

# MEDICS Change Notification System Enhancements

Feb 2014



# Overview of MEDICS Enhancements

## Improved MEDICS System Functions:

- Identify and verify applicable change types and SMDR device listings
- Filter out relevant risk class SMDR listings
- Increased supporting document categories, mirroring GN-21 Annex 1: Change Notification Checklist

FSCA Declaration (system enhancement)

Risk Class (system enhancement)

Type of Change (s) (dynamic list)

Device Listing(s) (dynamic list)

Supporting Documents  
(expanded document categories)

# MEDICS Change Notification Application (All risk classes)

1. Access [change@medics](mailto:change@medics) e-Service from HSA website.

Link: <http://www.hsa.gov.sg/publish/hsaportal/en/services/medics.html>

## MEDICS e-Services

### [apply@medics](mailto:apply@medics)

- Dealer's Licence & Registrant's Account
- Product registration
- Export-Only Unregistered Medical Devices
- Certificates

### [change@medics](mailto:change@medics)

Licence/registration/notification:

- Withdrawal
- Amendment for Dealer's license / Submission of update of Class A Medical Device Exemption List
- Amendment for Registrant's account
- Cancellation
- **Change Notification for Registered Devices**

# Main Page

2. After logging in and accepting terms and conditions, the following screen will appear. Fill in all mandatory fields (\*) in section 1 Applicant Info.

APPLICATION FORM			
<a href="#">1. Applicant Info</a>	<a href="#">2. Change Notification</a>	<a href="#">3. Affected Device Listing</a>	<a href="#">Please refer to the Guidelines on the...</a>
<a href="#">4. Dossier &amp; Supporting Document(s)</a>	<a href="#">5. Remarks</a>		

Job Reference No. : MD14500118I  
 Status Date : 06/01/2014

Submission Date : 06/01/2014  
 Status : Draft

## 1. APPLICANT INFO

Change the following info if you are applying on behalf of the applicant.

Name : *	<input type="text" value="Wang Lee Hom"/>	NRIC/Passport No. : *	<input type="text" value="G8001888K"/>
Tel. No. : *	<input type="text" value="96262137"/>	Fax No. : *	<input type="text" value="12323"/>
Email : *	<input type="text" value="leehom@prism.com"/>		

## 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 A and 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.

### 3. Click on Add/Edit Info under section 2 to select the Types of Changes

## 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 A and 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](#)

#### 4. Select the applicable *FSCA and/or AE* category

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

#### APPLICATION FORM

- |                                     |                               |                            |  |
|-------------------------------------|-------------------------------|----------------------------|--|
| 1. Applicant Info                   | <b>2. Change Notification</b> | 3. Affected Device Listing | <a href="#">Please refer to the Guidelines on the...</a> |
| 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 **Filed Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).** → **No FSCAs and/or AE changes**
- SOME** of the changes submitted in this application are related to **Filed Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).** → **Mixture of normal, and FSCAs and/or AE changes**
- ALL** of the changes submitted in this application are related to **Filed Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).** → **FSCAs and/or AE changes only**

#### Medical Device Class

- Class A
- Class B
- Class C
- Class D

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

Update Form

Close

Best viewed using Internet Explorer 7.0 and above. | [Privacy Statement](#) | [Terms of Use](#) | [HSA Data Protection Policy](#) | [Rate Our Website](#)

# CN Application Submission Scenario 1: Selection of Single Risk Class



## Scenario 1: Selection of Single Risk Class

5 (a) (i). Select applicable risk class and click Add/ Update when done

- ✓ None of the changes submitted in this application are related to FSCA and/or AEs
  - Select single risk class

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

### APPLICATION FORM

1. Applicant Info	2. Change Notification	3. Affected Device Listing	<a href="#">Please refer to the Guidelines on the...</a>
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 **Filed Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).**
- SOME** of the changes submitted in this application are related to **Filed Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).**
- ALL** of the changes submitted in this application are related to **Filed Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).**

#### Medical Device Class

- Class A
- Class B
- Class C
- Class D

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

**Note:** Changes to FSCA/ AEs and Risk Class sections are not possible after submission of CN application. Amendments will require withdrawal and resubmission of application, hence verify selections carefully before submission.

