



Applicant User Guide

Singapore Health Product Access and Regulatory E-System (SHARE)

Health Sciences Authority

Change Log

Version	Date	Author	Comments
1.0	14/07/2025		First version published on HSA webpage
1.1	14/07/2025		Screenshots updated
1.2	04/08/2025		Screenshots updated

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1. Introduction

The Singapore Health Product Access and Regulation E-System (SHARE) is a digital platform that supports the Health Sciences Authority (HSA) in the regulation of health products. Currently, SHARE provides regulatory support for Cell, Tissue, and Gene Therapy Products (CTGTP) and Medical Devices (MD).

This user guide focuses on the functionalities of SHARE that support the regulation and management of Medical Devices (SHARE-MD). In SHARE-MD, applicants can view medical device information online and perform various transactions related to medical devices, such as registration, licensing, change notifications, and more.

The table below describes the different applications available in SHARE-MD.

Submission Type	Application Type	Description
Product Notification	New	Notify HSA of newly introduced Class A medical devices intended for supply in Singapore.
Product Notification	Amendment	Inform HSA of any modifications made to existing Class A medical devices already notified.
Product Notification	Cancellation	Notify HSA to formally cancel previously notified Class A medical devices from the Singapore market.
Product Registration	New	Submit an application to register your medical device with HSA before supplying it in Singapore.
Product Registration	Retention	Maintain the active registration of a medical device already approved by HSA.
Product Registration	Cancellation	Formally cancel the registration of a medical device previously approved by HSA.
Product Registration	Change Notification	To notify HSA prior to implementing changes to your medical device.
Product Registration	Change of Registrant	Request the transfer of registration ownership to another registrant, initiated by the accepting company (new registrant).
Product Registration	Fulfilment Of Approval Conditions	Provide additional supporting documents required to meet approval conditions for your registered medical devices.
Product Registration	Global Update of Importers	Update the list of importers for your registered medical devices.
Dealer's Licence	New	Apply for a licence to import, manufacture, or supply medical devices in Singapore.
Dealer's Licence	Amendment	To update or change the details of your existing dealer's licences.
Dealer's Licence	Renewal	Renew an existing dealer's licence before it expires to continue operations.
Dealer's Licence	Cancellation	Submit a request to cancel your current dealer's licence.

Submission Type	Application Type	Description
Dealer's Licence	Fulfilment Of Approval Conditions	Provide necessary documentation to meet conditions required for maintaining the dealer's licence.
Special Access Route	New	Apply for Special Access Route for the import and supply of unregistered medical devices for clinical use, export or re-export, non-clinical purposes, or for the import of registered medical devices on a single consignment basis.
Special Access Route	Distribution Records	Notify HSA of distribution records of devices imported under SAR to ensure traceability.
Special Access Route	Fulfilment Of Approval Conditions	Submit required documentation to fulfil the approval conditions of an SAR licence.
Export Certificate	New	For local manufacturers to apply for an export certificate for locally manufactured medical devices that are not registered with or notified to HSA.
Free Sale Certificate	New	For companies to request for a free sale certificate for medical devices notified on Class A Medical Device Database or registered on the Singapore Medical Device Register (SMDR).

2. Terminology and Abbreviation

This section consists of abbreviations and definitions generic to all sections.

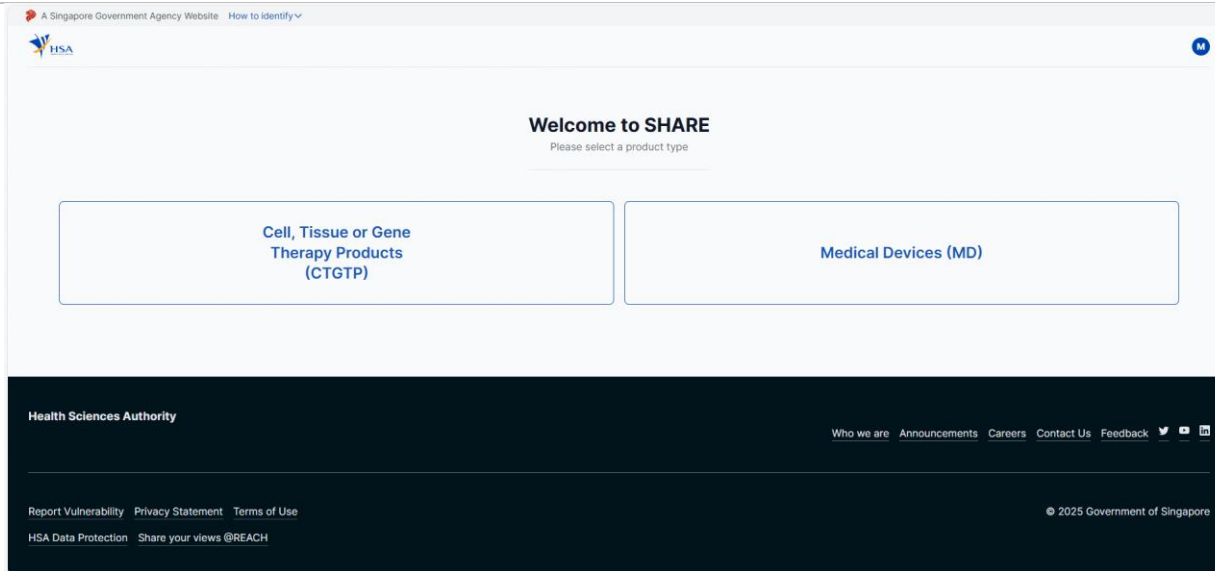
Terms	Definition
Applicant	An individual appointed by the company to make a submission to HSA
Class B/C/D Products	Products registered in SHARE. Class B/C/D/D (contains registrable therapeutic/medicinal product) indicates the product's risk classification. Class D (contains registrable therapeutic/medicinal product) itself is a combination product (Device-Drug).
CN	Change Notification
CoR	Change of Registrant
Corppass	Authorisation system for entities to manage digital service access of employees who need to perform corporate transactions.
CSDT	Common Submission Dossier Template
DASH	Digital All-in-one System for Health products
Dealer	Entity that performs the following activity – import, wholesale, or manufacture Medical Devices
Dossier	Set of documents which are uploaded by an Applicant for an Application Form
FSCA	Field Safety Corrective Action
GIRO	General Interbank Recurring Order
GMD	General Medical Device
HSA	Health Sciences Authority
IL	Importer's Licence
IR	Input Request
IVD	In-Vitro Diagnostic
MD	Medical Devices
MEDICS	Medical Device Information Communication System
ML	Manufacturer's Licence
OTP	One-Time-Password
QMS	Quality Management System
Query	A question raised by officer to request more information or clarity
Registrant	Person/Company who applied for and obtained the registration of the health product under the Health Products Act
SAR	Special Access Route
SHARE	Singapore Health Product Access and Regulatory E-System

Terms	Definition
SHARE-MD	Singapore Health Product Access and Regulatory E-System focusing on Medical Devices
SMDR	Singapore Medical Device Register
TAT	Turnaround Time
UDI	Unique Device Identifier
UEN	Unique Entity Number
WD	Working Day
WL	Wholesaler's Licence

3. Log in

1		Enter the URL in the search bar URL: https://share.hsa.gov.sg/
2		Applicant will be brought to the main page of SHARE when they access the URL above. Press Login with Corppass

3



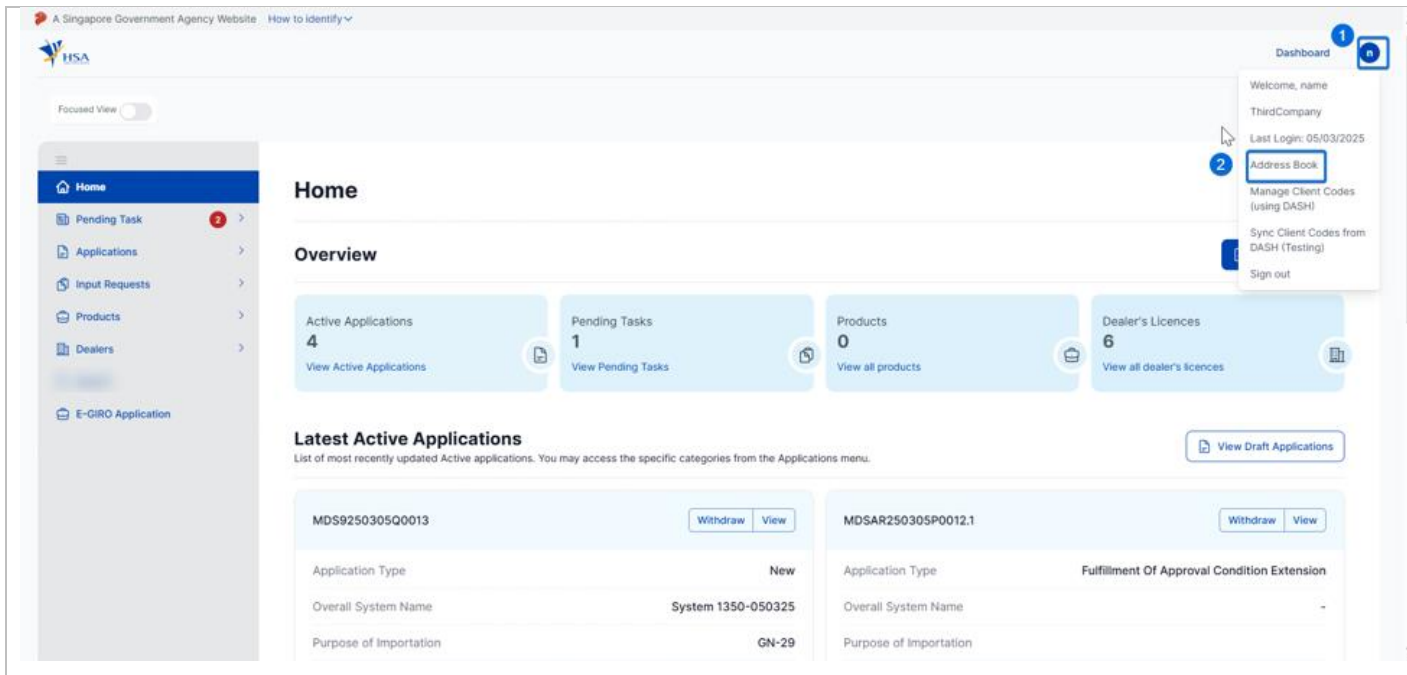
Applicants would be able to choose the product type that they would like to apply for.

4. Overview

4.1. Set Up

4.1.1. Address book

Applicants will be able to maintain their notification preferences by adding the contact details of key personnel to the Company Address Book.



The screenshot shows the HSA dashboard interface. On the left is a sidebar menu with options: Home, Pending Task (with a red notification badge), Applications, Input Requests, Products, Dealers, and E-GIRO Application. The main content area is titled 'Home' and 'Overview'. It features four summary cards: 'Active Applications' (4), 'Pending Tasks' (1), 'Products' (0), and 'Dealer's Licences' (6). Below these is a section for 'Latest Active Applications' with two application cards. A user menu is open in the top right corner, showing options: Welcome, name, ThirdCompany, Last Login: 05/03/2025, Address Book (highlighted with a blue box and a '2' in a blue circle), Manage Client Codes (using DASH), Sync Client Codes from DASH (Testing), and Sign out. A '1' in a blue circle is next to the 'Dashboard' label in the menu.

Steps:

- 1) Select
- 2) Select 'Address Book'

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HSA

Dashboard

Company Address Book

[Add Contact](#)

S. No.	Contact Person	Contact Number	Email	Head of Regulatory	Main Contact Person	
1	Sarah	+65-...	Sarah@company.com	☐	☐	
2	Tre Nikolaus	+15-3...	...	☒	☒	Edit Delete

- 3) Mark the contact person as 'Head of Regulatory'
- 4) Mark the contact person as 'Main Contact Person' who will receive email notifications generated by SHARE relating to all processes under the company UEN, including submission acknowledgements, input request notifications, renewal reminders, approval notifications etc.
- 5) Edit the existing contact details
- 6) Delete the existing contact details
- 7) Add a contact person

The company address book functions as a global update for the address book, ensuring synchronisation across various applications submitted under the same company's UEN. All contacts listed under the company address book, indicated as the "Main Contact Person" will receive notifications for ALL applications submitted under the same UEN.

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Company Address Book

S. No.	Contact Person
1	Tre Nikolaus

8

Contact Person *

9

Contact Number *

10

Email *

11

Head of Regulatory

12

Main Contact Person

+65

-

☐

☐

Cancel

Save

13

8) Add the name of contact person

9) Add the contact number

10) Add the email address

11) Applicants are required to mark at least one contact person as 'Head of Regulatory'

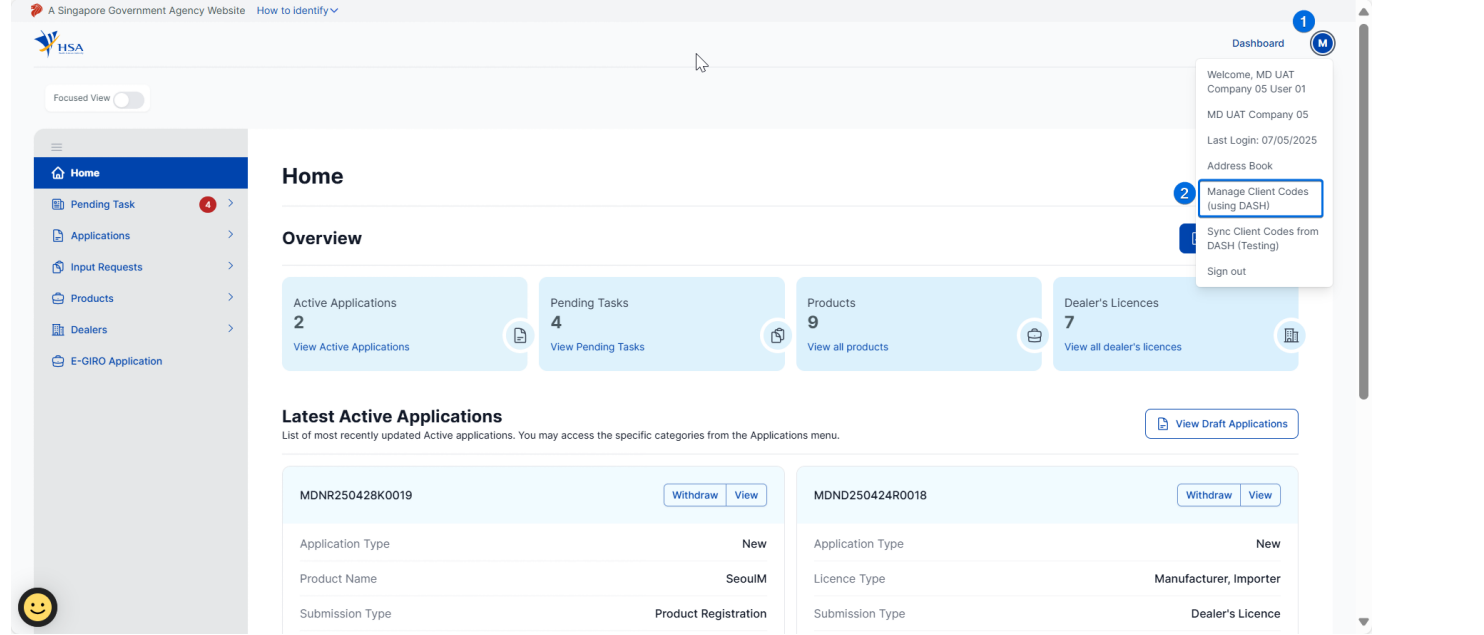
12) (Optional) Mark the contact person as 'Main Contact Person'

13) Save and submit the new contact details

4.1.2. Billing Information

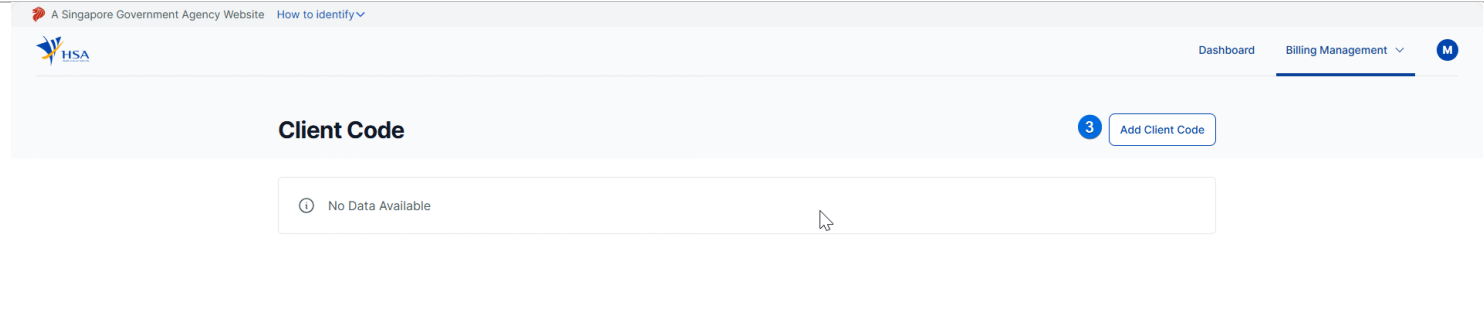
Applicants will be able to maintain their billing account by accessing “Manage Client Codes”.

Please note that the billing account is shared between Cell, Tissue, and Gene Therapy Products (CTGTP) and Medical Devices (MD). Thus, for companies that have existing billing account, there is no need to set up a new billing account.



The screenshot shows the HSA Dashboard. At the top, there is a navigation bar with the HSA logo and a 'How to identify' link. Below this is a 'Focused View' toggle. The left sidebar contains a 'Home' menu with links to 'Pending Task', 'Applications', 'Input Requests', 'Products', 'Dealers', and 'E-GIRO Application'. The main content area is titled 'Home' and features an 'Overview' section with four cards: 'Active Applications' (2), 'Pending Tasks' (4), 'Products' (9), and 'Dealer's Licences' (7). Below this is a 'Latest Active Applications' section with two application cards. The first card shows application ID MDNR250428K0019, application type 'New', product name 'SeoulM', and submission type 'Product Registration'. The second card shows application ID MDND250424R0018, application type 'New', licence type 'Manufacturer, Importer', and submission type 'Dealer's Licence'. A 'View Draft Applications' button is located to the right of the 'Latest Active Applications' section. A user profile dropdown menu is open in the top right corner, showing options like 'Manage Client Codes (using DASH)' and 'Sync Client Codes from DASH (Testing)'.

1) Select
2) Select 'Manage Client Codes (using DASH)'



The screenshot shows the 'Client Code' page. At the top, there is a navigation bar with the HSA logo and a 'How to identify' link. Below this is a 'Client Code' section with a 'Add Client Code' button. The main content area shows a message 'No Data Available'.

3) Add Client Code
4) Edit the existing Client Code

Note: Applicants can only set up a new billing account if they don't have existing billing account

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HSA

Dashboard [Billing Management](#)

Client Code

Client Code Name	Workday Client Code	Contact Person	Contact Number	Email	Address	Payment Mode	Status
Company	WC00012346	Jane Doe	+65-		01, First Street, #01-01, First Tower, Singapore 123456	GIRO	Active
111	C-00389140	Test11	+65-		123, Test11, #12-12, Test11, Singapore 123456	GIRO	Active
19	C-00389118	Test9	+65-		123, Test9, #12-12, Test9, Singapore 123456	GIRO	Active

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HSA

Client Code

① No Data Available

① If you are setting up a new billing account, please note that it may take 1-2 working days for us to process your information. Once processed, you will be able to perform transactions.

UEN MDUATCompany05UEN

Company Name MD UAT Company 05 (updated as of 07 May 2025) [Retrieve Latest](#)

Client Code Name *

Billing Contact Person *

Phone Device Type *

Billing Contact Number * 65 -

Postal Code * [Get Address](#)

Block / Number *

Level - Unit -

Street Name *

Building Name

Billing Email *

Payment Mode Online

- 5) Fill the Client Code information
- 6) Fill the Refund Bank Details
- 7) Save and submit the new billing account

Note: For setting up a new billing account, it may take 1-2 working days for it to be processed. Once processed, Applicants will be able to perform transactions.

6

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Refund Bank Details

This bank details are for refund purposes only. This would be different from the GIRO bank details that you have created with the Finance team.

Bank Name *

Bank Account Holder Name *

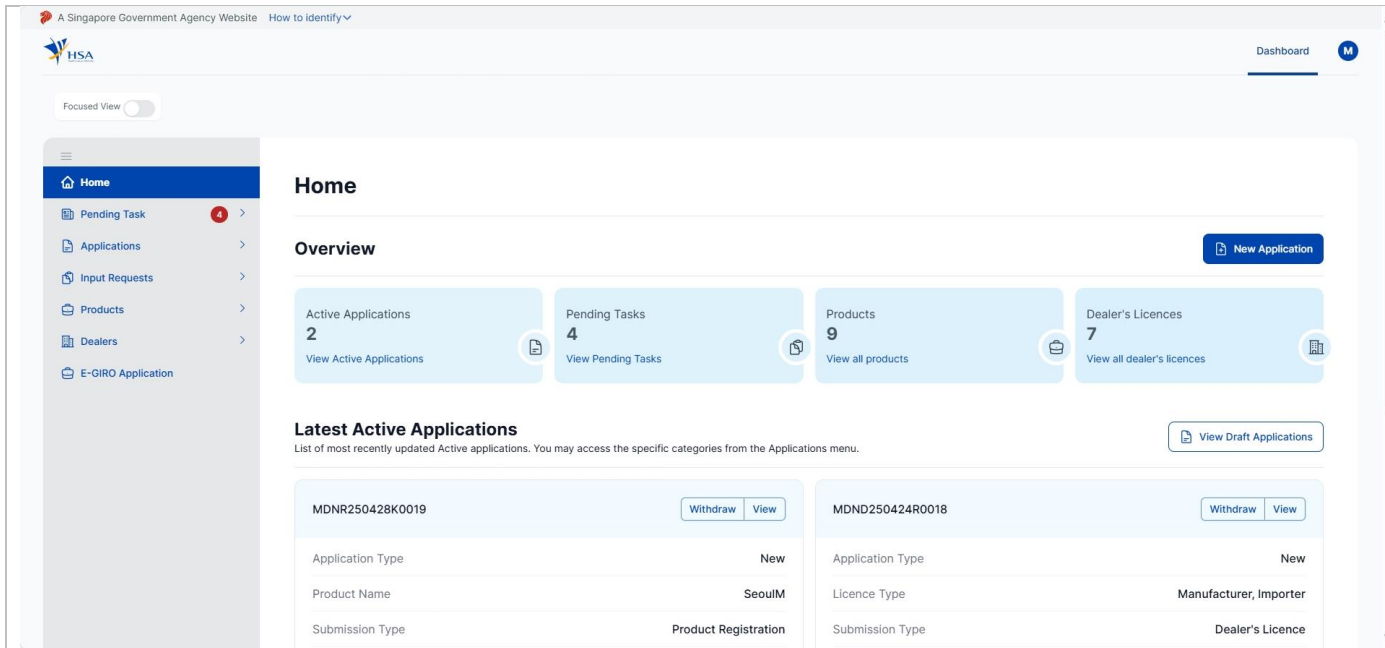
Bank Account Number *

7

Save

4.2. Dashboard

The Home Page is where you land when you log in. The dashboard gives an overview of statuses of all the applications. It helps to navigate directly to the respective pages when clicked.



The screenshot shows the HSA Home Dashboard. On the left is a navigation menu with links: Home, Pending Task (4), Applications, Input Requests, Products, Dealers, and E-GIRO Application. The main content area is titled 'Home' and 'Overview'. It features four blue cards: 'Active Applications' (2), 'Pending Tasks' (4), 'Products' (9), and 'Dealer's Licences' (7). Below these is a section for 'Latest Active Applications' showing two application details with fields for Application Type, Product Name, and Submission Type. A 'New Application' button is located in the top right of the Overview section.

Home-Dashboard

The left panel serves the purpose of aiding applicants in navigating through the following options:

Pending Tasks
Applications
Input Requests
Products Dealers

Applicants would be able to create a new application by clicking on the “New Application” button.

The blue cards serve the following functions:

Active Applications:

- Displays all applications submitted by the applicant pending HSA approval.

Pending Tasks:

- Allows applicants to click and assess all tasks that require their response.

Products:

- Presents a list of products.

Dealer’s Licences:

- Presents a list of dealer’s licences.

Latest Active Applications:

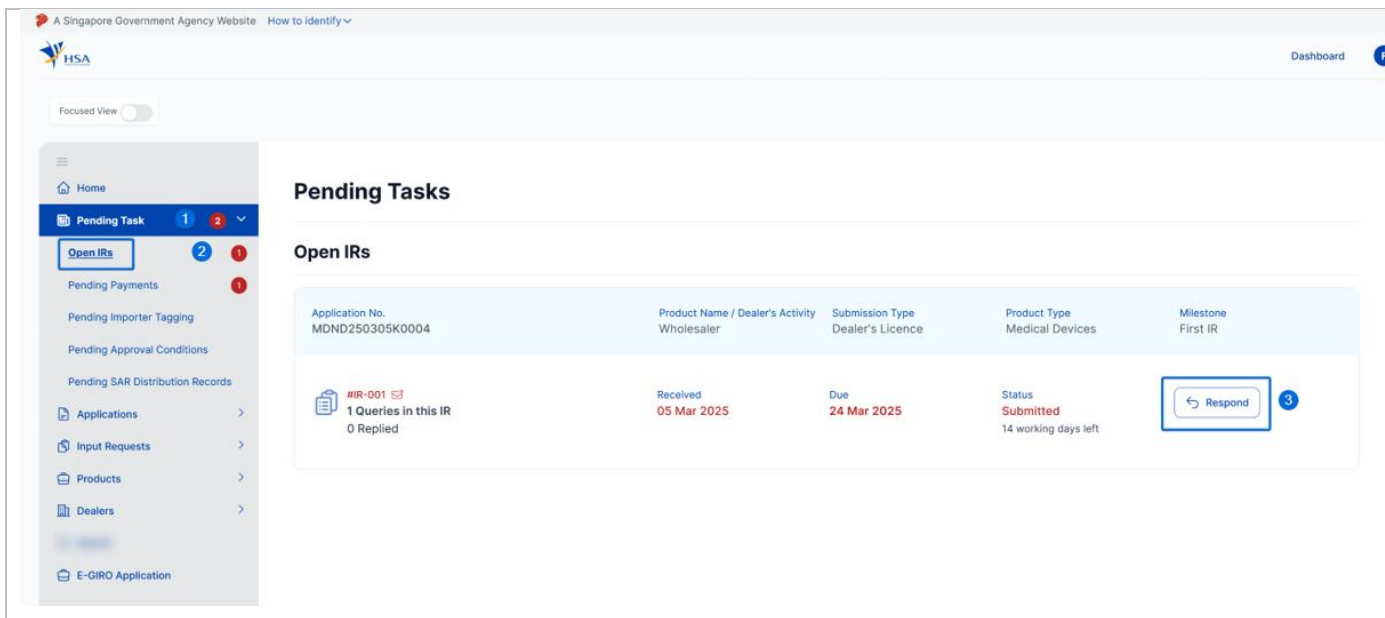
	- Displays the latest active Applications submitted by the Applicant that are still in the review stage, along with key information about the Applications. The Applicant can perform actions such as viewing the details of the Application and initiating a withdrawal. Applicants could view all draft applications by clicking 'View Draft Applications'.
--	---

4.3. Pending Tasks

Displays the number of tasks that are pending action from the Applicant, including:

- Input Requests (IRs) that are pending the Applicant's response
- Pending Payment for online payment invoices
- Acceptance of Assignment as Importer of Products
- Fulfilment of Approval Conditions application drafts that are pending the Applicant's submission by the Approval Condition due date
- SAR Distribution Records application drafts that are pending the Applicant's submission within 30 days after expiry of the SAR Licence, or within 30 days after the date of last export/supply, whichever earlier.

4.3.1. Open IRs



Pending Tasks

Open IRs

Application No.	Product Name / Dealer's Activity	Submission Type	Product Type	Milestone
MDND250305K0004	Wholesaler	Dealer's Licence	Medical Devices	First IR

#IR-001
1 Queries in this IR
0 Replied

Received: 05 Mar 2025
Due: 24 Mar 2025
Status: Submitted
14 working days left

[Respond](#)

Input Requests (IR) are raised by officers seeking additional information and awaiting applicant's response.

The Open IRs list displays the number of queries in the IR, received date, due date, status, and a respond button. Clicking on the respond button redirects to the IR details page with all the change logs.

- 1) Navigate to 'Pending Tasks'
- 2) Select 'Open IRs'
- 3) Applicants would be able to respond to the Input Request.

4.3.2. Pending Payments

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Dashboard
M

Focused View

Home

Pending Task
1
18

Open IRs
5

Pending Payments
2
12

Pending Importer Tagging
1

Pending Approval Conditions

Pending SAR Distribution Records

Applications
>

Input Requests
>

Products
>

Dealers
>

Pending Tasks

Pending Payment

12 item(s) found

S/N	Application Number	Submission Type	Application Type	Task Number	Client Code	Am Pay	Action
1	MDNR250319E0005	Product Registration	New	LucianaCompanyUEN-2503-00035	WC-661248	\$3,;	Pay 3
2	MDNR250319B0020	Product Registration	New	LucianaCompanyUEN-2503-00039	WC-661248	\$3,;	Pay
3	Draft	Special Access Route	New	LucianaCompanyUEN-2504-00016	WC-661248	\$39	Pay

- 1) Navigate to 'Pending Tasks'
- 2) Select 'Pending Payments'
- 3) Applicants would be able to make payments

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4.3.3. Pending Importer Tagging

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Dashboard
M

Focused View

- Home
- Pending Task** 1 5
- Open IRs 2
- Pending Payments 2
- Pending Importer Tagging** 2 1
- Pending Approval Conditions
- Pending SAR Distribution Records
- Applications >
- Input Requests >
- Products >
- Dealers >

Pending Tasks

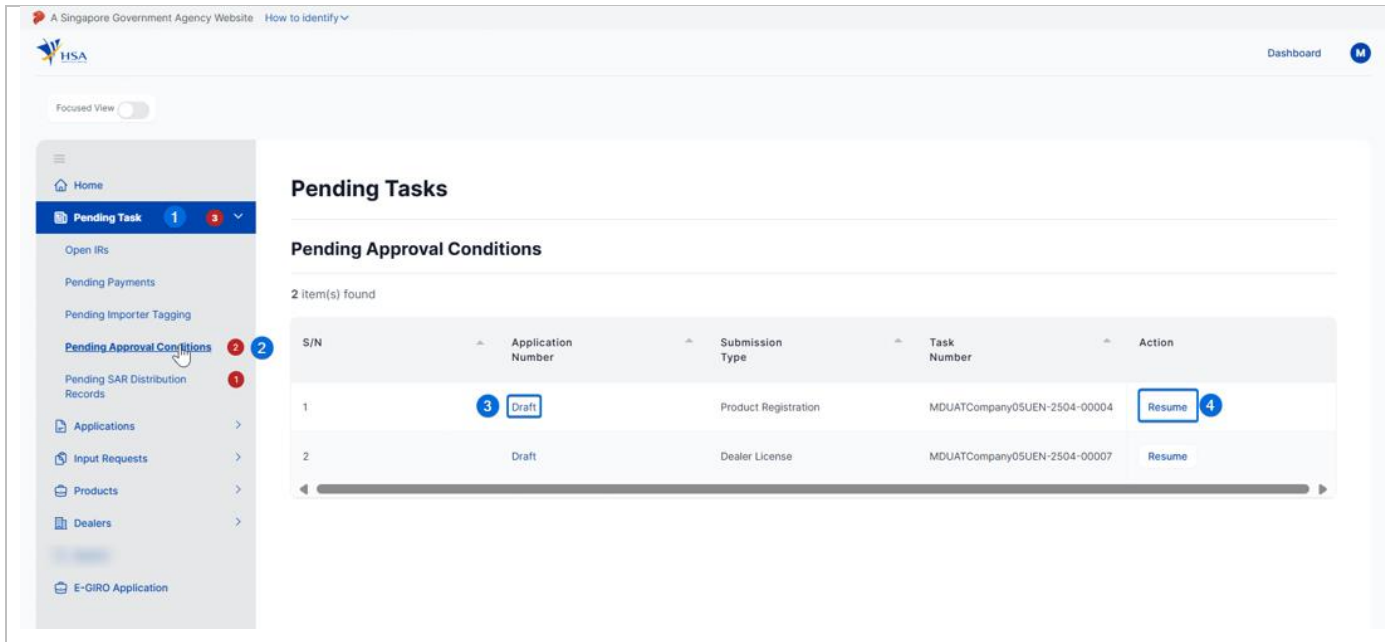
Pending Importer Tagging

1 item(s) found

S/N	Application Number	Submission Type	Task Number	Action
1	MDUL250409J0018	Product Registration	MDUATCompany15UEN-2504-	Review 3

- 1) Navigate to 'Pending Tasks'
- 2) Select 'Pending Importer Tagging'
- 3) Applicants would be able to review, accept or reject the assignment as importer for the selected product.

4.3.4. Pending Approval Conditions

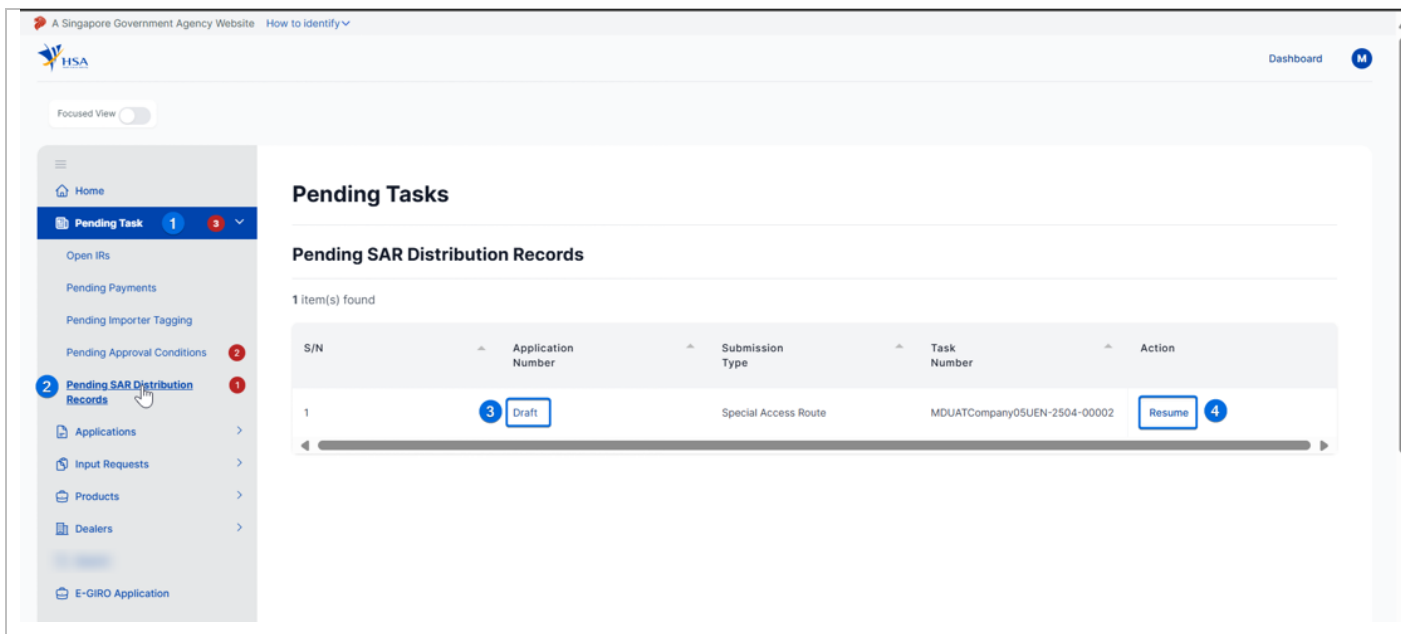


The screenshot shows the HSA Pending Tasks page. The left sidebar contains a menu with 'Pending Task' highlighted, which has a red notification badge with the number 3. Below it, 'Pending Approval Conditions' is highlighted with a red badge with the number 2. The main content area is titled 'Pending Tasks' and 'Pending Approval Conditions'. It shows 2 item(s) found. The table below lists the pending tasks:

S/N	Application Number	Submission Type	Task Number	Action
1	Draft	Product Registration	MDUATCompany05UEN-2504-00004	Resume
2	Draft	Dealer License	MDUATCompany05UEN-2504-00007	Resume

- 1) Navigate to 'Pending Tasks'
- 2) Select 'Pending Approval Conditions'
- 3) The system will automatically create the **Error! Not a valid result for table.** draft application 10 working days before the approval condition due date. Applicants would be able to review the Draft application of **Error! Not a valid result for table.**
- 4) Applicants would be able to continue to fill and submit the **Error! Not a valid result for table.** draft application.

4.3.5. Pending SAR Distribution Records



The screenshot displays the 'Pending Tasks' section of the SHARE system. The sidebar on the left contains navigation links, with 'Pending SAR Distribution Records' highlighted. The main content area shows a table of pending records. The table has columns for S/N, Application Number, Submission Type, Task Number, and Action. A single record is listed with S/N 1, Application Number MDUATCompany05UEN-2504-00002, Submission Type Special Access Route, and Task Number MDUATCompany05UEN-2504-00002. The record is in 'Draft' status, and a 'Resume' button is visible next to it.

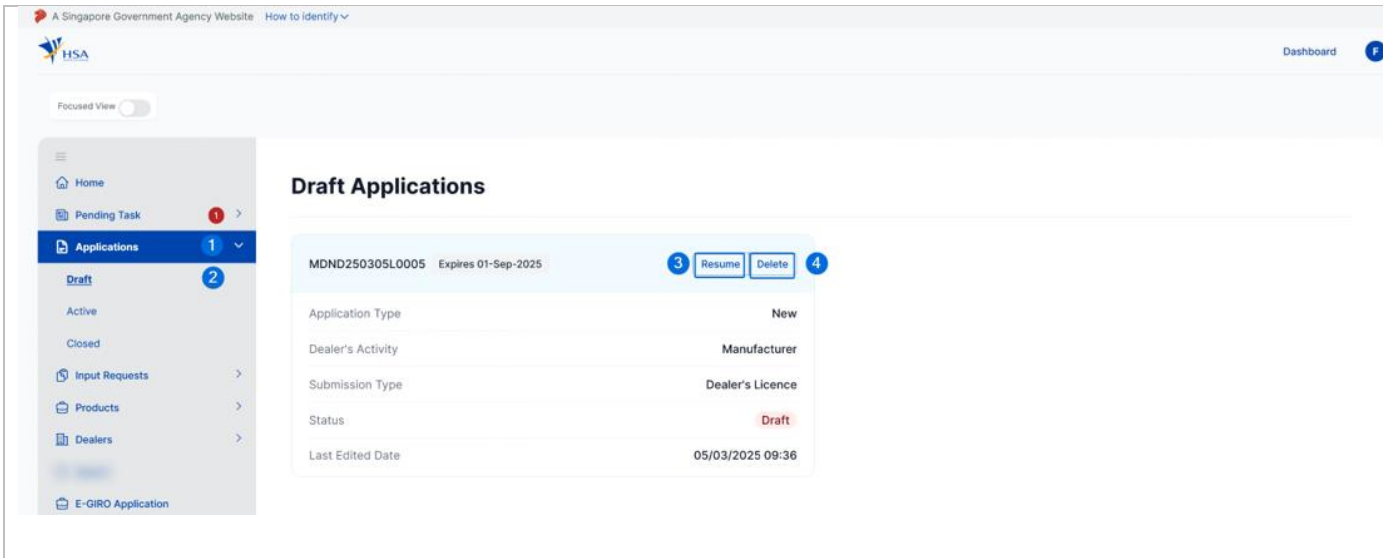
S/N	Application Number	Submission Type	Task Number	Action
1	MDUATCompany05UEN-2504-00002	Special Access Route	MDUATCompany05UEN-2504-00002	Resume

- 1) Navigate to 'Pending Tasks'
- 2) Select 'Pending SAR Distribution Records'
- 3) The system will automatically create the of SAR Distribution Record draft application on the day of SAR expiry date.
- 4) Applicants would be able to continue to fill and submit the SAR Distribution Record draft application.

4.4. Applications

The applicant can save a draft while creating the application and resume it from the dashboard.

4.4.1. Draft



The screenshot shows the HSA dashboard interface. On the left is a sidebar with a menu containing 'Home', 'Pending Task', 'Applications' (highlighted with a blue bar and a red '1'), 'Draft' (highlighted with a blue bar and a blue '2'), 'Active', 'Closed', 'Input Requests', 'Products', 'Dealers', and 'E-GIRO Application'. The main content area is titled 'Draft Applications'. It displays a table with one application entry: MDND250305L0005, Expires 01-Sep-2025. The application details are shown in a card format: Application Type: New, Dealer's Activity: Manufacturer, Submission Type: Dealer's Licence, Status: Draft (in red text), and Last Edited Date: 05/03/2025 09:36. At the top right of the card are two buttons: 'Resume' (highlighted with a blue '3') and 'Delete' (highlighted with a blue '4').

At any stage, an application can be saved as a draft before submission. All the drafts are listed in the dashboard.

The application will be autosaved every few minutes and will also be saved whenever the applicants click on the next section.

- 1) Navigate to 'Applications'
- 2) Select 'Draft'
- 3) Applicants can resume the application and submit
- 4) Applicants can delete the application

The screenshot shows the 'Active Applications' page in the HSA system. The left sidebar contains navigation links: Home, Pending Task, Applications (1), Draft, Active (2), Closed, Input Requests, Products, Dealers, and E-GIRO Application. The main content area displays two application cards. The first card, MDNR250428K0019, has callouts: 1 on the Applications link, 2 on the Active filter, 3 on the Withdraw button, and 4 on the View button. The second card, MDND250424R0018, also has callouts 3 and 4 on the Withdraw and View buttons respectively. Both cards show application details like Application Type, Product Name, Submission Type, Status, and Submission Date.

Application ID	Application Type	Product Name	Submission Type	Status	Submission Date
MDNR250428K0019	New	SeoulM	Product Registration	Processing	29/04/2025 02:19 PM
MDND250424R0018	New	Manufacturer, Importer	Dealer's Licence	Processing	24/04/2025 02:55 PM

4.4.3. Closed

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How to identify


HSA

Dashboard

Focused View

Home

Pending Task

Applications

Draft

Active

Closed

Input Requests

Products

Dealers

E-GIRO Application

Closed Applications

MDND250305i0002

Application Type

Dealer's Activity

Submission Type

Status

Closure Date

New

Manufacturer

Dealer's Licence

Closed

05/03/2025 09:25

View

1) Navigate to 'Application'

2) Select 'Closed'

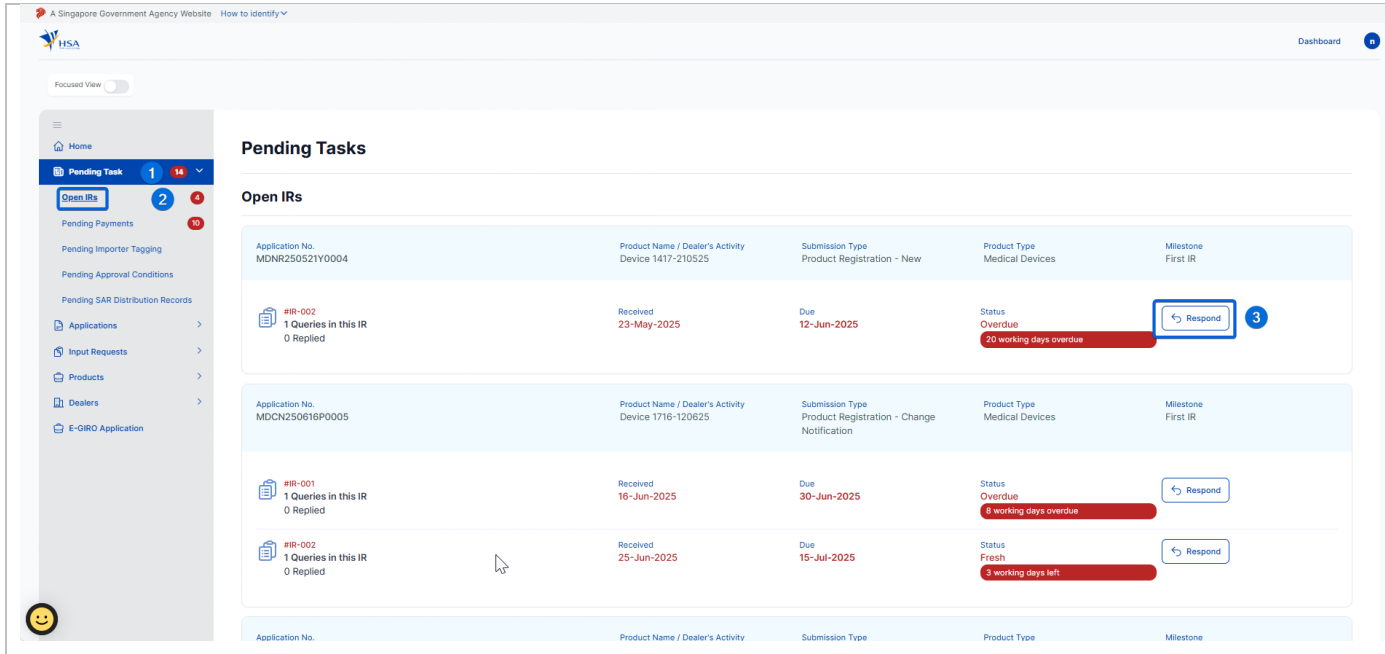
3) Applicants can view the application

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4.5. Input Requests

Input Requests (IR) are initiated by officers seeking additional information and awaiting the applicant's response.

