



**PIHAK BERKUASA PERANTI PERUBATAN
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TEL : (+603)8230 0300



Ref : MDR-20230324-70075
Date : 11-04-2023

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. : **IVDC9540322-106750**

Medical Device Name : **SARS-COV-2 ANTIGEN RAPID TEST CASSETTE**

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.

FOR MEDICAL INNOVATION VENTURES
SDN.BHD (MEDIVEN) USE ONLY

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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

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