# Scenario 1: Selection of Single Risk Class

## 5 (a) (ii). System will determine relevant Types of Change(s) and display for selection

- Changes are listed on MEDICS in the same order as that in *GN-21: Change Notification Guidance, Table 1 – Categories of Change Notification*

Table 1 - Categories of Change Notification

Proposed type of change	Change Notification Category
<b>1. Change in Manufacturing Facility, Process and Quality Management System (QMS)</b>	<b>Change Notification</b>
<b>1 A</b> All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes	<p><b>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.</b></p> <p>Selected FSCA Declaration <b>Non-FSCA</b> Selected Risk Class <b>Class C</b></p>
<b>1 B</b> All changes to manufacturing processes (including changes made to outsourced processes) that result in a change in specifications of a registered medical device	<p><input checked="" type="checkbox"/> <b>Change in Manufacturing Facility, Process and Quality Management System</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Changes to manufacturing and/or sterilisation facilities with no changes to manufacturing and/or sterilisation processes</li> <li><input type="checkbox"/> Changes to manufacturing processes (including changes made to outsourced processes) that result in a change in specifications of a registered medical device</li> <li><input type="checkbox"/> Changes to sterilisation processes (including changes made to outsourced processes)</li> <li><input type="checkbox"/> Changes to Quality Management System (QMS) certificates for manufacturing and sterilisation facilities <ul style="list-style-type: none"> <li><input type="checkbox"/> an update of certificate QMS validity date</li> <li><input type="checkbox"/> a cancellation of QMS certificate for one of the multiple existing manufacturing facilities (that is not due to safety, quality and/or efficacy of the device)</li> <li><input type="checkbox"/> a change in certification body with no change in scope of the certification</li> <li><input type="checkbox"/> an expansion of scope of the QMS certification which does not affect the registered medical device</li> <li><input type="checkbox"/> other changes</li> </ul> </li> </ul> <p><input type="checkbox"/> <b>Changes in Design or Specifications of a registered medical device</b></p> <p><input type="checkbox"/> <b>Changes to materials in a General Medical Device</b></p> <p><input type="checkbox"/> <b>Changes to materials in an In-Vitro Diagnostic (IVD) Medical Device</b></p> <p><input type="checkbox"/> <b>Changes to labelling of medical device</b></p>

## Scenario 1: Selection of Single Risk Class

5 (a) (iii). Select checkboxes in front of blue headers to expand relevant categories of change

- Change in Manufacturing Facility, Process and Quality Management System**
- 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**



- Change in Manufacturing Facility, Process and Quality Management System**
- Changes in Design or Specifications of a registered medical device**
  - All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device
    - Change only involves a design change that does not affect the safety, quality or efficacy of the medical device (e.g. changes that improve device ergonomics, aesthetic modification of the device, etc.)
    - Other Changes
  - All changes in specifications of a registered medical device
    - Software version number changes only due to changes
      - i) solely to correct an inadvertent software error which does not add new functions, does not pose any safety risk and is intended to bring the system to specification  
AND/OR
      - ii) which augment interfacing to other non-medical peripherals such as printers or VDUs and which has no diagnostic or therapeutic function  
AND/OR
      - iii) which only modifies the appearance of the user interface with no risk to diagnostic or therapeutic function of the device  
AND/OR
      - iv) which involves other changes that does not affect safety, quality or efficacy of the medical device
    - Others
  - Changes to the IVD analyser that does not impact the performance specifications of the test kits
- 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**

# Scenario 1: Selection of Single Risk Class

## 5 (a) (iv). Select changes and click Update Form

- Identify relevant change type and select field in MEDICS

1. Changes in Design or Specifications of a registered medical device	
<b>2 A</b> All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device	Are classified as <b>Technical Changes</b> that require approval from HSA prior to implementation.
<b>Unless the change only</b> - involves a design change that does not affect the safety, quality or efficacy of the medical device (e.g. changes that improve device ergonomics, aesthetic modification of the device)	Shall be classified as <b>Notifications</b> . These changes may be implemented immediately upon successful receipt of the Change Notification application by HSA.

E.g. To select Design change (Tech)

Under MEDICS change list, select checkboxes under blue and pink category headers, then select

Other Changes

System will recognise this as a Design change (Tech).



Change in Manufacturing Facility, Process and Quality Management System

**Changes in Design or Specifications of a registered medical device**

All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device

Change only involves a design change that does not affect the safety, quality or efficacy of the medical device (e.g. changes that improve device ergonomics, aesthetic modification of the device, etc.)

