

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 <u>Application (Special Authorisation Routes)</u> 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
 - <u>CorpPass</u> (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.



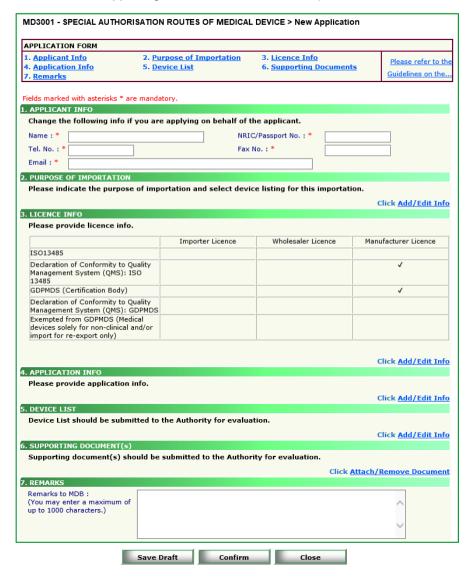
ONLINE APPLICATION FORM

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

| 1. APPLICANT INFO | |
|---|-----------------------|
| Change the following info if you are applying on beha | lf of the applicant. |
| Name:* | NRIC/Passport No. : * |
| Tel. No. : * | Fax No. : * |
| Email: * | |

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

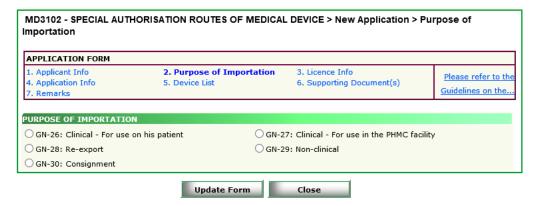
Items 1 to 3 are pre-populated from CRIS Company Account database and can be updated or replaced.

Last Update: August 2019

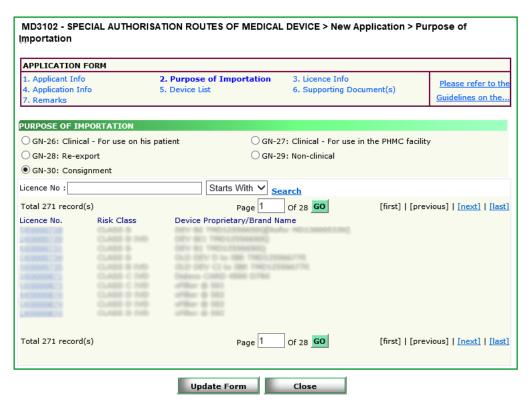


PART 2 - Purpose of Importation

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.



| | Models | | | | | |
|-----|--|---------------------------|---------------|------------|------------|--|
| No. | Medical Speciality | Overall System Name | Model Name | Identifier | Quantities | Unit of Measurements (UOM) (pieces, units, vials, etc) If the UOM is in boxes, please list the quantities to be found in each box. |
| | Microbiology | DEV 82 79012556650Q | ME S | HIS. | | |
| | Microbiology | (DEV 82 TWD12556450Q | PR22 | 162 | | |
| | Microbiology | DEV 82 7WD12556450Q | 943 | (4) | | |
| | principal de la companya de la compa | DEV 82 790175564500 | 2000 | 1000 | | |
| | 1 | DEV 82 790125566500 | 1000 | 100 | | |
| | Update Form Close | | | | | |

Click "Update Form" to proceed.

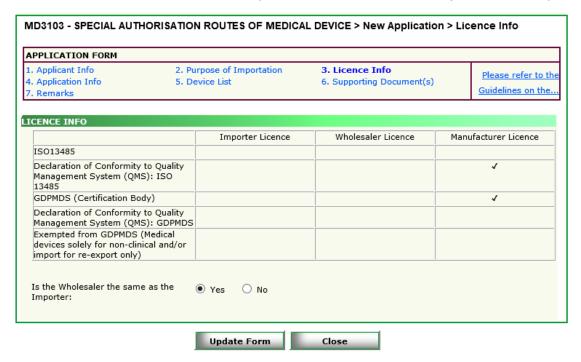
PART 3 - Licence Info

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.

