

## Quick Guide to Application for Product Registration of a Class B/C/D Medical Device

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

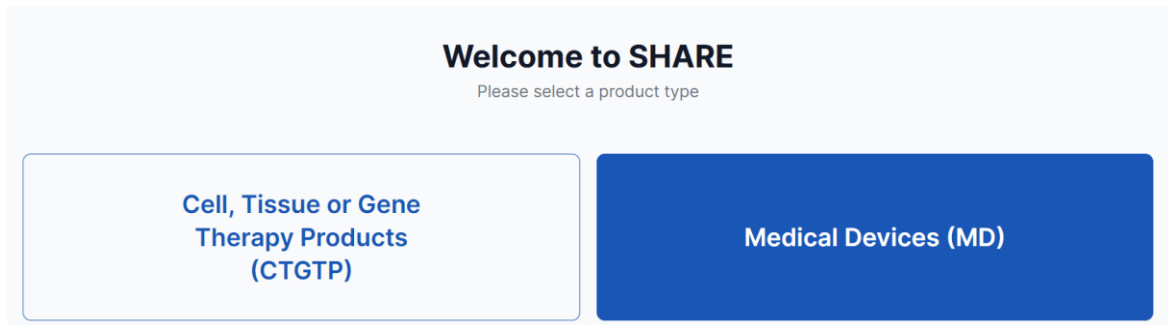
The information in the following guidance documents is useful for the application:

1. **GN-13** Guidance on the Risk Classification of General Medical Devices
2. **GN-14** Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices
3. **GN-15** Guidance on Medical Device Product Registration
4. **GN-17** Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
5. **E-Submission Guide** for General Medical Devices for ASEAN CSDT based Submissions
6. **GN-18** Guidance on Preparation of a Product Registration Submission for IVD MD using the ASEAN CSDT
7. **E-Submission Guide** for IVD MD for ASEAN CSDT based Submissions

## INSTRUCTIONS

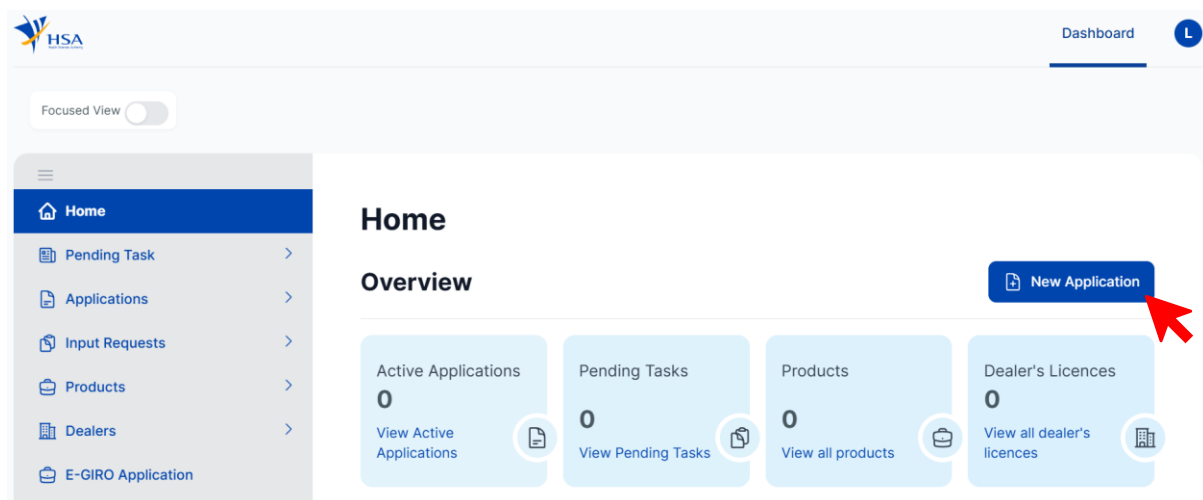
### 1. Logging into SHARE

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




### 2. Creating a new Product Registration application

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



Under Details page, applicants can select

- 'Product Registration' from the 'Submission Type' dropdown list.
- 'New' from the 'Application Type' dropdown list.
- 'General Medical Device' or 'In-Vitro Diagnostic Device' from the 'Device Type' dropdown list.
- 'ASEAN CSDT' from the 'Dossier Format' dropdown list.



Dashboard

## New Application - Getting Started

Focused View

1. Details

2. Checklist

### Details

**Instruction for this page**  
Please select the required product type and submission type for your application.

Product Type

Medical Devices

Submission Type

Product Registration

Application Type

New

Device Type

General Medical Device

Dossier Format


ASEAN CSDT

Cancel this application and go back to Dashboard

Cancel

Next

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

New

Device Type

General Medical Device

Dossier Format

ASEAN CSDT

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 the application for a Product Registration of a Class B/C/D Medical Device to obtain marketing clearance for its import and supply in Singapore.

Please note that only medical device dealers who have been licensed by HSA can engage in the manufacture, import and/or wholesale of medical devices in Singapore. To apply for an Importer's, Wholesaler's and/or Manufacturer's Licence, please submit a Dealer's Licence application.

