HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-15: Guidance on Medical Device Product Registration

Revision 12

HSA
Health Sciences Authority

CONTENTS

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors.

REVISION HISTORY

Guidance Version (Effective Date) *[3 latest revisions]*	Revision
R10 ► GN-15: Revision 10 (24 January 2024)	R10
R11 ► GN-15: Revision 11 (01 March 2024)	R11
R12 ► GN-15: Revision 12 (06 August 2025)	R12

**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown.*

1. INTRODUCTION

The Health Products Act (*Act*) and Health Products (Medical Devices) Regulations 2010 (*Regulations)* require medical devices, other than those exempted by the *Regulations*, to be registered with HSA prior to placing them on the Singapore market.

This guidance document is meant to assist applicants in the registration of medical devices under the *Act* and *Regulations*. This guidance should be read together with the other relevant guidance documents including but not restricted to GN-12, GN-13, GN-14, GL-07, GN-17, GN-18 and GN-34.

Applicants are strongly encouraged to familiarise themselves with the criteria and requirements for review processes outlined in this guidance and the other relevant guidance documents before submitting their applications. Incomplete submissions and untimely responses to queries will result in unnecessary delays to the registration process and thus, will have a negative impact on the target processing timelines**.** Applications with the incorrect risk classification of devices may result in the re-submission of the applications according to the appropriate risk class.

If there are any contradiction between the guidance documents and any written law, the latter shall take precedence.

Applicants are reminded that, notwithstanding the registration of a medical device under the *Act*, the supply and use of any medical device in Singapore should also comply with the requirements under other applicable legislations (e.g. Healthcare Services Act, Professional Registration Acts[1], Radiation Protection Act).

[1] Professional Registration Acts include Medical Registration Act, Dental Registration Act and others.

1.1. Scope

This guidance document describes the procedures and general requirements for the submission of an application for a new Product Registration for medical devices.

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*The Singapore Health Product Access and Regulatory E-System (SHARE) is the integrated digital platform that serves as the centralised system for managing regulatory submissions and transactions for health products, including medical devices. ◄

1.2. Definitions

Definitions that do not indicate they are set out in the *Act* or *Regulations* are intended as guidance in this document. These definitions are not taken verbatim from the above-mentioned legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

APPLICANT: for the purposes of this guidance document, an applicant is the person applying for a medical device registration.

EXPORT: with its grammatical variations and cognate expressions, means to take or cause to be taken out of Singapore by land, sea or air.

IMPORT: with its grammatical variations and cognate expressions, means to bring or cause to be brought into Singapore by land, sea or air.

INTENDED USE *(as set out in the Regulations)*: in relation to a medical device or its process or service, means the objective intended use or purpose, as reflected in the specifications, instructions and information provided by the product owner of the medical device.

LABEL (*as set out in the Act*): in relation to a health product or an active ingredient, means any written, printed or graphic representation that appears

on or is attached to the health product or active ingredient or any part of its packaging, and includes any informational sheet or leaflet that accompanies the health product or active ingredient when it is being supplied.

MANUFACTURE (*as set out in the Act*): in relation to a health product, means to make, fabricate, produce or process the health product and includes:-

- any process carried out in the course of so making, fabricating, producing or processing the health product; and
- the packaging and labelling of the health product before it is supplied.

MEDICAL DEVICE: means a medical device as described in the First Schedule of the *Act*.

MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP): Medical Device Single Audit Program administered by The International Medical Device Regulators Forum (IMDRF)

PRODUCT OWNER *(as set out in the Regulations)*: in relation to a health product, means 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.

REGISTRANT (*as set out in the Act*): in relation to a registered health product, means the person who applied for and obtained the registration of the health product under the *Act*.

SERIOUS DETERIORATION IN THE STATE OF HEALTH (*as set out in the Regulations*): in relation to a person, means —

- a life-threatening illness or injury suffered by that person;
- a permanent impairment of a bodily function of that person;
- any permanent damage to any part of that person's body; or
- a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.

STERILE STATE *(as set out in the Regulations)*: in relation to a medical device, means a state free of viable micro-organisms.

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.

WHOLESALE *(as set out in the Act)*: in relation to a health product, means any one or more of the following: -

- supplying the health product to a person who obtains the health product for the purposes of supplying it again to some other person;
- supplying the health product to a person as a commercial sample in the normal course of a lawful trade;
- supplying the health product to a Government department or statutory body which requires the health product for the purposes of the public service or use in connection with the exercise of any statutory power;
- supplying the health product to a person or an institution concerned with scientific education or research which requires the health product for the purpose of education or research;
- supplying the health product to a person who requires the health product for the purpose of enabling him to comply with any requirements made by, or in pursuance of, any written law with respect to the medical treatment of

persons employed by that person in any business or trade carried out by that person;

- supplying the health product to a person who requires to use the health product, other than by way of administration to one or more persons, for the purpose of his business or trade;
- supplying the health product by export to a party outside Singapore.

2. RISK CLASSIFICATION FOR MEDICAL DEVICES

Medical devices are classified into four risk classes based on its inherent risk which depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use. Other considerations in risk classification include its intended user(s), its mode of operation and the technology used.

Examples of factors influencing risk classification of a general medical device include the contact duration with the body, degree of invasiveness, whether the medical device delivers medicinal products or energy to the patient, whether they are intended to have a biological effect on the patient and local versus systemic effects, etc. A general medical device may also be incorporated with a medicinal product in an ancillary role to achieve its intended purpose (please refer to **Section 7.** for more information on such products).

