

Quick Guide to Change Notification for Registered Medical Devices

The Singapore Health Product Access and Regulatory E-System (SHARE) supports the regulation and management of Medical Devices (SHARE-MD). Applicants can apply for the registration of medical devices with the Authority to obtain marketing clearance for its import and supply in Singapore.

This application process will take approximately 30 minutes.

The time taken varies depending on the number and sizes of the file attachments. Each upload has a maximum size limit of 5GB. If applicant have multiple files that exceed this limit when compressed, the applicant can upload it as individual files instead of a single zipped file. Each individual file upload maintains the 5GB size limit. This flexibility allows submission of large documentation sets while staying within the system's parameters. SHARE accepts the following file formats:

- PDF files (.pdf)
- Microsoft Office files (.docx, .pptx, .xlsx)
- Image files (.bmp, .gif, .jpeg, .jpg, .png, .tif, .tiff)
- Video files (.avi, .mpeg, .mpg)
- OpenOffice files (.ods)
- Other formats (.csv, .rtf, .txt)

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.)

Note: All devices mentioned in this guide are purely for illustrative purposes. Please input the appropriate information relevant to your actual device when submitting your application.

REFERENCES

The information in the following guidance document is useful for the application:

1. GN-21 Guidance on Change Notification for Registered Medical Devices

INSTRUCTIONS

1. Logging into SHARE

Upon login to [HSA SHARE - Login](#), applicants can select Medical Devices (MD) to proceed with the application.

Welcome to SHARE

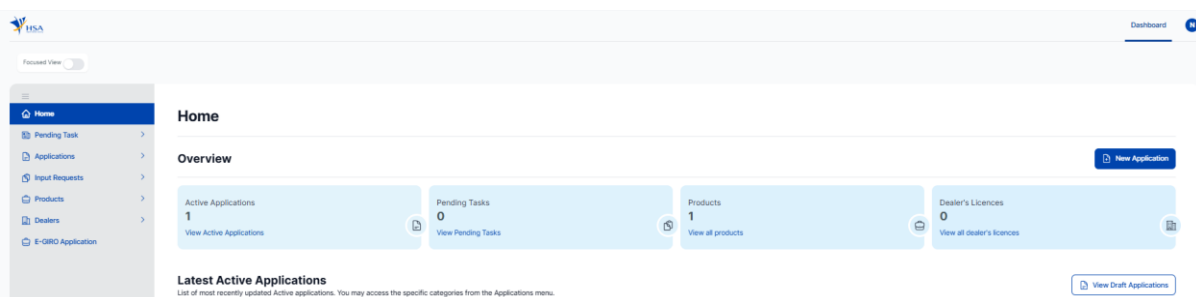
Please select a product type

**Cell, Tissue or Gene
Therapy Products
(CTGTP)**

Medical Devices (MD)

2. Creating a new Product Registration (Change Notification) application

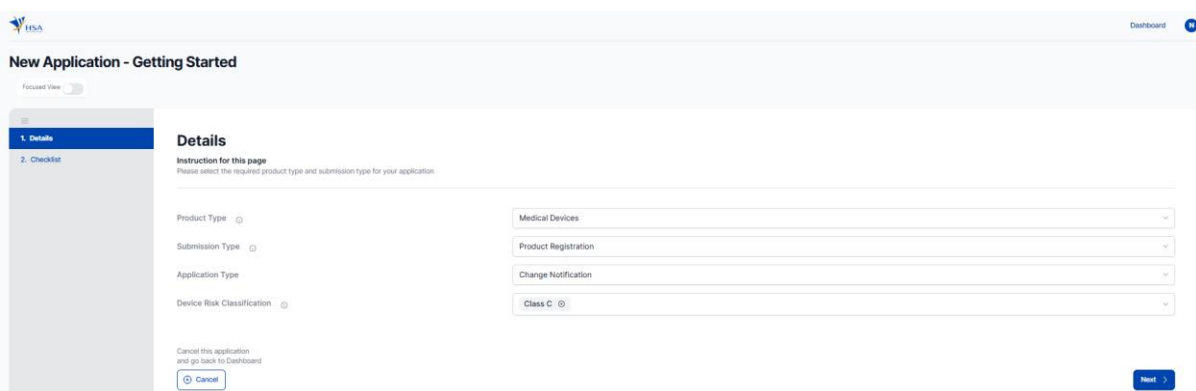
Under the Home tab, applicants would be able to create a new application by clicking on the 'New Application' button.



The screenshot shows the 'Home' dashboard of the SHARE system. On the left is a sidebar menu with options: Home, Pending Task, Applications, Input Requests, Products, Dealers, and E-QRIO Application. The main content area is titled 'Home' and includes an 'Overview' section with four cards: 'Active Applications' (1), 'Pending Tasks' (0), 'Products' (1), and 'Dealer's Licences' (0). Each card has a 'View' button. A 'New Application' button is located in the top right of the Overview section. Below the Overview section is a 'Latest Active Applications' section with a list of applications and a 'View Draft Applications' button.


