MDS – G27

Guidance on Digital Health Products

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Introduction

Purpose

The purpose of this guidance is to clarify the categories of digital health products that fall under the regulatory scope of the Saudi Food and Drug Authority (SFDA). It provides an overview of the major categories within digital health, outlines the regulatory approach for such technologies, and clarifies the distinction between what qualifies as a regulated medical device and what falls under general wellness products.

Scope

This guidance applies to digital health products with various technologies. It is intended to support medical device manufacturers and software developers seeking to obtain Medical Devices Marketing Authorization (MDMA) for digital health products within KSA, as well as for end users of these products.

This guidance covers the following key categories within the digital health field:

- Software as a Medical Device (SaMD).
- Mobile Health Applications (mHealth apps).
- Digital Therapeutics (DTx).
- Health Information Technology (HIT).
- Telemedicine.
- Wearable Devices.
- Virtual Reality & Augmented Reality (VR/AR).
- Artificial Intelligence and Machine Learning (AI/ML).
- General Wellness Devices.

Background

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

1. Digital Health Products

Digital health refers to the use of Information and Communication Technologies (ICT) to improve health outcomes and optimize the delivery of healthcare services. Digital health technologies have a wide range of uses, ranging from public health applications to medical device applications.

1.1. Qualification of Digital Health Products as Medical Devices

Medical device that incorporate digital health technologies is defined as a product or solution that incorporates software, connectivity, sensors or digital tools and is intended for medical purposes. These applications may be intended for use as standalone medical devices, integrated within a medical or diagnostic device, or as adjunct tools that support the use of other medical products such as devices, drugs, or biologicals.

Whether a digital health product qualifies as a medical device depends on its intended use, as defined 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 falling within the definition of a "Medical Device" under the “Medical Devices Law”, 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 qualified as a medical device.

1.2. Categories of Digital Health Products

1.2.1. Software as a Medical Device (SaMD)

The International Medical Device Regulators Forum (IMDRF) provides a widely accepted definition for SaMD:

"Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." (IMDRF SaMD Working Group, 2013).

The majority of digital health products fall within this category. SaMD refers exclusively to standalone software, and include software intended for in vitro diagnostic (IVD) purposes. It can function independently or in conjunction with other products, and may interface with other software, hardware, or general-purpose platforms to fulfill its intended medical purpose. SaMD may operate on either a general-purpose computing platform (e.g., a smartphone or PC) or a medical-purpose computing platform. In contrast, software that is embedded within a hardware medical device and intended to operate, drive, or control that device is not considered SaMD. Such software is referred to as Software in a Medical Device (SiMD) and is outside the scope of this guidance.

Standalone software that is intended to drive or influence the use of a hardware medical device is not necessarily considered SaMD. Its regulatory qualification depends on whether it serves a medical purpose.

- If the software drives or influences a hardware medical device and has a medical purpose, it qualifies as SaMD and is regulated independently.
- If the software drives or influences a hardware medical device but lacks a medical purpose of its own, it is considered as an accessory and is regulated accordingly.
- If the software solely intended to operates or controls a hardware medical device without contributing to any medical functionality, it is not considered SaMD, although

it may still be subject to regulation as an accessory if it supports the device's functionality.

Table 1 summarizes these scenarios and their corresponding regulatory implications.

Scenario	Qualification	Regulatory Implication
The software drives/influences a hardware medical device and has a medical purpose	SaMD	Regulated independently as SaMD
The software drives/influences a hardware medical device but does not have a medical purpose on its own	Accessory	Considered an accessory to the medical device and regulated accordingly
The software is solely used to operate or control a hardware device without medical functionality	Not SaMD, but may be an accessory	- Regulated only if it is intended to assist the functionality of the device

Table 1. Qualification of standalone software that is intended to drive or influence a hardware medical device.

See (Figure 1) for an overview of the regulatory decision flow for software qualification as a medical device.

