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PREFACE

R6.1 ► 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. ◄ R6.1
1. INTRODUCTION

The Health Products Act (Act) and Health Products (Medical Devices) Regulations (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, GN-17 and GN-18.

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 Health Products Act, the supply and use of any medical device in Singapore should also comply with the requirements under other applicable legislations (e.g. Private Hospitals and Medical Clinics Act, Professional Acts*, Radiation Protection Act).

* Professional 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.

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.

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

The inherent risk of a medical device 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 include the duration of medical device contact with the body, the degree of invasiveness, whether the medical device delivers medicinal products or energy to the patient, whether they are intended to have a biological affect 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). General medical devices are classified into four risk classes as shown below:

Table 1: Classification system for General Medical Devices

<table>
<thead>
<tr>
<th>CLASS</th>
<th>RISK LEVEL</th>
<th>EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Low Risk</td>
<td>Wheelchairs / tongue depressors</td>
</tr>
<tr>
<td>B</td>
<td>Low-moderate Risk</td>
<td>Hypodermic Needles / suction equipment</td>
</tr>
<tr>
<td>C</td>
<td>Moderate-high Risk</td>
<td>Ventilators / bone fixation plates</td>
</tr>
<tr>
<td>D</td>
<td>High Risk</td>
<td>Heart valves / implantable defibrillators</td>
</tr>
</tbody>
</table>

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

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

More information regarding the risk classification rules for general medical devices and *in vitro* diagnostic 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.
3. REGISTRATION OF MEDICAL DEVICES

Regulatory controls for medical devices are titrated according to the inherent risks associated with the medical devices. All medical devices including \textit{in vitro diagnostic} medical devices must be registered with HSA prior to placing them on the Singapore market unless exempted by the \textit{Regulations}. Some of the low risk Class A devices are deemed to be of very low risk and hence are exempted from product registration under the \textit{Regulations}. However, these exempted Class A devices are still subject to the other controls under the \textit{Act} and \textit{Regulations} and any other applicable legislations.

3.1. Exempted Class A Medical Devices from Product Registration

Class A medical devices supplied in non-sterile state are exempted from product registration but product registration requirements would still apply to Class A medical devices that are supplied in sterile state.

In the event that the exempted Class A medical devices are intended for use with another registrable medical device in a closed SYSTEM, these exempted Class A devices should be included in the application to register the registrable device. Upon successful registration of the registrable device, these exempted Class A devices would be listed together with the registered device on the Singapore Medical Device Register (SMDR). Examples include reusable surgical instruments that are specifically intended for use with a registered or registrable Class C or D implant system or an IVD analyser that is specifically intended for use with a registered or registrable test kit.

Although Class A medical devices supplied in a non-sterile state have been exempted from product registration, these medical devices shall comply with the Essential Principles for Safety and Performance for Medical Devices in the First Schedule of the \textit{Regulations} prior to their placement on the Singapore market. The duties and obligations under Part VIII of the \textit{Act} remain applicable to dealers of such devices and the manufacture, import, supply, storage,
presentation and advertisement of exempted Class A medical devices remain under the purview of the Act and Regulations. For further information on the requirements for Class A medical devices that are supplied in a non-sterile state, please refer to GN-22 Guidance for Dealers on Class A Medical Devices Exempted from Product Registration.

3.2. Submission Requirements for Product Registration

All information and documents submitted in support of the registration of Class B, 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.

All documents to be submitted in support of product registration must be provided in English. All information on the labels of medical devices supplied in Singapore must be provided in English. Information in non-English language(s) may be included on the labels but the applicant must ensure that the non-English information provides complete, accurate and unbiased information on the product and is consistent with the English information.

3.3. Grouping Requirements for Product Registration

Each submitted application shall contain only one of the following:

- a SINGLE medical device;
- one medical device FAMILY;
- one medical device SYSTEM;
- one medical device TEST KIT;
- one medical device IVD CLUSTER;
• one medical device GROUP;
• one dental grouping term (DGT).

Please refer to GN-12 Guidance on Grouping of Medical Devices for Product Registration for the relevant grouping criteria for each category.
4. MODULE 1 - REGISTRATION OF CLASS A MEDICAL DEVICES

4.1. Submission Requirements

The following documents should be submitted in support of the application to register a Class A medical device:

- Letter of Authorisation (Refer to ANNEX 1 for the template for this letter)
- Copies (in English and in original colour) of:
  - the primary and secondary labels on the medical device and its packaging. Labels must be provided for all the components of a medical device system, members of a medical device family and accessories submitted for registration. Alternatively, a representative label may be submitted for variants, provided the variable fields on the artwork are annotated, and the range of values for the variable fields are indicated (Refer to GN 23: Guidance on Labelling for Medical Devices);
  - the instructions for use (where applicable);
  - the patient information leaflet (where applicable); and
  - the promotional material (including brochures and catalogues).
- Information on the sterilisation method(s) and sterilisation validation standard(s). Sterilisation validation report should be submitted in the event that the sterilisation processes employed do not conform to the appropriate international sterilisation standards.
- The ISO 13485 quality management system certificates for the
  - Manufacturing site;
  - Sterilisation site; and
  - Contract manufacturer site (if applicable).

