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Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
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Ref : (9) MDA.600-1/6/27 Jld 2
Date : 6 December 2021

Multiplex Enterprise
No.53a, Jalan Mohd Tahir 8,
Klang, 41200, Selangor
(Attention to: **Adam Ng Cen Yee**)

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 **6/12/2021** to **6/12/2022** 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

Appendix 1

Medical Device Details

Name of Medical Device	:	Eagle Bio SARS-CoV-2 Antigen IVD Kit Lollipop (Self Testing)
Brand/Model	:	EAGLE BIO
Identifier	:	HN06
Sample type	:	Saliva
Intended Use	:	The SARS-CoV-2 Antigen IVD Kit Lollipop is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigen in human saliva, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronavirus antigen. It will provide information for clinical doctors to prescribe correct medications
Brief Description	:	The SARS-CoV-2 Antigen IVD Kit Lollipop is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to Novel coronavirus. The test strip is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coronavirus; the reaction membrane contains the secondary antibodies for Novel coronavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane. When the test device was inserted into saliva sample, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coronavirus is present in the sample, a complex formed between the anti-Novel coronavirus conjugate and the virus will be caught by the specific anti- Novel coronavirus monoclonal coated on the T region. Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C. The SARS-CoV-2 Antigen IVD Kit Lollipop product can detect SARS-Cov-2 nucleoprotein(mainly) and spike protein. More than 90% antibody used in SARS-CoV-2 Antigen IVD Kit Lollipop is anti-nucleoprotein of SARS-Cov-2 and target protein is SARS-Cov-2 nucleoprotein. The rest antibody used in SARS-CoV-2 Antigen IVD Kit Lollipop is anti-Spike protein and target protein is SARS-Cov-2 Constant fragment of Spike protein. At present, whether the N501Y in the United Kingdom or the 501Y.V2 in South Africa, the variant fragments are mainly the RBD fragment of the S protein, and the target fragments of the antibodies used in Novel Coronavirus SARS-CoV-2 Antigen IVD Kit Lollipop have not been mutated. So, the SARS-CoV-2 Antigen IVD Kit Lollipop can reliably detect the SARS-Cov-2 variants. So, the SARS-CoV-2 Antigen IVD Kit Lollipop can reliably detect the nucleoprotein and spike protein of genetic SARS-Cov-2 variants
Lot Number	:	20210902-01
Manufacturer's name	:	Shenzhen Reagent Technology Co., Ltd. P.R.China

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.