Table 1: Classification system for General Medical Devices

CLASS	RISK LEVEL	EXAMPLES
A	Low Risk	Wheelchairs, Tongue depressors
B	Low-moderate Risk	Hypodermic needles, Suction equipment
C	Moderate-high Risk	Ventilators, Bone fixation plates
D	High Risk	Heart valves, Implantable defibrillators

For medical devices used for an *in vitro* diagnostic purpose, commonly known as *in vitro* diagnostic (IVD) medical devices, the following factors are considered during risk classification: intended purpose of the medical device, technical/scientific/medical expertise of the intended user (lay person or professional), importance of the information to the diagnosis (sole determinant or one of several), and impact of the results to the individual and/or to public health.

Table 2: Classification system for *In Vitro* Diagnostic Medical Devices

CLASS	RISK LEVEL	EXAMPLES
A (IVD)	Low Individual Risk and Low Public Health Risk	Specimen collection tubes, General culture media
B (IVD)	Moderate Individual Risk and/or Low Public Health Risk	Pregnancy tests, Anti-Nuclear Antibody tests, Urine test strips
C (IVD)	High Individual Risk and/or Moderate Public Health Risk	Blood glucose tests, HLA typing tests, PSA screening tests, Rubella tests
D (IVD)	High Individual Risk and High Public Health Risk	Screening for HIV, ABO blood grouping tests

More information regarding the risk classification rules for general medical devices and IVD medical devices can be found in GN-13 Guidance on the Risk Classification of General Medical Devices and GN-14 Guidance on the Risk Classification of *In Vitro* Diagnostic Medical Devices, respectively. Details and considerations on risk classification and product registration of IVD analysers can be found in GN-34 Guidance Document for IVD Analysers. R12 ► GL-07 Guidelines on Risk Classification of Software as a Medical Device (SaMD) and Qualification of Clinical Decision Support Software (CDSS) provides more information on risk classification of SaMD and clarify on the qualification of CDSS. ◄

3. REGISTRATION OF MEDICAL DEVICES

Regulatory controls for medical devices are titrated according to the inherent of risks associated with the medical devices. All medical devices including IVD medical devices must be registered with HSA prior to placing them on the Singapore market unless exempted by the *Regulation*s. Medical devices that are exempted from product registration are still subject to the controls under the *Act* and *Regulations* and any other applicable legislations.

3.1. Class A Medical Devices

Class A medical devices are exempted from product registration. Although exempted from product registration, these medical devices shall comply with the Essential Principles for Safety and Performance for Medical Devices as specified in the *Regulations* prior to their placement on the Singapore market. The duties and obligations under Part VIII of the *Act* remain applicable to dealers of such devices and the manufacture, import, supply, storage, presentation and advertisement of Class A medical devices remain under the purview of the *Act* and *Regulations*.

R12 ► Manufacturers and importers of Class A medical devices are required to submit a Product Notification to list their Class A devices on the "Class A Medical Device Database" on the HSA website. For further information on the requirements for Class A medical device, please refer to GN-22 Guidance for Dealers on Class A Medical Devices Exempted from Product Registration. ◄

3.2. Grouping Requirements for Product Registration

Each product registration application shall contain only one grouping of medical device as prescribed in the following guidance documents:

- GN-12-1 Guidance on Grouping of Medical Devices for Product Registration – General Grouping Criteria
- GN-12-2 Guidance on Grouping of Medical Devices for Product Registration - Device Specific Grouping Criteria.

Examples of possible grouping of medical devices:

- a SINGLE medical device;
- one medical device FAMILY;
- one medical device SYSTEM;
- one medical device TEST KIT;
- one medical device GROUP;
- one dental grouping term (DGT);
- one device specific grouping of hearing aids;
- one device specific grouping of IHC IVD reagents;
- one device specific grouping of FISH probes IVD reagents; or
- one device specific grouping of IVF media.

Please refer to the above guidance documents for the relevant grouping criteria for each category.

3.3. Telehealth Medical Devices, Devices for Modification of Appearance or Anatomy and 3D-printed Medical Devices

There are additional regulatory requirements and guidelines specific to Telehealth medical devices, Devices for Modification of Appearance or Anatomy (intended for aesthetic-related purposes) and 3D-printed medical devices. Please refer to the following document for more information:

i. Regulatory Guideline for Telehealth Products
ii. Regulatory Guideline for Devices for Modification of Appearance or Anatomy for more information.
iii. Regulatory Guideline for 3D-printed Medical Devices

4. REGISTRATION OF CLASS B MEDICAL DEVICES

4.1. Evaluation Routes

There are three evaluation routes for Class B medical devices:

(i) Full Evaluation Route

(ii) Abridged Evaluation Route

(iii) Immediate Class B Registration (IBR) Evaluation Route

***NOTE**: The immediate, expedited and abridged evaluation route applies to medical devices that have been evaluated and have obtained marketing clearances or approvals in at least one of the Global Harmonization Task Force (GHTF) founding members (Australia, Canada, European Union, Japan and United States of America).*

The abridged and immediate evaluation routes are set out according to a confidence-based approach, leveraging on the approvals by HSA's medical device reference regulatory agencies and/or prior safe marketing history. The types of approvals that qualify for the abridged and immediate evaluation routes are:

- ✓ Australia Therapeutic Goods Administration (TGA) Device Registration Licence
- ✓ Health Canada (HC) Device Registration Licence
- ✓ Japan Ministry of Health, Labour and Welfare (MHLW)
  - Pre-Market Certification (Ninsho) from a Japanese Registered Certification Body
  - Pre-Market Approval (Shonin) from MHLW
- ✓ US Food and Drug Administration (US FDA)
  - 510K clearance
  - De Novo
  - Premarket Approval (PMA)
- ✓ European Union Notified Bodies (EU NB) via EC certificates issued according to
  - Directive 93/42/EEC Annex II section 3 or Annex V for Class IIa
  - Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III or MDR Annex XI PART A for Class IIa

- Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs
- In Vitro Diagnostic Medical Device Regulation (IVDR) Annex IX Chapter I and Chapter III for Class B IVD

NOTE: Class B, C and D medical devices that are classified and approved/cleared as Class I or Class II exempt in the above reference agencies do not qualify for the abridged, expedited or immediate routes based on these respective approvals.

