GUIDE TO APPLICATION FOR SPECIAL AUTHORISATION ROUTES

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows an Importer to apply for the special authorisation routes with the Authority for local commerce.

The online Application (Special Authorisation Routes) 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.

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.

REFERENCES

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

- GN-26: Clinical - For use on his patient
- GN-27: Clinical - For use in the PHMC facility
- GN-28: Re-export
- GN-29: Non-clinical
- GN-30: Consignment

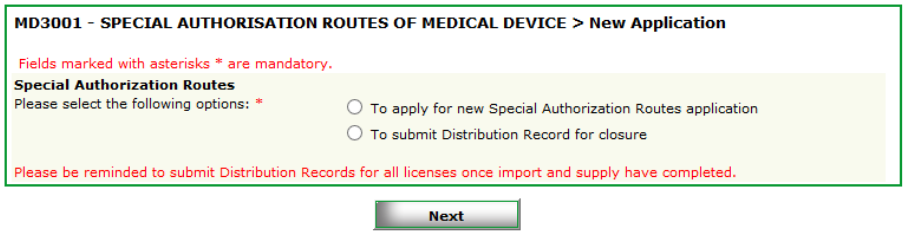
PAYMENT

Please click here for the Tables of Fees for Special Authorisation Routes.

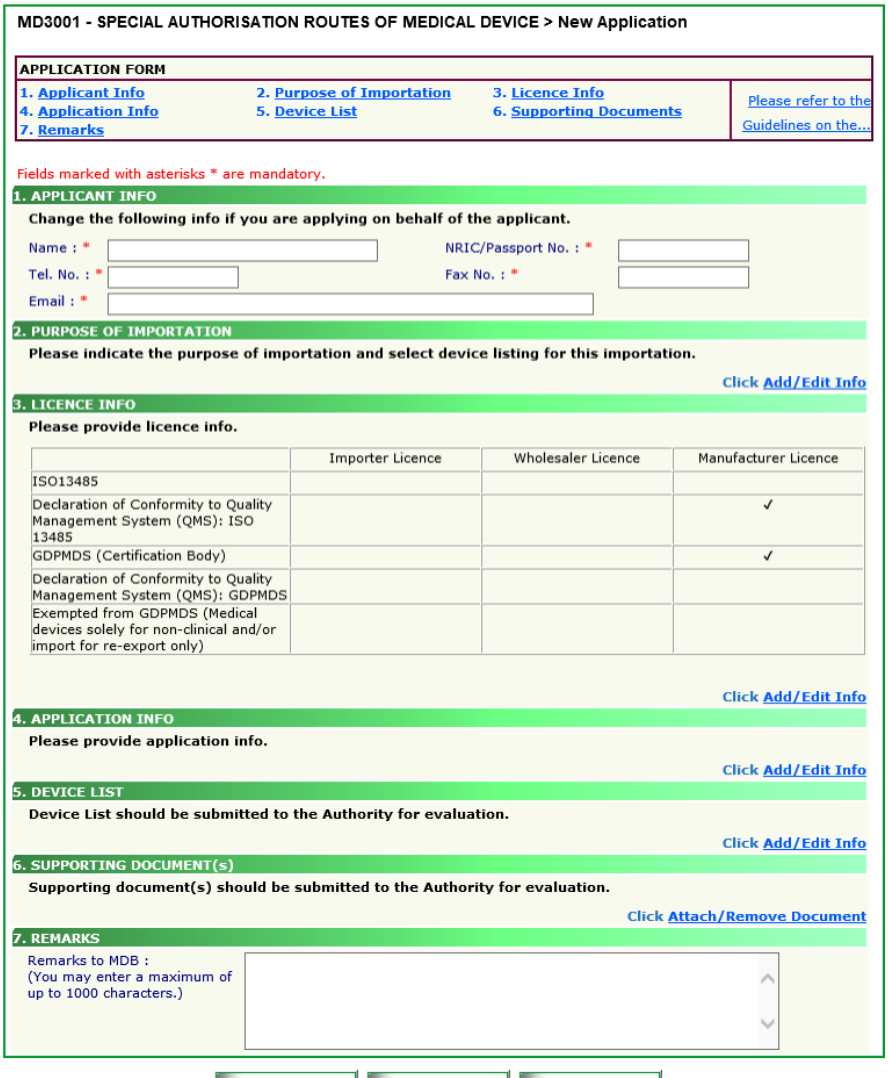
ONLINE APPLICATION FORM

There are two application types:

- Special Authorisation Routes
- Distribution Record



This online Application Form consists of 7 parts (via Applicant Info; Purpose of Importation; Licence Info; Application Info; Device List; Supporting Documents; and Remarks).



For Part 2, 3, 4 and 5, click on "**Add/Edit Info**" to access that section of the on-line form.

For Part 6, click on "**Attach/Remove Document**" to attach relevant supporting documents

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

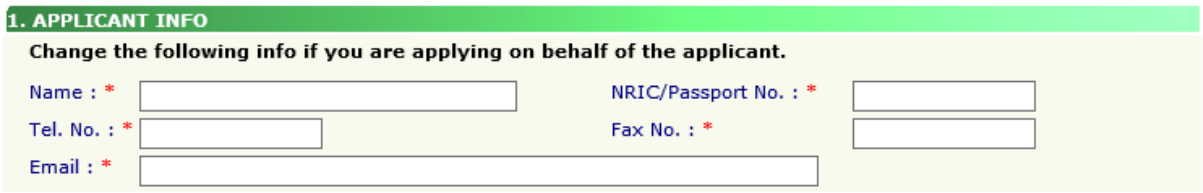
Button - Save Draft
Allows the applicant to save the Application Form for retrieval and submission at a later time. A transaction number will be assigned.

