

# **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 <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 <u>cris@hsa</u>.

## **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 <u>here</u> 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).

PPLICATION FORM			
Applicant Info 2. F	urpose of Importation	3. Licence Info	Diagon refer to
Application Info 5. [	Device List	6. Supporting Documen	ts Please refer to
Remarks			Guidelines on t
elds marked with asterisks * are man	datory.		
APPLICANT INFO			
Change the following info if you a	re applying on behalf of t	the applicant.	
Name : *	NRI	C/Passport No. : *	
Fel. No. : *	Fax	No. : *	
Email : *			
PORPOSE OF IMPORTATION	nentation and coloct dow	ee listing for this important	len
Please indicate the purpose of im	portation and select devi	ce listing for this importat	ion.
			Click Add/Edit I
LICENCE INFO			
lease provide licence info.			
	Importer Licence	Wholesaler Licence	Manufacturer Licence
ISO13485			
Declaration of Conformity to Quality			1
Management System (QMS): ISO			
13485 GDPMDS (Certification Body)			
Declaration of Conformity to Quality			· · · · · · · · · · · · · · · · · · ·
Management System (QMS): GDPMD:	s		
Exempted from GDPMDS (Medical			
devices solely for non-clinical and/or import for re-export only)			
			Click Add/Edit I
APPLICATION INFO			
rease provide application into.			
			Click Add/Edit I
DEVICE LIST			
Device List should be submitted t	o the Authority for evalua	ation.	
			Click Add/Edit I
SUPPORTING DOCUMENT(s)			
Supporting document(s) should b	e submitted to the Autho	rity for evaluation.	
		Click	Attach/Remove Docum
REMARKS			
temarks to MDB :			
You may enter a maximum of			~
ip to 1000 characters.)			
			$\sim$



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 a	pplying on behalf 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.



### PART 2 – Purpose of Importation

This section is to select the purpose of importation.

MD3102 - SPECIAL AUT Importation	HORISATION ROUTES OF ME	EDICAL DEVICE > New Application > F	Purpose of
APPLICATION FORM			
1. Applicant Info 4. Application Info 7. Remarks	<b>2. Purpose of Importa</b> 5. Device List	tion 3. Licence Info 6. Supporting Document(s)	Please refer to the Guidelines on the
PURPOSE OF IMPORTATIO	DN		
OGN-26: Clinical - For use	on his patient (	GN-27: Clinical - For use in the PHMC fac	ility
◯ GN-28: Re-export	(	GN-29: Non-clinical	
○ GN-30: Consignment			
	Update Form	Close	

When "GN-30" is selected:

APPLICATION F	ORM		-		14
<ol> <li>Applicant Info</li> <li>Application Inf</li> <li>Remarks</li> </ol>	ō	2. Purpose of Importation 5. Device List	3. Licence Info 6. Supporting D	ocument(s)	<u>Please refer to the</u> <u>Guidelines on the</u>
PURPOSE OF IM	PORTATION				
🔾 GN-26: Clinica	l - For use on his	patient 🛛 🔾 GN	-27: Clinical - For use	in the PHMC fac	ility
🔾 GN-28: Re-exp	port	⊖ gn	-29: Non-clinical		
GN-30: Consig	Inment				
Licence No :		Starts With V	Search		
Total 271 record(	s)	Page 1	Of 28 GO	[first]   [p	revious]   [next]   [las
icence No.	Risk Class	Device Proprietary/Brand	Name		
Total 271 record(	s)	Page 1	Of 28 GO	[first]   [p	revious]   <u>[next]</u>   <u>[las</u>

Click on Licence No. for Device Model listing.

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



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.
	Mandalahaga	DEV 82 710125544500	100	993		
	Norshalap	DEV BJ THD125544500	142	142		
	Hersindage	DEV &I THD125544500	10	183		
	Phase allocations in the	DEV BJ THD12556650Q	144	1016		
	Marcalaulaga	DEV BJ THD125544500	145	145		

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.

PPLICATION FORM			
. Applicant Info . Application Info . Remarks	2. Purpose of Importation 5. Device List	3. Licence Info 6. Supporting Document(s)	Please refer to t Guidelines on the
CENCE INFO			
	Importer Licence	Wholesaler Licence	Manufacturer Licence
ISO13485			
Declaration of Conformity to Quali Management System (QMS): ISO 13485	ty		~
GDPMDS (Certification Body)			√
Declaration of Conformity to Qualit Management System (QMS): GDPI	ty MDS		
Exempted from GDPMDS (Medical devices solely for non-clinical and/ import for re-export only)	or		
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.