4.5.1. Open IRs



The screenshot shows the 'Pending Tasks' section of the HSA system. The left sidebar contains navigation links: Home, Pending Task (1), Open IRs (2), Pending Payments (10), Pending Importer Tagging, Pending Approval Conditions, Pending SAR Distribution Records, Applications, Input Requests, Products, Dealers, and E-GIRO Application. The main content area is titled 'Pending Tasks' and 'Open IRs'. It displays a table of open input requests with columns: Application No., Product Name / Dealer's Activity, Submission Type, Product Type, and Milestone. The table lists three IRs, each with a 'Respond' button. The first IR is for Application No. MDNR250521Y0004, received on 23-May-2025, due on 12-Jun-2025, and is 'Overdue' (20 working days overdue). The second IR is for Application No. MDCN250616P0005, received on 16-Jun-2025, due on 30-Jun-2025, and is 'Overdue' (8 working days overdue). The third IR is for Application No. MDCN250616P0005, received on 25-Jun-2025, due on 15-Jul-2025, and is 'Fresh' (3 working days left). A red bar at the bottom of the table indicates the total number of IRs: 3.

Application No.	Product Name / Dealer's Activity	Submission Type	Product Type	Milestone
MDNR250521Y0004	Device 1417-210525	Product Registration - New	Medical Devices	First IR
#IR-002 1 Queries in this IR 0 Replied	Received 23-May-2025	Due 12-Jun-2025	Status Overdue 20 working days overdue	Respond
MDCN250616P0005	Device 1716-120625	Product Registration - Change Notification	Medical Devices	First IR
#IR-001 1 Queries in this IR 0 Replied	Received 16-Jun-2025	Due 30-Jun-2025	Status Overdue 8 working days overdue	Respond
#IR-002 1 Queries in this IR 0 Replied	Received 25-Jun-2025	Due 15-Jul-2025	Status Fresh 3 working days left	Respond

Input Requests (IR) are raised by officers seeking additional information and awaiting applicant's response.

The Open IRs list displays the number of queries in the IR, received date, due date, status, and a respond button. Clicking on the respond button redirects to the IR details page with all the change logs.

- 1) Navigate to 'Pending Tasks'
- 2) Select 'Open IRs'
- 3) Applicants would be able to respond to the Input Request.

Application For Product Registration (New)

Pending IR Application No. MDNR250424F0009

Focused View

- IR Details
- Supporting Documents
- Company Details
- Application Details
- Sites
- Product Information
- Change Management
- Evaluation Route
- Payment Details
- Review
- Input Requests
 - All IRs
- Application Admin
 - Audit Trail

IR Details

Instructions for this page:
Please respond to all queries in this IR before submitting your response.
For third party entity access please share the following link with your third party entity: here

#IR-001	Received 24-Apr-2025	Due 09-May-2025	Status Fresh	4 Request upload access to Third Party Entity
---------	-------------------------	--------------------	-----------------	---

Sender MD Vincent All Roles	Phone +65-1234567890	Email vincent_
--------------------------------	-------------------------	-------------------

1 Queries

MD Vincent All Roles
Product Owner Information (Editable by Applicant)
24-Apr-2025

6

7

8

View Thread

Reply

Go to section

Sent in #IR-001

Could you update the name

9

Submit Response to IR

- Applicants can request upload access to Third Party Entity. For more information, please refer to **Error! Not a valid result for table..**

Applicants can

- Request Extension for the selected IR.
- Applicants can view the thread.

Applicants can

- Reply IR.
- Applicants can go to the section for which IR is raised by clicking 'Go to section'.
- Applicants are required to click the 'Submit Response to IR' button in order to submit the response after replying to the IR.

Request Extension

Application For Product Registration (New)

Pending IR

Application No. MDNR250424F0009

IR Details

Supporting Documents

Company Details

Application Details

Sites

Product Information

Change Management

Evaluation Route

Payment Details

Review

Input Requests

All IRs

Application Admin

Audit Trail

IR Details

Instructions for this page:

Please respond to all queries in this IR before submitting your response.

For third party entity access

#IR-001

1 Query in this IR

0 Replied

Sender

MD Vincent All Roles

1 Queries

MD Vincent All Roles

30 Product Owner Information (Editable by Applicant)

24-Apr-2025

Sent in #IR-001

Could you update the name

No reply

Request Extension

View Thread

Reply

Go to section

Submit Response to IR

Extension Confirmation

You are requesting to extend due date for input request #IR-001.

Remarks

Enter your remarks

Cancel

Confirm

Applicants can request to extend due date for IR.

Page 30 of 273

Edit

Focused View

IR Details

Supporting Documents

Company Details

Application Details

Sites

Product Information

Change Management

Evaluation Route

Payment Details

Review

Input Requests

All IRs

Application Admin

Audit Trail

Product Information

1

2

3

1 Queries

Edit

Edit History

Product Owner Information

Product Owner 1 (Local)

Product Owner Name

Target

Address

3D, RIVER VALLEY ROAD, CQ @ CLARKE QUAY, Singapore 179023

Device Listing

Device 1

Device Type

General Medical Device

Device Name

Hotta System

Intended Use

no

Is Standalone

No

Machine Learning-enabled Medical Device

No

If the device contains connectivity / interfacing capabilities, please select all that apply

Internet

Risk Class

Class C

Medical Specialty

Anaesthesiology

Is the device for Professional Use Only?

Yes

Is the In Vitro Diagnostic (IVD) device for

Not Applicable

Subsections

Product Owner Information

Device Listing

- Applicants can view details of queries.
- Applicants can edit the subsection for which the IR is raised.
- Applicants can view the edit history of the field, which will show both current and previous value.

Page 31 of 273

Focused View

IR Details

Supporting Documents

Company Details

Application Details

Sites

Product Information

Change Management

Evaluation Route

Payment Details

Review

Input Requests

All IRs

Application Admin

Audit Trail

Product Information

Product Owner Information

Device Listing

Edit Data for Product Owner Information

Product Owner Information *

Please provide product owner information for each product.

Product Owner (Local)

Product Owner Name

Target

Address

3D, RIVER VALLEY ROAD, CQ @ CLARKE QUAY, Singapore 179023

Edit

Delete

Cancel

Save

Applicants can edit the data in the subsection for which the IR is raised.

Focused View

IR Details

Supporting Documents

Company Details

Application Details

Sites

Product Information

Change Management

Evaluation Route

Payment Details

Review

Input Requests

All IRs

Application Admin

Audit Trail

Product Info

Product Owner

Product Owner 1

Product Owner Name

Address

Device Listing

Device 1

Device Type

Device Name

Intended Use

Is Standalone

Machine Learning

If the device contains interfacing capabilities that apply

Risk Class

Medical Specialty

Is the device for Patient Use

Is the In Vitro Diagnostic

Edit History for Product Owner Information

Previous values

Product Owner 1

Product Owner Name

Target

Address

3D, RIVER VALLEY ROAD, CQ @ CLARKE QUAY, Singapore 179023

Changes in Current IR

Product Owner 1

Product Owner Name

Happy

Address

3D, RIVER VALLEY ROAD, CQ @ CLARKE QUAY, Singapore 179023

Audit Trail

Data on 24/04/2025 11:01 AM

+

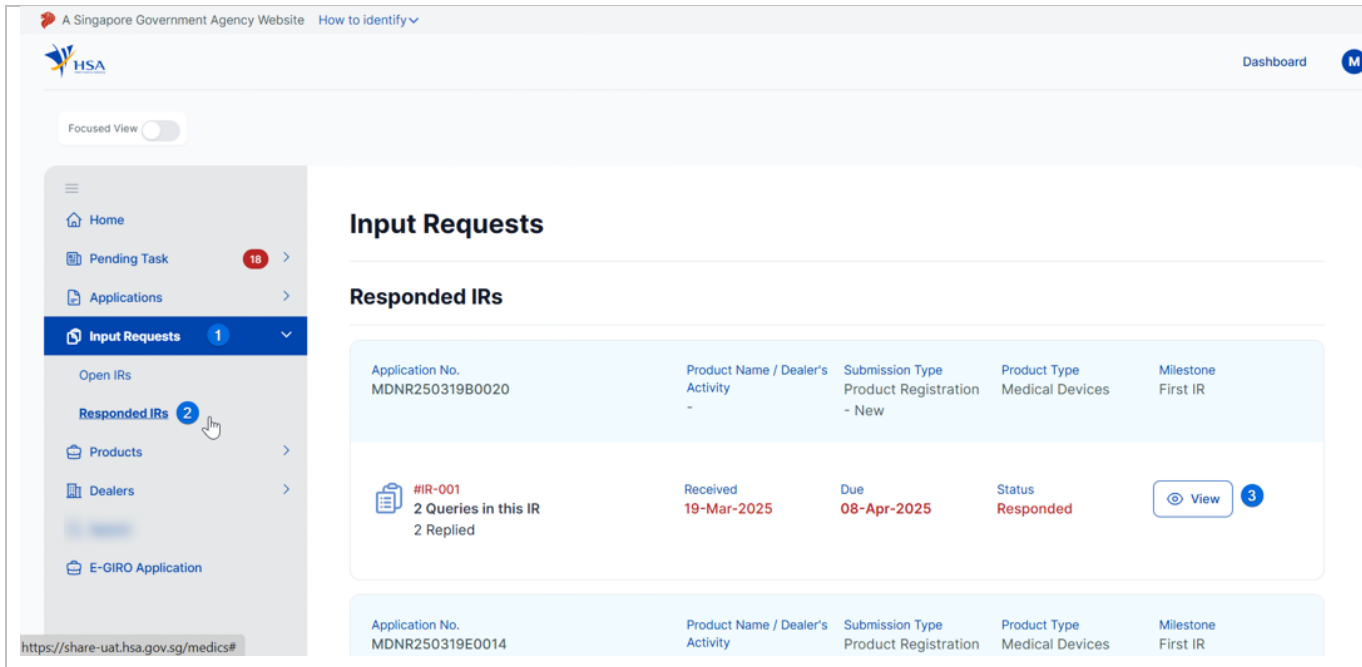
Close

Applicants can view the edit history where it will show the previous values and changes in the current IR. In Audit Trail, applicants can view when the history of the changes made in the subsection.

Reply IR

- 1) Applicants can reply to the query.
- 2) Applicants can make reference to a file uploaded in the Supporting Documents section in the reply.

4.5.2. Responded IRs



The screenshot shows the 'Input Requests' page in the SHARE system. The left sidebar contains navigation links: Home, Pending Task (18), Applications, Input Requests (1), Open IRs, Responded IRs (2), Products, Dealers, and E-GIRO Application. The main content area is titled 'Input Requests' and features a 'Responded IRs' section. This section displays a table of responded input requests. The first entry is for Application No. MDNR250319B0020, with Product Name / Dealer's Activity as '-', Submission Type as Product Registration - New, Product Type as Medical Devices, and Milestone as First IR. Below this, a card for #IR-001 shows 2 Queries in this IR, 2 Replied, Received on 19-Mar-2025, Due on 08-Apr-2025, and Status as Responded. A 'View' button with a notification badge (3) is present. The second entry in the table is for Application No. MDNR250319E0014, with Product Name / Dealer's Activity as Activity, Submission Type as Product Registration, Product Type as Medical Devices, and Milestone as First IR.

Application No.	Product Name / Dealer's Activity	Submission Type	Product Type	Milestone
MDNR250319B0020	-	Product Registration - New	Medical Devices	First IR
#IR-001	2 Queries in this IR 2 Replied	Received 19-Mar-2025	Due 08-Apr-2025	Status Responded
MDNR250319E0014	Activity	Product Registration	Medical Devices	First IR

Input Requests initiated by officers to which the applicant has already responded are displayed here.

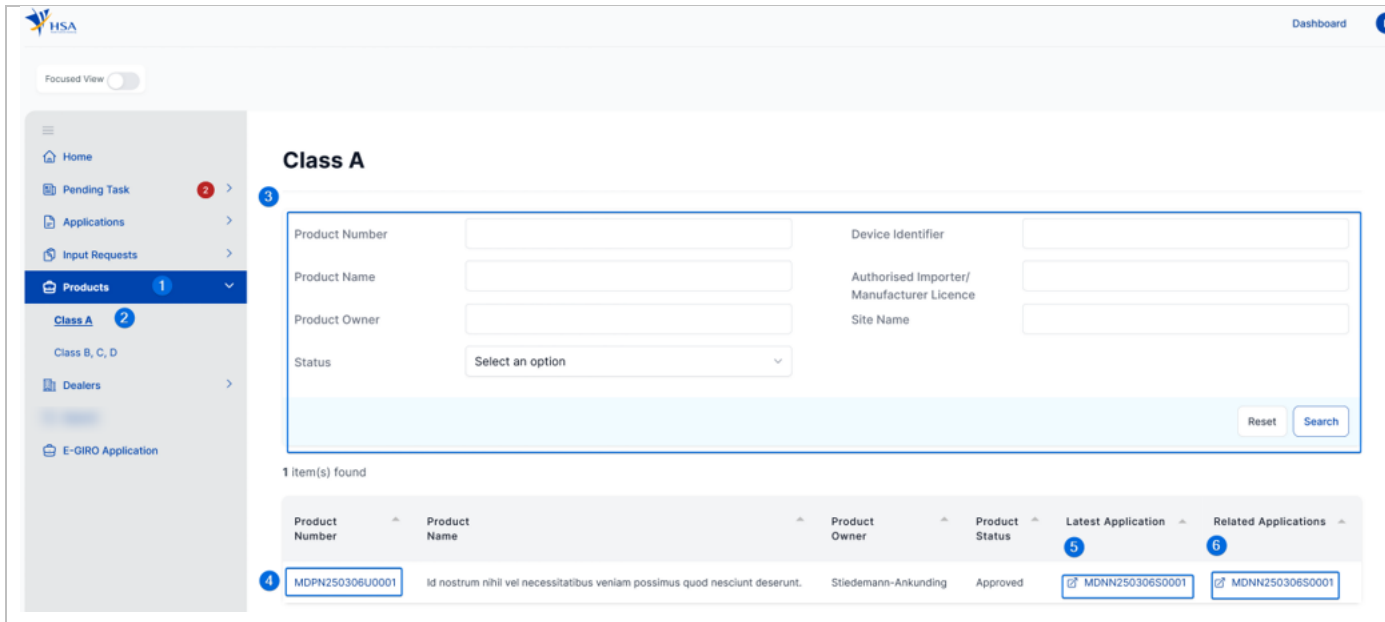
The Responded IRs list displays the number of queries in the IR, received date, due date, status, and a view button.

- 1) Navigate to 'Input Requests'
- 2) Select 'Responded IRs'
- 3) Applicants can view the IR details page with all the replied change logs.

4.6. Products

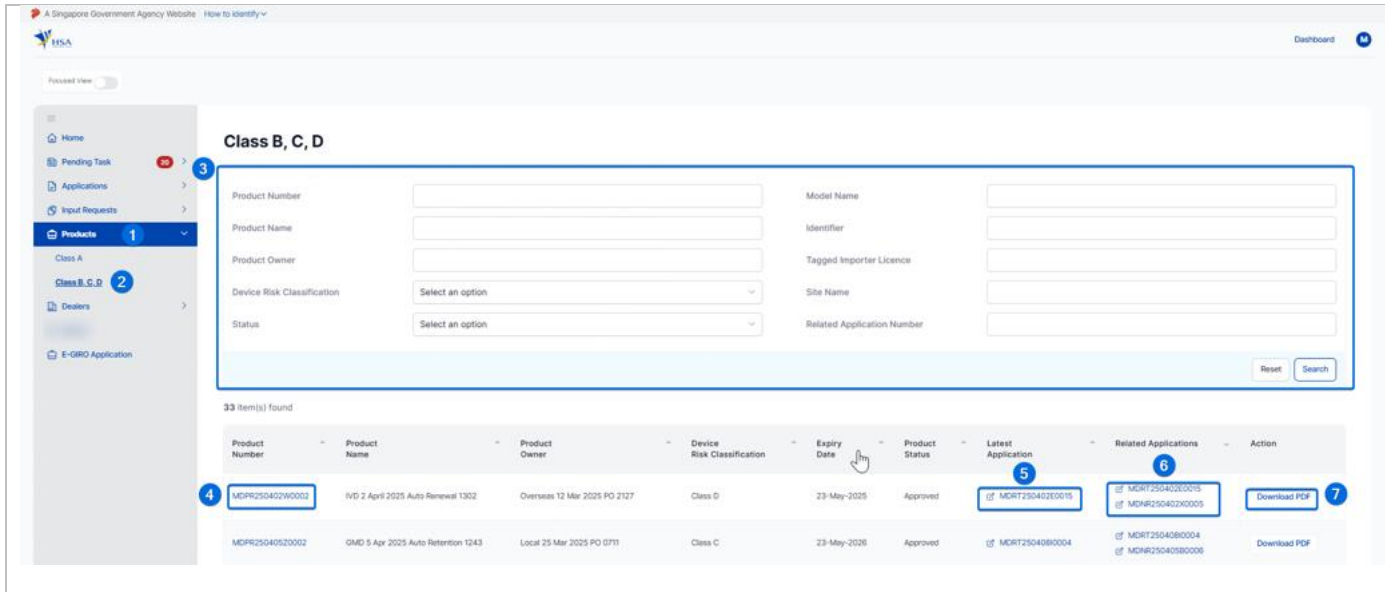
This section displays Product information such as product number, product name, product owner, product status, related application, and other relevant information.

4.6.1. Class A



- 1) Navigate to 'Products'
- 2) Select 'Class A'
- 3) Search for results by entering the required data in the search table and clicking 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 4) View the details of the product.
- 5) View the details of latest applications
- 6) View the details of related applications

4.6.2. Class B, C, D



Class B, C, D

Product Number: Model Name:

Product Name: Identifier:

Product Owner: Tagged Importer Licence:

Device Risk Classification: Site Name:

Status: Related Application Number:

33 item(s) found

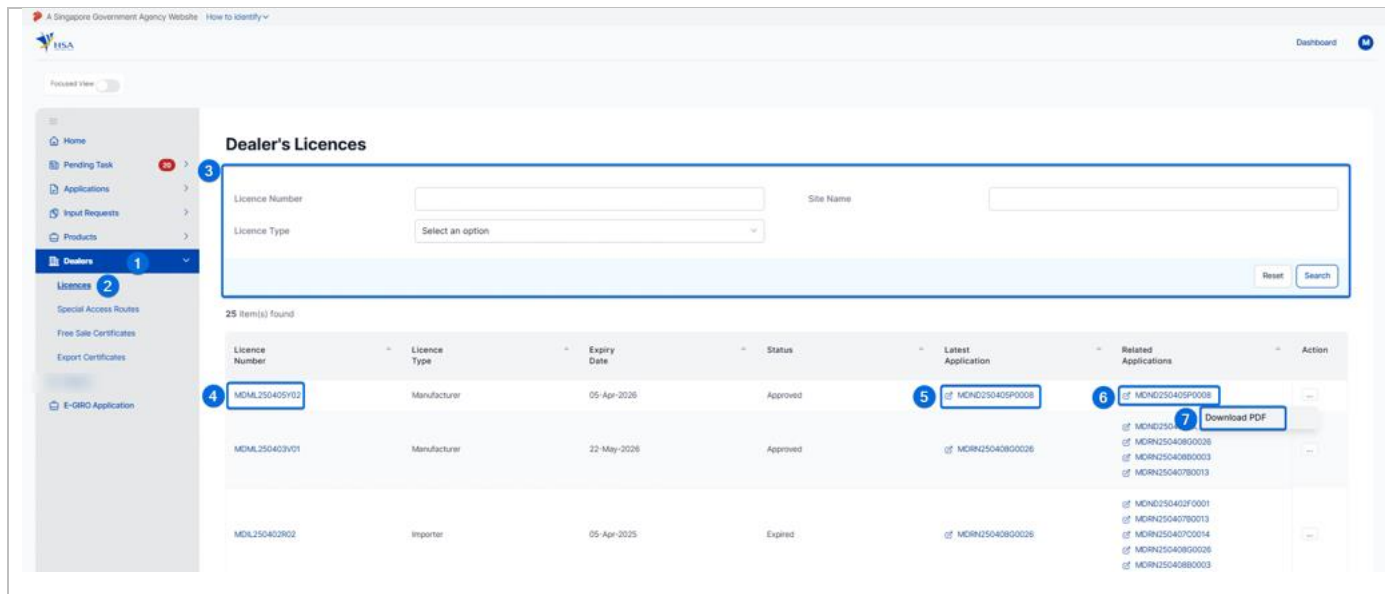
Product Number	Product Name	Product Owner	Device Risk Classification	Expiry Date	Product Status	Latest Application	Related Applications	Action
MDR250402W0003	IVD 2 April 2025 Auto Renewal 1302	Overseas 12 Mar 2025 PO 2127	Class D	23-May-2025	Approved	MDRT250402E0015	MDRT250402E0015 MDR250402W0005	Download PDF
MDR25040520002	GMD 5 Apr 2025 Auto Retention 1243	Local 25 Mar 2025 PO 0711	Class C	23-May-2026	Approved	MDRT250408E0004	MDRT250408E0004 MDR250408E0008	Download PDF

- 1) Navigate to 'Products'
- 2) Select 'Class B, C, D'
- 3) Search for results by entering the required data in the search table and clicking the 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 4) View the details of the product.
- 5) View the details of latest applications
- 6) View the details of related applications
- 7) Download PDF copy of the product registration details

4.7. Dealers

This section displays Dealer's information such as licence number, expiry date, licence status, related application, and other relevant information.

4.7.1. Licences



Dealer's Licences

Search Form:

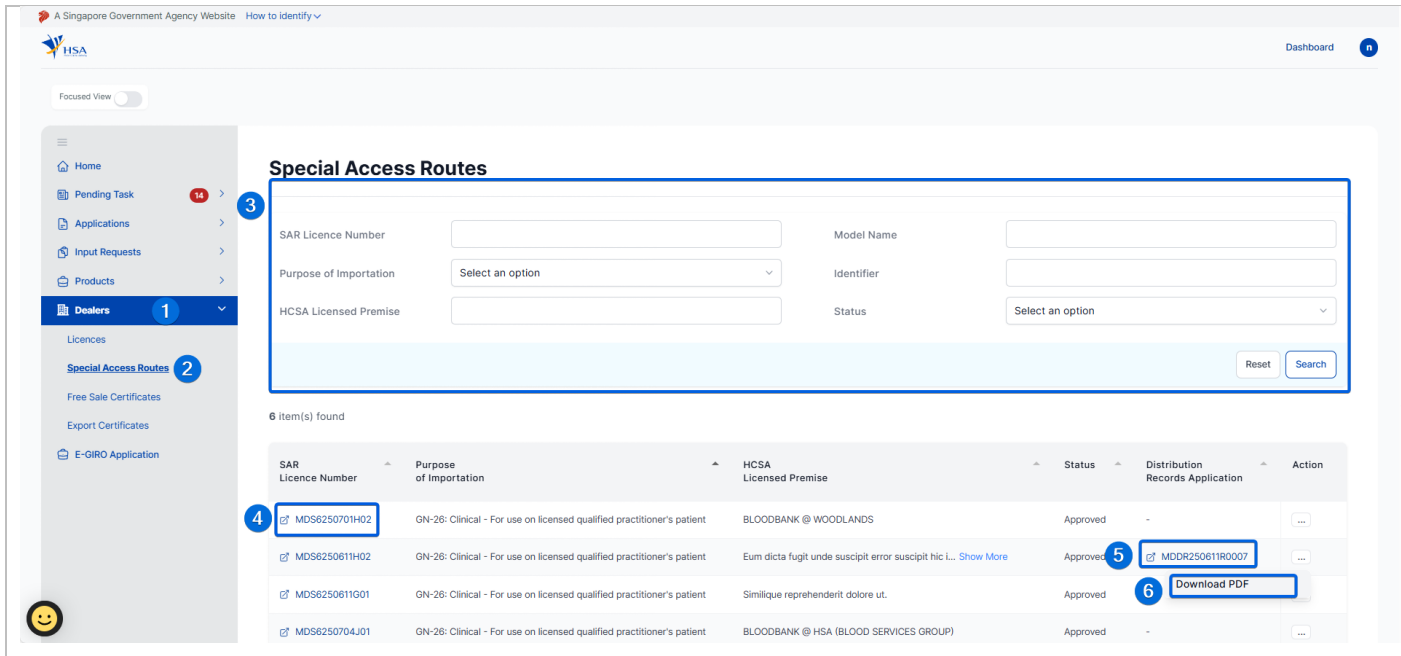
- Licence Number:
- Site Name:
- Licence Type:
- Buttons:

25 item(s) found

Licence Number	Licence Type	Expiry Date	Status	Latest Application	Related Applications	Action
MDML250405Y02	Manufacturer	05-Apr-2026	Approved	MDND250405P0006	MDND250405P0006	Download PDF
MDML250403V01	Manufacturer	22-May-2026	Approved	MDND25040800026	MDND25040800026 MDND25040800023 MDND25040780013	
MDKL250402R02	Importer	05-Apr-2025	Expired	MDND25040800026	MDND250402P0001 MDND25040780013 MDND25040700014 MDND25040800026 MDND25040800003	

- 1) Navigate to 'Dealers'
- 2) Select 'Licences'
- 3) Search for results by entering the required data in the search table and clicking the 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 4) View the details of the licence.
- 5) View the details of latest applications
- 6) View the details of related applications
- 7) Download PDF copy of the licence

4.7.2. Special Access Routes



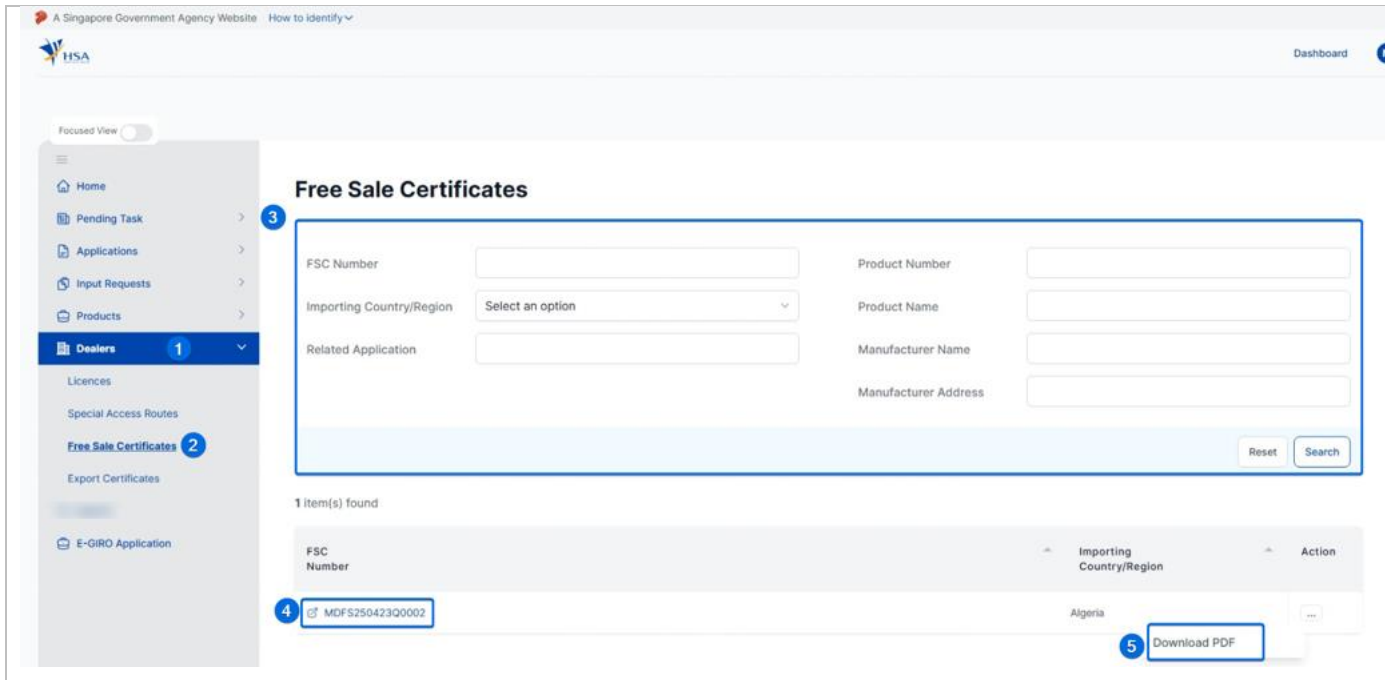
Special Access Routes

6 Item(s) found

SAR Licence Number	Purpose of Importation	HCSA Licensed Premise	Status	Distribution Records Application	Action
MDS6250701H02	GN-26: Clinical - For use on licensed qualified practitioner's patient	BLOODBANK @ WOODLANDS	Approved	-	...
MDS6250611H02	GN-26: Clinical - For use on licensed qualified practitioner's patient	Eum dicta fugit unde suscipit error suscipit hic l... Show More	Approved	MDDR250611R0007	...
MDS6250611G01	GN-26: Clinical - For use on licensed qualified practitioner's patient	Similique reprehenderit dolore ut.	Approved		Download PDF
MDS6250704J01	GN-26: Clinical - For use on licensed qualified practitioner's patient	BLOODBANK @ HSA (BLOOD SERVICES GROUP)	Approved	-	...

- 1) Navigate to 'Dealers'
- 2) Select 'Special Access Routes'
- 3) Search for results by entering the required data in the search table and clicking the 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 4) View the details of application.
- 5) View the Distribution Records Application.
- 6) Download PDF copy of the certificate.

4.7.3. Free Sale Certificates



Free Sale Certificates

FSC Number Product Number

Importing Country/Region Product Name

Related Application Manufacturer Name

Manufacturer Address

1 item(s) found

FSC Number	Importing Country/Region	Action
MDFS250423Q0002	Algeria	Download PDF

- 1) Navigate to 'Products'
- 2) Select 'Free Sale Certificates'
- 3) Search for results by entering the required data in the search table and clicking the 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 4) View the details of application.
- 5) Download PDF copy of the certificate

4.7.4. Export Certificates

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HSA Dashboard

Focused View ☐

Home 12 >

Pending Task 12 >

Applications >

Input Requests >

Products >

Dealers 1 >

Licences

Special Access Routes

Free Sale Certificates

Export Certificates 2

E-GIRO Application

Export Certificates

3

EXC Number

Importing Country/Region

Related Application

Product Owner Name

Product Name

Manufacturer Name

Manufacturer Address

2 item(s) found

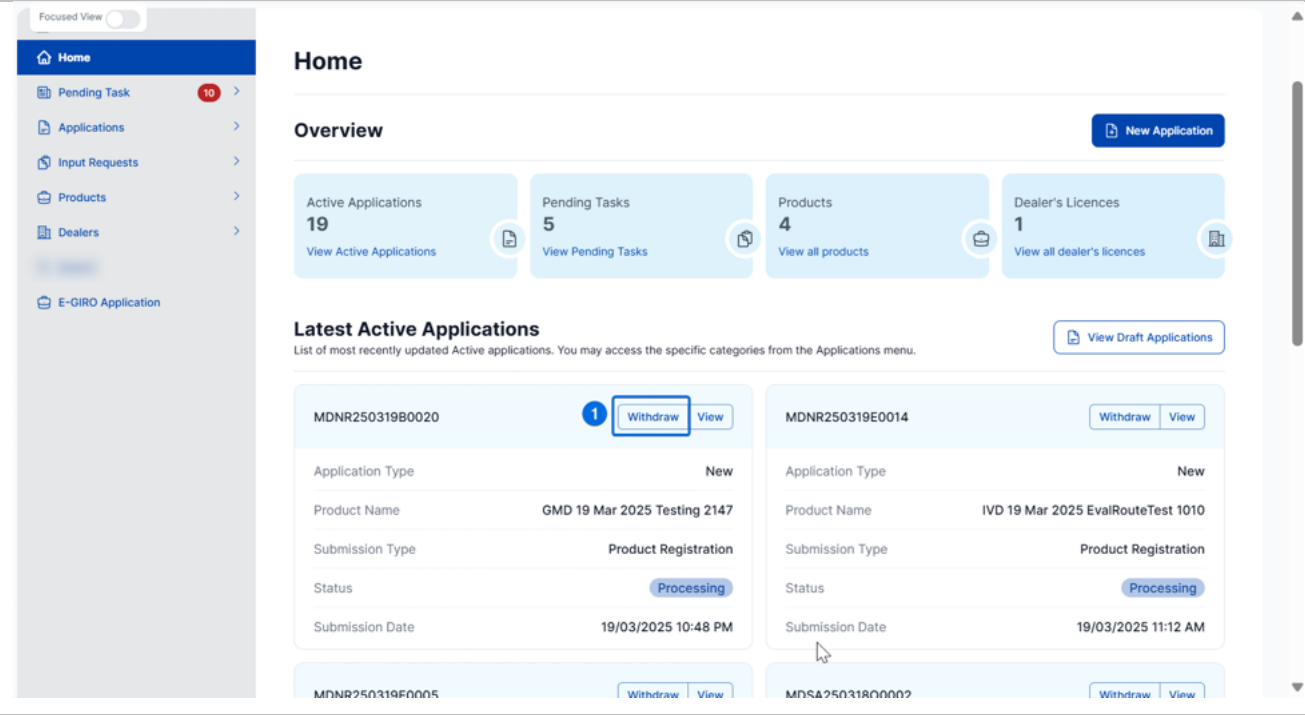
EXC Number	Product Owner Name	Importing Country/Region	Action
4 ☐ MDEX250620T0011	Callie Mertz	Iran	...
☐ MDEX250620S0010	Callie Mertz	Israel	5 Download PDF

- 1) Navigate to 'Dealers'
- 2) Select 'Export Certificates'
- 3) Search for results by entering the required data in the search table and clicking the 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 4) View the details of application.
- 5) Download PDF copy of the certificate

4.8. Withdrawal

Applicants can withdraw the application any time before the closure of the application.

4.8.1. Product Registration



The screenshot shows the HSA SHARE system Home page. The Overview section displays four key metrics: Active Applications (19), Pending Tasks (5), Products (4), and Dealer's Licences (1). Below this, the Latest Active Applications section lists two applications. The first application, MDNR250319B0020, has a 'Withdraw' button highlighted with a red box. The second application, MDNR250319E0014, also has 'Withdraw' and 'View' buttons. The third application, MDNR250319F0005, and the fourth application, MDSA25031800002, also have 'Withdraw' and 'View' buttons.

- 1) Applicants can select the **'Withdraw'** option to withdraw individual device listing from the product registration application

Note: if all products within an application are withdrawn, the entire application is considered withdrawn.

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HSA [Dashboard](#)

Withdraw Application For Product Registration

Focused View ☐

1. Device Listing
2. Submit

You are withdrawing a Product Registration for Medical Devices

Device Listing

Select Devices to Withdraw

Device Name	Device Risk Classification	Medical Specialty Area	Is the device for Professional Use Only?
☒ Accusamus	Class B	General Hospital	Yes

[Cancel](#) [Review Withdrawal](#)

- 2) Applicants have the option to select various products within a given application.
- 3) Applicants will review the withdrawal

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HSA [Dashboard](#)

Withdraw Application For Product Registration

Focused View ☐

1. Device Listing
2. Submit

You are withdrawing a Product Registration for Medical Devices

Submit

Are you sure? Items will be withdrawn instantly.

The devices listed below will be withdrawn instantly without an approval process.

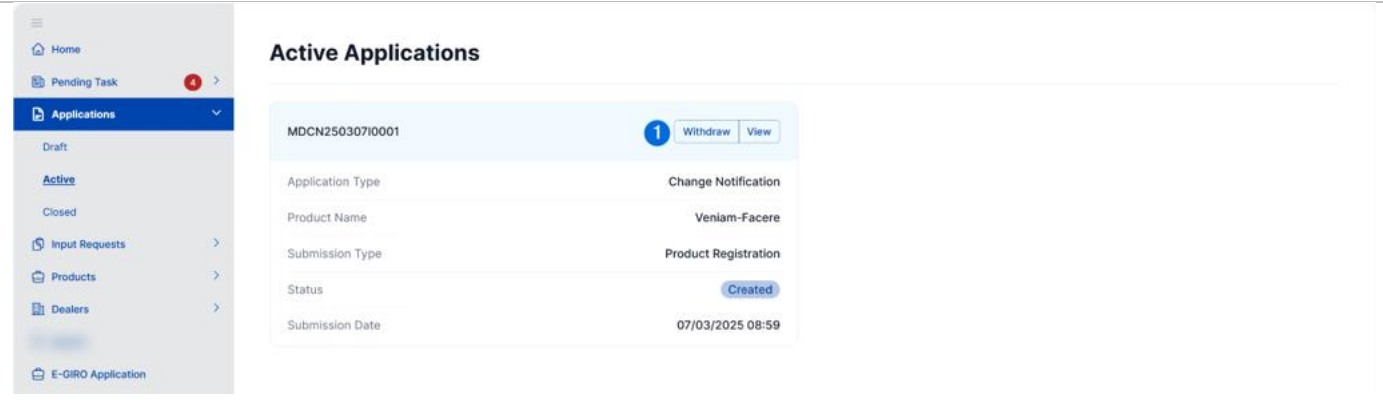
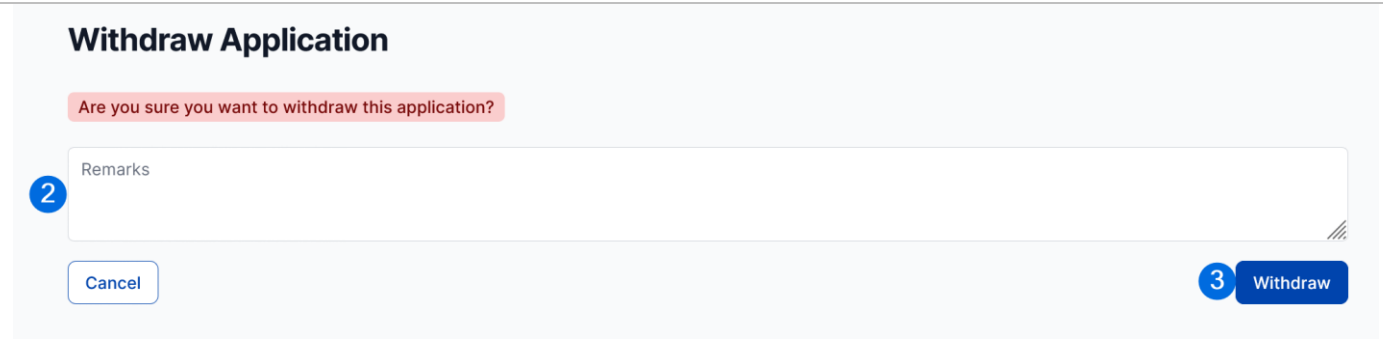
Accusamus

Remarks

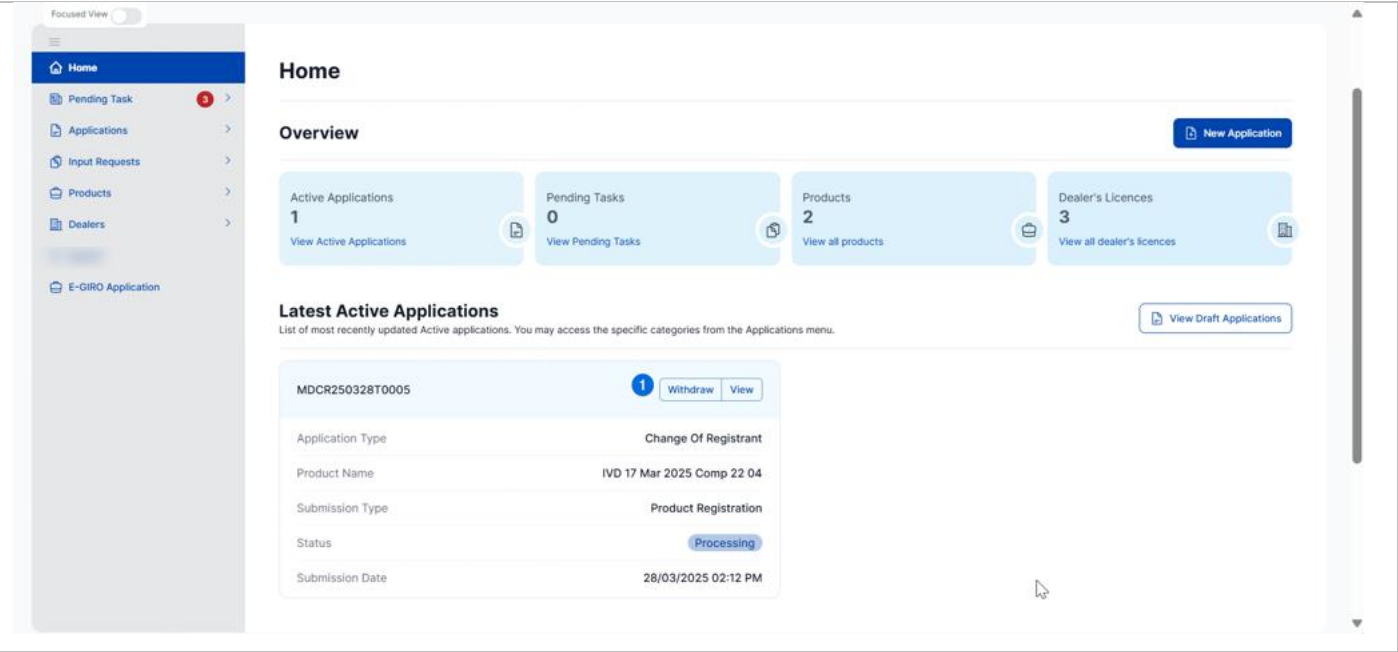
[Back](#) [Confirm Withdrawal](#)

- 4) (Optional) Add remarks
- 5) Applicants need to confirm the required product they want to withdraw.

4.8.2. Change Notification

	1) Applicants can select the ‘Withdraw’ option to withdraw application while the application is pending HSA approval.
	2) (Optional) Add remarks 3) Applicants need to confirm the withdrawal.

4.8.3. Change of Registrant



The screenshot shows the 'Home' page of the HSA SHARE system. On the left is a sidebar with navigation links: Home, Pending Task (with a red notification badge), Applications, Input Requests, Products, Dealers, and E-GIRO Application. The main content area is titled 'Home' and includes an 'Overview' section with four cards: 'Active Applications' (1), 'Pending Tasks' (0), 'Products' (2), and 'Dealer's Licences' (3). Below this is the 'Latest Active Applications' section, which lists a single application with ID 'MDCR250328T0005'. This application is of type 'Change Of Registrant', for product 'IVD 17 Mar 2025 Comp 22 04', with submission type 'Product Registration'. Its status is 'Processing' (indicated by a blue pill) and it was submitted on '28/03/2025 02:12 PM'. Above the application details are 'Withdraw' and 'View' buttons. A 'New Application' button is located in the top right of the Overview section, and a 'View Draft Applications' button is in the top right of the Latest Active Applications section.

- 1) Applicants can select the **'Withdraw'** option to withdraw application while the application is pending HSA approval.

A Singapore Government Agency Website [How to identify](#) Dashboard M

Withdraw Application

Are you sure you want to withdraw this application?