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



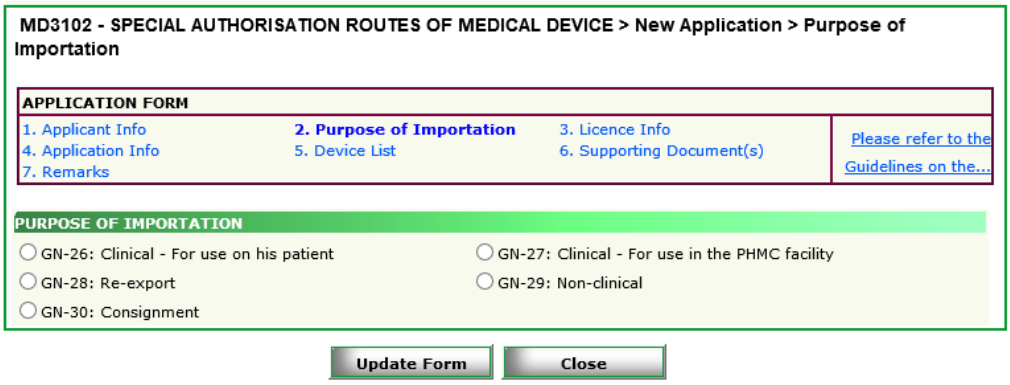
The applicant refers to the individual designated by the company as contact point for any correspondence regarding this application. This section requires the applicant to fill in the following:

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

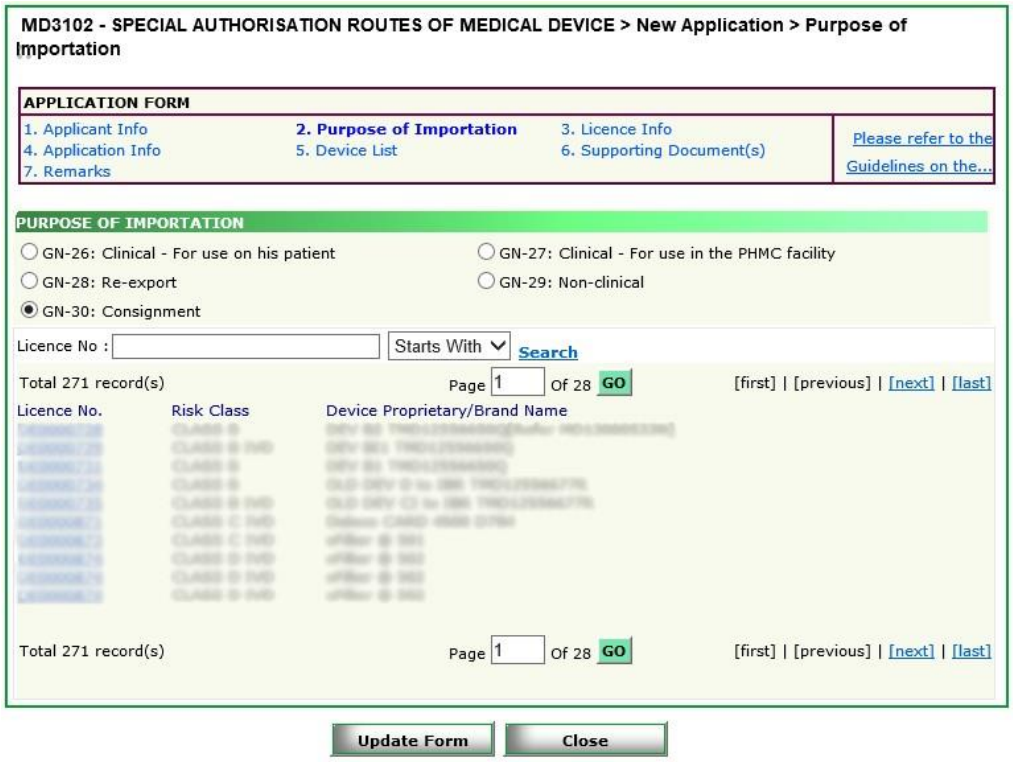
Items 1 to 3 are pre-populated from CRIS Company Account database and can be updated or replaced.

PART 2 – Purpose of Importation

This section is to select the purpose of importation.

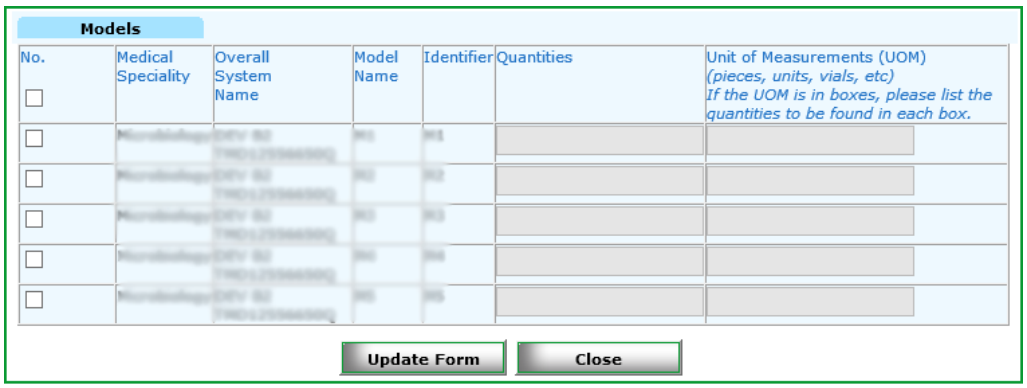


When **"GN-30"** is selected:



Click on Licence No. for Device Model listing.