Evaluation Routes	**Eligibility Criteria**
Full Evaluation Route	A medical device that has **not obtained any prior approval** from any of HSA's reference regulatory agencies at the point of application will be subject to the full evaluation route.
Abridged Evaluation Route	A medical device that has obtained **at least one** reference regulatory agency approval for a labelled use identical to that intended for marketing in Singapore at the point of submission will qualify for the abridged evaluation route.
Immediate Class B Registration (IBR) Evaluation Route	A Class B medical device may qualify for registration via the IBR route if it fulfils the following conditions at the point of submission: **(A) Condition 1:** (i) Obtained approval from **at least one** of HSA's <u>independent</u> reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore; [HSA's medical device <u>independent</u> reference regulatory agencies are HC, MHLW, US FDA and TGA/EU NB and the corresponding approvals listed]

	(ii) R10 ► Marketed for **at least three years** in the above independent reference regulatory agency's jurisdiction; ◄ (iii) **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, defined as a) no reported deaths; b) no reported serious deterioration in the state of health[2] of any person; and c) no open field safety corrective actions (including recalls) at the point of submission. (iv) **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. This includes non-registration such as refusal to register of specific models in an application. **OR** **(B) Condition 2:** (i) Approvals by **at least two** of HSA's independent reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore; [HSA's medical device independent reference regulatory agencies are HC, MHLW, US FDA and TGA/EU NB and the corresponding approvals listed]

[2] Serious deteriorations in the state of health, in relation to a person means: (a) a life-threatening illness or injury suffered by that person; (b) a permanent impairment of a bodily function of that person; (c) any permanent damage to any part of that person's body; or (d) a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.

	(ii) **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 market introduction of the medical device(s), globally, defined as a) no reported deaths; b) no reported serious deterioration in the state of health[2] of any person; and c) no open field safety corrective actions (including recalls) at the point of submission. (iii) **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. This includes non-registration such as refusal to register specific models in an application.
Immediate Class B Registration (IBR) Evaluation Route **[Solely for standalone medical mobile application]**	A Class B standalone medical mobile application may qualify for registration via the IBR route if it fulfils the following conditions at the point of submission: (i) Obtained approval from **at least one** of HSA's <u>independent</u> reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore; [HSA's medical device <u>independent</u> reference regulatory agencies are HC, MHLW, US FDA and TGA/EU NB and the corresponding approvals listed] (ii) No safety issues globally associated with the use of the medical device(s) when used as intended by the product

[2] Serious deteriorations in the state of health, in relation to a person means: (a) a life-threatening illness or injury suffered by that person; (b) a permanent impairment of a bodily function of that person; (c) any permanent damage to any part of that person's body; or (d) a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.

	owner, in the last three years or since market introduction of the medical device(s), globally, defined as a) no reported deaths; b) no reported serious deterioration in the state of health[2] of any person; and c) no open field safety corrective actions (including recalls) at the point of submission. (iii) 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. This includes non-registration such as refusal to register specific models in an application.

4.2. Submission Requirements

All information and documents submitted in support of the registration of Class B medical devices must be compiled in the ASEAN Common Submission Dossier Template (CSDT) format. Please refer to the guidance documents GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT and GN-18 Guidance on Preparation of a Product Registration Submission for IVD Medical Devices using the ASEAN CSDT to understand how to prepare a submission dossier for product registration.

You may also refer to **ANNEX 5** for the summary of submission requirements.

For medical device with labelled use beyond the inherent performance of the device, additional clinical data may be requested to substantiate the proposed label use.

[2] Serious deteriorations in the state of health, in relation to a person means: (a) a life-threatening illness or injury suffered by that person; (b) a permanent impairment of a bodily function of that person; (c) any permanent damage to any part of that person's body; or (d) a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.

Applicants are reminded that with the streamlined submission requirements for IBR, they are required to ensure all relevant documentation (e.g. essential principles checklist, etc) are kept on file and made available upon HSA's request.

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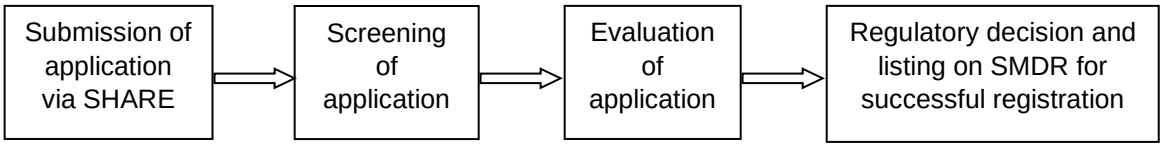
4.3. Processing of Applications



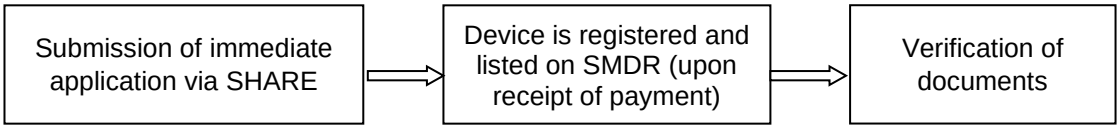
Upon submission, the application fee will be charged. The application dossier will be verified for eligibility and completeness before acceptance for evaluation. In the event that the application does not qualify for the selected route, it must be re-routed to the correct evaluation route and the respective evaluation fees shall apply.

Once the dossier is accepted for evaluation, the evaluation fees will be charged. Applicants may choose their preferred payment mode (e.g. GIRO or online payment options) at the point of application submission in SHARE.