Under Details page, applicants can select

- 'Product Registration' from the 'Submission Type' dropdown list.
- 'Change Notification' from the 'Application Type' dropdown list.
- Device risk class(es) from the 'Device Risk Classification' dropdown list.



The screenshot shows the 'New Application - Getting Started' page. It has a sidebar with '1. Details' and '2. Checklist'. The main content area is titled 'Details' and includes an instruction: 'Please select the required product type and submission type for your application.' Below this are four dropdown menus: 'Product Type' (Medical Devices), 'Submission Type' (Product Registration), 'Application Type' (Change Notification), and 'Device Risk Classification' (Class C). At the bottom left, there is a 'Cancel' button and a 'Next' button.

Under Checklist page, applicants can review their selections and Instructions before proceeding to Create Application.


Dashboard

New Application - Getting Started

☐ Focused View


1. Details

2. Checklist

Checklist

Instruction for this page
Review your selections and prepare for your application.

Product Type	Medical Devices
Submission Type	Product Registration
Application Type	Change Notification
Device Risk Classification	Class C



Based on your selection, your application process will take approximately 30 minutes.
Please review the instructions to ensure a timely completion of the process.

You are about to start a Change Notification application. 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 product registration of a medical device, and/or if there are changes or proposed changes that may affect the safety, quality or efficacy of a registered medical device.

Submission Instructions

- In general, any changes to the documents submitted in the previously approved 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 application for the purpose of evaluation of the medical device(s) for marketing clearance.
- Please refer to GN-21 Guidance on Change Notification for Registered Medical Devices for the supporting documentary requirements for each type of change.

For more information, please visit our [website](#).

Change Product or Submission Type

You will not be able to change your Product or Submission type after this page.

3. Selecting Change Notification Details

Applicants will need to select the applicable change type(s) for the application.

The example below shows the change types for the update of Quality Management System validity date (Type 1E), editorial changes in the indications for use (Type 5Aii) and addition of new medical devices to a device listing (Type 6Ai) selected.

Dashboard

Draft Application No. (Draft)
Last saved at 24 June 2025 10:26 AM

Application For Product Registration (Change Notification)

Focused View

- [Change Notification Details](#)
- [Change Notification Information](#)
- [Supporting Documents](#)
- [Company Details](#)
- [Application Details](#)
- [Sites](#)
- [Product Information](#)
- [Change Management](#)
- [Payment Details](#)
- [Review](#)
- [Declaration](#)

Change Notification Details

- ☒ 1. Change in Manufacturing Facility, Process and Quality Management System
 - ☐ 1A. Addition, deletion, or shift/change of manufacturing and/or sterilisation facilities with no change to specifications of a registered medical device and/or sterilisation process
 - ☐ 1B. Changes in the manufacturing process to Additive Manufacturing (3D-printing), or to refurbish a registered device
 - ☐ 1C. Changes to manufacturing site and/or processes that result in a change in specifications of a registered medical device
 - ☐ 1D. Changes to sterilisation method and related processes
 - ☒ 1E. Changes to Quality Management System (QMS) certificate validity date for manufacturing and sterilisation facilities
- ☐ 2. Changes in Design or Specifications of a registered medical device
- ☐ 3. Changes to materials in a General Medical Device
- ☐ 4. Changes to materials in an In-Vitro Diagnostic (IVD) Medical Device
- ☒ 5. Changes to labelling of medical device
 - ☒ 5A. All changes to the labelling of medical devices that involve addition and/or revision of the approved indications for use
 - ☐ 5Ai. All changes to the labelling of medical devices that involve addition and/or revision of the approved indications for use
 - ☒ 5Aii. Changes only involves editorial changes / rephrasing / reduction of indications for use
 - ☐ 5B. All changes to the labelling of medical devices that involves addition, removal and/or revision of warnings, precautions, contraindications and/or adverse events
 - ☐ 5C. Labelling changes that modify the approved method of use
 - ☐ 5D. Labelling changes that involves rephrasing of existing information in instructions for use
 - ☐ 5E. Other labelling changes
 - ☒ 6. Changes to registered medical devices listing information
 - ☒ 6A. Addition of new medical devices to a device listing
 - ☒ 6Ai. Addition of new medical devices to a device listing
 - ☐ 6Aii. Unless changes only involves the addition of new devices of the same design, that only involves:
 - New models within the existing range of sizes already registered
 - An increase or reduction in the number of identical devices in a pack of a registered device without breach of individual primary packaging
 - An increase or reduction of volume that does not affect specifications of the device (e.g. shelf life, stability, performance, and sterility)
 - Addition of models due to repackaging of existing models within the same SMDR listing in different combinations without breach of individual primary packaging
 - ☐ 6Aiii. Unless change involves an addition of new device or software identifier with no change to the performance characteristics or specifications of the device
 - ☐ 6B. All deletion of models from device listing
 - ☐ 6C. All changes to product name AND/OR product identifier
 - ☐ 6D. All changes in product owner including changes in product owner name and address
 - ☐ 6E. Submission of Unique Device Identifier (UDI) Data Elements for Registered Devices
This change type is applicable only for updating UDI data elements of registered medical devices. It shall not be used for amending information resulting from new device modifications or inclusion of information that has not been approved, which require a separate change notification, change type or application.
 - ☐ 7. Changes to Change Management Program
 - ☐ 8. Other Changes - Applicable only upon receipt of email from HSA, authorising submission under this category

