

GUIDE TO APPLICATION FOR PRODUCT REGISTRATION OF HIGHER RISK MEDICAL DEVICE(S) – CLASS B

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant to apply for the registration of higher risk medical devices with the Authority for local commerce.

The online [Application \(Product Registration for Higher risk medical device\)](#) in MEDICS may take an average of 5-10 minutes to fill in.

The time taken varies depending on the number and sizes of the file attachments, configurations of your computer and network system, Internet performance, etc. The recommended computer and network configurations are at the following URL:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/MEDICS_e-Services/Accessing_MEDICS/System_Requirement_for_accessing_MEDICS.html

Please note that the time stated above excludes time taken for preparatory work in relation to filing the online form (e.g. scanning documents for file attachments.)

INSTRUCTIONS

In order to use this e-Service in MEDICS, you must have all of the following:

- 1. Personal Access Authentication to log on**
 - [CorpPass](#) (Singapore Corporate Access), a corporate digital identity for business and other entities to transact with Government online services, OR
 - [HSA PIN](#) (HSA Personal Identification Number), password for overseas individual, supplied by HSA
- 2. A CRIS Company Account for MEDICS** (Client Registration & Identification Services), an account to enable a local company to gain access to MEDICS. See details at cris@hsa.
- 3. A Registrant Account** that is held by a local company who registers medical devices on behalf of a Product Owner.

In the application, you need to provide the following information:

- 1) Each application is for registration of only one SINGLE medical device, or medical device FAMILY, or medical device SYSTEM or GROUP, or TEST KIT for IVD. Please refer to the following guidance documents for more information:
 - GN-12 Guidance on Grouping of Medical Devices for Product Registration
- 2) The softcopy of the supporting documents must be prepared in the ASEAN CSDT format. Please refer to the following [guidance documents](#) for more information:
 - GN-15-R1 Guidance on Medical Device Product Registration
 - GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
 - GN-18 Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostics (IVD) Medical Devices using the ASEAN CSDT

REFERENCES

The information in the following guidance documents is useful for the application.

- GN-12 Guidance on Grouping of Medical Devices for Product Registration
- GN-15-R1 Guidance on Medical Device Product Registration
- GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
- GN-18 Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostics (IVD) Medical Devices using the ASEAN CSDT
- GN-13-R1 Guidance on the Risk Classification of General Medical Devices

PAYMENT

Please click [here](#) for the Tables of Fees for Certification, Licence and Product Registration for Medical Devices.

ONLINE APPLICATION FORM

This online Application Form consists of 8 parts (via Applicant Info; Device Info; Priority Review Scheme; Details of Reference Agency; Device Details; Evaluation Route; Dossier & Supporting Documents; and Remarks).

MD0410 - PRE-MARKET APPLICATION FOR MEDICAL DEVICE > New Application

APPLICATION FORM			
1. Applicant Info	2. Device Info	3. Priority Review Scheme	Please refer to the
4. Details of Reference Agency	5. Device Details	6. Evaluation Route	Guidelines on the...
7. Dossier & Supporting Document(s)	8. Remarks		

Fields marked with asterisks * are mandatory.

1. APPLICANT INFO

Change the following info if you are applying on behalf of the applicant.

Name : * NRIC/Passport No. : *

Tel. No. : * Fax No. : *

Email : *

Drafter Assignment

Drafter type : Staff Partner

Available Company's Drafters :

2. DEVICE INFO

Please provide the details of one or more of the same kind of devices.

[Click Add/Edit Info](#)

3. Priority Review Scheme

Please note that applications under Priority Review Scheme will be reviewed via the Full Evaluation Route with relevant evaluation fees applicable.

I would like to opt in for the Priority Review Scheme: * Yes No

i) Does your application meet the Priority Review qualifying criteria ii) and iii)? * Yes No

ii) Please select the relevant healthcare focus area: *

- Cancer
- Diabetes
- Ophthalmic Diseases
- Cardiovascular diseases
- Infectious Diseases

iii) Please select the relevant description to your device: *

Note: Please be reminded that submission of detailed justification for your selection in (iii) is required as part of documentary requirements.