Evaluation of the dossier by HSA is based on the dataset submitted by the applicant. If clarifications or additional information is required, HSA will issue an input request to the applicant. A regulatory decision will be made based on the outcome of HSA's evaluation of the submitted dossier. Only applications which satisfy the registration requirements will be registered and listed on the SMDR upon receipt of payment.

The stop-clock period begins when HSA issues an input request and ends only upon receipt of a complete and satisfactory response that addresses the queries or gaps identified.

4.3.1 Processing of application for IBR Evaluation Route



For immediate routes, medical devices will be listed on SMDR upon successful submission and receipt of full payment. The payment processing times to transaction completion will vary according to the selected payment mode:

- Online payment: Immediate processing (recommended for urgent applications)
- GIRO payment: 3 to 5 working days (please ensure that there are sufficient funds in the account)

As medical devices are registered immediately upon successful submission and receipt of payment, applicants are reminded to ensure the application fulfils **ALL** the eligibility criteria and that all the required information is entered correctly and accurately. Any IBR application which fails to fulfil **ALL** the eligibility criteria specified under **Section 4.1** or a non-Class B medical device submitted via the IBR evaluation route would result in cancellation of the registration and fees will NOT be refunded.

HSA will verify the documents submitted in after successful submission. Based on the intended use of the medical device by the product owner, additional registration conditions may be imposed post-registration. ◄

4.4. General Notes

The evaluation routes are set out according to a confidence-based approach, leveraging on reference agency approvals and prior safe marketing history. Applicants should be familiar with the criteria and documentary requirements for each evaluation route because each route will have different criteria and documentary requirements. An applicant can make a submission via one of the evaluation routes if the regulatory pre-requisites eligibility criteria of the selected route are fulfilled. All medical device(s) in each submitted application, whether

as a SINGLE, FAMILY, SYSTEM or GROUP grouping must fulfil the eligibility criteria of the selected evaluation route.

As IBR is an immediate registration route, applicants are reminded to ensure that applications made via this route fulfil all the registration requirements as set up in the regulation and must be adequately substantiated by evidence of quality, safety and performance/efficacy and provide the information for verification purposes upon request of HSA. Furthermore, the device listing is subject to cancellation if it is incorrectly submitted and there will be no refund of the fees paid.

Summary of the evaluation routes for Class B and their corresponding documentation requirements are attached in **ANNEX 4** and **ANNEX 5**, respectively.

5. REGISTRATION OF CLASS C AND D MEDICAL DEVICES

5.1. Evaluation Routes

There are four evaluation routes for Class C and D medical devices:

(i) Full Evaluation Route

(ii) Abridged Evaluation Route

(iii) Expedited Evaluation Route

a. Expedited Class C Registration (ECR)

b. Expedited Class D Registration (EDR)

(iv) Immediate Class C Registration (ICR) Evaluation Route [solely for Standalone Medical Mobile Application]

NOTE: *The immediate, expedited and abridged evaluation route applies to medical devices that have been evaluated and have obtained marketing clearances or approvals in at least one of the Global Harmonization Task Force (GHTF) founding members (Australia, Canada, European Union, Japan and United States of America).*

The abridged, expedited and immediate evaluation routes are set out according to a confidence-based approach, leveraging on the approvals by HSA's medical device reference regulatory agencies and/or prior safe marketing history. The types of approvals that qualify for abridged, expedited and immediate evaluation routes are:

- ✓ Australia Therapeutic Goods Administration (TGA) Device Registration Licence
- ✓ Health Canada (HC) Device Registration Licence
- ✓ Japan Ministry of Health, Labour and Welfare (MHLW)
  - Pre-Market Certification (Ninsho) from a Japanese Registered Certification Body
  - Pre-Market Approval (Shonin) from MHLW
- ✓ US Food and Drug Administration (US FDA)
  - 510K clearance
  - De Novo
  - Premarket Approval Application (PMA)

- ✓ European Union Notified Bodies (EU NB) via EC certificates issued according to
    - Directive 93/42/EEC Annex II section 3 or Annex III coupled with Annex V of MDD for Class IIb
    - Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III, including assessment of technical documentation for implantables, or MDR Annex X coupled with Annex XI PART A for Class IIb

    - Directive 93/42/EEC Annex II section 3 and 4 for Class III
    - Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III, including assessment of the technical documentation for Class III

    - Directive 90/385/EEC Annex II section 3 and 4 for Active Implantable Medical Devices
      (Note: *Directive 90/385/EEC is incorporated into MDR and active implantable medical device is Class III under MDR)*

    - Directive 98/79/EC Annex IV including sections 4 and 6 for List A IVDs
    - IVDR Annex IX Chapter I and Chapter III, including assessment of technical documentation for Class D IVD

    - Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs
    - In Vitro Diagnostic Medical Device Regulation (IVDR) Annex IX Chapter I and Chapter III, including assessment of technical documentation for companion diagnostics, self-testing & near-patient testing devices, or IVDR Annex X coupled with Annex XI (except section 5) for Class C IVD

Approvals from EU and TGA will qualify as independent reference regulatory agency's approval only if the devices have been reviewed and approved by the respective agencies and the devices are not registered based on the Mutual Recognition Agreement (MRA).

NOTE: Class B, C and D medical devices that are classified and approved/cleared as Class I or Class II exempt in the above reference agencies do not qualify for the abridged, expedited or immediate routes based on these respective approvals.