2 Remarks

3

Health Sciences Authority

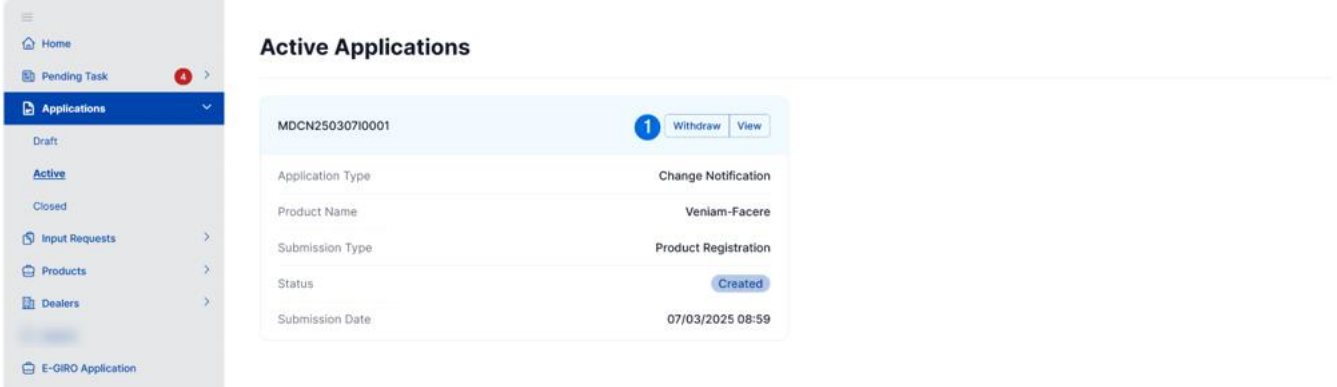
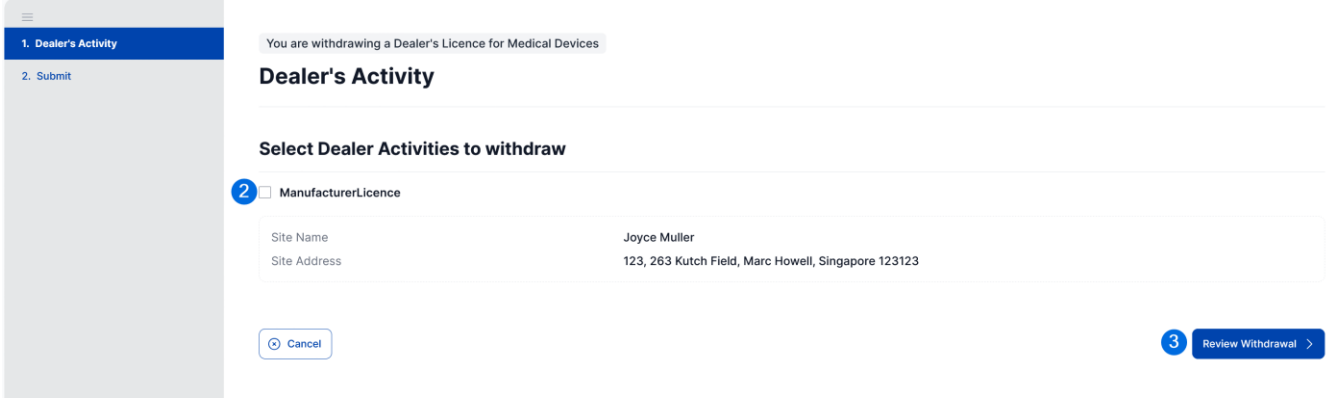
[Who we are](#) [Announcements](#) [Careers](#) [Contact Us](#) [Feedback](#) [Twitter](#) [YouTube](#) [LinkedIn](#)

[Report Vulnerability](#) [Privacy Statement](#) [Terms of Use](#) © 2025 Government of Singapore

[HSA Data Protection](#) [Share your views @REACH](#)

- 2) (Optional) Add remarks
- 3) Applicants need to confirm the withdrawal.

4.8.4. Dealer's Licence (New)

	1) Applicants can select the 'Withdraw' option to withdraw individual dealer activity from the dealer licence application Note: if all dealer activities within an application are withdrawn, the entire application is considered withdrawn.
	2) Applicants have the option to select various dealers within a given application. 3) Applicants will review the withdrawal

1. Dealer's Activity

2. Submit

You are withdrawing a Dealer's Licence for Medical Devices

Submit

Are you sure? Items will be withdrawn instantly.

The dealer activities listed below will be withdrawn instantly without an approval process.

ManufacturerLicence

Remarks

4

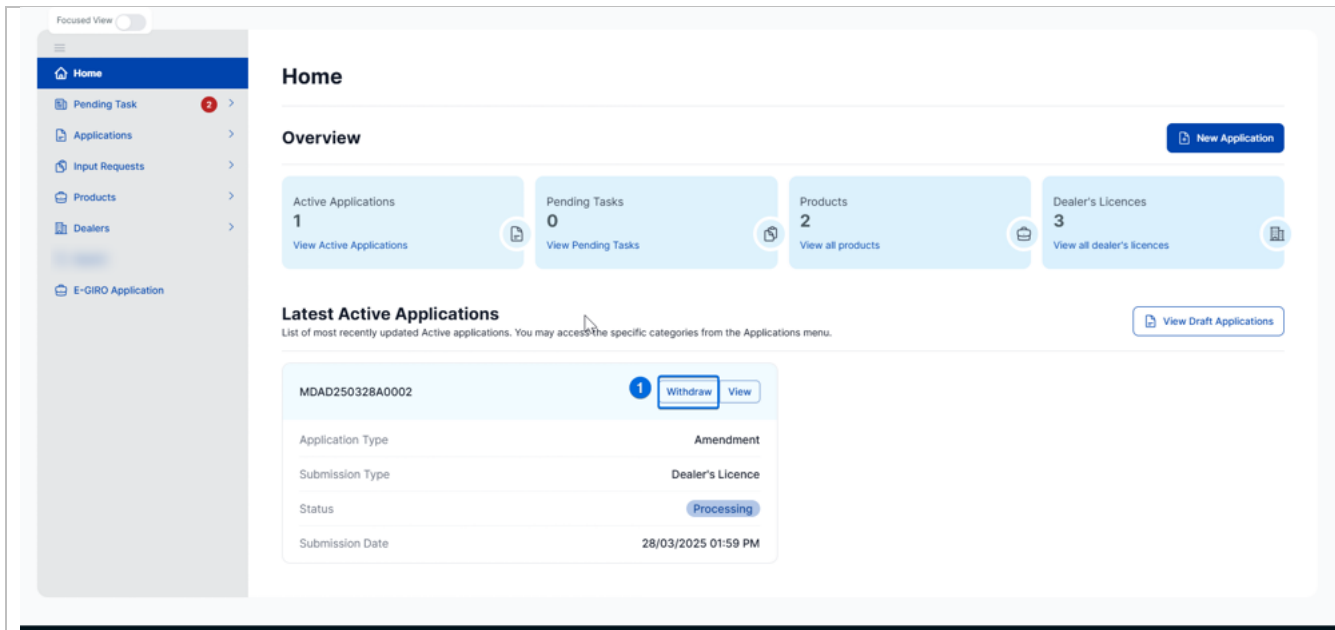
Remarks

< Back

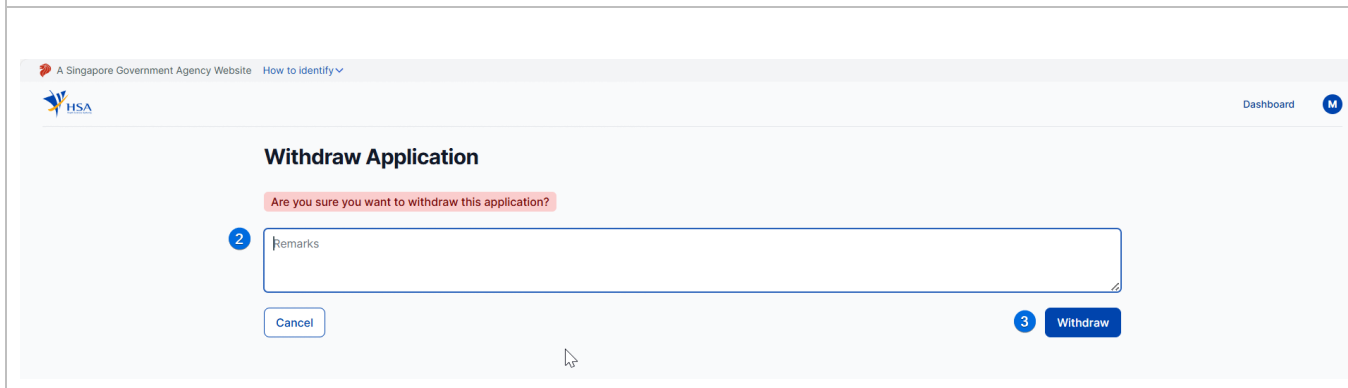
5 Confirm Withdrawal

- 4) (Optional) Add remarks
- 5) Applicants need to confirm the required dealer they want to withdraw.

4.8.5. Dealer's Licence (Amendment)

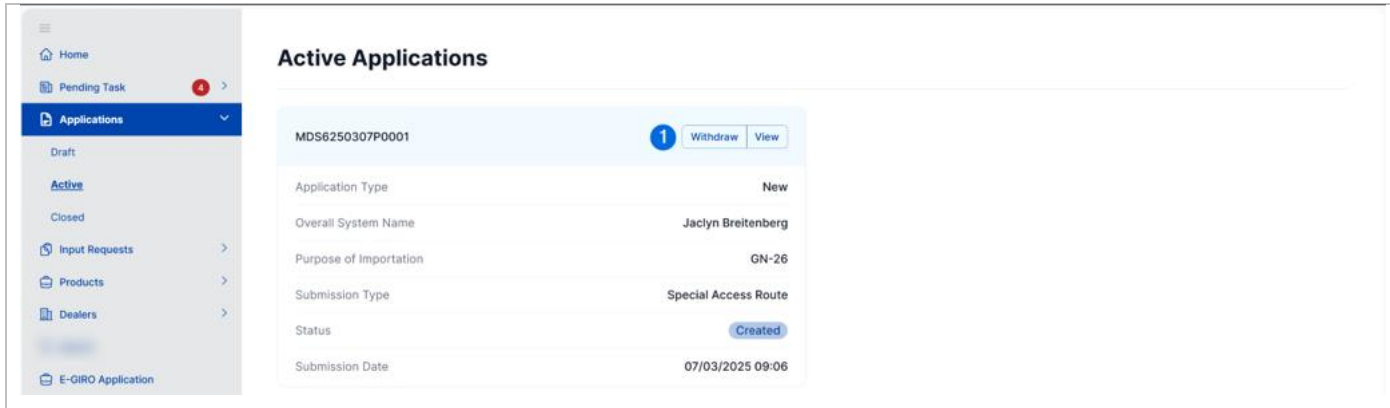
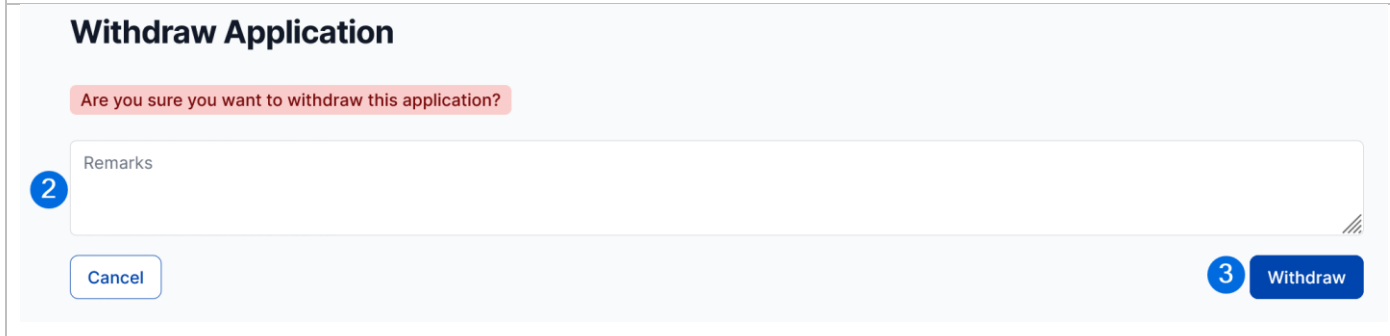


- 1) Applicants can select the **'Withdraw'** option to withdraw application while the application is pending HSA approval.

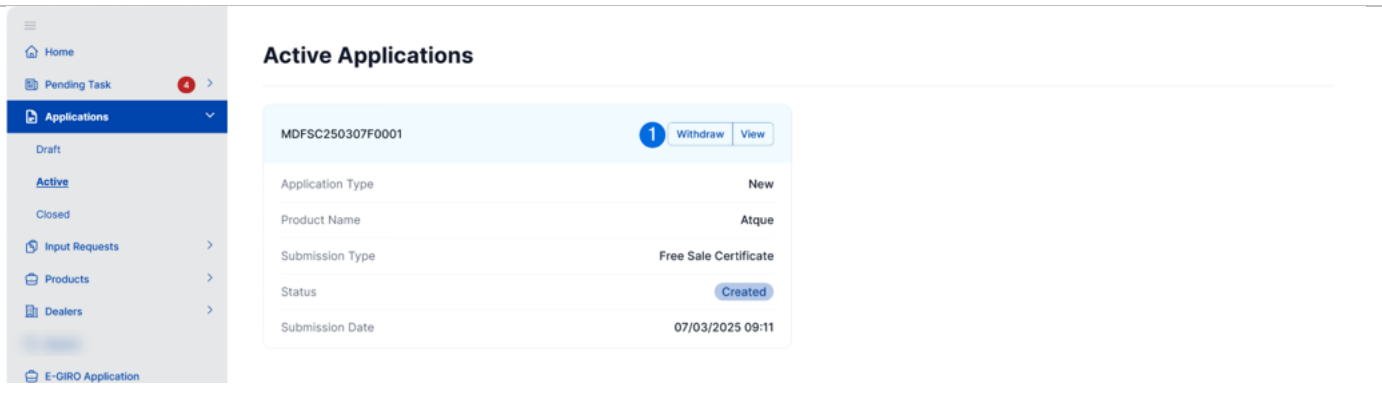
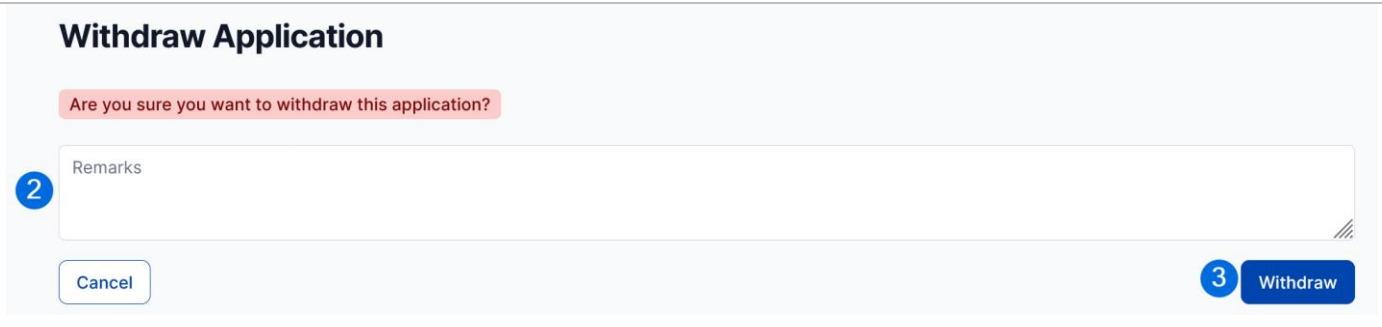


- 2) (Optional) Add remarks
- 3) Applicants need to confirm the withdrawal.

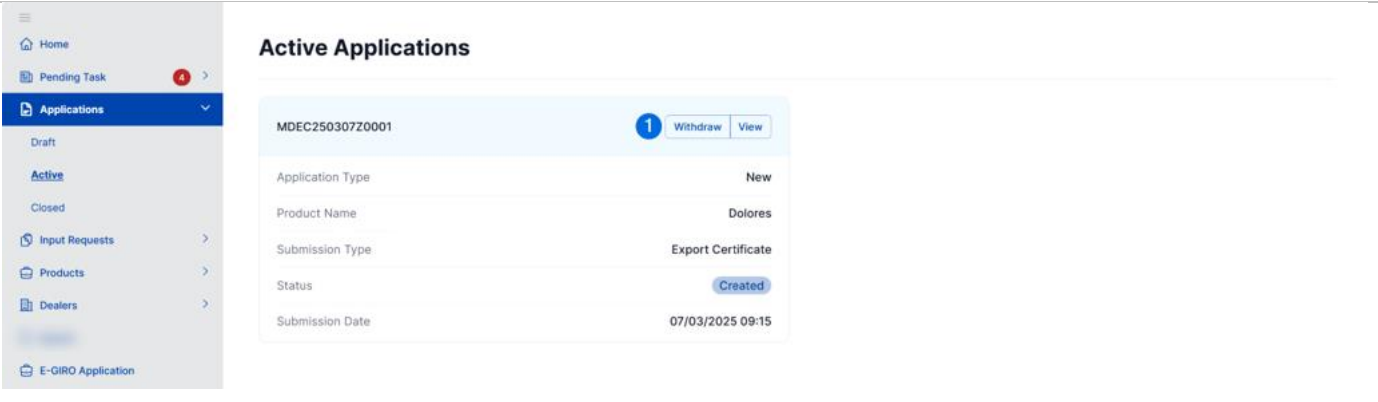
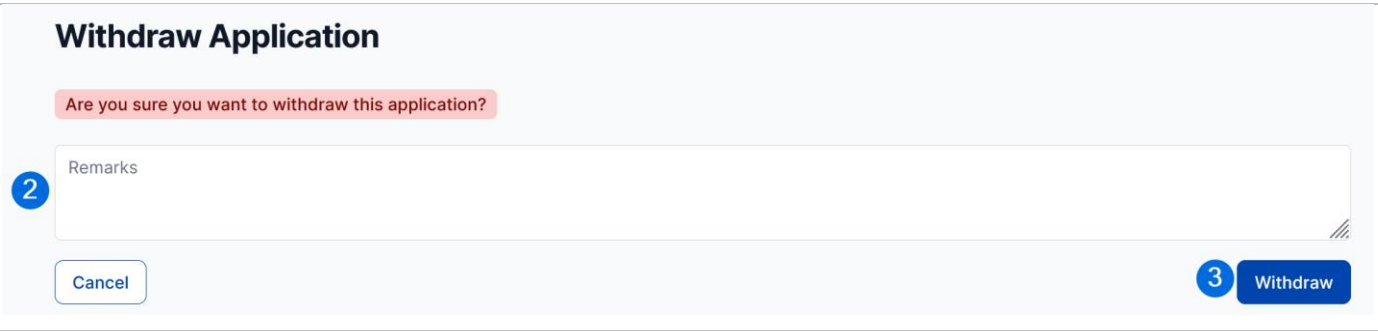
4.8.6. Special Access Route

	1) Applicants can select the 'Withdraw' option to withdraw application while the application is pending HSA approval.
	2) (Optional) Add remarks 3) Applicants need to confirm the withdrawal

4.8.7. Free Sale Certificates

	1) Applicants can select the 'Withdraw' option to withdraw application while the application is pending HSA approval.
	2) (Optional) Add remarks 3) Applicants need to confirm the withdrawal

4.8.8. Export Certificates

	1) Applicants can select the ‘Withdraw’ option to withdraw application while the application is pending HSA approval.
	2) (Optional) Add remarks 3) Applicants need to confirm the withdrawal

4.9.1. Product Notification

1) Create new application

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HSA 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

2 Submission Type

Product Notification

3 Application Type

Cancellation

Cancel this application
and go back to Dashboard

Cancel

Next >

- 2) Select 'Product Notification' from the 'Submission Type' dropdown list
- 3) Select 'Cancellation' from the 'Application Type' dropdown list

A Singapore Government Agency Website
How to identify


Dashboard
F

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 Notification
Application Type	Cancellation



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 the cancellation of previously notified Class A medical devices.

Submission Instructions

This cancellation of product notification application is for a single Importer's/Manufacturer's Licence.
Please submit a separate application if you wish to amend previously notified products under a different licence.

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

Change Product or Submission Type

< Back

4
Create Application

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

4) Create cancellation application

Cancel Application For Product Notification

Focused View

Device Selection

Submit

You are cancelling a Product Notification for Medical Devices

Device Selection

Select Devices to Cancel

5

Notification Number

Product Name

Product Owner Name

Intended Use

Identifier

Reset

Filter

6

	Notification Number	Product Name	Product Owner Name	Intended Use	Identifier	Effective Date
☐	MDPN250630W0003	06 7814 Testing 07	06 7814 Testing 05	06 7814 Testing 08	06 7814 Testing 09	dd/mm/yyyy
☐	MDPN250630U0001	05 7814 Testing 07	05 7814 Testing 05	05 7814 Testing 08	05 7814 Testing 09	dd/mm/yyyy

7

Cancellation Reasons

☐ Quality and/or Safety Issue(s)

☐ Business Decision

☐ Product Discontinued

☐ Others, please specify

Cancel

8

Review Cancellation

- 5) Search for results by entering the required data in the search table and clicking 'Filter' button. If the applicants enter multiple search criteria, the system will apply an 'AND' search to refine the results.
- 6) Applicants can select the device they want to cancel and set the effective date of cancellation
- 7) Select the reason for cancellation
- 8) Review the cancellation form

A Singapore Government Agency Website [How to identify](#)

HSA [Dashboard](#) **F**

Cancel Application For Product Notification

Focused View ☐

1. Device Selection

2. Submit

You are cancelling a Product Notification for Medical Devices

Submit

Are your sure? Items will be cancelled from their chosen effective dates.

The devices listed below will be cancelled.

Id nostrum nihil vel necessitatibus veniam possimus quod nesciunt deserunt.; Cancellation effective on 07 Mar 2025

Cancellation Reasons:
Product Discontinued
Others, please specify:
Dolor necessitatibus voluptates animi nesciunt eligendi.

[Back](#)

9 [Confirm Cancellation](#)

- 9) Applicants need to confirm the device(s) that they would like to cancel

A Singapore Government Agency Website

How to identify

HSA

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Focused View

Home

Pending Task29

Applications

Input Requests

Products

Dealers

E-GIRO Application

Home

Overview

1

New Application

Active Applications107

Pending Tasks29

Products53

Dealer's Licences21

View Active Applications

View Pending Tasks

View all products

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.

MDNL250704V0004

WithdrawView

Application TypeNew

Licence TypeManufacturer

Submission TypeDealer's Licence

StatusProcessing

MDNL250704U0003

WithdrawView

Application TypeNew

Licence TypeImporter

Submission TypeDealer's Licence

StatusPending IR

1) Create new application

1) Create new application

A Singapore Government Agency Website [How to identify](#)

HSA 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 ⓘ

2 Product Registration

Application Type

3 Cancellation

Cancel this application and go back to Dashboard

- 2) Select 'Product Registration' from the 'Submission Type' dropdown list
- 3) Select 'Cancellation' from the 'Application Type' dropdown list

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

4) Create cancellation application

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard

Cancel Application For Product Registration

You are cancelling a Product Registration for Medical Devices

Device Listing

5

Select Devices to Cancel

Approved Device Number Name

Product Owner Name Device Risk Classification

Approved Device Number	Name	Product Owner Name	Intended Use	Device Risk Classification	Effective Date		
6	☒	MDPR250306Z0002	Veniam-Facere	Stiedemann-Ankundung	Consequatur in molestiae quaerat necessitatibus.	Class B	07/03/2025

Reasons for Cancellation

7

☐ Quality and/or Safety Issue(s)

☐ Business Decision

☒ Product Discontinued

☒ Others, please specify

Temporibus mollitia a sint sunt voluptatem.

8

- 5) Search for results by entering the required data in the search table and clicking 'Filter' button. If the applicants enter multiple search criteria, the system will apply an 'AND' search to refine the results.
- 6) Applicants can select the device they want to cancel and set the effective date of cancellation
- 7) Select the reason for cancellation
- 8) Review the cancellation form

A Singapore Government Agency Website [How to identify](#)

HSA [Dashboard](#)

Cancel Application For Product Registration

Focused View ☐

Device Listing

Submit

You are cancelling a Product Registration for Medical Devices

Submit

Are you sure? Items will be cancelled from their chosen effective dates.

The products listed below will be cancelled.

Abbott Alinity i Active-B12 (Holotranscobalamin); Cancellation effective on 26-Sep-2025

Reasons for Cancellation:
Quality and/or Safety Issue(s)

Declaration:

9 ☐ I attest to the possession of records of supply and records of complaints, up to the cancellation date of the medical device listing(s), for the registered medical device(s). I am obliged to maintain these records for the period stipulated in the Health Products (Medical Devices) Regulations and provide such records when requested by the Authority.

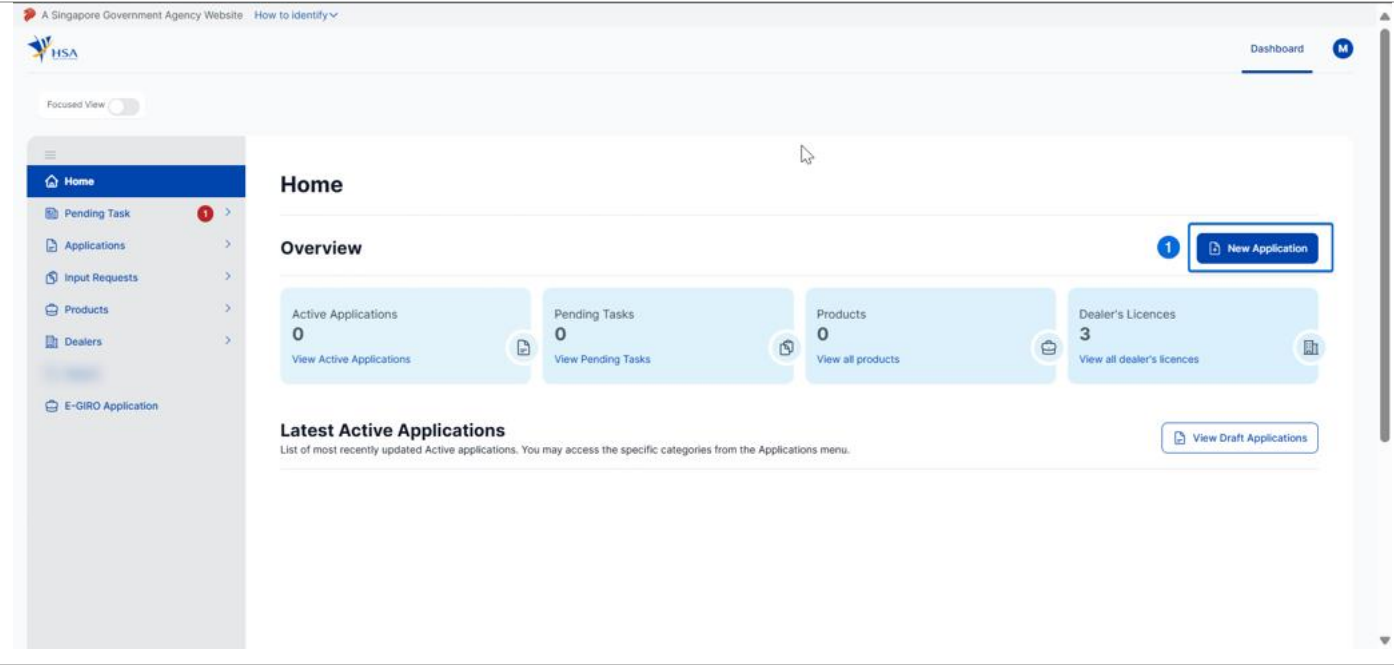
☐ I am no longer registered with Accounting and Corporate Regulatory Authority of Singapore (ACRA) as a business entity. I attest that I have transferred records of supply and records of complaints of the registered medical device(s) to the Product Owner.

[< Back](#)

10 [Confirm Cancellation](#)

- 9) Applicants need to select the appropriate declaration
- 10) Applicants need to confirm the device(s) that they would like to cancel

4.9.3. Dealer’s Licence



1) Create new application

A Singapore Government Agency Website [How to identify](#)

HSA 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

2

Submission Type ⓘ

Dealer's Licence

3

Application Type

Cancellation

Cancel this application and go back to Dashboard

Cancel

Next >

- 2) Select 'Dealer's Licence' from the 'Submission Type' dropdown list
- 3) Select 'Cancellation' from the 'Application Type' dropdown list

Page 64 of 273

4) Create cancellation application

A Singapore Government Agency Website [How to identify](#)

HSA [Dashboard](#)

Cancel Application For Dealer's Licence

Focused View ☐

1. Licence Type
2. Submit

You are cancelling a Dealer's Licence for Medical Devices

Licence Type

Select Dealer Activities to cancel

☒ **Manufacturer | MDML250312U01**

Site Name
Manufacturing Site 1

Effective Date for Cancellation

Please select the effective date of cancellation

☐ **Importer | MDIL250323S01**

Site Name
Site 23 Mar 2025 Valid QMS 1553

☐ **Importer | MDIL250323W05**

Site Name
Site 23 Mar 2025 NonQMS 1601

☐ **Importer | MDIL250318E09**

Site Name
Site 18 Mar 2025 ISO 1939

☐ **Wholesaler | MDWL250318Q07**

Site Name
Site 18 Mar 2025 ISO 1939

☐ **Wholesaler | MDWL250323L06**

Site Name
Site 23 Mar 2025 NonQMS 1601

☐ **Wholesaler | MDWL250323H02**

Site Name
Site 23 Mar 2025 Valid QMS 1553

☐ **Manufacturer | MDML250323Z04**

Site Name
Site 23 Mar 2025 NonQMS 1601

☐ **Manufacturer | MDML250318H08**

Site Name
Site 18 Mar 2025 ISO 1939

- 5) Applicants can select the licences that they want to cancel and set the effective date of cancellation
- 6) Review the cancellation form

A Singapore Government Agency Website

How to identify

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M

Cancel Application For Dealer's Licence

Focused View

1. Licence Type

2. Submit

You are cancelling a Dealer's Licence for Medical Devices

Submit

Are your sure? Items will be cancelled from their chosen effective dates.

The activities listed below will be cancelled.

Manufacturer | MDML250312U01 ; Cancellation effective on 31-Mar-2025

< Back

7 Confirm Cancellation

7) Applicants need to confirm the licence(s) that they would like to cancel

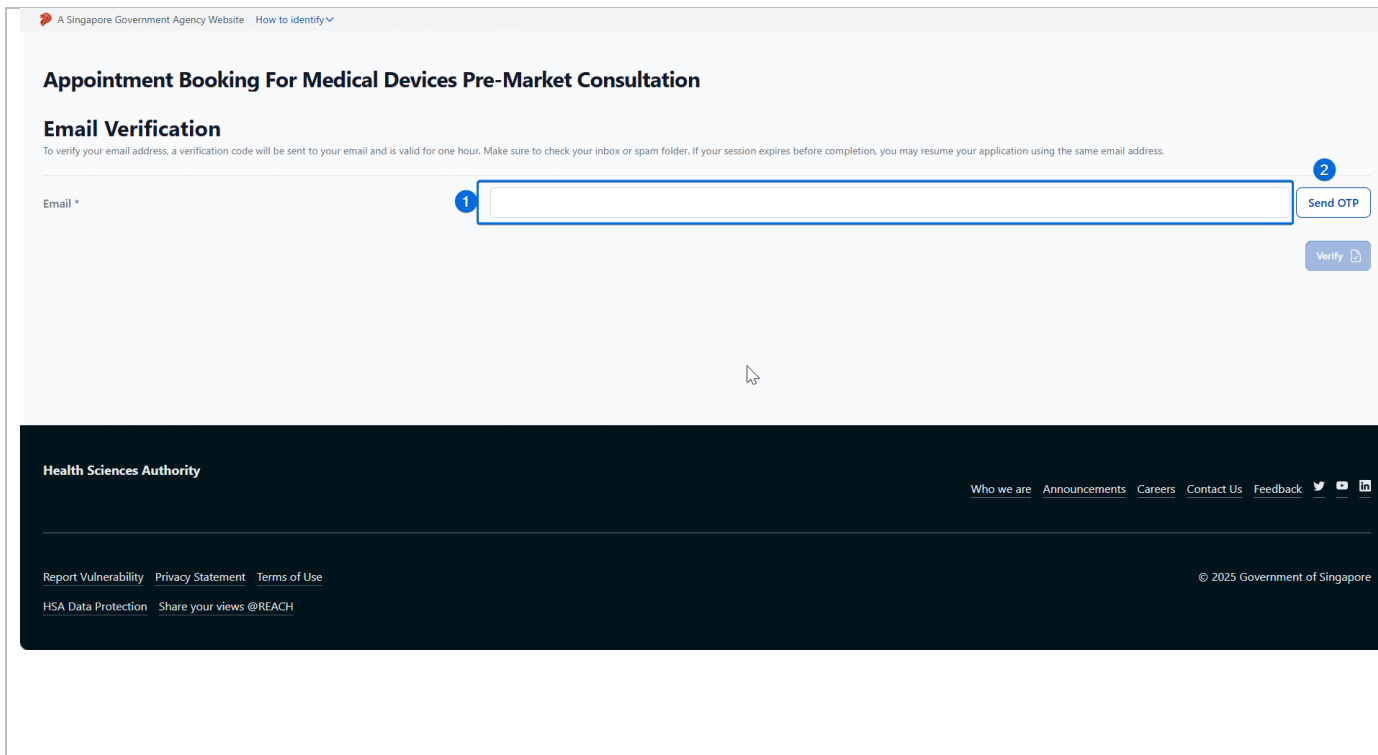
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5. Application Guide

5.1. Appointment Booking

Appointment Booking function allows companies to consult HSA on regulatory requirements during the medical device development or seek feedback on device dossier before submission.

5.1.1. Verification



A Singapore Government Agency Website [How to identify](#)

Appointment Booking For Medical Devices Pre-Market Consultation

Email Verification

To verify your email address, a verification code will be sent to your email and is valid for one hour. Make sure to check your inbox or spam folder. If your session expires before completion, you may resume your application using the same email address.

Email *

1

2 [Send OTP](#)

[Verify](#)

Health Sciences Authority

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[Report Vulnerability](#) [Privacy Statement](#) [Terms of Use](#)

[HSA Data Protection](#) [Share your views @REACH](#)

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URL:

<https://share.hsa.gov.sg/medics/ConsultationAppointment/EmailVerification>

As the system does not require login to access this feature, to ensure secure access, Applicants must verify their email through a 2-factor authentication process.

- 1) Applicants need to type in their email address.
- 2) Applicants can click 'Send OTP'. The OTP must be used within **the validity period of 1 Hour**. However, applicants can **request a new OTP after 10 Minutes**, invalidating the previous OTP. After 1 Hour the OTP expires, the Applicant will need to request a new OTP.

A Singapore Government Agency Website [How to identify](#)

Appointment Booking For Medical Devices Pre-Market Consultation

Email Verification

To verify your email address, a verification code will be sent to your email and is valid for one hour. Make sure to check your inbox or spam folder. If your session expires before completion, you may resume your application using the same email address.

✔ OTP has been sent to your email. ✕

Email *

sarah.li@thesoftwarepractice.com Resend OTP in 09:57

Verification Code *

3

X53-

Verify

Health Sciences Authority

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- 3) Applicants can enter the verification code in their email and then select “Verify”.

5.1.2. Applicant Information

A Singapore Government Agency Website

How to Identify

Appointment Booking For Medical Devices Pre-Market Consultation

Focused View

Applicant Information

Booking Information

Device Information

Supporting Documents

Review

Declaration

Applicant Information

Name *

Contact Number *

+ 65

Email

Applicant email address

Alternative Email *

Purpose of Consultation *

Personal

Business

Company Name *

Postal Code *

Get Address

Block / Number *

Level - Unit

Street Name *

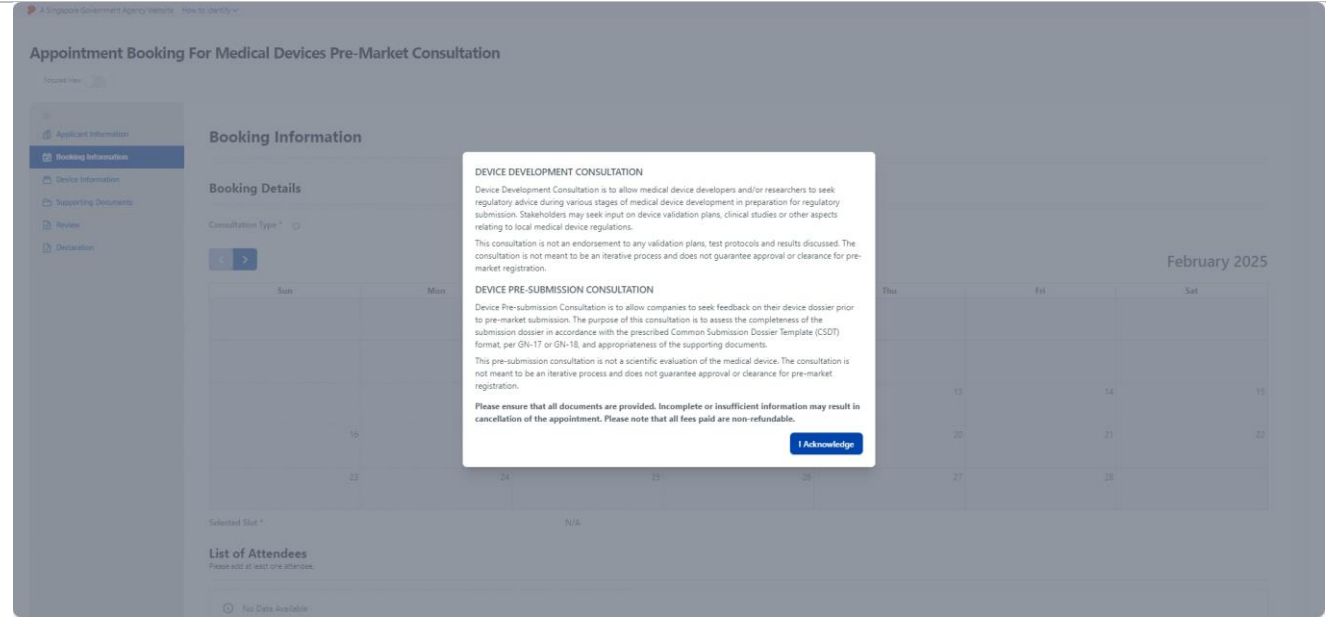
Building Name

Cancel

Booking Information

Applicants need to input applicant information.

5.1.3. Booking Information



Applicants must review and acknowledge the information about the different Consultation Types.

Applicants can understand the purpose of each type and can choose the correct one, as it will affect the fee amount and subsequent activities.

Applicants can choose **consultation type** which should be either 'Device Pre-Submission' or 'Device Development'.

Device Pre-Submission

A Singapore Government Agency Website | How to identify

Appointment Booking For Medical Devices Pre-Market Consultation

Focused View

- Applicant Information
- Booking Information**
- Device Information
- Supporting Documents
- Review
- Declaration

Booking Information

Booking Details

1 Consultation Type * ☐ Device Development ☒ Device Pre-Submission

2

<

>

May 2025

Sun	Mon	Tue	Wed	Thu	Fri	Sat
	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Selected Slot * 15 May 2025, 14:00 SGT

List of Attendees

Please add at least one attendee.

No Data Available

3 Add Attendee

Device Information >

< Back

- 1) Applicants need to choose 'Device Pre-submission' as consultation type.
- 2) Applicants can select from the available time slots which haven't been greyed out.
- 3) Applicants need to fill out at least one attendee's information by selecting 'Add Attendee'.

A Singapore Government Agency Website [How to identify](#)

Appointment Booking For Medical Devices Pre-Market Consultation

Focused View

[Applicant Information](#)

[Booking Information](#)

[Device Information](#)

[Supporting Documents](#)

[Review](#)

[Declaration](#)

Device Information

4

Have you enquired on this medical device previously? *

Device Name *

Device Type * ⓘ

Medical Specialty *

Product Owner Name *

Proposed Risk Classification * ⓘ

Based on Rule *

Proposed Evaluation Route * ⓘ

Proposed Grouping Type * ⓘ

☐ Yes ☐ No

☐ General Medical Device ☐ In-Vitro Diagnostic Device

Select an option

☐ Class B (Low moderate risk)
☐ Class C (Moderate high risk)
☐ Class D (High risk)

☐ Full
☐ Abridged
☐ Expedited
☐ Immediate

☐ Single
☐ Family
☐ System
☐ Test Kit
☐ Cluster
☐ Device Specific (GN-12-2)

[< Back](#)

[Supporting Documents >](#)

4) Applicants need to fill out the device information.

Device Development

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Appointment Booking For Medical Devices Pre-Market Consultation

Focused View

- Applicant Information
- Booking Information**
- Device Information
- Supporting Documents
- Review
- Declaration

Booking Information

Booking Details

1 Consultation Type * ☒ Device Development ☐ Device Pre-Submission

2

May 2025

Sun	Mon	Tue	Wed	Thu	Fri	Sat
	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Selected Slot * 15 May 2025, 14:00 SGT

List of Attendees

Please add at least one attendee.

No Data Available

3 Add Attendee

4 Meeting Agenda

Please tick all applicable topics concerns and provide a 'Brief Summary' of the overall questions & concerns below

Topics *

- ☐ General regulatory requirements in Singapore
- ☐ Regulatory Strategy
- ☐ Risk Classification
- ☐ Product Claims
- ☐ Design Validation
- ☐ Clinical Trials
- ☐ Others

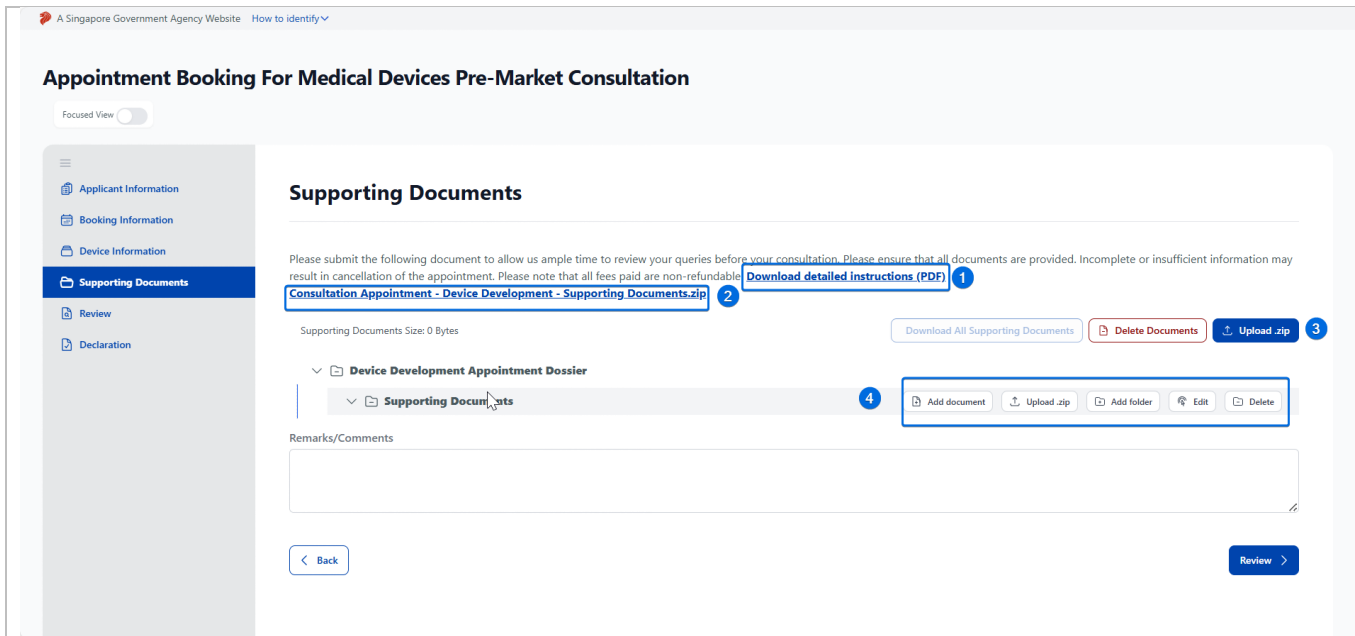
Brief Summary *

< Back Device Information >

- 1) Applicants need to choose 'Device Development' as consultation type.
- 2) Applicants can select from the available time slots which have not been greyed out.
- 3) Applicants need to fill out at least one attendee's information by selecting 'Add Attendee'.
- 4) Applicants must be filled out 'Meeting Agenda' by selecting all applicable topic concerns and providing a brief summary of the meeting agenda.

5) Applicants need to fill out Device Information in this page.

5.1.4. Supporting Documents



- 1) Applicants can download detailed instructions for guidance
- 2) Applicants can download the Dossier Template as a zipped folder
- 3) Applicants can add the necessary files to the relevant folders within the Dossier Template and upload the zip file
- 4) Applicants can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - Add document
 - Upload zip file
 - Add folder
 - Edit folder
 - Delete folder

The system will validate the uploaded documents to ensure they meet the requirements.

Detailed instructions for guidance can be downloaded for further assistance.

5.1.5. Review

A Singapore Government Agency Website

How to identify

Appointment Booking For Medical Devices Pre-Market Consultation

Focused View

- Applicant Information
- Booking Information
- Device Information
- Supporting Documents
- Review**
- Declaration

Review

Applicant Information

Name	Sarah
Contact Number	+65-87878787
Email	sarah
Alternative Email	steph@
Purpose of Consultation	Business
Company Name	Test Company 001
Address	3D, RIVER VALLEY ROAD, CQ @ CLARKE QUAY, Singapore 179023

Booking Details

Consultation Type	Device Development
Appointment Details	15 May 2025, 14:00 SGT

List of Attendees

Name	Company Name	Designation
------	--------------	-------------

Review page displays the summary of all the sections filled before the declaration.