Tick on the Model checkbox and fill in Quantities and Unit of Measurements.



Click **"Update Form"** to proceed.

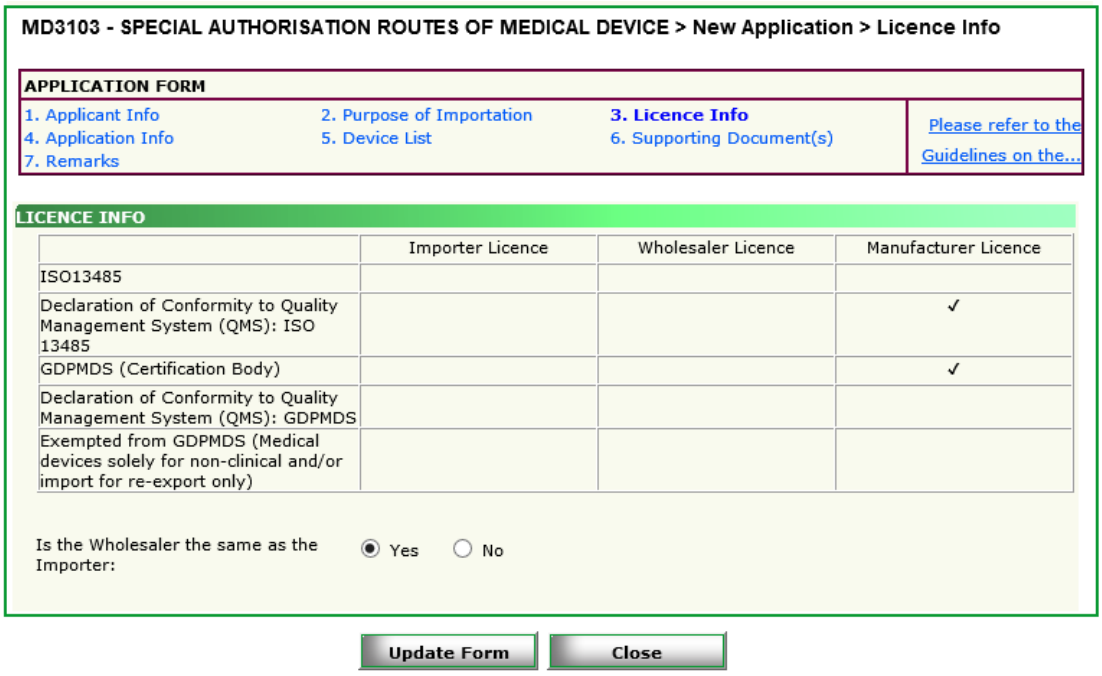
PART 3 – Licence Info

This section is only applicable for GN-26, GN-27, GN-28, & GN-29.

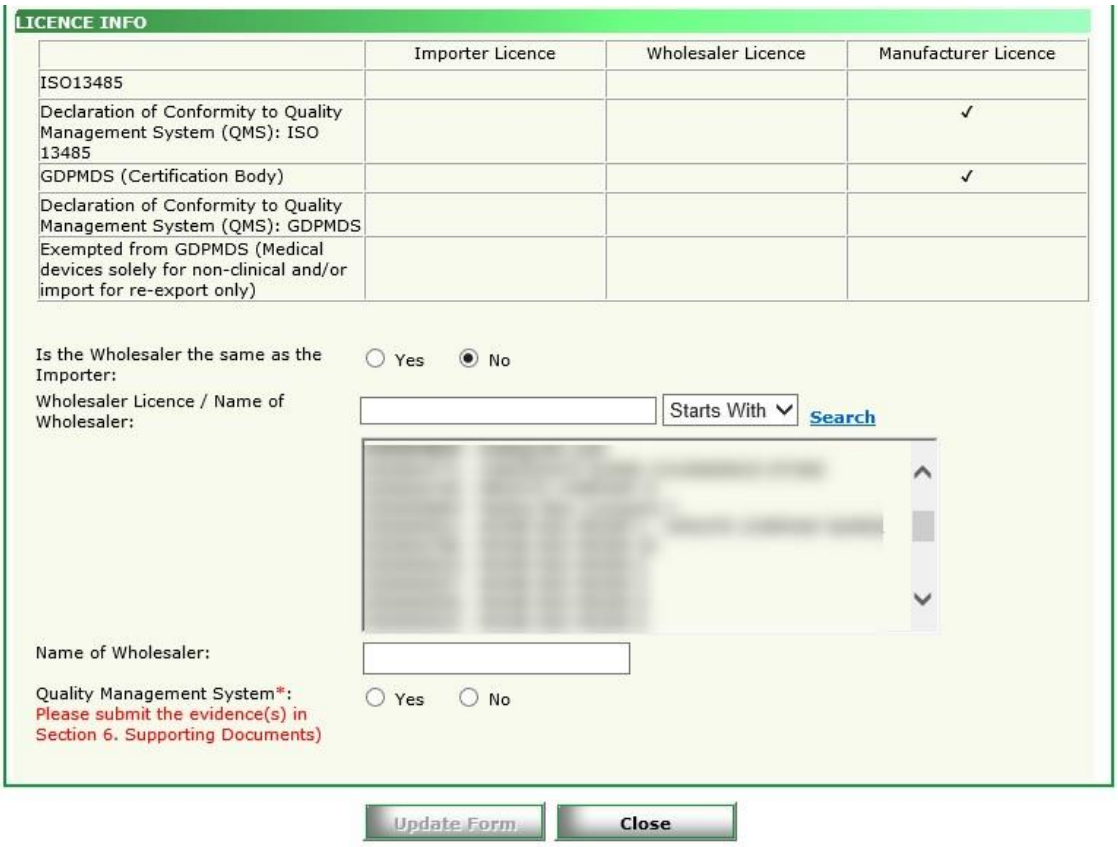
The licence information reflected in this section refer to the types of dealer licence(s) held by the importing company.

