PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Aras 6, Prima 9, Prima Avenue II,
Blok 3547, Persiaran Apec,
63000 Cyberjaya, Selangor
Malaysia.

Tel: (+603)8230 0300
Faks: (+603)8230 0200
Portal Rasmi: www.mda.gov.my
Email: mdb@mda.gov.my

Ref : (20) MDA.600-1/6/27

Date : 28 September 2021

HYGEIA INSTRUMENTS (MALAYSIA) SDN BHD
3A-A-139, Kompleks Bukit Jambul, Jalan Rumbia
Bayan Lepas, 11900 Pulau Pinang, Malaysia.
(Attention to: **Robert Ziegler**)

Dear Sir/Madam,

CONDITIONAL APPROVAL FOR IMPORTATION AND DISTRIBUTION OF MEDICAL DEVICE (COVID-19 SELF TEST KIT)

With reference to the above, I wish to inform that the Authority grants your establishment a conditional approval for the importation and distribution of medical device as listed in **Appendix 1.**

2. Please be informed that the validity of this conditional approval is from **28/9/2021** to **28/9/2022** and is subject to the following:

i) Your establishment shall ensure that the medical device under this conditional approval complies with safety and performance requirements as stipulated in Medical Device Act 2012 (Act 737);
ii) Your establishment shall adhere to the conditions as stipulated in **Appendix 2.**
iii) The use of COVID-19 self test kit shall be limited for screening purpose only and all test results need further confirmation using RT-PCR.

3. This conditional approval for importation and distribution of this medical device is an interim measure in response to the current public health need during COVID-19 pandemic. This letter shall not be used for the purpose of promoting or advertising of the product and it does not exempt you from abiding to any laws or requirements by any other authorities of Malaysia.

Thank you,

(AHMAD SHARIFF BIN HAMBALI)
Chief Executive
Medical Device Authority
Ministry of Health Malaysia

Ref : (20) MDA.600-1/6/27
Date : 28 September 2021

Appendix 1

Medical Device Details

Name of Medical Device	:	Newgene Bioengineering COVID-19 Antigen Detection Kit (for home self-use)
Brand/Model	:	Newgene
Identifier	:	COVID-19-NG08
Sample type	:	Saliva
Intended Use	:	This product is suitable for the qualitative detection of novel coronavirus in deep throat saliva sample for home self-use. It provides an aid in the diagnosis of infection with novel coronavirus.
Brief Description	:	This product is suitable for the qualitative detection of novel coronavirus in deep throat saliva sample for home self-use. It provides an aid in the diagnosis of infection with novel coronavirus
Lot Number	:	20210721-01
Manufacturer's name	:	New Gene (Hangzhou) Bioengineering Co. Ltd., P.R. China

MEDICAL DEVICE AUTHORITY
MINISTRY OF HEALTH

Appendix 2

Conditions:

1) The conditional approval for importation and distribution of the medical device listed in Appendix 1 is valid for one year.

2) An establishment given the conditional approval shall—

   i) collect data related to safety and performance of the medical device and shall submit the report to the Authority on a regular basis or when it is required by the Authority;

   ii) submit any information requested by the Authority within the prescribed period;

   iii) comply with any directions issued by the Authority from time to time;

   iv) comply with labelling requirements stipulated in Sixth Schedule of the Medical Device Regulations 2012, in particular instruction for use and disposal method, including using infographic, to make it easily understood by lay persons;

   v) provide suitable and adequate storage to ensure proper conservation of the medical device in accordance with the manufacturer's instruction;

   vi) perform inspection on the primary packages of the medical device and any breached packages shall be disposed off appropriately;

   vii) distribute the medical device only to licensed community pharmacies and healthcare institutions and they may sell the medical device online subject to appropriate distribution method specified by the manufacturer;

   viii) establish adequate precautions and control to prevent deterioration or damage of the medical devices up until the point of use;

   ix) ensure the delivery of medical devices adhere to the conditions specified by the manufacturer;

   x) provide documentation of all medical devices supplied to customers, the quantity supplied, the batch or lot number and/or model and serial number;

   xi) establish and maintain an appropriate distribution records up to retail distribution of the medical device to the end-user;

   xii) keep the record of delivery transactions as the proof of supply of the medical device to customers;

   xiii) dispose off medical device in accordance with regulatory requirements and any other applicable statutory requirements; and

   xiv) not carry out any secondary assembly activities on the medical device unless the manufacturers instruction states otherwise;

3) All information pertaining to this medical device including all supporting documents shall be kept at the premises and shall be made available upon request by the Authority.

4) An establishment shall establish and maintain a post-market surveillance system to monitor the traceability of the medical device throughout the supply chain.

5) The Authority reserves the right to make a visit or inspection to the establishment at any time without prior notice.

6) The Authority may revoke the conditional approval or may take legal action should the establishment fails to comply with any conditions imposed by the Authority.

7) An establismhent shall inform MDA on the new lot number of the same batch, in order to issue a new evaluation letter.

MEDICAL DEVICE AUTHORITY
MINISTRY OF HEALTH