5.1.6. Declaration

A Singapore Government Agency Website

How to identify

Appointment Booking For Medical Devices Pre-Market Consultation

Focused View

Applicant Information

Booking Information

Device Information

Supporting Documents

Review

Declaration

Declaration

☐ I hereby attest that the information provided is accurate, authentic, and complete.

☐ I acknowledge that this Medical Device Development Consultation is not an endorsement to any validation plans, test protocols and results discussed. The consultation does not guarantee approval or clearance for pre-market registration. Discussion and advice provided during the consultation are solely based on the information submitted to the authority prior to this appointment.

Back

Submit

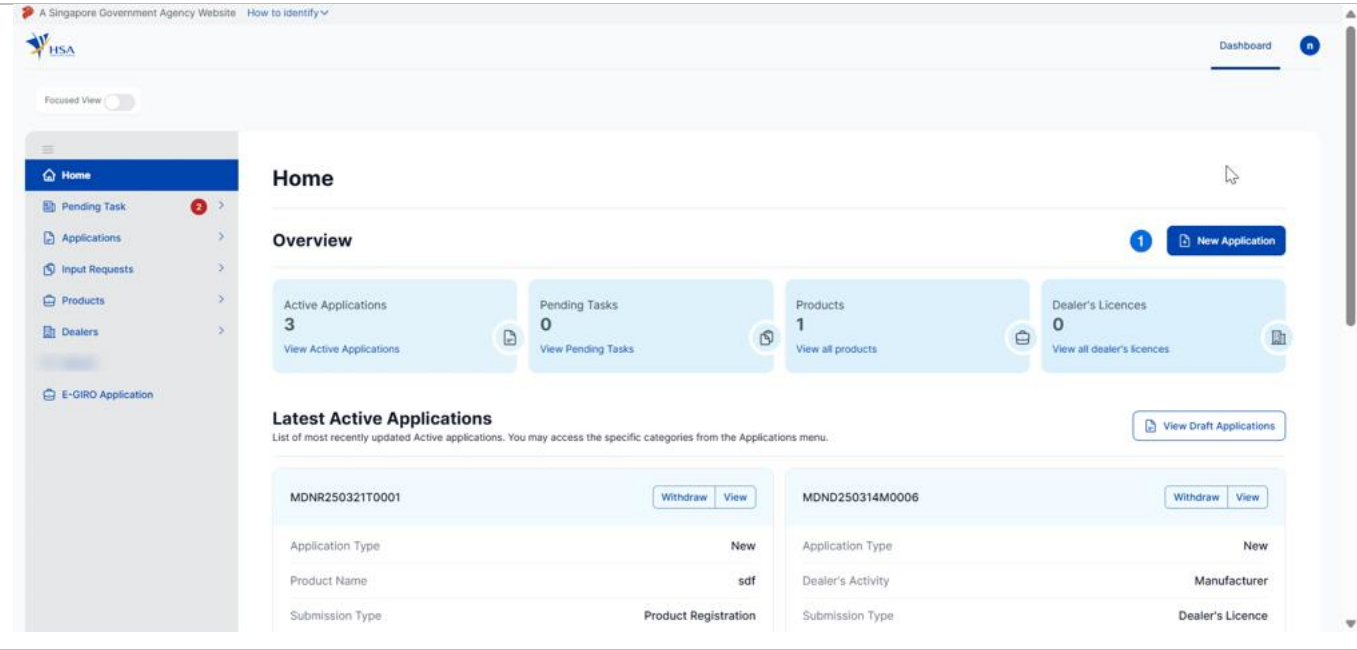
For all appointment booking applications, applicants are required to complete the declaration before submission.

5.2. Dealer’s Licence

Dealer’s Licence(s) are required for companies that intend to manufacture, import or wholesale medical devices in Singapore.

5.2.1. New

5.2.1.1. Getting Started – Details



- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.

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

2 Submission Type Dealer's Licence

3 Application Type New

Dealer's Licence

4 Dealer's Activity

☐ Manufacturer
☐ Importer
☐ Wholesaler

Cancel this application and go back to Dashboard

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Dealer's Licence' from the 'Submission Type' dropdown list
- 3) Applicants can select 'New' from the 'Application Type' dropdown list
- 4) Applicants can select the type of activity they would like to apply for by checking the boxes. Applicants would be able to submit multiple dealer's activities under one application.

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Health Sciences Authority

Dashboard

n

New Application - Getting Started

Focused View

1. Details

2. Checklist

Product Type

Submission Type

Application Type

Dealer's Activity

Medical Devices

Dealer's Licence

New

Manufacturer

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 Dealer Licence for the manufacture, import and wholesale of Medical Devices in Singapore. Please ensure you have the proper supporting documents as per GN-02 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Device e.g. GDPMDS certificate.

Submission Instructions

Please refer to the submission guide for dealers' licences.

View Checklist

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

Change Product or Submission Type

< Back

5

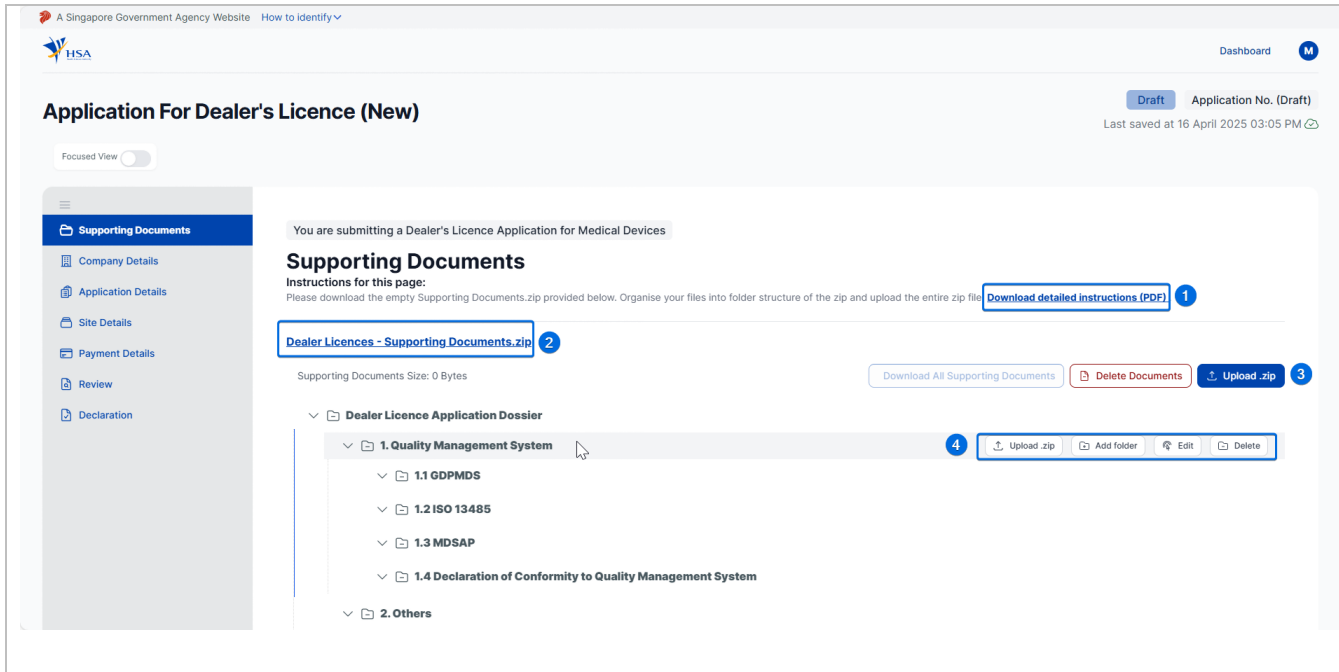
Create Application

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

5) Applicants can create the application.

Note: Once the application is created, applicant would not be able to add or remove dealer’s activity from the application

5.2.1.2. Supporting Documents

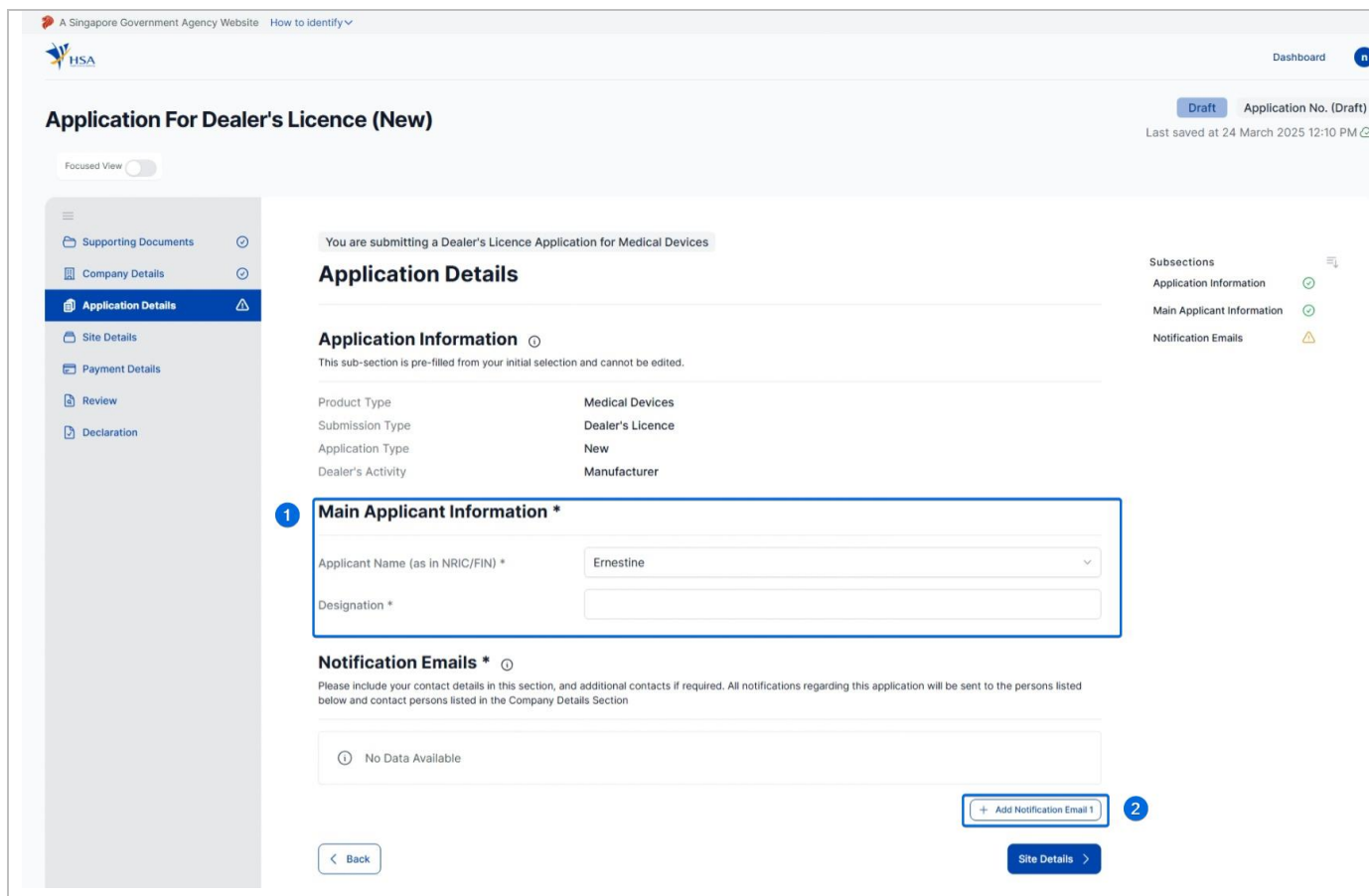


- 1) Applicants can download detailed instructions for guidance
- 2) Applicants can download the Dossier Template as a zipped folder
- 3) Applicants can add the necessary files to the relevant folders within the Dossier Template and upload the zip file
- 4) Applicants can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - Add document
 - Upload zip file
 - Add folder
 - Edit folder
 - Delete folder

- 1) Applicants can click on the company address book, opening a new tab that allows them to

update the company's address book. For more details, please refer to 4.1.1 Address book.

5.2.1.4. Application Details



Main Application Information

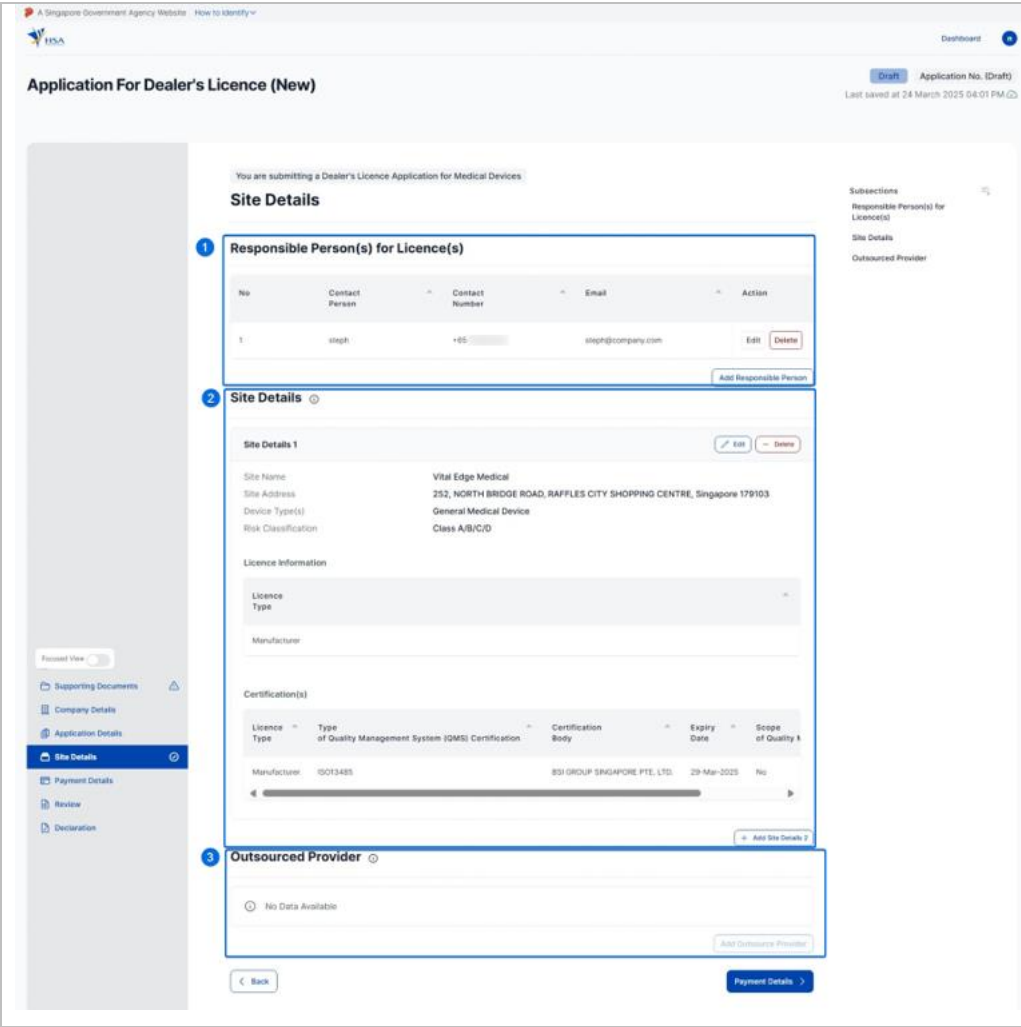
- 1) The **applicant's name** is automatically populated based on the name retrieved from Corppass during login. The **designation field** is to be filled in by the applicant, reflecting their current position within the company.

Notification Emails

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.

- 2) Applicants can update the notification email by selecting 'Add Notification Email'.

5.2.1.5. Site Details



Responsible Person(s) for Licence(s)

- 1) Applicants need to input responsible person(s) for the selected dealer's activity during the application creation process by clicking on '+ Add Responsible Person'.

Site Details

- 2) Applicants need to input site particulars for the selected dealer's activity during the application creation process by clicking on 'Add Site Details'.

Outsourced Provider

- 3) Applicants need to input outsourced provider for the selected dealer's activity during the application creation process by clicking on "Add Outsourced provider" (if applicable).

Add Site Details

A Singapore Government Agency Website [How to identify](#)

HSA

Dashboard

Application For Dealer's Licence (New)

Draft Application No. (Draft)

Focused View

Supporting Documents ☒

Company Details ☒

Application Details ☒

Site Details ☒

Payment Details ☐

Review ☐

Declaration ☐

You are submitting a

Site Details

Responsible Person

No

1

Site Details

No Data Available

Outsourced Person

No Data Available

Add Site Details 1

Site Address

Site Name *

Postal Code *

Block / Number *

Level - Unit -

Street Name *

Building Name

Device Type(s) * ☐ General Medical Device ☐ In-vitro Diagnostic Device (IVD)

Please select all that apply

Risk Classification * ☐ Class A ☐ Class A/B/C/D

Licence Information

Please add all applicable licence types under this site

Licence Type *

Applicants are required to complete all mandatory fields indicated by "*", and subsequently.

- 4) Applicants need to fill in the site address
- 5) Applicants should choose the appropriate Licence Type and click "Add Licence Type".

Application For Dealer's Licence (New)

Focused View

Supporting Documents

Company Details

Application Details

Site Details

Payment Details

Review

Declaration

You are submitting

Site Details

Responsible

1

Site Details

No Data Available

Outsourced

No Data Available

Add Site Details 1

Manufacturer

Delete

6 Certification(s)

Licence Type *

Manufacturer Licence

Quality Management System *

ISO13485

Certification Body *

Select Certification Body

Expiry Date *

dd/mm/yyyy

Scope of Quality Management System *

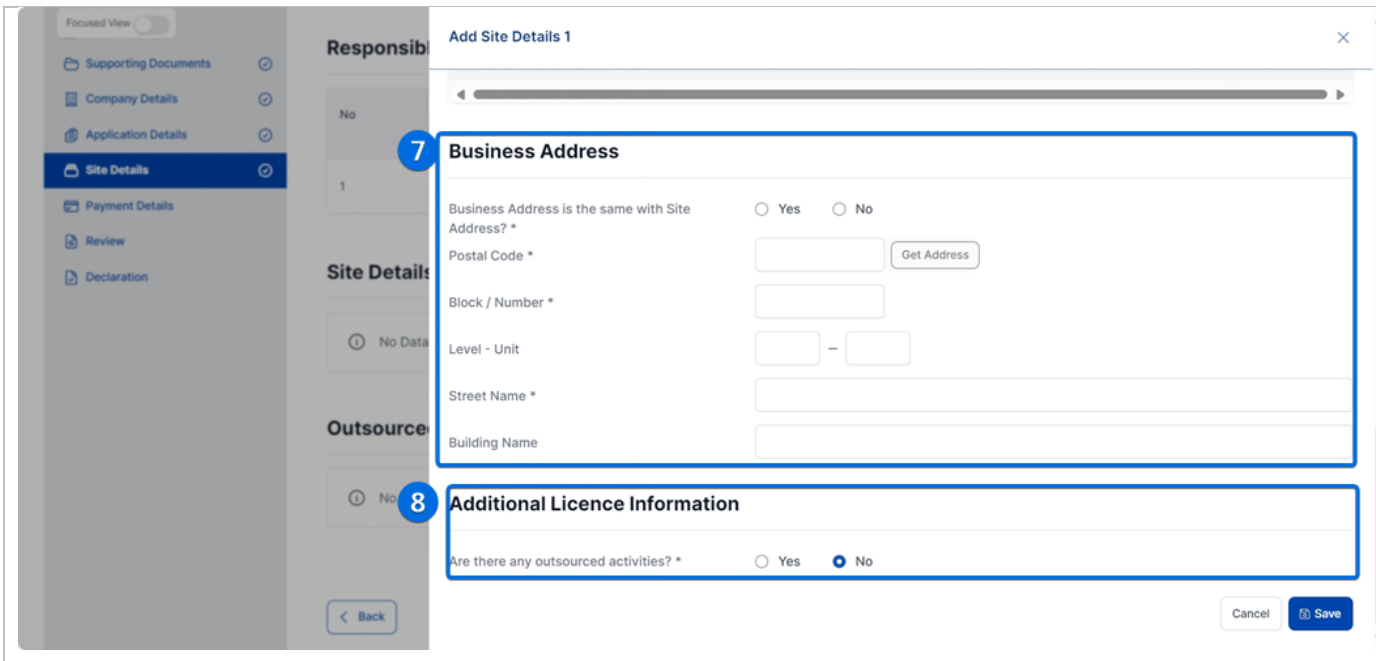
Add Certification

No Data Available

Cancel

Save

- 6) Applicants are required to fill in the Licence information for their site and click “Add Certificate”



Add Site Details 1

7 Business Address

Business Address is the same with Site Address? * ☐ Yes ☐ No

Postal Code *

Block / Number *

Level - Unit -

Street Name *

Building Name

8 Additional Licence Information

Are there any outsourced activities? * ☐ Yes ☒ No

For licence(s) with 'GDPMDs' certification, Applicants are required to provide further details.

- 7) Applicants are required to fill in the Business Address for their site.
- 8) Applicants can indicate if there are any outsourced activities. If it is indicated as 'Yes', the "Add Outsource Provider" button in the Site Details section will be enabled.

5.2.1.6. Payment Details

A Singapore Government Agency Website

How to identify

HSA

Dashboard

Application For Dealer's Licence (New)

Draft

Application No. (Draft)

Last saved at 24 March 2025 12:26 PM

Focused View

Supporting Documents

Company Details

Application Details

Site Details

Payment Details

Review

Declaration

You are submitting a Dealer's Licence Application for Medical Devices

Payment Details

Billing Information *

1

Client Code *

C-00389131

Postal Code

123456

Block / House No.

123

Level / Unit

12 - 12

Street Name

Test13 edit by ishan

Building Name

Test13

Payment Information *

2

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

GIRO

Online

Charge Code	Description	Quantity	Price
MEDAPPMFG	Application Fee for Manufacturer	1	\$1,110.00
Subtotal			\$1,110.00
Tax			\$0.00
Total			\$1,110.00

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 >

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

- 1) Applicants can select the client code from the dropdown list.
- 2) Applicants will have two payment options, GIRO and Online payment. Applicants need to choose the preferred payment mode.

5.2.1.7. Review

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How to identify

HSA

Health Sciences Authority

Dashboard

n

Application For Dealer's Licence (New)

Draft Application No. (Draft)

Last saved at 24 March 2025 12:27 PM

Focused View

Supporting Documents

Company Details

Application Details

Site Details

Payment Details

Review

Declaration

You are submitting a Dealer's Licence Application for Medical Devices

Review

Supporting Documents

Supporting Documents Size: 0 Bytes

Download All Supporting Documents

Dealer Licence Application Dossier

1. Quality Management System

1.1 GDPMDS

1.2 ISO 13485

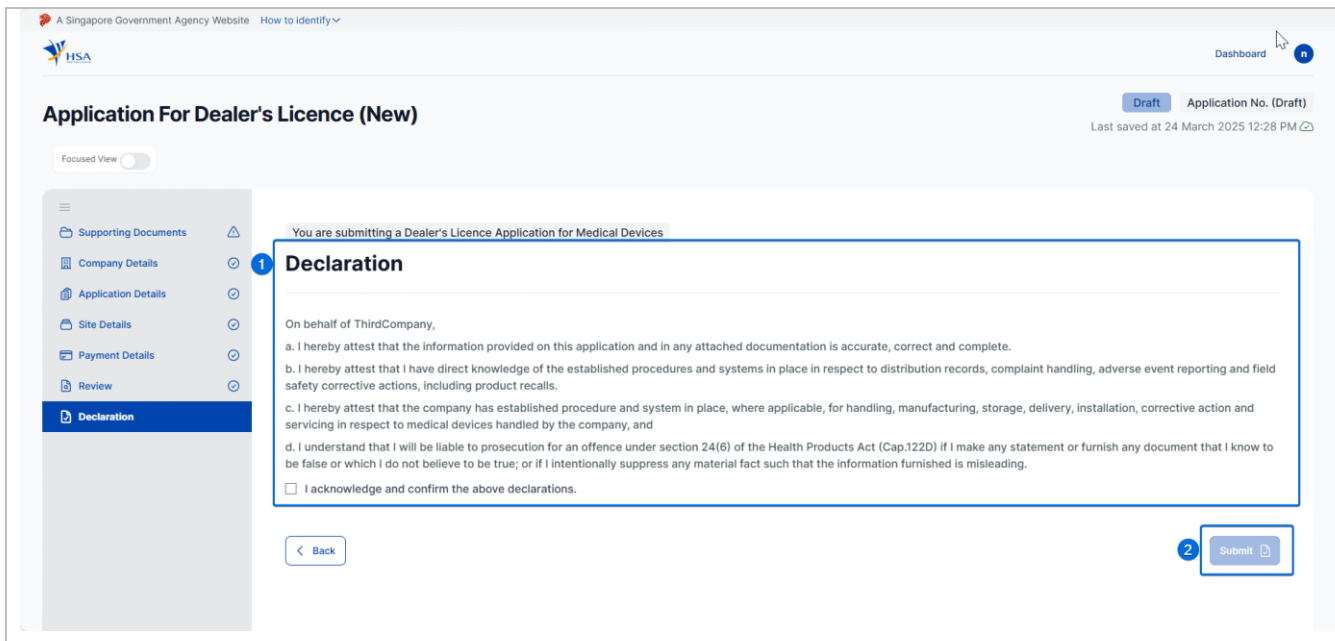
1.3 MDSAP

1.4 Declaration of Conformity to Quality Management System

2. Others

Review page displays the summary of all the sections filled before the declaration.

5.2.1.8. Declaration



A Singapore Government Agency Website How to Identify

HSA Dashboard

Application For Dealer's Licence (New) Draft Application No. (Draft) Last saved at 24 March 2025 12:28 PM

Focused View

Supporting Documents

Company Details

Application Details

Site Details

Payment Details

Review

Declaration

You are submitting a Dealer's Licence Application for Medical Devices

Declaration

On behalf of ThirdCompany,

a. I hereby attest that the information provided on this application and in any attached documentation is accurate, correct and complete.

b. I hereby attest that I have direct knowledge of the established procedures and systems in place in respect to distribution records, complaint handling, adverse event reporting and field safety corrective actions, including product recalls.

c. I hereby attest that the company has established procedure and system in place, where applicable, for handling, manufacturing, storage, delivery, installation, corrective action and servicing in respect to medical devices handled by the company, and

d. I understand that I will be liable to prosecution for an offence under section 24(6) of the Health Products Act (Cap.122D) if I make any statement or furnish any document that I know to be false or which I do not believe to be true; or if I intentionally suppress any material fact such that the information furnished is misleading.

☐ I acknowledge and confirm the above declarations.

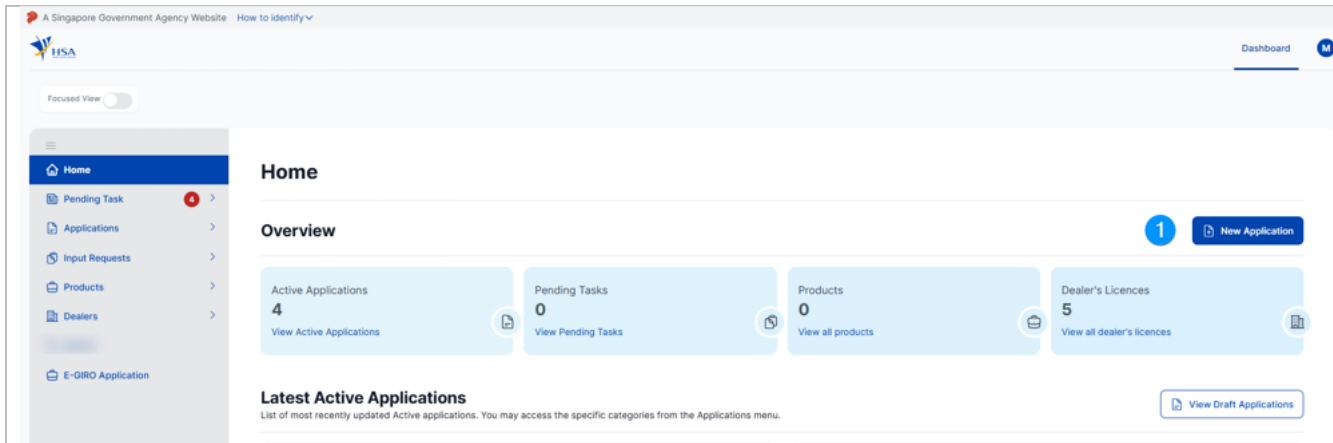
< Back

Submit

- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

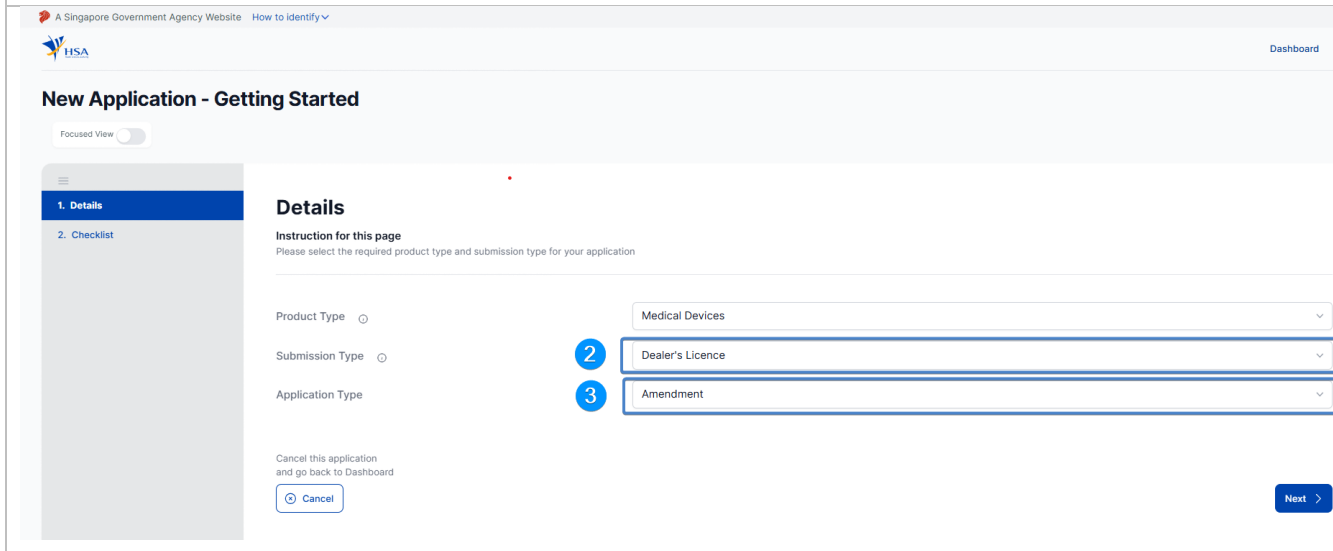
5.2.2. Amendment

5.2.2.1. Getting Started – Details



The screenshot shows the HSA Dashboard. The top navigation bar includes the HSA logo, a user profile icon, and a 'Dashboard' link. A sidebar on the left contains links to Home, Pending Task (with a red notification badge), Applications, Input Requests, Products, Dealers, and E-GIRO Application. The main content area is titled 'Home' and features an 'Overview' section with four cards: 'Active Applications' (4), 'Pending Tasks' (0), 'Products' (0), and 'Dealer's Licences' (5). 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 'View Draft Applications' button.

- 1) Applicants would be able to create a new application by clicking on the “**New Application**” button.



The screenshot shows the 'New Application - Getting Started' page. The top navigation bar includes the HSA logo, a user profile icon, and a 'Dashboard' link. A sidebar on the left contains links to 1. Details and 2. Checklist. The main content area is titled 'Details' and features an 'Instruction for this page' section. Below this is a form with three dropdown menus: 'Product Type' (Medical Devices), 'Submission Type' (Dealer's Licence), and 'Application Type' (Amendment). The 'Submission Type' and 'Application Type' dropdowns are highlighted with blue boxes and numbered 2 and 3 respectively. At the bottom of the form, there is a 'Cancel' button and a 'Next' button.

Applicants can select the type of application they want to submit.

- 2) Applicants can select ‘Dealer’s Licence’ from the ‘Submission Type’ dropdown list
- 3) Applicants can select ‘Amendment’ from the ‘Application Type’ dropdown list

A Singapore Government Agency Website
How to identify


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	Dealer's Licence
Application Type	Amendment



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 Dealer Licence for the manufacture, import and wholesale of Medical Devices in Singapore. Please ensure you have the proper supporting documents as per GN-02 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Device e.g. GDPMS certificate.

Submission Instructions

Please refer to the submission guide for dealers' licences.



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

Change Product or Submission Type

Back

4

Create Application

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

4) Applicants can create the application.

5.2.2.2. Amendment Information

Application For Dealer's Licence (Amendment)

Draft

Application No. (Draft)

Last saved at 25 March 2025 10:37 AM

Focused View

Amendment Information

Supporting Documents

Company Details

Application Details

Licence Details

Payment Details

Review

Declaration

1

☐ Add a new site to existing licence

☐ Amend existing sites

Cancel

Supporting Documents

1) Applicants would be able to choose the type of amendment (Add a new site to existing licence and amend existing sites). Applicants can make these 2 changes in one application.

Application For Dealer's Licence (Amendment)

Draft Application No. (Draft)

Last saved at 25 March 2025 10:48 AM

Amendment Information

Some of the sites cannot be selected because they are already included in an existing Open Dealer's Licence Amendment application

- ☒ Add a new site to existing licence
- ☒ Amend existing sites

Site Selection

Site Name

Device Type

Select device type

Licence Type

Risk Classification

Select licence type

Select risk classification

Licence Number

Reset

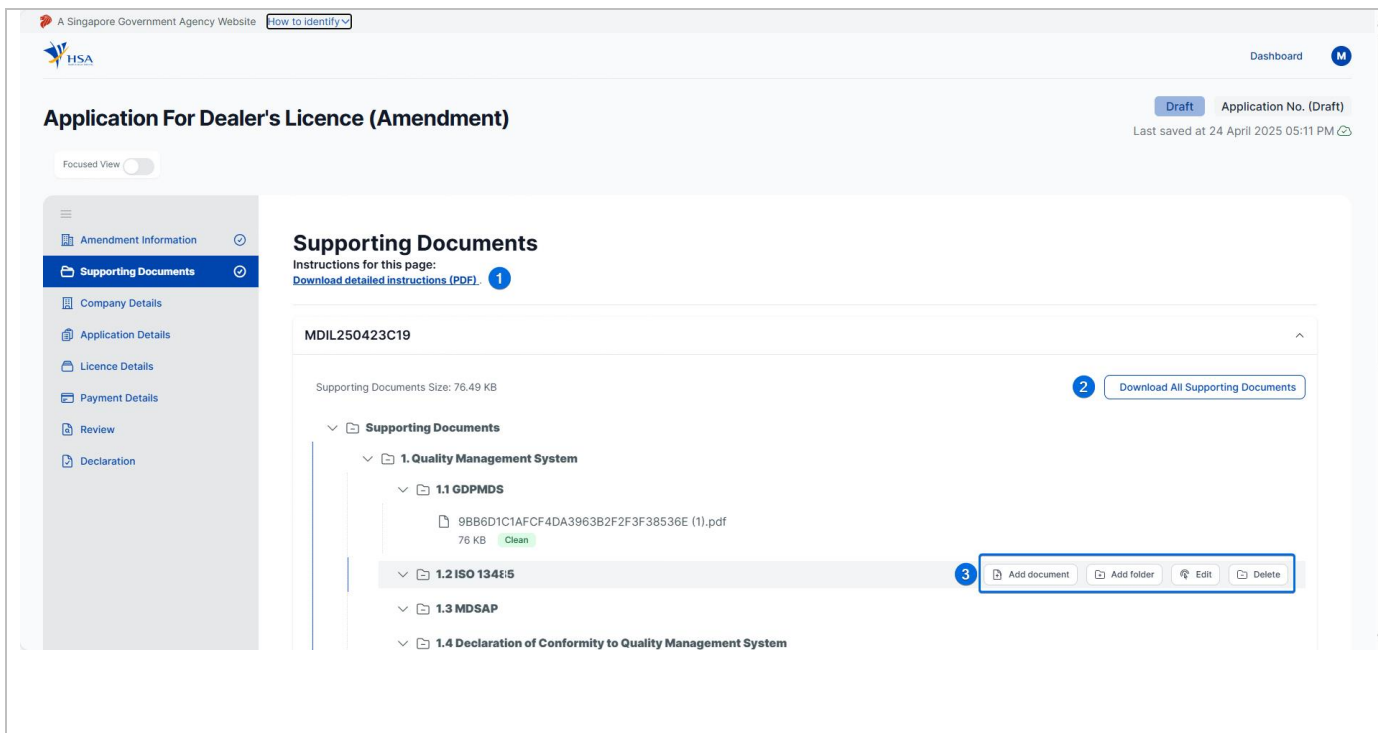
Filter

Site Name	Device Type(s)	Risk Classification	Site Address	Licence Type	Licence Number
☐ Site 18 Feb 2025 WL 1842	In-vitro Diagnostic Device (IVD), General Medical Device	Class A	472A, MACPHERSON ROAD, Singapore 368189	Wholesaler	MDWL250318N04
☒ Site 18 Feb 2025 WL & IL 1843	General Medical Device, In-vitro Diagnostic Device (IVD)	Class A/B/C/D	206, YIO CHU KANG ROAD, Singapore 545652	Importer, Wholesaler	MDIL250318A05, MDWL250318N04
☐ Jurong	In-vitro Diagnostic Device (IVD), General Medical Device	Class A/B/C/D	1, Ave 1, #01-01, Singapore 123456	Wholesaler, Importer	MDWL250319S08, MDIL250319D07

Applicants are required to carry out these steps if “Amend existing sites” is selected.

- 2) Applicants can select their desired sites for amendment though filtering
- 3) Applicants can select sites that they want to amend though checkboxes. Applicants can only choose sites that are not currently included in another open Dealer's Licence Amendment application.

5.2.2.3. Supporting Documents



The screenshot displays the 'Supporting Documents' page for an 'Application For Dealer's Licence (Amendment)'. The page includes a sidebar with navigation links: Amendment Information, Supporting Documents (selected), Company Details, Application Details, Licence Details, Payment Details, Review, and Declaration. The main content area shows a document tree for application MDIL250423C19. The tree structure is as follows:

- Supporting Documents (Size: 76.49 KB)
 - 1. Quality Management System
 - 1.1 GDPMDS
 - 9BB6D1C1AFCF4DA3963B2F2F3F38536E (1).pdf (76 KB, Clean)
 - 1.2 ISO 13485
 - 1.3 MDSAP
 - 1.4 Declaration of Conformity to Quality Management System

Annotations on the screenshot:

- 1: Download detailed instructions (PDF)
- 2: Download All Supporting Documents
- 3: Add document, Add folder, Edit, Delete

This page will show the related licence supporting documents. Applicants can download the supporting document, and they can also add more supporting documents if needed.

- 1) Applicants can download detailed instructions for guidance
- 2) Applicants can download the submitted supporting documents
- 3) Applicants can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - a. Add document
 - b. Upload zip file
 - c. Add folder
 - d. Edit folder
 - e. Delete folder

5.2.2.4. Company Details

Application For Dealer's Licence (Amendment)

Draft

Application No. (Draft)

Last saved at 25 March 2025 10:52 AM

Focused View

Amendment Information

Supporting Documents

Company Details

Application Details

Licence Details

Payment Details

Review

Declaration

Company Details

Company Information

This sub-section is pre-filled from your login and requires no action on your part.

Company Name

MD UAT Company 09

UEN

MDUATCompany09UEN

Company Address *

Clear ACRA Address

Postal Code *

98946

Block / Number *

114

Level - Unit

19 - 6

Street Name *

TANJONG BEACH WALK

Building Name

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	MD UAT Company 09 CP	+65-	

Subsections

Company Information

Company Address

Contact Information

< Back

Application Details >

Applicants can navigate to other sections within the application form by clicking the section name on the left panel.

Company Information

This information is **auto populated based on the Corppass login**. Applicants cannot edit any of the information for this section

Company Address

This field is automatically populated based on the ACRA address. However, applicants can clear the pre-filled address and manually enter it if needed.

Do note that changing the address field in the application form **does not change/update any address in ACRA.*

Contact Information

The contact Information refers to a global list of company's default contact details that would be notified for all Applications within the Company.

1) Applicants can click on the company address book, opening a new tab that allows them to

Page 98 of 273

update the company's address book. For more details, please refer to 4.1.1 Address book.

5.2.2.5. Application Details

Focused View ☐

Amendment Information

Supporting Documents

Company Details

Application Details

Licence Details

Payment Details

Review

Declaration

Application Details

Application Information ⓘ

This sub-section is pre-filled from your initial selection and cannot be edited.

Product Type	Medical Devices
Submission Type	Dealer's Licence
Application Type	Amendment

Main Applicant Information *

1

Applicant Name (as in NRIC/FIN) *

MD UAT Company 09 User 01

Designation *

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

ⓘ No Data Available

2

+ Add Notification Email 1

< Back

Licence Details >

Main Application Information

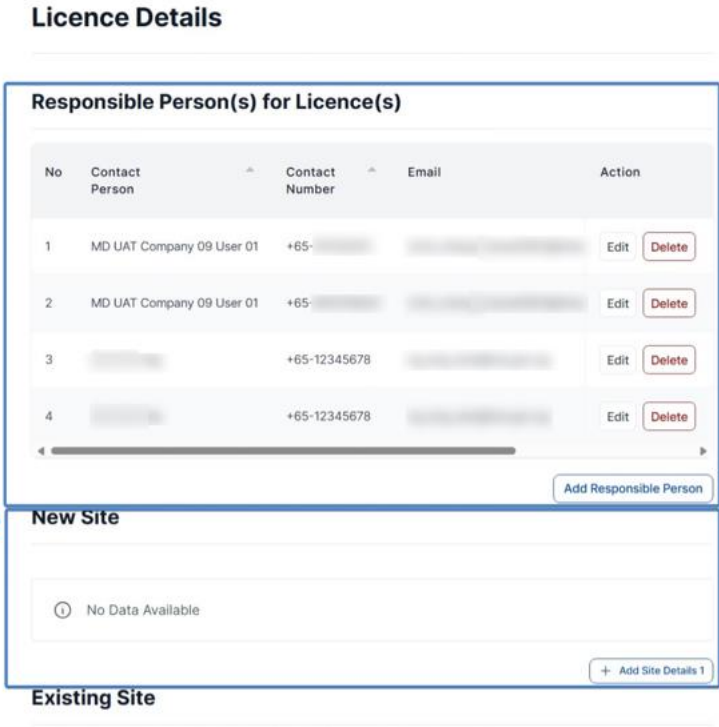
- The **applicant's name** is automatically populated based on the name retrieved from Corppass during login. The **designation field** is to be filled in by the applicant, reflecting their current position within the company.

Notification Emails

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.

- Applicants can update the notification email by selecting "**Add Notification Email.**"

5.2.2.6. Licence Details



Licence Details

1 Responsible Person(s) for Licence(s)

No	Contact Person	Contact Number	Email	Action
1	MD UAT Company 09 User 01	+65-12345678	[Redacted]	Edit Delete
2	MD UAT Company 09 User 01	+65-12345678	[Redacted]	Edit Delete
3	[Redacted]	+65-12345678	[Redacted]	Edit Delete
4	[Redacted]	+65-12345678	[Redacted]	Edit Delete

2 New Site

No Data Available

Existing Site

Subsections

- Responsible Person(s) for Licence(s)
- New Site
- Existing Site
- Outsourced Provider

Responsible Person(s) for Licence(s)

1) Applicants can do the following:

- Input responsible person(s) for the selected dealer's activity during the application creation process by clicking on '+ Add Responsible Person'
- Edit existing responsible person(s) by clicking on 'Edit'
- Delete existing responsible person(s) by clicking on 'Delete'

Add Site

If Applicants have chosen "Add a new site to existing licence" in "Amendment Information" section:

2) Applicants need to input site particulars and tag it to existing licence(s) during the application creation process by clicking on 'Add Site Details'. Please refer to Section 6.2.1.5 for detailed instruction of adding new site.

Existing Site

3) Applicants can amend existing sites if they have chosen "Amend

3

Existing Site

Site Details 1 Edit

Site Name: Jurong

Site Address: 1, Ave 1, #01-01, Singapore 123456

Device Type(s): In-vitro Diagnostic Device (IVD), General Medical Device

Risk Classification: Class A/B/C/D

Licence Information

Licence Type

(MDWL250319S08) Wholesaler

(MDIL250319D07) Importer

Certification(s)

Licence Type	Type of Quality Management System (QMS) Certification	Certification Body
(MDWL250319S08) Wholesaler	GDPMDS - Secondary Assembly - Cold-chain Management	A-EUROF
(MDIL250319D07) Importer	GDPMDS - Secondary Assembly - Cold-chain Management	A-EUROF

Additional Information

This is additional information required for the GDPMDS QMS and will be applied to all licence types that incorporate it.