The applicant is required to select whether the Wholesaler is the same as the Importer.

- If the Wholesaler is the same as the Importer', select "Yes" and click **"Update Form"** to proceed.



- If **"No"** is selected for 'Is the Wholesaler the same as the Importer', applicant is required to select the Wholesaler from the dropdown list or specify the Name of Wholesaler involved.
- Applicant is required to input the Name of Wholesaler if the Wholesaler cannot be found in the dropdown list and indicate if Quality Management System is available (for GN-26 and GN-27 applications only). Evidence has to be submitted in Section 6. Supporting Documents if Yes is selected for Quality Management System.
- Click **"Update Form"** to proceed.



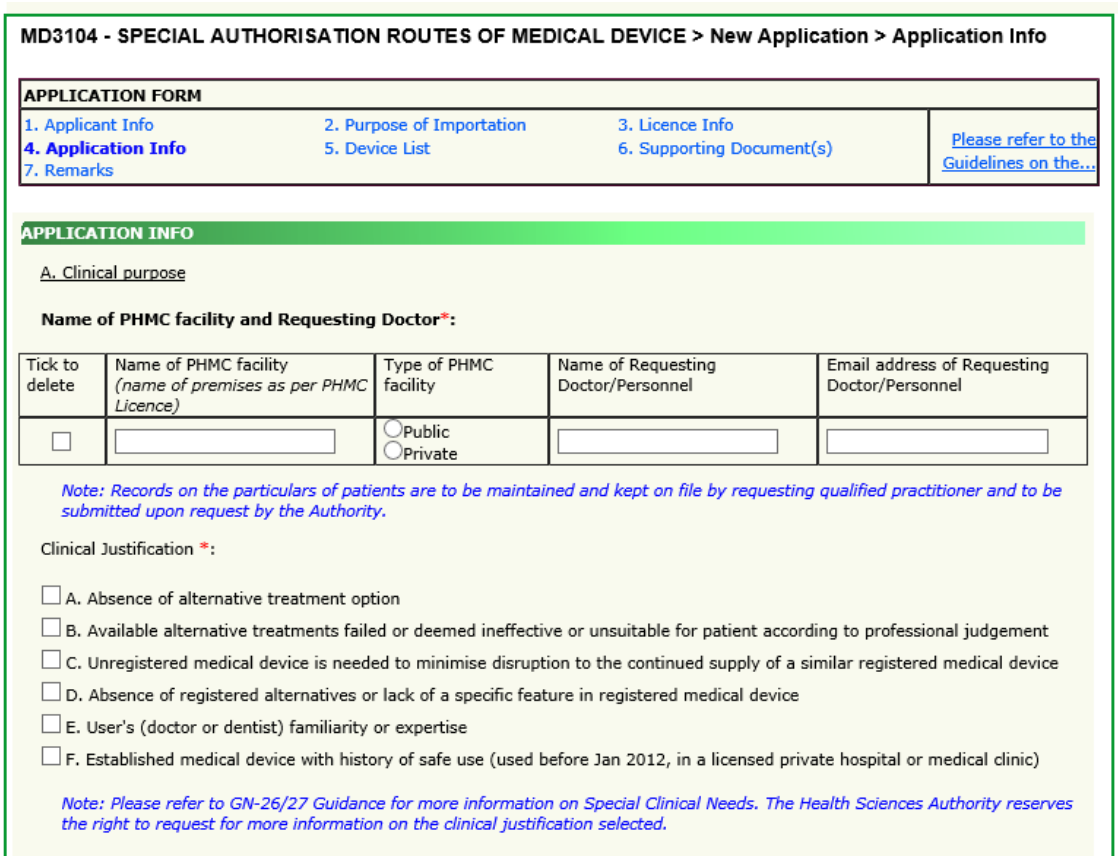
PART 4 – Application Info

The applicant is required to fill selective section based on the selected route.

Section A. Clinical purpose is only applicable for GN-26 & GN-27.

When GN-26 is selected, the applicant is required to:

- Provide information on PHMC facility, requesting qualified practitioner.
- Select the applicable clinical justification indicated on the request form completed by the qualified practitioner.
- Request form signed by qualified practitioner shall be scanned and uploaded in PART 6 – Supporting Document(s) under "5. Doctor's Declaration"



MD3104 - SPECIAL AUTHORISATION ROUTES OF MEDICAL DEVICE > New Application > Application Info

APPLICATION FORM

1. Applicant Info | 2. Purpose of Importation | 3. Licence Info
4. Application Info | 5. Device List | 6. Supporting Document(s)
7. Remarks

Please refer to the Guidelines on the...

APPLICATION INFO

A. Clinical purpose

Name of PHMC facility and Requesting Doctor*:

Tick to delete	Name of PHMC facility *(name of premises as per PHMC Licence)*	Type of PHMC facility	Name of Requesting Doctor/Personnel	Email address of Requesting Doctor/Personnel
☐		○Public ○Private		

Note: Records on the particulars of patients are to be maintained and kept on file by requesting qualified practitioner and to be submitted upon request by the Authority.