- The device is intended for a medical purpose with no existing alternative treatment or means of diagnosis
- The device represents a breakthrough technology that provides a clinically meaningful advantage over existing legally marketed technology

[Click Save](#)

4. DETAILS OF REFERENCE AGENCY

Please provide details of Reference Agency.

(Note: Details of reference agencies in this section shall apply to **all models** submitted in this application.)

[Click Add/Edit Info](#)

5. DEVICE DETAILS

Please provide more details for the devices added in section 2 above.

[Click Add/Edit Info](#)

6. EVALUATION ROUTE

Please enter details of reference agency in section 4.

Route Definition:

Immediate B Registration (IBR):
Approval by 1 of HSA's independent reference agencies and marketed in at least ONE jurisdiction or Singapore without safety issues for at least 3 years.

OR

Approval by 2 of HSA's independent reference agencies.

OR

Standalone Medical Mobile Application with approval by at least 1 of HSA's independent reference agencies.

Immediate C Registration (ICR):
Standalone Medical Mobile Application with approval by at least 1 of HSA's independent reference agencies

Expedited C Registration (ECR):
ECR 1: Approval by 1 of HSA's independent reference agencies and marketed in Singapore and any market without safety concerns for at least 3 years.
ECR 2: Approval by 2 of HSA's independent reference agencies.

Expedited D Registration (EDR): Approval by 2 of HSA's independent reference agencies.

7. DOSSIER & SUPPORTING DOCUMENT(S)

Dossier & supporting document(s) should be submitted to the Authority for evaluation.

[Click Attach/Remove Document](#)

8. REMARKS

Remarks to MDB :
(You may enter a maximum of up to 1000 characters.)

For Part 2, 4, 5 and 6, click on “Add/Edit Info” to access that section of the on-line form.
For Part 3, make relevant selections and click “Save” to proceed.
For Part 7, click on “Attach/Remove Document” to attach relevant supporting documents.

At the end of the application form, there are 3 button options:

Button - Save Draft

Allows the applicant to save the Application Form for retrieval and submission at a later time. A transaction number will be assigned.

The saved Application Form can be retrieved from “My Drafts” in the Workbench@MEDICS.

Button – Confirm

Allows the applicant to confirm the completed Application Form and the company’s declaration on the form before submitting it to MDB. To amend any mistake, click on the “<< Previous” Button to return to the Application Form. Before the application is submitted, the applicant may print a copy the application for his record.

Button – Close

Closes the application form without saving any changes made.

PART 1 – Applicant Info



The applicant refers to the individual designated by the company as contact point for any correspondence regarding this application. This section requires the applicant to fill in the following:

- 1) Name
- 2) NRIC/Passport No
- 3) Contact Telephone Number
- 4) Contact Fax Number
- 5) Contact E-mail

Items 1 to 3 are pre-populated from CRIS Company Account database and can be updated or replaced.

Drafter Assignment

This is to allow designated staff or external partner to prepare the application form as a drafter. Note that the completed application will then need to be submitted by someone authorised as a submitter.

A Submitter is allowed to prepare drafts and submit applications without the help of an intermediary drafter. The role of the current login user is displayed at the top of the screen under the Login ID.

- 1) *Drafter type*: The applicant can select either a “**Staff**” or “**Partner**”
- 2) *Available Company’s Drafters*: Once the above is selected, the corresponding list of drafters will then be selectable from the drop down list.

The list of available drafter depends on the user setting in the [CRIS Management Module](#). The CRIS Administrator is able to set up company users or service providers/partners to be drafter for this e-Service.

PART 2 – Device Info

MD0411 - PRE-MARKET APPLICATION FOR MEDICAL DEVICE > New Application > Add Device Info

APPLICATION FORM			
1. Applicant Info	2. Device Info	3. Priority Review Scheme	Please refer to the Guidelines on the...
4. Details of Reference Agency	5. Device Details	6. Evaluation Route	
7. Dossier & Supporting Document(s)	8. Remarks		

Fields marked with asterisks * are mandatory.