Business Address: 1, Ave 1, #01-01, Singapore 123456

Are there any outsourced activities? Yes

4

Outsourced Provider

No	Outsource Provider Company Name	Outsourced Activity	Add	Action
1	K&N	Distribution, Storage, Secondary Assembly	3, A	Edit Delete

Back Payment Details

existing sites” in “Amendment Information” section.

Outsourced Provider

For licence(s) with ‘GDPMDS’ certification, Applicants are required to provide further details.

4) Applicants can do the following:

- Input outsourced provider for the selected dealer's activity during the application creation process by clicking on “Add Outsourced provider”.
- Edit existing outsourced provider by clicking “Edit”
- Delete existing outsourced provider by clicking “Delete”

5.2.2.7. Payment Details

Focused View ☐

Amendment Information

Supporting Documents

Company Details

Application Details

Licence Details

Payment Details

Review

Declaration

Payment Details

Subsections

Billing Information

Payment Information

Billing Information *

Client Code *

WC-541209

Postal Code

257784

Block / House No.

82

Level / Unit

-

Street Name

TAMAN NAKHODA

Building Name

VILLA DELLE ROSE

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
	Subtotal		\$0.00
	Tax		\$0.00
	Total		\$0.00

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

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

- Applicants can select the client code from the dropdown list
- Applicants will have two payment options, GIRO and Online payment. Applicants need to choose the preferred payment mode.

5.2.2.8. Review

Application For Dealer's Licence (Amendment)

Draft
Application No. (Draft)

Last saved at 25 March 2025 02:54 PM

Focused View

- Amendment Information
- Supporting Documents
- Company Details
- Application Details
- Licence Details
- Payment Details
- Review**
- Declaration

Review

Amendment Information

☒ Add a new site to existing licence
☒ Amend existing sites

Site Name	Device Type(s)	Risk Classification	Site Address	Licence Type
Jurong	In-vitro Diagnostic Device (IVD), General Medical Device	Class A/B/C/D	1, Ave 1, #01-01, Singapore 123456	

Review page displays the summary of all the sections filled before the declaration. For Dealer's Licence Amendment in particular, the Review page also show before and after view of the amended sections.

Page 103 of 273

Existing Site

Previous Values

Current Value

Site Details 1

Site Name

Site Address

Device Type(s)

Risk Classification

Licence Information

Licence Type

Licence Number

Certification(s)

Licence Type

Licence Number

Type of Quality Management System (QMS) Certification

Certification Body

Expiry Date

Scope of Quality Management System

Site Details 1

Site Name

Site Address

Device Type(s)

Risk Classification

Licence Information

Licence Type

Licence Number

Certification(s)

Licence Type

Licence Number

Type of Quality Management System (QMS) Certification

Certification Body

Expiry Date

Scope of Quality Management System

5.2.2.9. Declaration

Amendment Information

Supporting Documents

Company Details

Application Details

Licence Details

Payment Details

Review

Declaration

1

Declaration

On behalf of MD UAT Company 09,

a. I hereby attest that the information provided on this application and in any attached documentation is accurate, correct and complete.

b. I hereby attest that I have direct knowledge of the established procedures and systems in place in respect to distribution records, complaint handling, adverse event reporting and field safety corrective actions, including product recalls.

c. I hereby attest that the company has established procedure and system in place, where applicable, for handling, manufacturing, storage, delivery, installation, corrective action and servicing in respect to medical devices handled by the company, and

d. I understand that I will be liable to prosecution for an offence under section 24(6) of the Health Products Act (Cap.122D) if I make any statement or furnish any document that I know to be false or which I do not believe to be true; or if I intentionally suppress any material fact such that the information furnished is misleading.

☐ I acknowledge and confirm the above declarations.

2

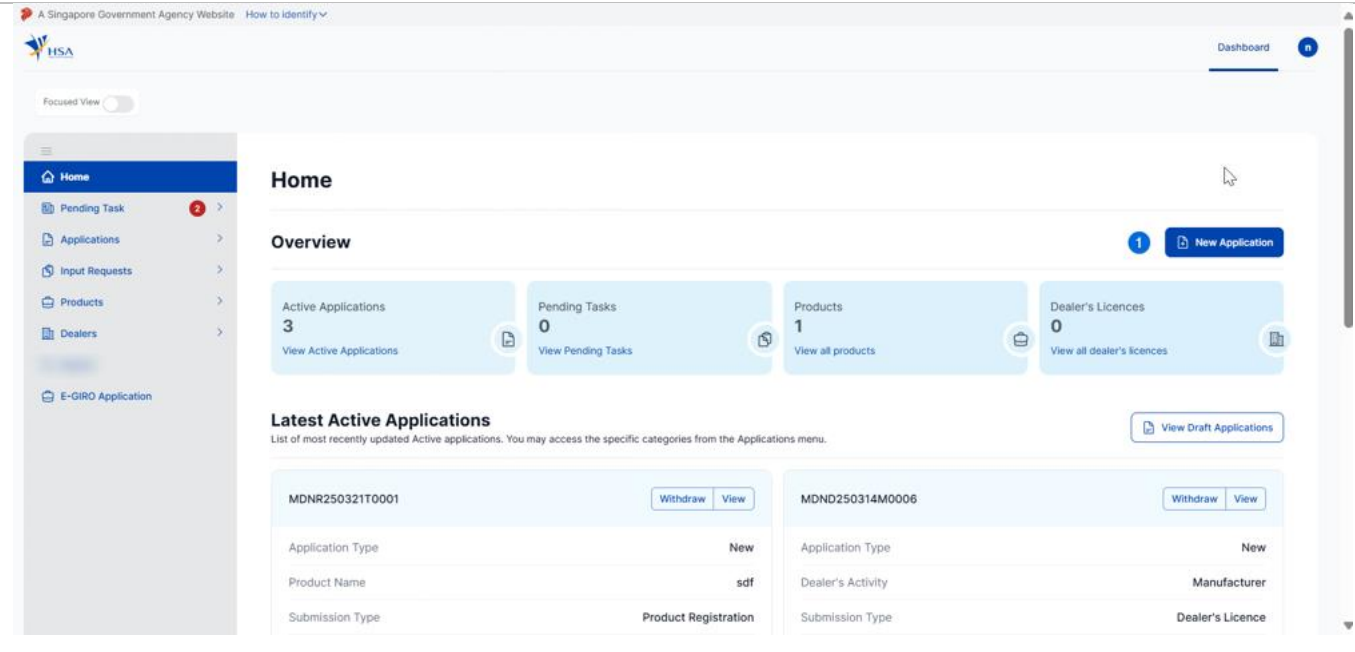
Submit

- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

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5.2.3. Renewal

5.2.3.1. Getting Started-Details



- 1) Applicants would be able to create a new application by clicking on the “**New Application**” button.

A Singapore Government Agency Website [How to identify](#)

HSA

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

2 Submission Type

Dealer's Licence

3 Application Type

Renewal

Cancel this application
and go back to Dashboard

Cancel

Next

Applicants would be able to select the type of application they want to submit.

- Applicants would be able to select 'Dealer's Licence' from the 'Submission Type' dropdown list.
- Applicants would be able to select 'Renewal' from the 'Application Type' dropdown list.

A Singapore Government Agency Website

How to Identify

HSA

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

Submission Type

Application Type

Medical Devices

Dealer's Licence

Renewal

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 Renewal for Dealer's Licence for the manufacture/import/wholesale of Medical Devices in Singapore.

Submission Instructions

Please refer to the submission guide for dealers' licences.

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

Change Product or Submission Type

< Back

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

4

Create Application

4) Applicants would be able to create the application.

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5.2.3.2. Licence List

Application For Dealer's Licence (Renewal)

Draft Application No. (Draft)

Last saved at 10 April 2025 01:51 PM

Focused View

Licence List

Payment Details

Review

Declaration

You are submitting a Dealer's Licence Application for Medical Devices

Licence List

Select Licences to Renew

☐	Licence No.	Licence Type	Licence Site Name	Expiry Date
☐	MDIL250402R02	Importer	Site 2 Apr 2025 Non QMS 0851	05-Apr-2025
☐	MDIL250323S01	Importer	Site 23 Mar 2025 Valid QMS 1553	26-May-2025
☐	MDML250330U01	Manufacturer	Site 30 Mar 2025 Renewal 1323	30-Mar-2025
☐	MDML250405B05	Manufacturer	Site 5 Apr 2025 Manual Renewal	06-Jun-2025
☐	MDIL250330R02	Importer	Site 30 Mar 2025 Renewal 1323	03-Jun-2025
☐	MDWL250330G03	Wholesaler	Site 30 Mar 2025 Renewal 1323	29-May-2025
☐	MDWL250323H02	Wholesaler	Site 23 Mar 2025 Valid QMS 1553	03-Jun-2025

Cancel

Payment Details

1) Applicants would be able to select the licences to renew by checking the respective licence's checkbox.

5.2.3.3. Payment Details

Focused View

Licence List

Payment Details

Review

Declaration

You are submitting a Dealer's Licence Application for Medical Devices

Subsections

Billing Information

Payment Information

Payment Details

Billing Information *

Client Code *

WC-661248

WC-661248

Postal Code

Block / House No.

Level / Unit

Street Name

Building Name

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
MEDRETMFG	Renewal Fee for Manufacturer	1	\$1,110.00

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

- Applicants would be able to select the client code from the dropdown list.
- Applicants will have two payment options, GIRO and Online payment. Applicants need to choose the preferred payment mode.

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5.2.3.4. Review

A Singapore Government Agency Website

How to identify

HSA

DashboardM

DraftApplication No. (Draft)

Last saved at 10 April 2025 01:55 PM🕒

Focused View

Licence List✔

Payment Details✔

Review

Declaration

You are submitting a Dealer's Licence Application for Medical Devices

Review

Licence List

Licence No.	Licence Type	Licence Site Name	Expiry Date
MDML250330U01	Manufacturer	Site 30 Mar 2025 Renewal 1323	30-Mar-2025

⚡

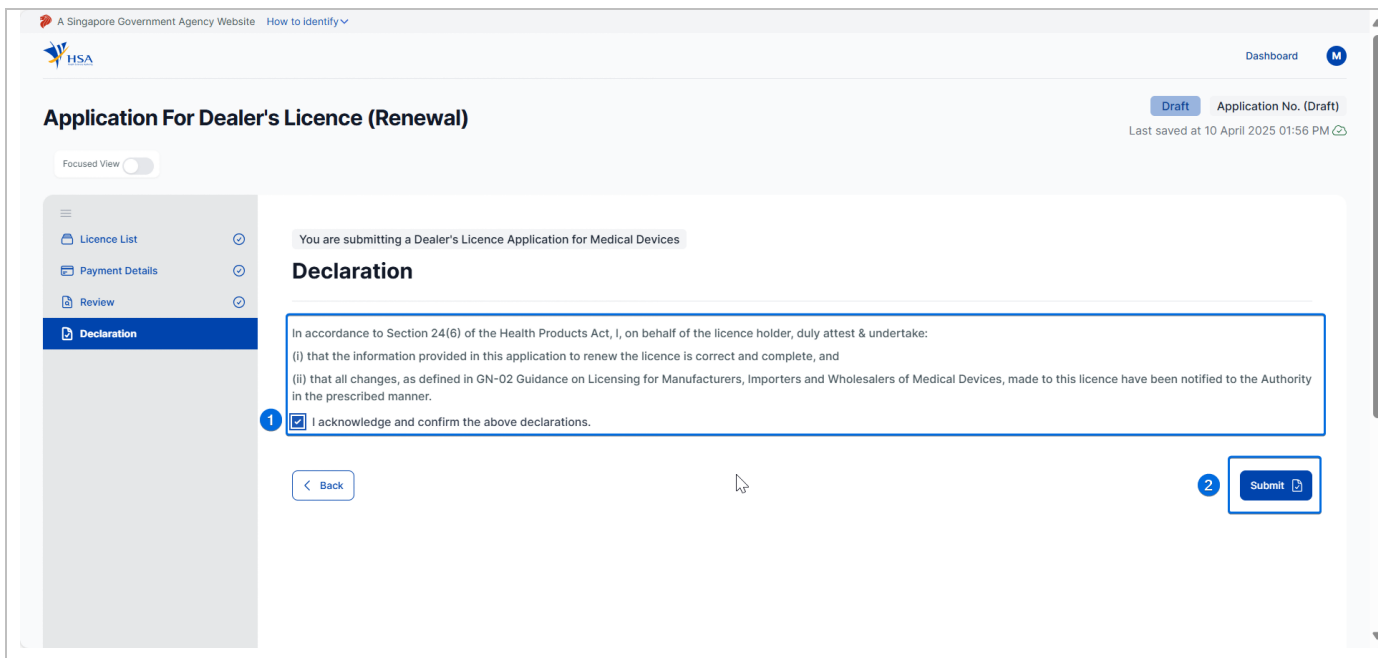
Billing Information

Client Code	WC-661248
Postal Code	558755
Block / House No.	61
Level / Unit	-

Review page displays the summary of all the sections filled before the declaration.

Review page displays the summary of all the sections filled before the declaration.

5.2.3.5. Declaration



The screenshot shows the 'Application For Dealer's Licence (Renewal)' page on the HSA website. The page is titled 'Application For Dealer's Licence (Renewal)' and includes a 'Draft' status and 'Application No. (Draft)'. A 'Focused View' toggle is present. The left sidebar contains a menu with 'Licence List', 'Payment Details', 'Review', and 'Declaration' (selected). The main content area displays a declaration form with the following text:

You are submitting a Dealer's Licence Application for Medical Devices

Declaration

In accordance to Section 24(6) of the Health Products Act, I, on behalf of the licence holder, duly attest & undertake:

- (i) that the information provided in this application to renew the licence is correct and complete, and
- (ii) that all changes, as defined in GN-02 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices, made to this licence have been notified to the Authority in the prescribed manner.

1 ☒ I acknowledge and confirm the above declarations.

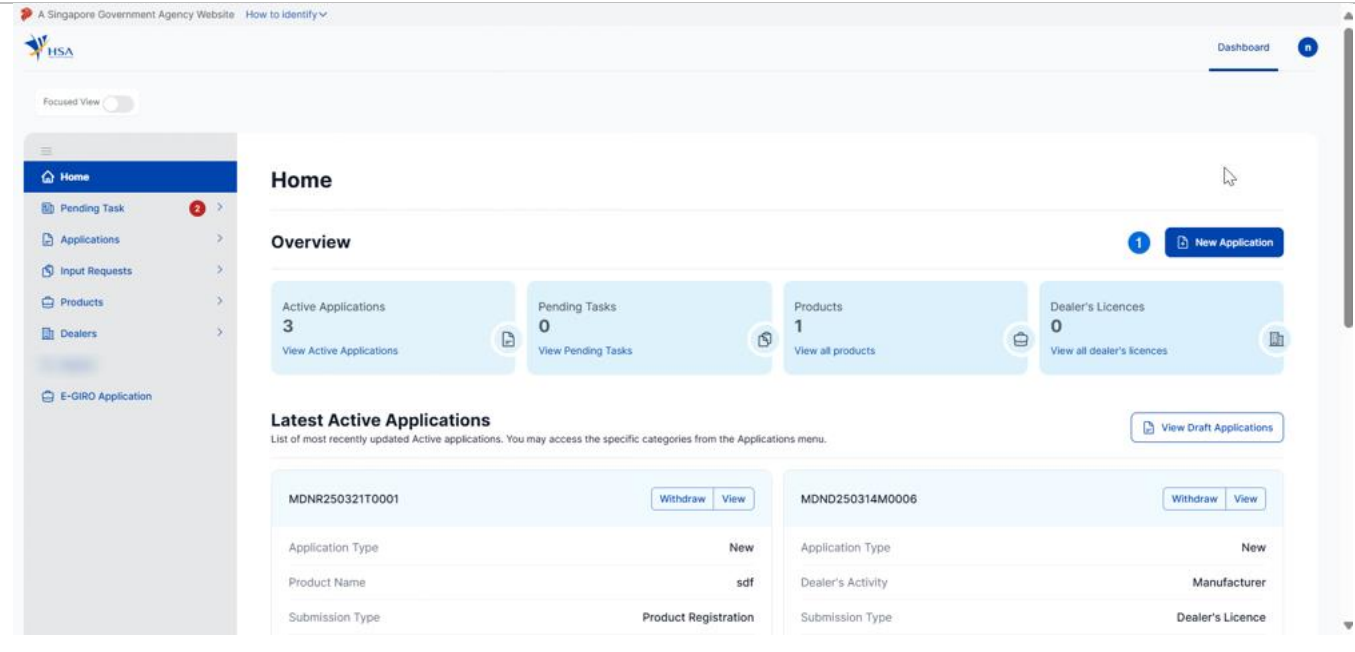
2

At the bottom, there are 'Back' and 'Submit' buttons. The 'Submit' button is highlighted with a blue border and a '2' in a circle next to it.

- 1) Applicants need to acknowledge and confirm the declaration.
- 2) Applicants would be able to submit the application.

5.2.4. Fulfilment Of Approval Condition

5.2.4.1. Getting Started-Details



- 1) Applicants would be able to create a new application by clicking on the “**New Application**” button.

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard

New Application - Getting Started

Focused View ☐

1. Details

2. Review

3. Checklist

Details

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

Product Type ⓘ

Medical Devices

2 Submission Type ⓘ

Dealer's Licence

3 Application Type

Fulfilment Of Approval Conditions

Cancel this application and go back to Dashboard

Applicants would be able to select the type of application they want to submit.

- 2) Applicants would be able to select 'Dealer's Licence' from the 'Submission Type' dropdown list.
- 3) Applicants would be able to select 'Fulfilment Of Approval Conditions' from the 'Application Type' dropdown list.

5.2.4.2. Getting Started- Review

A Singapore Government Agency Website How to identify

HSA Dashboard

New Application - Getting Started

Focused View

1. Details

2. Review

3. Checklist

Review

Instruction for this page
Please select the fulfillment of conditions.

1 Licence Number Application Number

Reset Filter

MDWL250318Q07 Application Number MDND250318L0010

2

Approval Conditions	Date
☒ Custom condition	21-Mar-2025
☐ Custom condition 2	21-Mar-2025

MDWL250402G03 Application Number MDND250402F0001

Approval Conditions	Date
☐ Specific condition 2 April 2025 0932	10-Apr-2025
☐ Specific condition 2 April 2025 0933	07-Apr-2025

MDIL250402R02 Application Number MDND250402F0001

Approval Conditions	Date
☐ Specific condition 2 April 2025 0932	08-Apr-2025
☐ Specific condition 2 April 2025 0934	08-Apr-2025

3 Request Extension

4 Next

Back

- 1) Applicants would be able to use the filter to find a specific Product/Licence.
- 2) Applicants would be able to select the approval conditions to fulfil by checking the respective approval condition's checkbox.
- 3) Applicants can 'Error! Not a valid result for table.'
- 4) Applicants would be able to create the application.

Request Extension



Dashboard

M

Request Extension

Focused View

1. Details

Review

Declaration

Details

1

MDIL250402R02

Application Number MDND250402F0001

Approval Conditions

Specific condition 2 April 2025 0932

Date

08-Apr-2025

2

Remarks

3

Desired Due Date

dd/mm/yyyy

Cancel

Review

The applicant will be redirected to Request Extension form.

- 1) Applicants would be able to see the selected approval conditions for the extension request.
- 2) Applicants would be able to put remarks for the extension request.
- 3) Applicants would be able to select the “Desired Due Date”.

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A Singapore Government Agency Website

How to identify

HSA

Dashboard

Request Extension

Focused View

1. Details

Review

Declaration

Review

4

Your request

MDIL250402R02

Application Number MDND250402F0001

Approval Conditions

Date

Specific condition 2 April 2025 0932

08-Apr-2025

Remarks: no

Desired Due Date: 26-Apr-2025

< Back

Declaration >

4) Review page displays the summary of all the sections filled before the declaration.

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A Singapore Government Agency Website [How to identify](#)

HSA Dashboard M

Request Extension

Focused View ☐

- 1. Details
- Review
- Declaration**

Declaration

5

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.
2. I, on behalf of my company, am fully aware that the quality, safety and efficacy of the submitted products will not be evaluated by the HSA.
3. I, on behalf of my company, must comply where applicable, with the Health Products Act and their corresponding regulations. I must also comply with all other applicable laws and their regulations.

☐ I acknowledge and confirm the above declarations.

[< Back](#)

6 [Submit](#)

- 5) Applicants need to acknowledge and confirm the declaration.
- 6) Applicants would be able to submit the extension request.

5.2.4.3. Fulfilment of Approval Condition

A Singapore Government Agency Website

How to identify

HSA

Dashboard

M

Application For Fulfilment Of Approval Condition

Draft

Application No. (Draft)

Last saved at 20 March 2025 11:24 AM

Focused View

Fulfillment of Approval Condition

Review

Declaration

1

Upload Files for All Conditions

Excepturi

Approval Conditions	Date	Actions
Product Lorem ipsum		
Uploaded files:	22-Mar-2025	2 Upload Files
3 Screenshot 2025-03-20 at 10-25-08 HSA SHARE - Applicant - Fulfilment of Approval Condition.png		

Cancel

Review

- 1) Applicants would be able to upload files for all conditions
- 2) Applicants would be able to upload files for specific condition
- 3) Applicants would be able to download and delete files

5.2.4.4. Review

Application For Fulfilment Of Approval Condition

Last saved at 14 April 2025 11:44 AM

Focused View

Fulfilment of Approval Condition

Review

Declaration

Review

Fulfilment of Approval Condition

Product: MDWL250318Q07

Approval Conditions	Date
Custom condition	
Uploaded files:	21-Mar-2025
9BB6D1C1AFCF4DA3963B2F2F3F38538E.pdf	

< Back

Declaration >

Review page displays the summary of all the sections filled before the declaration.

A Singapore Government Agency Website | How to identify

HSA

Dashboard

Draft Application No. (Draft)

Last saved at 14 April 2025 11:44 AM

Application For Fulfilment Of Approval Condition

Focused View

Fulfilment of Approval Condition

Review

Declaration

Declaration

1. I, on behalf of my company, confirm that the information submitted is true and accurate.
2. I, on behalf of my company, must comply where applicable, with the Health of Products Act and its corresponding regulations. I must also comply with other applicable laws and their regulations.

1 ☐ I acknowledge and confirm the above declarations.

< Back

2 Submit

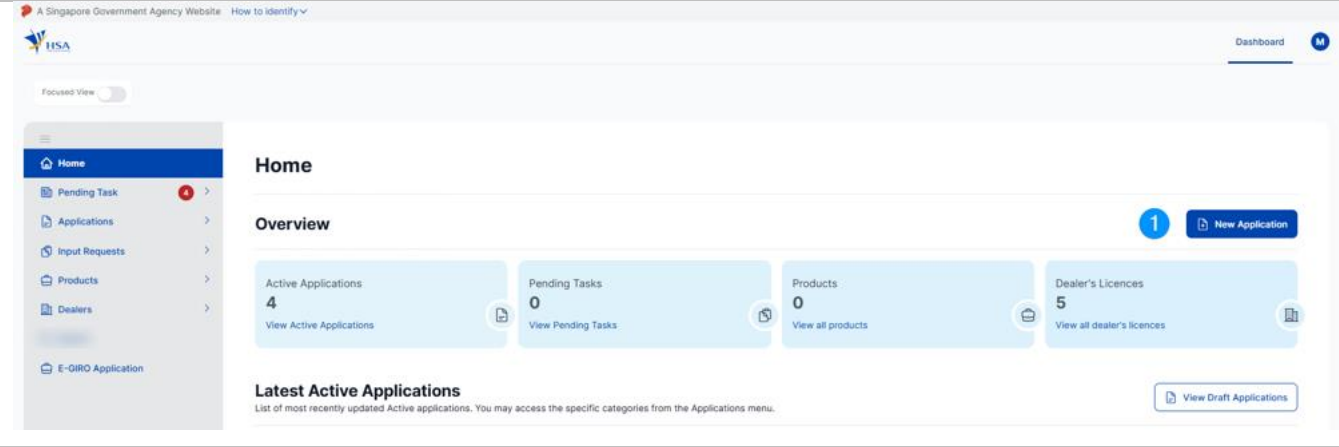
- 1) Applicants need to acknowledge and confirm the declaration.
- 2) Applicants can submit the application.

5.3. Product Registration

Companies are required to register their medical device with HSA before supplying it in Singapore.

5.3.1. New

5.3.1.1. Getting Started – Details



- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.

A Singapore Government Agency Website [How to identify](#)

HSA

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
2 Submission Type	Product Registration
3 Application Type	New
4 Device Type	General Medical Device
5 Dossier Format	ASEAN CSDT

Cancel this application and go back to Dashboard

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Product Registration' from the 'Submission Type' dropdown list
- 3) Applicants can select 'New' from the 'Application Type' dropdown list
- 4) Applicants can select the device type from the dropdown list
- 5) Applicants can select the dossier format

A Singapore Government Agency Website
How to identify
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](#)

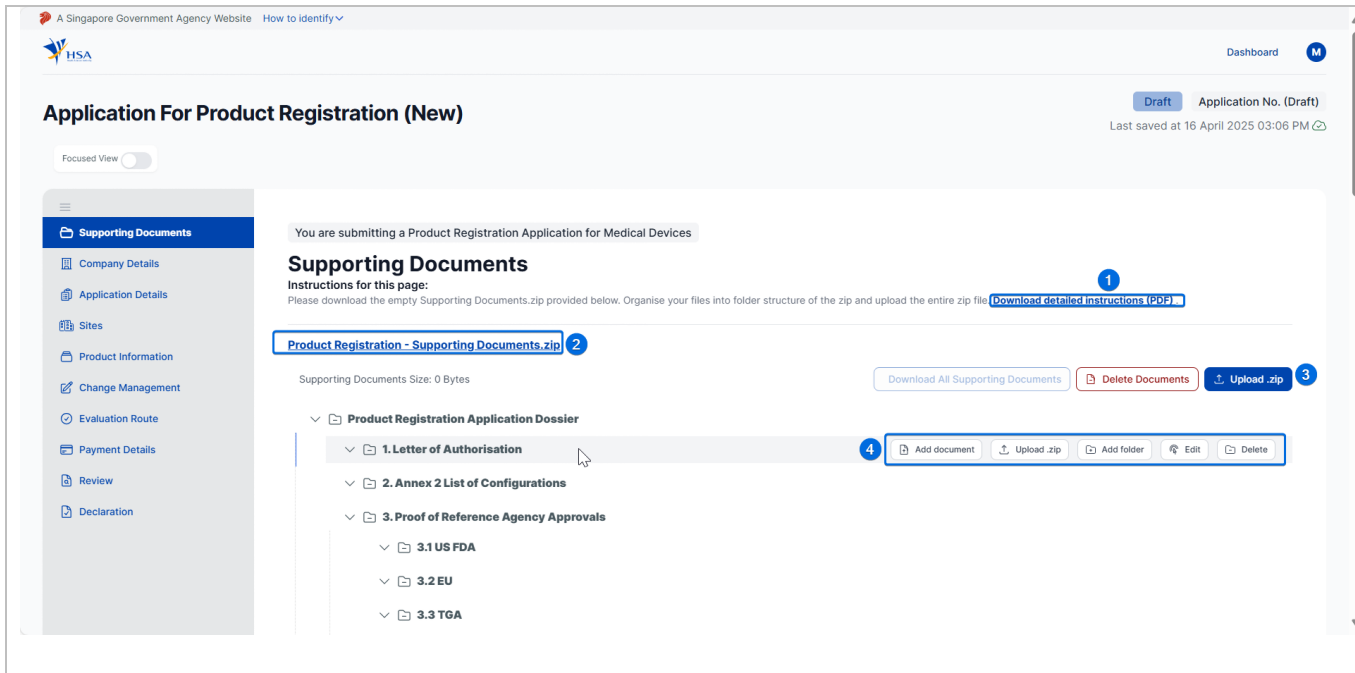
Change Product or Submission Type

Back

6 Create Application

6) Applicants can create the application.

5.3.1.2. Supporting Documents



A Singapore Government Agency Website How to identify

HSA Dashboard M

Application For Product Registration (New)

Draft Application No. (Draft)
Last saved at 16 April 2025 03:06 PM

Focused View

Supporting Documents

You are submitting a Product Registration Application for Medical Devices

Supporting Documents

Instructions for this page:
Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file [Download detailed instructions \(PDF\)](#)

[Product Registration - Supporting Documents.zip](#)

Supporting Documents Size: 0 Bytes

[Download All Supporting Documents](#) [Delete Documents](#) [Upload .zip](#)

Product Registration Application Dossier

1. Letter of Authorisation

2. Annex 2 List of Configurations

3. Proof of Reference Agency Approvals

3.1 US FDA

3.2 EU

3.3 TGA

Add document Upload .zip Add folder Edit Delete

- 1) Applicants can download detailed instructions for guidance
- 2) Applicants can download the Dossier Template as a zipped folder
- 3) Applicants can add the necessary files to the relevant folders within the Dossier Template and upload the zip file
- 4) Applicants can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - Add document
 - Upload zip file
 - Add folder
 - Edit folder
 - Delete folder

5.3.1.3. Company Details

A Singapore Government Agency Website [How to Identify](#)

HSA

Dashboard

Application For Product Registration (New)

Draft Application No. MDNR250307A0004
Last saved at 07 March 2025 03:06 PM

You are submitting a Product Registration Application for Medical Devices

Company Details

Company Information
This sub-section is pre-filled from your login and requires no action on your part.

Company Name Kreiger Inc
UEN Mock_609166543

Company Address *

[Clear ACRA Address](#)

Postal Code * 779815
Block / Number * 949
Level - Unit 57 - 88
Street Name * Keaton Prairie
Building Name Oklahoma

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	Franata	+65-23456789	

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

Subsections
Company Information
Company Address
Contact Information

Focused View ☐

Supporting Documents [+](#)

Company Details

Application Details

Sites

Product Information

Change Management

Evaluation Route

Payment Details

Review

Declaration

Applicants can navigate to other sections within the application form by clicking the section name on the left panel.

Company Information

This information is **auto populated based on the Corppass login**. Applicants cannot edit any of the information for this section

Company Address

This field is automatically populated based on the ACRA address. However, applicants can clear the pre-filled address and manually enter it if needed.

*Do note that changing the address field in the application form **does not change/update any address in ACRA**.

Contact Information

The contact Information refers to a global list of company's default contact details that would be notified for all Applications within the Company.

- Applicants can click on the company address book, opening a new tab that allows them to

update the company's address book. For more details, please refer to 4.1.1 Address book.

5.3.1.4. Application Details

A Singapore Government Agency Website How to Identify

HSA Dashboard

Application For Product Registration (New) Draft Application No. MDNR250307A0004 Last saved at 07 March 2025 03:06 PM

You are submitting a Product Registration Application for Medical Devices

Application Details

Application Information
This sub-section is pre-filled from your initial selection and cannot be edited.

Product Type	Medical Devices
Submission Type	Product Registration
Application Type	New
Device Type	General Medical Device

1 Main Applicant Information *

Applicant Name (as in NRIC/FIN) *	Franata
Designation *	Test

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

No Data Available

2 + Add Notification Email 1

< Back Sites >

Main Application Information

- 1) The **applicant's name** is automatically 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.

Notification Emails

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.

- 2) Applicants can update the notification email by selecting 'Add Notification Email'.

5.3.1.5. Sites

A Singapore Government Agency Website How to identify

HSA Dashboard

Application For Product Registration (New) Draft Application No. (Draft) Last saved at 22 April 2025 04:52 PM

You are submitting a Product Registration Application for Medical Devices

Sites
Instructions for this page:
Please provide at least one Manufacturer – either Overseas or Local

Subsections
Overseas Manufacturers
Local Manufacturers

Focused View

Supporting Documents
Company Details
Application Details
Sites
Product Information
Change Management
Evaluation Route
Payment Details
Review
Declaration

1 Overseas Manufacturers

Overseas Manufacturer 1 Edit Delete

Overseas Manufacturer Name	test		
Overseas Manufacturer Address	3d valley road, Algeria		
Type of Accreditations	Accreditations	Expiry Date	
	Japan MHLW Ordinance 169	26-Feb-2026	

+ Add Overseas Manufacturer 2

2 Local Manufacturers

Local Manufacturer 1 Delete

Local Manufacturer Licence/Dealer's Licence Number	MDML250422Y12		
Local Manufacturer Name	MD UAT Company 05		
Local Manufacturer Address	17C, DUBLIN ROAD, #17-30, Singapore 239806		
Site Details	Star Vista (3D, RIVER VALLEY ROAD - , CQ @ CLARKE QUAY, 179023 Singapore)		
Type of Accreditations	Accreditations	Expiry Date	
	ISO 13485	22-Nov-2028	

+ Add Local Manufacturer 2

< Back Product Information >

Overseas Manufacturers

1) The applicant can do the following:

- Add new overseas manufacturer for the current product(s) by clicking on 'Add Overseas Manufacturer' button and filling in the details
- Edit current overseas manufacturer(s) by clicking on the 'Edit' button of the desired overseas manufacturer(s)

Local Manufacturers

2) The applicant can do the following:

- Add new local manufacturer for the current product(s) by clicking on 'Add Local Manufacturer' button and filling in the details
- Edit current local manufacturer(s) selected by clicking on the 'Edit' button of the desired local manufacturer(s)

5.3.1.6. Product Information

A Singapore Government Agency Website How to Identify

HSA

Dashboard

Application For Product Registration (New)

Draft Application No. (Draft)
Last saved at 16 April 2025 03:39 PM

You are submitting a Product Registration Application for Medical Devices

Product Information

1 **Product Owner Information ***

Please provide product owner information for each product.

Product Owner (Local)		Edit	Delete
Product Owner Name:	Sarah		
Address	3D, RIVER VALLEY ROAD, CQ @ CLARKE QUAY, Singapore 179023		

2 **Device Listing ***

Device 1		Edit	Delete
Device Type	General Medical Device		
Device Name	Tesla 007		
Intended Use	Test 3		
Is Standalone	No		
Machine Learning-enabled Medical Device	No		
If the device contains connectivity / interfacing capabilities, please select all that apply	Internet		
Risk Class	Class C		
Medical Specialty	Cardiovascular		
Is the device for Professional Use Only?	No		
Is the In Vitro Diagnostic (IVD) device for self-testing?	Not Applicable		
Biological Material Component	Human		
Are any models supplied sterile?	Yes		
Justification if no importer assigned	no		
Models	Add 3		

+ Add Device 2

< Back

Change Management >

Subsections

- Product Owner Information
- Device Listing

- There will be only one Product Owner for the Products in this Application. Product Owner can be either Overseas or Local. The applicant can do the following:
 - Add new product owner for the current product(s) by clicking on 'Add Product Owner' button and filling in the details
 - Edit current product owner(s) by clicking on the 'Edit' button of the desired product owner(s)
 - Remove current product owner(s) by clicking on the "Delete" button of the desired product owner(s)
- The applicant can add and edit the device's information of the product
- The applicant can add the device's models

Add Device

Application For Product Registration (N

Focused View

Supporting Documents

Company Details

Application Details

Sites

Product Information

Change Management

Evaluation Route

Payment Details

Review

Declaration

You are submitting a

Product Information

Product Owner Information

Device Listing

Device Type

General Medical Device

Device Name *

Intended Use *

Standalone Medical Mobile Application (also known as Software as Medical Device (SaMD), in IMDRF context) *

Yes

No

Machine Learning-enabled Medical Device *

Yes

No

If the device contains connectivity / interfacing capabilities, please select all that apply *

Internet

LAN

Wireless LAN

Bluetooth

Able to interface (via e.g. USB cable) with computing device (laptop, mobile phone, tablet, and etc.)

Others

N.A

Device Risk Classification *

Select Device Risk Classification

Medical Specialty *

Select Medical Specialty

Is the device for Professional Use Only? *

Yes

No

Is the In Vitro Diagnostic (IVD) device for self-

Yes

No

Not Applicable

Applicants need to fill in all the details about the device they want to submit.

Page 129 of 273

Application For Product Registration (N

Focused View

Supporting Documents

Company Details

Application Details

Sites

Product Information

Change Management

Evaluation Route

Payment Details

Review

Declaration

You are submitting a

Product Info

Product Owne

Please provide product o

Product Owner (L

Product Owner Na

Address

Device Listing

No Data Avail

Back

Add Device 1

Is the device for Professional Use Only? *

Yes

No

Is the In Vitro Diagnostic (IVD) device for self-testing? *

Yes

No

Not Applicable

Biological Material Component

Human

Bovine

Ovine

Porcine

Animal (Others)

Plant

Others

Are any models supplied sterile? *

Yes

No

Local Authorised Importer Licence Number

Get Importer's Details

Local Authorised Importer Name

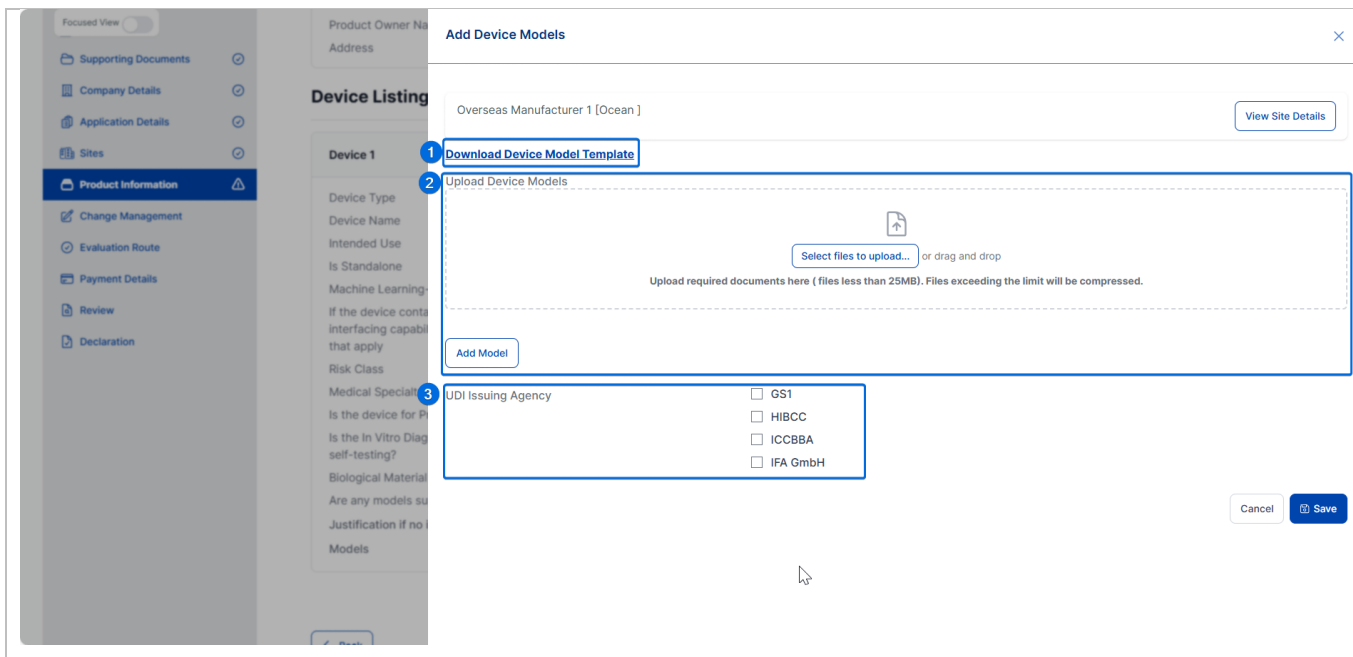
Add Dealer

Justification if no importer assigned *

Cancel

Save

Add Device Model



Add Device Models

Product Owner Name
Address

Device Listing

Device 1

Device Type
Device Name
Intended Use
Is Standalone
Machine Learning
If the device contains
interfacing capabilities
that apply
Risk Class
Medical Specialization
Is the device for Pre-
Clinical Testing
Is the In Vitro Diagnostic
self-testing?
Biological Material
Are any models submitted
Justification if no
Models

Overseas Manufacturer 1 [Ocean]

[View Site Details](#)

1 Download Device Model Template

2 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](#)

3 UDI Issuing Agency

☐ GS1
☐ HIBCC
☐ ICCBBA
☐ IFA GmbH

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

- 1) Applicants can download an Excel template file to fill in device information.
- 2) Applicants can upload the Excel file to the system to add multiple models at a time or add model individually by clicking 'Add Model'.
- 3) Applicants need to select UDI Issuing Agency if any of the models have UDI-DI or DM-DI data.

5.3.1.7. Change Management

A Singapore Government Agency Website

How to identify

HSA

Health Sciences Authority

Dashboard

F

Application For Product Registration (New)

Draft

Application No. MDNR250307A0004

Last saved at 07 March 2025 03:10 PM

Focused View

Supporting Documents

Company Details

Application Details

Sites

Product Information

Change Management

Evaluation Route

Payment Details

Review

Declaration

You are submitting a Product Registration Application for Medical Devices

Change Management

Change Management Program

Change Management Program – a voluntary program to facilitate timely implementation of software changes for Standalone Medical Mobile Application

I would like to opt-in for the Change Management Program

Yes

No

< Back

Evaluation Route >

Subsections

Change Management Program

This section contains Change Management Program, a voluntary program to facilitate timely implementation of changes for Medical Devices.

Page 132 of 273

5.3.1.8. Evaluation Route

A Singapore Government Agency Website

How to identify?

Dashboard

Application For Product Registration (New)

Draft

Application No. MDNR250307A0004

Last saved at 07 March 2025 03:10 PM

Supporting Documents

Company Details

Application Details

Sites

Product Information

Change Management

Evaluation Route

Payment Details

Review

Declaration

Focused View

You are submitting a Product Registration Application for Medical Devices

Evaluation Route

Priority Review Scheme *

Please note that applications under the Priority Review Scheme will be reviewed via the Full Evaluation Route with relevant evaluation fees applicable.

I would like to opt-in for Priority Review Scheme

No

Yes

Evaluation Route Determinants *

Please provide details of Reference Agency.
(Note: Details of reference agencies in this section shall apply to all models submitted in this application.)

Relevant Reference Agency Approval(s) obtained for all device models to be submitted in this application.

☒ European Union (EU)

☐ US Food and Drug Administration (US FDA)

☐ Australia Therapeutic Goods Administration (TGA)

☐ Health Canada

☐ Japan Ministry of Health, Labour and Welfare (MHLW)

☐ None of the above

All device models to be submitted in this application are marketed in at least one jurisdiction without safety issues for at least 3 years.

No

Yes

Were any models to be submitted in this application rejected or withdrawn or refused registration by any of the reference agencies or Singapore Health Sciences Authority before?

No

Yes

Other Evaluation Route Determinants

Please provide details of any previously certified reference agencies. If your product has approvals from one or more agencies, it may qualify for abridged or immediate evaluation routes.

Please select the categories that apply to all the device model(s) to be submitted in this application.

☒ Active implantable medical devices (e.g. Pacemaker, neurostimulators)

☐ Implantable devices in direct contact with the central circulatory system or central nervous system

☐ Hip, knee and Shoulder joint replacement

☐ Devices incorporating a registrable drug in an ancillary role

☐ HIV test kits (screening and diagnosis)

☐ Blood or tissue donor compatibility tests

Evaluation Route *

Please select the evaluation route for product registration. The options available are based on your input above.

Evaluation Route *

Full Class C

MD Class C Full Eva Fee

Estimated Fees\$6,250.00

Turnaround time (TAT in working days)220

Next-Generation Medical Device Initiative

Once NextGen initiative is selected, the application will proceed with FULL evaluation route. Relevant evaluation fees apply. To enrol into this initiative, please ensure all required documentation for the NextGen initiative is submitted. This initiative will not be applicable if you wish to leverage an approval from HSA's reference agencies.

I would like to opt-in for the Next-Generation Medical Device Initiative

No

Yes

< Back

Payment Details >

Subsections

Priority Review Scheme

Evaluation Route Determinants

Other Evaluation Route Determinants

Evaluation Route

Next-Generation Medical Device Initiative

Based on the information provided by the Applicant in the Product Information and Evaluation Route section, the applicable Evaluation Routes will be in a dropdown for the user to select.

TAT and cost of the evaluation route selected will be shown to the Applicant so they can make an informed decision.

5.3.1.9. Payment Details

A Singapore Government Agency Website

How to identify

HSA

Dashboard

Application For Product Registration (New)

Draft Application No. (Draft)

Last saved at 22 April 2025 04:41 PM

Errors

Please ensure that you have entered a value for the 'Payment Schedule' field.

You are submitting a Product Registration Application for Medical Devices

Payment Details

Billing Information *

Client Code * W123412304

Postal Code 239806

Block / House No. 17C

Level / Unit 17 - 30 - 17 - 30

Street Name DUBLIN ROAD

Building Name nan

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 GIRO

Online

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

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

- 1) Applicants can select the client code from the dropdown list
- 2) Applicants will have two payment options, GIRO and Online payment. Applicants need to choose the preferred payment mode.
- 3) Depending on selected payment mode and evaluation route, Applicants can select the preferred payment schedule.