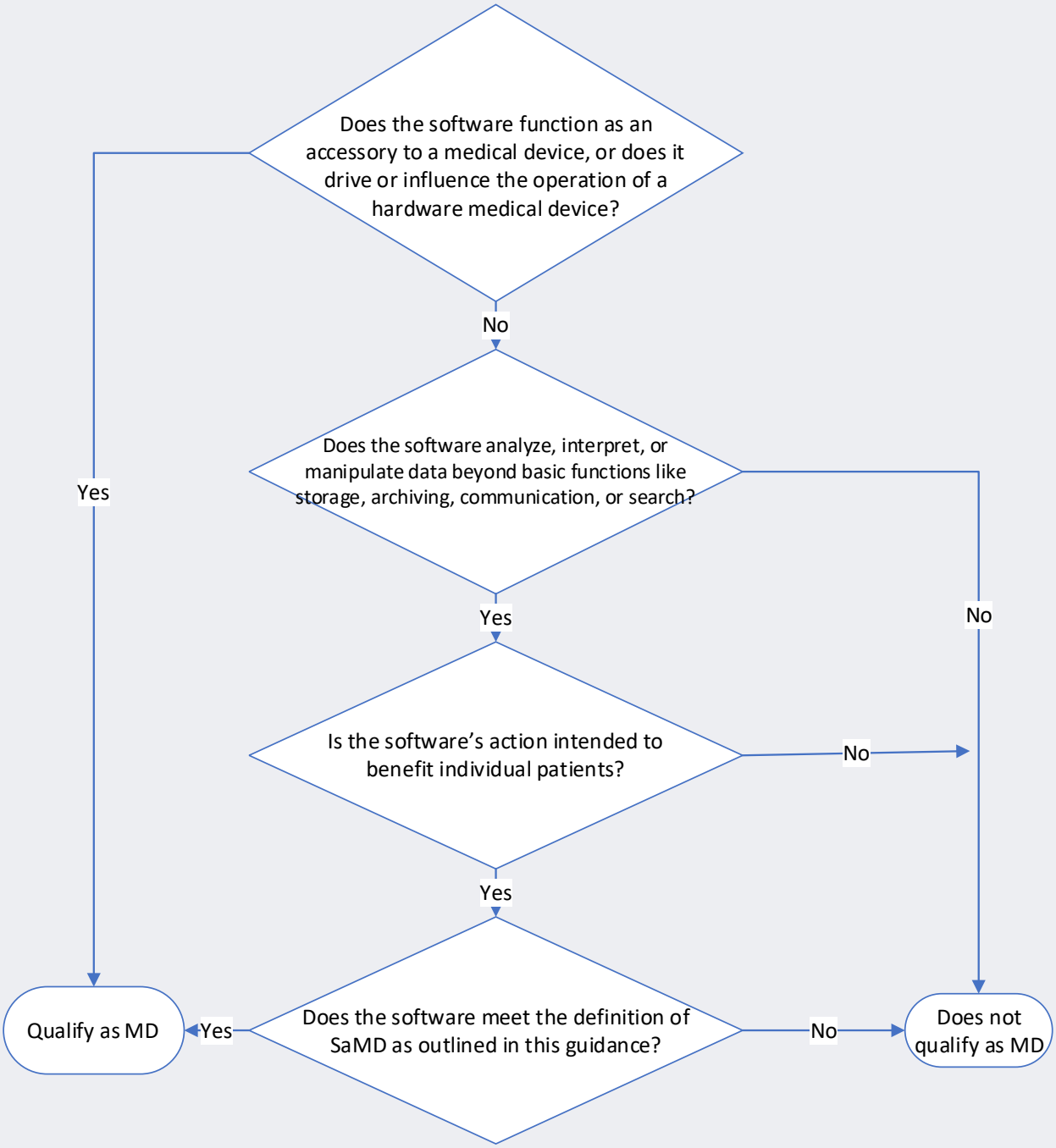

Figure 1. Regulatory decision pathway for software qualification.

When SaMD meets the definition of an IVD medical device, it falls under the regulatory framework for IVD medical devices, as outlined in (MDS-REQ 1). Furthermore, if the SaMD is explicitly intended by its manufacturer to be used in conjunction with an IVD medical device (meaning that it operates independently but complements the IVD device to enable it to achieve its intended purpose), it is also considered within the scope of the IVD regulation and shall be treated as an IVD SaMD in its own right (see Figure 2).