Clinical Justification *:

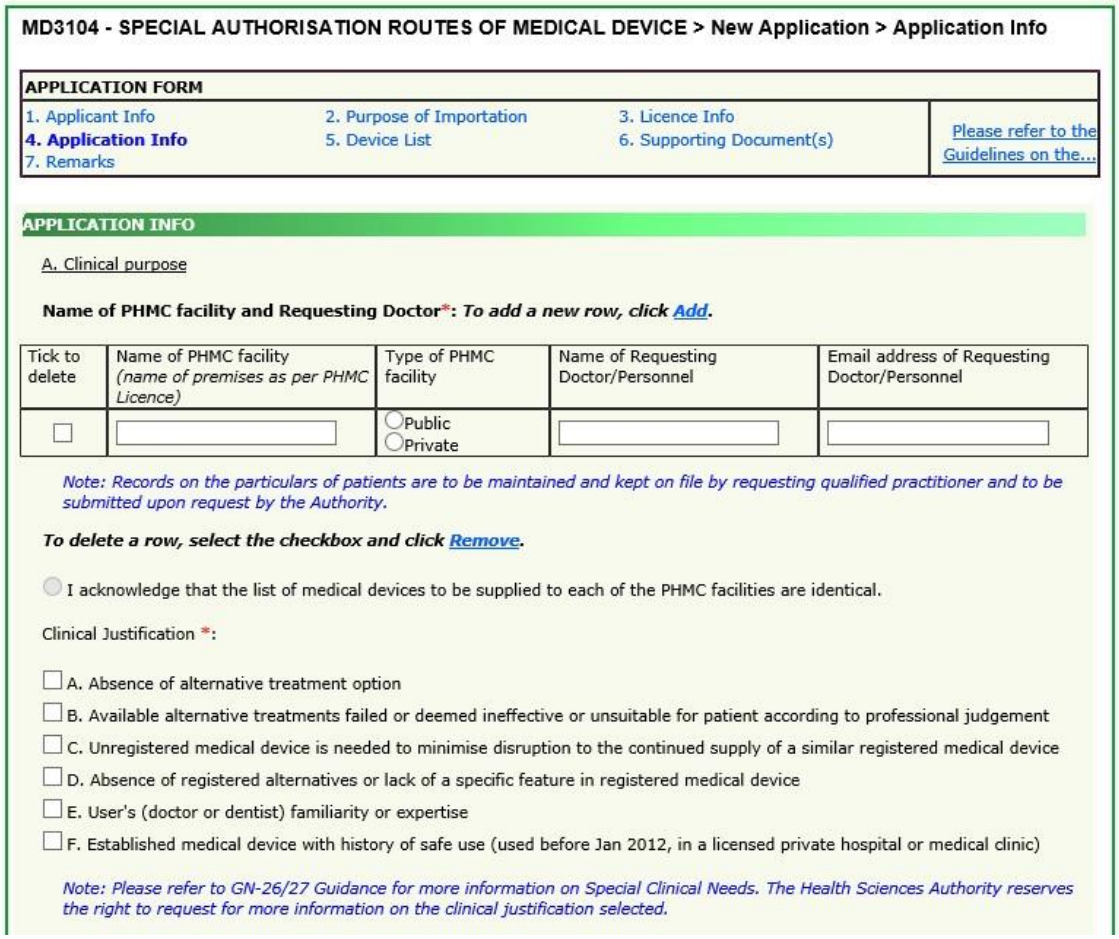
- ☐ A. Absence of alternative treatment option
- ☐ B. Available alternative treatments failed or deemed ineffective or unsuitable for patient according to professional judgement
- ☐ C. Unregistered medical device is needed to minimise disruption to the continued supply of a similar registered medical device
- ☐ D. Absence of registered alternatives or lack of a specific feature in registered medical device
- ☐ E. User's (doctor or dentist) familiarity or expertise
- ☐ F. Established medical device with history of safe use (used before Jan 2012, in a licensed private hospital or medical clinic)

Note: Please refer to GN-26/27 Guidance for more information on Special Clinical Needs. The Health Sciences Authority reserves the right to request for more information on the clinical justification selected.

When GN-27 is selected, the applicant is required to

- Provide information on PHMC facility, requesting HOD (or equivalent) of the PHMC.
- Select the applicable clinical justification indicated on the request form completed by the HOD (or equivalent) of the PHMC.
- Request form signed by HOD (or equivalent) of the PHMC shall be scanned and uploaded in PART 6 – Supporting Document(s) under "5. Doctor's Declaration"
- 'Add'/'Remove buttons are available for applicant to add/remove row(s) if there are more than 1 PHMC facility involved in the GN-27 application.

The applicant is required to acknowledge that the list of medical devices to be supplied to each of the PHMC facilities are identical if there are multiple PHMCs.



MD3104 - SPECIAL AUTHORISATION ROUTES OF MEDICAL DEVICE > New Application > Application Info

APPLICATION FORM

1. Applicant Info | 2. Purpose of Importation | 3. Licence Info
4. Application Info | 5. Device List | 6. Supporting Document(s)
7. Remarks

Please refer to the Guidelines on the...

APPLICATION INFO

A. Clinical purpose

Name of PHMC facility and Requesting Doctor*: *To add a new row, click Add.*

Tick to delete	Name of PHMC facility *(name of premises as per PHMC Licence)*	Type of PHMC facility	Name of Requesting Doctor/Personnel	Email address of Requesting Doctor/Personnel
☐		○Public ○Private		

Note: Records on the particulars of patients are to be maintained and kept on file by requesting qualified practitioner and to be submitted upon request by the Authority.