ADD DEVICE INFO

Device Proprietary/Brand Name : * Symbol

(Full device name as per label, including product owner name. E.g. if product owner is ABC Pte Ltd and full name as per device label is XYZ Wound Dressing, please input the Device Proprietary/Brand Name as "ABC XYZ Wound Dressing")

Description of intended use : *

(What the product is used for as stated in the Instructions for Use /Operating Manual/ Brochure (if IFU is not available). You may enter a maximum of up to 1000 characters.)

In Vitro Diagnostic Device : * Yes No

Standalone Medical Mobile Application : * Yes No

(Standalone Medical Mobile Application refers to a software and/or mobile application that is intended to function by itself and are not intended for use to control or affect the operation of other hardware medical devices.)

Medical Device Class : * -- Select Medical Device Class -- Classification

[View Classification Response](#)

To add a new device, enter the device info and click [Add](#).

Close

Item 1: Device Proprietary/Brand Name

The applicant is required to provide the name of the device as it appears on the product label.

Item 2: Description of intended use

The applicant is required to provide the intended purpose of the device according to the specifications of the product owner as stated on the product label, instruction of use or promotional materials.

Item 3: In vitro Diagnostic Device

The applicant is required to select whether the device is an *in-vitro* diagnostic device or not.

Item 4: Standalone Medical Mobile Application

The applicant is required to select whether the device is a **Standalone Medical Mobile Application**.

Standalone Medical Mobile Application refers to a software and/or mobile application that is intended to function by itself and are not intended for use to control or affect the operation of other hardware medical devices.

Item 5: Selection from a list of classification

The applicant is required to select the device class of the product. Please refer to the following guidance documents for more information:

- GN-13-R1 Guidance on the Risk Classification of General Medical Devices

Click on **“Add”** to add the device after completing all the fields.

To remove a device from the **“list of device(s) added”**, select the corresponding checkbox and click **“Remove”**.

To edit the device info after adding the device to the list, select the corresponding checkbox and click **“[Edit]”**

Click the **“Update Form”** Button when all devices are added.

Note:

Only devices of the same class can be added.

Risk Class as added here will determine the fields required to be filled in in part 3 below.

PART 3 – Priority Review Scheme

3. Priority Review Scheme

Please note that applications under Priority Review Scheme will be reviewed via the Full Evaluation Route with relevant evaluation fees applicable.

I would like to opt in for the Priority Review Scheme: * Yes No

i) Does your application meet the Priority Review qualifying criteria ii) and iii)? * Yes No

ii) Please select the relevant healthcare focus area: *

- Cancer
- Diabetes
- Ophthalmic Diseases
- Cardiovascular diseases
- Infectious Diseases

iii) Please select the relevant description to your device: *

Note: Please be reminded that submission of detailed justification for your selection in (iii) is required as part of documentary requirements.

- The device is intended for a medical purpose with no existing alternative treatment or means of diagnosis
- The device represents a breakthrough technology that provides a clinically meaningful advantage over existing legally marketed technology

[Click Save](#)

Click the “**Save**” Button when the changes are completed.

Note: If “**Yes**” was selected to opt in for Priority Review Scheme,

- PART 4 - Details of Reference Agency will not be required
- PART 6 – Evaluation Route”: only “FULL” evaluation route option will be available

PART 4 – Details of Reference Agency

This section requires the applicant to fill in the **Details of Reference Agency** and answer the following questions where applicable:

- 1) Marketed in at least **TWO** jurisdictions without safety issues for at least 3 years
- 2) Marketed in at least **ONE** jurisdiction or Singapore without safety issues for at least 3 years
- 3) Was the registration of this medical device **rejected** by any of the reference agencies or Singapore?
- 4) Was the registration of this medical device **withdrawn** in any of the reference agencies or Singapore?