Certificate of the US FDA Quality System Regulations or Japan MHLW Ordinance 169 can be submitted in place of the ISO 13485 certificate. In

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1 The CSDT format is not required for sterile Class A medical devices product registration submissions.
these cases, the latest audit reports for the relevant site shall also be submitted for product registration.

For the manufacturing and sterilisation sites that do not conform to the ISO 13485, US FDA Quality System Regulations or the Japan MHLW Ordinance 169, the Product Owner will be required to provide an attestation that the manufacturer(s) have an adequate Quality Management System (QMS) in place. The details and format of this attestation can be found in GN-11 Guidance on the Declaration of Conformity.

A summary of the documentary requirements for Class A medical devices is attached in ANNEX 2.

4.2. Processing of Application

Upon submission via the Medical Device Information and Communication System (MEDICS), the product application fee will be charged immediately. Review of the application by HSA is based on the data set submitted by the applicant. An input request will be issued to the applicant if clarification or additional information is required. A regulatory decision is made based on the outcome of HSA’s review of the submitted application. Only applications which satisfy the registration requirements will be registered and listed on the SMDR.

The stop-clock starts whenever HSA issues an input request and ends when HSA receives a complete and satisfactory response from the applicant.
5. MODULE 2 - REGISTRATION OF CLASS B MEDICAL DEVICES

5.1. Evaluation Routes

There are four evaluation routes for Class B medical devices:

(i) Full Evaluation Route
(ii) Abridged Evaluation Route
(iii) Expedited Class B Registration (EBR) Evaluation Route
(iv) Immediate Class B Registration (IBR) Evaluation Route

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 of the Class B devices. The types of approvals that qualify for the 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 from a Japanese Registered Certification Body
  - Pre-Market Approval from MHLW
- US Food and Drug Administration (US FDA)
  - 510K clearance
  - 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 devices
5.1.1. Full Evaluation Route

5.1.1.1. Eligibility Criteria

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**.

5.1.1.2. Submission Requirements

- Letter of Authorisation (Refer to **ANNEX 1** for the template for this letter)
- Annex 2 for GN-17 and GN-18: List of configurations of medical devices to be registered
- Common Submission Dossier Template (CSDT)
  - Executive Summary
  - Essential Principles Checklist and Declaration of Conformity (Refer to GN-11 for the Declaration of Conformity template)
  - Device Description
  - Detailed Information of Design Verification and Validation Documents
    - Full reports of Preclinical Studies including the detailed sterilisation validation, if applicable
    - Clinical Evidence, including publications and full reports of the studies referenced in the clinical evaluation report
  - Proposed Device Labelling
  - Risk Analysis
  - Manufacturer Information
    - Name and address of the manufacturing site(s)
- Proof of Quality Management System – e.g. ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169
- Manufacturing Process – Flow Chart

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.

### 5.1.1.3. Processing of Application

![Flow Chart Diagram]

Upon submission via MEDICS, an application fee will be charged immediately. The application dossier will be verified for completeness before the application is accepted for evaluation. Any question regarding the dossier will need to be addressed via input requests.

Upon acceptance of the dossier for evaluation, the evaluation fees will be charged. The payment mode (GIRO or progressive payment or others) will depend on the applicant’s selection at the point of submission in MEDICS.

Evaluation of the dossier by HSA is based on the data set submitted by the applicant. An input request will be issued to the applicant if clarification or additional information is required. A regulatory decision is 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.
The stop-clock starts whenever HSA issues an input request and ends when HSA receives a complete and satisfactory response from the applicant.

5.1.2. **Abridged Evaluation Route**

5.1.2.1. **Eligibility Criteria**

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 time of submission will qualify for the **abridged evaluation route**.