If your medical device is a Class A Medical Device, please submit a Product Notification application instead of this Product Registration application. Please refer to the following guidance document for more information on medical device risk classification:

- GN-13 Guidance on the Risk Classification of General Medical Devices
- GN-14 Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices

#### Submission Instructions

In this application, you would need to provide the following information:

- Each application is for registration of only one SINGLE medical device, or medical device FAMILY, or medical device SYSTEM or GROUP, or TEST KIT for IVD. Please refer to the following guidance document for more information:
  - GN-12 Guidance on Grouping of Medical Devices for Product Registration
- The softcopy of the supporting documents must be prepared in the ASEAN CSDT format. Please refer to the following guidance documents for more information:
  - GN-15 Guidance on Medical Device Product Registration
  - GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
  - E-Submission Guide for General Medical Devices for ASEAN CSDT based Submissions
  - GN-18 Guidance on Preparation of a Product Registration Submission for IVD MD using the ASEAN CSDT
  - E-Submission Guide for IVD MD for ASEAN CSDT based Submissions

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

View Checklist

Change Product or Submission Type

Back

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

Create Application

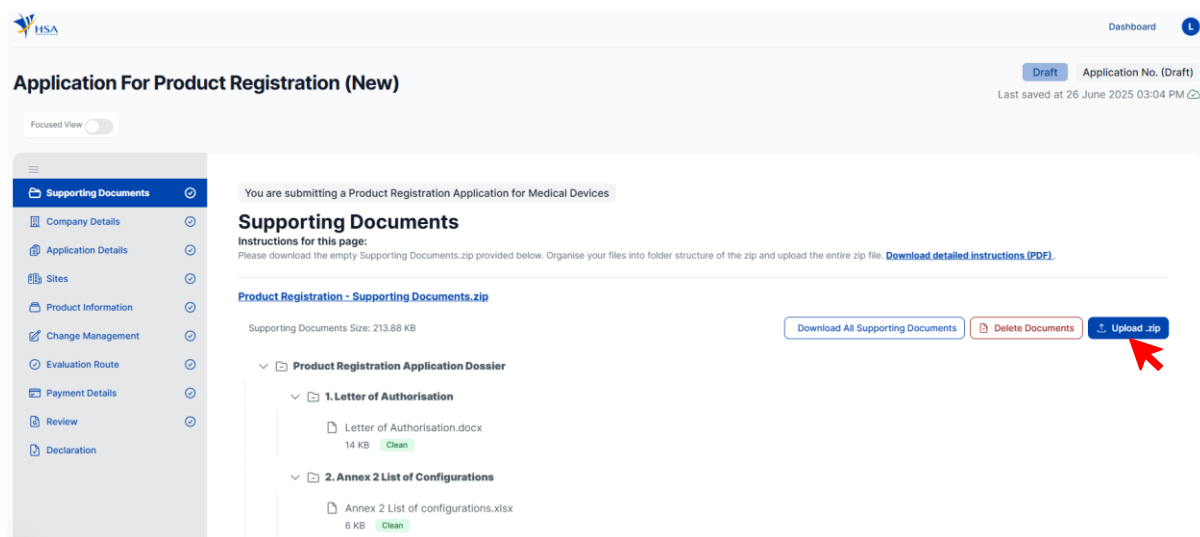
v1.0

### 3. Preparing supporting documents

- 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 \(PDF\)](#).

### 4. Uploading files into Supporting Documents

- Click on the Upload.zip button

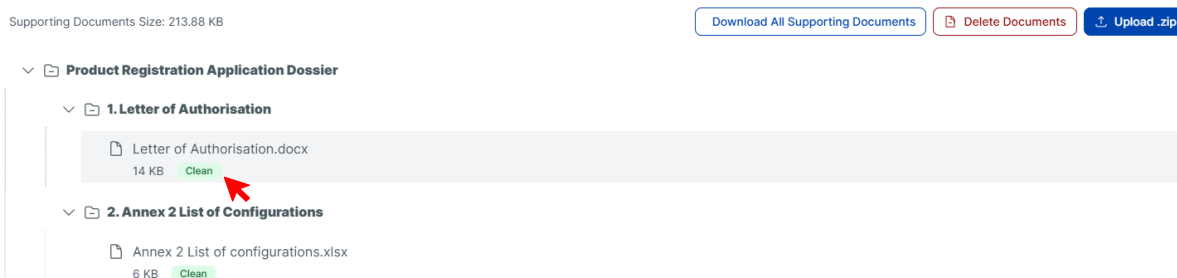


- Click on the Yes button when confirmation message appears asking to replace the existing file structure.

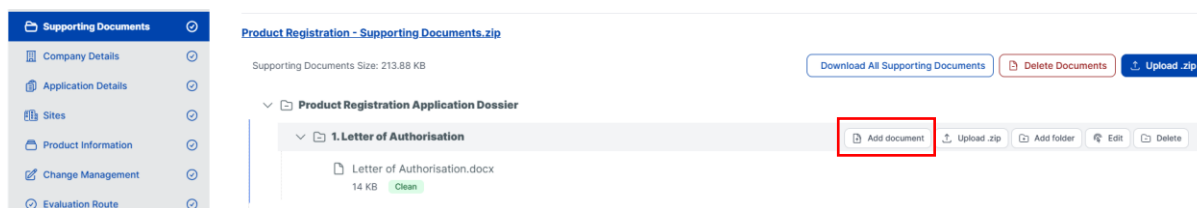
 The entire list of files in this structure will be replaced. Confirm this action?



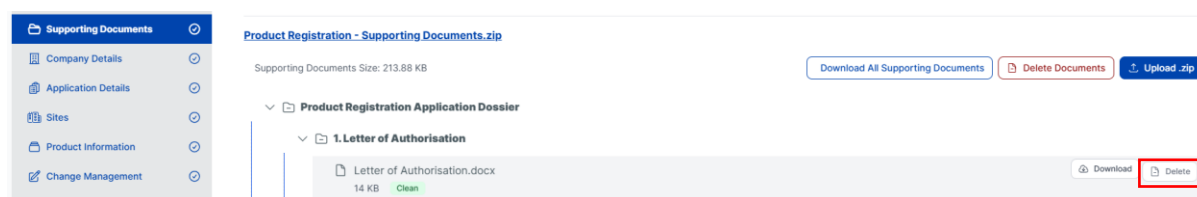
- The system will start processing the files as indicated by the "Processing" tag. You may continue with the rest of the application while the file(s) is/are processing. After the file(s) is/are processed, the file(s) will be tagged with the "Clean" tag.