To delete a row, select the checkbox and click Remove.

○ I acknowledge that the list of medical devices to be supplied to each of the PHMC facilities are identical.

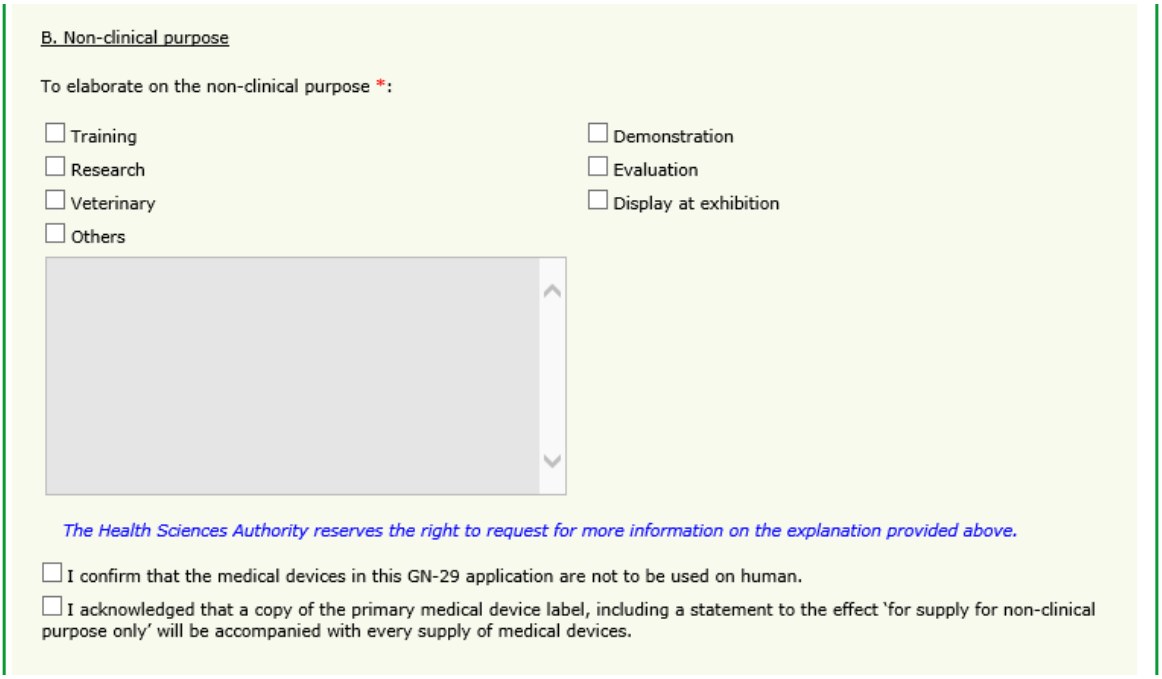
Clinical Justification *:

☐ A. Absence of alternative treatment option
☐ B. Available alternative treatments failed or deemed ineffective or unsuitable for patient according to professional judgement
☐ C. Unregistered medical device is needed to minimise disruption to the continued supply of a similar registered medical device
☐ D. Absence of registered alternatives or lack of a specific feature in registered medical device
☐ E. User's (doctor or dentist) familiarity or expertise
☐ F. Established medical device with history of safe use (used before Jan 2012, in a licensed private hospital or medical clinic)

Note: Please refer to GN-26/27 Guidance for more information on Special Clinical Needs. The Health Sciences Authority reserves the right to request for more information on the clinical justification selected.