5.3.1.10. Review

A Singapore Government Agency Website

How to identify

HSA

Dashboard

F

Application For Product Registration (New)

Draft Application No. MDNR250307A0004

Last saved at 07 March 2025 03:11 PM

You are submitting a Product Registration Application for Medical Devices

Review

Supporting Documents

Supporting Documents Size: 0 Bytes

Download All Supporting Documents

Product Registration Application Dossier

1. Letter of Authorisation

2. Annex 2 List of Configurations

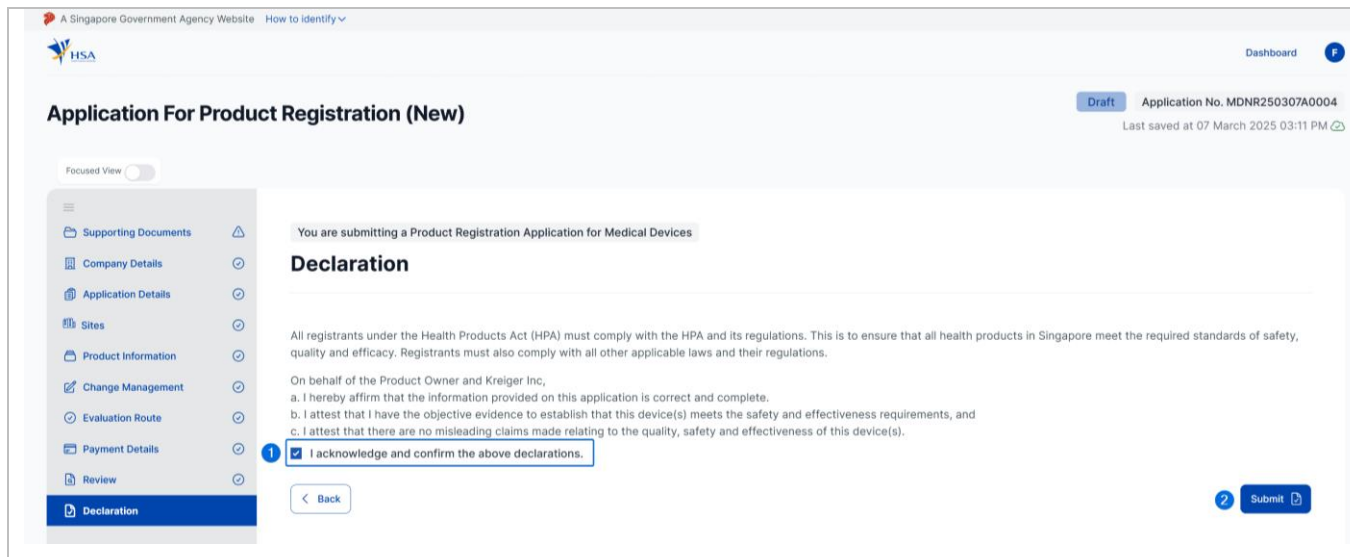
3. Proof of Reference Agency Approvals

- 3.1 US FDA
- 3.2 EU
- 3.3 TGA
- 3.4 Health Canada
- 3.5 Japan MHLW

4. Declarations

- 4.1 Declaration of Labelling
- 4.2 Marketing History Declaration

5.3.1.11. Declaration



A Singapore Government Agency Website How to identify

HSA Dashboard

Application For Product Registration (New) Draft Application No. MDNR250307A0004 Last saved at 07 March 2025 03:11 PM

Focused View

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

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 Kreiger Inc,

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, and

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

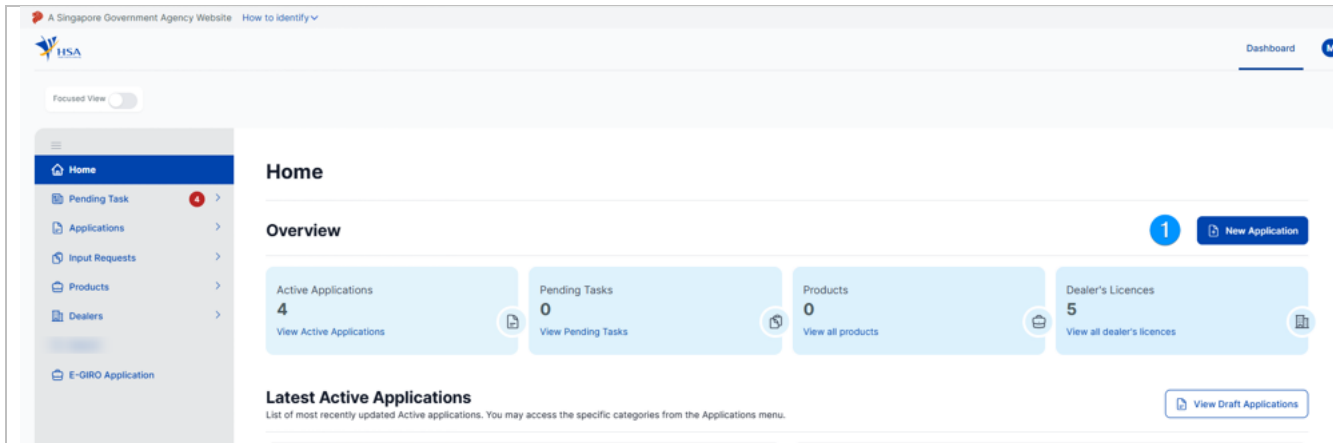
1 ☒ I acknowledge and confirm the above declarations.

< Back Submit

- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

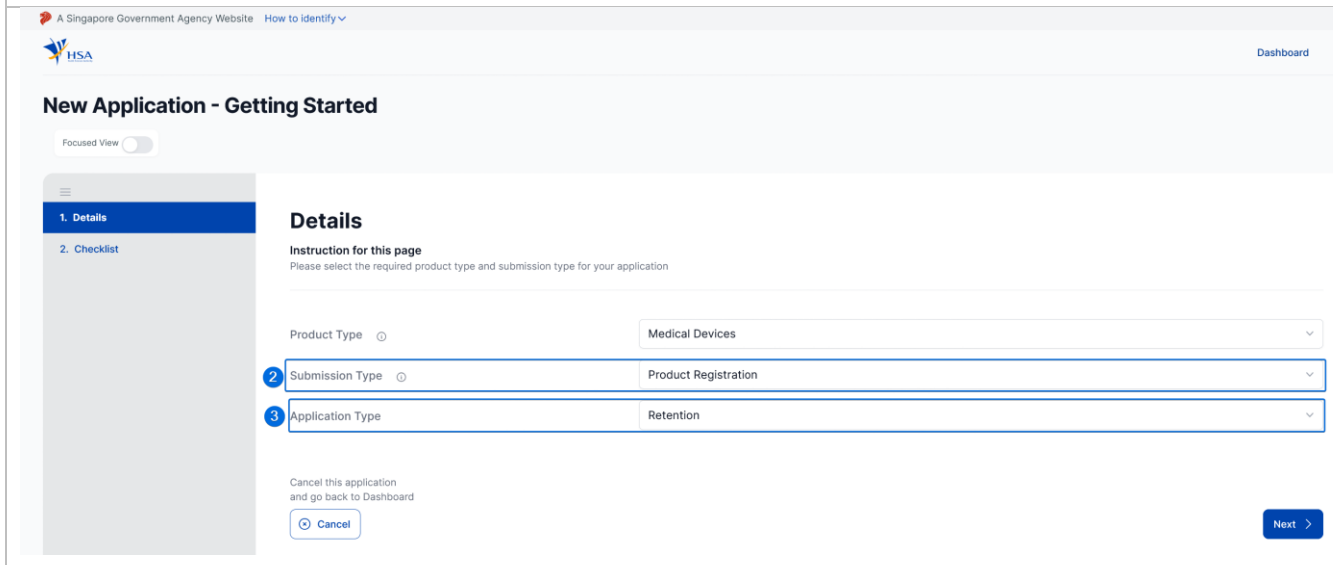
5.3.2. Retention

5.3.2.1. Getting Started



The screenshot shows the HSA Dashboard. The top navigation bar includes the HSA logo, a 'How to identify' dropdown, and a 'Dashboard' link. A 'Focused View' toggle is present. The left sidebar contains a menu with 'Home', 'Pending Task' (with a red notification badge), 'Applications', 'Input Requests', 'Products', 'Dealers', and 'E-GIRO Application'. The main content area is titled 'Home' and features an 'Overview' section with four cards: 'Active Applications' (4), 'Pending Tasks' (0), 'Products' (0), and 'Dealer's Licences' (5). 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 'View Draft Applications' button.

- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.



The screenshot shows the 'New Application - Getting Started' page. The top navigation bar includes the HSA logo, a 'How to identify' dropdown, and a 'Dashboard' link. The left sidebar contains a menu with '1. Details' and '2. Checklist'. The main content area is titled 'Details' and features an 'Instruction for this page' section with the text 'Please select the required product type and submission type for your application'. Below this are three dropdown menus: 'Product Type' (selected: Medical Devices), 'Submission Type' (selected: Product Registration), and 'Application Type' (selected: Retention). At the bottom, there is a 'Cancel' button and a 'Next' button.

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Product Registration' from the 'Submission Type' dropdown list
- 3) Applicants can select 'Retention' from the 'Application Type' dropdown list

A Singapore Government Agency Website
How to identify

HSA
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	Retention



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 the retention of medical device(s) that have been given marketing clearance.

Submission Instructions

Please be reminded that it is the responsibility of the registrant to keep track of the annual retention due date. Failure to make the necessary payment may lead to cancellation of the registration of the medical device. Once the device listing is cancelled, import and supply of that medical device is not permitted.

Please be reminded that it is the responsibility of the registrant to keep track of the annual retention due date. Failure to make the necessary payment may lead to cancellation of the registration of the medical device.

If fee payment is not received within 30 days after the due date, justification for late retention payment (Show Cause) must be provided in your retention application. Device listings will be cancelled if retention fee payment is not received within 60 days after the due date. Once the device listing is cancelled, import and supply of that medical device is not permitted.

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

Change Product or Submission Type

< Back

4 Create Application

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

4) Applicants can create the application.

5.3.2.2. Product List

Application For Product Registration (Retention)

Draft

Application No. (Draft)

Last saved at 16 April 2025 03:06 PM

Focused View

Device Listing

Payment Details

Review

Declaration

You are submitting a Retention Application for Medical Devices

Device Listing

1 Select Devices to Retain

Product Number

Device Name

Product Owner Name

Device Risk Classification

Select an option

Reset

Filter

2

Product Number	Product Owner Name	Device Name	Device Risk Classification	Due Date
☒ MDP250324C0005	Local 12 Mar 2025 PO 2035 Updated	GMD 24 Mar 2025 C 1604	Class C	26-May-2025

Cancel

Payment Details

- Search for results by entering the required data in the search table and clicking 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- Applicants would be able to select the products to retain by checking the respective product's checkbox.

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5.3.2.3. Payment Details

A Singapore Government Agency Website How to identify

HSA

Dashboard

Application For Product Registration (Retention)

Draft Application No. (Draft)

Last saved at 16 April 2025 03:07 PM

Focused View

Device Listing

Payment Details

Review

Declaration

You are submitting a Retention Application for Medical Devices

Payment Details

Billing Information *

1 Client Code * WC-661248

Postal Code 558755

Block / House No. 61

Level / Unit -

Street Name CHARTWELL DRIVE

Building Name wsd

Payment Information *

2 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 GIRO

Online

Charge Code	Description	Quantity	Price
MEDRETCLSC	Retention Fee for Class C Reg MD (Class C)	1	\$67.00
	Subtotal		\$67.00
	Tax		\$0.00
	Total		\$67.00

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

Show Cause >

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

- 1) Applicants can select the client code from the dropdown list
- 2) Applicants will have two payment options, GIRO and Online payment. Applicants need to choose the preferred payment mode.

5.3.2.4. Review

A Singapore Government Agency Website
How to identify


Dashboard
M

Application For Product Registration (Retention)

Draft
Application No. (Draft)
Last saved at 16 April 2025 03:07 PM

Focused View

Device Listing
Payment Details
Review
Declaration

You are submitting a Retention Application for Medical Devices

Review

Device Listing

Product Number	Product Owner Name	Device Name	Device Risk Classification	Due Date
MDPR250324C0005	Local 12 Mar 2025 PO 2035 Updated	GMD 24 Mar 2025 C 1604	Class C	26-May-2025

Show Cause

No Data Available

Billing Information

Review page displays the summary of all the sections filled before the declaration.

Page 141 of 273

5.3.2.5. Declaration

A Singapore Government Agency Website
How to identify



Dashboard

Application For Product Registration (Retention)

Draft

Application No. (Draft)

Last saved at 16 April 2025 03:07 PM

Focused View

Device Listing

Payment Details

Review

Declaration

You are submitting a Retention Application for Medical Devices

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 of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

In accordance to Section 30(10) of the Health Products Act, I, on behalf of the product owner and registrant, duly attest & undertake:

- (i) that this registrant remains authorised by the product owner to be the registrant of medical devices under this listing,
- (ii) that the registrant remains aware and complies with all product registration conditions issued for medical devices under this listing,
- (iii) that all certifications (e.g. ISO 13485 certificate for manufacturing site) relating to the product registration remain valid and will be submitted to the Authority upon request, and
- (iv) that all changes, as defined in GN-21 Guidance on Change Notification, made to medical devices registered under this listing have been notified to the Authority in the prescribed manner.

1

☐
I acknowledge and confirm the above declarations.

< Back

2

Submit

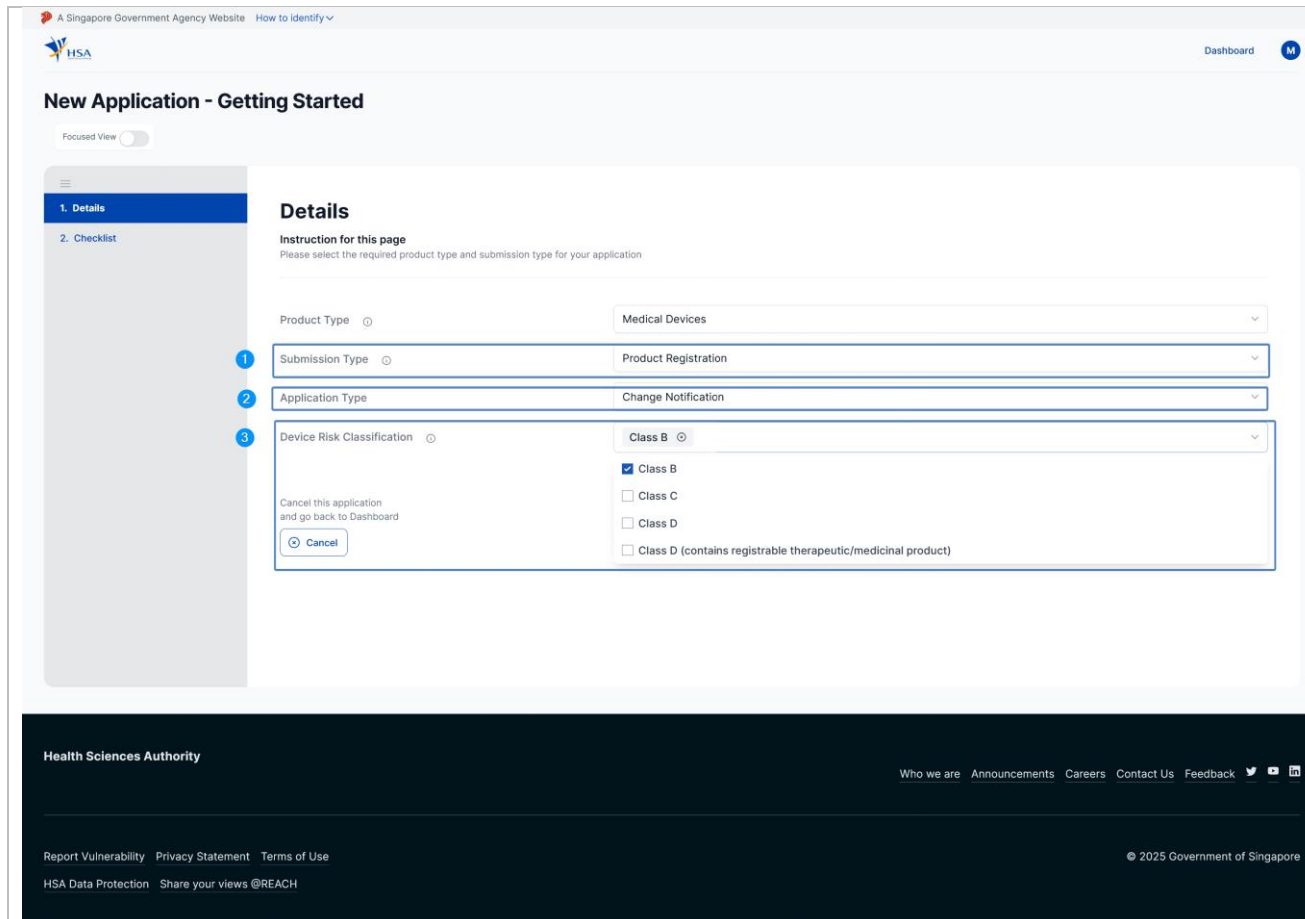
- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

Page 142 of 273

5.3.3. Change Notification

Applicants can submit Change Notification to inform HSA of changes to approved Class B, C or D medical devices.

5.3.3.1. Getting Started – Details



A Singapore Government Agency Website How to identify

HSA

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

1 Submission Type

2 Application Type

3 Device Risk Classification

☒ Class B
☐ Class C
☐ Class D
☐ Class D (contains registrable therapeutic/medicinal product)

Cancel this application and go back to Dashboard

Health Sciences Authority

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Applicants can select the type of application they want to submit.

- 1) Applicants can select 'Product Registration' from the 'Submission Type' dropdown list
- 2) Applicants can select 'Change Notification' from the 'Application Type' dropdown list
- 3) Applicants can select one or multiple Device Risk Classification for from the "Device Risk Classification" dropdown list.

5.3.3.2. CN Details

1) Applicants can check the relevant change notification checklist to inform the changes made to the products in the application. Based on the selection, the system will conclude the Overall Change Category.

2) The page will also show the overall change type, the estimated fees and the turnaround time.

5.3.3.3. CN Information

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard

Application For Product Registration (Change Notification) Draft Application No. (Draft)
Last saved at 13 March 2025 09:28 AM

Change Notification Information

Select Devices to Amend

Approved Product Number

Product Owner

Device Risk Classification

Reset Search

Approved Product Number	Device Name	Device Risk Classification	Product Owner	Intended Use	Retention Due Date
☒ MDP250313E0018	Rerum	B	Hane	Quibusdam repellat cupiditate voluptatem delectus.	13-Mar-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).

< Back Supporting Documents >

Health Sciences Authority

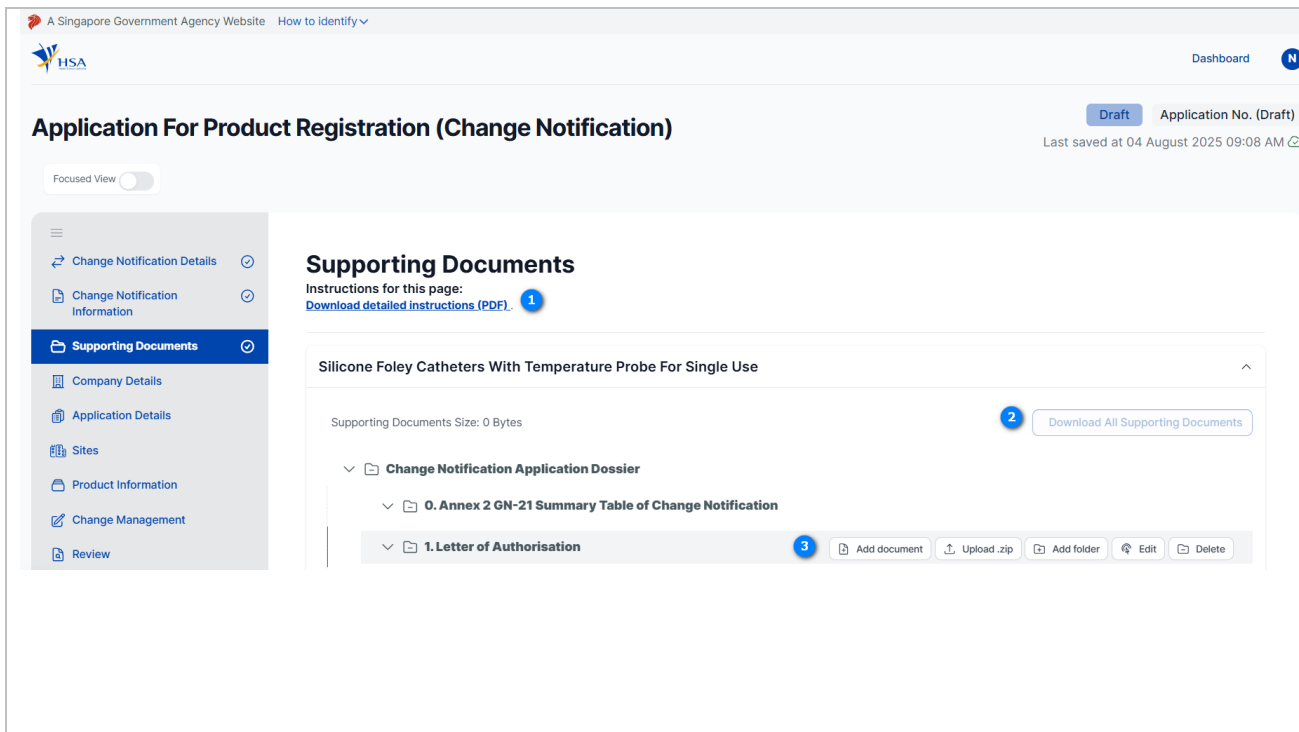
[Who we are](#) [Announcements](#) [Careers](#) [Contact Us](#) [Feedback](#) [Twitter](#) [Facebook](#) [LinkedIn](#)

[Report Vulnerability](#) [Privacy Statement](#) [Terms of Use](#) © 2025 Government of Singapore

[HSA Data Protection](#) [Share your views @REACH](#)

- 1) Applicants can enter Approved Product Number, Product Owner or Device Risk Classification to narrow down the list of products below.
- 2) Applicants need to select the devices that they wish to amend by checking the respective checkboxes. If the selected device listing has another ongoing CN application, there will be limitations fields which applicant can make edits to.
- 3) Applicants need to select if there are any changes to the medical device(s) due to FSCA(s) or AE(s).

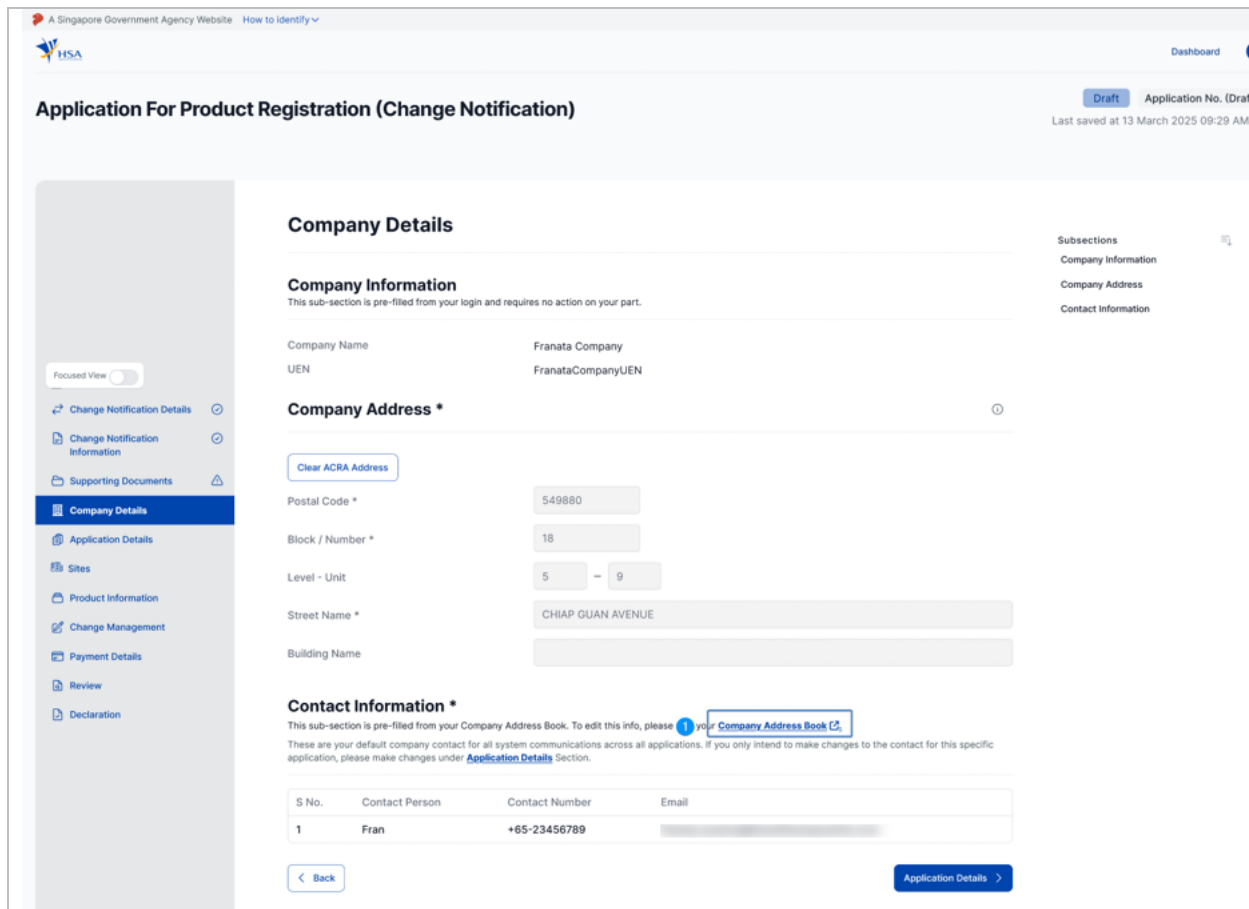
5.3.3.4. Supporting Documents



This page will show the related product supporting documents. Applicants can download the supporting documents, and they can also add more supporting documents if needed.

- 1) Applicants can download detailed instructions for guidance
- 2) Applicants can download the submitted supporting documents
- 3) Applicants can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - a. Add document
 - b. Upload zip file
 - c. Add folder
 - d. Edit folder
 - e. Delete folder

5.3.3.5. Company Details



Application For Product Registration (Change Notification)

Company Details

Company Information
This sub-section is pre-filled from your login and requires no action on your part.

Company Name: Franata Company
UEN: FranataCompanyUEN

Company Address *

Clear ACRA Address

Postal Code *: 549880
Block / Number *: 18
Level - Unit: 5 - 9
Street Name *: CHIAP GUAN AVENUE
Building Name:

Contact Information *
This sub-section is pre-filled from your Company Address Book. To edit this info, please [click here](#) to 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	Fran	+65-23456789	

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

Applicants can navigate to other sections within the application form by clicking the section name on the left panel.

Company Information

This information is **auto populated based on the Corppass login**. Applicants cannot edit any of the information for this section

Company Address

This field is automatically populated based on the ACRA address. However, applicants can clear the pre-filled address and manually enter it if needed.

*Do note that changing the address field in the application form **does not change/update any address in ACRA**.

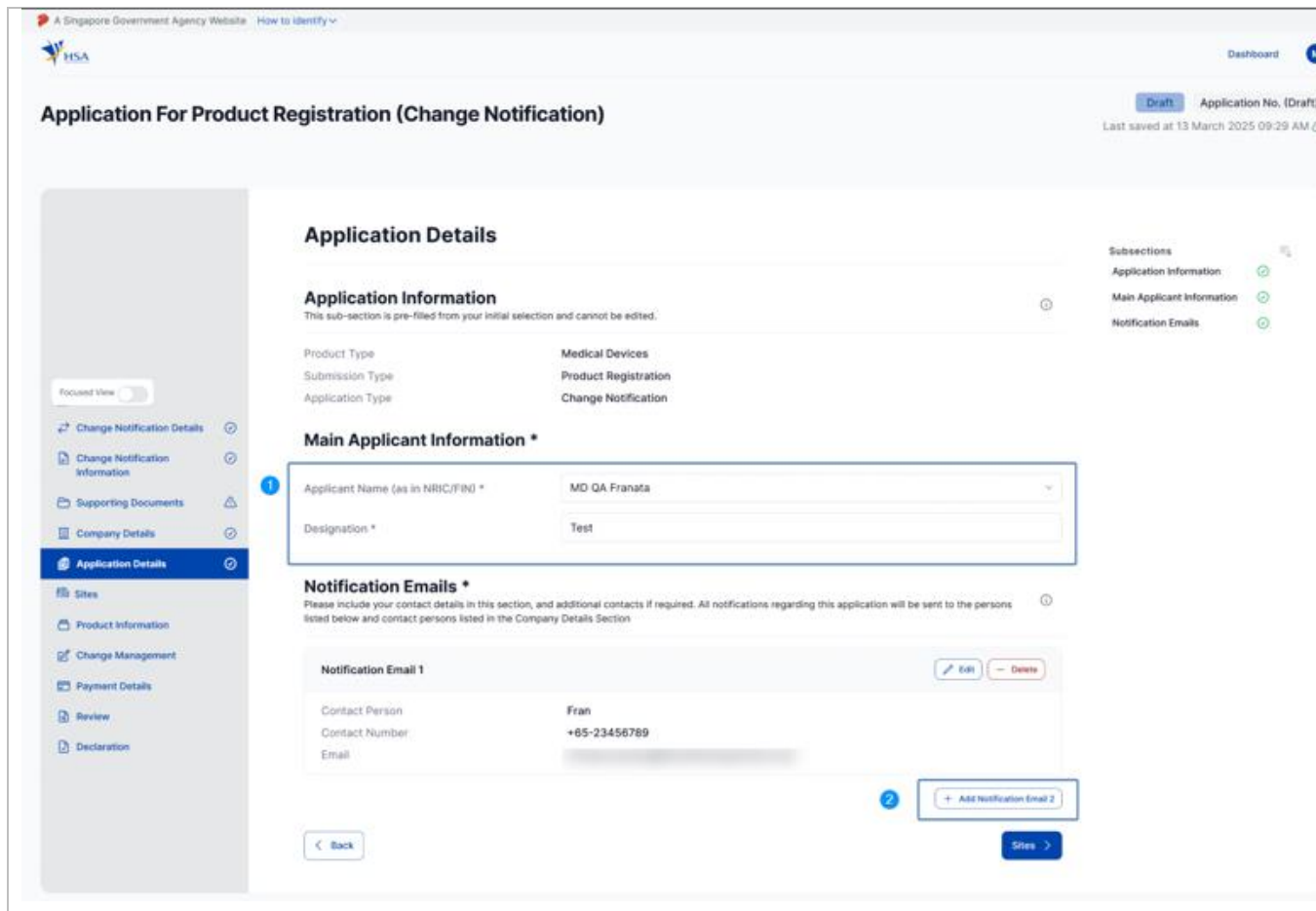
Contact Information

The contact Information refers to a global list of company's default contact details that would be notified for all Applications within the Company.

Applicants can click on the company address book, opening a new tab that allows them to update the company's

address book. For more details, please refer to 4.1.1 Address book

5.3.3.6. Application Details



Main Application Information

- 1) The **applicant's name** is automatically 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.

Notification Emails

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.

- 2) The applicant can update the notification email by selecting "**Add Notification Email.**"

5.3.3.7. Sites

A Singapore Government Agency Website
How to identify

HSA
Dashboard
M

Application For Product Registration (Change Notification)
Draft
Application No. (Draft)
Last saved at 13 March 2025 09:30 AM

Focused View

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

Sites

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

Overseas Manufacturers

Overseas Manufacturer 1

Overseas Manufacturer Name

Hunter47

Overseas Manufacturer Address

1553 Shields Knolls, Denmark

Type of Accreditations

Accreditations

ISO 13485

Expiry Date

03-Oct-2026

Add Overseas Manufacturer 2

Local Manufacturers

Local Manufacturer 1

Local Manufacturer Licence/Dealer's Licence Number

MDML250313X03

Local Manufacturer Name

Franata Company

Local Manufacturer Address

18, CHIAP GUAN AVENUE, #05-09, Singapore 549880

Site Details

Jennings Kihn (123, 45744 Armstrong Parkways 4 - 5, Demario Orn, 123123 Singapore)

Type of Accreditations

Add Local Manufacturer 2

Back
Product Information

Overseas Manufacturers

- 1) The applicant can do the following:
 - a. Add new overseas manufacturer for the current product(s) by clicking on 'Add Overseas Manufacturer' button and filling in the details
 - b. Edit current overseas manufacturer(s) by clicking on the 'Edit' button of the desired overseas manufacturer(s)

Local Manufacturers

- 2) The applicant can do the following:
 - a. Add new local manufacturer for the current product(s) by clicking on 'Add Local Manufacturer' button and filling in the details
 - b. Edit current local manufacturer(s) selected by clicking on the 'Edit' button of the desired local manufacturer(s)

5.3.3.8. Product Information

Application For Product Registration (Change Notification)

Draft
Application No. (Draft)
Last saved at 13 March 2025 09:30 AM

Product Information

1

Product Owner Information *

Please provide product owner information for each product.

Product Owner 1 (Local)	
Product Owner Name	Hane
Address	123, 36181 Watsica Wall, #06-07, Katherine Volkman, Singapore 123123

Edit
Delete

+ Add Product Owner 2

Device Listing *

2
Edit

Product Owner	Hane							
Device Type	General Medical Device							
Device Name	Rerum							
Intended Use	Quibusdam repellat cupiditate voluptatem delectus.							
Is Standalone	No							
Machine Learning-enabled Medical Device	No							
If the device contains connectivity / interfacing capabilities, please select all that apply	LAN, Internet							
Risk Class	Class B							
Medical Specialty	Clinical chemistry							
Is the device for Professional Use Only?	Yes							
Is the In Vitro Diagnostic (IVD) device for self-testing?	Not Applicable							
Biological Material Component	Human, Bovine							
Are any models supplied sterile?	Yes							
Local Dealer	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Dealer Licence Number</th> <th style="width: 30%;">Dealer Name</th> <th style="width: 30%;">Dealer Type</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px 5px;">MDIL250313S02</td> <td style="padding: 2px 5px;">Franaata Company</td> <td style="padding: 2px 5px;">Importer</td> </tr> </tbody> </table>		Dealer Licence Number	Dealer Name	Dealer Type	MDIL250313S02	Franaata Company	Importer
Dealer Licence Number	Dealer Name	Dealer Type						
MDIL250313S02	Franaata Company	Importer						

3

4

Models
+ Add Device 2

Back
Change Management

- 1) The applicant can do the following:
 - a. Add new product owner for the current product(s) by clicking on 'Add Product Owner' button and filling in the details
 - b. Edit current product owner(s) by clicking on the 'Edit' button of the desired product owner(s)
 - c. Remove current product owner(s) by clicking on the "Delete" button of the desired product owner(s)
- 2) The applicant can edit the details of the selected product(s) in the 'Change Notification Information' page.
- 3) The applicant can edit the model's information of the product selected in the 'Change Notification Information' page.
- 4) The applicant can add more device listings

Note: Editable fields are determined based on the selected checklist in the CN Details section.

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5.3.3.9. Change Management

A Singapore Government Agency Website

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HSA

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Application For Product Registration (Change Notification)

DraftApplication No. (Draft)

Last saved at 23 April 2025 01:40 PM ↻

Focused View

☰

↶ Change Notification Details ✓

📄 Change Notification Information ✓

📁 Supporting Documents ✓

🏢 Company Details ✓

📋 Application Details ✓

🌐 Sites ✓

📦 Product Information ✓

✔ Change Management

🔍 Review

📝 Declaration

Change Management

Change Management Program

Change Management Program – a voluntary program to facilitate timely implementation of software changes for Standalone Medical Mobile Application.

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

Pre-specified Changes

Please enter one pre-specified change per row.

①

No Data Available

< Back

Payment Details >

Subsections

Change Management Program

Pre-specified Changes

This section contains Change Management Program, a voluntary program to facilitate timely implementation of changes for Medical Devices.

5.3.3.10. Payment Details

A Singapore Government Agency Website

How to identify

HSA

Dashboard

M

Application For Product Registration (Change Notification)

Draft

Application No. (Draft)

Last saved at 13 March 2025 09:31 AM

Change Notification Details

Change Notification Information

Supporting Documents

Company Details

Application Details

Sites

Product Information

Change Management

Payment Details

Review

Declaration

Focused View

1

Client Code *

WC-372604

Postal Code

123123

Block / House No.

123

Level / Unit

4 - 3

Street Name

6838 Grimes-Howe Lane

Building Name

Furman Upton

2

GIRO

GIRO

Online

Charge Code	Description	Quantity	Price
MEDCLS-BNF	Ntftn Fee for Adm/Rev CN-Class B Reg MD	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 >

Subsections

Billing Information

Payment Information

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

- 1) Applicants can select the client code from the dropdown list
- 2) Applicants will have two payment options, GIRO and Online payment. Applicants need to choose the preferred payment mode.

5.3.3.11. Review

A Singapore Government Agency Website How to identify ▼



Dashboard 

Application For Product Registration (Change Notification)

Draft Application No. (Draft) Last saved at 13 March 2025 09:31 AM ☰

Focused View 



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

Review

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
 - ☒ 1Ci. Changes to manufacturing site
 - ☒ 1Cii. All other changes
- ☒ 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

- ☒ 2A. All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device
 - ☒ 2Ai. All changes to the control mechanisms, operating principles, sterile primary packaging and/or design characteristics of a registered medical device, except for changes impacting software version
 - ☒ 2Aii. Changes that impact software version that fall under:
 - Software changes 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
 - Software changes which augment interfacing to other non-medical peripherals such as printers or VDUs and which has no diagnostic or therapeutic function
 - Software changes which only modifies the appearance of the user interface with no risk to diagnostic or therapeutic function of the device
 - Software changes solely to address a cybersecurity vulnerability

Review page displays the summary of all the sections filled before the declaration.

A Singapore Government Agency Website

How to identify

HSA

Dashboard

M

Application For Product Registration (Change Notification)

Draft

Application No. (Draft)

Last saved at 13 March 2025 09:31 AM

Focused View

Change Notification Details

Change Notification Information

Supporting Documents

Company Details

Application Details

Sites

Product Information

Change Management

Payment Details

Review

Declaration

Declaration

1

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 and/or

☒ 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.

On behalf of the Product Owner and Franata Company,

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

2

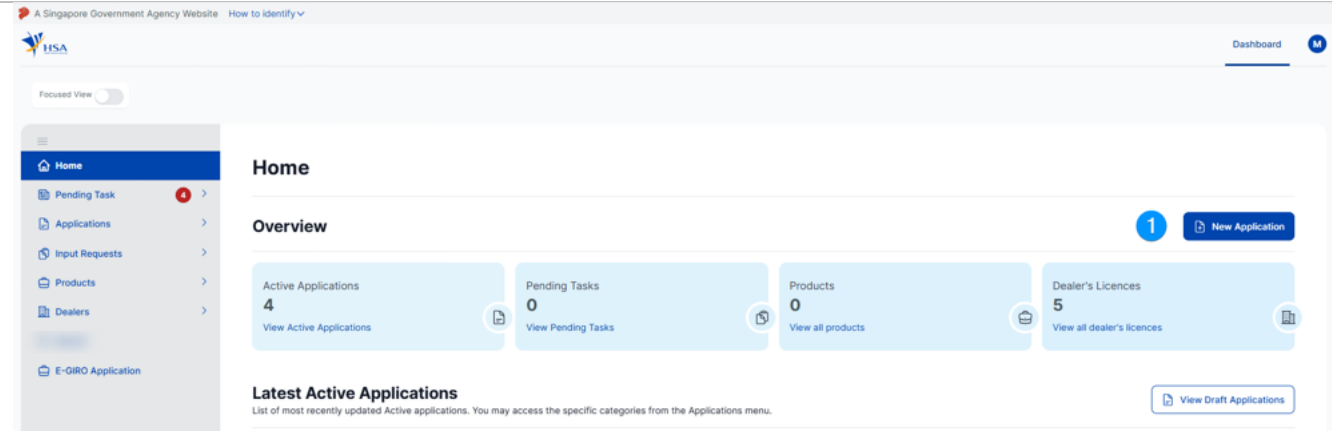
Submit

- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

5.3.4. Change of Registrant

A change of registrant application has to be made to HSA, when there is a change of registrant for a registered medical device. The change of registrant application is to be made by the Accepting Company (the newly appointed registrant).

5.3.4.1. Getting Started – Details



The screenshot shows the HSA dashboard interface. On the left is a sidebar menu with options: Home, Pending Task (with a red notification badge), Applications, Input Requests, Products, Dealers, and E-GIRO Application. The main content area is titled 'Home' and 'Overview'. It features four summary cards: 'Active Applications' with a count of 4, 'Pending Tasks' with a count of 0, 'Products' with a count of 0, and 'Dealer's Licences' with a count of 5. Each card has a 'View' link. A 'New Application' button is prominently displayed in the top right of the overview section, accompanied by a blue circle with the number '1'. Below the summary cards is a section for 'Latest Active Applications' with a 'View Draft Applications' button.

1) Applicants would be able to create a new application by clicking on the ‘New Application’ button.

A Singapore Government Agency Website [How to identify](#)

HSA [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
2 Submission Type	Product Registration
3 Application Type	Change of Registrant
4 Relinquishing Company	Luciana Company
5 Product Owners	Select Product Owner
Search	
Cancel this application and go back to dashboard	

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Product Registration' from the 'Submission Type' dropdown list.
- 3) Applicants can select 'Change of Registrant' from the 'Application Type' dropdown list.
- 4) Applicants can select the relevant relinquishing company.
- 5) Applicants can select the select the relevant product owner.

6) Applicants can create the application.

5.3.4.2. Product List

A Singapore Government Agency Website [How to Identify](#)

HSA Dashboard M

Application For Product Registration (Change Of Registrant) Draft Application No. (Draft)
Last saved at 20 March 2025 11:13 AM

Focused View ☐

Product List

1 Select Products to Transfer

Approved Product Number Product Name

	Approved Product Number	Product Name	Retention Due Date
☐	MDPR250312W0002	GMD 12 Mar 2025 UAT 2036	12/03/2026

Supporting Documents >

- 1) Search for results by entering the required data in the search table and clicking the 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 2) Applicants need to choose which products they would like to transfer to their company.

5.3.4.3. Supporting Documents

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard M

Application For Product Registration (Change Of Registrant) Draft Application No. (Draft)
Last saved at 16 April 2025 03:08 PM

Focused View ☐

Supporting Documents

Instructions for this page:
Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file.

[Download detailed instructions \(PDF\)](#)

[Change of Registrant - Supporting Documents.zip](#)

Supporting Documents Size: 0 Bytes Download All Supporting Documents Delete Documents Upload .zip

✓ **COR Application Dossier**

✓ **1. Letter of Authorisation** Add document Upload .zip Add folder Edit Delete

✓ **2. Letter of Request**

✓ **3. Annex 2 Relinquishing Company Declaration Form**

✓ **4. Other documents**

Remarks/Comments

- 1) Applicants can download detailed instructions for guidance
- 2) Applicants can download the Dossier Template as a zipped folder
- 3) Applicants can add the necessary files to the relevant folders within the Dossier Template and upload the zip file
- 4) Applicants can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - Add document
 - Upload zip file
 - Add folder
 - Edit folder
 - Delete folder

5.3.4.4. New Appointed IL

A Singapore Government Agency Website
How to identify



Dashboard

M

Application For Product Registration (Change Of Registrant)

Draft

Application No. (Draft)

Last saved at 20 March 2025 11:13 AM

Focused View

Product List

Supporting Documents

Appointed Importers

Company Details

Application Details

Payment Details

Review

Declaration

Appointed Importers

0 item(s) selected

Approved Product Number	Product Name	Appointed Importers	Replace/ Add Importer(s)
MDPR250312W0002	GMD 12 Mar 2025 UAT 2036		Add Importer

Back

Company Details

Applicants can add a newly appointed importer licence to the product by entering the Dealer’s Licence Number and click on Get Dealer’s Details to automatically fill up the fields with the information of that importer.

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5.3.4.5. Company Details

A Singapore Government Agency Website | How to identify

HSA

Dashboard

Application For Product Registration (Change Of Registrant)

Draft Application No. (Draft)
Last saved at 20 March 2025 11:14 AM

Company Details

Company Information
This sub-section is pre-filled from your login and requires no action on your part.