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

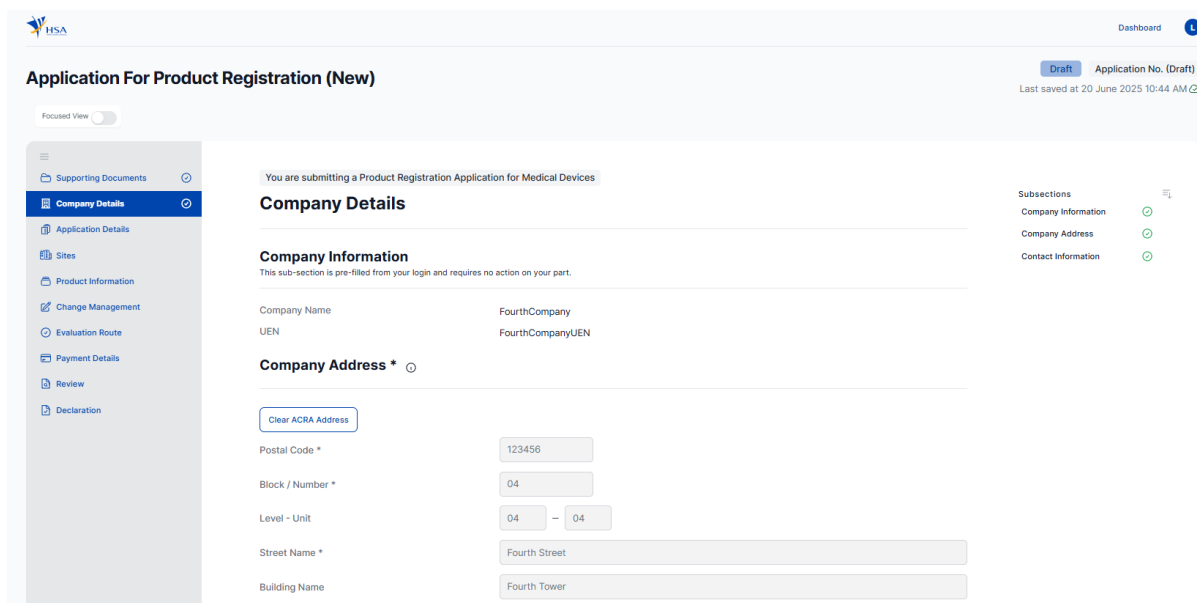


- e) To delete a file in the existing folder structure. Hover the mouse over the file and click on the Delete button.



## 5. Company and application details

Company details are auto-populated based on ACRA information. Applicants may edit 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](#).

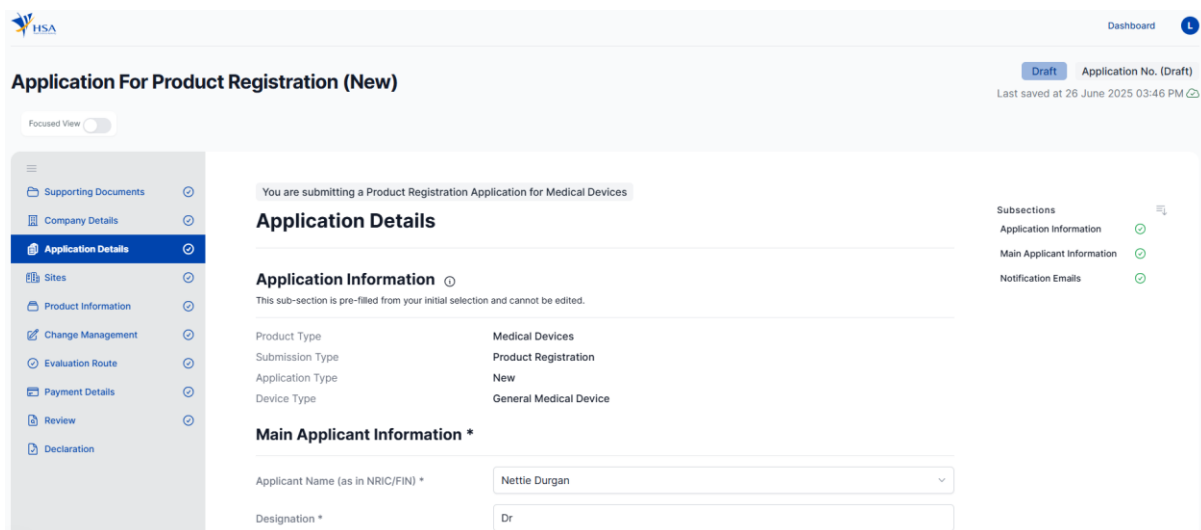
These are your default company contact for all system communications across all applications. If you only intend to make changes to the contact for this specific application, please make changes under [Application Details](#) Section.

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

[< Back](#)

[Application Details >](#)

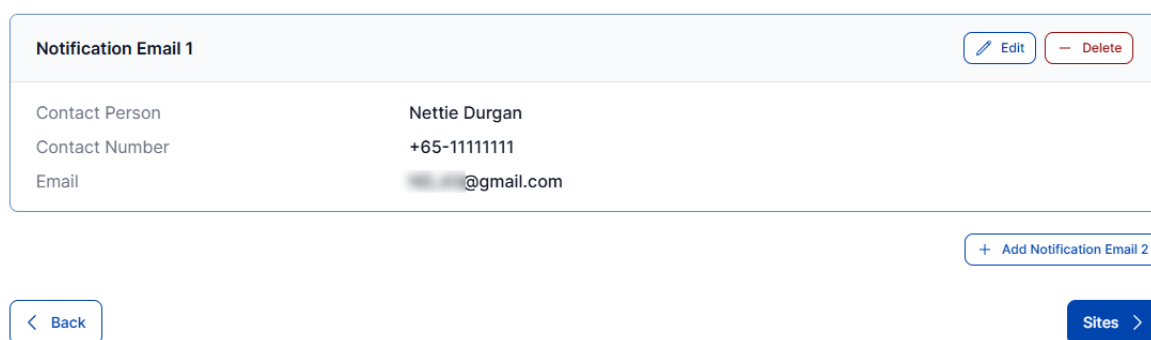
Applicant's name is auto populated based on the name retrieved from Corppass during login. The designation field is to be filled in by the applicant, reflecting their current position within the company.