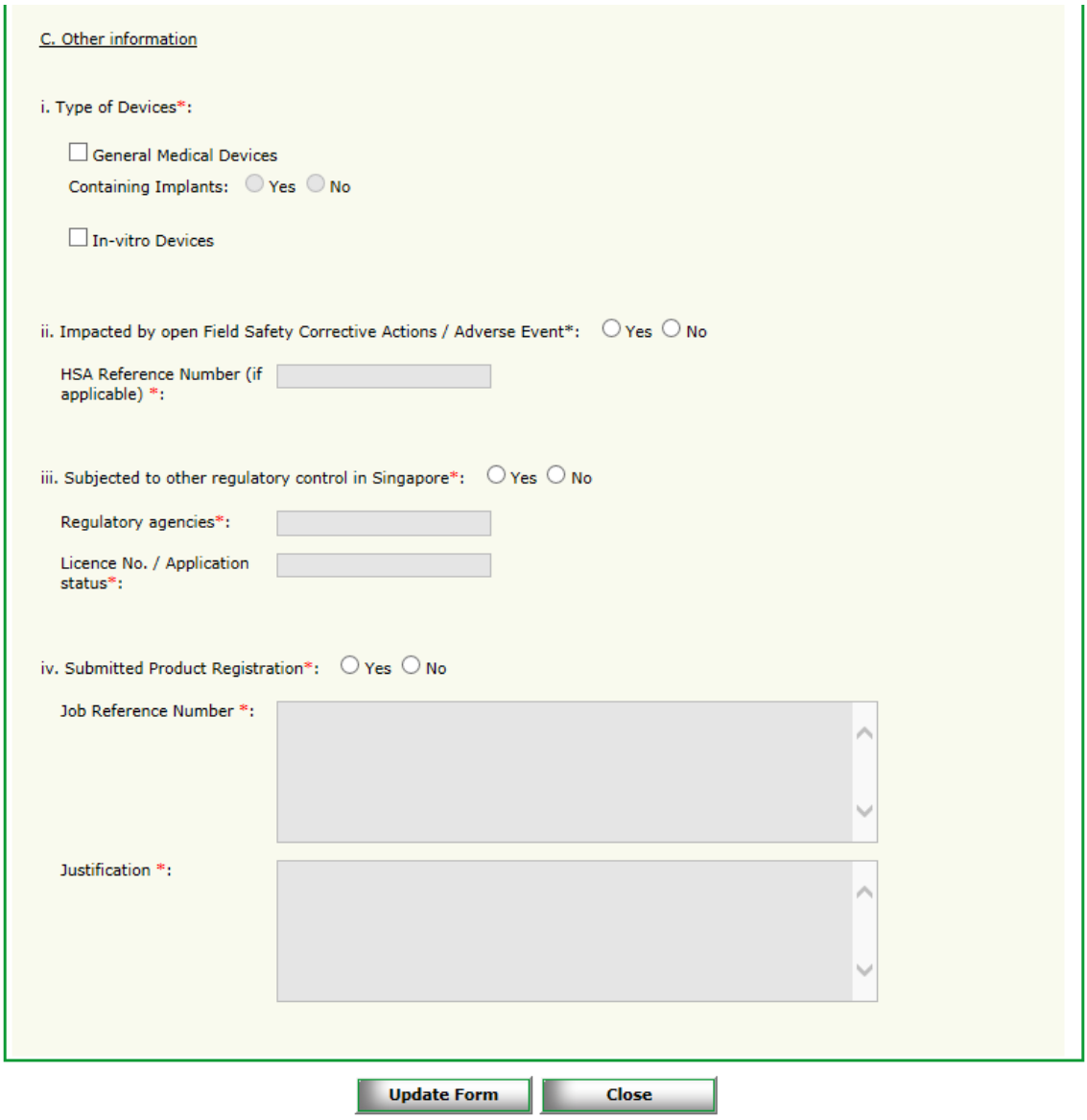
Section B. Non-clinical purpose is only applicable for GN-29.

The applicant is required to elaborate on the non-clinical purpose if 'Others' checkbox is selected.



Section C. Other information is required for all the routes.

The applicant is required to fill in all the related information below.



Click **"Update Form"** to proceed.

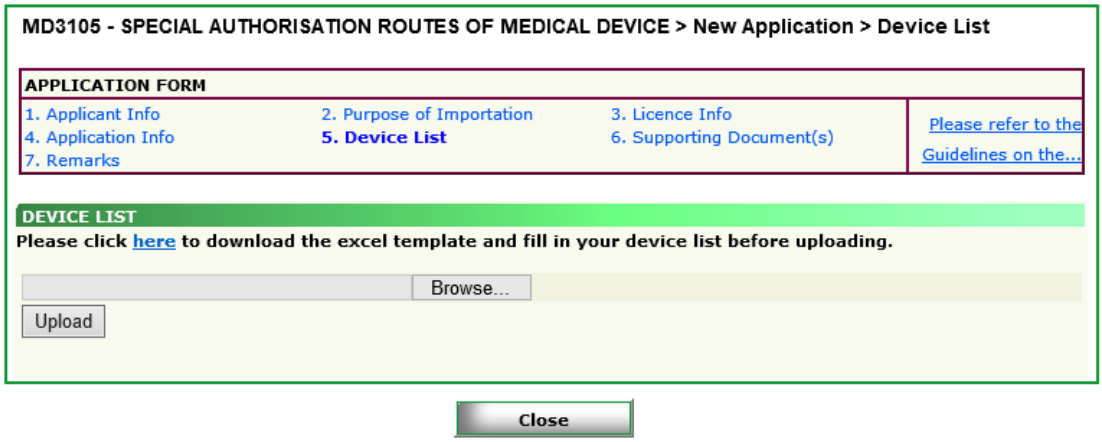
PART 5 – Device List

This section requires the applicant to upload device list.

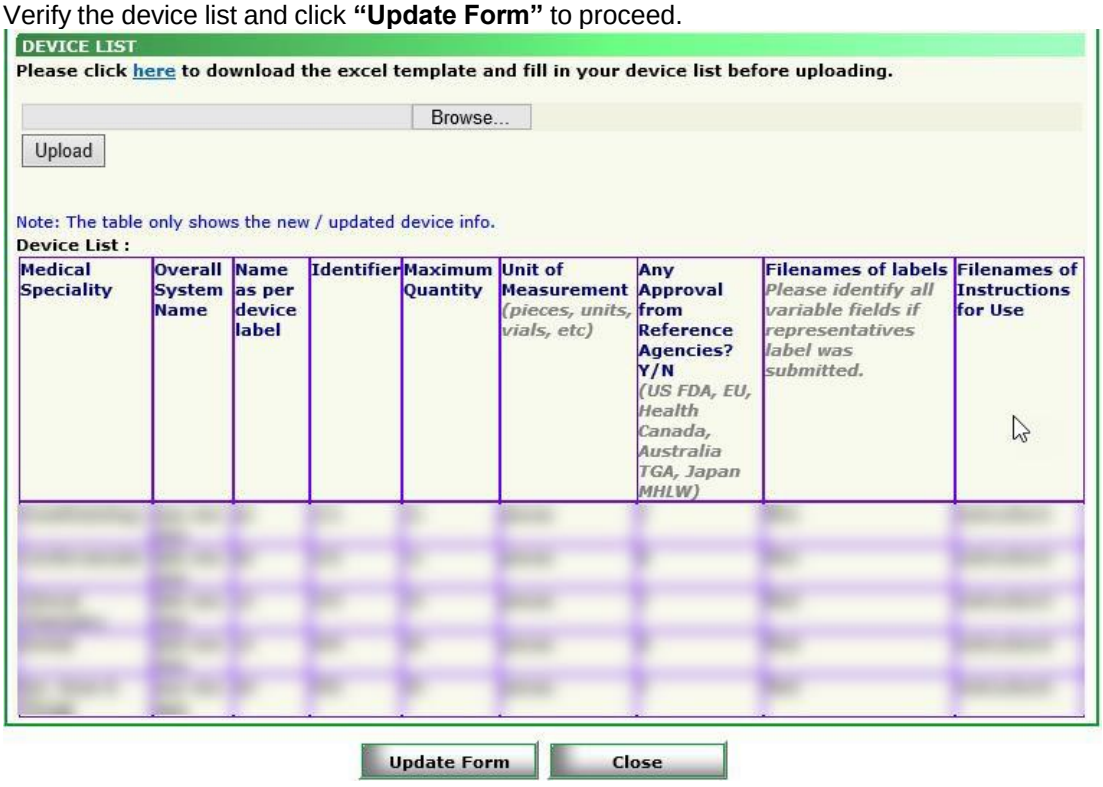
The device list is available for download either from the MEDICS system "Click Here", or on the HSA website.

