REGULATORY GUIDELINE FOR TELEHEALTH PRODUCTS

Medical Devices Branch

April 2019

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INTRODUCTION

1.1 Objective

The Health Sciences Authority (HSA) is issuing these guidelines to provide clarity on the types of Telehealth products that are regulated as medical devices, as well as its current regulatory approach and requirements for such products regulated by HSA. The guidelines reflect HSA's current policy stance and practice, and should not be misconstrued as a new regulatory control on Telehealth products.

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1.2 Background

Telehealth products are instruments, apparatus, machines or software (including mobile applications) that are involved in the provision of healthcare services over physically separate environments via infocomm technologies (including mobile technology), categorised into four broad domains:

- Tele-collaboration;
- Tele-treatment;
- Tele-monitoring;
- Tele-support.

As not all Telehealth products in the market are medical devices, this document serves to provide clear guidelines on identifying a Telehealth medical device.

As a general rule, a Telehealth product **intended for medical purposes** such as investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process; will be classified as a medical device subject to regulatory controls by HSA.

In recent years, Telehealth technology has advanced at a rapid pace of innovation and introduced a myriad of benefits, along with some potential risks to public health. As part of Singapore's Smart Nation initiatives, HSA aims to refine and streamline its regulatory framework for Telehealth medical devices, so as to promote better innovation and efficiency in our healthcare sector.

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The regulatory approach adopted will be largely similar to the regulatory principles applied in the regulation of the other medical devices – they are:

- Risk-based regulation – HSA employs a rule-based approach (GN-13: Guidance on Risk Classification of General Medical Devices) to classify medical devices into four risk classes (A, B, C & D), according to the nature of the device and its intended functions. The level of scrutiny and regulatory requirements on a medical device will in turn commensurate with its risk class.
- Confidence-based regulation – The evaluation routes (e.g. Immediate Class B/C Registration route, Expedited Class C/D Registration routes and etc.) for medical devices are set out according to a confidence based approach by leveraging on the approvals of HSA's reference regulatory agencies and/or prior safe marketing history of the medical devices. The submission requirements (GN-15: Guidance on Medical Device Product Registration) are titrated according to the evaluation routes that the device qualifies.

This will allow faster access to new and innovative Telehealth medical devices to provide high quality Telehealth services to healthcare professionals, patients and consumers, whilst safeguarding public health.

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1.3 Scope

This document applies to all Telehealth products which include hardware devices, software and mobile applications, specifically on the classification and regulation of such products.
It does not cover the practice of Telehealth services as this falls out of HSA's purview.

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1.4 Definitions

PRODUCT OWNER (as stated in the Medical Device Regulations): in relation to a health product, is defined as a person who —
supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

TELEHEALTH: The provision of healthcare services over physically separate environments via infocomm technologies, categorised into four broad domains:

- Tele-collaboration;
- Tele-treatment;
- Tele-monitoring;
- Tele-support.

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TELE-COLLABORATION: It refers to interactions between (facility-based or mobile) onsite and remote healthcare professionals for clinical purposes e.g. referral, co-diagnosis, supervision or case review.

TELE-TREATMENT: It refers to the provision of direct clinical care e.g. triage, history, examination, diagnosis and treatment including robotic surgery from a remote location via infocomm technologies (including mobile technology).

TELE-MONITORING: It refers to biomedical and other forms of data collection directly from patients (or through caregivers) by remote systems, which are used by healthcare professionals for clinical purposes such as vital signs monitoring and home nursing. Tele-monitoring is used in remote chronic disease management e.g. management of hypertension (blood pressure), diabetes (blood glucose) and coronary heart disease (weight, ECG).

TELE-SUPPORT: It refers to the use of online services for non-clinical (i.e. educational and administrative) purposes to support the patient, caregiver or user.

TELEHEALTH PRODUCTS: All forms of devices, including hardware devices, software and mobile applications, used in the delivery of Telehealth services.