Evaluation Routes	Eligibility Criteria
Full Evaluation Route	A medical device that has **not obtained any prior approval** from any of HSA's reference regulatory agencies at the point of application will be subject to the full evaluation route.
Abridged Evaluation Route	A medical device that has obtained **at least one** reference regulatory agency approval for a labelled use identical to that intended for marketing in Singapore at the point of submission will qualify for the abridged evaluation route.
Expedited Class C Registration (ECR) Evaluation Route	A Class C medical device may qualify for registration via the ECR-1 or ECR-2 route if it fulfils the following conditions at the point of submission: **(A) ECR-1**: (i) Obtained approval from **at least one** of HSA's <u>independent</u> reference regulatory agencies for a labelled use identical to that intend for marketing in Singapore; (ii) R10 ► Marketed for **at least three years** in the above <u>independent</u> reference regulatory agency's jurisdiction; and ◄ (iii) **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, defined as

	a) no reported deaths; b) no reported serious deterioration in the state of health[2] of any person; and c) no open field safety corrective actions (including recalls) at the point of submission (iv) **No 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. This includes non-registration such as refusal to register specific models in an application. **OR** **(B) ECR-2:** (i) Obtained approvals from **at least two** of HSA's <u>independent</u> reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore. (ii) **No 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. This includes non-registration such as refusal to register specific models in an application. The following Class C devices are **excluded** from submission via the ECR route:

[2] Serious deteriorations in the state of health, in relation to a person means: (a) a life-threatening illness or injury suffered by that person; (b) a permanent impairment of a bodily function of that person; (c) any permanent damage to any part of that person's body; or (d) a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.

	(i) Hip, knee and shoulder joint replacement non bio-active implants (e.g. non-bioactive metal/polymer implants). These devices will have to be registered via Full or Abridged routes only.
Expedited Class D Registration (EDR) Evaluation Route	A Class D medical device may qualify for registration via the EDR route if it fulfils the following conditions at the point of submission: (i) Obtained approvals from **at least two** of HSA's <u>independent</u> reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore. (ii) **No 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. This includes non-registration such as refusal to register specific models in an application. The following Class D devices are **excluded** from submission via the EDR route: (i) Active implantable devices (e.g. pacemakers, neurostimulators) (ii) Implantable devices in direct contact with the central circulatory system or central nervous system (iii) Hip, knee and shoulder joint replacement (e.g. bioactive implants) (iv) Devices incorporating a registrable drug in an ancillary role (v) IVD assays (excluding IVD analysers) intended for: • HIV testing (screening and diagnosis)

	• Blood/ tissue donor compatibility testing These devices will have to be registered via Full or Abridged routes only.
Immediate Class C Registration (ICR) Evaluation Route [Solely for standalone medical mobile application]	A Class C standalone medical mobile application may qualify for registration via the ICR route if it fulfils the following conditions at the point of submission: (i) Obtained approval from **at least one** of HSA's independent reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore; (ii) 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, defined as a) no reported deaths; b) no reported serious deterioration in the state of health[2] of any person; and c) no open field safety corrective actions (including recalls) at the point of submission. (iii) 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. This includes non-registration such as refusal to register specific models in an application.

[2] Serious deteriorations in the state of health, in relation to a person means: (a) a life-threatening illness or injury suffered by that person; (b) a permanent impairment of a bodily function of that person; (c) any permanent damage to any part of that person's body; or (d) a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.

5.2. Submission Requirements

All information and documents submitted in support of the registration of Class C and D medical devices must be compiled in the ASEAN Common Submission Dossier Template (CSDT) format. Please refer to the guidance documents GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT and GN-18 Guidance on Preparation of a Product Registration Submission for IVD Medical Devices using the ASEAN CSDT to understand how to prepare a submission dossier for product registration.

You may also refer to **ANNEX 7** for the summary of submission requirements.

For medical device with labelled use beyond the inherent performance of the device, additional clinical data may be requested to substantiate the proposed label use.

Applicants are reminded that with the streamlined submission requirements for ICR, they are required to ensure all relevant documentation (e.g. essential principles checklist etc) are kept on file and made available upon HSA‘s request.

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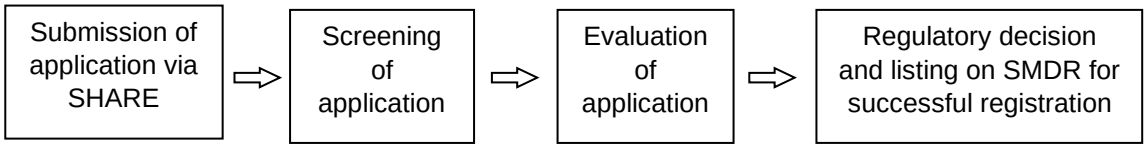
5.3. Processing of Applications



Upon submission, the application fee will be charged. The application dossier will be verified for eligibility and completeness before acceptance for evaluation. In the event that the application does not qualify for the selected route, it must be re-routed to the correct evaluation route and the respective evaluation fees shall apply.

Upon acceptance of the dossier, the evaluation fees will be charged. Applicants may choose their preferred payment mode (e.g. GIRO or online payment options) for application submission.

Evaluation of the dossier by HSA is based on the dataset submitted by the applicant. If clarifications or additional information is required, HSA will issue an input request to the applicant. A regulatory decision will be made based on the outcome of HSA's evaluation of the submitted dossier. Only applications which satisfy the registration requirements will be registered and listed on the SMDR upon receipt of payment.

The stop-clock period begins when HSA issues an input request and ends only upon receipt of a complete and satisfactory response that addresses the queries or gaps identified. ◄

5.4. General Notes

The evaluation routes are set out leveraging on reference agency's approvals and prior safe marketing history. Applicants should be familiar with the criteria and documentary requirements for each evaluation route. An applicant can make a submission via one of the evaluation routes if the regulatory pre-requisites eligibility criteria of the selected route can be fulfilled. All medical

device(s) in each submitted application, whether as a SINGLE, FAMILY, SYSTEM or GROUP grouping must fulfil the eligibility criteria of the selected evaluation route.