Other Changes

**Update Form**

Close

## Scenario 1: Selection of Single Risk Class

5 (a) (v). System will return to *Change Notification* page. Verify change type selected is correct, and click Update Form

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

### APPLICATION FORM

- |                                     |                               |                            |  |
|-------------------------------------|-------------------------------|----------------------------|--|
| 1. Applicant Info                   | 2. <b>Change Notification</b> | 3. Affected Device Listing | <a href="#">Please refer to the Guidelines on the...</a> |
| 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 **Filed Safety Corrective Action (FSCA)** and/or **Reportable Adverse Events (AE)**.
- SOME** of the changes submitted in this application are related to **Filed Safety Corrective Action (FSCA)** and/or **Reportable Adverse Events (AE)**.
- ALL** of the changes submitted in this application are related to **Filed Safety Corrective Action (FSCA)** and/or **Reportable Adverse Events (AE)**.

#### Medical Device Class

- Class A
- 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

#### Changes in Design or Specifications of a registered medical device

All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device

*Other Changes*

Update Form

Close

## 6. Message prompt will appear. Select Ok

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 & Submission

**Change Notification**

**Declaration of Changes**

**NONE** of the Filed Safety Data

**SOME** of the Filed Safety Data

**ALL** of the Filed Safety Data

**Medical Device Class**

Class A

Class B

Class C


Class D

To select/update

**Selected Type of Change(s) for Change Notification**

Changes in Design or Specifications of a registered medical device

Message from webpage

 Please ensure that changes submitted are identical and applicable to all device listings

If there are changes to software version, please indicate the affected model and latest corresponding software version number in Section 5. Remarks to MDB in the following format:  
Model Name (Product Identifier): Latest software version number

OK

### Note:

- a) Verify changes submitted are identical
  - For cross dossier and/or multiple risk class listings

# Main Page

7. System returns to Main Page. Input software version into REMARKS section, if applicable.

## 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.

S/No.	Device Name	Document Name	Description	Size (KB)	Uploaded Date
-------	-------------	---------------	-------------	-----------	---------------

[Click Attach/Remove Document](#)

## 5. REMARKS

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

ABC X-Ray System (12340) : Version 2.0

Save Draft

Confirm

Close

### Note:

#### b) Format of software version

- Model Name (Product Identifier): Latest software version number
- Model Name 2 (Product Identifier 2): Latest software version number

# Main Page

8. Under Affected Device Listing section, select 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.

S/No.	Device Name	Document Name	Description	Size (KB)	Uploaded Date
-------	-------------	---------------	-------------	-----------	---------------

[Click Attach/Remove Document](#)

### 5. REMARKS

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

ABC X-Ray System (12340): Version 2.0

Save Draft

Confirm

Close

### 9. Select affected device listing(s) and click Add

- **MEDICS system display only listings relevant to risk class selected in Change Notification page. [Refer to section 5 a) i), slide 8]**

#### MD2517 - CHANGE NOTIFICATION FOR REGISTERED DEVICE > New Application > Affected Device Listing

##### APPLICATION FORM

- |                                     |                        |                                   |                                      |
|-------------------------------------|------------------------|-----------------------------------|--------------------------------------|
| 1. Applicant Info                   | 2. Change Notification | <b>3. Affected Device Listing</b> | Please refer to the                  |
| 4. Dossier & Supporting Document(s) | 5. Remarks             |                                   | <a href="#">Guidelines on the...</a> |

##### Search Device(s) for Change Notification for Registered Device

Please take note that the list below will only contains these selected medical devices class (active device only)

Selected FSCA Declaration **Non-FSCA**

Selected Risk Class **Class C**

Dossier No :

Licence No :

Device Proprietary/Brand Name :

Starts With

[Search](#)

Total 11 record(s)

Page 1 Of 2 [GO](#)

[first] | [previous] | [\[next\]](#) | [\[last\]](#)