R2.0 ► WELLNESS DEVICE: A device or software which is intended by its Product Owner to be used only to enable or encourage the user of the device or software to adopt or maintain a healthy lifestyle, or for the user's general wellbeing, but not to be used for any specific medical purposes. ◄

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CATEGORISATION OF TELEHEALTH PRODUCTS AS MEDICAL DEVICES

The **intended use** of the Telehealth products will determine whether it will be regulated as a medical device. The intended use is reflected on the specifications, instructions and information provided by the Product Owner of the device.

If the Telehealth product is intended by the Product owner to be used for investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process, it is a Telehealth medical device and is subject to HSA's regulatory control.

On the other hand, if the Telehealth product is intended by the Product Owner to be used R2.0 ► as a wellness device ◄ (e.g. intended for fitness tracking), but is able to perform such medical function/ purpose (e.g. monitoring heart rate), Product Owners are required to include the following "clarification statement" (or equivalent) on their labels to clearly inform the users of the product's appropriate use:

R2.0 ► *"This device or software is intended for use only for general wellbeing purposes or to encourage or maintain a healthy lifestyle, and is not intended to be used for any medical purpose (such as the detection, diagnosis, monitoring, management 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 consult a physician for any medical advice required."* ◄

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CATEGORISATION OF TELEHEALTH PRODUCTS AS MEDICAL DEVICES

This information should be presented clearly to the users, where practicable (e.g. Packaging, Instructions for use (IFU) or splash screen/loading screen in a mobile application).

This is necessary to ensure that users do not misconstrue any health-related information accessed through these devices as medical advice. Users should still seek proper medical advice from a physician regarding any health-related issues.

For a step by step decision tree to determine whether a Telehealth product is a Telehealth medical device, please refer to Flowchart 1 for more details.

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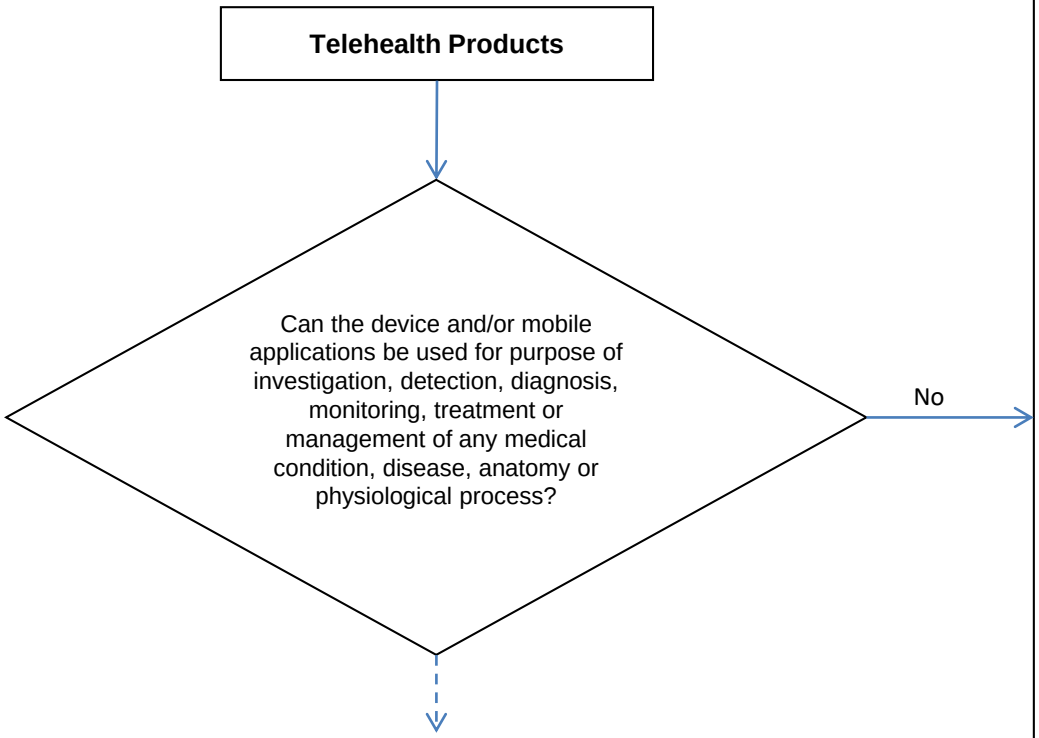
Flowchart 1: Is a Telehealth product a Medical Device?