MD0418 - PRE-MARKET APPLICATION FOR MEDICAL DEVICE > New Application > Details of Reference Agency

APPLICATION FORM			
1. Applicant Info	2. Device Info	3. Priority Review Scheme	
4. Details of Reference Agency	5. Device Details	6. Evaluation Route	Please refer to the Guidelines on the...
7. Dossier & Supporting Document(s)	8. Remarks		

Details of Reference Agency

- US Food and Drug Administration (US FDA)
- Japan Ministry of Health, Labour and Welfare (MHLW)
- European Union (EU)
- Health Canada (HC)
- Australia Therapeutic Goods Administration (TGA)
- None of the above

1. Marketed in at least **TWO** jurisdictions without safety issues for at least 3 years : Yes No

2. Marketed in at least **ONE** jurisdiction or Singapore without safety issues for at least 3 years : Yes No

3. Was the registration of this medical device **rejected** by any of the reference agencies or Singapore? Yes No

4. Was the registration of this medical device **withdrawn** in any of the reference agencies or Singapore? Yes No

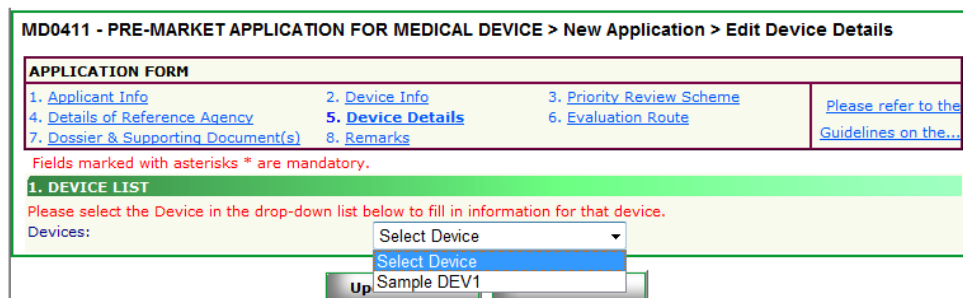
Update Form
Close

Note: If “**Yes**” was selected for question 3 and/or 4, the following new fields will be displayed to be filled in:

- Reason for rejection and Details for rejection for question 3
- Reason for withdraw and Details for withdraw for question 4

PART 5 – Device Details

This section requires the applicant to fill in the Device Details. Select the device you wish to fill in from the Devices drop-down list



After selecting the devices, the following fields and sub-sections will be displayed:

- 1) *Device Proprietary/Brand Name*
 - *Description of intended use*
 - *Medical Specialty Area*
 - *HS Code*
 - *HSA Product Code*
 - *Professional Use Only*
 - *Biological Material Component*
 - *Custom-made Device*
 - *Device with measuring function*
 - *System or Procedure Pack*
 - *Sterile Medical Device*
 - *Description*
- 2) *Product Owner Info*
- 3) *Manufacturing Site(s) Info*
- 4) *Model(s) Info*
- 5) *Importer & Wholesaler Info*

For sections 2, 3 4 and 5, click on “**Add/Edit Info**” to access the sub-section and fill in the details accordingly.

MD0411 - PRE-MARKET APPLICATION FOR MEDICAL DEVICE > New Application > Edit Device Details

APPLICATION FORM


1. Applicant Info	2. Device Info	3. Priority Review Scheme	Please refer to the Guidelines on the...
4. Details of Reference Agency	5. Device Details	6. Evaluation Route	
7. Dossier & Supporting Document(s)	8. Remarks		

Fields marked with asterisks * are mandatory.

1. DEVICE LIST

Please select the Device in the drop-down list below to fill in information for that device.

Devices:

Device Proprietary/Brand Name : * 

(Full device name as per label, including product owner name. E.g. if product owner is ABC Pte Ltd and full name as per device label is XYZ Wound Dressing, please input the Device Proprietary/Brand Name as "ABC XYZ Wound Dressing")

Description of intended use : *

(What the product is used for as stated in the Instructions for Use / Operating Manual / Brochure (if IFU is not available). You may enter a maximum of up to 1000 characters.)

If you want to change Risk Class, please go back to section 2 Device Info.

In Vitro Diagnostic Device : * Yes No

Standalone Medical Mobile Application : * Yes No

Medical Device Class : *

Medical Specialty Area : *

Professional Use only : No Yes
(A "for professional use only" medical device is a medical device that is to be used on an individual solely by, or under the supervision of a qualified practitioner.)