Medical devices that are excluded from the expedited routes have been deemed to require in-depth evaluation. These devices can only be registered via Full or Abridged evaluation route.

Summary of the evaluation routes and their corresponding documentation requirements are attached in **ANNEX 6** and **ANNEX 7**, respectively.

6. PRIORITY REVIEW SCHEME

The Priority Review Scheme provides the option for applicants to gain faster registration and market entry for their medical devices that are submitted to HSA through the **Full evaluation route**. Applicants could opt for one of the two routes under the Priority Review Scheme if a Class B, C or D medical device fulfils the following qualification criteria:

(A) Route 1

(i) Intended use falls under one of the five healthcare focus areas:

- Cancer
- Diabetes
- Ophthalmic diseases
- Cardiovascular diseases
- Infectious diseases; and

(ii) Intended for an unmet clinical need, which defined as:

a) Intended for a medical purpose with **no existing alternative** treatment or means of diagnosis; or

b) Represents a breakthrough technology that provides a **clinically meaningful advantage** over existing legally marketed technology

(B) Route 2

Medical device that do not meet the qualification criteria for Route 1.

Medical devices incorporating registrable therapeutic/medicinal products are not eligible for the Priority Review Scheme.

For more information on the scheme, please refer to: http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Regulatory_Updates/md_initiatives.html	

7. MEDICAL DEVICES INCORPORATING MEDICINAL PRODUCT

By the design and intent of the product owner, a medical device may be incorporated with a therapeutic/medicinal product in an ancillary role (chemical drug or biologic), to achieve its intended purpose. The regulatory controls applicable (i.e. medical device or therapeutic/medicinal product) to such products including both medical device and therapeutic/medicinal product components is determined based on their primary mode of action (PMOA).

"Primary mode of action (PMOA)" means the mode of action that makes the greatest contribution to the overall intended therapeutic purpose of the combined product.

A product that does not achieves its PMOA in or on the human body by pharmacological, immunological or metabolic means will be regulated as a medical device under the *Act*.

Examples of medical devices incorporating a therapeutic/medicinal product that are regulated as medical device include:

- Drug eluting stents
- Dermal filler incorporating analgesic

Medical devices incorporating registrable therapeutic/medicinal products are classified as Class D medical devices. The product registration applications for such devices will be jointly evaluated by the Medical Devices Cluster (MDC) together with the Therapeutic Products Branch (TPB) of HSA. Such devices would qualify for the abridged evaluation route if the product is approved as a medical device in at least one of HSA's medical device reference regulatory agencies **and** the chemical or biological component has been evaluated and approved by at least one competent drug regulatory agency, as defined by the World Health Organisation (WHO). The product registration applications for such products should be submitted via the full evaluation route if they **do not** qualify for the abridged route.

Where such medical devices incorporate therapeutic/medicinal products exempted from medicinal product registration, the risk classification would follow the medical device risk class.

The applicant can enquire with HSA about the product classification for such products to determine the applicable regulatory control. Such enquiries should be submitted using the Health Products Classification Form found on the HSA website (https://go.gov.sg/product-classification-form).

8. TURN-AROUND-TIME (TAT) FOR PRODUCT REGISTRATION

HSA shall endeavour to meet the target processing timelines for all submitted applications. Applicants should ensure that the dossiers are complete before submission. Incomplete submissions and untimely responses to queries will result in unnecessary delays to the registration process and thus, will have a negative impact on the target processing timelines.

The target turn-around-time (TAT) for product registration applications commences from the date of receipt of the application and does not include 'stop-clock time' due to input requests for clarifications and additional information.

In the event that the medical device is a subject of a field safety corrective action (FSCA), the application will be placed on stop-clock until resolution of the FSCA or any action HSA deems necessary.

R12► The target TAT can be found on the HSA website. ◄

9. PRODUCT REGISTRATION FEES

The product registration application fees and evaluation fees can be found on the HSA website.

The application fee is payable at the point of submission. Evaluation fees are payable upon acceptance of the application for evaluation.

The application fees are **non-refundable** once the application has been successfully submitted. The applicant should ensure that the product registration application is compiled according to the prevailing required format and requirements.

The evaluation fees are **non-refundable** once the application is accepted for evaluation, regardless of the final decision by HSA. Withdrawal of the application after the application is accepted will result in **forfeiture** of the evaluation fees. Rejection of the application by HSA will also result in the **forfeiture** of the evaluation fees.

R12► The progressive payment scheme for evaluation fees is an opt-in scheme at the time of application submission. This is eligible for applicants who make payment via GIRO and applicable only to full, abridged and expedited routes. ◄

10. CHANGES TO A REGISTERED MEDICAL DEVICE

Registrants are required to submit a “Change Notification” application, if there are any changes or proposed changes to particulars provided in relation to the registration of the medical device, and/or if there are any changes or proposed changes that may affect the safety, quality or efficacy of a registered medical device.

Please refer to GN-21 Guidance on Change Notification for Registered Medical Devices, for the types of changes and required documents to be provided for a Change Notification submission.

AMENDMENT OF DEVICE LISTING

In cases of any typographical errors incurred in the device listing information on the SMDR, the registrant may submit a written request to HSA for the necessary amendments.

11. ANNUAL RETENTION FEE

An annual retention fee is payable in order to retain the registration of the medical device on the SMDR.

Payment reminders will be sent to the email address provided by the registrant. However, it is the responsibility of the registrant to keep track of the annual retention due date. Failure to make the necessary payment may lead to cancellation of the registration of the medical device.

If fee payment is not received within 30 days after due date, justification for late retention payment (Show Cause) must be provided in the retention application. Device listings will be cancelled if retention fee payment is not received within 60 days after due date. Once the device listings is cancelled, import and supply of that medical device is not permitted.