Not medical device.

Examples:

1. Commercial off-the-shelf mobile platforms (e.g. generic smartphones and tablets) that are not intended to be used for medical purpose by the Product Owner.
2. Online educational medical information (Tele-support).
3. Webcam to monitor the movements of elderly people at home remotely (Tele-monitoring).
4. Apps that can calculate BMI or total water content based on specific input parameters but do not perform any diagnosis or therapeutic functions.
5. Telehealth products that are intended solely for communication purposes such as video conference systems that are intended solely to perform remote consultations between clinics and patients.
6. Software is intended solely for storing, retrieving of medical data and does not process the information for patient management/monitoring or diagnosis of medical condition.

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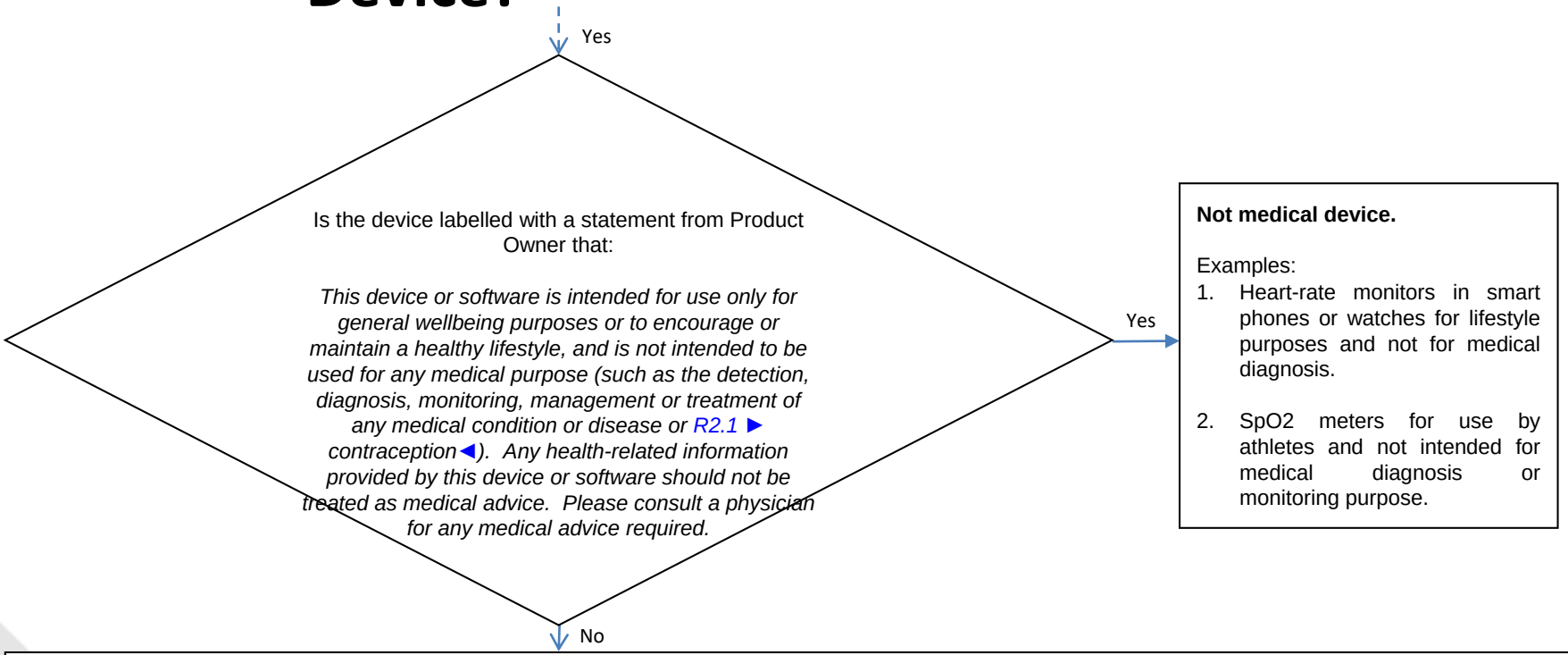
Flowchart 1: Is a Telehealth product a Medical Device?



