



Ref : (22) MDA.600-1/6/27 Jld

Date : 24 September 2021

SPD Scientific Sdn Bhd  
F-G-45, Block F, Jalan PJU 1A/3,  
Taipan 2 Damansara, Ara Damansara,  
47301 Petaling Jaya, Selangor Darul Ehsan  
(Attention to: **Hor Zian Khang**)

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 **24/9/2021** to **24/9/2022** 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

**Medical Device Details**

Name of Medical Device	:	Whistling™ Test 2019-nCoV Saliva Ag Easy Test
Brand/Model	:	Guangzhou Decheng Biotechnology Co., LTD
Identifier	:	0709D6G001
Sample type	:	Saliva
Intended Use	:	It is intended for the in vitro qualitative detection of N-protein antigen from 2019-nCoV in human saliva specimens. It is suitable for self-testing use.
Brief Description	:	<p>The Midstream is a lateral flow immunoassay intended for the in vitro qualitative detection of N-protein antigen from 2019-nCoV in human saliva specimens. The Midstream can be used for individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection.</p> <p>Individuals have to actively swab the inside of the mouth and tongue to collect oral fluid using the integrated absorber tip of the Midstream. Take the absorbent tip out from the mouth when the purple color moves across the result window in the center of the midstream. No further processing is required. It is suitable for self-testing use.</p>
Lot Number	:	70210701
Manufacturer's name	:	Guangzhou Decheng Biotechnology Co., LTDChina.

**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.