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.

### Notification Emails \* ?

Please include your contact details in this section, and additional contacts if required. All notifications regarding this application will be sent to the persons listed below and contact persons listed in the Company Details Section

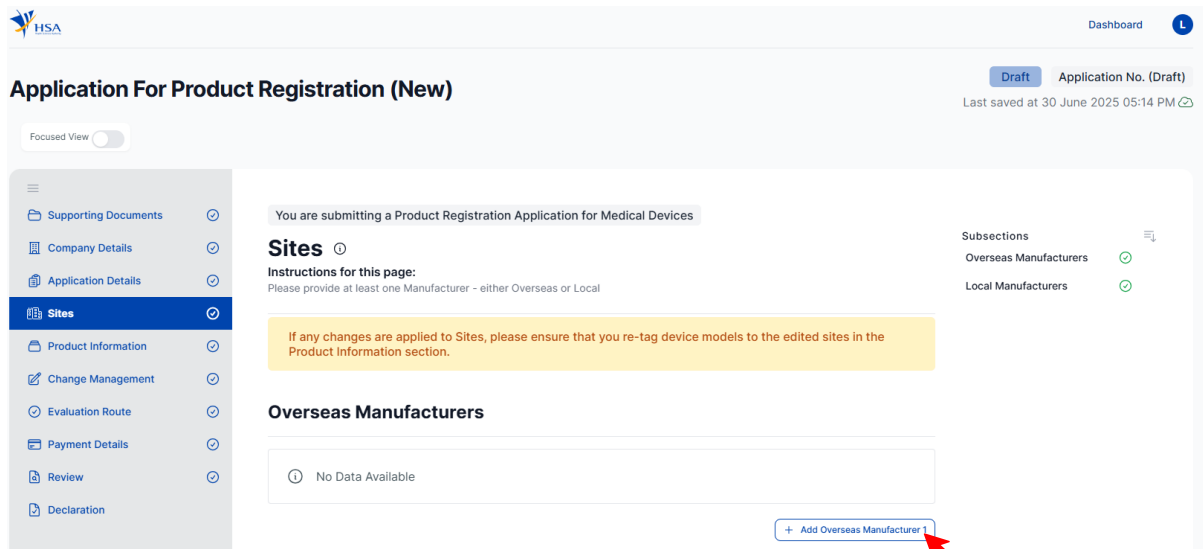


## 6. Adding manufacturing sites

Applicants are to provide at least one Manufacturer, either Overseas or Local, including contract manufacturers and sterilisation sites.

For Overseas Manufacturers, applicants can do the following:

- a) Add overseas manufacturer for the current product(s) by clicking on 'Add Overseas Manufacturer' button.



**Application For Product Registration (New)**

Draft Application No. (Draft)  
Last saved at 30 June 2025 05:14 PM

**Sites**

You are submitting a Product Registration Application for Medical Devices

**Instructions for this page:**  
Please provide at least one Manufacturer - either Overseas or Local

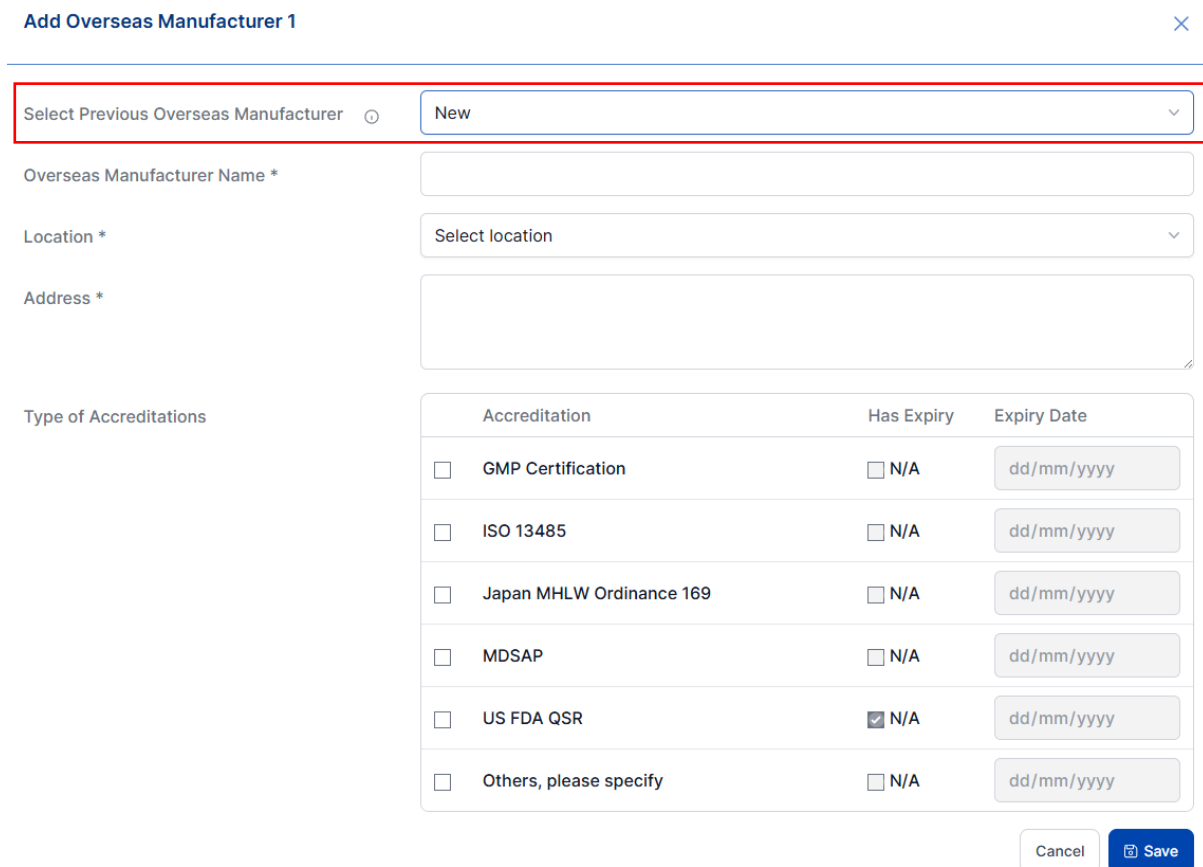
If any changes are applied to Sites, please ensure that you re-tag device models to the edited sites in the Product Information section.