5.1.2.2. **Submission Requirements**

- Letter of Authorisation (Refer to **ANNEX 1** for the template for this letter)
- Annex 2 for GN-17 and GN-18: List of Configurations of Medical Devices to be registered
- Proof of approval by reference regulatory agency (e.g. approval letters, certificates)
- Common Submission Dossier Template (CSDT)
  a) Executive Summary
  b) Essential Principles Checklist and Declaration of Conformity (Refer to GN-11 for the Declaration of Conformity template)
  c) Device Description
  d) Summary of Design Verification and Validation Documents
    - Summary of Preclinical Studies including the sterilisation validation if applicable
    - Clinical Evidence
  e) Proposed Device Labelling
f) Risk Analysis (if applicable)

g) Manufacturer Information

- Name and address of the manufacturing site(s)

- Proof of Quality Management System – Eg: ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169

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.

5.1.2.3. Processing of Application

Upon submission via MEDICS, an application fee will be charged immediately. The application dossier will be verified for completeness before the application is accepted for evaluation. Any questions regarding the dossier will need to be addressed via input requests. If the application submitted does not qualify for the abridged route, the application will be required to be re-routed to the full evaluation route and the full evaluation fees shall apply.

Upon acceptance of the dossier for evaluation, the evaluation fees will be charged. The payment mode (GIRO or progressive payment or others) will depend on the applicant’s selection at the point of submission in MEDICS.

Evaluation of the dossier by HSA is based on the data set submitted by the applicant. An input request will be issued to the applicant if clarification or additional information is required. A regulatory decision is 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.

The stop-clock starts whenever HSA issues an input request and ends when HSA receives a complete and satisfactory response from the applicant.

5.1.3. Expedited Class B Registration (EBR) Evaluation Route

5.1.3.1. Eligibility Criteria

A Class B medical device may qualify for registration via the EBR-1 or EBR-2 route if it complies with the following conditions at the point of submission:

(A) EBR-1:

(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;

[HSA’s medical device independent reference regulatory agencies are HC, MHLW, US FDA and TGA/EU NB and the corresponding approvals listed under Section 5.1 Evaluation Routes]

(ii) 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;

2 Or the medical device has been marketed in Singapore for at least 3 years as stated in the proof of marketing history. For devices that are part of a test kit or a system, an invoice or declaration containing the kit name or system will be sufficient.
b) no reported serious deterioration in the state of health\(^3\) of any person; and

c) no open field safety corrective actions (including recalls) at the point of submission.

OR

(B) EBR-2:

(i) obtained approvals from at least two of HSA’s independent reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore.

5.1.3.2. **Submission Requirements**

- Letter of Authorisation (Refer to ANNEX 1 for the template for this letter)

- Annex 2 for GN-17 and GN-18: List of configurations of medical devices to be registered

- Proof of approval from independent reference regulatory agencies – [Note: one independent reference agency for EBR-1 and two independent reference agencies for EBR-2]

- Proof of marketing history in the same independent reference regulatory agency’s jurisdictions i.e. Invoice with date, proof of sale or a declaration on marketing history (Refer to ANNEX 3 for the template for this declaration) – [Note: for EBR-1 only]

- Declaration of no safety issues globally (Refer to ANNEX 4 for the template for this declaration) – [Note: for EBR-1 only]

- Common Submission Dossier Template (CSDT)

\(^3\) 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.
a) Executive Summary

b) Essential Principles Checklist and Declaration of Conformity
   (Refer to GN-11 for the Declaration of Conformity template)

c) Device Description

d) Summary of Design Verification and Validation Documents
   - Summary of Preclinical Studies including summary of sterilisation validation if applicable
   - Clinical Evidence

e) Proposed Device Labelling

f) Risk Analysis (if applicable)

g) Manufacturer Information
   - Name and address of the manufacturing site(s)
   - Proof of Quality Management System – e.g. ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169

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.

5.1.3.3. Processing of Application

Upon submission via MEDICS, an application fee will be charged immediately. The application will be verified for eligibility for EBR and the dossier will be verified for completeness. Once confirmed, the application will be accepted for
evaluation. The evaluation fees will be charged at this point. In view of the shortened processing timeline, progressive payment will not be an option available for applications submitted via this route. If the application submitted does not qualify for the expedited route, the application will be required to be re-routed to the abridged or full evaluation route and the respective evaluation fees shall apply.

Evaluation of the dossier by HSA is based on the data set submitted by the applicant. An input request will be issued to the applicant if clarification or additional information is required. A regulatory decision is 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.

The stop-clock starts whenever HSA issues an input request and ends when HSA receives a complete and satisfactory response from the applicant.

5.1.4. Immediate Class B Registration (IBR) Evaluation Route

5.1.4.1. Eligibility Criteria

A Class B medical device may qualify for registration via the IBR route if it complies with the following conditions R6.1 at the point of submission R6.1:

(i) approvals by at least two of HSA’s independent reference regulatory agencies for intended use identical to that submitting for registration in Singapore;

[HSA’s independent reference regulatory agencies are HC, MHLW, US FDA and TGA/EU NB and the corresponding approvals listed under Section 5.1 Evaluation Routes.]
(ii) marketed for at least three years in two of the independent reference regulatory agencies’ jurisdictions;

(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\(^3\) of any person; and
   c) no open field safety corrective actions (including recalls) at the point of submission; and

(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.