Overall Change Category	
	Technical Change Turn Around Time Estimate Fees
	75 Working days \$ 1890

[Cancel](#)
[Change Notification Information](#)

4. Selecting Change Notification Information

Applicants will need to select the product(s) to be included in the CN application; and check on the appropriate checkbox for the FSCA information.

FDA
Dashboard

Application For Product Registration (Change Notification)

Draft Application No. (Draft)
Last saved at 24 June 2025 10:21 AM

Focused View

- Change Notification Details
- Change Notification Information**
- Supporting Documents
- Company Details
- Application Details
- Sites
- Product Information
- Change Management
- Payment Details
- Review
- Declaration

Change Notification Information

Select Devices to Amend

Approved Product Number	<input type="text"/>
Product Owner	<input type="text"/>
Device Name	<input type="text"/>
Device Risk Classification	<div>Select an option ▼</div>

Approved Product Number	Device Name	Device Risk Classification	Product Owner	Intended Use	Retention Due Date
<input checked="" type="checkbox"/> MDPR25062480001	Silicone Foley Catheter	Class C	43 Manufacturing	It can be used for clinical routine catheterization or drainage, and can be used with the monitor to continuously monitor the bladder temperature of patients.	24-Jun-2026

FSCA Information

Changes to Medical Devices due to Adverse Events (AEs) and/or Field Safety Corrective Actions (FSCAs):

Please declare if there are any changes to the medical device(s) due to FSCA(s) or AE(s):

- ☒ 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).

☒ The added model(s) is/are not a subject of an open reportable adverse event and/or an on-going field safety corrective action, and does not contain corrections that are the subject of an ongoing field safety corrective action and/or local adverse event.

< Back
Supporting Documents >

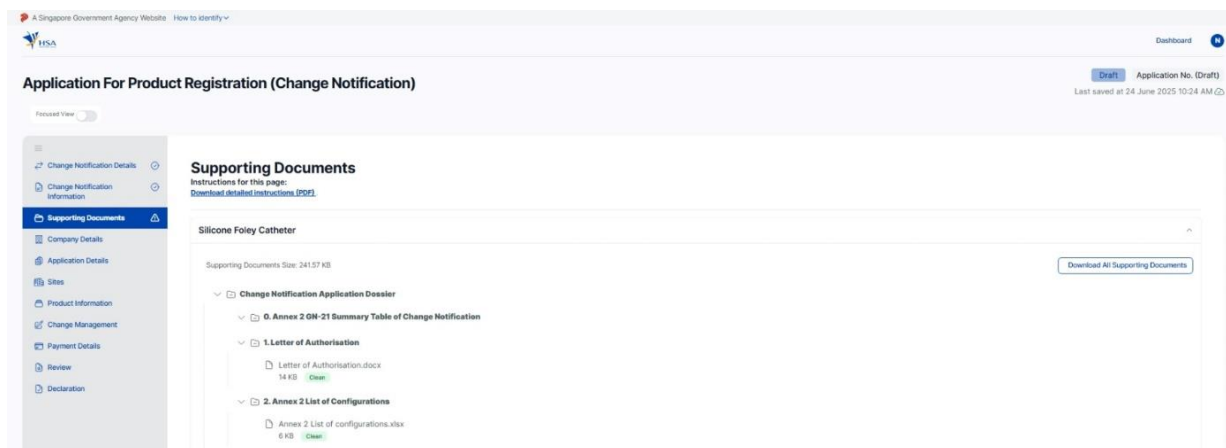
5. Preparing supporting documents

To upload supporting documents, applicants can

- Applicants can download the empty Supporting Documents Template zip file
- Unzip the downloaded zip file
- Add in supporting documents into the folder
- Compress (zip) the completed folder to the standard zip format – the extension of the compressed file should be '.zip'. Please do not compress the folder to other zip formats, e.g., '.7zip', '.rar', etc
- For more instructions, please refer to [Download detailed instructions \(PDF\)](#).

