

Examples and Situations of Personal Use Medical Device

Case 1

Ali, who travels to the United Kingdom bought a blood pressure monitor for his own use from a pharmacy. He has a history of hypertension and uses a blood pressure monitor to monitor his blood pressure readings. He wants to bring the blood pressure monitor to Malaysia through the passenger's baggage.

Solution

Fall under the category of personal use medical devices.

Case 2

Abu, who travels to the United States of America, bought 500 COVID-19 IVD self-test kits from a pharmacy. He wants to bring 500 self-test kits to Malaysia through hand-carry for his own monitoring.

Solution

Do not fall under the category of personal use medical devices due to unreasonable quantities.

Case 3

Farid intends to buy rechargeable hearing aids for his father from the online platform. His father has a written recommendation from a registered healthcare professional to treat his hearing loss problem. The hearing aid's model is recommended by the ENT specialist and will be shipped to Malaysia through an international courier.

Solution

Fall under the category of personal use medical devices.

Case 4

Carol purchased a pack of 50 strips of the IVD Early Detection Pregnancy Test for her own use from the foreign online platform. She does not have a written recommendation from a registered medical practitioner to justify her purchase and the same brand and types of pregnancy test kits are available and registered in Malaysia.

Solution

Do not fall under the category of personal use medical device as the same brands are available and registered in Malaysia. She shall use the pregnancy test kits that have been registered with MDA.

Case 5

Shafiq bought a pulse oximeter, 2 boxes of medical face masks, and 5 COVID-19 self-test kits from a pharmacy in India because he was infected with COVID-19 while travelling. He has proof

of a positive COVID-19 test result and intends to bring along all medical devices to Malaysia through passenger baggage.

Solution

Fall under the category of personal use medical devices.

Case 6

Aishah purchased a Continuous Positive Airway Pressure (CPAP) machine from an online platform for her father, who has a medical report from a registered medical practitioner. After completing the payment and receiving the delivery tracking number from the seller, the device will be shipped via an international courier. Aishah plans to appoint a forwarding agent to handle the import clearance process on her behalf.

Solution

Fall under the category of personal use medical device.

Case 7

Dr Azizah has finished her medical studies at Harvard Medical School. She intends to purchase her stethoscope set through an online platform. The stethoscope is for diagnostic and screening purposes on patients.

Solution

Dr. Azizah is not permitted to import her stethoscope for personal use into Malaysia, as it is classified as a professional-use medical device and its importation is considered 'placing it on the market' under the Act 737.

Case 8

Liza wishes to import 10 sets of injectable dermal filler without prescription from a medical practitioner for her own use to reduce wrinkles and fine lines in her face. However, based on the IFU provided by the manufacturer, the dermal filler shall be operated by the medical practitioner who has appropriate training and experience about the anatomy at and around the injection site.

Solution

Liza is not allowed to import injectable dermal filler for personal use into Malaysia because it is a professional-use medical device that requires a prescription from a registered healthcare professional. Furthermore, the administration of dermal fillers requires proper medical expertise as the procedure must be performed by a qualified professional to ensure safety and prevent complications.

Case 9

Pak Mat is interested in buying one infrared pain relief device that was advertised in foreign online shopping platform. He experienced sore muscles, and that medical device is intended to be used to promote blood circulations and relieve muscle strain. The IFU stated that the medical device is safe to use by lay users if they comply with the instruction for use completely while using the medical device.

Solution

Fall under the category of personal use medical device.

Case 10

Klinik HQ is importing 5 sets of blood pressure monitors from China for use across its clinics in Malaysia, specifically for patient diagnosis. During the customs clearance process, however, Klinik HQ submitted a purchase order and invoice issued by an establishment that acts as an importer, rather than using a medical device registration certificate by MDA.

Solution

Medical devices which are deemed to be for a commercial or clinical purpose may be seized at the border, as they are not considered to be for personal use

Case 11

Ali bought an unregistered brand of pulse oximeter from an online platform for his own use, using his company's name for the purchase. However, the transaction was actually made under the name of company ABC. The medical device was restricted at the point of entry by the Royal Malaysian Customs Department, requesting further clarification from Ali.

Solution

Medical devices which are deemed to be for a commercial or bought under company name may be seized at the border, as they are not considered to be for personal use.

Case 12

Mr. Adam, a Malaysian citizen who frequently engages in sports, often experiences muscle soreness and minor injuries. He discovers a reusable cold therapy pack from an international online marketplace, intended for pain relief and injury recovery and has better cooling retention than those available locally. Wanting to use it for personal recovery without the recommendation from healthcare professionals, he orders 2 packs from an overseas supplier. Upon arrival at entry point, the package was detained by the Royal Malaysian Customs Department. This case was referred to the Medical Device Authority (MDA) for the purpose to obtain MDA approval.

Solution

Falls under category for personal use.