<input type="checkbox"/>	Licence No.	Dossier No.	Risk Class	Device Proprietary/Brand Name	Expiry Date
<input type="checkbox"/>	*DE0001023	<a href="#">C3162A60-10</a>	CLASS C	20101122 DMC A3[Refer MD12560218W]	06/08/2012
<input type="checkbox"/>	*DE0001017	<a href="#">C3162D1F-10</a>	CLASS C	20101129 DMC AA4[Refer MD11559828W]	30/06/2012
<input type="checkbox"/>	*DE0001037	<a href="#">C3162D2B-10</a>	CLASS C	20101129 DMC AA1 SUP[Refer MD11559703B]	27/12/2011
<input type="checkbox"/>	*DE0001041	<a href="#">C3163764-10</a>	CLASS C IVD	20101214 DMC AA3 SUP	05/01/2012
<input type="checkbox"/>	*DE0001060	<a href="#">C3175D63-11</a>	CLASS C	D	05/09/2011
<input type="checkbox"/>	*DE0001068	<a href="#">C318094C-11</a>	CLASS C	D	27/10/2012
<input type="checkbox"/>	*DE0000998	<a href="#">C319315A-10</a>	CLASS C	DMC_DEV_20100319_002 UPI[Refer MD11559811F]	30/06/2012
<input type="checkbox"/>	*DE0001004	<a href="#">C319362D-10</a>	CLASS C	DMC_DEV_UPI_20100331_001[Refer MD11560206K]	30/06/2011
<input type="checkbox"/>	*DE0001071	<a href="#">C31C522F-12</a>	CLASS C	DEV_DMC_20120830_002	02/09/2013
<input type="checkbox"/>	*DE0022691	<a href="#">C40E334B29-14</a>	CLASS C	Device A 02012014[Refer MD14500118I]	01/01/2015

**Only Class C SMDR listings displayed**

##### Legend:

\* A pending Change Notification for Registered Device has been created for the device.

^ The IBR Pre-Market application for the device is still under post-approval review.

Total 11 record(s)

Page 1 Of 2 [GO](#)

[first] | [previous] | [\[next\]](#) | [\[last\]](#)

To add device(s) for Change Notification for Registered Device, check the checkbox(es) and click [Add.](#)

**10. Selected listings will be displayed at bottom of page. Click Update Form to return to Main Page.**

### Selected Device(s) for Change Notification for Registered Device

Total 2 record(s)

Page  Of 1 **GO**

[\[first\]](#) | [\[previous\]](#) | [\[next\]](#) | [\[last\]](#)

<input type="checkbox"/>	Licence No.	Dossier No.	Device Proprietary/Brand Name
<input type="checkbox"/>	<a href="#">DE0022691</a>	<a href="#">C40E334B29-14</a>	Device A 02012014
<input type="checkbox"/>	<a href="#">DE0022692</a>	<a href="#">C40E334B29-14</a>	Device B 02012014

Total 2 record(s)

Page  Of 1 **GO**

[\[first\]](#) | [\[previous\]](#) | [\[next\]](#) | [\[last\]](#)

**To edit device, click Licence No.**

**To remove device(s), check the checkbox(es) and click [remove](#).**

**Update Form** **Close**

# Main Page

11. Under Dossier & Supporting Document(s) section, select Attach/ Remove Document

### 3. AFFECTED DEVICE LISTING

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

#### Device listing affected

1. (DE0022691) **Device A 02012014** (CLASS C), HS Code:30049091, HSA Product Code:Refer to CRPNS
2. (DE0022692) **Device B 02012014** (CLASS C), HS Code:30049091, HSA Product Code:Refer to CRPNS

#### Estimated Amount

\$1700.00

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.)

Save Draft

Confirm

Close

## 12. Select relevant listing(s) under each document type

- Only upload the sections relevant to your change.
- It is mandatory to upload the *Annex 2 Summary Table of Change Notification\**.

### 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...](#)


Job Reference No. : MD14500118I

Status Date : 06/01/2014

Submission Date : 06/01/2014

Status : Draft

### DOSSIER & SUPPORTING DOCUMENT(S)

Please refer to the [Guidelines](#)  on the documents to be attached for different category of Medical Device classes and IVD category for Change Notification for Registered Device.