Biological Material Component :
(Use 'CTRL' key to select/deselect the item(s))

Human
Bovine
Ovine
Porcine
Animal (Others)

Custom-made Device : No Yes

Device with measuring function : No Yes

System or Procedure Pack : No Yes

Sterile Medical Device : No Yes

Description of :

i) Custom-made Device
ii) Device with Measuring Function
iii) System or Procedure Pack
iv) Sterile Medical Device
(* Mandatory if this is a Custom-made Device / Device with Measuring Function / System or Procedure Pack / Sterile Medical Device, max 255 chars)

2. PRODUCT OWNER INFO

Please provide product owner info. [Click Add/Edit Info](#)

3. MANUFACTURING SITE(S) INFO

Please provide manufacturing site(s) info. [Click Add/Edit Info](#)

4. MODEL(S) INFO

Please provide model(s) info. [Click Add/Edit Info](#)

5. IMPORTER & WHOLESALER INFO

Please provide Importer & Wholesaler Info. [Click Add/Edit Info](#)

To update device, enter the device info and click [Update](#).

Product Owner Info:

MD0476 - PRE-MARKET APPLICATION FOR MEDICAL DEVICE > New Application > Product Owner Info

APPLICATION FORM			
1. Applicant Info	2. Device Info	3. Product Owner Info	Please refer to the Guidelines on the...
4. Manufacturing Site(s) Info	5. Model(s) Info	6. Importer & Wholesaler Info	
7. Remarks from MDB	8. Remarks		

Fields marked with asterisks * are mandatory.

PRODUCT OWNER INFO

Product Owner Name : [Click Populate](#)

To add a new Product Owner particulars in below section if it does not exist in the selection list, click on [Add New](#).

Close

- Select a Product Owner from the drop-down list
- Click **“Populate”** to select it

Fields marked with asterisks * are mandatory.

PRODUCT OWNER INFO

Product Owner Name : [Click Populate](#)

To add a new Product Owner particulars in below section if it does not exist in the selection list, click on [Add New](#).

Product Owner Info

Company Name : *

Address Type : *

Postal Code : *

Block/No. :

Street Name :

Building Name :

Level - Unit :

Country : *

Main Tel. No : *

Contact Person : *

Contact Tel. No. : *

Contact Email : *

(For future communication and email notification.)

Update Form **Close**

- Modify the contact details if necessary

Note: if your product owner is not in the drop-down list, click on **“Add New”** to manually add and select the newly added product owner.

Manufacturing Site(s) Info:

MD0472 - PRE-MARKET APPLICATION FOR MEDICAL DEVICE > New Application > Manufacturing Site(s) Info

APPLICATION FORM

1. [Manufacturing Site\(s\) Info](#) 2. [Add/Update Manufacturing Site](#) [Please refer to the Guidelines on the...](#)

Fields marked with asterisks * are mandatory.

MANUFACTURING SITE(S) INFO

Site Location : Local Overseas

Site Name : Starts With [Click Search](#)

To add a new manufacturing site, click [Add New Site](#).

- Use the search function to search for existing manufacturing site(s)
- Select the manufacturing site(s) from the result list
- Click “Add” to add the selected site(s)
- To remove, select the site(s) from the **List of Manufacturing Site(s) selected**, then click “Remove”

Fields marked with asterisks * are mandatory.

MANUFACTURING SITE(S) INFO

Site Location : Local Overseas

Site Name : Contains [Click Search](#)

List of Manufacturing Site(s)

Total 7 records Page 1 of 1 [Go](#) [\[first\]](#) | [\[previous\]](#) | [\[next\]](#) | [\[last\]](#)

S/No.	<input type="checkbox"/>	Site Name	Quality System/Expiry Date
1.	<input type="checkbox"/>		
2.	<input type="checkbox"/>		
3.	<input type="checkbox"/>		
4.	<input type="checkbox"/>		
5.	<input type="checkbox"/>		
6.	<input type="checkbox"/>		
7.	<input type="checkbox"/>		

To select a manufacturing site, select the checkbox and click [Add](#).
To add a new manufacturing site, click [Add New Site](#).