**Overseas Manufacturers**

No Data Available

+ Add Overseas Manufacturer 1

- b) Create new records for Overseas Manufacturer by selecting 'New' under Select Previous Overseas Manufacturer dropdown list.



**Add Overseas Manufacturer 1**

Select Previous Overseas Manufacturer: New

Overseas Manufacturer Name \*

Location \*  
Select location

Address \*

Type of Accreditations

Accreditation	Has Expiry	Expiry Date
<input type="checkbox"/> GMP Certification	<input type="checkbox"/> N/A	dd/mm/yyyy
<input type="checkbox"/> ISO 13485	<input type="checkbox"/> N/A	dd/mm/yyyy
<input type="checkbox"/> Japan MHLW Ordinance 169	<input type="checkbox"/> N/A	dd/mm/yyyy
<input type="checkbox"/> MDSAP	<input type="checkbox"/> N/A	dd/mm/yyyy
<input type="checkbox"/> US FDA QSR	<input checked="" type="checkbox"/> N/A	dd/mm/yyyy
<input type="checkbox"/> Others, please specify	<input type="checkbox"/> N/A	dd/mm/yyyy

Cancel Save

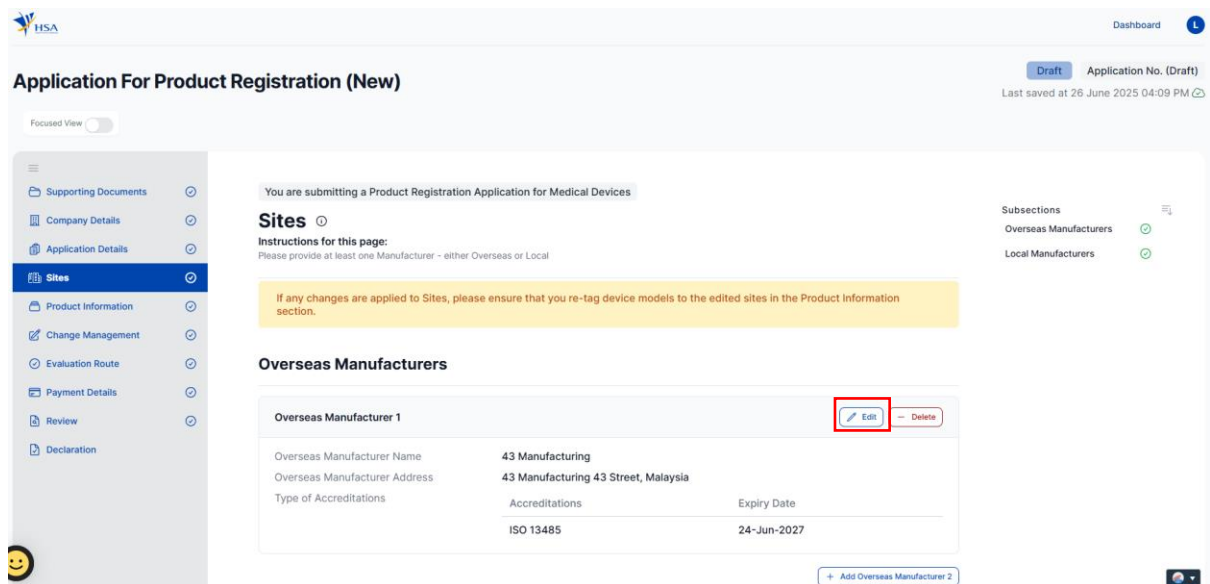
- c) Select existing sites from the Select Previous Overseas Manufacturer dropdown list to auto-populate the existing Overseas Manufacturer information.

## Edit Overseas Manufacturer 1



Select Previous Overseas Manufacturer	43 Manufacturing (43 Street)				
Overseas Manufacturer Name *	43 Manufacturing (43 Street) *				
Location *	Malaysia				
Address *	43 Street				
Type of Accreditations	<table border="1"> <thead> <tr> <th>Accreditations</th> <th>Expiry Date</th> </tr> </thead> <tbody> <tr> <td>ISO 13485</td> <td>14-Oct-2027</td> </tr> </tbody> </table>	Accreditations	Expiry Date	ISO 13485	14-Oct-2027
Accreditations	Expiry Date				
ISO 13485	14-Oct-2027				
<div> <span>Cancel</span> <span>Save</span> </div>					

- d) Edit current overseas manufacturer(s) by clicking on the 'Edit' button of the desired overseas manufacturer(s).



**Application For Product Registration (New)**

**Sites**

**Overseas Manufacturers**

Overseas Manufacturer 1		
Overseas Manufacturer Name	43 Manufacturing	
Overseas Manufacturer Address	43 Manufacturing 43 Street, Malaysia	
Type of Accreditations	Accreditations	Expiry Date
	ISO 13485	24-Jun-2027

For Local Manufacturers, applicant can auto-populate the Dealer's Details by entering the Local Manufacturer License/ Dealer's License Number.



