

GUIDE TO CHANGE NOTIFICATION FOR REGISTERED DEVICES

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant to submit a Change Notification application to higher risk medical devices that have been given marketing clearance.

The online [Change Notification for Registered Device](#) in MEDICS may take an average of 5-15 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, OR
 - [HSA PIN](#) (HSA Personal Identification Number), password for overseas individual, supplied by HSA
- 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.
- 3. A Registrant Account** that is held by a local company who registers medical devices on behalf of a Product Owner.
- 4. Medical device(s)** with market clearance and listed in the Singapore Medical Device Register (SMDR).

Please take note of the following when submitting a new change notification application:

- 1) The Change Notification Application is meant to notify HSA if there are any changes or proposed changes to any particulars provided in relation to the registration of medical device, and/or if there are any changes or proposed changes that may affect the safety, quality or efficacy of a registered medical device.
- 2) In general, any changes to the documents submitted in the original application would need to be submitted. Also any documents that support the changes being reported are required. These enclosures are to be submitted as attachments in the e-application for the purpose of evaluation of the device for marketing clearance.
- 3) The MEDICS system will not allow for another submission of a new change notification application for the same device listing, when there is a pending change notification application. The pending application needs to be approved before submitting a new change notification application.
- 4) The MEDICS system will not allow submission of a new change notification application for the device that is pending IBR Pre-Market post approval. The IBR application needs to be approved before submitting a new change notification application.

REFERENCES

The information in the following [Regulatory Guidances](#) is useful for the application.

- GN-21: Guidance on Change Notification for Registered Medical Devices

PAYMENT

Please click [here](#) for the Tables of Fees for Change Notification for Medical Devices.

ONLINE APPLICATION FORM

This online Application Form consists of 5 parts (via Applicant Info; Change Notification; Affected Device Listing; Dossier and Supporting Document(s); Remarks)

MD2510 - CHANGE NOTIFICATION FOR REGISTERED DEVICE > New Application

APPLICATION FORM			
1. Applicant Info	2. Change Notification	3. Affected Device Listing	Please refer to the Guidelines on the...
4. Dossier & Supporting Document(s)	5. Remarks		

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 : *

Drafter Assignment

Drafter type : Staff Partner

Available Company's Drafters : ▼

2. CHANGE NOTIFICATION

Change Notification

Note:

For Technical Changes:
 Technical Changes for Class C and D medical devices affect the safety, quality or efficacy of these medical devices. These require HSA's approval prior to implementation of the change in Singapore.

For Review Changes:
 Review Changes for Class B medical devices affect the safety, quality or efficacy of these medical devices. These require HSA's approval prior to implementation of the change in Singapore.

For Administrative Changes:
 Administrative Changes include changes to the information submitted at the point of registration of the medical device and typically affect the SMDR listing information. These require HSA's approval prior to implementation of the change in Singapore.

For Notifications:
 Notifications Changes may be implemented immediately upon successful receipt of the Change Notification application by HSA.

[Click Add/Edit Info](#)

3. AFFECTED DEVICE LISTING

Please select device listing affected by this Change Notification for Registered Device.

[Click Add/Edit Info](#)

4. DOSSIER & SUPPORTING DOCUMENT(S)

Dossier & supporting document(s) should be submitted to the Authority for evaluation.

[Click Attach/Remove Document](#)

5. REMARKS

Remarks to MDB :

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

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

For Part 4, 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.

Drafter Assignment

This is to allow designated staff or external partner to prepare the application form as a drafter. Note that the completed application will then need to be submitted by someone authorised as a submitter.

A Submitter is allowed to prepare drafts and submit applications without the help of an intermediary drafter. The role of the current login user is displayed at the top of the screen under the Logon ID.

- 1) *Drafter type*: The applicant can select either a “**Staff**” or “**Partner**”
- 2) *Available Company's Drafters*: Once the above is selected, the corresponding list of drafters will then be selectable from the drop down list.

The list of available drafter depends on the user setting in the [CRIS Management Module](#). The CRIS Administrator is able to set up company users or service providers/partners to be drafter for this e-Service.

PART 2 – Change Notification

MD2519 - CHANGE NOTIFICATION FOR REGISTERED DEVICE > New Application > Change Notification

APPLICATION FORM			
1. Applicant Info	2. Change Notification	3. Affected Device Listing	Please refer to the Guidelines on the...
4. Dossier & Supporting Document(s)	5. Remarks		

Change Notification

Declaration if there are any changes due to FSCA or AE

NONE of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA)** and/or **Local Reportable Adverse Events (AE)**.

SOME of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA)** and/or **Local Reportable Adverse Events (AE)**.

ALL of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA)** and/or **Local Reportable Adverse Events (AE)**.

Medical Device Class

Class B

Class C

Class D

To select/ update Type of Change(s) for Change Notification Click [Add/Update](#).

