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

Туре	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

The Board of Directors of K-One Technology Berhad ("K-One Tech" or "Company" or "K-One Group") had on 27 October 2021 announced that the Medical Device Authority ("MDA") under the Ministry of Health, Malaysia had granted conditional approval for its wholly-owned subsidiary, K-One MediTech Sdn Bhd ("K-One MediTech") to import and distribute COVID-19 Antigen Self-Test Kit (Saliva) manufactured by Labnovation Technologies Inc, China ("Labnovation Tech") in Malaysia. The conditional approval is valid for a period of one year; from 26 October 2021 to 26 October 2022.

Further to the above mentioned announcement, the Board of Directors of K-One Tech wishes to inform that K-One MediTech has on 17 August 2022 received approval with validity period extended to 14 August 2027 for the import and distribution of the said COVID-19 Antigen Self-Test Kit in Malaysia. As a recap, the 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.

The Board of K-One Tech is of the opinion that the extension of the validity period until 14 August 2027 for the distribution and supply of the said COVID-19 Self-Test Kit (Saliva) is in the best interest of the K-One Group. COVID-19 Antigen Self-Test Kits with MDA approvals are expected to be still in market demand despite the world claiming endemicity as COVID-19 lingers on with variants and sub-variants. The end of COVID-19 remains unclear.

This announcement is dated 17 August 2022.

Announcement Info	
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