

1 CONSULTATION ON PROPOSED REGULATORY GUIDELINES FOR 2 TELEHEALTH DEVICES

3 1. Introduction

5 1.1 Objective

7 The Health Sciences Authority (HSA) invites feedback and comments from our
8 stakeholders to review the proposed regulatory guidelines on Telehealth devices.

9 As not all Telehealth devices in the market are medical devices, this guideline is
10 intended to provide clarity on the types of Telehealth devices that are medical
11 devices, as well as the proposed regulatory approach and requirements for such
12 Telehealth devices regulated by HSA.

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14 1.2 Background

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16 Telehealth devices are instruments, apparatus, machines or software (including
17 mobile applications) that are involved in the provision of healthcare services over
18 distance via infocomm technologies, categorised into three broad service areas:

- 19 • Clinical services e.g. Tele-radiology, Tele-consultation
- 20 • Education e.g. Educational web portals
- 21 • Administration e.g. Care management systems

22 Depending on the Telehealth device's intended purpose, it may be classified as a
23 medical device. Therefore, this document serves to provide clear guidelines on
24 identifying a Telehealth medical device.

25 As a general rule, a Telehealth device **intended for medical purposes** such as i)
26 the diagnosis of disease or medical conditions, or ii) the cure, mitigation, treatment,
27 or iii) prevention of disease, or iv) is intended to affect the structure or any function of
28 the body of humans; will be classified as a medical device that falls under the
29 purview of the HSA.

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

35 This regulatory approach adopted will be largely similar to the 2 regulatory principles
36 in the regulations of the other medical devices – they are:

- 37 • Risk-based regulation – HSA employs a rule-based approach ([GN-13:](#)
38 [Guidance on Risk Classification of General Medical Devices](#)) to classify
39 medical devices into four risk classes (A, B, C & D), according to the nature of
40 the device and its intended functions. The level of scrutiny and regulatory
41 requirements on a medical device will in turn commensurate with its risk class.
42
- 43 • Confidence-based regulation – The evaluation routes (e.g. Immediate Class B
44 Registration route, Expedited Class B/C/D Registration routes and etc.) for
45 medical devices are set out according to a confidence based approach by
46 leveraging on the approvals of HSA’s reference regulatory agencies and/or
47 prior safe marketing history of the medical devices. The submission
48 requirements are titrated according to the evaluation routes that the device
49 qualifies.

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

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54 **1.3 Scope**

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56 This document applies to all Telehealth devices with or without medical intent, which
57 include hardware devices, software and mobile applications.

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59 **1.4 Definitions**

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61 **PRODUCT OWNER (as stated in the Medical Device Regulations):** in relation to a
62 health product, is defined as a person who —

- 63 • supplies the health product under his own name, or under any trade mark,
64 design, trade name or other name or mark owned or controlled by him; and
- 65 • is responsible for designing, manufacturing, assembling, processing, labelling,
66 packaging, refurbishing or modifying the health product, or for assigning to it a
67 purpose, whether those tasks are performed by him or on his behalf.

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69 **TELEHEALTH:** The provision of healthcare services over distance via infocomm
70 technologies, categorised into three broad service areas:

- 71 • Clinical services e.g. Tele-radiology, Tele-consultation

- 72 • Education e.g. Educational web portals
73 • Administration e.g. Care management systems

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

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77 **2. Classification of Telehealth Devices as Medical Devices**

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79 The **intended use** of the Telehealth device will determine whether it will be classified
80 as a medical device. The intended use is reflected on the specifications, instructions
81 and information provided by the Product Owner or manufacturer of the device.

82 When the intended use of a Telehealth device is for i) the diagnosis of disease or
83 medical conditions, or ii) the cure, mitigation, treatment, or iii) prevention of disease,
84 or iv) is intended to affect the structure or any function of the body of humans, then it
85 is a medical device and is subject to HSA's regulatory control.

86 For a step by step decision tree if a Telehealth device is or is not a medical device,
87 please refer to Flowchart 1 for more details.