The device is a Medical Device.

Examples:

1. Remote Surgical Systems that allow doctors to perform surgery on a patient even though they are not physically in the same location.
2. Remote patient monitoring device:
   - Software or application that monitors and transfers patient's data to a central viewing station for display and patient monitoring.
   - Software or application that displays ECG or other vital signs in remote location as transmitted from patient side for monitoring purpose.
3. Mobile medical apps that transform a mobile platform into a regulated medical device.
   - Mobile apps that use a sensor or lead that is connected to a mobile platform to measure and display the electrical signal produced by the heart (electrocardiograph or ECG).
   - Mobile apps that use an attachment to the mobile platform to measure blood oxygen saturation for diagnosis and monitoring of specific disease or condition.

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RISK CLASSIFICATION OF TELEHEALTH MEDICAL DEVICES

As with all other medical devices, the Telehealth medical devices are classified into different risk classification (as shown in Table 1), depending on the nature of the device and its intended functions.

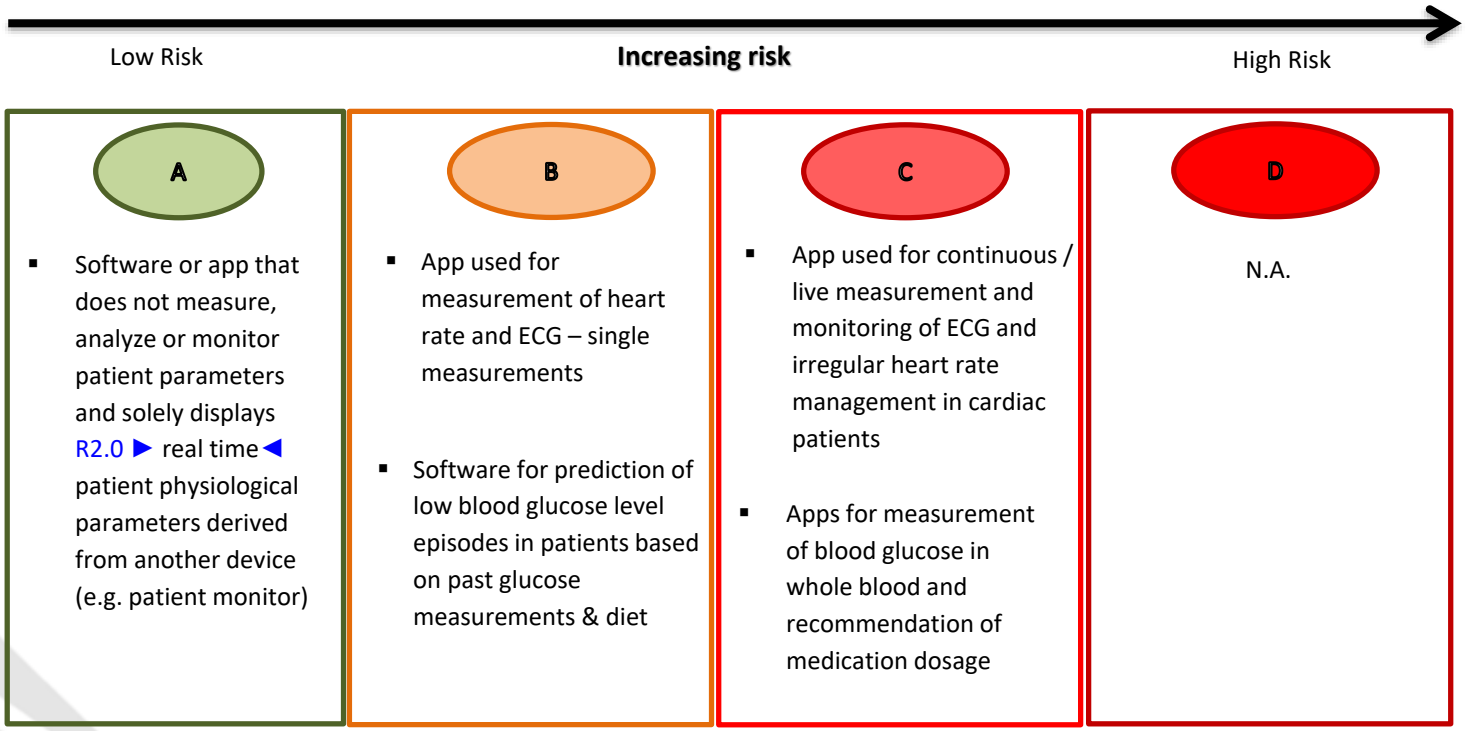