Company Name: Franata Company
UEN: FranataCompanyUEN

Company Address *

Clear ACRA Address

Postal Code *: 549880
Block / Number *: 18
Level - Unit: 5 - 9
Street Name *: CHIAP GUAN AVENUE
Building Name:

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	Fran	+65-23456789	

< Back Application Details >

Subsections:
Company Information: ☒
Company Address: ☒
Contact Information: ☒

Focused View: ☐ ☒

Product List ☒
Supporting Documents ☐
Appointed Importers ☒
Company Details ☒
Application Details ☐
Payment Details ☐
Review ☐
Declaration ☐

Applicants can navigate to other sections within the application form by clicking the section name on the left panel.

Company Information

This information is **auto populated based on the Corppass login**.

Applicants cannot edit any of the information for this section

Company Address

This field is automatically populated based on the ACRA address.

However, applicants can clear the pre-filled address and manually enter it if needed.

*Do note that changing the address field in the application form **does not change/update any address in ACRA**.

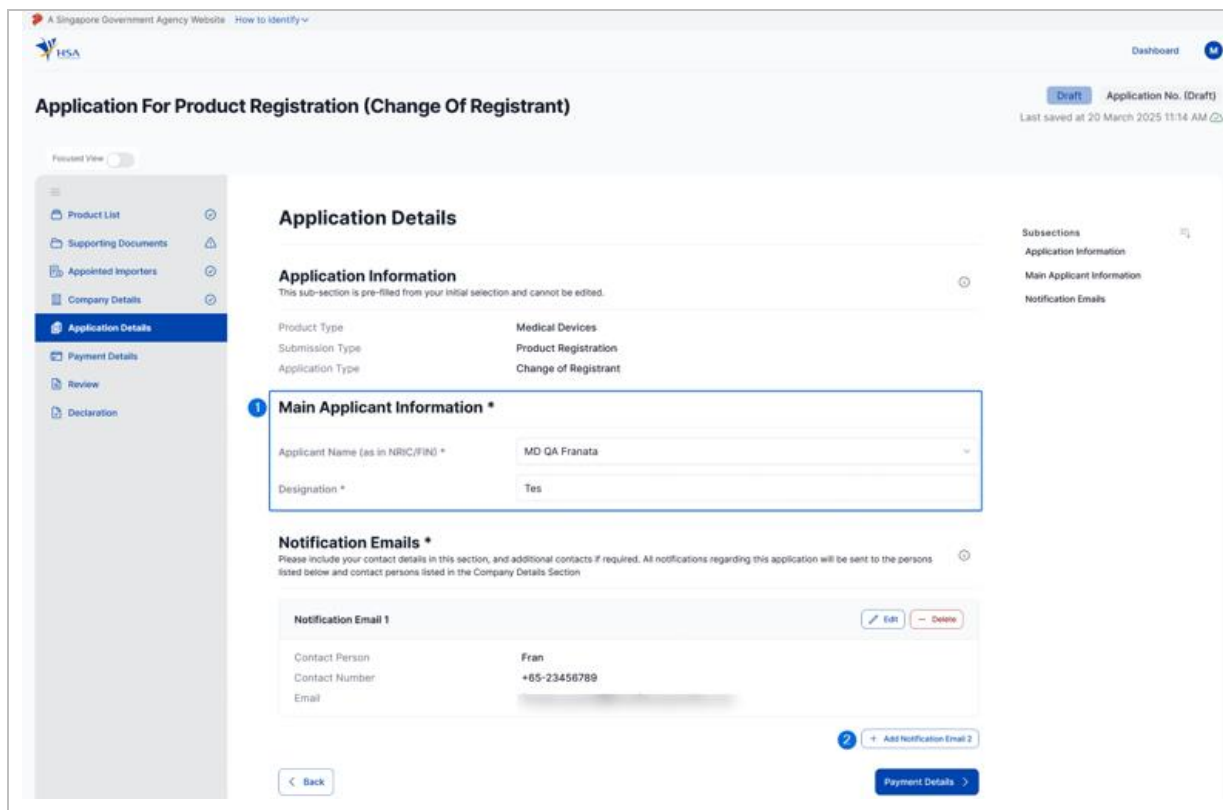
Contact Information

The contact Information refers to a global list of company's default contact details that would be notified for all Applications within the Company.

- 1) Applicants can click on the company address book, opening a new tab that allows them to

update the company's address book. For more details, please refer to 4.1.1 Address book.

5.3.4.6. Application Details



Application For Product Registration (Change Of Registrant)

Application Details

Application Information
This sub-section is pre-filled from your initial selection and cannot be edited.

Product Type: Medical Devices
Submission Type: Product Registration
Application Type: Change of Registrant

1 Main Applicant Information *

Applicant Name (as in NRIC/PIN) *: MD QA Franata
Designation *: Tes

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

Notification Email 1	
Contact Person	Fran
Contact Number	+65-23456789
Email	

2 + Add Notification Email 2

[< Back](#) [Payment Details >](#)

Main Application Information

- 1) The **applicant's name** is automatically 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.

Notification Emails

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.

- 2) The applicant can update the notification email by selecting 'Add Notification Email'.

5.3.4.7. Payment Details

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard

Application For Product Registration (Change Of Registrant) Draft Application No. (Draft)
Last saved at 20 March 2025 11:15 AM

Payment Details

Billing Information *

1 Client Code * WC-372604

Postal Code 123123

Block / House No. 123

Level / Unit 4 - 3

Street Name 6838 Grimes-Howe Lane

Building Name Furman Upton

Payment Information *

2 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
MEDAPPCNG-REG	App Fee to change Registrant of MD	1	\$880.00
	Subtotal		\$880.00
	Tax		\$0.00
	Total		\$880.00

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](#)

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

- 1) Applicants can select the client code from the dropdown list
- 2) Applicants will have two payment options, GIRO and Online payment. Applicants need to choose the preferred payment mode.

A Singapore Government Agency Website

How to identify

HSA

DashboardM

Application For Product Registration (Change Of Registrant)

DraftApplication No. (Draft)
Last saved at 20 March 2025 11:15 AM

Focused View

Product List

Supporting Documents

Appointed Importers

Company Details

Application Details

Payment Details

Review

Declaration

Review

Product List

Supporting Documents

Remarks/Comments

Appointed Importers

Company Information

Company Address

Contact Information

Approved Product Number

Product Name

Retention Due Date

MDPR250312W0002

GMD 12 Mar 2025 UAT 2036

12/03/2026

Supporting Documents Size: 0 Bytes

Download All Supporting Documents

COR Application Dossier

1.Letter of Authorisation

2.Letter of Request

3.Annex 2 Relinquishing Company Declaration Form

4.Other documents

No remarks or comments

Approved Product Number

Product Name

Appointed Importers

MDPR250312W0002

GMD 12 Mar 2025 UAT 2036

MDIL250313S02

Company Name

UEN

Franata Company

FranataCompanyUEN

Address

18, CHIAP GUAN AVENUE, #05-09, Singapore 549880

Contact Information

Review page displays the summary of all the sections filled before the declaration.

5.3.4.9. Declaration

A Singapore Government Agency Website
How to Identify


Dashboard
M

Application For Product Registration (Change Of Registrant)

Draft
Application No. (Draft)
Last saved at 20 March 2025 11:15 AM

Focused View

Product List
Supporting Documents
Appointed Importers
Company Details
Application Details
Payment Details
Review
Declaration

Declaration

1
☒ I acknowledge and accept the appointment by the Product Owner as the new Registrant for the registered medical device(s) submitted in this application and duly acknowledge and accept my duties and obligations as a Registrant;
☒ I shall comply with all the conditions of approval applicable to the registered medical device(s) submitted in this application and conditions imposed on the Registrant; and
☐ Please tick if applicable:

I attest that I will take possession of all records of supply and complaints of the above medical device(s) previously held by the relinquishing company up to the date of approval of this Change of Registrant application by HSA. I am obliged to maintain these records for the period stipulated in the Health Products (Medical Devices) Regulations and provide such records to the Authority in the event of a field safety corrective action or when requested by the Authority.

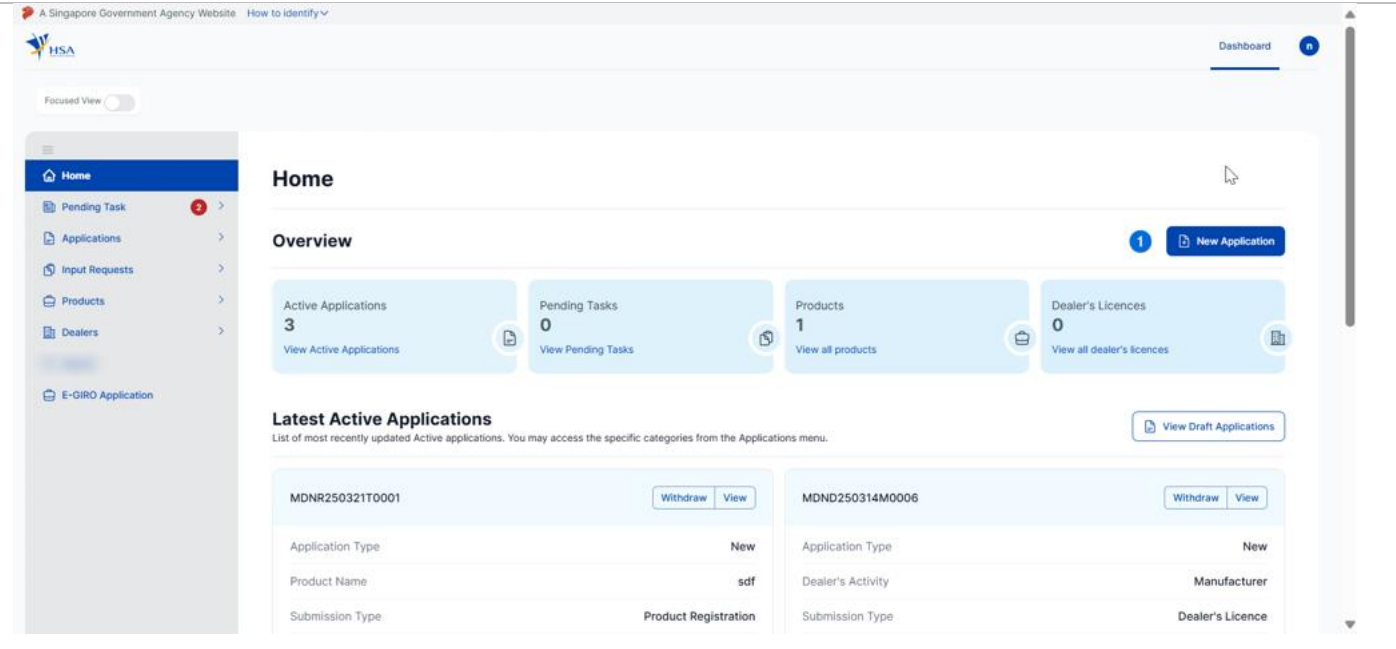
Back
Submit
2

- Applicants need to acknowledge and confirm the declaration
- Applicants can submit the application

Page 165 of 273

5.3.5. Fulfilment Of Approval Condition

5.3.5.1. Getting Started- Details



- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.

A Singapore Government Agency Website
How to identify


Dashboard
M

New Application - Getting Started

Focused View

1. Details
2. Review
3. Checklist

Details

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

Product Type

Medical Devices

2 Submission Type

Product Registration

3 Application Type

Fulfillment Of Approval Conditions

Cancel this application and go back to Dashboard

Cancel

Next

- Applicants would be able to select the type of application they want to submit.
- Applicants would be able to select 'Product Registration' from the 'Submission Type' dropdown list.
 - Applicants would be able to select 'Fulfillment Of Approval Conditions' from the 'Application Type' dropdown list.

5.3.5.2. Getting Started- Review

A Singapore Government Agency Website How to identify

HSA Dashboard M

New Application - Getting Started

Focused View

- Details
- Review**
- Checklist

Review

Instruction for this page
Please select the fulfillment of conditions.

- Product Name Product Number Reset Filter
- | Approval Conditions | Date |
|---|-------------|
| ☐ The registrant need to contact HSA | 08-May-2025 |

ht

Approval Conditions	Date
☐ The registrant need to submit summary report	26-Apr-2025
☐ The Registrant shall submit summary report of the complaints/feedback received globally on the machine learning feature(s) through post-market monitoring on a yearly basis for up to 3 years.	23-Nov-2026

Product Number MDNR250423W0001

Product Number MDNR250422C0026

Request Extension

< Back Next >

- 1) Applicants would be able to use the filter to find a specific Product.
- 2) Applicants would be able to select the approval conditions to fulfil by checking the respective approval condition's checkbox.
- 3) Applicant can **'Error! Not a valid result for table.'**

A Singapore Government Agency Website | How to identify

HSA

Dashboard

New Application - Getting Started

Focused View

- 1. Details
- 2. Review
- 3. Checklist

Checklist

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

Product Type	Medical Devices
Submission Type	Product Registration
Application Type	Fulfillment Of Approval Conditions

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 to fulfil an approval condition for your registered product.

Product for Fulfilment

Approval Conditions	Date
Product Lorem ipsum	22-Mar-2025

Submission Instructions

Please select the approval condition you wish to fulfil and submit the relevant supporting documents.

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

Change Product or Submission Type

< Back

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

4 Create Application

4) Applicants would be able to create the application.

Request Extension



Dashboard

Request Extension

Focused View

1. Details

Review

Declaration

Details

1

MDIL250402R02

Application Number MDND250402F0001

Approval Conditions

Specific condition 2 April 2025 0932

Date

08-Apr-2025

2

Remarks

3

Desired Due Date

dd/mm/yyyy

Cancel

Review

- The applicant will be redirected to Request Extension form.
- 1) Applicants would be able to see the selected approval conditions for the extension request.
 - 2) Applicants would be able to put remarks for the extension request.
 - 3) Applicants would be able to select the “Desired Due Date”.

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard M

Request Extension

Focused View ☐

- 1. Details
- 2. Review**
- 3. Declaration

Review

Your request

MDIL250402R02	Application Number MDND250402F0001
Approval Conditions	Date
Specific condition 2 April 2025 0932	08-Apr-2025

Remarks: no
Desired Due Date: 26-Apr-2025

[< Back](#) [Declaration >](#)

- 4) Review page displays the summary of all the sections filled before the declaration.

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard M

Request Extension

Focused View ☐

- 1. Details
- Review
- Declaration**

Declaration

5

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.
2. I, on behalf of my company, am fully aware that the quality, safety and efficacy of the submitted products will not be evaluated by the HSA.
3. I, on behalf of my company, must comply where applicable, with the Health Products Act and their corresponding regulations. I must also comply with all other applicable laws and their regulations.

☐ I acknowledge and confirm the above declarations.

[< Back](#)

6 [Submit](#)

- 5) Applicants need to acknowledge and confirm the declaration.
- 6) Applicants would be able to submit the extension request.

5.3.5.3. Fulfilment of Approval Condition

A Singapore Government Agency Website
How to identify


HSA

Dashboard
M

Application For Fulfilment Of Approval Condition

Draft
Application No. (Draft)
Last saved at 20 March 2025 11:24 AM

Focused View

Fulfilment of Approval Condition
Review
Declaration

Fulfilment of Approval Condition

1
Upload Files for All Conditions

Excepturi

Approval Conditions	Date	Actions
Product Lorem ipsum		
Uploaded files: 3 Screenshot 2025-03-20 at 10-25-08 HSA SHARE - Applicant - Fulfilment of Approval Condition.png	22-Mar-2025	2 Upload Files

Cancel

Review

- 1) Applicants would be able to upload files for all conditions
- 2) Applicants would be able to upload files for specific condition
- 3) Applicants would be able to download and delete files

Page 173 of 273

5.3.5.4. Review

A Singapore Government Agency Website

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HSA

Health Sciences Authority

Dashboard

M

Application For Fulfilment Of Approval Condition

Draft

Application No. (Draft)

Last saved at 20 March 2025 11:25 AM

Focused View

Fulfilment of Approval Condition

Review

Declaration

Review

Fulfilment of Approval Condition

Product: Excepturi

Approval Conditions

Product Lorem ipsum

Uploaded files:

Screenshot 2025-03-20 at 10-25-08 HSA SHARE - Applicant - Fulfilment of Approval Condition.png

Date

22-Mar-2025

< Back

Declaration >

Review page displays the summary of all the sections filled before the declaration.

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A Singapore Government Agency Website

How to identify

HSA

Dashboard

M

Application For Fulfilment Of Approval Condition

Draft

Application No. (Draft)

Last saved at 20 March 2025 11:25 AM

Focused View

Fulfilment of Approval Condition

Review

Declaration

1

☒ I acknowledge and confirm the above declarations.

< Back

2

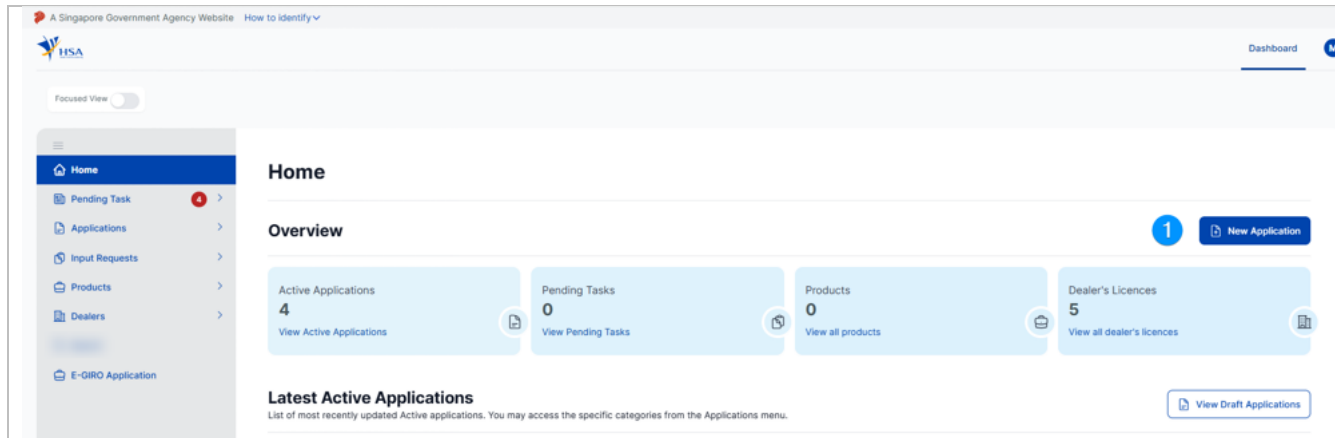
Submit

1) Applicants need to acknowledge and confirm the declaration

2) Applicants can submit the application

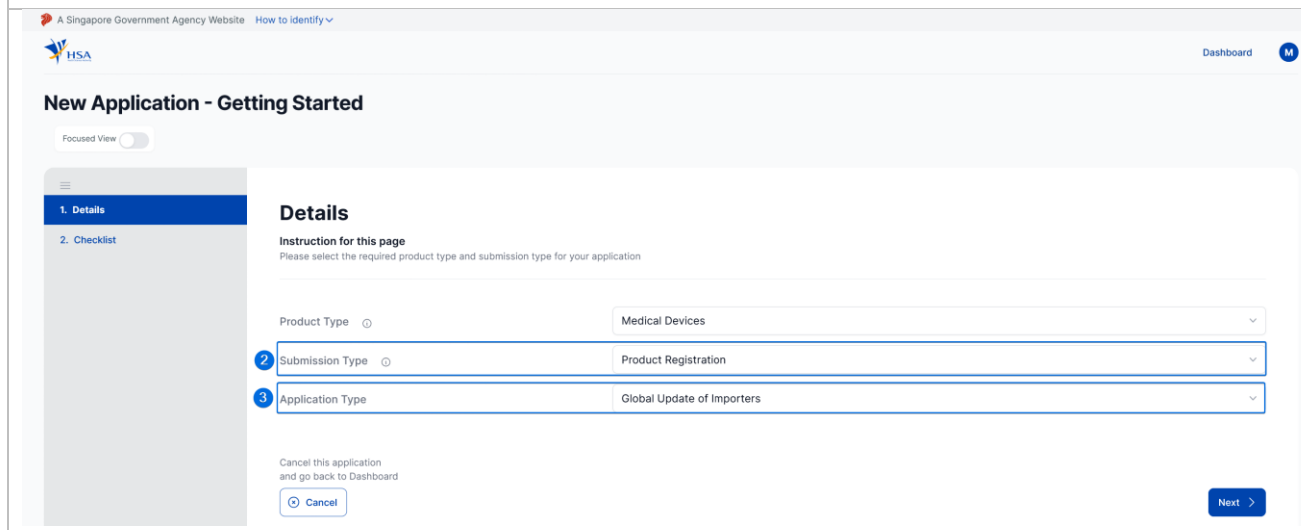
5.3.6. Global Update of Importers

5.3.6.1. Getting Started



The screenshot shows the HSA Dashboard. The top navigation bar includes the HSA logo, a 'How to identify' dropdown, and a 'Dashboard' link. A 'Focused View' toggle is present. The left sidebar contains links for Home, Pending Task (with a red notification badge), Applications, Input Requests, Products, Dealers, and E-GIRO Application. The main content area is titled 'Home' and features an 'Overview' section with four cards: 'Active Applications' (4), 'Pending Tasks' (0), 'Products' (0), and 'Dealer's Licences' (5). 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.

- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.



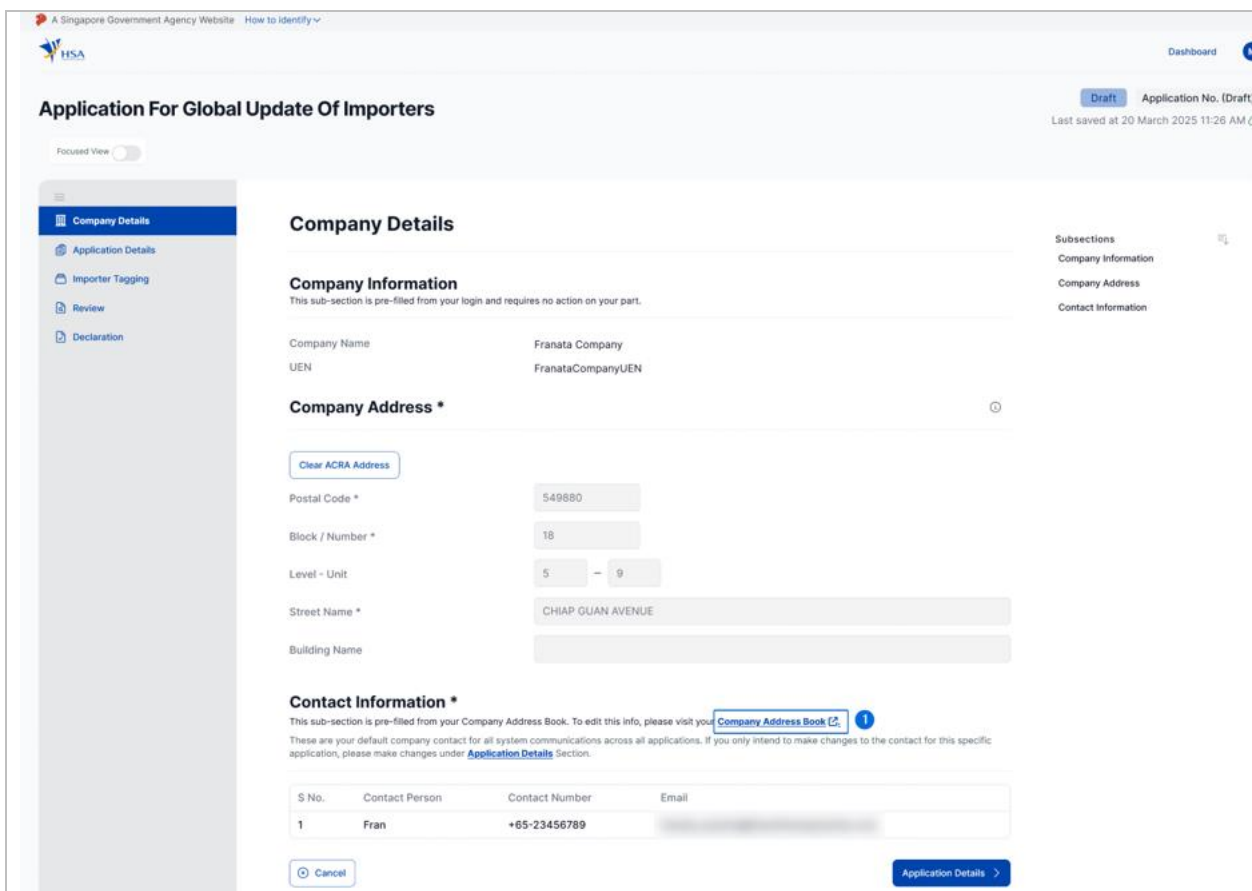
The screenshot shows the 'New Application - Getting Started' page. The top navigation bar includes the HSA logo, a 'How to identify' dropdown, and a 'Dashboard' link. A 'Focused View' toggle is present. The left sidebar contains links for 1. Details and 2. Checklist. The main content area is titled 'Details' and features an 'Instruction for this page' section. Below this is a form with three dropdown menus: 'Product Type' (Medical Devices), 'Submission Type' (Product Registration), and 'Application Type' (Global Update of Importers). A 'Cancel' button is located at the bottom left, and a 'Next' button is at the bottom right.

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Product Registration' from the 'Submission Type' dropdown list
- 3) Applicants can select 'Global Update of Importers' from the 'Application Type' dropdown list

4) Applicants can create the application.

5.3.6.2. Company Details



Application For Global Update Of Importers

Draft Application No. (Draft)

Last saved at 20 March 2025 11:26 AM

Company Details

Company Information

This sub-section is pre-filled from your login and requires no action on your part.

Company Name Franata Company

UEN FranataCompanyUEN

Company Address *

Clear ACRA Address

Postal Code * 549880

Block / Number * 18

Level - Unit 5 - 9

Street Name * CHIAP GUAN AVENUE

Building Name

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	Fran	+65-23456789	

Cancel Application Details

Applicants can navigate to other sections within the application form by clicking the section name on the left panel.

Company Information

This information is **auto populated based on the Corppass login**.

Applicants cannot edit any of the information for this section

Company Address

This field is automatically populated based on the ACRA address.

However, applicants can clear the pre-filled address and manually enter it if needed.

***Do note that changing the address field in the application form **does not** change/update any address in ACRA.**

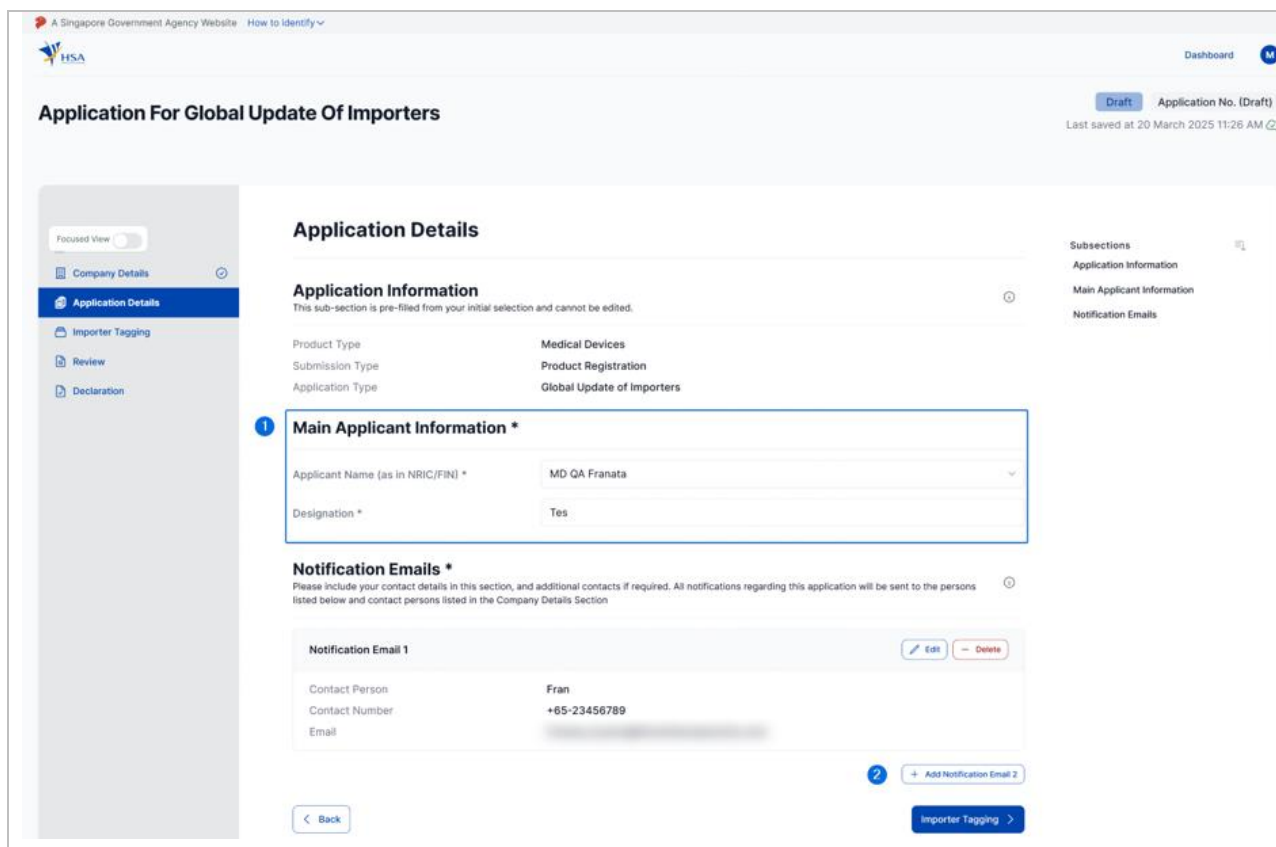
Contact Information

The contact Information refers to a global list of company's default contact details that would be notified for all Applications within the Company.

- 1) Applicants can click on the company address book, opening a new tab that allows them to

update the company's address book. For more details, please refer to 4.1.1 Address book.

5.3.6.3. Application Details



Main Application Information

- 1) The **applicant's name** is automatically 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.

Notification Emails

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.

- 2) The applicant can update the notification email by selecting 'Add Notification Email'.

5.3.6.4. Importer Tagging

A Singapore Government Agency Website [How to identify](#)

HSA

Dashboard M

Application For Global Update Of Importers

Draft Application No. (Draft)
Last saved at 20 March 2025 11:28 AM

Focused View ☐

- Company Details
- Application Details
- Importer Tagging**
- Review
- Declaration

1

Product Number

Product Owner

Device Name

Device Risk Classification

Tagged Importer

Select an option

Reset

Filter

Product Number	Product Owner	Device Name	Device Risk Classification	Expiry Date	Retention Due Date	Tagged Importers	Action
MDPR250313D0017	Hane	Excepturi	D	13/03/2026 09:24 AM	13/03/2026 09:24 AM	MDIL250313S02	2 Manage Importer(s)
MDPR250313C0016	Hane	Cum dicta	C	13/03/2026 09:24 AM	13/03/2026 09:24 AM	MDIL250313S02	Manage Importer(s)
MDPR250313E0018	Hane	Rerum	B	13/03/2026 09:24 AM	13/03/2026 09:24 AM	MDIL250313S02	Manage Importer(s)

< Back

Review >

- 1) Search for results by entering the required data in the search table and clicking 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 2) Applicants would be able to manage the importer licence tied to the selected products.

- 3) Applicants need to fill in the importer's licence number which they want to assign as Importer for the selected product and click 'Get Importer's Details'.

5.3.6.5. Review



Dashboard
M

Application For Global Update Of Importers

Draft
Application No. (Draft)
Last saved at 20 March 2025 11:28 AM

Focused View

Company Details
Application Details
Importer Tagging
Review
Declaration

Review

Company Information

Company Name

Franata Company

UEN

FranataCompanyUEN

Company Address

Address

18, CHIAP GUAN AVENUE, #05-09, Singapore 549880

Contact Information

S No.	Contact Person	Contact Number	Email
1	Fran	+65-23456789	

Application Information

Product Type

Medical Devices

Submission Type

Product Registration

Application Type

Global Update of Importers

Main Applicant Information

Applicant Name (as in NRIC/FIN)

MD QA Franata

Designation

Tes

Notification Emails

Notification Email 1

Contact Person

Fran

Contact Number

+65-23456789

Email

Importer Tagging

Back

Declaration

Review page displays the summary of all the sections filled before the declaration.

Page 182 of 273

5.3.6.6. Declaration

A Singapore Government Agency Website
How to Identify


Dashboard
M

Application For Global Update Of Importers

Draft
Application No. (Draft)
Last saved at 20 March 2025 11:29 AM

Focused View

Company Details
Application Details
Importer Tagging
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 of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

On behalf of Franata Company,

a. I hereby attest that the information provided on this application and in any attached documentation is accurate, correct and complete.

b. I hereby attest that the company has established procedure and system in place, where applicable, for handling, manufacturing, storage, delivery, installation, corrective action and servicing in respect to medical devices handled by the company, and

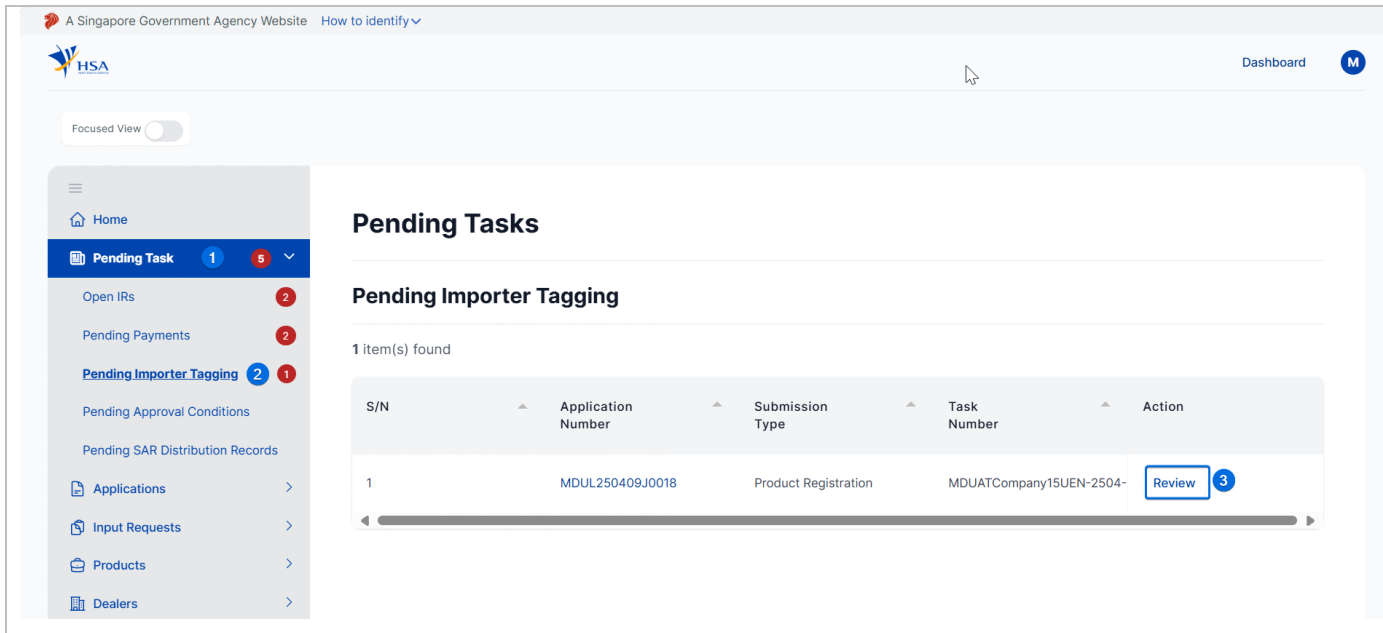
I have thoroughly reviewed and verified the accuracy, correctness, and completeness of this application for the issuance of the requested certificate.

1
☒ I acknowledge and confirm the above declarations.

Back
Submit

- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

5.3.6.7. Tagged Importer Company's Actions



The screenshot shows the HSA user interface. At the top, there is a header with the HSA logo, a navigation bar with 'A Singapore Government Agency Website' and 'How to identify', and a 'Dashboard' link. Below the header, there is a 'Focused View' toggle. On the left, a sidebar menu lists various tasks: 'Home', 'Pending Task' (with a sub-menu), 'Open IRs', 'Pending Payments', 'Pending Importer Tagging' (highlighted with a blue circle and a red notification badge), 'Pending Approval Conditions', 'Pending SAR Distribution Records', 'Applications', 'Input Requests', 'Products', and 'Dealers'. The main content area is titled 'Pending Tasks' and 'Pending Importer Tagging'. It shows '1 item(s) found' and a table with the following data:

S/N	Application Number	Submission Type	Task Number	Action
1	MDUL250409J0018	Product Registration	MDUATCompany15UEN-2504-	Review (with a blue circle and a red notification badge)

- 1) Navigate to 'Pending Tasks'
- 2) Select 'Pending Importer Tagging'
- 3) Tagged importer company would be able to review the assignment as importer for the selected product.

A Singapore Government Agency Website
How to Identify
Dashboard
M

Application For Global Update Of Importers

Focused View

Acceptance of Appointment

Acceptance of Appointment as Importer of Registered Device

The following company has appointed you as the importer of their products. Please review their request and accept the appointment. Upon acceptance, the Singapore Medical Device Register will be updated to reflect the appointment.

Company Information

Company Name: MD QA Lucid Company
UEN: MDQALucidCompanyUEN

Company Address

Address: 27, KRANJI WAY, #09-30, Singapore 739437

Contact Information

S No.	Contact Person	Contact Number	Email
1	MD QA Lucid CP	+65-80132322	

Main Applicant Information

Applicant Name (as in NRIC/FIN): MD QA Lucid
Designation: BA

Notification Emails

Notification Email 1

Contact Person	h
Contact Number	+65-99999999
Email	

Importer Tagging

Product Number	Product Owner	Device Name	Device Risk Classification	Expiry Date	Retention Due Date	Importer
MDPR250423A0012	Murray Med	OMD 23 Apr 2025 IBR1 1450	Class B	23/04/2026	23/04/2026	MDIL250422W14

Cancel

4
Reject
Accept

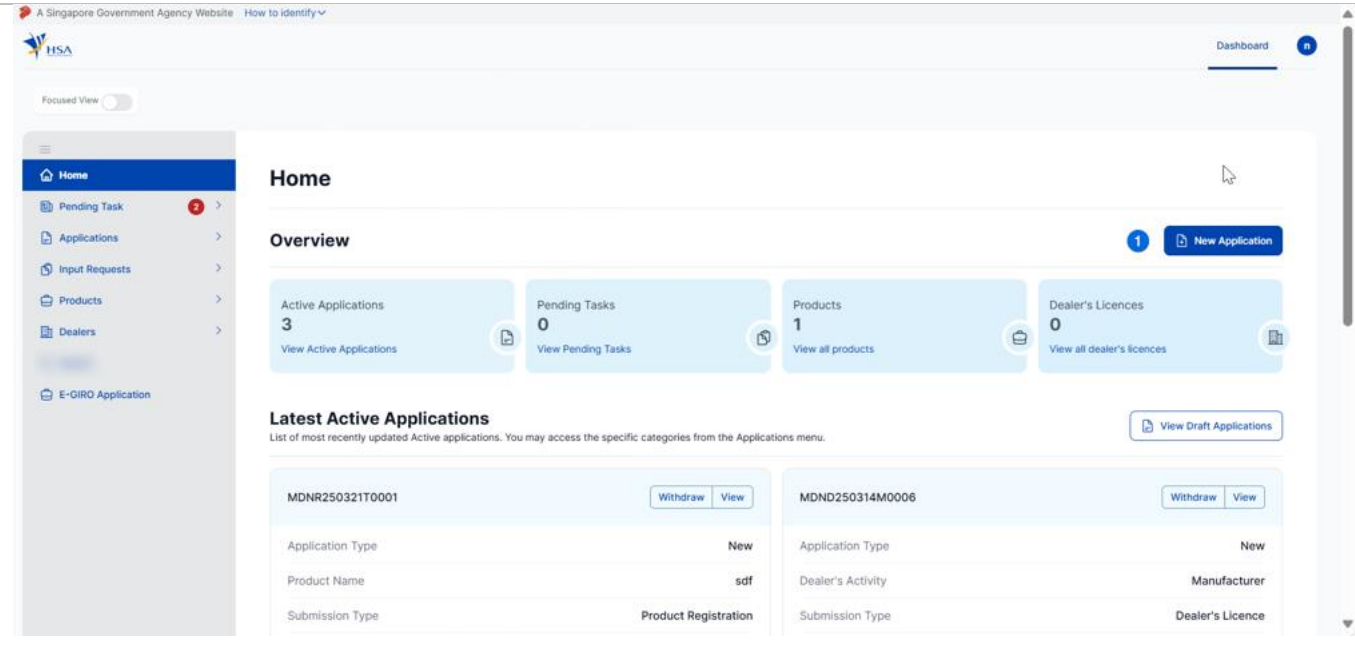
4) Tagged importer company would be able to approve or reject the assignment as importer for the selected product.

5.4. Product Notification

Companies need to notify HSA of their newly introduced Class A medical devices intended for supply in Singapore.

5.4.1. New

5.4.1.1. Getting Started



- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.

A Singapore Government Agency Website [How to identify](#)

HSA 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

2 Submission Type Product Notification

3 Application Type New

Device Risk Classification Class A

4 Authorised Importer/Manufacturer Licence MDIL250403T03 (Importer Licence)

Cancel this application and go back to Dashboard

MDML250405Y02 (Manufacturer Licence)
MDML250403V01 (Manufacturer Licence)
MDML250312U01 (Manufacturer Licence)
MDIL250323W05 (Importer Licence)
MDML250412U01 (Manufacturer Licence)

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Product Notification' from the 'Submission Type' dropdown list
- 3) Applicants can select 'New' from the 'Application Type' dropdown list
- 4) Applicants can select the authorised importer or manufacturer Licence they would like to tie to the products in the application.

A Singapore Government Agency Website
How to identify


Dashboard
M

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 Notification
Application Type	New
Device Risk Classification	Class A
Authorised Importer/Manufacturer Licence	MDIL250403T03 (Importer Licence)



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 Notification for Class A Medical Device(s).

Please note that the list of Class A medical devices manufactured or imported shall be updated prior to the import and/or supply of the Class A medical devices in Singapore.

Submission Instructions

This product notification is for a single Importer's/Manufacturer's Licence.
Please submit a separate application if you wish to list products under a different licence.

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

5
Create Application


5) Applicants can create the application.

5.4.1.2. Company Details

A Singapore Government Agency Website | How to identify

HSA

Dashboard

Application For Product Notification (New)

Draft Application No. (Draft)

Last saved at 15 April 2025 09:46 AM

You are submitting a Product Notification Application for Medical Devices

Company Details

Company Information

This sub-section is pre-filled from your login and requires no action on your part.

Company Name: Luciana Company

UEN: LucianaCompanyUEN

Company Address *

Clear ACRA Address

Postal Code *: 437943

Block / Number *: 148

Level - Unit: 16 - 6

Street Name *: MEYER ROAD

Building Name:

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	Viqa	+65-	
2	sarah	+65-	
3	MD QA Luciana CP	+65-	
4	Test2	+65-	test@abc.com

Cancel

Application Details

Applicants can navigate to other sections within the application form by clicking the section name on the left panel.

Company Information

This information is **auto populated based on the Corppass login**.

Applicants cannot edit any of the information for this section

Company Address

This field is automatically populated based on the ACRA address. However, applicants can clear the pre-filled address and manually enter it if needed.

*Do note that changing the address field in the application form **does not change/update any address in ACRA**.