Item 1: Declaration of FSCA and AE

Select the applicable description of Field Safety Corrective Action (FSCA) and Reportable Adverse Events (AE) relating to the change submitted in this Change Notification.

Item 2: Medical Device Class

Select the relevant risk class(es) of the devices involved in the changes to be submitted in this Change Notification.

Please note that if multiple risk classes are selected for changes not due to FSCA or AE, only selected categories of change will be allowed. Please refer to GN-21 Guidance on Change Notification for Registered Medical Devices Section 4 for further information.

Click the “Add/Update” Button to select the Type of Changes

MD2519 - CHANGE NOTIFICATION FOR REGISTERED DEVICE > New Application > Change Notification

APPLICATION FORM			
1. Applicant Info	2. Change Notification	3. Affected Device Listing	Please refer to the Guidelines on the...
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Change Notification

Please take note that any updates on the Type of Change below, it may impact (by resetting) the changes made to the affected device info or (by removing) addition of new device in this application.

Selected FSCA Declaration **Non-FSCA**
 Selected Risk Class **Class B**

Change in Manufacturing Facility, Process and Quality Management System

Addition, deletion, or shift of manufacturing and/or sterilisation facilities with no change to specifications of a registered medical device and/or sterilisation process

Changes in the manufacturing process to Additive Manufacturing (3D-printing), or to refurbish a registered device

Changes to manufacturing site and/or processes that result in a change in specifications of a registered medical device

Changes to sterilisation method and related processes

Changes to Quality Management System (QMS) certificates for manufacturing and sterilisation facilities

The change only involves an update of QMS certificate validity date

The change only involves a change of QMS certificate scope for one of the multiple existing manufacturing facilities (that is not due to safety, quality and/or efficacy of the device)

The change only involves a change in certification body with no change in scope of the certification

Changes in Design or Specifications of a registered medical device

Changes to materials in a General Medical Device

Changes to materials in an In-Vitro Diagnostic (IVD) Medical Device

Changes to labelling of medical device

Changes to registered medical devices listing information

Other Changes - Applicable only upon receipt of email from HSA, authorising submission under this category

Please refer to *GN-21 Guidance on Change Notification for Registered Medical Devices Section 3 Change Type Assessment Flowcharts* to determine the applicable Type of Change to be selected for your proposed change.

Select the applicable Type of Change and click **“Update Form”**

MD2519 - CHANGE NOTIFICATION FOR REGISTERED DEVICE > New Application > Change Notification

APPLICATION FORM

1. Applicant Info 2. **Change Notification** 3. Affected Device Listing [Please refer to the Guidelines on the...](#)
 4. Dossier & Supporting Document(s) 5. Remarks

Change Notification

Declaration if there are any changes due to FSCA or AE

NONE of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA)** and/or **Local Reportable Adverse Events (AE)**.
 SOME of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA)** and/or **Local Reportable Adverse Events (AE)**.
 ALL of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA)** and/or **Local Reportable Adverse Events (AE)**.

Medical Device Class

Class B
 Class C
 Class D

To select/update Type of Change(s) for Change Notification Click [Add/Update](#).

Selected Type of Change(s) for Change Notification

Change in Manufacturing Facility, Process and Quality Management System

Changes to Quality Management System (QMS) certificates for manufacturing and sterilisation facilities
The change only involves an update of QMS certificate validity date

The selected type of change will be displayed under “Selected Type of Change(s) for Change Notification”.

Please verify and click **“Update Form”**

A summary of the type of change and overall category of change (i.e. Technical, Review, Administrative or Notification) will be indicated in the main application form.

2. CHANGE NOTIFICATION

Change Notification

Note:
For Technical Changes:
 Technical Changes for Class C and D medical devices affect the safety, quality or efficacy of these medical devices. These require HSA's approval prior to implementation of the change in Singapore.
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For Notifications:
 Notifications Changes may be implemented immediately upon successful receipt of the Change Notification application by HSA.

FSCA/AE Declaration
 Non-FSCA

Risk Class
 Class B

Type of Changes

Change in Manufacturing Facility, Process and Quality Management System

Changes to Quality Management System (QMS) certificates for manufacturing and sterilisation facilities
The change only involves an update of QMS certificate validity date

For Official Use Only: Create New SMDR Listing(s)
 No

Overall Category of Change
 Notification

Highest Risk Class
 Class B

Please note that for changes to Medical Devices that requires HSA approval, as defined in GN-21, they shall not be supplied until approval has been granted.

[Click Add/Edit Info](#)

MD2571 - CHANGE NOTIFICATION FOR REGISTERED DEVICE > New Application > Affected Device Listing > Change Notification for Registered Device

APPLICATION FORM			
1. Change Notification	2. Device Info	3. Product Owner Info	Please refer to the Guidelines on the...
4. Manufacturing Site(s) Info	5. Model(s) Info	6. Importer & Wholesaler Info	
7. Remarks			

Registration No. :

Dossier No. :

Fields marked with asterisks * are mandatory.