5.1.4.2. Submission Requirements

- Letter of Authorisation (Refer to ANNEX 1 for the template for this letter)
- Annex 2 for GN-17 and GN-18: List of configurations of medical devices to be registered
- Proof of approval from independent reference regulatory agencies
- Proof of marketing history in the same two independent reference regulatory agencies’ jurisdictions i.e. Invoice with date, proof of sale or a declaration on marketing history (Refer to ANNEX 3 for the template for this declaration)

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\(^3\) 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.
• Declaration of no safety issue globally (Refer to ANNEX 1 for the template for this declaration)

• Common Submission Dossier Template (CSDT):

   a) Executive Summary
   b) Device Description
   c) For sterile device only: declaration of conformity to ISO sterilisation standards for sterile medical devices. If not in conformity to ISO sterilisation standards, a summary of sterilisation validation is required.
   d) Proposed Device Labelling
   e) Manufacturer Information
      - Name and address of the manufacturing site(s)
      - Proof of Quality Management System – Eg: ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169

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

5.1.4.3. Processing of Application

Upon successful submission via the MEDICS, the medical device will be registered immediately and will be listed on the SMDR within an hour. An email notification regarding the successful registration of the device will be
sent within 48 hours of submission in MEDICS. The total fees will also be charged immediately upon successful submission for this route. As devices are registered immediately upon successful submission, applicants are reminded to ensure the application fulfils **ALL** the eligibility criteria and that all the required information is entered correctly and accurately.

HSA will verify the documents submitted in MEDICS after successful submission. Based on the intended use of the device by the Product Owner, additional registration conditions may be imposed post-registration.

The IBR evaluation route facilitates immediate market access for the medical devices. Any IBR application which fails to fulfil the **ALL** the registration criteria specified under **Section 5.1.4.1** for the IBR evaluation route or a non-Class B medical device submitted via the IBR evaluation route would result in **cancellation of the registration** and the registration fee will NOT be refunded.

### 5.2. 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. The application will be required to be re-routed to the correct evaluation route (except for IBR) if the application does not fulfil the eligibility criteria.

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 5 and ANNEX 6, respectively.
6. MODULE 3 - REGISTRATION OF CLASS C AND D MEDICAL DEVICES

6.1. Evaluation Routes

There are three 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)

The abridged and expedited 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 and expedited Class C and D 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)
   - o Pre-Market Certification (Ninsho) from a Japanese Registered Certification Body;
   - o Pre-Market Approval (Shonin) from MHLW
✓ US Food and Drug Administration (US FDA)
   - o 510K clearance
   - o Premarket Approval Application (PMA)
✓ European Union Notified Bodies (EU NB) via EC certificates issued according to
o Directive 93/42/EEC Annex II section 3 or Annex III coupled with Annex V of MDD for Class IIB

o Directive 93/42/EEC Annex II section 3 and 4 for Class III

o Directive 90/385/EEC Annex II section 3 and 4 for Active Implantable Medical Devices

o Directive 98/79/EC Annex IV including sections 4 and 6 for List A IVDs

o Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs

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).

6.1.1. Full Evaluation Routes

6.1.1.1. Eligibility Criteria

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.

6.1.1.2. Submission Requirements

- Letter of Authorisation (Refer to ANNEX 1 for the template for this letter)
- Annex 2 for GN-17 and GN-18: List of configurations of medical devices to be registered
- Common Submission Dossier Template (CSDT)
  a) Executive Summary
b) Essential Principles Checklist and Declaration of Conformity
(Refer to GN-11 for the Declaration of Conformity template)

c) Device Description

d) Detailed Information of Design Verification and Validation
Documents
  - Full reports of Preclinical Studies including the detailed
    sterilisation validation and shelf life studies if applicable
  - Clinical Evidence – Clinical Evaluation Report including
    publications and full reports of the studies referenced in
    the clinical evaluation report

e) Proposed Device Labelling

f) Risk Analysis

g) Manufacturer Information
  - Name and address of the manufacturing site(s)
  - Proof of Quality Management System – e.g. ISO13485
    Certificate, Conformity to US FDA Quality System
    Regulations or Japan MHLW Ordinance 169
  - Manufacturing Process – Flow Chart

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

6.1.1.3. Processing of Application

```
Submission of application via MEDICS → Verification of application → Evaluation of application → Regulatory decision and listing on SMDR for successful registration
```
Upon submission via MEDICS, an application fee will be charged immediately. The application dossier will be verified for completeness before the application is accepted for evaluation. Any question regarding the dossier will need to be addressed via input requests.