	Importer Licence	Wholesaler Licence	Manufacturer Licence
IS013485			
Declaration of Conformity to Quality Management System (QMS): ISO 13485			1
GDPMDS (Certification Body)			1
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		
Is the Wholesaler the same as the Importer: Wholesaler Licence / Name of Wholesaler:	○ Yes ● No	Starts With V	urch
Is the Wholesaler the same as the Importer: Wholesaler Licence / Name of Wholesaler:	O Yes  No	Starts With 🗸 Sea	urch
Is the Wholesaler the same as the Importer: Wholesaler Licence / Name of Wholesaler:	O Yes  No	Starts With 🗸 Sea	arch
Is the Wholesaler the same as the Importer: Wholesaler Licence / Name of Wholesaler:	○ Yes ● No	Starts With V Sea	urch
Is the Wholesaler the same as the Importer: Wholesaler Licence / Name of Wholesaler: Name of Wholesaler:	O Yes  No	Starts With ✓ Sea	arch



### 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"

APPLICA	FION FORM					
1. Applicar <b>4. Applica</b> 7. Remark	nt Info <b>ation Info</b> s	2. Purj 5. Dev	pose of Importation ice List	3. Licence Info 6. Supporting Documen	t(s)	<u>Please refer to the</u> <u>Guidelines on the</u>
APPLICAT <u>A. Clinic</u>	ION INFO					
Name o	of PHMC facility and Req	uesting	Doctor*:			
Tick to delete	Name of PHMC facility (name of premises as pe Licence)	er PHMC	Type of PHMC facility	Name of Requesting Doctor/Personnel	Email addres Doctor/Perso	s of Requesting onnel
			OPublic OPrivate			
Note: subm Clinical 1	Records on the particular itted upon request by the Justification *:	s of patie Authorit	ents are to be maintai y.	ined and kept on file by requestin	g qualified prac	titioner and to be
	sence of alternative treat	ment opt	ion			
C. Ur	registered medical device	ents raile is neede	ed to minimise disrupt	ion to the continued supply of a	similar registere	d medical device
D. Ab	osence of registered altern	atives or	lack of a specific fea	ture in registered medical device	j	
🗌 E. Us	er's (doctor or dentist) far	miliarity	or expertise			
F. Es	tablished medical device v	vith histo	ory of safe use (used b	pefore Jan 2012, in a licensed pri	vate hospital or	medical clinic)
Note: the rig	Please refer to GN-26/27 ght to request for more in	Guidanc formatio	e for more informatio n on the clinical justifi	n on Special Clinical Needs. The l cation selected.	Health Sciences	Authority reserves



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.

APPLIC	ATION FORM			
1. Applica 4. Applica 7. Reman	ant Info 2. Pu cation Info 5. De ks	rpose of Importation vice List	3. Licence Info 6. Supporting Docu	ment(s) <u>Please refer to t</u> <u>Guidelines on the</u>
APPLICA	TION INFO			
A. Clini	cal purpose			
Name	of PHMC facility and Requestin	g Doctor*: <i>To add a</i>	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		
Note	Records on the particulars of pai	OPrivate	ained and kent on file by requi	esting qualified practitioner and to be
Note subr To del I ac Clinical	Records on the particulars of pain mitted upon request by the Authon ete a row, select the checkbox knowledge that the list of medical Justification *:	OPrivate ients are to be mainta ty. and click <u>Remove</u> . devices to be supplied	ained and kept on file by reque	esting qualified practitioner and to be
Note subr To del I ac Clinical	Records on the particulars of pain mitted upon request by the Authon ete a row, select the checkbox knowledge that the list of medical Justification *: whether a select the select of the select the select the select of the select of the select the select of the select of the select of the select the select of the select of the select of the select the select of the select of the select of the select of the select the select of the sele	OPrivate ients are to be mainta ty. and click <u>Remove</u> . devices to be supplied bution led or deemed ineffect	ained and kept on file by requi	esting qualified practitioner and to be s are identical.
Note subi To del I ac Clinical A. A B. A C. U	E: Records on the particulars of pain mitted upon request by the Authon ete a row, select the checkbox knowledge that the list of medical Justification *: whence of alternative treatment of valiable alternative treatments fain Inregistered medical device is need absence of registered alternatives	OPrivate ients are to be mainta ty. and click <u>Remove</u> . devices to be supplied betion led or deemed ineffect led to minimise disrup or lack of a specific fea	ained and kept on file by requi d to each of the PHMC facilities tive or unsuitable for patient a ption to the continued supply o ature in registered medical de	esting qualified practitioner and to be s are identical. according to professional judgement of a similar registered medical device vice



