

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

MD3001 - SPECIAL AUTHORISATION ROUTES OF MEDICAL DEVICE > New Application

Fields marked with asterisks * are mandatory.

Special Authorization Routes
Please select the following options: *

To apply for new Special Authorization Routes application

To submit Distribution Record for closure

Please be reminded to submit Distribution Records for all licenses once import and supply have completed.

Next

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

MD3001 - SPECIAL AUTHORISATION ROUTES OF MEDICAL DEVICE > New Application

APPLICATION FORM

1. Applicant Info	2. Purpose of Importation	3. Licence Info	Please refer to the Guidelines on the...
4. Application Info	5. Device List	6. Supporting Documents	
7. 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 : *

2. PURPOSE OF IMPORTATION
Please indicate the purpose of importation and select device listing for this importation. [Click Add/Edit Info](#)

3. LICENCE INFO
Please provide licence info.

	Importer Licence	Wholesaler Licence	Manufacturer Licence
ISO13485			
Declaration of Conformity to Quality Management System (QMS): ISO 13485			✓
GDPMDS (Certification Body)			✓
Declaration of Conformity to Quality Management System (QMS): GDPMDS			
Exempted from GDPMDS (Medical devices solely for non-clinical and/or import for re-export only)			

[Click Add/Edit Info](#)

4. APPLICATION INFO
Please provide application info. [Click Add/Edit Info](#)

5. DEVICE LIST
Device List should be submitted to the Authority for evaluation. [Click Add/Edit Info](#)

6. SUPPORTING DOCUMENT(S)
Supporting document(s) should be submitted to the Authority for evaluation. [Click Attach/Remove Document](#)

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

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 behalf of the applicant.	
Name : *	<input type="text"/>
NRIC/Passport No. : *	<input type="text"/>
Tel. No. : *	<input type="text"/>
Fax No. : *	<input type="text"/>
Email : *	<input type="text"/>

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.

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.
<input type="checkbox"/>						
<input type="checkbox"/>						
<input type="checkbox"/>						
<input type="checkbox"/>						
<input type="checkbox"/>						
<input type="checkbox"/>						

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.

MD3103 - SPECIAL AUTHORISATION ROUTES OF MEDICAL DEVICE > New Application > Licence Info

APPLICATION FORM			
1. Applicant Info	2. Purpose of Importation	3. Licence Info	Please refer to the Guidelines on the...
4. Application Info	5. Device List	6. Supporting Document(s)	
7. Remarks			

LICENCE INFO			
	Importer Licence	Wholesaler Licence	Manufacturer Licence
ISO13485			
Declaration of Conformity to Quality Management System (QMS): ISO 13485			✓
GDPMDS (Certification Body)			✓
Declaration of Conformity to Quality Management System (QMS): GDPMDS Exempted from GDPMDS (Medical devices solely for non-clinical and/or import for re-export only)			

Is the Wholesaler the same as the Importer: Yes No

- 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.

LICENCE INFO

	Importer Licence	Wholesaler Licence	Manufacturer Licence
ISO13485			
Declaration of Conformity to Quality Management System (QMS): ISO 13485			✓
GDPMDS (Certification Body)			✓
Declaration of Conformity to Quality Management System (QMS): GDPMDS			
Exempted from GDPMDS (Medical devices solely for non-clinical and/or import for re-export only)			

Is the Wholesaler the same as the Importer: Yes No

Wholesaler Licence / Name of Wholesaler: Starts With [Search](#)

^
v

Name of Wholesaler:

Quality Management System*: Yes No
Please submit the evidence(s) in Section 6. Supporting Documents

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	Please refer to the Guidelines on the...
4. Application Info	5. Device List	6. Supporting Document(s)	
7. Remarks			

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
<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> Public <input type="radio"/> Private	<input type="text"/>	<input type="text"/>

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	Please refer to the Guidelines on the...
4. Application Info	5. Device List	6. Supporting Document(s)	
7. Remarks			

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 <small>(name of premises as per PHMC Licence)</small>	Type of PHMC facility	Name of Requesting Doctor/Personnel	Email address of Requesting Doctor/Personnel
<input type="checkbox"/>	<input style="width: 90%;" type="text"/>	<input type="radio"/> Public <input type="radio"/> Private	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>

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.

B. Non-clinical purpose

To elaborate on the non-clinical purpose *:

<input type="checkbox"/> Training	<input type="checkbox"/> Demonstration
<input type="checkbox"/> Research	<input type="checkbox"/> Evaluation
<input type="checkbox"/> Veterinary	<input type="checkbox"/> Display at exhibition
<input type="checkbox"/> Others	

The Health Sciences Authority reserves the right to request for more information on the explanation provided above.

I confirm that the medical devices in this GN-29 application are not to be used on human.

I acknowledged that a copy of the primary medical device label, including a statement to the effect 'for supply for non-clinical purpose only' will be accompanied with every supply of medical devices.

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*: Yes No

HSA Reference Number (if applicable)*:

iii. Subjected to other regulatory control in Singapore*: Yes No

Regulatory agencies*:

Licence No. / Application status*:

iv. Submitted Product Registration*: Yes No

Job Reference Number *:

Justification *:

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.

MD3106 - SPECIAL AUTHORISATION ROUTES OF MEDICAL DEVICE > New Application > Supporting Document(s)

APPLICATION FORM			
1. Applicant Info	2. Purpose of Importation	3. Licence Info	Please refer to the Guidelines on the...
4. Application Info	5. Device List	6. Supporting Document(s)	
7. Remarks			

SUPPORTING DOCUMENT(S)

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

1.Instruction for Use	<input type="text"/>	Browse...
2.Device Label	<input type="text"/>	Browse...
3.PHMC licence (mandatory for GN-27)	<input type="text"/>	Browse...
4.MCR card (mandatory for GN-26)	<input type="text"/>	Browse...
5.Doctor's declaration (mandatory for GN-26 and GN-27)	<input type="text"/>	Browse...
6.Quality Management System (mandatory if GN26/GN27 is selected in Section 2 and applicant selected 'Yes' for valid QMS for Importer)	<input type="text"/>	Browse...
7.Quality Management System (mandatory if GN26/GN27 is selected in Section 2 and applicant selected 'Yes' for valid QMS for Wholesaler)	<input type="text"/>	Browse...
8.Other documents	<input type="text"/>	Browse...

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

Close

- 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”.

List of Document(s) Attached

Document(s) scanned is virus-free.

S/No.		Document Name	Description	Size (KB)	Uploaded Date
1.	<input type="checkbox"/>	Notes.txt	Other documents	1	23/08/2019

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

Update Form

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.

7. REMARKS

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

END OF DOCUMENT