

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: **IVDB16702389119**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

07/02/2024 - 06/02/2029

Sijil ini adalah dengan ini diberi kepada: **LUCKYANGEL TO U**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

**212-B, MEDAN PUTRA SEBERANG JALAN PUTRA,
05150 ALOR SETAR
KEDAH DARUL AMAN**

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 **FSH ONE STEP FOLLICLE-STIMULATING HORMONE TEST (COLLOIDAL GOLD)**
Medical Device Name

Kelas **CLASS B** Jenama **LUCKY2U**
Class Brand

Kelompok **IVD TEST KIT**
Group

Displin **Immunochemistry** Kategori **Fertility/Pregnancy**
Discipline Category Hormones/ Proteins

Nama dan alamat pembuat: **EQUINOX BIOTECH CO., LTD.**
Name and address of **ROOM116, 1/F, TRANSPORTATION BUREAU BUILDING, NO. 95, YINGBIN**
manufacturer **AVENUE, HUACHENG SUBDISTRICT, HUADU DISTRICT, GUANGZHOU CITY,**
GUANGDONG, P. R. ,
510806
CHINA

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Lucky2u FSH One Step Follicle-Stimulating hormone Test (Colloidal Gold)	RH-FSH-S	This product is a rapid, one-step, visual test for the qualitative detection of follicle stimulating hormone (FSH) in human urine. It is intended for self-testing.
2	Lucky2u FSH One Step Follicle-Stimulating hormone Test (Colloidal Gold)	RH-FSH-C	This product is a rapid, one-step, visual test for the qualitative detection of follicle stimulating hormone (FSH) in human urine. It is intended for self-testing.
3	Lucky2u FSH One Step Follicle-Stimulating hormone Test (Colloidal Gold)	RH-FSH-B	This product is a rapid, one-step, visual test for the qualitative detection of follicle stimulating hormone (FSH) in human urine. It is intended for self-testing.
"End Of Product List"			