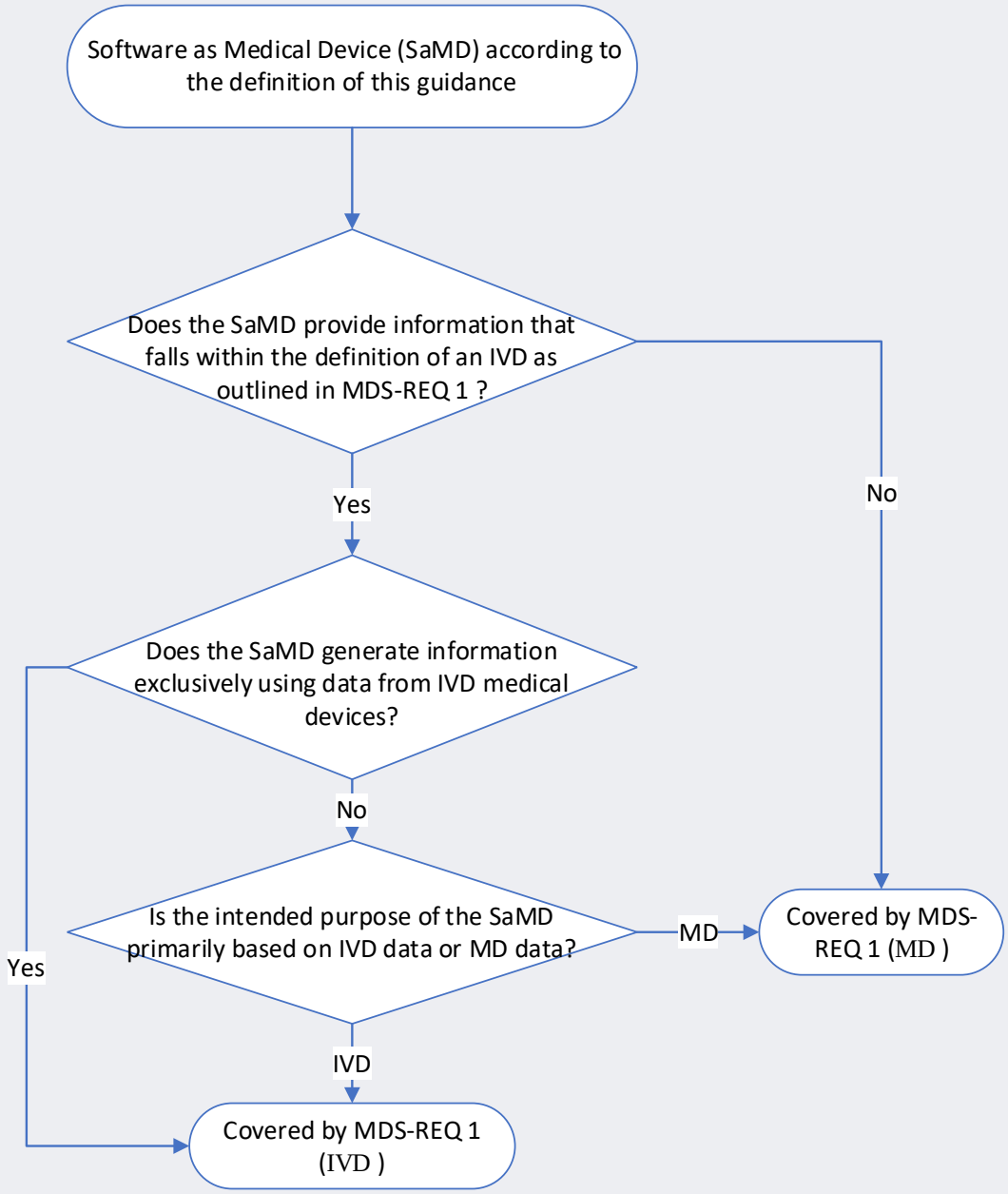

Figure 2. Pathway for determining SaMD qualification as IVD or MD.

Example of SaMD:

- Software that monitors vital signs (e.g., heart rate, blood glucose levels) and alerts patients or healthcare providers to critical changes. This software has a direct medical purpose of detecting and managing a health condition.