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89 **3. Telehealth devices intended for general well-being** 90 **purposes**

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92 In recent years, there is an increased adoption of general well-being/lifestyle devices
93 among the general population with the rapid growth of the Telehealth technology. A
94 general well-being device is typically intended to encourage users to maintain and
95 track their healthy lifestyle which include the following:

- 96 • A wireless wearable pedometer that counts each step a person takes as an
97 everyday exercise counter;
98
99 • Heart-rate monitors in smart phones or watches that is meant for tracking of
100 general fitness.

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102 Please note that such Telehealth devices intended for well-being or lifestyle purposes
103 will **not** be regulated as medical devices. For such devices, manufacturers are
104 required to include the following "clarification statement" (or equivalent) on their
105 labels:

106 *“The devices and/or mobile applications are not intended for use in the detection,*
107 *diagnosis, monitoring, management or treatment of any medical condition or disease.*
108 *Any health-related information accessed through the devices and/or applications*
109 *should not be treated as medical advice. Users should seek any medical advice from*
110 *a physician.”*

111 HSA would like to emphasise that users should not misconstrue any health-related
112 information accessed through these devices as medical advice. Users should still
113 seek proper medical advice from a physician regarding any health-related issues.

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133 **Flowchart 1: Is a Telehealth Device a Medical Device?**

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Telehealth Devices

Can the device and/or mobile applications be used for purpose of investigation, detection, diagnosis, treatment or management of any medical condition, disease, anatomy or physiological process?

No

Yes

Is the device labelled with a statement from product owner that:
The devices and/or mobile applications are not intended for use in the detection, diagnosis, monitoring, management or treatment of any medical condition or disease. Any health-related information accessed through the devices and/or applications should not be treated as medical advice. Users should seek any medical advice

Yes

No

Not medical device.

Examples:

1. Online educational medical information (Tele-support).
2. Webcam to monitor the movements of elderly people at home remotely (Tele-monitoring).
3. Apps that can calculate BMI or total water content based on specific input parameters but do not perform any diagnosis or therapeutic functions.
4. 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.
5. Telehealth devices 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. Telehealth devices that is intended solely to automate administrative operations in a health care setting such as automated billing system.

Not medical device.

Examples:

1. Heart-rate monitors in smart phones or watches for lifestyle purposes and not for medical diagnosis.
2. SPO2 meters for use by athletes and not intended for medical diagnosis or monitoring purpose

The device is a Medical Device

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 app that monitors and transfers patient's data to a central viewing station for display and active patient monitoring.
 - Software or app that displays ECG or other vital signs in remote location as transmitted from patient side.
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 of specific disease or condition.

4. Risk Classification of Telehealth Devices that are Medical Devices

As with all other medical devices, the Telehealth devices can also be classified into either one of the four Class A-D devices, depending on the nature of the device and its intended functions. If the device intends to monitor or predict any disease or medical conditions, then it will be in a higher risk category compared to a device which just displays a data. This is because of the greater impact on patient health and safety if the patient uses the Telehealth device and if it should not function as intended.

Hence, in lieu of the higher risk profile, the level of scrutiny and regulatory requirements by HSA will also vary accordingly. Below are examples of Telehealth devices of various risk classes.

