

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 <u>Change Notification for Registered Device</u> 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
 - <u>CorpPass</u> (Singapore Corporate Access), a corporate digital identity for business and other entities to transact with Government online services, OR
 - <u>HSA PIN</u> (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 <u>Regulatory Guidances</u> is useful for the application.

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

PAYMENT

Please click <u>here</u> 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)

Applicant Info 2. Change Notification 3. Affected Device Listing Dossier & Supporting Document(s) 5. Remarks Change the following info if you are applying on behalf of the applicant. Name: Name: Remarks Applicant Info Change the following info if you are applying on behalf of the applicant. Name: Applicant Info Change the following info if you are applying on behalf of the applicant. Name: Follow: Follow: Change the following info if you are applying on behalf of the applicant. Name: Follow: For Assignment Drafter Assignment Draf	PLICATION FORM				
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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

1. APPLICANT INFO			
Change the following info if ye	ou are applying on beh	alf of the applicant.	
Name : *		NRIC/Passport No. : *	5
Tel. No. : *		Fax No. : *	
Email : *			
Drafter Assignment			
Drafter type :	Staff O Partner		
Available Company's Drafters :	Select Drafter 🔻		

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:

Name
 NRIC/Passport No
 Contact Telephone Number
 Contact Fax Number
 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 <u>CRIS Management Module</u>. 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

APPLICATION FORM			
1. Applicant Info 4. Dossier & Supporting Document(s)	2. Change Notification 5. Remarks	3. Affected Device Listing	Please refer to the Guidelines on the
Change Notification			
Declaration if there are any change MONE of the changes submitted in th Field Safety Corrective Action (I SOME of the changes submitted in th Field Safety Corrective Action (I ALL of the changes submitted in this Field Safety Corrective Action (I	s due to FSCA or AE his application are related to FSCA) and/or Local Reportable his application are related to FSCA) and/or Local Reportable application are related to FSCA) and/or Local Reportable	Adverse Events (AE). Adverse Events (AE). Adverse Events (AE).	
Medical Device Class			
J Class B			
Class C Class D Class D			

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 N	lotification
APPLICATION FORM	
1. Applicant Info 2. Change Notification 3. Affected Device Listing	Please refer to the
4. Dossier & Supporting Document(s) 5. Remarks	Guidelines on the
Change Notification	
Please take note that any updates on the Type of Change below, it may impact (by resetting) to the affected device info or (by removing) addition of new device in this application.	he changes made to
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 specificati medical device and/or sterilisation process	ons of a registered
Changes in the manufacturing process to Additive Manufacturing (3D-printing), or to refurbish a regi	stered device
Changes to manufacturing site and/or processes that result in a change in specifications of a register	red medical device
Changes to sterilisation method and related processes	
Changes to Quality Management System (QMS) certificates for manufacturing and sterilisation facilities	es
✓ 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 multple existing manuis not due to safety, quality and/or efficacy of the device)	facturing facilities (that
\square The change only involves a change in certification body with no change in scope of the certification	on
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	
U Other Changes - Applicable only upon receipt of email from HSA, authorising submission un	der this category
Update Form Close	

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"

APPLICATION FORM			
1. Applicant Info 4. Dossier & Supporting Document(s)	2. Change Notification 5. Remarks	3. Affected Device Listing	Please refer to the Guidelines on the
Change Notification			
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 ✓ Field Safety Corrective Action (I Iedical Device Class ✓ Class B Class C Class D o select/update Type of Change(s) Selected Type of Change(s) 	FSCA) and/or Local Reportable) for Change Notification Click Change Notification	Adverse Events (AE). Add/Update.	
 ✓ Field Safety Corrective Action (I fedical Device Class ✓ Class B Class C Class D o select/update Type of Change(s; Selected Type of Change(s) for Change in Manufacturing Facility, P 	FSCA) and/or Local Reportable) for Change Notification Click Change Notification Process and Quality Manageme	Adverse Events (AE). Add/Update. ent System	
 Field Safety Corrective Action (I fedical Device Class Class B Class C Class D o select/update Type of Change(s) Selected Type of Change(s) for Change in Manufacturing Facility, P Change to Quality Management State 	FSCA) and/or Local Reportable) for Change Notification Click Change Notification Process and Quality Manageme ystem (QMS) certificates for manu	Adverse Events (AE). Add/Update. ent System facturing and sterilisation facilities	

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.