Examples of non-SaMD:

- Educational or informational software that provides general health or medical knowledge without offering patient-specific diagnoses, treatment recommendations, or clinical decisions support. These tools support awareness and education but are not considered medical devices.
- Communication software used for general interaction between patients and healthcare providers (e.g., secure messaging platforms) that do not analyze or interpret clinical data. While they facilitate healthcare communication, they lack a standalone medical function.
- Population-level analytics tools designed to identify health trends or patterns across groups without targeting individual patient diagnosis or treatment. These are used for public health or operational insights rather than direct patient care.

1.2.2. Mobile Health Applications (mHealth Apps)

A Mobile health application (mHealth app) is a software program designed to operate on mobile devices, such as smartphones, tablets, and wearables, with the purpose of performing one or more functions related to health, healthcare, or wellness. These apps often leverage the built-in features of mobile devices, such as camera, light sensors, vibration alerts, and motion detectors, to perform health-related functions. The goals are often to improve patient outcomes, enhance access to healthcare, increase healthcare efficiency, and empower individuals in managing their own health. They often intersect with telemedicine, particularly when mobile apps facilitate communication, health data tracking, or remote patient monitoring. When an mHealth app meets the definition of SaMD, it is regulated as SaMD and is generally used in one of the following ways:

- As a standalone app that transforms a mobile platform into a regulated medical device.
- As an accessory to a regulated medical device, supporting its medical functionality.

Examples of mHealth apps that qualify as medical devices:

- An app that helps epilepsy patients track seizure episodes and generates reports for their healthcare providers.
- An app that uses a smartphone’s built-in sensors to monitor blood glucose levels and recommend insulin dosage adjustments for diabetic patients.
- An app that processes medical imaging (e.g., radiology scans) to assist healthcare professionals in diagnostic decision-making.

Examples of mHealth apps that do not qualify as medical devices:

- An app that sends reminders for medication intake without managing dosage or providing drug-specific recommendations.
- An app that allows users to log meals and calculate nutritional content for general wellness purposes.

1.2.3. Digital Therapeutics (DTx)

Software-based interventions designed to treat, manage, or alleviate diseases, disorders, conditions, or injuries. DTx are evidence-based therapeutic interventions that have been clinically validated to produce measurable improvements in patient health outcomes. DTx can be used as a standalone therapy or in combination with other treatments, such as pharmacological therapy or in-person care. The treatment relies on the collection, analysis, and application of digital health data, enabling personalized and adaptive treatment pathways. DTx utilizes a range of digital technologies, including apps, sensors, VR/AR, and the Internet of Things (IoT) to encourage behavioral change, support adherence, and monitor clinical progress in real time. DTx are considered a type of SaMD and generally subject to regulation as medical devices.

Examples of DTx:

- Software for the treatment of insomnia that delivers cognitive behavioral therapy (CBT) techniques to improve sleep quality.
- An app for chronic low back pain that provides personalized exercise programs and integrates physiotherapy, relaxation techniques, and patient education.

1.2.4. Health Information Technology (HIT)

Health information technology (HIT) refers to the hardware, software, and systems used by healthcare professionals to store, retrieve, manage, share, and analyze patient's health data to support clinical decision-making and improve healthcare delivery. Common examples of HIT systems include:

- Electronic health records (EHRs)
- Health information systems (HIS)
- Decision support systems (DSS)
- Electronic prescribing (e-prescribing) software

In general, HIT products are not considered medical devices unless they are specifically intended to analyze or interpret medical information for the purpose of diagnosing, treating, mitigating, curing, or preventing a disease or health condition. In such cases, the product may be subject to regulatory oversight as a medical device. Some HIT products may consist of multiple integrated modules, but only certain modules meet the definition of a medical device. In such cases, only the modules that independently qualify as medical devices are subject to regulatory oversight. Accordingly, only the regulated module(s) should be submitted for regulatory review. The remaining non-medical modules are not required to be included in the submission, provided that their separation and non-medical function are clearly documented.

A HIT product does not qualify as a medical device if it is:

- Intended solely for administrative or communication support, such as appointment scheduling, patient admission, billing processing, or secure messaging. Examples include pharmacy systems used for medication dispensing and prescribing software used by physicians that facilitate documentation or workflow without performing clinical decision-making.
- Designed exclusively to store, transfer, convert formats, or display medical data or test results without any analysis or interpretation of the data. For instance, a clinical information system (CIS) that receives and stores data from a medical device, allowing

healthcare professionals to access and review the information at a later time, would fall into this category.