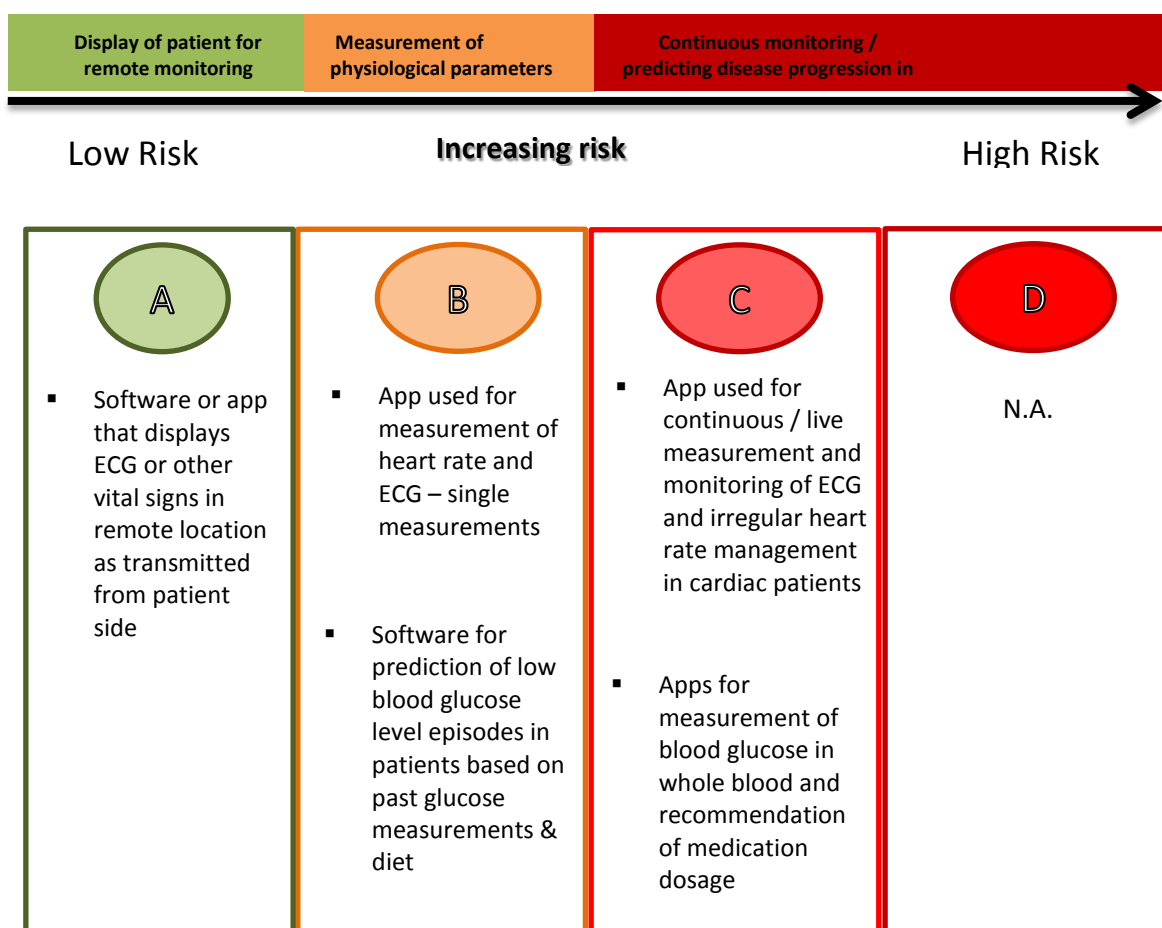
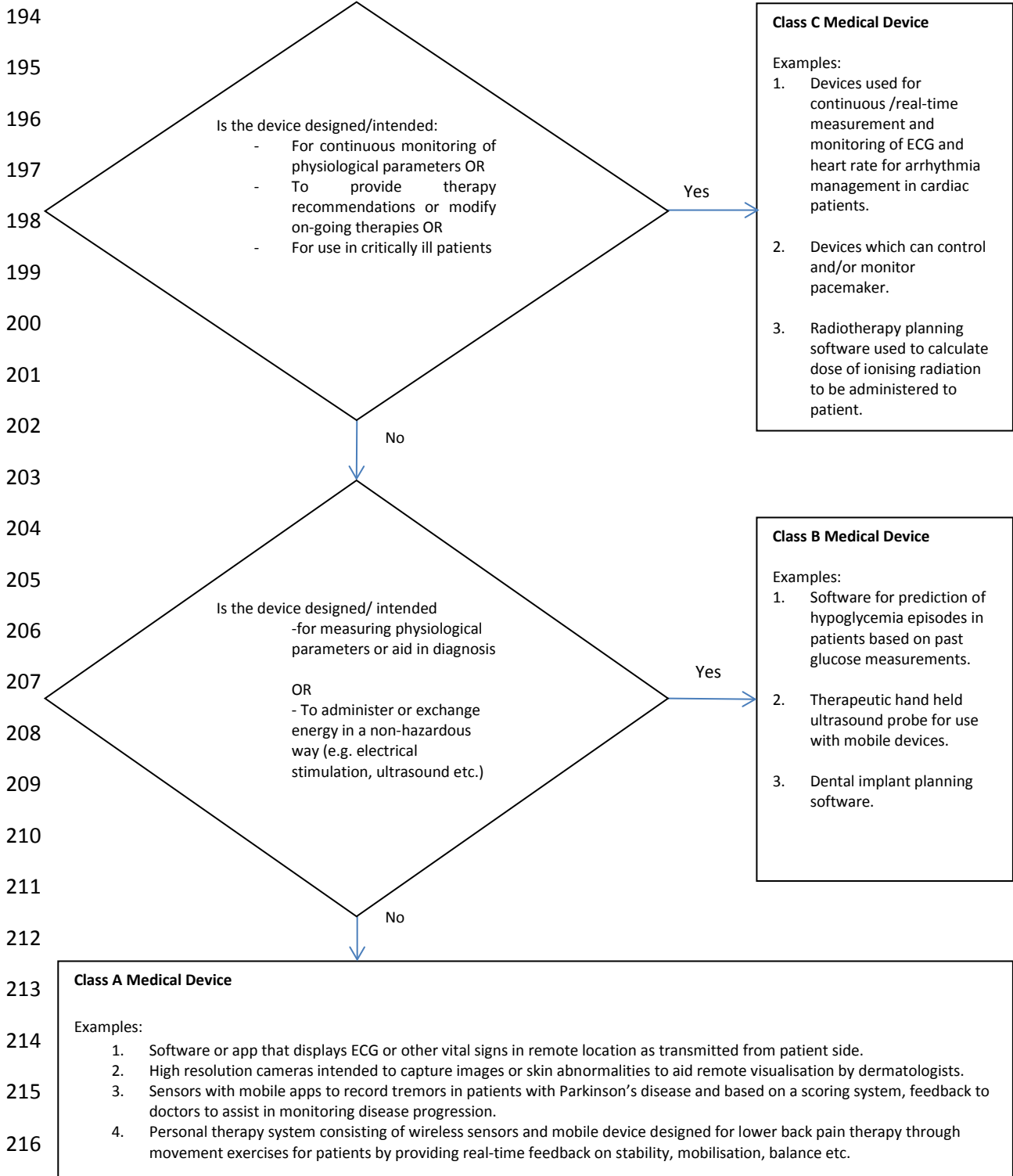


