



PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
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Ref. No. : (17) dlm. MDA.600-3/1/12 Jilid 67

Date : 11 May 2021

Dewina Consult Sdn Bhd

Lot 11, Jalan P/9B,
Kawasan Perusahaan Bangi,
43650 Bandar Baru Bangi, Selangor.
(attention to : Dr Ahmad Robin Wahab)

Dear Sir,

NOTIFICATION ON IMPORTATION/SUPPLY OF MEDICAL DEVICES FOR SPECIAL ACCESS UNDER THE MEDICAL DEVICE (EXEMPTION) ORDER 2016 :

- **Medical Device Name : New Gene Bioengineering COVID-19 Antigen Detection Kit**
- **Manufacturer : New Gene (Hangzhou) Bioengineering Co., Ltd.**

With regards to your notification dated 26th January 2021, I wish to inform you on the decision made by the Expert IVD Evaluation Committee Meeting held on 10th May 202 to your notification is as follows:

Recommended for Use.

2. Therefore, for the purpose of issuance of Special Access Letter, you are kindly requested to provide us with the required information as follows:

- i. Completed Special Access Route B Form (with the information on Section B, Medical Practitioner Details);
- ii. Customer Order Form (signed and stamped by the Public or Private Pathology Laboratory/Hospital) who is requesting the supply of COVID-19 Detection Kits during COVID-19 outbreak.

Thank you.

Yours Sincerely,


(AHMAD SHARIFF BIN HAMBALI)
Ketua Eksekutif,
Pihak Berkuasa Peranti Perubatan,
Kementerian Kesihatan Malaysia.