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

1.	<div style="border: 1px solid red; padding: 2px;">           All            Device A 020120            Device B 020120         </div>	Annex 1 GN-21: Change Notification Checklist	<input type="text"/>	<input data-bbox="1671 835 1806 863" type="button" value="Browse..."/>
2.	<div style="border: 1px solid blue; padding: 2px;">           All            Device A 020120            Device B 020120         </div>	Annex 2 GN-21: Summary Table of Change Notification *	<input type="text"/>	<input data-bbox="1671 985 1806 1013" type="button" value="Browse..."/>
3.	<div style="border: 1px solid blue; padding: 2px;">           All            Device A 020120            Device B 020120         </div>	Annex 3 GN-21: Medical Device Safety Declaration	<input type="text"/>	<input data-bbox="1671 1135 1806 1163" type="button" value="Browse..."/>
4.	<div style="border: 1px solid blue; padding: 2px;">           All            Device A 020120            Device B 020120         </div>	Letter of Authorization	<input type="text"/>	<input data-bbox="1671 1285 1806 1313" type="button" value="Browse..."/>

### 13. Click Browse to select the file you wish to upload for each required document type.


7.	All Device A 02012 Device B 02012	Justification for Addition of Product(s)	<input type="button" value="Browse..."/>
8.	All Device A 02012 Device B 02012	Regulatory Approval Certificate(s)	<input type="button" value="Browse..."/>
9.	All Device A 02012 Device B 02012	Device Information	<input type="button" value="Browse..."/>
10.	All Device A 02012 Device B 02012	Device Labelling (including Instructions for Use)	<input type="button" value="Browse..."/>
11.	All Device A 02012 Device B 02012	Design verification and validation documents including : <ul style="list-style-type: none"> <li>• Preclinical studies e.g. physical test data, biocompatibility studies, animal studies and software verification and validation studies</li> <li>• Meteorological requirements</li> <li>• Sterilisation validation (if applicable)</li> <li>• Shelf-life studies and projected useful life</li> </ul>	<input type="button" value="Browse..."/>
12.	All Device A 02012 Device B 02012	Clinical evidence	<input type="button" value="Browse..."/>
13.	All Device A 02012 Device B 02012	Risk Analysis	<input type="button" value="Browse..."/>

**14. Click Add Attachment to upload the selected file(s). After uploading all required documents, click Update Form.**

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

**List of Document(s) Attached**

Document(s) scanned is virus-free.

S/No.		Device Name	Document Name	Description	Size (KB)	Uploaded Date
1.	<input type="checkbox"/>	Device A 02012014	Annex 1 to GN-21 Change Notification Checklist.doc	Annex 1 GN-21: Change Notification Checklist	205	03/02/2014
2.	<input type="checkbox"/>	Device A 02012014	Annex 2 to GN-21 Summary Table of Change Notification.doc	Annex 2 GN-21: Summary Table of Change Notification	85	03/02/2014
3.	<input type="checkbox"/>	Device B 02012014	Annex 1 to GN-21 Change Notification Checklist.doc	Annex 1 GN-21: Change Notification Checklist	205	03/02/2014
4.	<input type="checkbox"/>	Device B 02012014	Annex 2 to GN-21 Summary Table of Change Notification.doc	Annex 2 GN-21: Summary Table of Change Notification	85	03/02/2014

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

**Update Form**

# Main Page

15. The Main Form will appear. Select Confirm when ready to submit.

### 3. AFFECTED DEVICE LISTING

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

**Device listing affected**

1. (DE0022691) **Device A 02012014** (CLASS C), HS Code:30049091, HSA Product Code:Refer to CRPNS
2. (DE0022692) **Device B 02012014** (CLASS C), HS Code:30049091, HSA Product Code:Refer to CRPNS

**Across Dossier**

No

**Estimated Amount**

\$1700.00

[Click Add/Edit Info](#)

### 4. DOSSIER & SUPPORTING DOCUMENT(S)

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

S/No.	Device Name	Document Name	Description	Size (KB)	Uploaded Date
1.	Device A 02012014	Annex 1 to GN-21 Change Notification Checklist.doc	Annex 1 GN-21: Change Notification Checklist	205	03/02/2014
2.	Device A 02012014	Annex 2 to GN-21 Summary Table of Change Notification.doc	Annex 2 GN-21: Summary Table of Change Notification	85	03/02/2014
3.	Device B 02012014	Annex 1 to GN-21 Change Notification Checklist.doc	Annex 1 GN-21: Change Notification Checklist	205	03/02/2014
4.	Device B 02012014	Annex 2 to GN-21 Summary Table of Change Notification.doc	Annex 2 GN-21: Summary Table of Change Notification	85	03/02/2014

[Click Attach/Remove Document](#)

