No. Siri: **052111**
Serial No.:

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: **IVDC3970722-108057**
Registration No.:

Tarikh Sah Pendaftaran: **08/11/2022 - 07/11/2027**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **MEDICAL INNOVATION VENTURES SDN BHD**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

1ST FLOOR, PLOT 88F, LINTANG BAYAN LEPAS 10,BAYAN LEPAS INDUSTRIAL PARK, PHASE 4, 11900 BAYAN LEPAS, PULAU PINANG, MALAYSIA.,
11900
BAYAN LEPAS PULAU PINANG PULAU MUTIARA

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
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **IVDC3970722-108057**
Registration No.:

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

Nama Peranti Perubatan *Medical Device Name*	**PRODETECT® COVID-19 ANTIGEN RAPID SELF-TEST**		
Kelas *Class*	**CLASS C**	Jenama *Brand*	**PRODETECT®**
Kelompok *Group*	**FAMILY**		
Displin *Discipline*	**Immunochemistry**	Kategori *Category*	**Viral Infection - Immunology**
Nama dan alamat pembuat: *Name and address of manufacturer*	**MEDICAL INNOVATION VENTURES SDN.BHD 1ST FLOOR OF PLOT 88F,LINTANG BAYAN LEPAS 10, BAYAN LEPAS INDUSTRIAL PARK, PHASE 4, 11900 BAYAN LEPAS, PENANG. , 11900 MALAYSIA**		

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	ProDetect® COVID-19 Antigen Rapid Self-Test	PR-CVDCAgN1S	ProDetect® COVID-19 Antigen Rapid Self-Test is a lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasal swab samples. The test serves as an aid in the diagnosis of coronavirus infection disease (COVID-19) in persons with clinical symptoms and the results of other laboratory tests. It is intended for home use. Reagent & Material supplied : 1 box , each containing: 1 test device with desiccant in a pouch,1 Prefilled extraction buffer ,1 Sterile nasal swab, 1 Biosafety bag and 1 leaflet with instruction for use.

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
2	ProDetect® COVID-19 Antigen Rapid Test	PR-CVDCAgN5S	ProDetect® COVID-19 Antigen Rapid Self-Test is a lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasal swab samples. The test serves as an aid in the diagnosis of coronavirus infection disease (COVID-19) in persons with clinical symptoms and the results of other laboratory tests. It is intended for home use. Reagent & Material supplied : 1 box (5 tests), containing : 1 test device with desiccant in a pouch,5 Prefilled extraction buffer ,5 Sterile nasal swab, 5 Biosafety bag and 1 leaflet with instruction for use.
3	ProDetect® COVID-19 Antigen Rapid Test	PR-CVDCAgN25S	ProDetect® COVID-19 Antigen Rapid Self-Test is a lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasal swab samples. The test serves as an aid in the diagnosis of coronavirus infection disease (COVID-19) in persons with clinical symptoms and the results of other laboratory tests. It is intended for home use. Reagent & Material supplied : 1 box (25 tests), containing : 1 test device with desiccant in a pouch,25 Prefilled extraction buffer ,25 Sterile nasal swab, 25 Biosafety bag and 1 leaflet with instruction for use.
"End Of Product List"			

PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA
ARAS 6, PRIMA 9, PRIMA AVENUE II, BLOCK 3547
PERSIARAN APEC, 63000 CYBERJAYA.
TEL : (+603)8230 0300

Medical Device AUTHORITY MALAYSIA

Ref : MDR-20230821-79569
Date : 12-09-2023

To whom it may concern,

Dear Sir/Madam,

CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (CATEGORY 2)

The above matter is referred.

Please be informed that your change notification request for the medical device as follows has been approved.

Establishment Name	: **MEDICAL INNOVATION VENTURES SDN BHD**
Medical Device Registration Certificate No.	: IVDC3970722-108057
Medical Device Name	: PRODETECT® COVID-19 ANTIGEN RAPID SELF-TEST
Description of Change	: **Refer Attachment of Approval**

2. This change notification shall be attached together with the medical device registration certificate. The validity of this document shall follow the date as stated in the medical device registration certificate.

Thank you,

MURALITHARAN PARAMASUA
CHIEF EXECUTIVE
Medical Device Authority,
Ministry of Health Malaysia.

Extension of Shelf-Life for ProDetect® Covid-19 Antigen Rapid Test, ProDetect® Covid-19 Antigen Rapid Self-Test and ProDetect® Covid-19 Antigen Rapid Self-Test (Saliva)

ProDetect® Covid-19 Antigen Rapid Test, ProDetect® Covid-19 Antigen Rapid Self-Test and ProDetect® Covid-19 Antigen Rapid Self-Test (Saliva) manufactured by Medical Innovation Ventures Sdn. Bhd. (MEDIVEN) are verified in the accelerated stability study to be stable up 30 months from the date of manufacture.

Detailed information of the shelf-life re-verification experiment is shown in Annex 1.