***Table 1**: Examples of Telehealth Medical Devices of various risk classes.*

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RISK CLASSIFICATION OF TELEHEALTH MEDICAL DEVICES

If the device is intended to monitor or predict any disease or medical conditions or to measure, analyze or monitor physiological parameters (e.g. SpO2, ECG measurement) it will be in a higher risk category as compared to a device that solely **displays** real time patient physiological parameters This is because of the greater impact on patient health and safety when the higher risk device fails.
Hence, the level of scrutiny and regulatory requirements on a medical device will commensurate with its risk class.

To determine the risk classification of Telehealth medical devices, please refer to Flowchart 2 (Risk Classification of Telehealth Medical Devices) for more details. The flowchart is based on the current risk classification rules as per GN-13 and is meant to provide guidance in layman terms.

The following sections are applicable to industry members that are dealing with Telehealth medical devices and standalone mobile applications that are medical devices.

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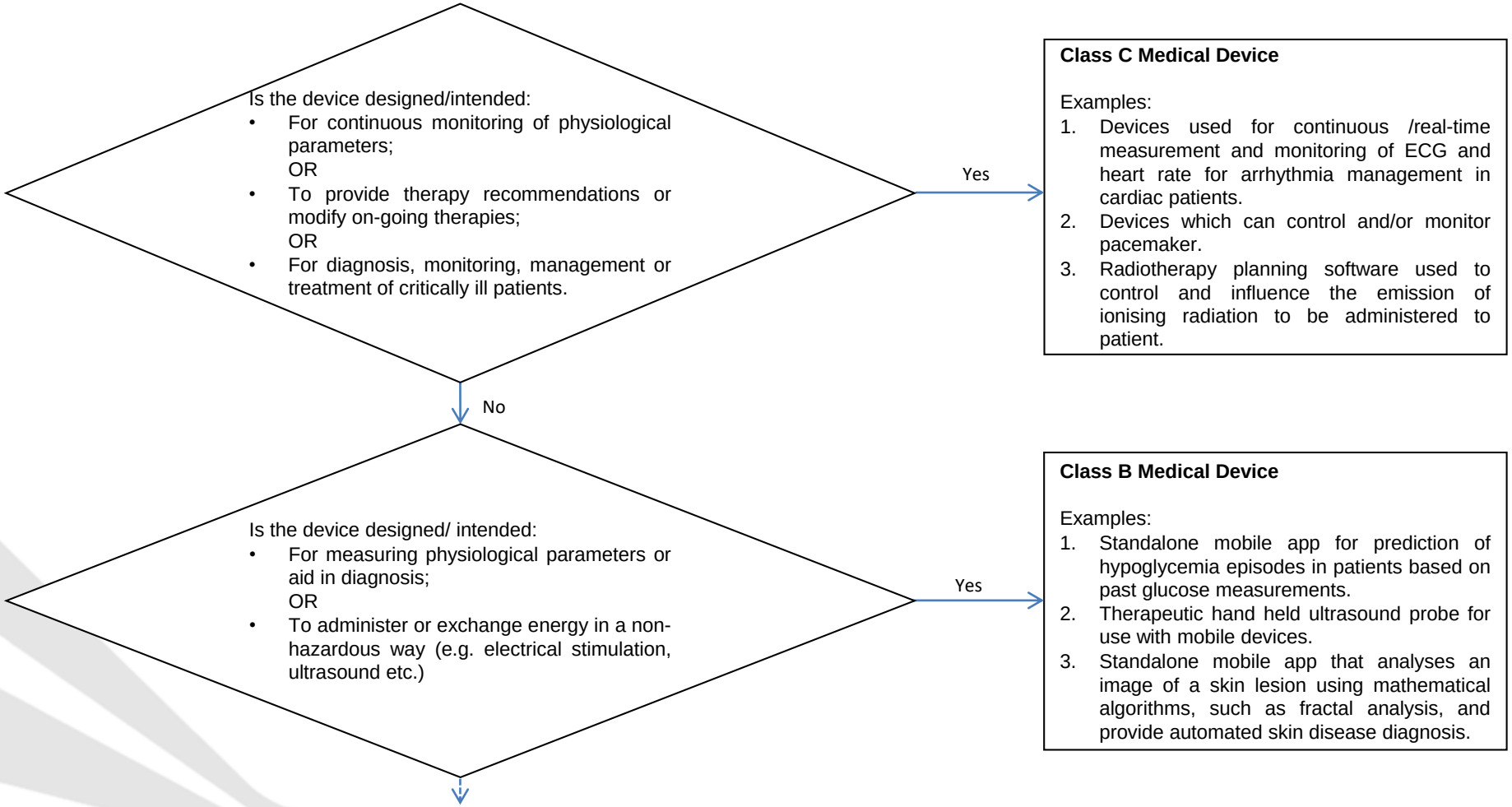
Flowchart 2: Risk Classification of Telehealth Medical Devices