Table 1: Examples of Telehealth Medical Devices of various risk classes.

To determine the risk classification of Telehealth devices that are classified as medical device, please refer to Flowchart 2 (Risk Classification of Telehealth Medical Devices) for more details.

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

193 **Flowchart 2: Risk Classification of Telehealth Medical Devices**



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218 5. Proposed Regulatory Controls for Telehealth Devices

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220 Telehealth devices that are “medical devices” are subject to the following medical
221 device regulatory controls:

- 222 a) Product Registration;
223 b) Dealer’s licence requirements;
224 c) Post-market obligations.

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226 (A) Product Registration:

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228 If you want to market a Telehealth medical device in Singapore, you will need to
229 obtain marketing clearance from HSA via Product Registration before import and
230 supply of the devices in Singapore. The submission requirements and process,
231 depending on the risk class of the Telehealth medical device, will follow as per [GN-
232 15](#): Guidance on Medical Device Product Registration.

Immediate Route (Only Class B MDs and Standalone Mobile applications)	Expedited Route (Class B, C and D MDs)	Abridged Route (Class B, C and D MDs)	Full Evaluation (Class B, C and D MDs)
<p>Criteria: <u>Class B MDs</u></p> <ul style="list-style-type: none"> • 2 Reference agency approvals • 3 years marketing history • No major safety issues <p><u>Standalone Mobile application (New)</u></p> <ul style="list-style-type: none"> • 1 Reference agency approval • No major safety issues globally 	<p>Criteria:</p> <ul style="list-style-type: none"> • 2 Reference agency approvals <p>Or</p> <ul style="list-style-type: none"> • 1 Reference agency approval • 3 years marketing history • No major safety issues globally 	<p>Criteria: 1 Reference agency approval</p>	<p>No Reference agency approval</p>
<p>Note: HSA’s reference agencies: Health Canada, US FDA, Australian Therapeutic Goods Administration, European Union and Japan Ministry of Health, Labor and Welfare.</p>			

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

235 Please note that low risk (i.e. Class A) Telehealth medical devices will be exempted
236 from Product Registration with HSA. Therefore, such devices are able to be
237 marketed immediately.

