shall always be confirmed by measuring the antibody level.
"End Of Product List"			