Registration of Class B Medical Devices

1 INTRODUCTION

Medical devices are classified based on a rule based risk classification system into four risk classes – Class A to D with Class A being the lowest risk class and this is in line with the recommendations from the Global Harmonization Task Force (GHTF). The risk presented by a particular medical device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use. Class B medical devices are typically of low-moderate risk and includes devices such as hypodermic needles, suction apparatus, pregnancy test kits and ultrasound imaging equipment.

This guidance should be read together with the other relevant guidance documents including but not restricted to GN-12, GN-13, GN-14, GN-15, GN-17 and GN-18.

2 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 agencies and/or prior marketing history of the Class B devices. The types of approvals that qualify for abridged, EBR and IBR 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; OR
  - Pre-Market Approval from MHLW
- US Food and Drug Administration (US FDA)
  - 510K clearance
  - PMA
✓ European Union Notified Bodies (NB) via EC certificates issued according to
  o Directive 93/42/EEC Annex II section 3 or Annex V for Class IIA 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

2.1 Full Evaluation Route

A medical device that has not obtained any prior approval from any HSA’s reference agencies at the point of application will be subject to full evaluation route.

2.1.1 Submission Requirements

• Letter of Authorisation

• Annex 2: List of configurations of medical devices to be registered

• Common Submission Dossier Template (CSDT)
  a) Executive Summary
  b) Essentials Principles Checklist and Declaration of Conformity
  c) Device Description
  d) 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
  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 label claims beyond the inherent performance of the device, additional clinical data may be requested to substantiate the proposed label use.

2.1.2 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 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 requirement will be listed on the Singapore Medical Device Register (SMDR).

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

2.2 Abridged Evaluation Route

A medical device that has obtained at least one reference 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.

2.2.1 Submission Requirements

- Letter of Authorisation
- Annex 2: List of configurations of medical devices to be registered
- Proof of approval by reference agency (e.g. approval letters, certificates)
- Common Submission Dossier Template (CSDT)
  
  h) Executive Summary
  i) Essential Principles Checklist and Declaration of Conformity
  j) Device Description
  k) Summary of Design Verification and Validation Documents
     - Summary of Preclinical Studies including the sterilisation validation if applicable
     - Clinical Evidence
  l) Proposed Device Labelling
  m) Risk Analysis (if applicable)
  n) 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 label claims beyond the inherent performance of the device, additional clinical data may be requested to substantiate the proposed label use.

2.2.2 Processing of application

![Flowchart of application process]

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. 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 requirement will be 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.

2.3 Expedited Class B Registration (EBR) Evaluation Route

2.3.1 Eligibility Criteria

The following medical devices are eligible for submission via the EBR evaluation route:

(A) EBR-1: a medical device that has obtained approval from at least one of HSA’s independent reference agencies for a labelled use identical to that intended for marketing in Singapore; and

- [HSA’s medical device independent reference regulatory agencies are HC, MHLW, US FDA and TGA/EU NB and the corresponding approvals listed under Section 2 Evaluation Route]

- been marketed for at least 3 years in the above independent reference agency’s jurisdiction [or in Singapore]¹; and

- no safety issues globally, defined as
  a) no reported deaths;
  b) no reported serious deterioration in the state of health²,

  globally, associated with the use of the medical device(s) when used as intended by the Product Owner, in the last three years; and

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¹ Or the medical device has been marketed in Singapore for at least 3 years as stated in the proof of marketing history.

² 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.

³ For devices that are part of a test kit or a system, an invoice containing the kit name or system will be sufficient.
c) no open field safety corrective actions (including recalls) at the point of submission

OR

(B) EBR-2: a medical device that has obtained approval from at least two of HSA’s independent reference agencies for a labelled use identical to that intended for marketing in Singapore.

2.3.2 Submission Requirements

- Letter of Authorisation
- Annex 2 List of configurations of medical devices to be registered
- Proof of approval from independent reference agencies – [Note: one independent reference agency for EBR-1 and two independent reference agencies for EBR-2]
- Proof of marketing history\(^3\) in the same independent reference agency’s jurisdictions i.e. Invoice with date, proof of sale or a declaration on marketing history (Refer to Annex C for the template for this declaration) – [Note: for EBR-1 only]
- Declaration of no safety issues globally (Refer to Annex D for the template for this declaration) – [Note: for EBR-1 only]
- Common Submission Dossier Template (CSDT)
  a) Executive Summary
  b) Essentials Principles Checklist and Declaration of Conformity
  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 label claims beyond the inherent performance of the device, additional clinical data may be requested to substantiate the proposed label use.

2.3.3 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.

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 requirement will be 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.