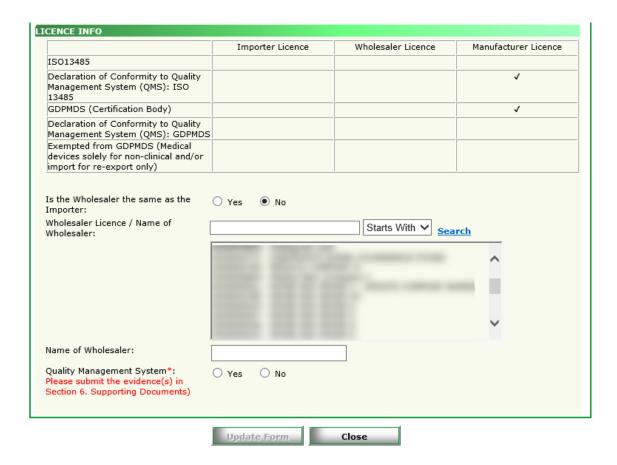
• If the Wholesaler is the same as the Importer', select "Yes" and click "Update Form" to proceed.



Last Update: August 2019 Page 5 of 13



- 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.



Last Update: August 2019



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"

| | | | EDICAL DEVICE > New Appli | | |
|---|--|--|--|---|--|
| ** | | . Purpose of Importation i. Device List | 3. Licence Info 6. Supporting Document | Please refer to the Guidelines on the | |
| A. Clinic | TION INFO al purpose of PHMC facility and Reque | sting Doctor*: | | | |
| Tick to delete | Name of PHMC facility (name of premises as per P Licence) | Type of PHMC facility | Name of Requesting Doctor/Personnel | Email address of Requesting Doctor/Personnel | |
| | | OPublic OPrivate | | | |
| Subm Clinical 3 | Records on the particulars of itted upon request by the Audustification *: | thority. | tained and kept on file by requesting | g qualified practitioner and to be | |
| C. Ur | nregistered medical device is | needed to minimise disru ves or lack of a specific fo | ctive or unsuitable for patient accord uption to the continued supply of a seature in registered medical device | | |
| ☐ 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. | | | | | |

Last Update: August 2019 Page **7** of **13**



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.

| | ION FORM | | | | | |
|---|---|--|--|---|--|-------------------------------|
| | | urpose of Importation 3. Licence Info evice List 6. Supporting Document(s | | ument(s) | Please refer to the Guidelines on the | |
| APPLICATI | ON INFO | | | | | |
| A. Clinica | I purpose | | | | | |
| Name of | PHMC facility and | Requesting | Doctor*: To add a | new row, click <u>Add</u> . | | |
| delete | Name of PHMC facili (name of premises a Licence) | | Type of PHMC facility | Name of Requesting Doctor/Personnel | Email add Doctor/Pe | ress of Requesting rsonnel |
| | | | OPublic OPrivate | | | |
| | Records on the parti ted upon request by | | | ined and kept on file by requ | resting qualified p | ractitioner and to be |
| | e a row, select the | checkbox a | nd click <u>Remove</u> . | | | |
| To delet | | | | | | |
| | owledge that the list | t of medical d | evices to be supplied | to each of the PHMC facilitie | s are identical. | |
| O I ackn | owledge that the list | t of medical d | evices to be supplied | to each of the PHMC facilitie | s are identical. | |
| O I ackn | - | | | to each of the PHMC facilitie | s are identical. | |
| I acknowledge I acknowledge I | ustification *: sence of alternative t | treatment opt | ion | to each of the PHMC facilitie | | ssional judgement |
| ☐ I ackn | ustification *: sence of alternative to silable alternative tre | treatment opt eatments faile | ion d or deemed ineffecti | | according to profe | |
| I ackn | ustification *: sence of alternative t silable alternative tre registered medical do | treatment opt eatments faile evice is neede | ion d or deemed ineffecti ed to minimise disrup | ve or unsuitable for patient | according to profe of a similar regist | |
| I ackn | ustification *: sence of alternative t silable alternative tre registered medical do | treatment opt eatments faile evice is neede alternatives or | ion d or deemed ineffect ed to minimise disrup lack of a specific fea | ive or unsuitable for patient to the continued supply | according to profe of a similar regist | |
| I acknowledge I | ustification *: sence of alternative to silable alternative tre registered medical de sence of registered a ser's (doctor or dentis | treatment opt eatments faile evice is neede alternatives or t) familiarity (| ion d or deemed ineffect ed to minimise disrup lack of a specific fea or expertise | ive or unsuitable for patient to the continued supply | according to profe of a similar regist evice | ered medical device |