### 5. REMARKS

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

**Save Draft**

**Confirm**

**Close**

# Main Page

16. Message prompt will appear. Select OK.

3. AFFECTED DEVICE LISTING

Please select device listing

Device listing affected

- (DE0022691)
- (DE0022692)

Across Dossier

No

Estimated Amount

\$1700.00


4. DOSSIER & SUPPORT DOCUMENTS

Dossier & support documents

S/No.	Device Name	Change Notification Checklist	Checked	Uploaded Date
1.	Device A 0			03/02/2014
2.	Device A 0			03/02/2014
3.	Device B 0			03/02/2014

Click [Add/Edit Info](#)

Message from webpage

 1. Please submit all changes collectively for all affected device listing in an application and note that a Change Notification for Registered Device application needs to be completed prior to submitting a new Change Notification for Registered Device application.

2. Please ensure that FSCA / Reportable AE declaration and Risk Classes are correctly selected; note that no further changes to FSCA / Reportable AE declaration and Risk Class Selection can be done upon submission.

Click <OK> to proceed, Click <Cancel> to further update the application.

**Note:**

- Final check that all changes have been included (no planned changes have been left out from this submission)
- A new CN application cannot be submitted for affected listings till pending CN application is cleared
- Ensure that FSCA/ AEs and Risk Class section has been correctly filled in. This section is not changeable once application is submitted to HSA

17. The Submit button is only enabled when the Declarations are accepted.

6. DECLARATION

On behalf of the Product Owner and **ABC Co Ltd.,,**

- a. I hereby affirm that the information provided on this application is correct and complete
- b. I attest that I have the objective evidence to establish that this device(s) meets the safety and effectiveness requirements
- c. I attest that there are no misleading claims made relating to the quality, safety and effectiveness of this device

**Accept**  Decline

<< Previous

Submit

Close

## 18. Proceed to payment advice page for payment and submission of application.

### PAYMENT ADVICE

Please indicate your payment mode and click Submit button to confirm payment. If you do not wish to proceed with payment, click on the Cancel button.

MOHB HSA PRISM 1  
5 ANG MO KIO STREET 62, NCS HUB, SINGAPORE 569141

Attn: Lee Hom Wang

Transaction Type : NEW - Change Notification for Registered Device  
Date/Time : 29/11/2013 13:44

Payment Mode :

Client Code : C13000996B

Job Reference No. : MD13560807N

Case No. : 13560807

Progressive Payment :  Full Payment  Progressive Payment

S/No.	Description	Unit Price (S\$)	Qty	Amount (S\$)
1.	Notification Fee - Class C Registered MD	500.00	1	500.00
2.	Application Fee - Class C Registered MD	1200.00	1	1200.00
			<b>Total (S\$):</b>	<b>1,700.00</b>

# CN Application Submission Scenario 2: Selection of Multiple Risk Class



## Scenario 2: Selection of Multiple Risk Class

5 (b) (i). Select applicable risk class. *[Steps 1 though 4 are identical for this scenario]*



None of the changes submitted in this application are related to FSCA and/or AEs

- Select multiple risk classes

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

#### APPLICATION FORM

1. Applicant Info	<b>2. Change Notification</b>	3. Affected Device Listing	<a href="#">Please refer to the Guidelines on the...</a>
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 Reportable Adverse Events (AE).**
- SOME** of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).**
- ALL** of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).**

##### Medical Device Class

- Class A
- Class B
- Class C
- Class D

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

## Scenario 2: Selection of Multiple Risk Class

5 (b) (ii). Select relevant changes and click Update Form to return to *Change Notification Page*.

**Closed list of changes will be displayed**

- *Change in product owner*
- *Change in manufacture site*
- *Addition of identical Class A non-sterile accessories*

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

#### APPLICATION FORM

1. Applicant Info	2. <b>Change Notification</b>	3. Affected Device Listing	<a href="#">Please refer to the Guidelines on the...</a>
4. Dossier & Supporting Document(s)	5. Remarks		

#### 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 A, Class B, Class C, Class D**

- Change in Manufacturing Facility, Process and Quality Management System**
- Changes to registered medical devices listing information**
  - Addition of new medical devices to a SYSTEM/ GROUP listing
    - Changes only involves an addition of Class A Exempted medical device accessories that complement the registered medical device as a closed system
  - All changes in Product Owner including changes in Product Owner Name and Address

**Update Form**

**Close**

Best viewed using Internet Explorer 7.0 and above. | [Privacy Statement](#) | [Terms of Use](#) | [HSA Data Protection Policy](#) | [Rate Our Website](#)

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## Scenario 2: Selection of Multiple Risk Class

5 (b) (iii). Verify change type selected is correct and click Update Form.