6. Uploading files into Supporting Documents

- Click on the Upload.zip button

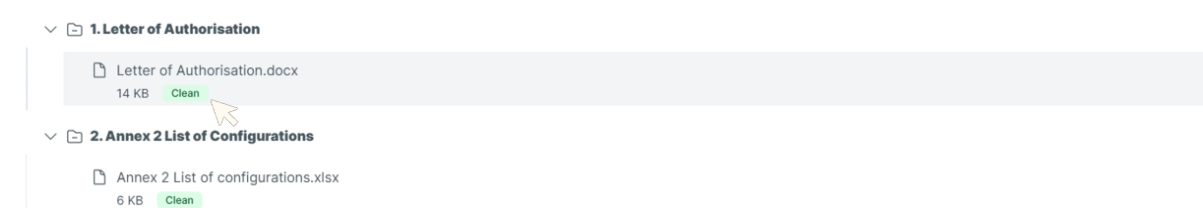


- Click on the Yes button when confirmation message appears asking to replace the existing file structure.

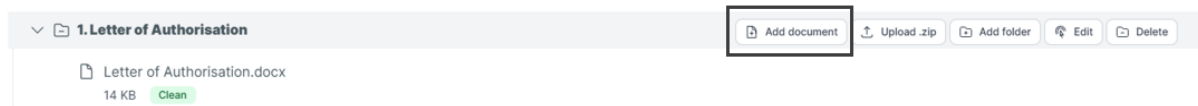
 The entire list of files in this structure will be replaced. Confirm this action?



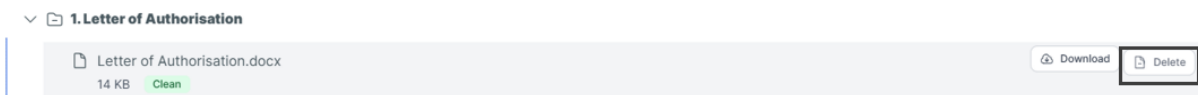
- The system will start processing the files as indicated by the "Processing" tag. You may continue with the rest of the application while the file(s) is/are processing. After the file(s) is/are processed, the file(s) will be tagged with the "Clean" tag.



- To upload additional files into the existing folder structure. Hover the mouse over any folder and click on Add Document.

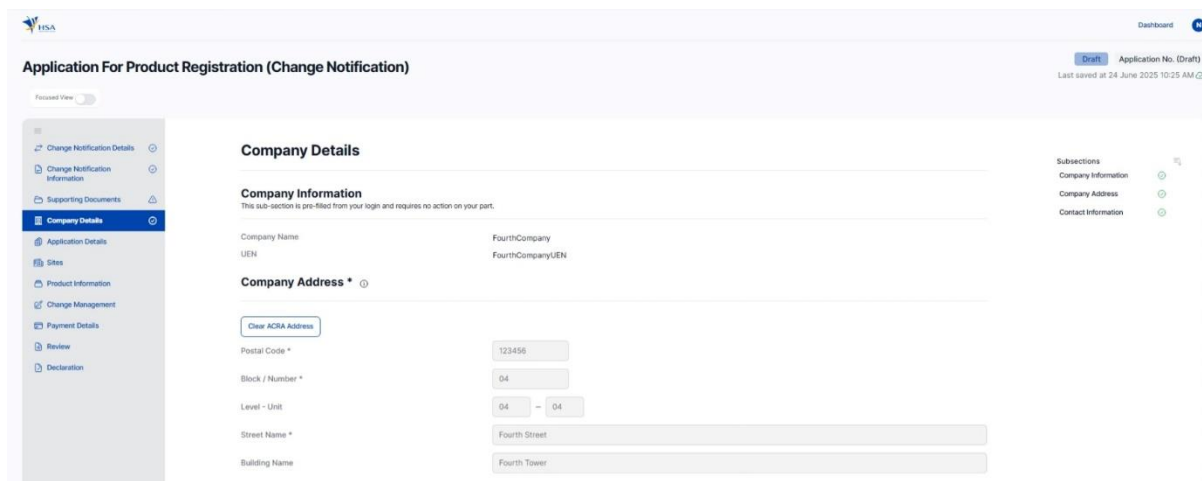


- e) To delete a file in the existing folder structure. Hover the mouse over the file and click on the Delete button

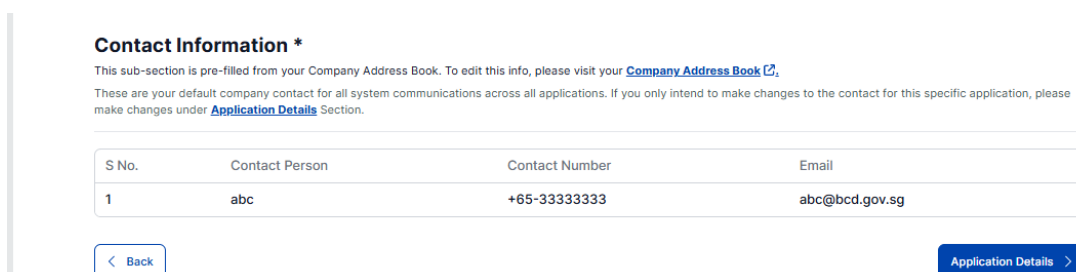


7. Company and application details

Company details is auto populated based on ACRA information. Applicants may enter the company address if needed.