Change Notification	
Note: For Technical Changes: Technical Changes for Clas require HSA's approval prio	s C and D medical devices affect the safety, quality or efficacy of these medical devices. These r to implementation of the change in Singapore.
For Review Changes: Review Changes for Class f approval prior to implemen	3 medical devices affect the safety, quality or efficacy of these medical devices. These require HSA's tation of the change in Singapore.
For Administrative Change Administrative Changes inc typically affect the SMDR lis	s: lude changes to the information submitted at the point of registration of the medical device and ting 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.
FSCA/AE Declaration	
Non-FSCA	
Risk Class	
Class B	
Type of Changes	
Change in Manufacturi	ng Facility, Process and Quality Management System
Changes to Quality Ma	anagement System (QMS) certificates for manufacturing and sterilisation facilities
The change only i	nvolves an update of QMS certificate validity date
For Official Use Only: (reate New SMDR Listing(s)
No	
Overall Category of Ch	ange
Notification	
Highest Risk Class	
Class B	
Please note that for ch not be supplied until a	anges to Medical Devices that requires HSA approval, as defined in GN-21, they shall pproval has been granted.
	Click Add/Edit Inf



PART 3 – Affected Device Listing

MD2517 - CHANGE NOTIFICATION	FOR REGISTERED DEVICE > New A	pplication > Affected Device Listing
APPLICATION FORM		
1. Applicant Info 4. Dossier & Supporting Document(s)	2. Change Notification 3. 5. Remarks	Affected Device Listing Please refer to the Guidelines on the
Search Device(s) for Change No	otification for Registered Device	
Please take note that the list below	will only contains these selected me	edical devices class (active device only)
Selected FSCA Declaration Non-FSCA Selected Risk Class Class B		
Dossier No :		
Licence No :		
Device Proprietary/Brand Name :		Starts With V Search
Total 61 record(s)	Page 1 Of 7 GO	[first] [previous] [next] [last]
Licence No. Dossier No. Ris CL CL CL CL CL CL CL CL CL CL CL CL CL	sk Class Device Proprietary/Brand Nan ASS B ASS B	ne Expiry Date
	tor the device is suit under post-approval	
Total 61 record(s) To add device(s) for Change Notific	Page 1 Of 7 GO	[hrst] [previous] <u>[next]</u> <u>[last]</u> he checkbox(es) and click <u>Add</u> .
	Update Form Close	

Only ACTIVE devices of the risk class selected in PART 2 – Change Notification will be displayed. Select affected device listings and click "Add"; selected devices will be populated in a table below:

APPLICATION FORM					
1. Applicant Info 4. Dossier & Supporting Docum	2. Change ent(s) 5. Remark	Notification	3. Affect	ed Device Listing	Please refer to the
Search Device(s) for Chan	ge Notificatio	n for Registered	Device		
Please take note that the list	below will only	contains these se	lected medical	devices class (acti	ve device only)
Selected FSCA Declaration Non-I Selected Risk Class Class B	FSCA				
Dossier No :					
icence No :					
)evice Pronrietary/Brand Name :			Starte	With X	
Sevice Proprietary, Brana Name .				Search	
otal 59 record(s)		Page 1	Of 6 GO	[first] [previo	ous] [next] [last
Licence No. Dossier No.	Risk Class CLASS B CLASS B CLASS B CLASS B CLASS B CLASS B CLASS B CLASS B CLASS B CLASS B	Device Proprietary,	Brand Name		Expiry Date
* A pending Change Notific	ation for Register	red Device has been	created for the de	evice.	
^ The IBR Pre-Market appl	ication for the de	vice is still under pos	t-approval review	.	
otal 59 record(s)		Page 1	Of 6 GO	[first] [previo	ous] <u>[next]</u> <u>[las</u>
o add device(s) for Change	Notification for	Registered Device	, check the che	ckbox(es) and clic	k Add.
Selected Device(s) for Cha	ange Notificati	on for Registere	Device		
iotal 2 record(s)		Bage 1	of 1 GO	[first] [nrevio	us] [next] [las
Licence No. Dossier No	CLASS B	Device Proprieta	y/Brand Name	final fibrary	100 [nove] [no
otal 2 record(s)		Page 1	Of 1 GO	[first] [previo	ous] [next] [las
o edit device, click Licence I o remove device(s), check t	1o. he checkbox(e	s) and click <u>remov</u>	<u>e</u> .		