Examples of HIT that qualify as medical devices:

- A laboratory information management system (LIMS) that automatically interprets lab results and generates potential diagnostic suggestions.
- A clinical decision support system (CDSS) that monitors patient data in real time and generates alerts for abnormal conditions requiring medical intervention.
- A voice scribe system that transcribes clinician-patient interactions and generates diagnostic suggestions.

1.2.5. Telemedicine

Telemedicine refers to the use of telecommunication technologies to deliver healthcare services remotely, including clinical consultations, diagnosis, treatment, and patient monitoring. Telemedicine systems may consist of hardware, software, or integrated digital platforms that enable healthcare professionals to provide medical care without requiring in-person interaction. Telemedicine is commonly categorized into three functional domains:

- Tele-collaboration: Communication and coordination between healthcare professionals, such as case referrals, obtaining second opinions, or collaborative diagnosis.
- Tele-treatment: Remote delivery of clinical care, including digital diagnostics, and interventions using technologies such as robotic-assisted surgery.
- Tele-monitoring: Remote collection, transmission, and clinical use of patient health data for ongoing monitoring and decision-making.

The software and tools used in telemedicine, particularly those intended for diagnosis, monitoring, or treatment, are typically subject to medical device regulation.

Example of a telemedicine application that qualifies as a medical device:

- A remote diagnostic platform that allows radiologists to access and interpret DICOM images.

Example of a telemedicine application that does not qualify as a medical device:

- General-purpose video conferencing tools used solely for communication—without integrated medical functionality.

1.2.6. Wearable Devices

A wearable medical device is defined as a device designed to be worn on the human body or attached to clothing for the purpose of monitoring health parameters, detecting physiological abnormalities, and, in some cases, delivering medical interventions. These devices typically integrate biosensors and software to collect, process, and sometimes act upon health-related data. Wearables that primarily collect general health or wellness data, such as heart rate or physical activity, are not typically qualified as medical devices, especially when they do not provide clinical interpretation or medical decision support.

Example of a wearable device that qualifies as a medical device:

- A wearable device that tracks general sleep patterns without offering diagnostic insights.

Example of a wearable device that does not qualify as a medical device:

- A wearable device that performs a medical assessment function or is used in conjunction with a regulated medical product, such as a smartwatch designed to detect irregular heart rhythms and alert the user to seek medical evaluation.

Common classifications of wearable medical devices:

1. Skin-based wearable devices: These devices are designed for non-invasive monitoring through skin contact. They are widely used for physiological and psychological tracking, supporting the diagnosis and management of conditions such as cardiovascular, respiratory, or neuromuscular disorders. For example, ECG patches, and wearable thermometers.
2. Biofluid-based wearable devices: These wearables analyze body fluids such as sweat, saliva, tears, or urine, which contain valuable biomarkers for continuous monitoring and diagnostic purposes. For example, sweat-based glucose monitors, and tear-analyzing smart contact lenses.

1.2.7. Virtual Reality & Augmented Reality (VR/AR)

VR and AR technologies in healthcare refer to immersive and interactive systems designed to support clinical, therapeutic, diagnostic, or rehabilitative purposes. VR fully immerses the user in a computer-generated, simulated environment, while AR enhances the real-world environment by overlaying digital content onto physical surroundings. These technologies are increasingly being integrated into medical devices to enhance patient care and clinical outcomes. VR and AR applications used solely for medical education, clinical training, or general wellness, without a diagnostic or therapeutic purpose, are not classified as medical devices.

Examples of medical applications of VR and AR technologies in regulated medical devices include:

- Assisting in surgical planning and intraoperative navigation.
- Delivering non-pharmacological pain management therapy.
- Supporting behavioral or cognitive rehabilitation, such as in cases of post-traumatic stress disorder (PTSD) or anxiety disorders.
- Facilitating physical therapy and motor skill recovery in post-injury or post-stroke patients.