2.4 Immediate Class B Registration (IBR) Evaluation Route

2.4.1 Eligibility Criteria

A medical device that fulfils the following criteria will be eligible for IBR:

- approval by at least two of HSA’s independent reference agencies for intended use identical to that submitting for registration in Singapore; and
• marketed for at least 3 years in both independent reference agencies’ jurisdictions; and

• no safety issues globally, defined as
  
  a) no reported deaths;
  
  b) no reported serious deterioration in the state of health

globally, associated with the use of the medical device(s) when used as intended by the Product Owner, in the last three years; and

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

In addition, the medical device should not have any rejection/withdrawal in any reference agency or prior rejection/withdrawal in Singapore due to quality, performance/efficacy or safety issues.

HSA’s independent reference regulatory agencies are HC, MHLW, US FDA and TGA/EU NB and the corresponding approvals listed under Section 2 Evaluation Route.

2.4.2 Submission Requirements

• Letter of Authorisation

• Annex 2 List of configurations of medical devices to be registered

• Proof of approval from independent reference agencies

• Proof of marketing history in the same two independent reference agencies’ jurisdictions i.e. Invoice with date, proof of sale or a declaration on marketing history (See Annex C for the template for this declaration)

• Declaration of no safety issue globally (See Annex D 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 label claims beyond the inherent performance of the device, additional clinical data may be requested post-registration to substantiate the proposed label use.

2.4.3 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 after 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 devices fulfil 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 registration requirement, ALL criteria specified under section 2.4.1 for the IBR evaluation route or a wrong risk class medical device submitted via the IBR evaluation route will result in cancellation of registration and the registration fee will NOT be refunded.

3  GENERAL NOTES
The evaluation routes are set out according to a confidence based approach, leveraging on reference agency approvals and prior 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 could make a submission via one of the evaluation routes if the regulatory pre-requisites of the selected route could be fulfilled. HSA reserves the right to re-route the evaluation route if the application could not fulfil the eligibility criteria.

As IBR is an immediate registration route, applicants are reminded to ensure that an application 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 the HSA. Furthermore, the device listing is subject to cancellation if it is incorrectly submitted and there will be no fee refund.

All aspects of the medical device’s quality including packaging, labelling (including instruction of use), and intended purpose/indications for use, intended for supply in Singapore shall be the same as that approved by the reference agencies that have approved the medical device.

A summary of the evaluation routes and its corresponding documentation requirements is attached in Annex A and B respectively.
### Summary of Evaluation Routes

<table>
<thead>
<tr>
<th>Evaluation Route</th>
<th>Full Abridged</th>
<th>Expedited Class B registration - EBR</th>
<th>Immediate Class B registration – IBR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criteria</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(at the time of submission)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Not approve by any of HSA medical device’s reference agencies</td>
<td>• At least 1 reference agency’s approval</td>
<td>• At least 2 independent reference agencies’ approvals</td>
<td></td>
</tr>
<tr>
<td>• Marketed for ≥ 3 years in the above independent reference agency’s jurisdiction*</td>
<td>• No safety issues globally</td>
<td>• Marketed for ≥ 3 years in the above 2 independent reference agencies’ jurisdiction</td>
<td></td>
</tr>
<tr>
<td>*Or the medical device has been marketed in Singapore for at least 3 years as stated in the proof of marketing history.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Targeted Turn-Around-Time</strong></th>
<th>160 working days#</th>
<th>100 working days#</th>
<th>60 working days#</th>
<th>Immediate listing upon successful submission in MEDICS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Fee</strong></td>
<td>S$4,000</td>
<td>S$2,300</td>
<td>S$1,400</td>
<td>S$1,400</td>
</tr>
</tbody>
</table>

#Excluding company’s response time to input request
## Annex B

### Summary of Submission Requirements

<table>
<thead>
<tr>
<th>Documentary Requirements</th>
<th>Full</th>
<th>Abridged</th>
<th>EBR -1 and 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,</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>Detailed reports</td>
<td>Summary</td>
<td>Summary</td>
<td>Sterilisation validation for Sterile device only³</td>
</tr>
<tr>
<td>o Preclinical studies</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>o Clinical evidence</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>10 Proposed device Labelling⁴</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>11 Risk Analysis</td>
<td>✓</td>
<td></td>
<td>If applicable</td>
<td>If applicable</td>
</tr>
<tr>
<td>12 Manufacturing site’s name and address</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>13 Proof of Quality Management System – 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>14 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 Medical devices with label claims beyond the inherent performance of the device, additional clinical data may be requested to substantiate the proposed label use.
Annex C

Marketing History 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 the medical devices have been marketed in

☐ the two reference regulatory agencies 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 reference regulatory agency 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 from the date of this declaration. 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 a false declaration is an offence under 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]
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 reported deaths
☐ No reported serious deterioration in the state of health

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]; and

☐ No open field safety corrective actions (including recalls) at the date of this letter

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

[List containing product names of medical devices]

I, the applicant, am aware that a false declaration is an offence under 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]

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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