List of Manufacturing Site(s) selected

S/No.	<input type="checkbox"/>	Site Name	Quality System/Expiry Date
1.	<input type="checkbox"/>		

Click on the Manufacturing site name to complete the Quality system/Expiry Date information.
To remove a manufacturing site from the above list, select the checkbox and click [Remove](#).

Note: if your manufacturing site does not exist, click on “Add New Site” to manually add and select the newly added manufacturing site.

Model(s) Info:

MD0473 - PRE-MARKET APPLICATION FOR MEDICAL DEVICE > New Application > Model Info

APPLICATION FORM

1. Applicant Info	2. Device Info	3. Product Owner Info	Please refer to the Guidelines on the...
4. Manufacturing Site(s) Info	5. Model(s) Info	6. Importer & Wholesaler Info	
7. Remarks from MDB	8. Remarks		

MODEL(S) INFO

Product Code for Accessories (Mandatory if model info is entered.): * --Select Product Code--

To add multiple model info (Click [here](#) (Right click & Save Target As) to download the excel template) :

Manufacturing Site(s) List

Site ID	Site Name	Site Address

Note: Please input the Site ID at the excel file as shown above for the upload.

Append to Existing Model List Clear Existing Model List

Model Name

Model Number

Description (Max 250 Characters)

Manufacturing Site(s)

Site Name (Postal Code) [Site ID]

- Select a **Product Code for Accessories**
- You can either download and fill in the Excel template to upload the Model list via the “**Upload**” function OR
- Manually fill in the following fields and “**Add to List**” the Model one by one
 - o Model Name
 - o Model Number
 - o Description
 - o Manufacturing Site(s)
- To remove, select the model(s) from the **Model(s) Added** list, then click “**Remove**”

Model Name

Model Number

Description (Max 250 Characters)

Manufacturing Site(s) Malaysia Site Name [C3401929-i12]

Site Name (Postal Code) [Site ID]

Model(s) Added

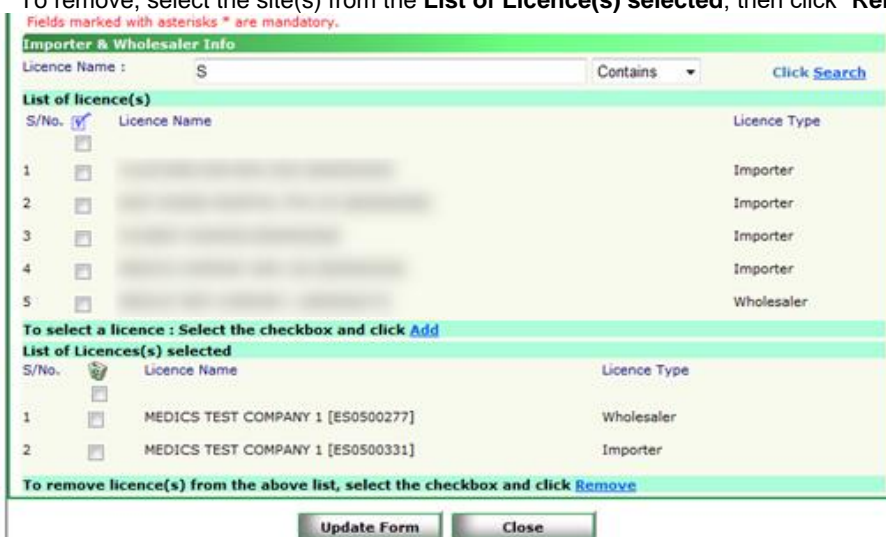
S/No.	Delete?	Model Name	Model Number	Description (Max 250 Characters)	Manufacturing Site(s)
1.	<input type="checkbox"/>	Model 01	Mo01	Model 01	

To remove a model from above list : Select the checkbox and click button.