Company Contact Information refers to the company's default contact for all applications within the company. If applicant intend to make changes to the contact for this specific application, please include additional contact details in the 'Notification Emails' field under the Application Details page.



Contact Information *

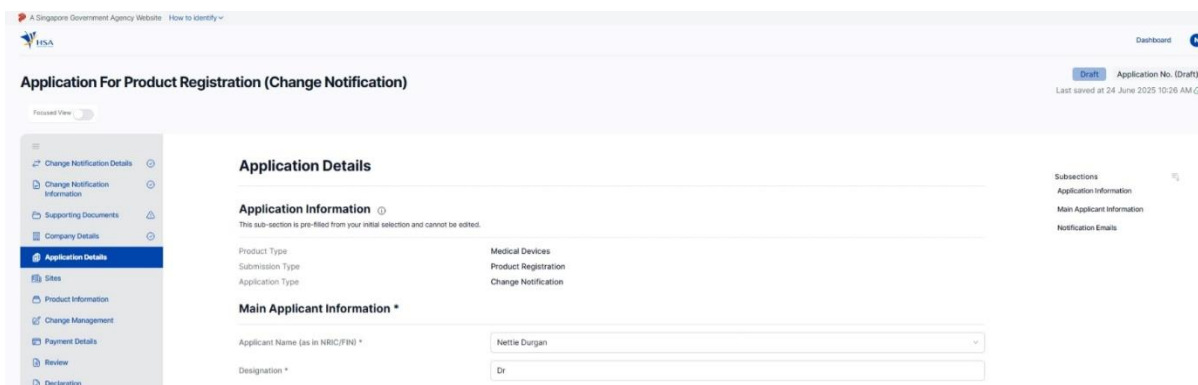
This sub-section is pre-filled from your Company Address Book. To edit this info, please visit your [Company Address Book](#).

These are your default company contact for all system communications across all applications. If you only intend to make changes to the contact for this specific application, please make changes under [Application Details](#) Section.

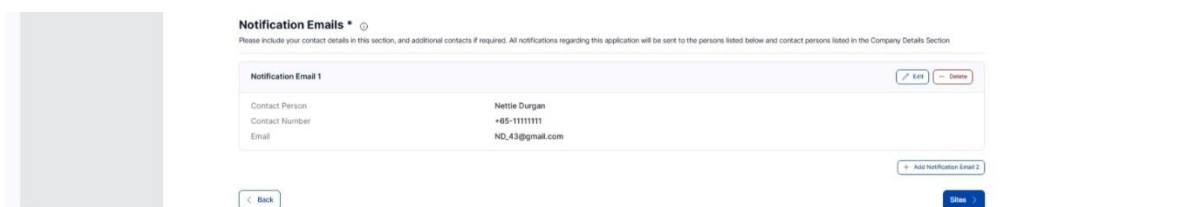
S No.	Contact Person	Contact Number	Email
1	abc	+65-33333333	abc@bcd.gov.sg

[Back](#) [Application Details](#)

Applicant's name is auto populated based on the name retrieved from Corppass during login. The designation field is to be filled in by the applicant, reflecting their current position within the company.



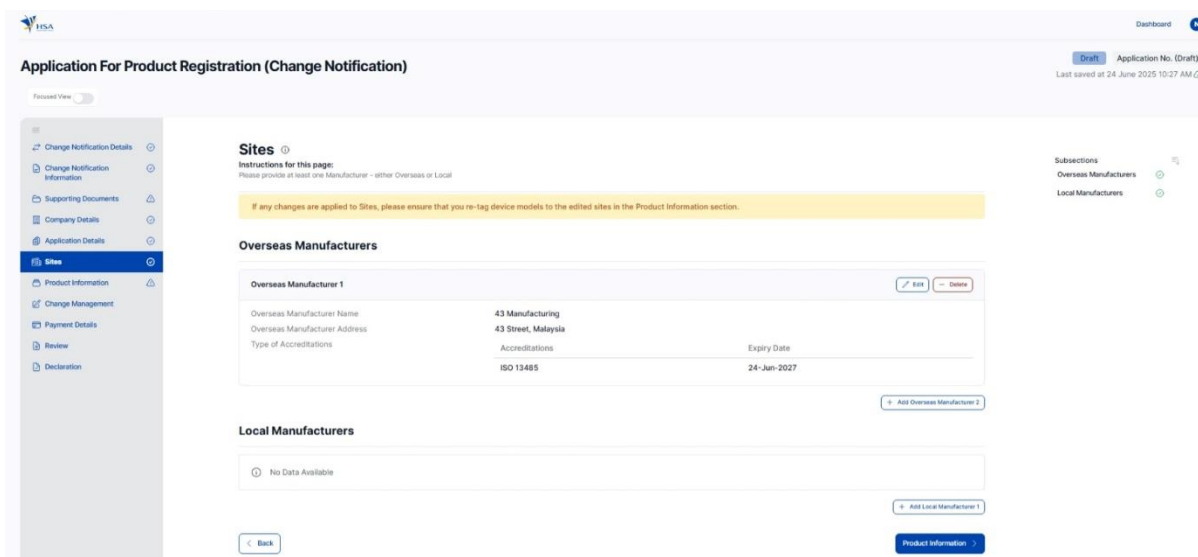
The contact details entered under Notification Emails are specific to the application. Notification Emails can be added to receive notifications exclusively for updates related to the application.