Upon acceptance of the dossier for evaluation, the evaluation fees will be charged. The payment mode (GIRO or progressive payment or others) will depend on the applicant’s selection at the point of submission in MEDICS.

Evaluation of the dossier by HSA is based on the data set submitted by the applicant. An input request will be issued to the applicant if clarification or additional information is required. A regulatory decision is 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.

The stop-clock starts whenever HSA issues an input request and ends when HSA receives a complete and satisfactory response from the applicant.

6.1.2. Abridged Evaluation Route

6.1.2.1. Eligibility Criteria

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 time of submission will qualify for the abridged evaluation route.

6.1.2.2. Submission Requirements

- Letter of Authorisation (Refer to ANNEX 1 for the template for this letter)
• Annex 2 for GN-17 and GN-18: List of configurations of medical devices to be registered.

• Proof of approval by reference regulatory agency (e.g. approval letters, certificates)

• Common Submission Dossier Template (CSDT)
  a) Executive Summary
  b) Essential Principles Checklist and Declaration of Conformity (Refer to GN-11 for the Declaration of Conformity template)
  c) Device Description
  d) Summary of Design Verification and Validation Documents
     - Summary of Preclinical Studies including the sterilisation validation and shelf life studies, if applicable
     - Clinical Evidence – Clinical Evaluation Report
  e) Proposed Device Labelling
  f) Risk Analysis
  g) Manufacturer Information
     - Name and address of the manufacturing site(s)
     - Proof of Quality Management System – Eg: ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169
     - Manufacturing Process – Flow Chart

6.1.2.3. Processing of Application

![Diagram showing the processing of an application: Submission of application via MEDICS, Verification of application, Evaluation of application, Regulatory decision and listing on SMDR for successful registration]
Upon submission via MEDICS, an application fee will be charged immediately. The application dossier will be verified for completeness before the application is accepted for evaluation. Any questions regarding the dossier will need to be addressed via input requests. If the application submitted does not qualify for the abridged route, the application will be required to be re-routed to the full evaluation route and the full evaluation fees shall apply.

Upon acceptance of the dossier for evaluation, the evaluation fees will be charged. The payment mode (GIRO or progressive payment or others) will depend on the applicant’s selection at the point of submission in MEDICS.

Evaluation of the dossier by HSA is based on the data set submitted by the applicant. An input request will be issued to the applicant if clarification or additional information is required. A regulatory decision is 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.

The stop-clock starts whenever HSA issues an input request and ends when HSA receives a complete and satisfactory response from the applicant.

6.1.3. Expedited Class C Registration (ECR) Evaluation Route

6.1.3.1. Eligibility Criteria

A Class C medical device may qualify for registration via the ECR-1 or ECR-2 route if it complies with the following conditions at the point of submission:

(A) ECR-1:
(i) obtained approval from at least one of HSA’s independent reference regulatory agencies for a labelled use identical to that intend 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 under Section 6.1 Evaluation Routes]

(ii) marketed for at least three years in the above independent 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 of any person; and

c) no open field safety corrective actions (including recalls) at the point of submission

OR

(B) ECR-2:

(i) obtained approvals from at least two of HSA’s independent reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore.

Approvals from EU and TGA will qualify as independent reference regulatory agency approvals only if the devices have been reviewed and approved by

\footnote{Or the medical device has been marketed in Singapore for at least 3 years as stated in the proof of marketing history. For devices that are part of a test kit or a system, an invoice or declaration containing the kit name or system will be sufficient.}

\footnote{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.}
the respective agencies and not registered based on the Mutual Recognition Agreement (MRA).

The following Class C devices are excluded from submission via the ECR evaluation route:

(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.

6.1.3.2. Submission Requirements

- Letter of Authorisation (Refer to ANNEX 1 for the template for this letter)
- Annex 2 for GN-17 and GN-18: List of configurations of medical devices to be registered
- Proof of approval from independent reference regulatory agencies—[Note: one independent reference agency for ECR-1 and two independent reference agencies for ECR-2]
- Proof of marketing history in the same independent reference regulatory agency’s jurisdictions i.e invoice with date, proof of sale or a declaration on marketing history (Refer to ANNEX 7 for the template for this declaration) – [Note: for ECR-1 only]
- Declaration of no safety issue globally (Refer to ANNEX 4 for the template for this declaration) – [Note: for ECR-1 only]
- Common Submission Dossier Template (CSDT)
  a) Executive Summary
  b) Essential Principles Checklist and Declaration of Conformity (Refer to GN-11 for the Declaration of Conformity template)
  c) Device Description
d) Summary of Design Verification and Validation Documents
   - Summary of Preclinical Studies including summary of sterilisation validation and shelf life studies, if applicable
   - Clinical Evidence - Clinical Evaluation Report

e) Proposed Device Labelling

f) Risk Analysis

g) Manufacturer Information
   - Name and address of the manufacturing site(s)
   - Proof of Quality Management System – e.g. ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169
   - Manufacturing Process – Flow Chart