1. CHANGE NOTIFICATION

Please provide change notification.

Change in Manufacturing Facility, Process and Quality Management System

Changes to Quality Management System (QMS) certificates for manufacturing and sterilisation facilities

The change only involves an update of QMS certificate validity date

[Click Add/Edit Info](#)

2. DEVICE INFO

Please provide device info.

Device Info

[Click Add/Edit Info](#)

3. PRODUCT OWNER INFO

Please provide product owner info.

[Click Add/Edit Info](#)

4. MANUFACTURING SITE(S) INFO

Please provide manufacturing site(s) info.

1.

[Click Add/Edit Info](#)

5. MODEL(S) INFO

Please provide model(s) info.

[Click Add/Edit Info](#)

6. IMPORTER & WHOLESALER INFO

Please provide Importer & Wholesaler Info.

[Click Add/Edit Info](#)

7. REMARKS

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

Click on “**Add/Edit Info**” to edit the relevant fields.

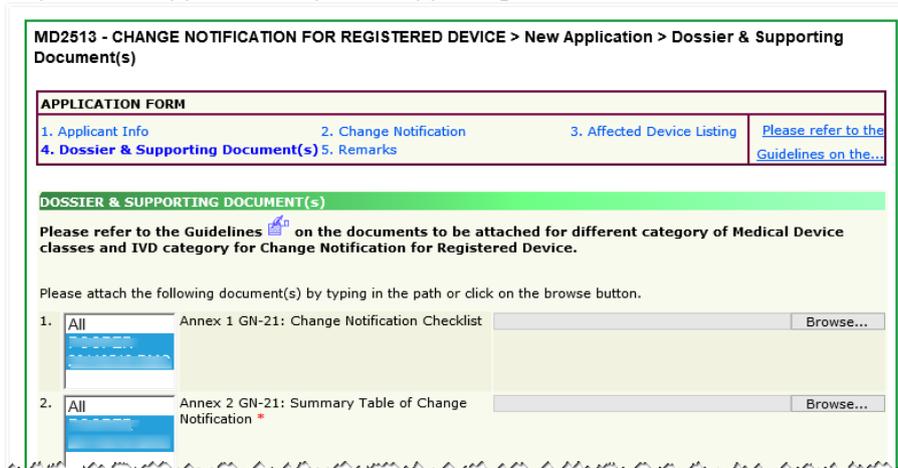
If the “**Add/Edit Info**” links are not available and you intend to make changes to the listing information, please review your Type of Changes selection in **PART 2 – Change Notification**.

If in doubt of which Type of Change is applicable, please refer to *GN – 21 Guidance to Change Notification*, or send in an enquiry at hsa_md_info@hsa.gov.sg to verify the Type of Change to be selected.

Click “**Update Form**” to save changes and return to the device listing page.

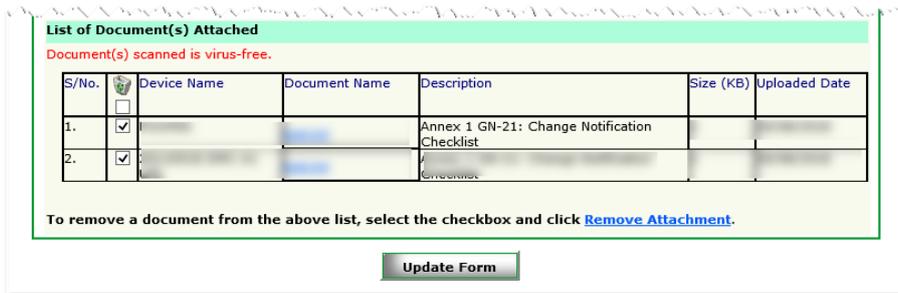
PART 4 – Dossier & Supporting Document(s)

This section requires the applicant to upload supporting documents for each device.



The supporting documents are attached by:

- selecting the device(s) from the selection box
- 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



S/No.	Device Name	Document Name	Description	Size (KB)	Uploaded Date
1.	<input checked="" type="checkbox"/>		Annex 1 GN-21: Change Notification Checklist		
2.	<input checked="" type="checkbox"/>		Annex 2 GN-21: Summary Table of Change Notification		

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.

Note:

- If a document is applicable for more than one device, you can select multiple devices from the selection box before browsing to the document and uploading it.
- If a document is applicable for ALL devices, you can select All from the selection box before browsing to the document and uploading it.
- If the device name is too long and you cannot distinguish them due to the limit of the section box, move the mouse over to the device name, the full name will be displayed below the mouse cursor.

PART 5 – Remarks



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

END OF DOCUMENT