No. Siri: 049734
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: **IVDC10583422-100689**
Registration No.:

Tarikh Sah Pendaftaran: **15/08/2022 - 14/08/2027**
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: **IVDC10583422-100689**
Registration No.:

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

Nama Peranti Perubatan **PRODETECT® COVID-19 ANTIGEN RAPID SELF-TEST (SALIVA)**
Medical Device Name

Kelas *Class*	**CLASS C**	Jenama *Brand*	**PRODETECT®**
Kelompok *Group*	**IVD TEST KIT**		
Displin *Discipline*	**Immunochemistry**	Kategori *Category*	**Viral Infection - Immunology**
Nama dan alamat pembuat: *Name and address of manufacturer*	**MEDICAL INNOVATION VENTURES SDN. BHD. 1ST FLOOR, PLOT 88F, LINTANG BAYAN LEPAS 10,BAYAN LEPAS INDUSTRIAL PARK, PHASE 4,11900 BAYAN LEPAS, PULAU PINANG, MALAYSIA., 11900 MALAYSIA**		

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Test Device	PR-CVDCAgS	The test is performed by applying the saliva sample to the sample well of the cassette and observing the formation of colored line.
2	Collection device	PR-CVDCAgS(C)	It consist of funnel and collection tube.It is use for collecting and extracting sample.
3	Single use buffer	PR-CVDCAgS(S)	To aid in sample collection and preparation.
4	Biosafety Bag	PR-CVDCAgS(B)	Discard the used test device into the biosafety bag.
"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

Ref : MDR-20230912-80883
Date : 09-10-2023

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.	: IVDC10583422-100689
Medical Device Name	: PRODETECT® COVID-19 ANTIGEN RAPID SELF-TEST (SALIVA)
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.

Ref : MDR-20230912-80883
Date : 09-10-2023

Attachment of Approval

Change Notification for Category 2

TYPE OF CHANGE(S)	DESCRIPTION OF CHANGE(S)
5.5.2 Changes in design or specifications of a registered medical device	
(c) All changes in specifications (including shelf life and stability) of a registered medical device.	Information has been updated in technical documents

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.