If the Type of Change selected in **PART 2 – Change Notification** involves a change in device listing information, click on the **Licence Number** of the relevant device listing to access the device information page to amend accordingly.

1. Change Notification 2. Device Info 3. Product Own 4. Manufacturing Site(s) Info 5. Model(s) Info 6. Importer & 1 6. Importer & 1 6. Importer & 1 6. Importer & 1 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 S	ter Info Please refer to Wholesaler Info Guidelines on th
Registration No. : Jossier No. : Fields marked with asterisks * are mandatory. I. CHANGE NOTIFICATION Please provide change ontification. Change in Manufacturing Facility, Process and Quality Management S	
ossier No. : ields marked with asterisks * are mandatory. . CHANGE NOTIFICATION Please provide change notification. Change in Manufacturing Facility, Process and Quality Management S	
rields marked with asterisks * are mandatory. . CHANGE NOTIFICATION Please provide change notification. Change in Manufacturing Facility, Process and Quality Management S	
. CHANGE NOTIFICATION Please provide change notification. Change in Manufacturing Facility, Process and Quality Management S	
Please provide change notification. Change in Manufacturing Facility, Process and Quality Management St	
Change in Manufacturing Facility, Process and Quality Management S	
	ystem
Changes to Quality Management System (QMS) certificates for manufacturin	ng and sterilisation facilities
The change only involves an update of QMS certificate validity date	
	Click Add/Edit 1
2. DEVICE INFO	
Please provide device info.	
Device Info	
THE CONTRACTOR OF A DESCRIPTION OF A DES	
	Click Add/Edit
PRODUCT OWNER INFO	
Please provide product owner mito.	
	Click Add/Edit
. MANUFACTURING SITE(s) INFO	
Please provide manufacturing site(s) info.	
1. COLUMN OF SMALL PROPERTY OF THE PARTY NAME.	
the second se	
	Click Add/Edit
Rease provide model(s) info	
rease provide model(s) mo.	
	Click Add/Edit
Please provide Importer & Wholesaler Info.	
riedse provide importer & vinotesaler fillo.	class a literation
	CIICK Add/Edit
Remarks to MDB ·	
(You may enter a maximum of	~
up to 1000 characters.)	
	\checkmark

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 <u>hsa_md_info@hsa.gov.sg</u> to verify the Type of Change to be selected.

Click "Update Form" to save changes and return to the device listing page.