8. Adding or editing manufacturing sites

Applicants are to provide additional manufacturer and/or sterilisation site details for the selected product(s) by clicking on 'Add Overseas Manufacturer' button.

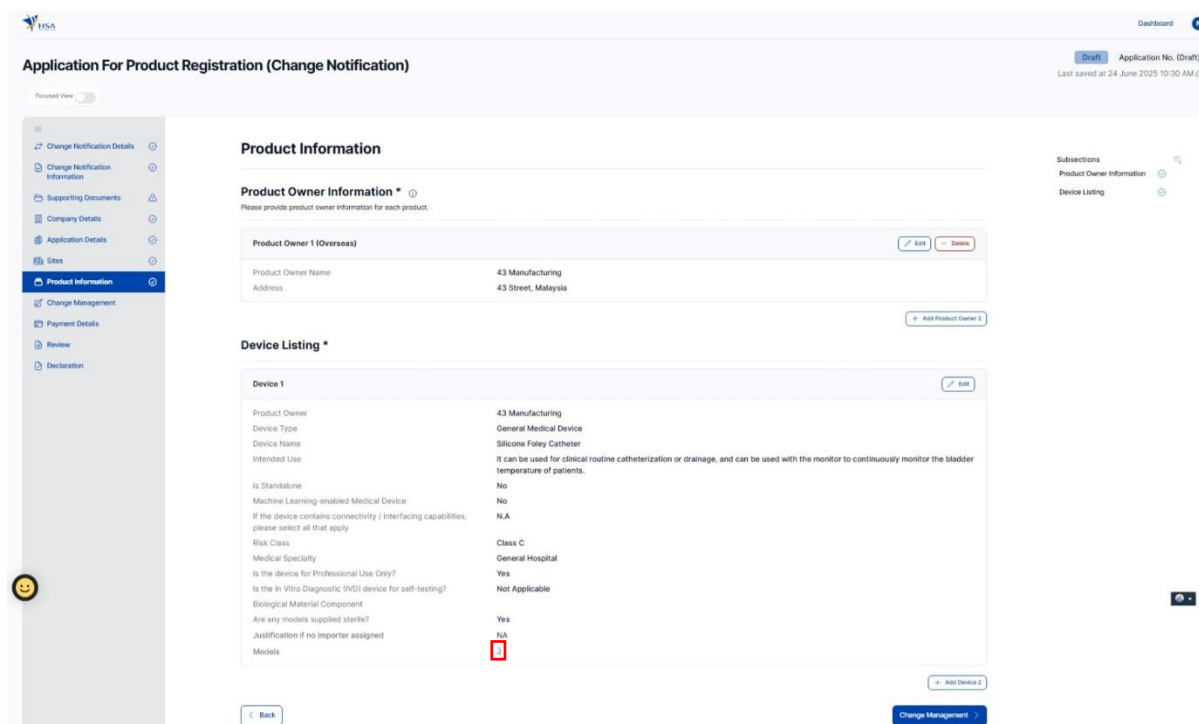
Applicants are to update existing manufacturer and/or sterilisation site details (e.g., ISO 13485 certificate expiry date) by clicking on 'Edit' button.



