

GUIDE TO APPLICATION FOR DISTRIBUTION RECORD

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

The online [Application \(Distribution Record\)](#) 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.

PAYMENT

There is no charge to the application for Distribution Record.

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 Authorisation Routes
Please select the following options: *

To apply for new Special Authorisation 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 5 parts (via Applicant Info; Licence Info; Distribution Records; Importer’s Declaration; and Supporting Documents).

MD3003 - DISTRIBUTION RECORD OF MEDICAL DEVICE > New Application

APPLICATION FORM			
1. Applicant Info	2. Licence Info	3. Distribution Records	Please refer to the Guidelines on the...
4. Importer’s Declaration	5. Supporting Document(s)		

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. LICENCE INFO

Please provide licence info.

[Click Add/Edit Info](#)

3. DISTRIBUTION RECORDS

This section is not applicable.

4. IMPORTER'S DECLARATION

This section is not applicable.

5. SUPPORTING DOCUMENT(S)

Supporting document(s) should be submitted to the Authority for evaluation.

[Click Attach/Remove Document](#)

Save Draft **Confirm** **Close**

For Part 2, click on “**Add/Edit Info**” to access that section of the on-line form.

For Part 5, 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.

PART 2 – Licence Info

MD3402 - DISTRIBUTION RECORD OF MEDICAL DEVICE > New Application > Licence Info

APPLICATION FORM			
1. Applicant Info	2. Licence Info	3. Distribution Records	Please refer to the Guidelines on the...
4. Importer's Declaration	5. Supporting Document(s)		

LICENCE INFO

Search Work Items

Licence No : Starts With [Search](#)

Total 2 record(s) Page 1 Of 1 [GO](#) [\[first\]](#) | [\[previous\]](#) | [\[next\]](#) | [\[last\]](#)

Licence No.	Expiry Date	Type of Routes
[Redacted]	[Redacted]	[Redacted]

Total 2 record(s) Page 1 Of 1 [GO](#) [\[first\]](#) | [\[previous\]](#) | [\[next\]](#) | [\[last\]](#)

Licence selected :

Declaration :

I declare that there is no import and supply of the medical devices listed in the above mentioned Authorisation.

I declare that there is import and/or supply of the medical devices listed in the above mentioned Authorisation.

Update Form
Close

Click “Update Form” to proceed.

Note:

- Click on the licence no link to select the licence.
Licence selected : [Redacted]
- If “I declare that there is no import and supply of the medical devices listed in the above mentioned Authorisation.” was selected,
 - PART 3 – Distribution Records will not be required
 - PART 4 – Importer’s Declaration will not be required
- If “I declare that there is import and/or supply of the medical devices listed in the above mentioned Authorisation.” was selected,
 - PART 3 – Distribution Records will be available

PART 3 – Distribution Records

This section requires the applicant to upload distribution records.

The distribution records are attached by:

- Browsing the local storage devices using the “Browse” button and then click on the “Upload” button.

MD3403 - DISTRIBUTION RECORD OF MEDICAL DEVICE > New Application > Distribution Records

APPLICATION FORM			
1. Applicant Info	2. Licence Info	3. Distribution Records	Please refer to the Guidelines on the...
4. Importer's Declaration	5. Supporting Document(s)		

DISTRIBUTION RECORDS
Please click [here](#) to download the attached Distribution Records template for return submission.

Browse...
Upload

Close

- Verify the distribution records list and click “Update Form” to proceed.

DISTRIBUTION RECORDS
Please click [here](#) to download the attached Distribution Records template for return submission.

Browse...
Upload

Note: The table only shows the new / updated device info.

Distribution Records :

Overall System Name	Name as per device label	Identifier	Maximum Quantity	Quantity Imported	Quantity Supplied	Balance Stocks

Update Form

Close

PART 4 – Importer’s Declaration

This section will be applicable only if applicant declare that there is import and supply of the medical devices listed in PART 2 - Licence Info, and satisfied below criteria in PART 3 - Distribution Records:

- (a) Scenario 1,
- ✓ Quantity imported <= Maximum quantity AND
 - ✓ No new record(s) added AND
 - ✓ Balance Stocks > 0.

4. IMPORTER’S DECLARATION

I acknowledged that company shall obtain/has obtained relevant licences for the continued supply of the balance stocks in this Special Authorization Licence, if any.

- Once radio button acknowledged and application submitted, status will be completed.
- Error message is prompted if the radio button is not selected upon submission

We noted that there are balance stocks. Please acknowledge the declaration to proceed with submission. The Health Sciences Authority reserves the rights to pursue for more information/evidences if the need arises.

(b) Scenario 2,

- ✓ Quantity imported > Maximum quantity OR
- ✓ Applicant added new record(s) OR
- ✓ Balance Stocks < 0.

4. IMPORTER'S DECLARATION

Please provide justification*:



- Error message is prompted if justification not provided

Please provide justification as there were new information or discrepancies found in the Distribution Record submitted.

(c) Scenario 3,

- ✓ Quantity imported <= Maximum quantity AND
- ✓ No new record(s) added AND
- ✓ Balance Stocks = 0.

Otherwise, when applicant declared there is no import and supply to grey off the Add/Edit link as below:

4. IMPORTER'S DECLARATION

This section is not applicable.

PART 5 – Supporting Document(s)

This section requires the applicant to upload supporting documents.

The supporting documents are attached by:

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

MD3405 - DISTRIBUTION RECORD OF MEDICAL DEVICE > New Application > Supporting Document(s)

APPLICATION FORM			
1. Applicant Info	2. Licence Info	3. Distribution Records	Please refer to the Guidelines on the...
4. Importer's Declaration	5. Supporting Document(s)		

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


1. Other documents

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

- 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](#).

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

END OF DOCUMENT