MDS – G025

Guidance on General Wellness Devices

Version Number: 1.0
Version Date: 12/03/2025

MDS-G-025-V1/250312

Table of Content

Introduction

In recent years, many new products and technologies have emerged in the domain of healthcare, such as wearable health devices, mobile health (mHealth), health information technology (HIT), and telemedicine. Some of these products are referred to as general wellness devices, and it is not always clear whether they fall under medical devices law and its implementing regulation.

General wellness devices are designed to promote overall well-being without being related to diagnosis, cure, mitigation, prevention, or treatment of a disease or condition (see definition of "Medical Device" in Annex 1). These devices can include both software and hardware products, such as video games, advanced digital gym equipment, software programs, mobile apps, and wearable devices. Examples of claims related to a healthy lifestyle for general wellness devices include, but not limited to, physical fitness, weight management, stress management, self-esteem, and sleep management.

Purpose

This guidance aims to clarify when health-related devices are considered as general wellness devices or medical devices.

Scope

This guidance applies to health-related devices with various intended uses.

This guidance is relevant for establishments aiming to to market health-related devices in KSA, as well as for users of these products.

For the purpose of this document, the definition of manufacturer apply to the manufacturer of general wellness devices as well.

Background

SFDA has issued this guidance document in accordance to the “Law of Medical Devices” issued by the Royal Decree No. (M/54) dated 6/7/1442 H through:

- Article 8 stipulated that “ Medical devices may not be circulated unless registered and a marketing authorization is obtained. The SFDA may exempt certain medical devices and supplies from the marketing authorization requirement upon verifying, in accordance with rules approved by the Board, that they are safe and are not intended to be used for commercial purposes.”
- Article 11 stipulated that “Imported medical devices may not be cleared unless approved by the SFDA.”

Qualification as Medical Device

Criteria

Whether health-related devices, sometimes presented as general wellness devices, qualify as medical devices depends on their intended use, which is determined by the manufacturer. Information in product labeling (marking), technical specifications, instructions for use, and any accompanying documents provided by the manufacturer should clearly indicate the intended purpose of the product. If the manufacturer intends the device to be used for purposes defined asmentioned in the definition of a “Medical Device” as stated in the “Medical Devices Law”, (see Annex (1)), such as prevention, investigation, detection, diagnosis, treatment, alleviation, compensation, replacement, monitoring, controlling, support or management of medical conditions, diseases, anatomical functions, or physiological processes, the device will be considered as a medical device, regardless if it is presented as a general wellness device. On the other hand, a device qualifies as a general wellness device if it:

1. Makes a general wellness claim without any reference to a medical condition or disease, and presents a low risk to the safety of users and other persons.

   Or

2. Makes a general wellness claim that make reference to a chronic disease, as long as the intended use of the device relates to living well with that the disease or mitigates the impact of that disease on people’s well-being, and presents a low risk to the safety of users and other persons.

If the general wellness device is invasive, or implanted, or involve a technology that can pose a risk to the safety of users or other persons, it shall comply with medical devices law and its implementing regulation, even though it has no intended medical purpose.

For some chronic diseases, such as type 2 diabetes, high blood pressure, and heart disease, it is well understood that a healthy lifestyle can reduce the impact of these diseases on well-being. Disease-related devices with a general wellness claim can still qualify as general wellness

devices as long as the claim is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition. Even if these devices make reference to a disease or condition, they differ from medical devices in that they are intended to help in reducing the impact of certain chronic diseases or conditions on people's lives, in the sense that it is well understood that healthy lifestyle is associated with living well with that disease or condition.

Examples

Health-related devices with possibly a general wellness claim that qualify as medical devices:

- Mobile app that monitor blood glucose level intended for managing type 2 diabetes.
- Software program that claims to treat or diagnose obesity.
- Mobile app that claims to treat an anxiety disorder.
- Digital gym equipment with a wearable chest strap to monitor heart rate that claims to detect signs of cardiovascular disease.

Health-related devices that qualify as general wellness devices:

- Fitness tracker that counts steps, log and track daily exercise activity, and make exercise or posture suggestions.
- Mobile app that promotes physical activity to maintain a healthy weight, which, as part of a healthy lifestyle, can help living well with high blood pressure.
- Software program that promotes healthy eating and provide tools for dietary tracking, calories counting, and dietary suggestions.
- Mobile app that promotes relaxation, track sleep pattern, and promotes healthy sleep habits which, as part of a healthy lifestyle, can help living well with stress.
- Wearable arm strap that monitor real-time heart rate during exercise, provide workout guidance, and recommend the right exercise intensity for individual's goals.
- Mobile app that provides educational information, reminders, or motivational guidance for smokers trying to quit.

In a situation where a health-related device with a general wellness claim is recommended, used, or prescribed by medical professionals for purposes that fall within the definition of a "Medical Device" as stated in the "Medical Devices Law" (listed in Annex (1)), and the manufacturer is aware of such use, the health-related device is "de facto" a medical device and thus subject to the requirements of medical devices law and its implementing regulation.

Regulatory Approach

The manufacturer of a health-related device shall comply with the "Requirements for Medical Devices Marketing Authorization (MDMA) (MDS-REQ 1), if:

1. The product qualifies as a medical device; or
2. The product qualifies as a general wellness device and is invasive, or implanted, or involves a technology that can pose a risk to the safety of users or other persons, even if it has no medical claim.

Labeling

If the health-related device qualifies as a general wellness device, the manufacturer shall clearly state in the labeling that the device is not intended for medical purpose.

Annexes

Annex (1): Definitions

Medical Device	Any instrument, apparatus, implement, implant device, in vitro reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; disinfection of medical devices and supplies; providing information for medical or personal purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
General Wellness Device	Product without a medical claim, the use of which can contribute to the wellbeing of individual persons.
Health-related Device	For the purpose of this document, either a medical device or a general wellness device.
Manufacturer	Any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
Mobile Health Application	App intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care.
Telemedicine	Use of advanced telecommunication technologies to exchange health information and provide healthcare services across geographic, time, social and cultural barriers.
Risk	Combination of the probability of occurrence of harm and the severity of that harm.

Annex (2): Further Relevant Reading

- Saudi Food and Drug Authority (SFDA). 2021. *Implementing Regulation of the Law of Medical Devices.*
- Saudi Food and Drug Authority (SFDA). 2021. *Requirements for Medical Devices Marketing Authorization (MDS-REQ 1).*
- Saudi Food and Drug Authority (SFDA). 2024. *Guidance on Artificial Intelligence (AI) and Machine Learning (ML) Enabled Medical Devices (MDS-G010).*
- Software as a Medical Device (SaMD): Key Definitions (IMDRF/SaMD WG/N10FINAL:2013)
- ISO/TS 82304-2:2021 *Health software — Part 2: Health and wellness apps — Quality and reliability*
- ISO/TR 16056-1:2004 *Health informatics — Interoperability of telehealth systems and networks — Part 1: Introduction and definitions*