OTHERS Medical Device Authority ("MDA") of Malaysia Approved COVID-19 Antigen Self-Test Kit (Saliva) For Distribution by K-One MediTech Sdn Bhd

K-ONE TECHNOLOGY BERHAD

Type	Announcement
Subject	OTHERS
Description	Medical Device Authority ("MDA") of Malaysia Approved COVID-19 Antigen Self-Test Kit (Saliva) For Distribution by K-One MediTech Sdn Bhd

1. Introduction

The Board of Directors of K-One Technology Berhad (“K-One Tech” or ‘Company” or “K-One Group”) wishes to announce that the Company’s wholly-owned subsidiary, K-One MediTech Sdn Bhd (K-One MediTech) has on 26 October 2021 received conditional approval from the Medical Device Authority ("MDA") under the Ministry of Health, Malaysia for the import and distribution of COVID-19 Antigen Self-Test Kit (Saliva) manufactured by Labnovation Technologies Inc. (Labnovation Tech) in China.

The said COVID-19 Antigen Self-Test Kit (Saliva) is intended for the qualitative detection of SARS-CoV-2 antigen in human saliva samples from a COVID-19 suspected person. It is intended for self-testing and home use with the outcome of the test results known in 15 minutes. The use of the COVID-19 Antigen Self-Test Kit shall be for screening purpose and all test results require confirmation using the COVID-19 RT-PCR (Reverse Transcription Polymerase Chain Reaction) test.

2. About Labnovation Tech & K-One MediTech

2.1 Labnovation Tech

Labnovation Tech, the developer and manufacturer of the COVID-19 Antigen Self-Test Kit named as Labnovation SARS-CoV-2 Antigen Saliva Rapid Test Kit is based in Shenzhen, Guangdong, China. It specializes in developing, manufacturing and marketing of various clinical laboratory instruments and diagnostic reagents. Since its establishment in 1997, Labnovation Tech has adopted international standards for its R&D and manufacturing and is ISO13485:2016 and ISO9001:2015 accredited in its Quality Management System. The said product produced by Labnovation Tech is CE approved.

2.2 K-One MediTech

K-One MediTech is a wholly-owned subsidiary of K-One Tech. It was incorporated in 2001. Its principal business and focus are in the development, manufacturing and supply of medical and healthcare products which includes medical devices, healthcare consumables, oral care gadgets and hospital equipment.

3. COVID-19 Antigen Self-Test Kit & Conditional Approval

Labnovation SARS-CoV-2 Antigen Saliva Rapid Test Kit with sensitivity of 96.7% and specificity of 100% is an innovative 15-minute economical rapid test that allows for faster and accurate screening of individuals, both symptomatic and asymptomatic. It is also more user friendly as it uses saliva specimen as opposed to the rapid antigen tests which use nasopharyngeal swabs to collect “nasal” specimen which may cause discomfort.

The salient points of the conditional approval include:

a) The import and distribution of the said COVID-19 Antigen Self-Test kit (Saliva) named as Labnovation SARS-CoV-2 Antigen Saliva Rapid Test Kit is for a period of one year from 26 October 2021 to 26 October 2022.

b) The distribution of the said COVID-19 Antigen Self-Test Kit (Saliva) is only to licensed community pharmacies and healthcare institutions and they may sell the medical device online subject to appropriate distribution method specified by Labnovation Tech.

The conditional approval will provide the opportunity for the K-One Group to further expand its medical device business while at the same time contribute in the fight against the COVID-19 pandemic by distributing or selling COVID-19 Antigen Self-Test Kits to facilitate mass and regular testing to mitigate the spread of the COVID-19 infections. With the government’s emphasis on COVID-19 self-test in conjunction with the reopening of most sectors of the economy, the market potential for the COVID-19 Antigen Self-Test Kits is forecasted to be significant and the K-One Group is geared to take a slice of the market.

4. Financial Effects

The conditional approval will have immaterial impact on the net assets and gearing of K-One Tech for the financial year ending 31 December 2021. It will not have any effect on the issued and paid-up share capital and the substantial shareholders’ shareholding in K-One Tech.

With distribution and marketing process anticipated to commence immediately and sales progressively scaling up during the one year period, it is expected to contribute positively to the earnings of K-One Tech for the financial years ending 31 December 2021 and 2022.

5. Risk Factors

The import and distribution of the said COVID-19 Antigen Self-Test Kits (Saliva) will be subjected to various risks which include supply-chain disruptions, pricing changes, market demand volatility, competition and currency rates fluctuation. Notwithstanding, the K-One Group has established a successful track record in undertaking manufacturing and distribution of medical devices which would help in mitigating such risks.

6. Approvals Required

The distribution and sales of the said COVID-19 Antigen Self-Test Kits (Saliva) does not require approval from the shareholders of K-One Tech or relevant authorities except MDA which it has gotten the necessary approval.

7. Directors' Statement

The Board of K-One Tech is of the opinion that the distribution and supply of the said COVID-19 Self-Test Kits (Saliva) is in the best interest of the K-One Group after considering its business potential in the prevailing COVID-19 self-test public awareness and support by the government as an important initiative to combat the spread of COVID-19 infections.

This announcement is dated 27 October 2021.

Announcement Info

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