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MEDICAL DEVICE GUIDANCE DOCUMENT

WEARABLE MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-
a) Medical Device Act 2012 (Act 737);
b) Medical Device Regulations 2012;
c) Medical Device (Duties and Obligations of Establishments) Regulations 2019; and
d) Medical Device (Advertising) Regulations 2019.

In this Guidance Document, the following verbal forms are used:
— “shall” indicates a requirement;
— “should” indicates a recommendation;
— “may” indicates a permission; and
— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the incident of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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WEARABLE MEDICAL DEVICE

1 Introduction

The advances in the development of wearable technology and remote monitoring devices are growing exponentially. Wearable technology is a type of technology that is incorporated in electronics that can be worn on the body, either as an accessory or as part of materials used in clothing. One of the major features of wearable technology is its ability to connect to the internet, enabling data to be exchanged between a network and the device.

Applications of wearable technologies include wearable cameras, smart clothing, wearable application platforms, smart glasses, health and happiness wearables, activity trackers, 3D motion sensors, and smartphone compatible watches also called smart watches.

The growth of the wearable technologies market is driven by factors such as the increasing awareness of personal health monitoring, incremental AI technological advancements, and the rising prevalence of chronic diseases and obesity.

Wearable products used nowadays can be regulated as medical devices or non-medical devices depending on their intended use, as claimed by the manufacturer.

2 Scope and application

The guidance document to determine the wearable products that fall within the definition of medical device as stipulated in Section 2 of Medical Device Act 2012 (Act 737).

This guidance document excludes the products that are intended for general wellness and do not have medical claims.

This guidance document is applicable to the establishments that are dealing with wearable medical devices.

3 Terms and definitions

For the purpose of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

3.1 general wellness product

A product or software which is intended by its manufacturer to enable or encourage the user of the product or software to adopt or maintain a healthy user's general wellbeing, but not to be used for any specific medical purposes and not intended to be used to diagnose, monitor, treat, mitigate or prevent diseases.

3.2 intended use

Objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

[SOURCE: Medical Device Regulations 2012]

3.3 label

Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

NOTE: The definition above refers to the human readable label.

3.4 labelling

The label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

NOTES:

1. Labelling can also be referred to as “information supplied by the manufacturer”.
2. Labelling can be in printed or electronic format and may either physically accompany the medical device or direct the user to where the labelling information can be accessed (such as through a website)

3.5 user

The person, either professional or lay, who uses a medical device.

4 Determination of wearable medical devices

The intended use of products as set by the manufacturer will determine whether they are wearable medical devices or general wellness products.

If the products fit the definition of medical device as defined in Section 2 of Act 737, they shall be registered and subject to regulatory requirements under Act 737.

In the case of products that are intended by the manufacturer to be used for wellness but are able to perform medical function or purposes, the manufacturers are required to include a statement or equivalent on their labels to clearly inform the users not to rely on the results of wearable products as a medical diagnosis and consult a healthcare professional for further action.

For example, if the wearable product is a fitness tracking watch but is able to measure blood oxygen saturation (SpO_2), the manufacturer should include the following statement or equivalent on the label:

- *"This device or software is not intended for diagnosis, prevention, monitoring, detection, or treatment of any medical condition or disease.";*
- *"Any health-related information provided by this device or software should not be treated as medical advice.";*
- *"Please rely on professional medical devices or consult a doctor for assistance."; or*
- *"Not intended for diagnosis purposes".*

The determination of classification whether the products is medical device or not can be submitted through the 'Product Classification' application form and email to classification@mda.gov.my. Establishment may refer to guideline MDA/GL/06 on *How to Apply for Product Classification Application Under Medical Device Act 2012 (Act 737).*

5 Regulatory requirements for wearable medical devices

All wearable medical devices shall fulfil the requirement as specified in Act 737 and its regulations as follows:

5.1 The establishments dealing with wearable medical device shall apply for establishment license from the Authority. Establishments may refer to guidance document *MDA/GD/0026 Licensing for Establishments.*

5.2 The establishments shall register the wearable medical device prior placing the medical device in the market. The registration requirements and procedures are depending on the risk classification of wearable medical device. Establishments may refer to guideline *MDA/GL/MD-01 How to Apply for Medical Device Registration under Medical Device Act 2012 (Act 737) Third Edition.*

5.3 The establishment shall ensure the wearable medical devices is conforms to the essential principle safety and performance of medical devices. Establishments may refer to *guidance document MDA/GD/0007 The Essential Principles of Safety and Performance of Medical Devices.*

5.4 Establishment shall ensure the wearable medical devices is comply to requirements stated in *MDA/GD/0026 Requirements for Labelling of Medical Devices.*

5.5 The use of Bahasa Malaysia on the labelling shall be required for home use wearable medical devices.

5.6 The establishments of wearable medical devices are obliged to perform post-market duties, including but not limited to reporting an incident, defects and

recall to MDA and ensuring appropriate investigation, to ensure the safety and performance of wearable medical device. Establishments may refer to the following guidance documents for further reference:

i. MDA/GD/0011 Complaint handling;

ii. MDA/GD/0012 Distribution records;

iii. MDA/GD/0013 Field Corrective Action (FCA);

iv. MDA/GD/0014 Mandatory Problem Reporting; and

v. MDA/GD/0015 Medical Device Recall

6 Examples of wearable products

The list of wearables products that classified as medical device and non-medical devices are as listed as below.

6.1 Wearable medical devices

a) Wrist-worn watch that sends electrocardiogram (ECG) rate, heart rate, Spo2, blood pressure, body temperature, breathing rate of a cardiac rehabilitation patient to a server for monitoring by a qualified healthcare professional.
b) Smartwatch that stores historical blood pressure information for a healthcare professional's later review.
c) Wearable medical device intended for use by patients with multiple chronic conditions that receives data from sensors, transmits data to the monitoring server, and identifies higher-level information such as tachycardia and signs of respiratory infections based on established medical knowledge and communicates this information to healthcare professional.
d) A wearable ECG monitor that analyses the wearer's cardiac rhythm for the purpose of screening for a serious heart condition.
e) Hospital wearable defibrillator continuously monitor patient's ECG for patients having high risk sudden cardiac arrest or ventricular tachycardia by administering a defibrillation shock in 60 seconds or less.
f) Wearable medical device which can control and/or monitor pacemaker.
g) Wearable exoskeleton rehabilitation robots worn on the patient's hand for treatment of damaged hand motor function caused by neuro-muscular-skeletal injuries.

Note: The above list is non-exhaustive and may be subject to change by Authority.

6.2 Wearable device not classified as medical device

a) Wrist-worn watch that stores walking distance, speed and number of steps taken to monitor healthy lifestyles.
b) Software of wearable device intended for maintaining or encouraging a healthy lifestyle, such as general wellness devices.
c) The monitoring of general fitness, general health (BMI, stress) and general wellbeing and do not produce medical purposes.

d) A smartwatch that monitors sleep and movement to assess and report on quality and quantity of sleep.
e) A wearable medical device that allows the wearer to track their heart rate for fitness.
f) A wearable medical device that records and tracks physiological measurements such as blood pressure, blood test results as part of a personal health record.
g) Heart-rate monitors in smart phones or smart watches for wellness purposes and not for medical diagnosis.
h) (SpO2) meters for use by athletes and not intended for medical diagnosis or monitoring purposes.

Note: The above list is non-exhaustive and may be subject to change by Authority.

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