6.1.3.3. Processing of Application

Upon submission via MEDICS, an application fee will be charged immediately. The application will be verified for eligibility for ECR and the dossier will be verified for completeness. Once confirmed, the application will be accepted for evaluation. The evaluation fees will be charged at this point. In the event that the application does not qualify for ECR, the application will be required to be re-routed to the abridged or full evaluation route and the respective evaluation fees shall apply.

Evaluation of the dossier by HSA is based on the data set submitted by the applicant. An input request will be issued to the applicant if clarification or additional information is required. A regulatory decision is 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.

The stop-clock starts whenever HSA issues an input request and ends when HSA receives a complete and satisfactory response from the applicant.

6.1.4. Expedited Class D Registration (EDR) Evaluation Route

6.1.4.1. Eligibility Criteria

A Class D medical device may qualify for registration via the EDR route if it complies with the following condition:

(i) obtained approvals from at least two of HSA’s independent reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore.

The following Class D devices are excluded from being registered via 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 devices intended for:
   • HIV testing (screening and diagnosis)
   • Blood/ tissue donor compatibility testing

These devices will have to be registered via Full or Abridged evaluation routes only.
6.1.4.2. Submission Requirements

- Letter of Authorisation (Refer to ANNEX 1 for the template for this letter)
- Annex 2 for GN-17 and GN-18: List of configurations of medical devices to be registered
- Proof of approval by reference regulatory agencies (e.g. approval letters, certificates)
- Common Submission Dossier Template (CSDT)
  a) Executive Summary
  b) Essential Principles Checklist and Declaration of Conformity (Refer to GN-11 for the Declaration of Conformity template)
  c) Device Description
  d) Summary of Design Verification and Validation Documents
     - Summary of Preclinical Studies including summary of sterilisation validation and shelf life studies, if applicable
     - Clinical Evidence – Clinical Evaluation Report
  e) Proposed Device Labelling
  f) Risk Analysis
  g) Manufacturer Information
     - Name and address of the manufacturing site(s)
     - Proof of Quality Management System – Eg: ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169
     - Manufacturing Process – Flow Chart
6.1.4.3. Processing of Application

Upon submission via MEDICS, an application fee will be charged immediately. The application will be verified for eligibility for EDR and the dossier will be verified for completeness. Once confirmed, the application will be accepted for evaluation. The evaluation fees will be charged at this point. In the event that the application does not qualify for EDR, the application will be required to be re-routed to the abridged or full evaluation route and the respective evaluation fee shall apply.

Evaluation of the dossier by HSA is based on the data set submitted by the applicant. An input request will be issued to the applicant if clarification or additional information is required. A regulatory decision is 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.

The stop-clock starts whenever HSA issues an input request and ends when HSA receives a complete and satisfactory response from the applicant.

6.2. 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. The application will be required to be re-routed to the correct evaluation route if the application does not fulfil the eligibility criteria.
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 8** and **ANNEX 9**, respectively.
7. MEDICAL DEVICES INCORPORATING MEDICINAL PRODUCT

By the design and intent of the product owner, a medical device may be incorporated with a medicinal product in an ancillary role (chemical drug or biologic), to achieve its intended purpose. The regulatory controls applicable (i.e. medical device or medicinal product) to such products including both medical device and 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 medicinal product that are regulated as medical device include:

- Drug eluting stents
- Dermal filler incorporating analgesic
- Antimicrobial silver dressings.

Medical devices incorporating registrable medicinal products are classified as Class D medical devices. The product registration applications for such devices will be jointly evaluated by the Medical Device Branch (MDB) 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 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 product enquiry form found on the HSA website.
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.

<table>
<thead>
<tr>
<th>Risk Classification</th>
<th>TAT for Registration (in working days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class A</td>
<td>30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Classification</th>
<th>TAT for Registration Routes (in working days)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Immediate</td>
</tr>
<tr>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Immediate Registration upon Submission</td>
<td>60</td>
</tr>
<tr>
<td>Class C</td>
<td>120</td>
</tr>
<tr>
<td>Class D</td>
<td>180</td>
</tr>
<tr>
<td>Class D, devices incorporating registrable medicinal products</td>
<td>220</td>
</tr>
</tbody>
</table>
9. PRODUCT REGISTRATION FEES

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

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

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.