The Auto-Retention Scheme for medical device listings has been implemented from 1 November 2016, and all registrants maintaining interbank GIRO accounts with HSA would be eligible for this scheme. The annual registration retention fees are **non-refundable**.

12. CANCELLATION OF REGISTRATION

Pursuant to section 37(1) of the *Act*, when a regulatory decision has been made on reasonable grounds to cancel a registered product, the registrant will be given written notice. The registrant will also be given an opportunity to be heard prior to the cancellation.

Once the registration is cancelled, the registrant and all dealers are required to immediately cease all activities related to the importation and supply of the affected medical devices.

ANNEX 1 - Letter of Authorisation Template

Letter of Authorisation Template

[To be printed on Company Letterhead of Product Owner]

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for *[name of Registrant (Company Name)]*

We, *[name of Product Owner (Company Name)]*, as the Product Owner, hereby authorise *[name of Registrant (Company Name)],* as the Registrant to prepare and submit applications for the evaluation and registration of medical devices to the Health Sciences Authority on our behalf.

This authorisation shall apply to the following medical devices:

[List containing product names of medical devices]

We also authorise *[name of Registrant (Company Name)]* to make declarations and to submit documents on our behalf, regarding the above medical devices, in support of this application. These declarations and submissions are made pursuant to the requirements of the Health Products Act, the Health Products (Medical Devices) Regulations and any other applicable laws that may also be in force.

This authorisation shall remain in effect until our notification to the Health Sciences Authority in writing (either by postal mail or email) that the authorisation is revoked.

We undertake to provide post-market support and assistance to the Registrant as may be required in relation to any matter involving the above medical devices.

We acknowledge that any non-compliance with any registration condition issued by the Health Sciences Authority in relation to medical devices registered on the Singapore Medical Device Register may result in the suspension or cancellation of the medical device registration.

We agree to assist the Health Sciences Authority with any request for information on the above medical devices.

Yours sincerely,

[Signature]

[Full Name and Title of Senior Company Official]
[Name and address of company]

ANNEX 2 - Marketing History Declaration Template

Marketing History Declaration Template

[To be printed on Company Letterhead of local Applicant]

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

I, *[name of Company]*, the Applicant for registration of the medical device(s) stated below, hereby declare that the medical devices have been marketed in the independent reference regulatory agency's jurisdiction for at least three years. The first date of market introduction in *[jurisdiction/country]* was *[mm/yyyy]*

This declaration shall apply to the following medical device(s):

[List containing product names of medical devices]

I, the Applicant, am aware that making a declaration which I know to be false is an offence under Section 30(10) of the Health Products Act (Cap. 122D) and may result in the cancellation of registration of the above medical devices under Section 37(1) of the Act.

Yours sincerely,

[Signature]

[Full Name and Title of Senior Company Official]
[Name and Address of Company]

ANNEX 3 - Safety Declaration Template

Safety Declaration Template

[To be printed on Company Letterhead of local Applicant]

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

I, *[name of Company]*, the Applicant for registration of the medical device(s) stated below, hereby declare that there are 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 from *[dd/mm/yyyy] to [dd/mm/yyyy]* **(Condition 1) or** since market introduction of the medical device(s), globally **(Condition 2)**:

☐ No reported deaths;

☐ No reported serious deterioration in the state of health[1] of any person; **and**

☐ No open field safety corrective actions (including recalls) at the point of submission of this application.

This declaration is made with respect to the following medical device(s):

[List containing product names of medical devices]

I, the Applicant, am aware that making a declaration which I know to be false is an offence under Section 30(10) of the Health Products Act (Cap. 122D) and may result in the cancellation of registration of the above medical devices under Section 37(1) of the Act.

Yours sincerely,

[Signature]

[Full Name and Title of Senior Company Official]
[Name and Address of Company]

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[1] Serious deterioration in the state of health, in relation to a person means: (a) a life-threatening illness or injury suffered by that person; (b) a permanent impairment of a bodily function of that person; (c) any permanent damage to any part of that person's body; or (d) a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.

ANNEX 4 - Summary of Evaluation Routes for Class B Medical Device Registration

Summary of Evaluation Routes for Class B Medical Device Registration

Evaluation Route	Full	Abridged	Immediate Class B registration – IBR
Criteria (at the point of submission)	Not approved by any of HSA reference regulatory agencies	Approval from at least 1 of HSA's reference regulatory agency	**For all Class B medical devices** **Condition 1** • Approval from at least 1 of HSA's independent reference regulatory agency • Marketed for ≥ 3 years in the above independent reference regulatory agency's jurisdictions • No safety issues globally • No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues. **OR** **Condition 2** • Approvals from at least 2 of HSA's independent reference regulatory agencies • No safety issues globally • No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues. **For standalone medical mobile applications** • Approval from at least 1 of HSA's independent reference regulatory agency • No safety issues globally • No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues.