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

#### APPLICATION FORM

- |                                     |                               |                            |  |
|-------------------------------------|-------------------------------|----------------------------|--|
| 1. Applicant Info                   | 2. <b>Change Notification</b> | 3. Affected Device Listing | <a href="#">Please refer to the Guidelines on the...</a> |
| 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 **Filed Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).**
- SOME** of the changes submitted in this application are related to **Filed Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).**
- ALL** of the changes submitted in this application are related to **Filed Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).**

##### Medical Device Class

- Class A
- 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

##### Changes to registered medical devices listing information

All changes in Product Owner including changes in Product Owner Name and Address

**Update Form**

**Close**

## Scenario 2: Selection of Multiple Risk Class

Proceed back to Main Page to select affected listings, upload supporting documents and submit application. *[Continue from Step 7 above in Slide 14]*

### 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.

S/No.	Device Name	Document Name	Description	Size (KB)	Uploaded Date
-------	-------------	---------------	-------------	-----------	---------------

Click [Attach/Remove Document](#)

### 5. REMARKS

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

Save Draft

Confirm

Close

# Application Draft Stage Amendments: Changes to FSCA/ AE and Risk Class Categories

## 5 (a) (v). Original Selection of FSCA/AE, Risk class and Type(s) of Changes

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

### APPLICATION FORM

- |                                     |                               |                            |  |
|-------------------------------------|-------------------------------|----------------------------|--|
| 1. Applicant Info                   | <b>2. Change Notification</b> | 3. Affected Device Listing | <a href="#">Please refer to the Guidelines on the...</a> |
| 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 **Filed Safety Corrective Action (FSCA)** and/or **Reportable Adverse Events (AE)**.
- SOME** of the changes submitted in this application are related to **Filed Safety Corrective Action (FSCA)** and/or **Reportable Adverse Events (AE)**.
- ALL** of the changes submitted in this application are related to **Filed Safety Corrective Action (FSCA)** and/or **Reportable Adverse Events (AE)**.

#### Medical Device Class

- Class A
- 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

#### Changes in Design or Specifications of a registered medical device

All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device

*Other Changes*

Update Form

Close

## 5 (a) (i). Original selection: No FSCA/ AEs, Risk Class C

### Declaration if there are any changes due to FSCA or AE

- NONE** of the changes submitted in this **Field Safety Corrective Action (FS)**
- SOME** of the changes submitted in this **Field Safety Corrective Action (FS)**
- ALL** of the changes submitted in this a **Field Safety Corrective Action (FS)**

### Medical Device Class

- Class A
- Class B
- Class C
- Class D

### Message from webpage



The system has detected a FSCA declaration and/or risk class section change, please take note that all prior selection on list of changes will be reset if it is found not common.

OK

Cancel



## 5 (a) (v). New selection: No FSCA/ AEs, Risk Class A, B, C & D

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

### Medical Device Class

- Class A
- Class B
- Class C
- Class D

## 5 (a) (vi). Select correct FSCA/ AE category and Risk Class, and update Type of Change

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

### APPLICATION FORM

- |                                     |                               |                            |  |
|-------------------------------------|-------------------------------|----------------------------|--|
| 1. Applicant Info                   | <b>2. Change Notification</b> | 3. Affected Device Listing | <a href="#">Please refer to the Guidelines on the...</a> |
| 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 Reportable Adverse Events (AE).**
- SOME** of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).**
- ALL** of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA) and/or Reportable Adverse Events (AE).**

#### Medical Device Class

- Class A
- Class B
- Class C
- Class D

1. Click here first

2. Then click Add/ Update

FSCA / Medical Device Class options are updated. Please click [here](#) to reload the updated Type of Changes.

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

### Selected Type of Change(s) for Change Notification

#### Changes in Design or Specifications of a registered medical device

All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device

*Other Changes*

Update Form

Close

## Draft Stage Amendments: Changes to FSCA/ AE and Risk Class

**5 (a) (vii).** System will revise and display types of changes relevant to new *FSCA/ AE* and *Risk Class* selected. Prior selected changes types will be deselected if irrelevant.