Product Registration Fees

<table>
<thead>
<tr>
<th>Risk Class</th>
<th>Application Fees</th>
<th>Evaluation Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>depending on class</td>
<td>IBR</td>
</tr>
<tr>
<td>Class A (Non-Exempt)</td>
<td>$25</td>
<td>$900</td>
</tr>
<tr>
<td>Class B</td>
<td>$500</td>
<td></td>
</tr>
<tr>
<td>Class C</td>
<td>$500</td>
<td></td>
</tr>
<tr>
<td>Class D</td>
<td>$500</td>
<td></td>
</tr>
<tr>
<td>Class D (devices incorporating medicinal products)</td>
<td>$500</td>
<td></td>
</tr>
</tbody>
</table>
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.

11. **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.
12. **ANNUAL RETENTION FEE**

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

The payment of the retention fee should be submitted via MEDICS. Submission via the system will be available 60 days before the due date of the annual retention fee. A payment reminder 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 suspension and cancellation of the registration of the medical device.

The annual registration retention fees are **non-refundable** once paid via MEDICS.

13. **SUSPENSION AND CANCELLATION OF REGISTRATION**

Pursuant to section 37(1) of the *Act*, when a regulatory decision has been made on reasonable grounds to suspend or 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 suspension or cancellation.

Once the registration is suspended or 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**

*To be printed on Company Letterhead of Product Owner*

Medical Device Branch  
Pre-Marketing Division  
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]*, 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 facsimile transmission) 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]

[Company stamp]
## ANNEX 2

### Summary of Submission Requirements (Class A)

<table>
<thead>
<tr>
<th>Document Requirements</th>
<th>Class A (sterile)</th>
<th>IVD Class A (sterile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Letter of Authorisation</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2 Proposed Device Labelling</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3 IFU, patient information leaflet and promotional material (including brochures and catalogues)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4 A list of all materials of animal, human, microbial and/or recombinant origin used and manufacturing process</td>
<td>if applicable</td>
<td>✓</td>
</tr>
<tr>
<td>5 Sources of all materials of animal, human, microbial and/or recombinant origin used and manufacturing process</td>
<td>if applicable</td>
<td>✓</td>
</tr>
<tr>
<td>6 Information on sterilisation method(s) and validation standard(s) used</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>7 Proof of Quality Management System (QMS) – E.g. ISO 13485 certificate, conformity to US FDA Quality System Regulations, Japan MHLW Ordinance 169 or attestation stating adequate QMS</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
ANNEX 3

Marketing History Declaration Template
(Class B Registration)

[To be printed on Company Letterhead of Applicant]

Medical Device Branch
Pre-Marketing Division
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 two independent reference regulatory agencies’ jurisdictions for at least three years. The first dates of market introduction in [jurisdiction/country] and [jurisdiction/country] were [mm/yyyy] and [mm/yyyy] respectively (for IBR.)

☐ the independent reference regulatory agency’s jurisdiction for at least three years. The first date of market introduction in [jurisdiction/country] was [mm/yyyy] (for EBR-1).

OR

☐ Singapore for at least three years. The first date of market introduction in Singapore was [mm/yyyy] (for EBR-1)

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]

[Company stamp]
ANNEX 4

Safety Declaration Template

[To be printed on Company Letterhead of Applicant]

Medical Device Branch
Pre-Marketing Division
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]:

☐ No reported deaths;

☐ No reported serious deterioration in the state of health¹ 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]

[Company stamp]

-----

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.
## Summary of Evaluation Routes for Class B Medical Device Registration

<table>
<thead>
<tr>
<th>Evaluation Route</th>
<th>Full Criteria</th>
<th>Abridged Criteria</th>
<th>Expedited Class B registration - EBR</th>
<th>Immediate Class B registration – IBR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EBR – 1</strong></td>
<td>Not approved by any of HSA's reference regulatory agencies</td>
<td>Approval from at least 1 of HSA’s reference regulatory agency</td>
<td>• Approval from at least 1 of HSA's independent reference regulatory agency</td>
<td>• Approvals from at least 2 of independent reference regulatory agencies</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Marketed for ≥ 3 years in the above independent reference regulatory agency’s jurisdiction*</td>
<td>• Marketed for ≥ 3 years in the above 2 independent reference regulatory agencies’ jurisdictions</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• No safety issues globally</td>
<td>• No safety issues globally</td>
</tr>
<tr>
<td><strong>EBR – 2</strong></td>
<td></td>
<td></td>
<td>• Approvals from at least 2 of HSA’s independent reference regulatory agencies</td>
<td>• No prior rejection/withdrawal by/from any independent reference regulatory agencies or HSA</td>
</tr>
</tbody>
</table>

*Or the medical device has been marketed in Singapore for at least 3 years as stated in the proof of marketing history.