## Add Local Manufacturer 1



Local Manufacturer Licence/Dealer's Licence Number	MDML250422Y12	<a href="#">Get Dealer's Details</a>
Local Manufacturer Name	MD UAT Company 05	
Postal Code *	239806	
Block / Number *	17C	
Level - Unit	17 - 30	
Street Name *	DUBLIN ROAD	
Building Name		
Site Details	Star Vista (3D, RIVER VALLEY ROAD - , CQ @ CLARKE QUAY, 179023 Singapore)	

Certification(s)


Type of Quality Management System (QMS) Certification	Certification Body	Expiry Date	Scope of Quality Management System
ISO13485	BUREAU VERITAS QUALITY ASSURANCE PTE. LTD.	22-Nov-2028	no

[Cancel](#)
[Save](#)

## 7. Adding device listing(s)

Applicant can add and edit the device's information of the product by clicking on 'Add Device' button.

### Device Listing \*

 No Data Available

[+ Add Device 1](#)

## Edit Device 1



Device Type	General Medical Device	
Device Name *	<input type="text" value="Silicone Foley Catheter"/>	
Intended Use *	<input type="text" value="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."/>	
Standalone Medical Mobile Application (also known as Software as Medical Device (SaMD), in IMDRF context) *	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Machine Learning-enabled Medical Device *	<input type="radio"/> Yes <input checked="" type="radio"/> No	
If the device contains connectivity / interfacing capabilities, please select all that apply *	<input type="checkbox"/> Internet <input type="checkbox"/> LAN <input type="checkbox"/> Wireless LAN <input type="checkbox"/> Bluetooth <input type="checkbox"/> Able to interface (via e.g. USB cable) with computing device (laptop, mobile phone, tablet, and etc.) <input type="checkbox"/> Others <input checked="" type="checkbox"/> N.A	
Device Risk Classification *	<input type="text" value="Class C"/>	
Medical Specialty *	<input type="text" value="General Hospital"/>	
Is the device for Professional Use Only? *	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are any models supplied sterile? *	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Local Authorised Importer Licence Number	<input type="text"/>	<input type="button" value="Get Importer's Details"/>
Local Authorised Importer Name	<input type="text"/>	
	<input type="button" value="+ Add Dealer"/>	
Justification if no importer assigned *	<input type="text"/>	
	<input type="button" value="Cancel"/>	<input type="button" value="Save"/>

## 8. Adding models into device listing(s)

Device's models can be updated after device listing is created by clicking 'Add' under Models section in the device listing.

## Device Listing \*

Device 1

[Edit](#)
[Delete](#)

Device Type	General Medical Device
Device Name	Silicone Foley Catheter
Intended Use	It can be used for clinical routine catheterization or drainag, and can be used with the monitor to continuously monitor the bladder temperature of patients.
Is Standalone	No
Machine Learning-enabled Medical Device	No
If the device contains connectivity / interfacing capabilities, please select all that apply	N.A
Risk Class	Class C
Medical Specialty	General Hospital
Is the device for Professional Use Only?	Yes
Is the In Vitro Diagnostic (IVD) device for self-testing?	Not Applicable
Biological Material Component	
Are any models supplied sterile?	Yes
Justification if no importer assigned	Not appointed.
Models	<a href="#">Add</a>

Model information can be uploaded using (i) the device model template that can be downloaded or (ii) adding the model individually by clicking 'Add Model'.

Note: For models which are to be included under a single device listing, please include the models under the same device listing. Do not create individual listing for each individual model.

## Add Device Models

Overseas Manufacturer 1 [ABCDEFGH]

[View Site Details](#)

[Download Device Model Template](#)

Upload Device Models



Select files to upload... or drag and drop

Upload required documents here ( files less than 25MB). Files exceeding the limit will be compressed.

[Add Model](#)

UDI Issuing Agency

- ☐ GS1
- ☐ HIBCC
- ☐ ICCBBA
- ☐ IFA GmbH

[Cancel](#)

[Save](#)

Applicants are to ensure models are assigned a manufacturing site by selecting the models and clicking on the 'Edit' button.

## Add Device Models

Overseas Manufacturer 1 [43 Manufacturing]

Local Manufacturer 1 [MD UAT Company 05]

[View Site Details](#)

[Download Device Model Template](#)

1 Models still missing Manufacturing Site tagging. Please select the models and assign a manufacturing site to them.

[Assign Manufacturers](#)

1 item(s) selected

<input checked="" type="checkbox"/>	Name as per Device Label*	Identifier*	Site(s)*	UDI-DI(s)	DM-DI(s)	Brief Description of Item (e.g. the key distinguishing a of each item (including Volur Diameter), SaMD Version num number and/or presence of I	Action
<input checked="" type="checkbox"/>	Silicon Foley Catheter	1234				Sterile Fr Catheter	<a href="#">Edit</a> <a href="#">Delete</a>

[Add Model](#)

[Reupload](#)