9. Editing product owner and device listing information

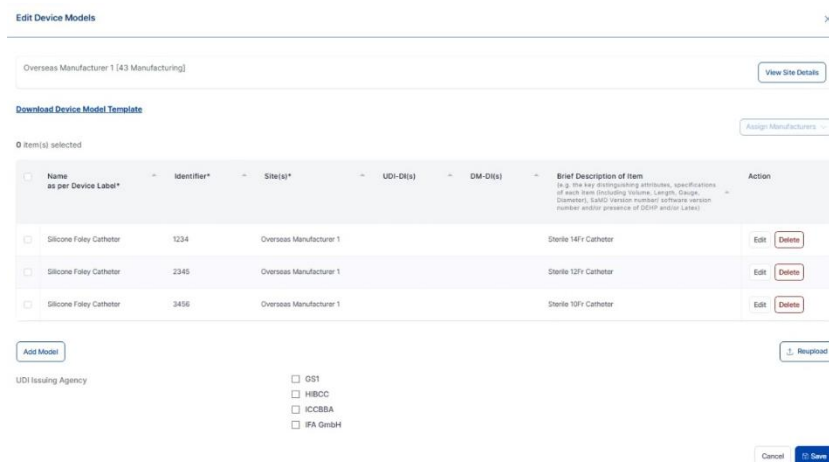
Applicant can edit product owner and device listing information by clicking 'Edit' button of the respective sections.

If there are changes to the site information, the updated site(s) need to be assigned to the model. This can be updated in the individual model section.



10. Adding or editing models in device listing(s)

To add or edit model information under a device listing, click on the Models field (in red above).



In the “Edit Device Models” section, applicants can add new models by clicking “Add Model” button and/or amend the following information of existing models:

- Name as per device listing
- Identifier
- UDI-DI & DM-DI
- Brief Description of Item
- Site(s)

Add Model

Name as per Device Label *

Identifier *

UDI-DI(s)

UDI-PI(s)

Brief Description of Item

Sites *

11. Change Management

Change Management Program is a voluntary program to facilitate timely implementation of software changes for Software as a Medical Device (SaMD).

For more information on the Change Management Program, please refer to our GN-37 Guidance on Change Management Program, available at: <https://www.hsa.gov.sg/medical-devices/guidance-documents>

Application For Product Registration (Change Notification)

Focus View

Change Management

Change Management Program

I would like to opt-in for the Change Management Program ☐ No

Pre-specified Changes

Subsections: Change Management Program, Pre-specified Changes

12. Choosing Payment Method

Applicants can select the client code from the dropdown list.

Application For Product Registration (Change Notification)

Focus View

Payment Details

Billing Information *

Client Code *

Postal Code

Block / House No.

Level / Unit

Street Name

Building Name

Subsections: Billing Information, Payment Information

Applicants may choose the preferred payment mode, GIRO or Online payment.

Companies with GIRO payment arrangement with HSA may choose online payment for urgent applications.

Payment Information *

Preferred Payment Mode *

For GIRO payments, it will typically takes 3 to 5 days to process. If your preferred payment mode is GIRO, please ensure that there are sufficient funds in the account. If this is an urgent application, it is recommended to select Online payment.

 GIRO

 Online

Charge Code	Description	Quantity	Price
MEDCLSC-AF	Appin Fee for Tech CN - Class C Reg MD	1	\$1,330.00
MEDCLSC-NF	Nftrn Fee for Adm/Tech CN-Class C Reg MD	1	\$560.00
Subtotal			\$1,890.00
Tax			\$0.00
Total			\$1,890.00


Payment Instructions

The above fees will be processed by HSA upon successful submission of this application. If your preferred payment mode is GIRO, please ensure that there are sufficient funds in the account.

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[Review >](#)

13. Review Application

Applicants to review the summary of all sections filled.


Dashboard

Application For Product Registration (Change Notification)
Processing
Application No. MDCN250624K0001

[Focused View](#)

- Change Notification Details
- Change Notification Information
- Supporting Documents
- Company Details
- Application Details
- Sites
- Product Information
- Change Management
- Payment Details
- Review**
- Input Requests
- Application Admin

Review

Change Notification Details

- 1. Change in Manufacturing Facility, Process and Quality Management System
 - 1E. Changes to Quality Management System (QMS) certificate validity date for manufacturing and sterilisation facilities
- 5. Changes to labelling of medical device
 - 5A. All changes to the labelling of medical devices that involve addition and/or revision of the approved indications for use
 - 5AL. Changes only involves editorial changes / rephrasing / reduction of indications for use
- 6. Changes to registered medical devices listing information
 - 6A. Addition of new medical devices to a device listing
 - 6AL. Addition of new medical devices to a device listing

Overall Change Category

☐ Turn Around Time
Estimate Fees


Technical Change
75 Working days
\$ 1890

Select Devices to Amend

Approved Product Number	Device Name	Device Risk Classification	Product Owner	Intended Use	Retention Due Date
MDPR250624B0001	Silicone Foley Catheter	Class C	43 Manufacturing	It can be used for clinical routine catheterization or drainage, and can be used with the monitor to continuously monitor the bladder temperature of patients.	24-Jun-2026

14. Declaration

Applicants to acknowledge and confirm the declaration before submitting the application.