*Excluding applicant's response time to input request
### ANNEX 6

**Summary of Submission Requirements (Class B)**

<table>
<thead>
<tr>
<th>Documentary Requirements</th>
<th>Full</th>
<th>Abridged</th>
<th>EBR-1 and EBR-2</th>
<th>IBR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Letter of Authorisation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2. Annex 2 List of Configurations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3. Proof of reference agency’s approval(s)</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4. Proof of marketing history in the reference agencies’ jurisdictions e.g. invoice with date, proof of sale or a declaration on marketing history</td>
<td></td>
<td>✓</td>
<td>✓ Only required for EBR-1</td>
<td>✓</td>
</tr>
<tr>
<td>5. Declaration of no safety issues globally</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>6. Executive Summary</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>7. Essential Principles Checklist and Declaration of Conformity</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>8. Device Description</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>9. Design verification and validation documents including:</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Preclinical studies e.g. physical test data, biocompatibility studies, animal studies and software verification and validation studies</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>Sterilisation validation for Sterile device only³</td>
</tr>
<tr>
<td>• Metrological requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sterilisation validation (if applicable)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Shelf-life studies and projected useful life</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Clinical Evidence⁴</td>
<td>✓</td>
<td></td>
<td></td>
<td>If applicable</td>
</tr>
<tr>
<td>11. Proposed Device Labelling⁴</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>12. Risk Analysis</td>
<td>✓</td>
<td></td>
<td></td>
<td>If applicable</td>
</tr>
<tr>
<td>13. Manufacturer Information (site’s name and address)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>14. Proof of QMS—Eg: ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>15. Manufacturing Process – Flow Chart</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 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.
ANNEX 7

Marketing History Declaration Template
(Class C Registration)

[To be printed on Company Letterhead of Applicant]

Medical Device Branch
Pre-Marketing Division
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 reference regulatory agency’s jurisdiction for at least three years. The first date of market introduction in [jurisdiction/country] was [mm/yyyy] (for ECR 1).

OR

☐ Singapore for at least three years. The first date of market introduction in Singapore was [mm/yyyy] (for ECR 1.)

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]

[Company stamp]
### ANNEX 8

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

<table>
<thead>
<tr>
<th>Evaluation Route</th>
<th>Full Criteria (at the time of submission)</th>
<th>Abridged Criteria</th>
<th>Expedited Class C registration - ECR</th>
<th>Expedited Class D registration - EDR</th>
</tr>
</thead>
</table>
|                  | 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  
OR  
ECR – 2  
• Approvals from at least 2 of HSA’s independent reference regulatory agencies | EDR  
• Approvals from at least 2 of HSA’s independent reference regulatory agencies |

*Or the medical device has been marketed in Singapore for at least 3 years as stated in the proof of marketing history.

#Excluding applicant’s response time to input request
# ANNEX 9

## Summary of Submission Requirements (Class C and D)

<table>
<thead>
<tr>
<th>Document Requirements</th>
<th>Full</th>
<th>Abridged</th>
<th>ECR-1 and ECR-2</th>
<th>EDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Letter of Authorization</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2 Annex 2 List of Configurations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3 Proof of reference agency’s approval(s)</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4 Proof of marketing history in the reference agencies’ jurisdictions e.g. invoice with date, proof of sale or a declaration on marketing history</td>
<td></td>
<td></td>
<td>✓ Only required for ECR-1</td>
<td></td>
</tr>
<tr>
<td>5 Declaration of no safety issues globally</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Executive Summary</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>7 Essential Principles Checklist and Declaration of Conformity</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>8 Device Description</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>9 Design verification and validation documents including:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Preclinical studies e.g. physical test data, biocompatibility studies, animal studies and software verification and validation studies</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Metrological requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sterilisation validation (if applicable)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Shelf-life studies and projected useful life</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 Clinical Evidence</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>11 Proposed Device Labelling</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>12 Risk Analysis</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>13 Manufacturer Information (site’s name and address)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>14 Proof of QMS – E.g. ISO13485 certificate, conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>15 Manufacturing process – Flow chart</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

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. The summary should include a brief description of the study objectives, test methods, results and conclusions.
Contact Information:

Medical Device Branch
Pre-marketing Division
Health Products Regulation Group
Health Sciences Authority

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Singapore 138667
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Fax: 6478 9028
Email: hsa_md_info@hsa.gov.sg