UDI Issuing Agency

- ☒ GS1
- ☐ HIBCC
- ☐ ICCBBA
- ☐ IFA GmbH

## Edit Model



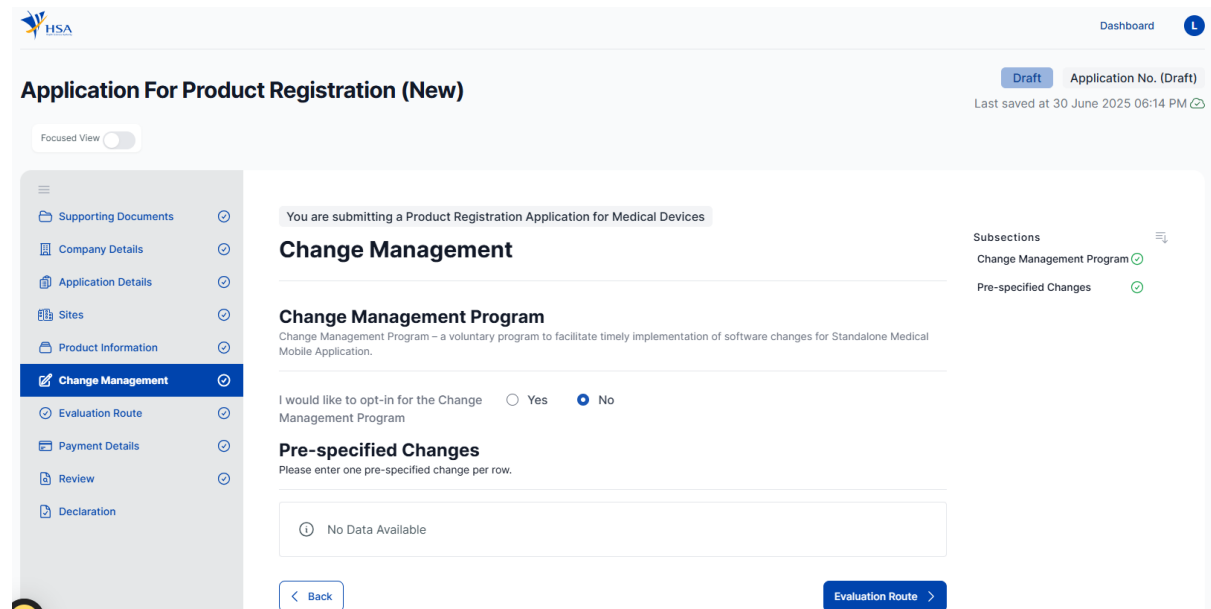
Name as per Device Label *	<input type="text" value="Silicon Foley Catheter"/>
Identifier *	<input type="text" value="1234"/>
UDI-DI(s)	<input type="text"/>
DM-DI(s)	<input type="text"/>
Brief Description of Item ⓘ	<input type="text" value="Sterile 14Fr Catheter"/>

Site(s) *	<div> <div>Overseas Manufacturer 1 ⓘ</div> <div>Local Manufacturer 1 ⓘ</div> </div> <div> <input type="text" value="Search"/> </div> <div> <input checked="" type="checkbox"/> Overseas Manufacturer 1           <input checked="" type="checkbox"/> Local Manufacturer 1       </div>
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## 9. 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>.

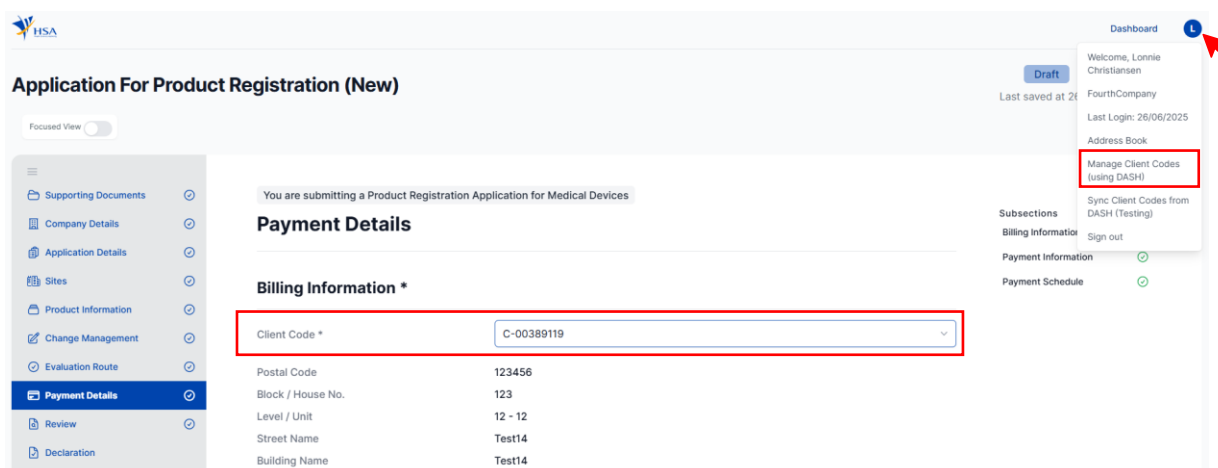


The screenshot shows the 'Application For Product Registration (New)' form in the HSA system. The 'Change Management' section is highlighted in the left sidebar. The main content area shows the 'Change Management' section, which includes a 'Change Management Program' section and a 'Pre-specified Changes' section. The 'Change Management Program' section has a question: 'I would like to opt-in for the Change Management Program' with radio buttons for 'Yes' and 'No' (selected). The 'Pre-specified Changes' section has a text input field with the placeholder 'No Data Available'.

## 10. Choosing Payment Method

Applicants with no client code will be able to set up a new billing account by accessing “Manage Client Codes” located on the top right corner profile icon. Setting up a new billing account may take 1-2 working days for it to be processed. Once processed, applicants will be able to perform transactions.

Applicants with existing client code can select the client code from the dropdown list.




Applicants may choose the preferred payment mode, GIRO or Online payment. Depending on the selected payment mode and evaluation route, applicants can select the preferred payment schedule.