Last Update: August 2019 Page 8 of 13



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.

| Training | Demonstration |
|---|--|
| Research | ☐ Evaluation |
| ✓ Veterinary✓ Others | ☐ Display at exhibition |
| | |
| | <u> </u> |
| The Health Sciences Authority reserv | the right to request for more information on the explanation provided above. |



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

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

| C. Other information | |
|---|----------|
| i. Type of Devices*: | |
| ☐ General Medical Devices Containing Implants: ○ Yes ○ No | |
| ☐ In-vitro Devices | |
| ii. Impacted by open Field Safety Corrective Actions / Adverse Event*: O Yes O No | 5 |
| applicable) *: | |
| iii. Subjected to other regulatory control in Singapore*: O Yes O No | |
| Regulatory agencies*: | |
| Licence No. / Application status*: | |
| | |
| iv. Submitted Product Registration*: O Yes O No | |
| Job Reference Number *: | |
| | |
| | V |
| | |
| Justification *: | ^ |
| | |
| | ~ |
| | |
| | _ |

Click "Update Form" to proceed.



PART 5 - Device List

This section requires the applicant to upload device list.

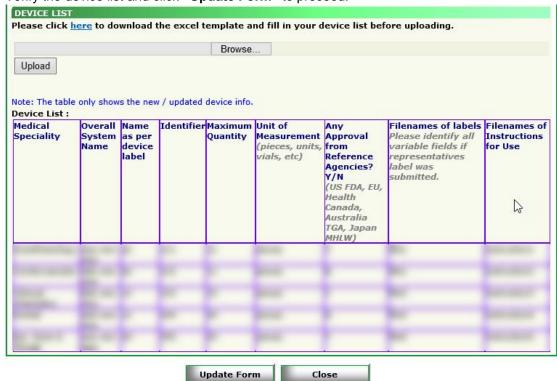
The device list is available for download either from the MEDICS system "Click Here", or on the HSA website.

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.



Last Update: August 2019

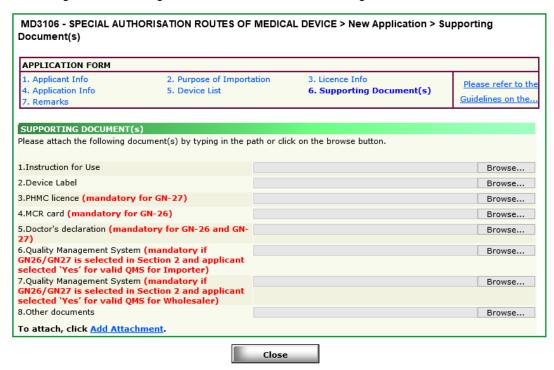


PART 6 - Supporting Document(s)

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.

Last Update: August 2019 Page 12 of 13



PART 7 - Remarks

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



END OF DOCUMENT

Last Update: August 2019 Page 13 of 13