Attach the device list by:

- Browsing the local storage devices using the "**Browse**" button and then click on the **"Upload"** button.



- Verify the device list and click **"Update Form"** to proceed.

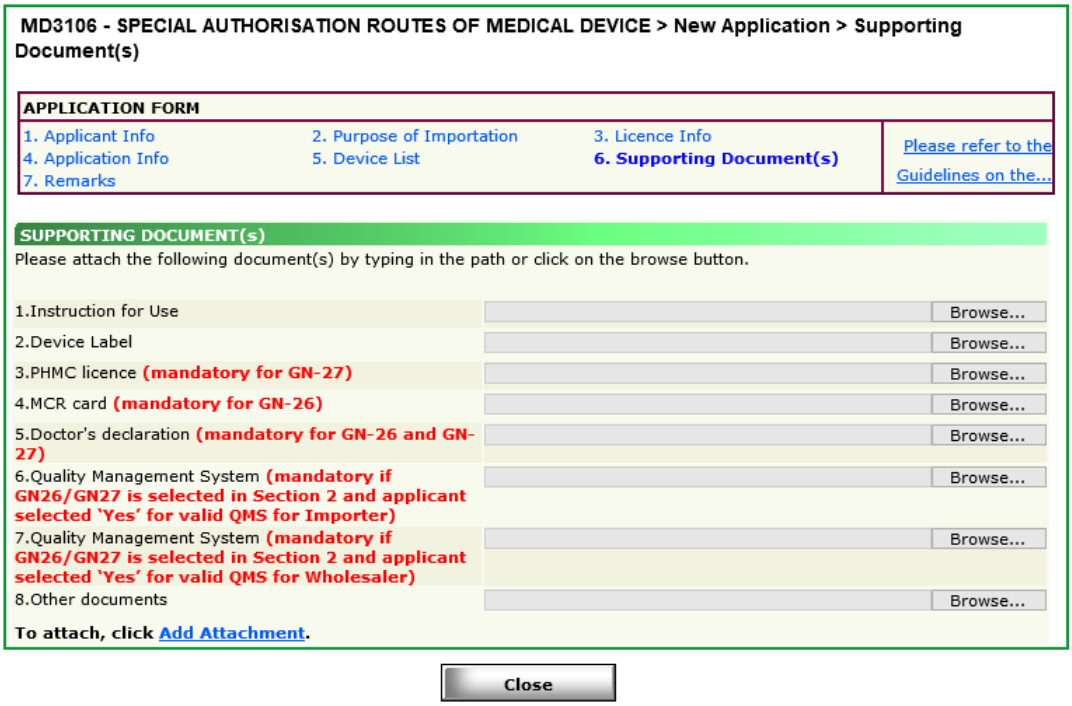


PART 6 – Supporting Document(s)

This section requires the applicant to upload supporting documents.

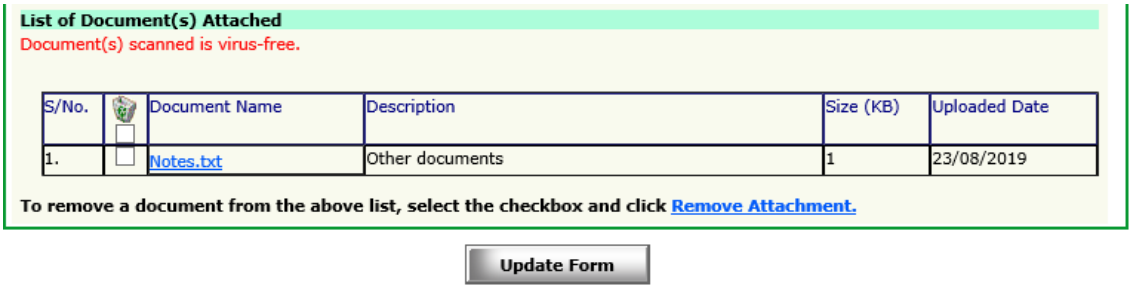
Attach the supporting documents by:

- Browsing the local storage devices for the documents using the "**Browse**" button.



- Attaching these documents by clicking on the "**Add Attachment**" after all documents have been selected.

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



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

PART 7 – Remarks

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

END OF DOCUMENT