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

### Payment Schedule \*

Payment Schedule \*

☒ Full
 ☐ Progressive

Charge Code	Description	Quantity	Price
MEDAPPMC	Pre-Market App - App Fee	1	\$560.00
Subtotal			\$560.00
Tax			\$0.00
Total			\$560.00

#### Payment Instructions

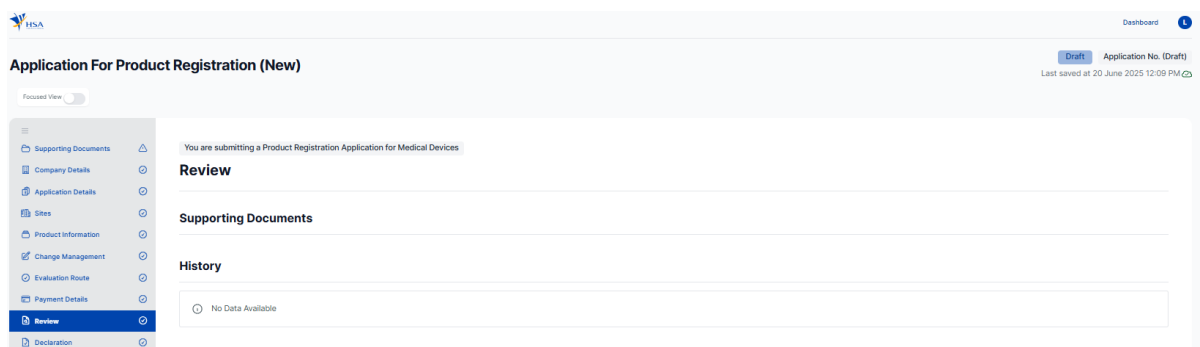
The above fees will be processed by HSA upon successful submission of this application. If your preferred payment mode is GIRO, please ensure that there are sufficient funds in the account.

[< Back](#)

[Review >](#)

## 11. Review Application

Applicants to review the summary of all sections filled.



**Application For Product Registration (New)**

Dashboard | Application No. (Draft) | Last saved at 20 June 2025 12:09 PM

Focused View

You are submitting a Product Registration Application for Medical Devices

**Review**

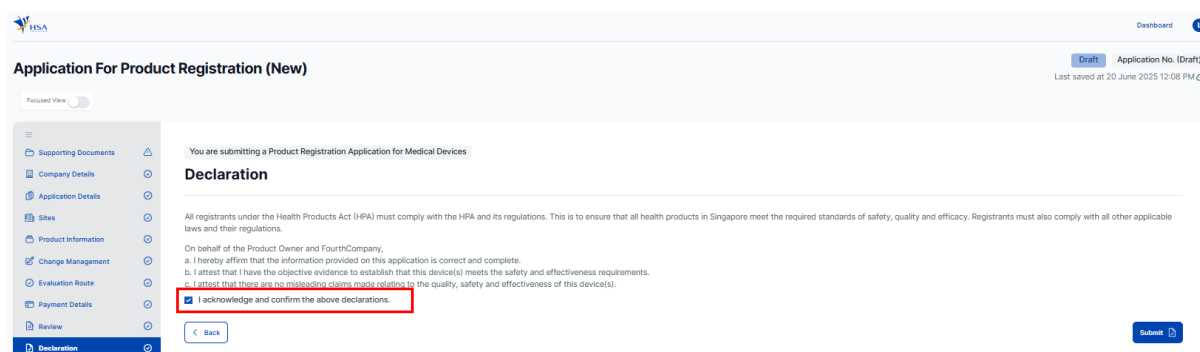
**Supporting Documents**

**History**

No Data Available

## 12. Declaration

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



**Application For Product Registration (New)**

Dashboard | Application No. (Draft) | Last saved at 20 June 2025 12:08 PM

Focused View

You are submitting a Product Registration Application for Medical Devices

**Declaration**

All registrants under the Health Products Act (HPA) must comply with the HPA and its regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Registrants must also comply with all other applicable laws and their regulations.

On behalf of the Product Owner and Fourth-Party,

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

## 13. 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.

HSA E-SERVICES: SINGAPORE HEALTH ...

TEST MODE

Pre-Market App - App Fee

SGD 560.00

Pay with  link





Or

Email


email@example.com

Payment method

Card




PayNow



PayNow is supported by bank apps and payment apps such as DBS, POSB, OCBC, UOB and GrabPay

You will be shown a QR code to scan using your preferred banking or payment app

Pay

Powered by  | [Terms](#) [Privacy](#)

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

HSA
Dashboard 1

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Focused View ☐

- [Home](#)
- Pending Task 1**
- [Open IRs](#)
- [Pending Payments 1](#)
- [Pending Importer Tagging](#)
- [Pending Approval Conditions](#)
- [Pending SAR Distribution Records](#)
- [Applications >](#)
- [Input Requests >](#)
- [Products >](#)
- [Dealers >](#)
- [E-GIRO Application](#)

## Pending Tasks

### Pending Payment


1 item(s) found

S/N	Application Number	Submission Type	Application Type	Task Number	Client Code	Amount Payable	Action
1	Draft	Product Registration	New	FourthCompany/UEN-2506-00004	C-00389119	\$560.00	<a href="#">Pay</a>

## 14. 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.





Dashboard

Focused View

Home

Pending Task1

Applications

Input Requests

Products

Dealers

E-GIRO Application

## Home

### Overview

New Application

Active Applications1

View Active Applications

Pending Tasks1

View Pending Tasks

Products2

View all products


Dealer's Licences0

View all dealer's licences

### Latest Active Applications

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

View Draft Applications



Dashboard

Focused View

Home

Pending Task1

Applications

Draft

Active

Closed

Input Requests

Products

Dealers

E-GIRO Application

## Draft Applications

Draft

View

Application Type	New
Product Name	Silicone Foley Catheter
Submission Type	Product Registration
Status	Pending Payment
Last Edited Date	30/06/2025 06:39 PM

Draft Expires 27-Dec-2025

ResumeDelete

Application Type	New
Product Name	-
Submission Type	Product Registration
Status	Draft
Last Edited Date	30/06/2025 05:31 PM

END OF DOCUMENT