ANNEX 5 - Summary of Submission Requirements (Class B)

Summary of Submission Requirements (Class B)

Documentary Requirements		Full	Abridged	IBR
1	Letter of Authorisation **(Annex 1)**	✓	✓	✓
2	Annex 2 List of Configurations	✓	✓	✓
3	Proof of reference agency's approval(s)		✓	✓
4	Proof of marketing history in the reference agencies' jurisdictions e.g. invoice with date, proof of sale or a declaration on marketing history **(Annex 2)**			✓ Only required for Condition 1
5	Declaration of no safety issues globally **(Annex 3)**			✓
6	Justification for an unmet clinical need	✓ Only required for Priority Review Scheme Route 1		
7	Executive Summary	✓	✓	✓
8	Essential Principles Checklist and Declaration of Conformity	✓	✓	
9	Device Description	✓	✓	✓
10	Design verification and validation documents including: • Preclinical studies e.g. physical test data, biocompatibility studies, animal studies, software verification and validation studies, R11► traceability analysis (only for Full evaluation route) ◄ and evidence to support the cybersecurity of connected medical devices • Metrological requirements • Sterilisation validation (if applicable) • Shelf-life studies and projected useful life	✓ Detailed reports[1]	✓ Summary[2]	✓ Sterilisation validation for Sterile devices only[3] Software verification and validation studies for standalone medical mobile applications only[4] Evidence to support the cybersecurity of connected medical devices
11	Clinical Evidence[5, 6]	If applicable		
12	Proposed Device Labelling[5]	✓	✓	✓
13	Risk Analysis	✓	✓	
14	Manufacturer Information (site's name and address)	✓	✓	✓

15	Proof of QMS – Eg: ISO13485[7] or MDSAP certificate , conformity to US FDA Quality System Regulations, or Japan MHLW Ordinance 169	✓	✓	✓
16	Manufacturing Process – Flow Chart	✓		

[1] Full study reports containing complete descriptions of the objectives, protocols, methods of data analysis, results and conclusions are to be provided.

[2] A summary of the studies undertaken is to be provided and should include a brief description of the study objectives, test methods, results and conclusions.

[3] A declaration of conformity to ISO Sterilisation standards is acceptable. If not, a summary report of sterilisation validation is required.

[4] Software version indicated in the report should tally with the version to be supplied in Singapore.

[5] For medical devices with labelled use beyond the inherent performance of the device, additional clinical data may be requested to substantiate the proposed label use.

[6] For IVD medical device undergoing full evaluation, clinical evaluation conducted by accredited clinical laboratories may be required.

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[7] Certification bodies for ISO 13485 must be either accredited by IAF recognised accreditation bodies or are EU MDR/IVDR Notified Bodies. ◄

ANNEX 6 - Summary of Evaluation Routes for Class C and D Medical Device Registration

Summary of Evaluation Routes for Class C and D Medical Device Registration

Evaluation Route	Full	Abridged	Expedited Class C registration - ECR	Expedited Class D registration - EDR	Immediate Class C registration - ICR
Criteria (at the point of submission)	Not approved by any of HSA's reference regulatory agencies	Approval from at least 1 of HSA's reference regulatory agencies	**ECR–1** • Approvals from at least 1 of HSA's independent reference regulatory agencies • Marketed for ≥ 3 years in the above independent reference regulatory agency's jurisdiction • No safety issues globally • No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues. **OR** **ECR–2** • Approvals from at least 2 of HSA's independent reference regulatory agencies • No prior rejection/ withdrawal by/from any independent reference regulatory	• Approvals from at least 2 of HSA's independent reference regulatory agencies • No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues.	**For standalone medical mobile applications** • Approval from at least 1 of HSA's independent reference regulatory agency • No safety issues globally • No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues.

			agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues.		

ANNEX 7 - Summary of Submission Requirements (Class C and D)

Summary of Submission Requirements (Class C and D)

Document Requirements		Full	Abridged	ECR-1 and ECR-2	EDR	ICR[1]
1	Letter of Authorisation **(Annex 1)**	✓	✓	✓	✓	✓
2	Annex 2 List of Configurations	✓	✓	✓	✓	✓
3	Proof of reference agency's approval(s)		✓	✓	✓	✓
4	Proof of marketing history in the reference agencies' jurisdictions e.g. invoice with date, proof of sale or a declaration on marketing history **(Annex 2)**			✓ Only required for ECR-1		
5	Declaration of no safety issues globally **(Annex 3)**					✓
6	Justification for an unmet clinical need	✓ Only required for Priority Review Scheme Route 1				
7	Executive Summary	✓	✓	✓	✓	✓
8	Essential Principles Checklist and Declaration of Conformity	✓	✓	✓	✓	
9	Device Description	✓	✓	✓	✓	✓
10	Design verification and validation documents including: • Preclinical studies e.g. physical test data, biocompatibility studies, animal studies, software verification and validation studies, R11► traceability analysis (only for Full evaluation route)◄ and evidence to support the cybersecurity of	✓ Detailed reports[2]	✓ Summary [3]	✓ Summary [3]	✓ Summary [3]	Software verification and validation studies for standalone medical mobile applications only[4] Evidence to support the cybersecurity of connected medical devices

	connected medical devices • Metrological requirements • Sterilisation validation (if applicable) • Shelf-life studies and projected useful life					
11	Clinical Evidence	✓[5]	✓	✓	✓	If applicable
12	Proposed Device Labelling	✓	✓	✓	✓	✓
13	Risk Analysis	✓	✓	✓	✓	
14	Manufacturer Information (site's name and address)	✓	✓	✓	✓	✓
15	Proof of QMS – E.g. ISO13485[6] or MDSAP certificate , conformity to US FDA Quality System Regulations, or Japan MHLW Ordinance 169	✓	✓	✓	✓	✓
16	Manufacturing process – Flow chart	✓	✓	✓	✓	

[1] For standalone medical mobile applications only.
[2] Full study reports containing complete descriptions of the objectives, protocols, methods of data analysis, results and conclusions are to be provided.
[3] A Summary of the studies undertaken is to be provided. The summary should include a brief description of the study objectives, test methods, results and conclusions.
[4] Software version indicated in the report should tally with the version to be supplied in Singapore.
[5] For IVD medical device undergoing full evaluation, clinical evaluation conducted by accredited clinical laboratories may be required.
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[6] Certification bodies for ISO 13485 must be either accredited by IAF recognised accreditation bodies or are EU MDR/IVDR Notified Bodies. ◄

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg

HSA
Health Sciences Authority