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Flowchart 2: Risk Classification of Telehealth Medical Devices

No

Class A Medical Device

Examples:

1. Software or app that does not measure, analyse or monitor patient parameters and solely displays real-time patient physiological parameters (e.g. heart-rate, ECG and etc.).
2. R2.1 ►Mobile app that is intended to collect and measure the degree of tremor in patients with Parkinson's disease via the smartphone inbuilt accelerometer. The information is later sent to the physician for review where the app itself does not carry out any analysis of the patient condition.◄

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REGULATORY CONTROLS FOR TELEHEALTH MEDICAL DEVICES

Telehealth products that are “medical devices” (Telehealth medical devices) are subject to the following medical device regulatory controls:

a) Product Registration; (where applicable)
b) Dealer’s licence requirements;
c) Post-market obligations.

(a) Product Registration:

In order to supply a Telehealth medical device in Singapore, the company is required to obtain marketing clearance for the device from HSA via Product Registration before supply of the devices in Singapore unless the device is a Class A device. The submission requirements and process, depending on the risk class of the Telehealth medical device, will follow as per GN-15: Guidance on Medical Device Product Registration.

Please note that Class A Telehealth medical devices will have exemption from Product Registration with HSA. Therefore, such devices are able to be supplied immediately.

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REGULATORY CONTROLS FOR TELEHEALTH MEDICAL DEVICES

R2.0 ▶

Evaluation Route	Immediate (Class B MDs and Standalone Medical Mobile Applications)	Expedited (Class C and D MDs)	Abridged (Class B, C and D MDs)	Full (Class B, C and D MDs)
Criteria	Class B MDs • 2 Reference agencies approval • No prior rejection/withdrawal by/from any Reference agency or HSA **OR** • 1 Reference agency approval • 3 years marketing history • No major safety issues globally • No prior rejection/withdrawal by/from any Reference agency or HSA Standalone Medical Mobile application • 1 Reference agency approval • No major safety issues globally • No prior rejection/withdrawal by/from any Reference agency or HSA	Class C and D MDs • 2 Reference agencies approval • No prior rejection/withdrawal by/from any Reference agency or HSA **OR** Class C MDs • 1 Reference agency approval • 3 years marketing history • No major safety issues globally • No prior rejection/withdrawal by/from any Reference agency or HSA	1 Reference agency approval	No Reference agency approval
	Note: HSA's reference agencies: Health Canada, US FDA, Australian Therapeutic Goods Administration, European Union and Japan Ministry of Health, Labour and Welfare. Please refer to the corresponding approvals indicated in GN-15			

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***Table 2**: The eligibility criteria for evaluation routes.*

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REGULATORY CONTROLS FOR TELEHEALTH MEDICAL DEVICES

Local manufacturers and importers that are dealing with such Class A Telehealth medical devices only will be required to declare these devices in the Class A exemption list found under the importer's and manufacturer's licences and update the list prior to import. Like all other medical devices, Telehealth medical devices undergo changes as part of their product life cycle. Please refer to GN-21: Guidance on Change Notification for Registered Medical Devices to determine whether a Change Notification submission to HSA is required for specific proposed changes to a medical device that is registered on the Singapore Medical Device Register (SMDR).

