OTHERS Medical Device Authority ("MDA") of Malaysia Grants Approval To K-One MediTech Sdn Bhd To Distribute Silicone Adhesive Tape Primarily Used For Wound Care Dressing

K-ONE TECHNOLOGY BERHAD

Type Announcement

Subject OTHERS

Description Medical Device Authority ("MDA") of Malaysia Grants Approval To K-

One MediTech Sdn Bhd To Distribute Silicone Adhesive Tape

Primarily Used For Wound Care Dressing

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 27 September 2022 received approval from the Medical Device Authority ("MDA") under the Ministry of Health, Malaysia to distribute and sell silicone adhesive tapes primarily used for wound care dressing. The K-One Group will sell the silicone adhesive tapes in Malaysia as an authorized representative of Wuhan Huawei Technology Co., Ltd ("WH Tech") which is the manufacturer based in China.

2. About WH Tech & K-One MediTech

2.1 WH Tech

WH Tech, the developer and manufacturer of the silicone adhesive tapes is based in Wuhan, Hubei, China. It specializes in developing, manufacturing and marketing of various advanced wound dressings and other medical products. Since its establishment in 2002, WH Tech has been accorded with ISO 9001, ISO 13485, FDA and CE certifications.

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. Silicone Adhesive Tapes For Wound Care Applications & MDA Approval

The silicone adhesive tapes are advanced wound dressings which come in three product types. The first two product categories are applicable to a variety of indwelling catheters, electrodes or other external fixations that require gentle but robust skin protection and adhesion, while the third product type helps to improve scar appearance (including hypertrophic and keloid) and restores skin to a more natural color and texture. It also alleviates itchy skin and discomfort associated with scars.

MDA has approved the distribution and sale of the above silicone adhesive tapes in three product categories for a period of five years from 26 September 2022 to 25 September 2027.

The approval will provide the opportunity for the K-One Group to further expand its medical device business. The silicone adhesive tape wound dressing market is growing as its demand is anticipated to increase in tandem with the rising trend of surgeries performed in Malaysia (and abroad). Moreover, increasing awareness relating to the employment of medical tapes for securement among physicians and patients and the rising incidence of wounds, burns, injuries are anticipated to spice up the market demand.

4. Financial Effects

The approval will have immaterial impact on the net assets and gearing of K-One Tech for the financial year ending 31 December 2022. It will not have any effect on the issued and paid-up share capital and the substantial shareholders' shareholding in K-One Tech.

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

5. Risk Factors

The import and distribution of the said silicone adhesive tapes 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 silicone adhesive tapes for wound care dressing do not require approval from the shareholders of K-One Tech or relevant authorities except MDA which it has received the necessary approval.

7. Directors' Statement

The Board of K-One Tech is of the opinion that the distribution and supply of the said silicone adhesive tapes primarily for wound care applications is in the best interest of the K-One Group after considering its potential and synergy to its existing healthcare business segment.

This announcement is dated 28 September 2022.

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Announcement Info	
Company Name	K-ONE TECHNOLOGY BERHAD
Stock Name	K1
Date Announced	28 Sep 2022
Category	General Announcement for PLC
Reference Number	GA1-28092022-00035