MD2517 - CHANGI	ENOTIFICATIO	ON FOR REC	SISTERED DEVICE	> New Applic	ation > Affected D	evice Listing
APPLICATION FO	RM					
1. Applicant Info 4. Dossier & Suppo	orting Document	2. Change (s) 5. Remark	Notification s	3. Affec	ted Device Listing	Please refer to the Guidelines on the
Search Device(s) for Change	Notification	for Registered	Device		
Please take note t	hat the list be ration Non-FSC	low will only A	contains these se	lected medica	l devices class (acti	ve device only)
Selected Risk Class	Class B					
Dossier No :						
Licence No :						
Device Proprietary/B	rand Name :			Starts	With V Search	
Total 59 record(s)			Page 1	Of 6 GO	[first] [previo	us] [next] [last]
Licence No.	Dossier No. nange Notificatic Market applicat	Risk Class CLASS B CLASS B	ed Device has been rice is still under pos Page 1	created for the o t-approval revie of 6 GO	levice. w. [first] [previc	Expiry Date
To add device(s) f	or Change Not	ification for	Registered Device	e, check the ch	eckbox(es) and clic	k <u>Add</u> .
Selected Device	(s) for Chang	e Notificati	on for Registere	d Device		
Total 2 record(s)	Dossier No.	Risk Class CLASS B CLASS B	Page 1 Device Proprieta	Of 1 GO ry/Brand Name	[first] [previo	us] [next] [last]
Total 2 record(s)			Page 1	Of 1 GO	[first] [previo	us] [next] [last]
To edit device, clic To remove device(k Licence No. (s), check the	checkbox(e	5) and click <u>remov</u>	<u>e</u> .		
		Upda	ate Form	Close		

Click "Update Form" to save all changes and return to main application page.

A summary of the affected device listings selected and an estimated fee for the current application will be displayed.

3. AFFECTED DEVICE LISTING	
Please select device listing affected by this Change Notification for Registered Device.	
Device listing affected	
1.	
2.	
Across Dossier	
Yes	
Estimated Amount	
\$0.00	
	Click Add/Edit Info

PART 4 – Dossier & Supporting Document(s)

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

APPLICATION FORM			
1. Applicant Info	2. Change Notification	3. Affected Device Listing	Please refer to t
4. Dossier & Supporting I	Document(s) 5. Remarks		Guidelines on the
OSSIER & SUPPORTING	DOCUMENT(s)		
	<u>"</u>		
lease refer to the Guide	lines 🍟 on the documents to be attach	ed for different category of M	edical Device
Please refer to the Guide lasses and IVD category	lines 🆆 on the documents to be attach r for Change Notification for Registered	ed for different category of Mo Device.	edical Device
Please refer to the Guide lasses and IVD category	lines 🆆 on the documents to be attach r for Change Notification for Registered	ed for different category of Mo Device.	edical Device
Please refer to the Guide classes and IVD category Please attach the following d	lines don the documents to be attach of Change Notification for Registered ocument(s) by typing in the path or click on t	ed for different category of M Device. he browse button.	edical Device
Please refer to the Guide classes and IVD category Please attach the following d	lines on the documents to be attach of Change Notification for Registered ocument(s) by typing in the path or click on t 1 GN-21: Change Notification Checklist	ed for different category of Mo Device. he browse button.	edical Device
Please refer to the Guide classes and IVD category Please attach the following d	lines ^{den} on the documents to be attach for Change Notification for Registered ocument(s) by typing in the path or click on t 1 GN-21: Change Notification Checklist	ed for different category of M Device. he browse button.	edical Device Browse
Please refer to the Guide classes and IVD category Please attach the following d	lines ^{do} on the documents to be attach r for Change Notification for Registered ocument(s) by typing in the path or click on t 1 GN-21: Change Notification Checklist	ed for different category of M Device. he browse button.	edical Device Browse
lease attach the following d	lines ^{do} on the documents to be attach r for Change Notification for Registered ocument(s) by typing in the path or click on t 1 GN-21: Change Notification Checklist	ed for different category of M Device. he browse button.	edical Device Browse
Please refer to the Guide classes and IVD category Please attach the following d I. All Annex	lines ^{do} on the documents to be attach r for Change Notification for Registered ocument(s) by typing in the path or click on t 1 GN-21: Change Notification Checklist	ed for different category of M Device. he browse button.	edical Device Browse

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.		-	Annex 1 GN-21: Change Notification Checklist	1.1	
2.		and the second s	Lineerine.		
		the shows list calles	t the checkbox and click Demove Att	- channel	

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

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

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

END OF DOCUMENT