1.2.8. Artificial Intelligence and Machine Learning (AI/ML)

AI/ML are technologies that enable software systems to learn from data, adapt, and improve performance over time without being explicitly programmed. In healthcare, AI/ML has the potential to enhance a wide range of applications, from early disease detection and diagnosis to workflow optimization, clinical decision support, and treatment planning. AI/ML-enabled software that meets a medical purpose is typically regulated as SaMD. However, AI/ML introduces unique complexities requiring enhanced regulatory approaches to ensure safety, effectiveness, transparency, and ethical use. The SFDA has established additional regulatory requirements specific to AI/ML-enabled medical devices. These focus on the following areas:

- **Validation & Verification (V&V):** Algorithms must be tested using diverse, high-quality datasets to demonstrate safety and effectiveness.
- **Data Quality & Governance:** Strict protocols must ensure data integrity, accuracy, privacy, and traceability throughout the entire device lifecycle.
- **Transparency & Explainability:** Clear documentation of algorithm functionality, limitations, and biases is required to support clinical understanding.
- **Risk Management:** A comprehensive framework must address potential risks including bias, cybersecurity, data privacy, and unintended outcomes.
- **Human Oversight:** The role of healthcare professionals must be defined, with safeguards for human review and intervention.
- **Lifecycle & Change Management:** Procedures must govern updates, re-validation, post-market performance monitoring, and documentation of algorithm changes.

2. General Wellness Devices

A digital health product qualifies as a general wellness device if it meets either of the following criteria:

1. Makes a general wellness claim that does not reference any specific medical condition or disease.
   Or
2. Makes a general wellness claim that references a chronic disease, provided that the intended use of the device relates to living well with that disease or mitigating its impact on individuals' well-being.

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. General wellness devices with a disease-related 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 reference a disease or condition, they differ from medical devices in that they are intended to reduce the impact of certain chronic diseases or conditions on individuals' lives—based on the widely accepted understanding that a healthy lifestyle contributes to improved quality of life for those living with such conditions. In a situation where a general wellness device 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", and the manufacturer is aware of such use, the device shall be subject to SFDA assessment to determine whether it should be classified as a medical device and regulated accordingly under the Medical Devices Law and its implementing regulation. Any identified off-label medical use of the product shall be promptly reported to the SFDA.

2.1. Labeling

If the digital health product qualifies as a general wellness device, the manufacturer shall clearly state in the labeling (in both Arabic and English) that the device is not intended for medical purposes.

3. Regulatory Provisions Governing Digital Health Products

Manufacturer of digital health product shall comply with the "Requirements for Medical Devices Marketing Authorization (MDMA) (MDS-REQ 1), if the product qualifies as a medical device.

An additional number of regulatory documents that constitute guidance governing medical devices that incorporate digital health technologies include:

- MDS-G23: Guidance on Software as a Medical Device.
- MDS-G10: Guidance on Artificial Intelligence (AI) and Machine Learning (ML) technologies based Medical Devices.
- MDS-G38: Guidance on Pre-Market Cybersecurity of Medical Devices.

Annexes

Annex (A): Definitions and Abbreviations

SFDA	Saudi Food and Drug Authority
KSA	Kingdom of Saudi Arabia
MDMA	Medical Device Marketing Authorization
Medical Device	Any instrument, apparatus, implement, implant, 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; sterilization of medical devices; providing information for medical or diagnostic 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.
In Vitro Diagnostic (IVD)	Means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.
Digital Health Medical Device	Software or digital technology-based device intended for medical purposes.
General Wellness Device	Product without a medical claim, the use of which can contribute to the wellbeing of individual persons.
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.
Risk	Means the combination of the probability of occurrence of harm and the severity of that harm.
Accessory for a medical device	Any material or product intended specifically to be used with a medical device or supply to enable it to achieve its purpose.
Software driving or influencing the use of a device	Software which is intended to drive or influence the use of a (hardware) medical device. It does not independently serve a medical purpose or generate information for medical use, as defined under medical device or IVD medical device regulations.
AI	Artificial Intelligence
ML	Machine Learning
MD	Medical Device

IVD	In Vitro Diagnostic
MDS	Medical Devices Sector
SaMD	Software as a Medical Device
SiMD	Software in a Medical Device
IMDRF	International Medical Device Regulators Forum
IoT	Internet of Things