Importer & Wholesaler Info:



- Use the search function to search for existing Importer(s) and Wholesaler(s)
- Select the Importer(s) and/or Wholesaler(s) from the result list
- Click “Add” to add the selected site(s)
- To remove, select the site(s) from the **List of Licence(s) selected**, then click “Remove”



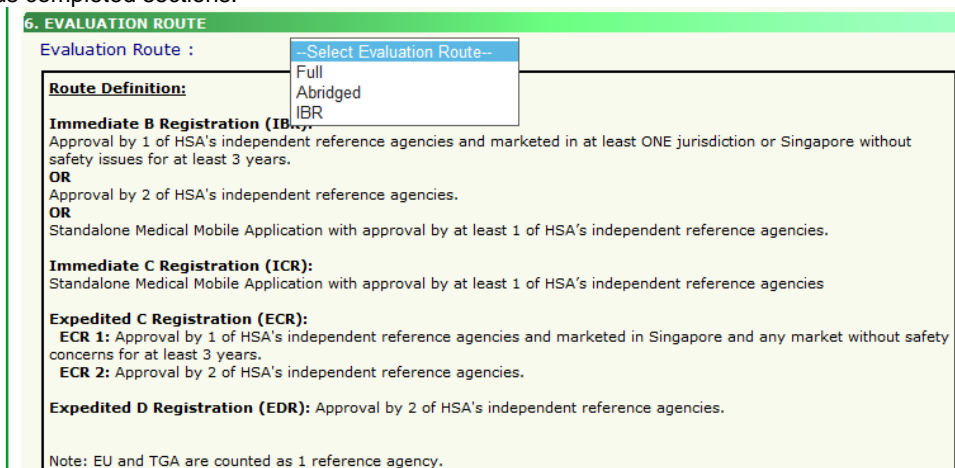
After filling all mandatory fields and sub-sections, click “**Update Form**” to save the Device Details.

Note:

- If there are multiple devices under the same draft, use the drop-down list at the top to switch between devices.
- After filling in the first device, switching to a new device will trigger the auto-copy function where all fields except the Model(s) Info are copied over for your convenience.

PART 6 – Evaluation Route

This section requires the applicant to select the Evaluation Route from the available options according to inputs in the previous completed sections.



PART 7 – Dossier & Supporting Document(s)

This section requires the applicant to upload supporting documents for each device.

The supporting document in ASEAN CSDT format can be attached under "Other document" in this section of the application.

The supporting documents are attached by:

- selecting the device(s) from the selection box
- browsing the local storage devices for the documents using the “**Browse**” button

DOSSIER & SUPPORTING DOCUMENT(S)

Please refer to the Guidelines on the documents to be attached for different category of Medical Device classes and IVD category for Pre-Market Application.

Please attach the following document(s) by typing in the path or click on the browse button.

1. All Letter of authorization *

Sample DEV 1

- attaching these documents by clicking on the “**Add Attachment**” after all documents have been selected

6. All Manufacturing Information (site's name and address) *

Sample DEV 1

To attach, click [Add Attachment](#).

To remove documents from the “**list of documents attached**”, select the corresponding checkbox and click “**Remove Attachment**”.

List of Document(s) Attached

Document(s) scanned is virus-free.

S/No.	<input type="checkbox"/>	Device Name	Document Name	Description	Size (KB)	Uploaded Date
1.	<input type="checkbox"/>	Sample DEV 1	Notes.txt	Letter of authorization	1	04/01/2013

To remove a document from the above list, select the checkbox and click [Remove Attachment](#).

Click the “**Update Form**” Button when all required documents are attached.

Note:

- If a document is applicable for more than one device, you can select multiple devices from the selection box before browsing to the document and uploading it.
- If a document is applicable for ALL devices, you can select All from the selection box before browsing to the document and uploading it.
- If the device name is too long and you cannot distinguish them due to the limit of the section box, move the mouse over to the device name, the full name will be displayed below the mouse cursor.

PART 8 – Remarks

This section is for the applicant to insert any remarks to MDB regarding the application.

8. REMARKS

Remarks to MDB :
(You may enter a maximum of up to 1000 characters.)

END OF DOCUMENT