238 Manufacturers and importers that are dealing with such Class A exempted Telehealth
239 medical devices only will be required to declare these devices in the list of their non-

240 sterile Class A medical devices under the importer's and manufacturer's licences and
241 update the list periodically.

242 **(B) Dealers' Licence requirements:**

243 If you want to engage in the manufacture, import and/or wholesale of Telehealth
244 medical devices in Singapore, you will need to obtain the appropriate required dealer
245 licences from HSA. The submission requirements and process will follow as per [GN-
246 02: Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical
247 Devices](#). This licensing requirement is to ensure proper traceability and post-market
248 monitoring of Telehealth medical devices marketed in Singapore.

249 For importers and wholesalers dealing with only Class A medical devices (sterile or
250 non-sterile), they may opt for the Quality Management System for Class A Medical
251 Devices (QMS CAD) scheme administered by HSA in-lieu of GDPMDS certification.
252 For more information, please refer to [GN-31: Guidance on Quality Management
253 System Requirements for Licensing of Importers and Wholesalers of Class A Medical
254 Devices](#).

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256 **(C) Post-market obligations:**

257 Dealers of Telehealth medical devices are obliged to perform post-market duties,
258 including but not limited to reporting of adverse events, defects and recall to HSA and
259 ensuring appropriate investigation, so as to assure the continued safe use of the
260 devices.

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

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265 **6. Regulatory Controls for Standalone Mobile Applications***
266 **that are Medical Devices**

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268 **Standalone Applications refers to applications that are intended to function by
269 themselves and are not intended for use with other hardware devices*

270 Please note that only standalone mobile applications that are distributed on local
271 online platforms will be regulated.

272 With the widespread growth and adoption of Telehealth technology, HSA is applying
273 a regulatory approach that is similar to other medical devices to facilitate faster
274 access to standalone mobile applications.

275 If a Class B and C standalone mobile application has been registered by one of
276 HSA's reference agencies, they may qualify for Immediate Registration Route. The
277 eligibility criteria at the point of submission are:

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

280 [HSA's independent reference regulatory agencies are i) Health Canada, ii) Japan's
281 Ministry of Health, Labour and Welfare, iii) United States Food and Drug
282 Administration, iv) Australian Therapeutic Goods Administration v) European Union
283 Notified Bodies and the corresponding approvals listed under Section 5.1 Evaluation
284 Routes of GN-15.]

285 • no safety issues globally associated with the use of the medical device(s)
286 when used as intended by the Product Owner, defined as
287 a. No reported deaths;
288 b. No reported serious deterioration in the state of health of any person;
289 and
290 c. No open field safety corrective actions (including recalls) at the point
291 of submission.

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

295 **7. Feedback Sought**

296 HSA welcomes your comments and feedback on the definitions, classification,
297 clarification statement and proposed regulations.

298 This consultation will be held from 17 Oct 2016 to 30 Nov 2016.

299 Please provide your name, the organisation you represent, mailing address, contact
300 number and email address to enable us to follow up with you to clarify any issues, if
301 necessary.

302 Where possible, you should highlight the specific regulation in the proposed draft you
303 are providing your comments on.

304 Please note that the contents of any written feedback submitted, and the identity of
305 the source, may be disclosed at the conclusion of this consultation. You may request
306 for the feedback provided to be treated with confidence on grounds that the
307 information is proprietary, confidential or commercially-sensitive. Such requests will
308 be taken into consideration.

309 Please email your feedback using the [prescribed template](#) to
310 **hprg_feedback@hsa.gov.sg** by **30 Nov 2016**.