**5 (a) (iii).** Original selection: **No FSCA/ AEs, Risk Class C** -Type of Changes applicable for Single Risk Class is displayed

- Change in Manufacturing Facility, Process and Quality Management System
- 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
  - Addition of new medical devices to a FAMILY listing
    - Changes only involves the addition of new devices of the same design, within the existing range of sizes already registered
    - involves addition of a new device with design change that does not affect the safety, quality or efficacy of the medical device (e.g. changes that improve device ergonomics, aesthetic modification of the device)
    - Other Changes
  - Addition of new medical devices to a SYSTEM/ GROUP listing
    - Changes only involves an addition of Class A Exempted medical device accessories that complement the registered medical device as a closed system
    - Other Changes

 **5 (a) (vii).** New selection: **No FSCA/ AEs, Risk Class A, B, C & D** – Type of Changes applicable for Multiple Risk Class is displayed

- Change in Manufacturing Facility, Process and Quality Management System
- Changes to registered medical devices listing information
  - Addition of new medical devices to a device listing
    - Changes only involves an addition of non-sterile Class A medical device accessories that complement the registered medical device as a closed system
  - All changes in Product Owner including changes in Product Owner Name and Address

## 5 (a) (viii). Select relevant changes and click Update Form

- Change in Manufacturing Facility, Process and Quality Management System
- Changes to registered medical devices listing information
  - Addition of new medical devices to a device listing
    - Changes only involves an addition of non-sterile Class A medical device accessories that complement the registered medical device as a closed system
  - All changes in Product Owner including changes in Product Owner Name and Address

**Update Form**

**Close**

5 (a) (ix). System will return to *Change Notification* page. Verify change type selected is correct, and click Update Form.

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

**APPLICATION FORM**

1. Applicant Info	<b>2. Change Notification</b>	3. Affected Device Listing	Please refer to the <a href="#">Guidelines on the...</a>
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 **Reportable Adverse Events (AE)**.
- SOME** of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA)** and/or **Reportable Adverse Events (AE)**.
- ALL** of the changes submitted in this application are related to **Field Safety Corrective Action (FSCA)** and/or **Reportable Adverse Events (AE)**.

**Medical Device Class**

- Class A
- 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**

**Changes to registered medical devices listing information**

All changes in Product Owner including changes in Product Owner Name and Address

Proceed back to Main Page to select affected listings, upload supporting documents and submit application. *[Continue from Step 7 above in slide 14]*

### 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.

S/No.	Device Name	Document Name	Description	Size (KB)	Uploaded Date
-------	-------------	---------------	-------------	-----------	---------------

Click [Attach/Remove Document](#)

### 5. REMARKS

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

Save Draft

Confirm

Close

# Notification Applications: Status Display



## “Notification” Status on MEDICS

1. “Pending”: Application is in **progress**
2. “Completed”: Application is **closed**

Total 1-10 of 147 record(s)		Page 1 of 15		Go		[ first ]	[ previous ]	[ next ]	[ last ]
S/No.	Transaction No.	Job Ref. No.	App. Type	Dossier No.	Job Type	Last Updated Date	Submitted Date	App. Status	
1.	<a href="#">TMD14500528C</a>		NEW		Change Notification for Registered Device	06/01/2014		Draft	
2.	<a href="#">TMD14500577Z</a>	MD14500132W	NEW		Change Notification for Registered Device	23/01/2014	23/01/2014	Completed	
3.	<a href="#">TMD14500571T</a>	MD14500129T	NEW		Change Notification for Registered Device	22/01/2014	22/01/2014	Pending	

**Note:** What if my “Completed” Notification application contains errors?

- Submit new Notification application and include an explanation in “Remarks” section.

***E.g. Please ignore earlier submitted Notification application MD12345678A due to <<summarise error in last submission>>. This CN application will replace application MD12345678A.***

# Removal of Pending Draft CN Applications from MEDICS System

## Important:

All pending draft Change Notification applications must be submitted latest 30 March 2014.

- Any remaining drafts will be removed as a result of implementation of new system on 1 April 2014.

# Thank You

Email: [hsa\\_md\\_info@hsa.gov.sg](mailto:hsa_md_info@hsa.gov.sg)