Dashboard

Application For Product Registration (Change Notification)
Draft
Application No. (Draft)

[Focused View](#)

- Change Notification Details
- Change Notification Information
- Supporting Documents
- Company Details
- Application Details
- Sites
- Product Information
- Change Management
- Payment Details
- Review
- Declaration**

Declaration

All applicants under the Medicines Act (MA) / Health Products Act (HPA) / Poisons Act (PA) must comply where applicable, with the MA/HPA/PA and their corresponding regulations. This is to ensure that all health products in Singapore meet the required standards.

☒ I declare that the medical device(s) in this Change Notification application conform(s) to the Essential Requirements for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations.

On behalf of the Product Owner and FourthCompany,

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.

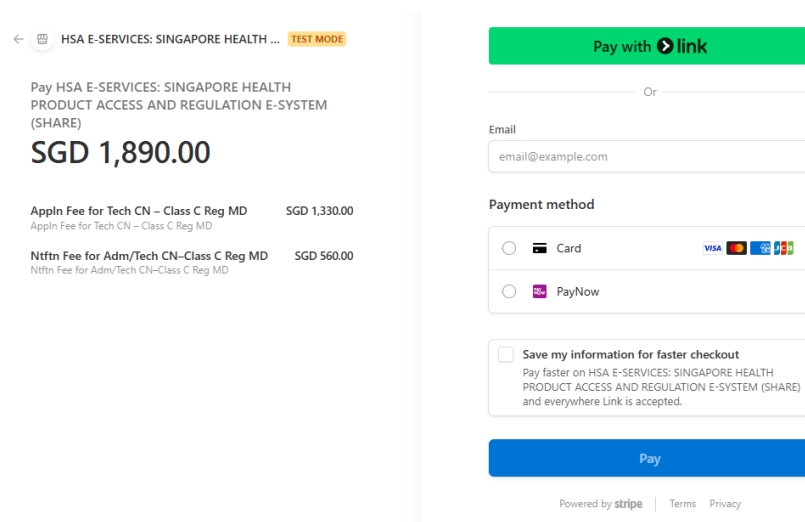
c. I attest that there are no misleading claims made relating to the quality, safety and effectiveness of this device(s).

☒ I acknowledge and confirm the above declarations.

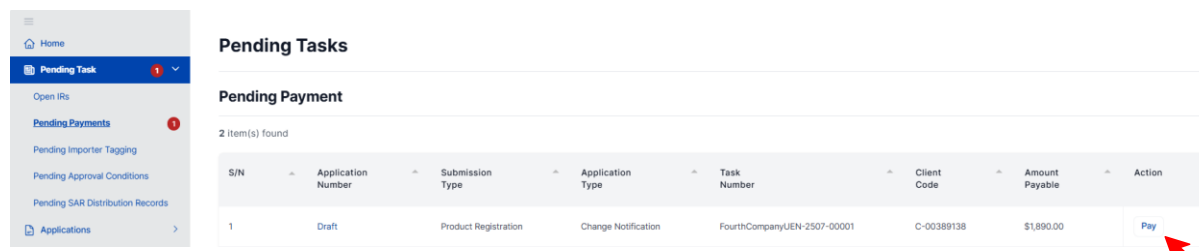
[< Back](#)
[Submit](#)

15. Online Payment

After submitting the application, companies choosing online payment can pay via card or PayNow through the STRIPE payment portal. Once payment is completed, please wait for the system to redirect you back to SHARE automatically.



If you encounter any issues with the online payment, please check the Pending Tasks page to locate and complete any outstanding payments.



S/N	Application Number	Submission Type	Application Type	Task Number	Client Code	Amount Payable	Action
1	Draft	Product Registration	Change Notification	FourthCompanyUEN-2507-00001	C-00389138	\$1,890.00	Pay

16. Accessing and Managing Drafts

Applicants can save the application as draft and complete it at a later time. To access your saved applications, applicants can go to the Dashboard page and select 'View Draft Applications'. Here you can view, edit or delete your drafts. Please note that draft applications will expire 180 days after the last edit date.

Home

Pending Task

Applications

Input Requests

Products

Dealers

E-GIRO Application

Home

Pending Task

Applications

Draft

Active

Closed

Input Requests

Products

Dealers

E-GIRO Application

Dashboard

1

Focused View

Home

Overview

Active Applications

1

View Active Applications

Pending Tasks

0

View Pending Tasks

Products

1

View all products

Dealer's Licences

0

View all dealer's licences

View Draft Applications

Latest Active Applications

List of most recently updated Active applications. You may access the specific categories from the Applications menu.

Draft Applications

Draft

Expires 06-Jan-2026

Resume

Delete

Application Type

Change Notification

Product Name

-

Submission Type

Product Registration

Status

Draft

Last Edited Date

10/07/2025 03:17 PM

Draft

Expires 06-Jan-2026

Resume

Delete

Application Type

Change Notification

Product Name

-

Submission Type

Product Registration

Status

Draft

Last Edited Date

10/07/2025 02:23 PM

END OF DOCUMENT