(b) Dealers' Licence requirements:
If you want to engage in the manufacture, import and/or wholesale of Telehealth medical devices in Singapore, you will need to obtain the appropriate dealer licences from HSA. The submission requirements and process will follow as per GN-02: Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices. This licensing requirement is to ensure proper traceability and post-market monitoring of Telehealth medical devices marketed in Singapore.
R2.0 ► For companies dealing with only Class A medical devices (sterile or non-sterile), they may submit a declaration of conformity (DoC) to a Quality Management System, in lieu of the ISO 13485 or GDPMDS certification, for the application of manufacturer, importer or wholesaler licence. For more information, please refer to GN-02 Guidance. ◄

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REGULATORY CONTROLS FOR TELEHEALTH MEDICAL DEVICES

(c) Post-market obligations:
Dealers of Telehealth medical devices are obliged to perform post-market duties, including but not limited to reporting of adverse events, defects and recall to HSA and ensuring appropriate investigation, so as to assure the continued safe use of the devices.

Healthcare professionals and users of Telehealth medical devices may also report any adverse events related to the use of a medical device or device failure related issues to HSA on a voluntary basis.

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REGULATORY CONTROLS FOR STANDALONE MOBILE APPLICATIONS THAT ARE MEDICAL DEVICES

Standalone Mobile Applications refers to R2.0 ►*a software and/or mobile application that is intended to function by itself and are not intended for use to control or affect the operation of other hardware medical devices.*◄

Typically such "standalone" mobile applications include algorithm based calculators of specific parameters for use in clinical practice or for use in diagnosis or managing a disease or condition. Such applications are required to be designed based on formulas with established scientific evidence and clinical utility.

Where such Class B or Class C Standalone Medical Mobile application has been registered by one of HSA's reference agencies and its clinical utility has been reviewed by the agency, they may qualify for Immediate Registration Route.

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REGULATORY CONTROLS FOR STANDALONE MOBILE APPLICATIONS THAT ARE MEDICAL DEVICES

The eligibility criteria for the Immediate Registration Route at the point of submission are:

- Approval by at least one of HSA's independent reference agencies for intended use identical to that submitting for registration in Singapore

[HSA's independent reference regulatory agencies are i) Health Canada, ii) Japan's Ministry of Health, Labour and Welfare, iii) United States Food and Drug Administration, iv) Australian Therapeutic Goods Administration v) European Union Notified Bodies and the corresponding approvals indicated in GN-15.]

- No safety issues globally associated with the use of the medical device(s) when used as intended by the Product Owner, in the last three years or since the launch of the medical device(s) globally, defined as
  a. No reported deaths;
  b. No reported serious deterioration in the state of health of any person; and
  c. No open field safety corrective actions (including recalls) at the point of submission.

- R2.0 ►No prior rejection/withdrawal of the medical device by/from any reference regulatory agency/that foreign jurisdiction(s) or HSA/Singapore due to quality, performance/efficacy or safety issues. ◄

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REGULATORY CONTROLS FOR STANDALONE MOBILE APPLICATIONS THAT ARE MEDICAL DEVICES

R2.0 ► Please refer to GN-15: Guidance on Medical Device Product Registration for further details on product registration, including submission requirements, process, turn-around-time and fees.

Please note that other standard regulatory controls (i.e. Dealers' Licence and Post-Market obligations) are still applicable to standalone mobile applications that are medical devices.

With the widespread and rampant adoption and use of mobile applications and virtual distribution of these applications and devices globally, it is important to note that only local online platforms are within the local regulatory purview. ◄

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CONTACT INFORMATION

Medical Devices Branch

Medical Devices Cluster

Health Products Regulation Group

Health Sciences Authority

11 Biopolis Way, #11-03 Helios

Singapore 138667

www.hsa.gov.sg

Email: hsa_md_info@hsa.gov.sg

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