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 *:	
Training	Demonstration
Research	Evaluation
Veterinary	Display at exhibition
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 ap	oplication are not to be used on human.
I acknowledged that a copy of the primary medical purpose only will be accompanied with every supply of	device label, including a statement to the effect `for supply for non-clinical
purpose only will be accompanied with every supply o	



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 Device	s Yes 🔍 No
In-vitro Devices	
ii. Impacted by open Field Saf	ety Corrective Actions / Adverse Event*: O Yes O No
HSA Reference Number (if applicable) *:	
iii. Subjected to other regulato	ory control in Singapore*: O Yes O No
Regulatory agencies*:	
Licence No. / Application status*:	
iv. Submitted Product Registra	ation*: $\bigcirc$ Yes $\bigcirc$ No
Job Reference Number *:	^
	<b>`</b>
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.

MD3105 - SPECIAL AUTHORISATION ROUTES OF MEDICAL DEVICE > New Application > Device List							
APPLICATION FORM							
1. Applicant Info 4. Application Info 7. Remarks	2. Purpose of Importation <b>5. Device List</b>	<ol> <li>3. Licence Info</li> <li>6. Supporting Document(s)</li> </ol>	<u>Please refer to the</u> <u>Guidelines on the</u>				
DEVICE LIST	nload the excel template and fill in	your device list before unloadin					
	Browse	your device list before aploading	y.				
Upload							
	Close						

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

Device List : Medical Speciality System Name device label label	Upload Note: The tabl	e only show	vs the nev	v / updated	Browse device info.				
	Device List : Medical Speciality	Overall System Name	Name as per device label	Identifier	Maximum Quantity	Unit of Measurement (pieces, units, vials, etc)	Any Approval from Reference Agencies? Y/N (US FDA, EU, Heaith Canada, Australia TGA, Japan MHLW)	Filenames of labels Please identify all variable fields if representatives label was submitted,	Filenames o Instructions for Use



#### 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.

APPLICATION FORM			
1. Applicant Info 4. Application Info 7. Remarks	2. Purpose of Importation 5. Device List	3. Licence Info 6. Supporting Document(s)	<u>Please refer to t</u> <u>Guidelines on the</u>
SUPPORTING DOCUMENT	<b>(s)</b>	k on the browse button	
lease attach the following	document(s) by typing in the path of cit	ck off the browse button.	
.Instruction for Use			Browse
Device Label			Browse
	ry for GN-27)		Browse
.PHMC licence (mandator			Drottoetti
.PHMC licence (mandator .MCR card (mandatory f	or GN-26)		Browse
JPHMC licence (mandator) I.MCR card (mandatory fr J.Doctor's declaration (mail 27)	or GN-26) ndatory for GN-26 and GN-		Browse
, PHMC licence (mandator , MCR card (mandatory fr , Doctor's declaration (mai ), Quality Management Syst SN26/GN27 is selected i selected 'Yes' for valid (	or GN-26) ndatory for GN-26 and GN- tem (mandatory if in Section 2 and applicant DMS for Importer)		Browse Browse
5,PHMC licence (mandator) 6,Doctor's declaration (mail 6,Quality Management Syst 5,026/GN27 is selected i 5,026/GN27 i	ior GN-26) ndatory for GN-26 and GN- im (mandatory if in Section 2 and applicant QMS for Importer) im (mandatory if in Section 2 and applicant DMS for Wholesaler)		Browse Browse Browse

 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.	1	Document Name	Description	Size (KB)	Uploaded Date	
1.		Notes.txt	Other documents	1	23/08/2019	
To remov	o remove a document from the above list, select the checkbox and click <u>Remove Attachment.</u>					
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