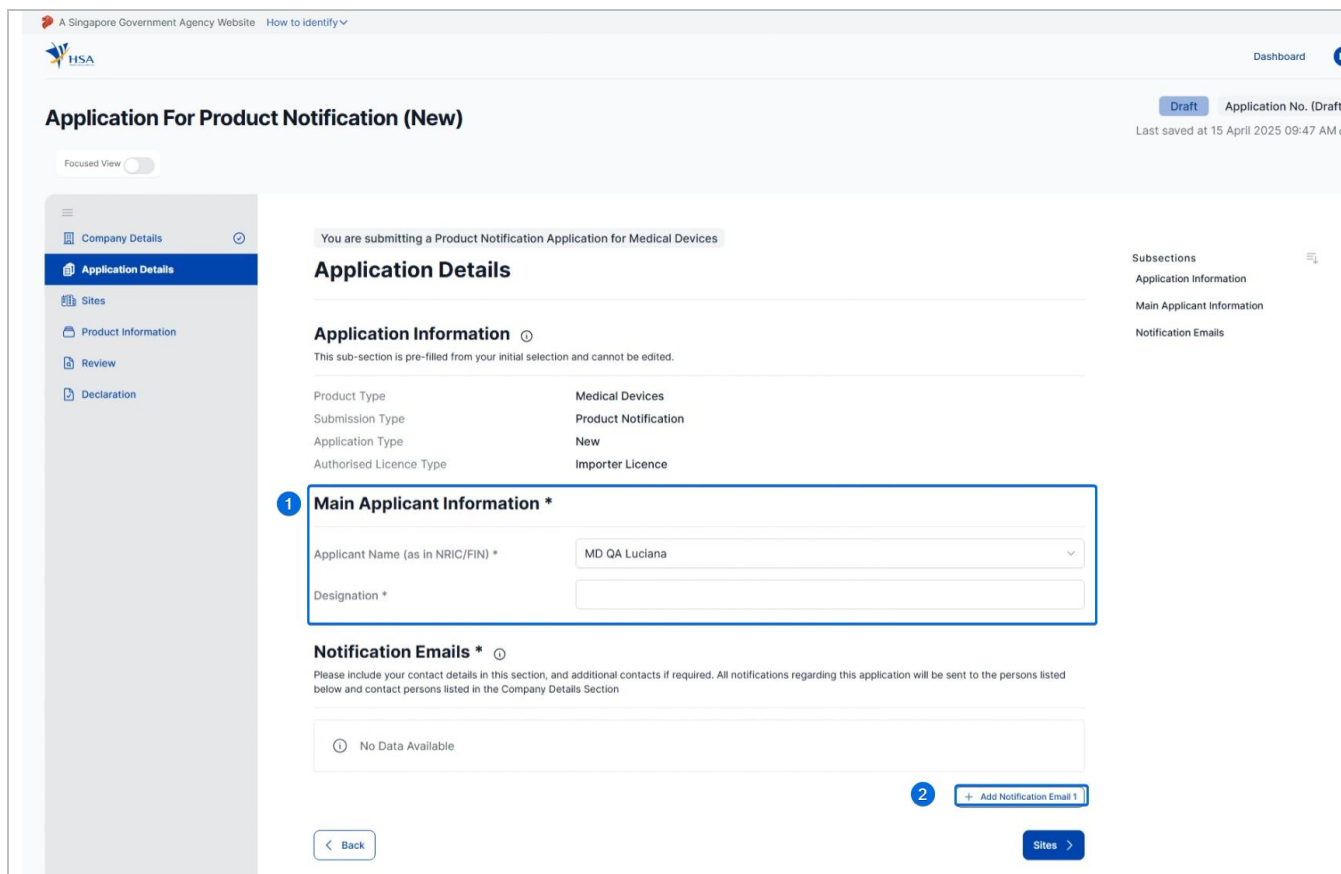
Contact Information

The contact Information refers to a global list of company's default contact details that would be notified for all Applications within the Company.

- Applicants can click on the company address book, opening a new tab that allows them to

update the company's address book. For more details, please refer to 4.1.1 Address book.

5.4.1.3. Applicant Details



Main Application Information

- 1) The **applicant's name** is automatically 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.

Notification Emails

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.

- 2) The applicant can update the notification email by selecting 'Add Notification Email'.

5.4.1.4. Sites

Application For Product Notification (New)

Draft

Application No. (Draft)

Last saved at 15 April 2025 09:48 AM

Focused View

Company Details

Application Details

Sites

Product Information

Review

Declaration

You are submitting a Product Notification Application for Medical Devices

Sites

Instructions for this page:

Please provide at least one Manufacturer - either Overseas or Local

Overseas Manufacturers

Overseas Manufacturer 1

Overseas Manufacturer Name

Ocean

Overseas Manufacturer Address

415 Thomas Street, Algeria

Edit

Delete

+ Add Overseas Manufacturer 2

Local Manufacturers

No Data Available

Back

Product Information

Subsections

Overseas Manufacturers

Local Manufacturers

If the Applicant selects a **manufacturer licence**, the sites associated with that licence will prefill the local manufacturer sites in the manufacturing sites section. Applicants will not be able to remove these sites from the manufacturing sites section. Applicants will still be able to add Overseas Manufacturer.

If the Applicant selects an **importer licence**, they will not be able to add local manufacturers in the manufacturing sites section.

At least one Manufacturer must be added for the Applicant to proceed with the Application.

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5.4.1.5. Product Information

A Singapore Government Agency Website How to identify

HSA

Dashboard M

Application For Product Notification (New)

Draft Application No. (Draft)

Last saved at 15 April 2025 09:56 AM

Focused View

Company Details ✓

Application Details ✓

Sites ✓

Product Information

Review

Declaration

You are submitting a Product Notification Application for Medical Devices

Product Information

1 Product Owner Information *

Please provide product owner information for each product.

No Data Available

+ Add Product Owner 1

2 Device Information

Please provide device information for your products.

Are any of your devices sterile? * ☐ Yes ☒ No

3 Device Listing *

Please download the excel template and fill in your devices before uploading.

Overseas Manufacturer 1 [Ocean]

View Site Details

[Class A Product Notification List.xlsx](#)

Upload device list

Select files to upload... or drag and drop

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

New Listing

< Back

Review >

Subsections

Product Owner Information

Device Information

Device Listing

Product Information

- Applicants need to add details of the Product Owners, such as their name and location. There can be multiple Product Owners of their product, product owners can be either local or foreign. Multiple local or foreign product owners and at least one product owner must be added for the applicant to proceed with the application.

Device Information

- Applicants need to declare if there are any sterile Medical Devices being notified.

Device Listing

- Applicants have the option to add products through two methods:
 - By uploading an Excel file. Applicants can download the template file by clicking on 'Class A Product Notification List.xlsx'.
 - By adding products individually via the 'New Listing' option, entering the details manually.

5.4.1.6. Review

A Singapore Government Agency Website
How to identify



Dashboard
M

Application For Product Notification (New)

Draft
Application No. (Draft)
Saving ...

Company Details
Application Details
Sites
Product Information
Review
Declaration

You are submitting a Product Notification Application for Medical Devices

Review

Company Information

Company Name
Luciana Company
UEN
LucianaCompanyUEN

Company Address

Address
148, MEYER ROAD, #16-06, Singapore 437943

Contact Information

S No.	Contact Person	Contact Number	Email
1	Viga	+65-1	
2	sarah	+65-1	

Review page displays the summary of all the sections filled before the declaration.

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A Singapore Government Agency Website

How to identify

HSA

DashboardM

DraftApplication No. (Draft)

Last saved at 15 April 2025 10:39 AM🕒

Focused View🔍

Company Details

Application Details

Sites

Product Information

Review

Declaration

You are submitting a Product Notification Application for Medical Devices

Declaration

On behalf of Luciana Company,

a. I hereby attest that the information provided on this application and in any attached documentation is accurate, correct and complete.

b. I hereby attest that I have direct knowledge of the established procedures and systems in place in respect to distribution records, complaint handling, adverse event reporting and field safety corrective actions, including product recalls.

c. I hereby attest that the company has established procedure and system in place, where applicable, for handling, manufacturing, storage, delivery, installation, corrective action and servicing in respect to medical devices handled by the company, and

d. I understand that I will be liable to prosecution for an offence under section 24(6) of the Health Products Act (Cap.122D) if I make any statement or furnish any document that I know to be false or which I do not believe to be true; or if I intentionally suppress any material fact such that the information furnished is misleading.

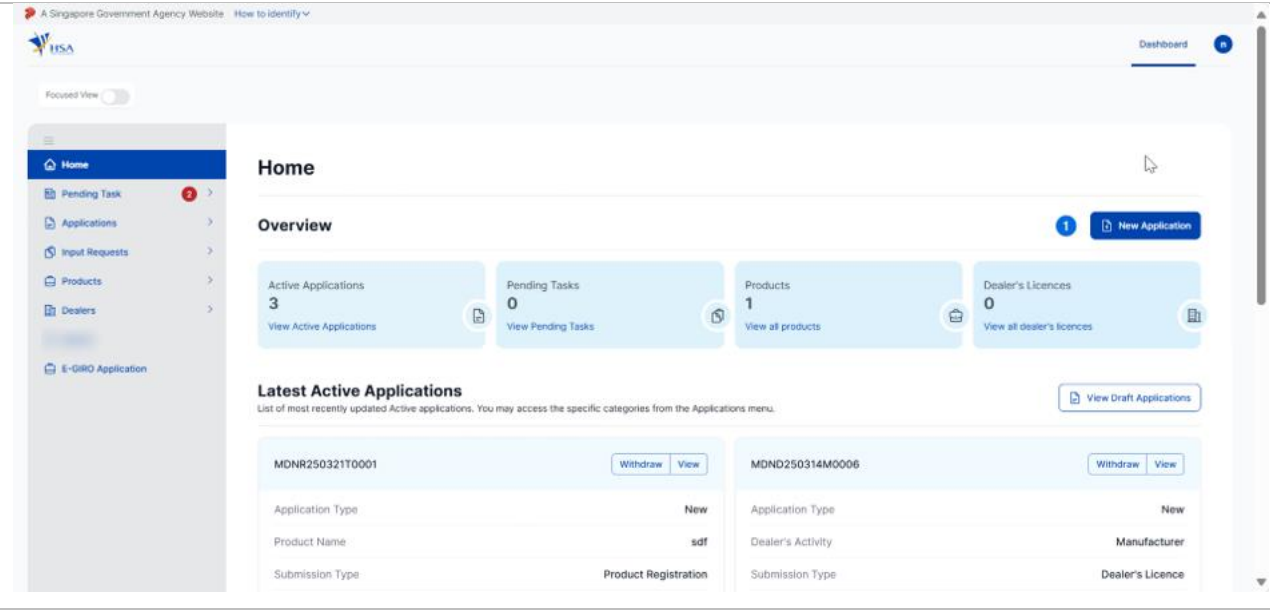
1☐ I acknowledge and confirm the above declarations.

< Back

2Submit📎

5.4.2. Amendment

5.4.2.1. Getting Started



- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.

A Singapore Government Agency Website [How to identify](#)

HSA [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

2 Submission Type
Product Notification

3 Application Type
Amendment

Device Risk Classification
Class A

4 Authorised Importer/Manufacturer Licence
Select an option
MDML250313X03 (Manufacturer Licence)

Cancel this application and go back to Dashboard

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Product Notification' from the 'Submission Type' dropdown list
- 3) Applicants can select 'Amendment' from the 'Application Type' dropdown list
- 4) Applicants can select the related authorised importer or manufacturer Licence of the product(s) they would like to amend in the application.

A Singapore Government Agency Website
How to Identify


Dashboard
M

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 Notification
Application Type	Amendment
Device Risk Classification	Class A
Authorised Importer/Manufacturer Licence	MDIL250604V02 (Importer Licence)


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 the amendment of previously notified Class A medical devices.

Please note that the list of Class A medical devices manufactured or imported shall be updated prior to the import and/or supply of the Class A medical devices in Singapore.

Submission Instructions

This amendment of product notification application is for a single Importer's/Manufacturer's Licence.
Please submit a separate application if you wish to amend previously notified products under a different licence.

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

Back
Create Application

5) Applicants can create the application.

5.4.2.2. Device Selection

A Singapore Government Agency Website [How to Identify](#)

HSA Dashboard

Application For Product Notification (Amendment) Draft Application No. (Draft)
Last saved at 13 March 2025 11:19 AM

Focused View

Device Selection

You are submitting a Product Notification Application for Medical Devices

1 Device Selection

Product Name Product Owners
Manufacturers Intended Use
Device Identifier (Model No.) UDI-DI
DM-DI

Reset Filter

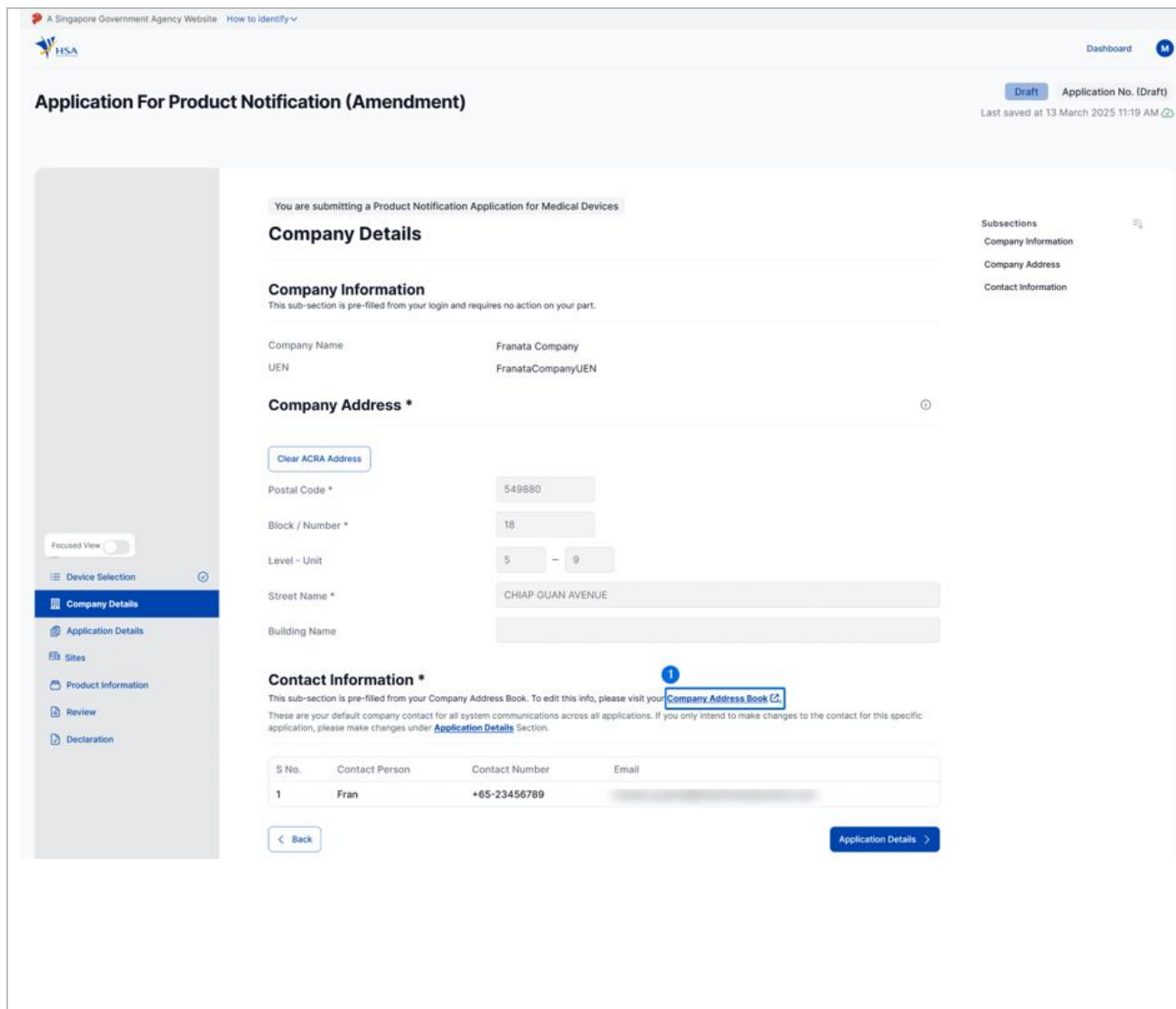
2

	Product Name	Product Owners	Manufacturers	Intended Use	Device Identifier (Model No.)	UDI-DI	DM-DI
☒	Sint	Hane	Franata Company, Hunter47	Dolorem accusantium commodi quae.	Ad eos		
☐	Fuga	Orn	Franata Company, Hunter47	Culpa provident corrupti repellat.	Animi		

Cancel Company Details

- 1) Applicants can search for products by entering the required data in the search table and clicking 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 2) Applicants can select the product by checking the box.

5.4.2.3. Company Details



Application For Product Notification (Amendment)

Company Details

Company Information
This sub-section is pre-filled from your login and requires no action on your part.

Company Name: Franata Company
UEN: FranataCompanyUEN

Company Address *

Clear ACRA Address

Postal Code *: 549880
Block / Number *: 18
Level - Unit: 5 - 9
Street Name *: CHIAP GUAN AVENUE
Building Name:

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	Fran	+65-23456789	

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

Applicants can navigate to other sections within the application form by clicking the section name on the left panel.

Company Information

This information is **auto populated based on the Corppass login**. Applicants cannot edit any of the information for this section

Company Address

This field is automatically populated based on the ACRA address. However, applicants can clear the pre-filled address and manually enter it if needed.

***Do note that changing the address field in the application form **does not** change/update any address in ACRA.**

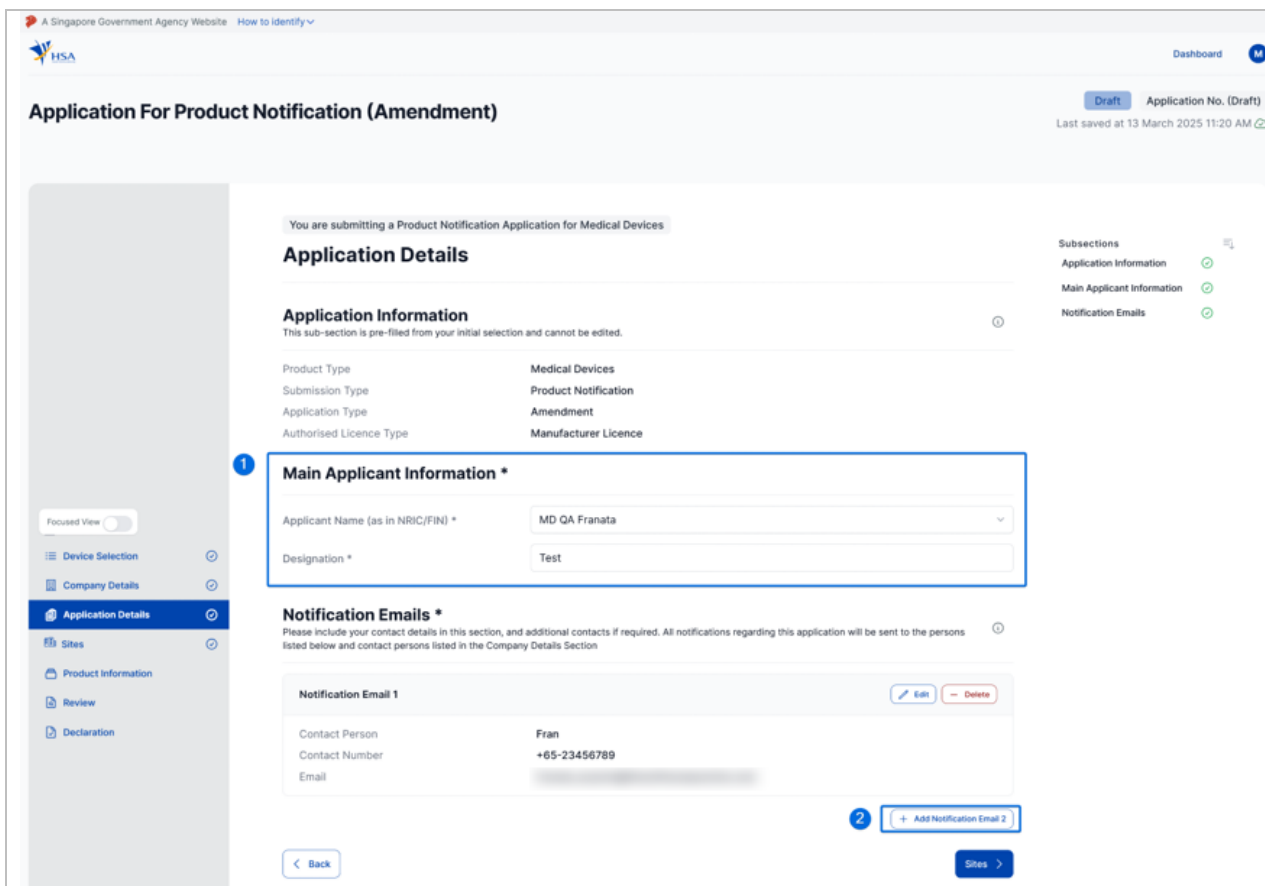
Contact Information

The contact Information refers to a global list of company's default contact details that would be notified for all Applications within the Company.

- 1) Applicants can click on the company address book, opening a new tab that allows them to

update the company's address book. For more details, please refer to 4.1.1 Address book.

5.4.2.4. Application Details



Application For Product Notification (Amendment)

You are submitting a Product Notification Application for Medical Devices

Application Details

Application Information
This sub-section is pre-filled from your initial selection and cannot be edited.

Product Type: Medical Devices
Submission Type: Product Notification
Application Type: Amendment
Authorised Licence Type: Manufacturer Licence

Main Applicant Information *

Applicant Name (as in NRIC/FIN) *: MD QA Franata
Designation *: Test

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

Notification Email 1

Contact Person: Fran
Contact Number: +65-23456789
Email: [Redacted]

2 [+ Add Notification Email 2](#)

[Back](#) [Sites](#)

Main Application Information

- 1) The **applicant's name** is automatically 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.

Notification Emails

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.

- 2) The applicant can update the notification email by selecting 'Add Notification Email'.

5.4.2.5. Sites

A Singapore Government Agency Website

How to identify

HSA

DashboardM

Application For Product Notification (Amendment)

DraftApplication No. (Draft)

Last saved at 13 March 2025 11:20 AM

Focused View

Device Selection

Company Details

Application Details

Sites

Product Information

Review

Declaration

You are submitting a Product Notification Application for Medical Devices

Sites

Instructions for this page:

Please provide at least one Manufacturer - either Overseas or Local

Subsections

Overseas Manufacturers

Local Manufacturers

Overseas Manufacturers

Overseas Manufacturer 1

Overseas Manufacturer Name

Hunter47

Overseas Manufacturer Address

1553 Shields Knolls, Denmark

+ Add Overseas Manufacturer 2

Local Manufacturers

Local Manufacturer 1

Local Manufacturer Licence/Dealer's
Licence Number

MDML250313X03

Local Manufacturer Name

Franata Company

Local Manufacturer Address

18, CHIAP GUAN AVENUE, #05-09, Singapore 549880

Site Details

Jennings Kihn (123, 45744 Armstrong Parkways 4 - 5, Demario Orn, 123123 Singapore)

< Back

Product Information >

If the Applicant selects a **manufacturer licence**, the sites associated with that licence will prefill the local manufacturer sites in the manufacturing sites section. Applicant will not be able to remove these sites from the manufacturing sites section. Applicant is still able to add Overseas Manufacturer.

If the Applicant selects an **importer licence**, they will not be able to add local manufacturers in the manufacturing sites section.

At least one Manufacturer must be added for the Applicant to proceed with the Application.

5.4.2.6. Product Information

A Singapore Government Agency Website
How to identify

HSA
Dashboard
M

Application For Product Notification (Amendment)
Draft
Application No. (Draft)
Last saved at 13 March 2025 11:20 AM

You are submitting a Product Notification Application for Medical Devices

Product Information

1
Product Owner Information *
Please provide product owner information for each product.

Product Owner 1 (Local)
Edit
Delete

Product Owner Name
Hane

Address
123, 36181 Watsica Wall, #06-07, Katherine Volkman, Singapore 123123

Add Product Owner 2

2
Device Information
Please provide device information for your products.

Are any of your devices sterile? *
☐ Yes
☒ No

3
Device Listing *
Please download the excel template and fill in your devices before uploading.
View Site Details

Class A Product Notification List.xlsx
Assign Product Owner
Assign Manufacturers

0 item(s) selected

	Product Owner	Device Name	Intended Use	Device Identifier (Model No.)	UDI-DI	DM-DI	UDI Issuance	Action
☐	Hane	Sint	Dolorem accusantium commodi quae.	Ad eos				Edit

Back
Review

Product Information

- Applicants need to add details of the Product Owners, such as their name and location. There can be multiple Product Owners of their product, product owners can be either local or foreign. Multiple local or foreign product owners and at least one product owner must be added for the applicant to proceed with the application.

Device Information

- Applicants need to declare if there are any sterile Medical Devices being notified.

Device Listing

- Applicants have the option to edit the product via the 'Edit' button.

5.4.2.7. Review

A Singapore Government Agency Website
How to identify


Dashboard

Application For Product Notification (Amendment)

Draft
Application No. (Draft)
Last saved at 13 March 2025 11:22 AM

Device Selection
Company Details
Application Details
Sites
Product Information
Review
Declaration

You are submitting a Product Notification Application for Medical Devices

Review

Company Information

Company Name

Franata Company

UEN

FranataCompanyUEN

Company Address

Address

18, CHIAP GUAN AVENUE, #05-09, Singapore 549880

Contact Information

S No.	Contact Person	Contact Number	Email
1	Fran	+65-23456789	

Review page displays the summary of all the sections filled before the declaration.

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5.4.2.8. Declaration

A Singapore Government Agency Website
How to Identify



Dashboard

M

Application For Product Notification (Amendment)

Draft

Application No. (Draft)

Last saved at 13 March 2025 11:22 AM

Focused View

Device Selection

Company Details

Application Details

Sites

Product Information

Review

Declaration

You are submitting a Product Notification Application for Medical Devices

Declaration

On behalf of Franata Company,

a. I hereby attest that the information provided on this application and in any attached documentation is accurate, correct and complete.

b. I hereby attest that I have direct knowledge of the established procedures and systems in place in respect to distribution records, complaint handling, adverse event reporting and field safety corrective actions, including product recalls.

c. I hereby attest that the company has established procedure and system in place, where applicable, for handling, manufacturing, storage, delivery, installation, corrective action and servicing in respect to medical devices handled by the company, and

d. I understand that I will be liable to prosecution for an offence under section 24(6) of the Health Products Act (Cap.122D) if I make any statement or furnish any document that I know to be false or which I do not believe to be true; or if I intentionally suppress any material fact such that the information furnished is misleading.

1

☒ I acknowledge and confirm the above declarations.

< Back

2

Submit

- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

Page 204 of 273

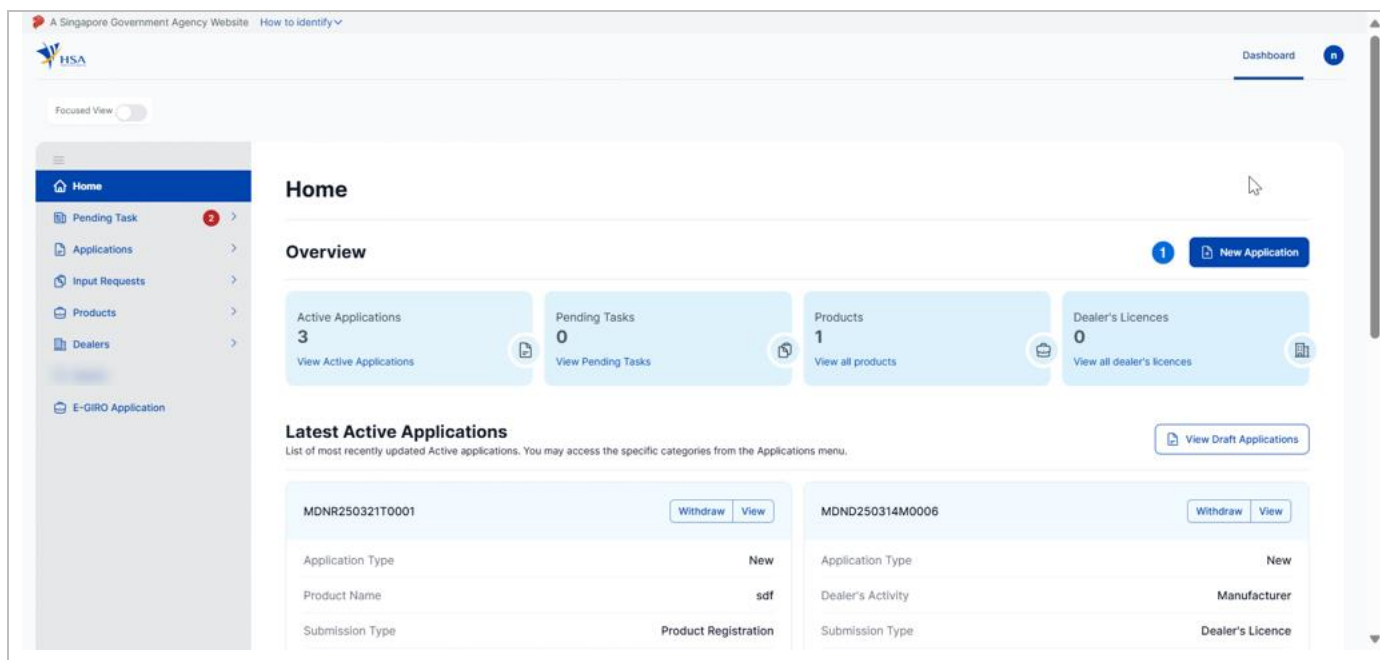
5.5. Special Access Route

Companies may choose to import and supply Medical Devices in Singapore through Special Access Route (SAR).

5.5.1. New

The SAR allows for the import and supply of unregistered medical devices for clinical use, export or re-export, non-clinical purposes, or for the import of registered medical devices on a single consignment basis. Each application must be approved by HSA before the products can be imported and supplied.

5.5.1.1. Getting Started – Details



- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.

A Singapore Government Agency Website [How to identify](#)

HSA [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

2

Submission Type

Special Access Route

3

Application Type

New

Cancel this application and go back to Dashboard

[Cancel](#)

[Next >](#)

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Special Access Route' from the 'Submission Type' dropdown list
- 3) Applicants can select 'New' from the 'Application Type' dropdown list

A Singapore Government Agency Website [How to Identify](#)

HSA Dashboard

New Application - Getting Started

Followed View

1. Details
2. Checklist

Checklist

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

Product Type	Medical Devices
Submission Type	Special Access Route
Application Type	New

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 an application for a Special Access Route (SAR). Please note that the applicant shall be the importer of the medical device(s).

Submission Instructions

Please refer to GN-35 Guidance on Special Access Route found on the HSA website for the list of supporting documents for each SAR route.

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

Change Product or Submission Type

[Back](#)

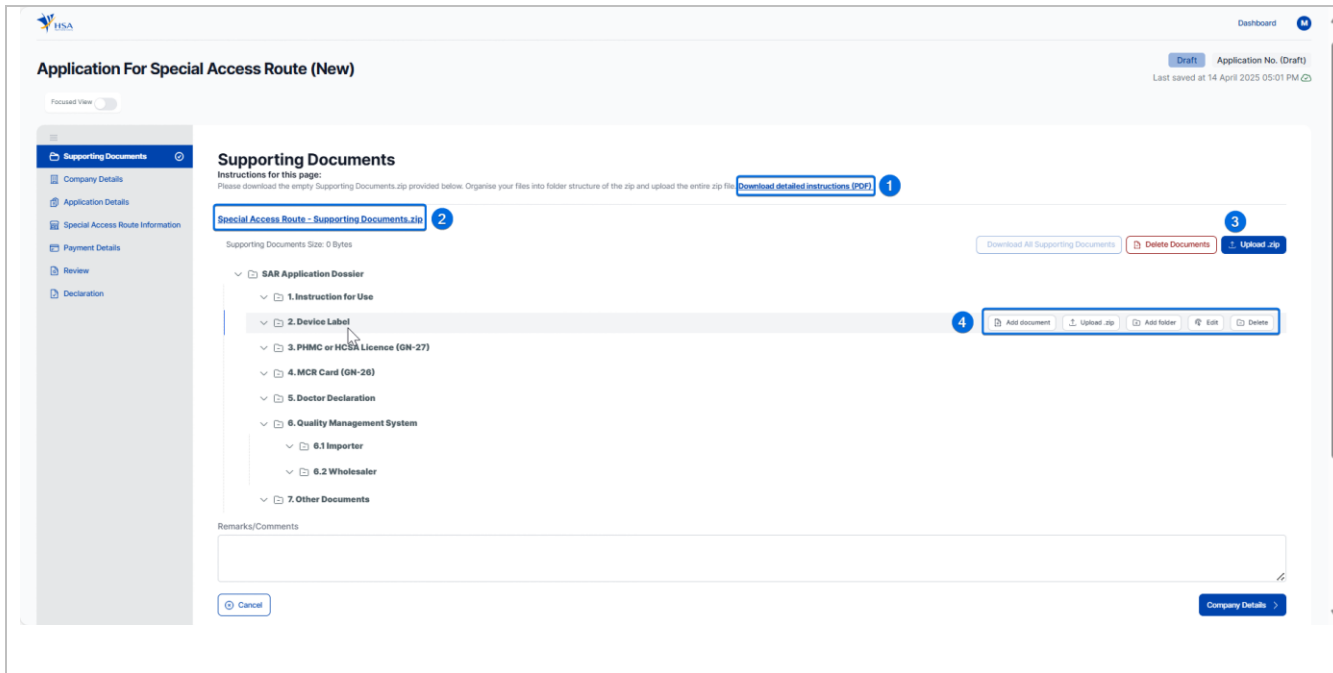
[View Checklist](#)

4 [Create Application](#)

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

4) Applicants can create the application.

5.5.1.2. Supporting Documents



Application For Special Access Route (New)

Dashboard | Draft | Application No. (Draft) | Last saved at 14 April 2025 05:01 PM

Supporting Documents

Instructions for this page:
Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file.

[Download detailed instructions \(PDF\)](#) 1

[Special Access Route - Supporting Documents.zip](#) 2

Supporting Documents Size: 0 Bytes

[Download All Supporting Documents](#) [Delete Documents](#) [Upload zip](#) 3

SAR Application Dossier

- 1. Instruction for Use
- 2. Device Label 4
- 3. PHMC or HCSA Licence (GN-27)
- 4. MCR Card (GN-26)
- 5. Doctor Declaration
- 6. Quality Management System
 - 6.1 Importer
 - 6.2 Wholesaler
- 7. Other Documents

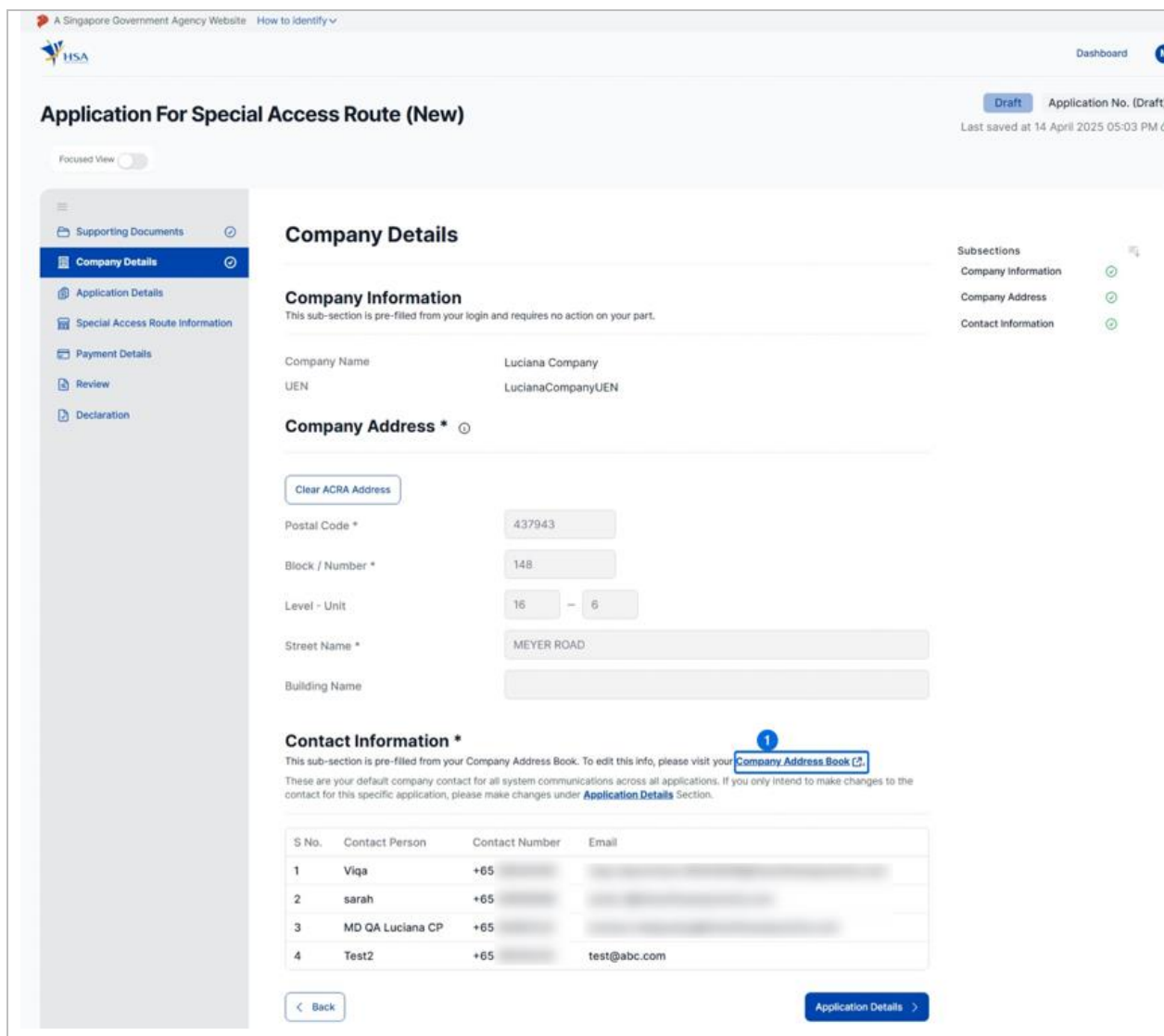
[Add document](#) [Upload zip](#) [Add folder](#) [Edit](#) [Delete](#)

Remarks/Comments

[Cancel](#) [Company Details](#)

- 1) Applicants can download detailed instructions for guidance
- 2) Applicants can download the Dossier Template as a zipped folder
- 3) Applicants can add the necessary files to the relevant folders within the Dossier Template and upload the zip file
- 4) Applicants can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - Add document
 - Upload zip file
 - Add folder
 - Edit folder
 - Delete folder

5.5.1.3. Company Details



A Singapore Government Agency Website | How to identify

HSA | Dashboard | M

Application For Special Access Route (New)

Draft | Application No. (Draft) | Last saved at 14 April 2025 05:03 PM

Focused View

Supporting Documents | **Company Details** | Application Details | Special Access Route Information | Payment Details | Review | Declaration

Company Details

Company Information

This sub-section is pre-filled from your login and requires no action on your part.

Company Name: Luciana Company
UEN: LucianaCompanyUEN

Company Address *

Clear ACRA Address

Postal Code *: 437943
Block / Number *: 148
Level - Unit: 16 - 6
Street Name *: MEYER ROAD
Building Name:

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	Viqa	+65	
2	sarah	+65	
3	MD QA Luciana CP	+65	
4	Test2	+65	test@abc.com

< Back | Application Details >

Applicants can navigate to other sections within the application form by clicking the section name on the left panel.

Company Information

This information is **auto populated based on the Corppass login**.

Applicants cannot edit any of the information for this section

Company Address

This field is automatically populated based on the ACRA address.

However, applicants can clear the pre-filled address and manually enter it if needed.

*Do note that changing the address field in the application form **does not change/update any address in ACRA**.

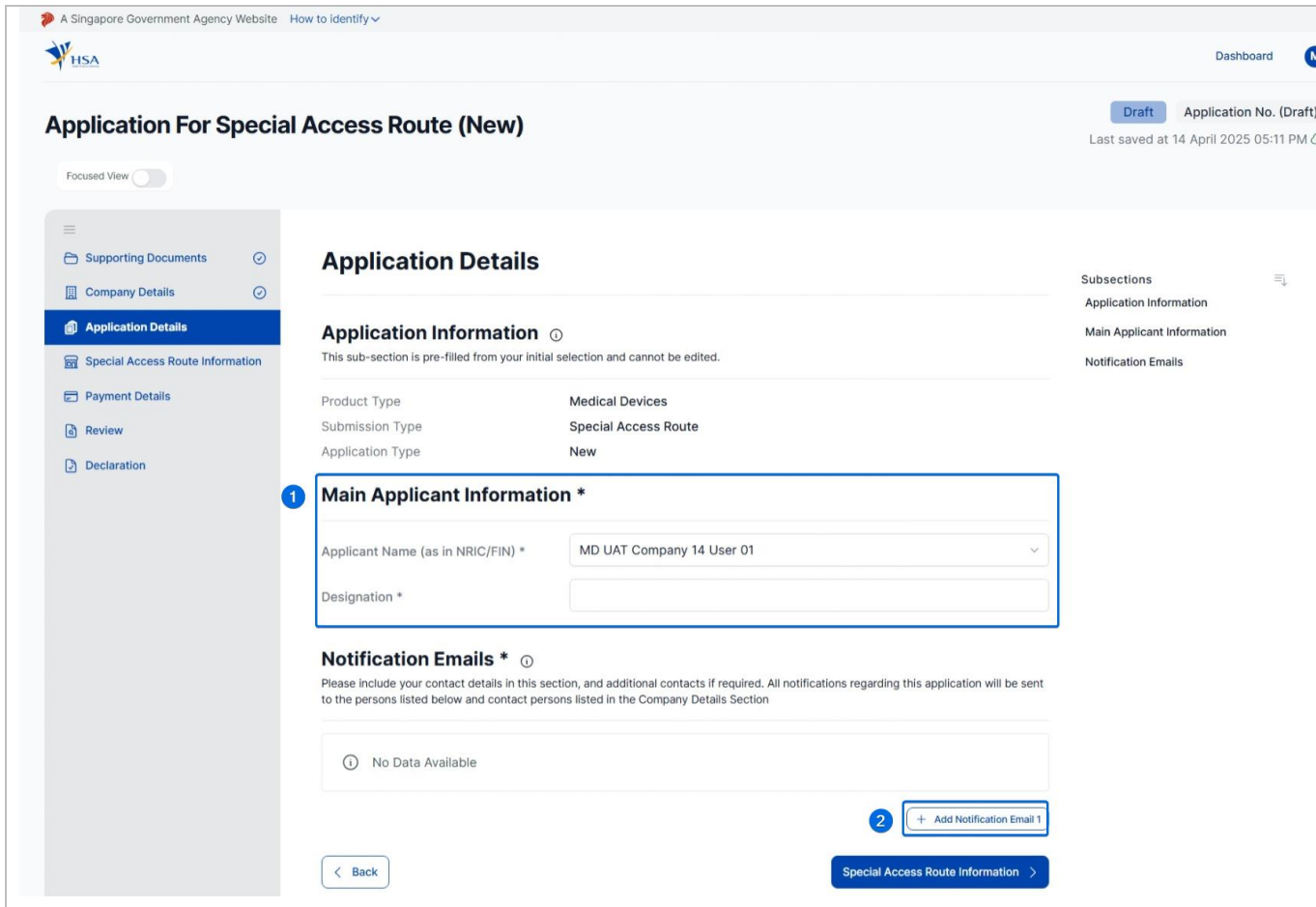
Contact Information

The contact Information refers to a global list of company's default contact details that would be notified for all Applications within the Company.

- Applicants can click on the company address book, opening a new tab that allows them to

update the company's address book. For more details, please refer to 4.1.1 Address book.

5.5.1.4. Application Details



Main Application Information

- 1) The **applicant's name** is automatically 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.

Notification Emails

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.

- 2) The applicant can update the notification email by selecting 'Add Notification Email'.

5.5.1.5. Special Access Route Information

Singapore Government Agency Website | How to identify | Dashboard

Application For Special Access Route (New) | Draft | Application No. (Draft) | Last saved at: 14 April 2025 05:12 PM

Supporting Documents | Company Details | Application Details | **Special Access Route Information** | Device Information | Payment Details | Review | Declaration

Special Access Route Information

1 Purpose of Importation *
Please ensure that the purpose of importation is correct as amendment and refund will not be allowed upon submission. Otherwise, please write to the Health Sciences Authority for confirmation.

Purpose of Importation *

- ☐ GN-26: Clinical - For use on licenced qualified practitioner's patient
- ☒ GN-27: Clinical - For use in the HCSA Licensed Premise
- ☐ GN-28: For export or re-export
- ☐ GN-29: For non-clinical purpose
- ☐ GN-30: Single Import Consignment

2 Licence Information

Licence No. | Licence Type

MDL250317C08 | Importer Licence

MDWL250317R09 | Wholesaler Licence

MDML250317F07 | Manufacturer Licence

Importer Licence | MDL250317C08

Wholesaler Licence | MDWL250317R09

	Importer Licence	Wholesaler Licence	Manufacturer Licence
ISO13485		✓	✓
Declaration of Conformity to Quality Management System (QMS): ISO13485			
GDPMDS			
Declaration of Conformity to Quality Management System (QMS): GDPMDS			
MDSAP			
Exempted from GDPMDS (Medical devices solely for non-clinical and/or import for re-export only)	✓		

Is the Wholesaler the same as the Importer? ☒ Yes ☐ No

3 Application Information

Clinical Purpose of Importation

☐ No Data Available

Other Information

1. Type of Devices *

☐ General Medical Devices ☐ In-Vitro Devices

2. Impacted by open Field Safety Corrective Actions or Adverse Events *

☐ Yes ☒ No

3. Subjected to other regulatory control in Singapore *

☐ Yes ☒ No

4. Submitted Product Registration *

☐ Yes ☒ No

Justification *

[Back](#) [Device Information](#)

Purpose of Importation

- 1) Applicants need to select the purpose of importation.

Licence Information

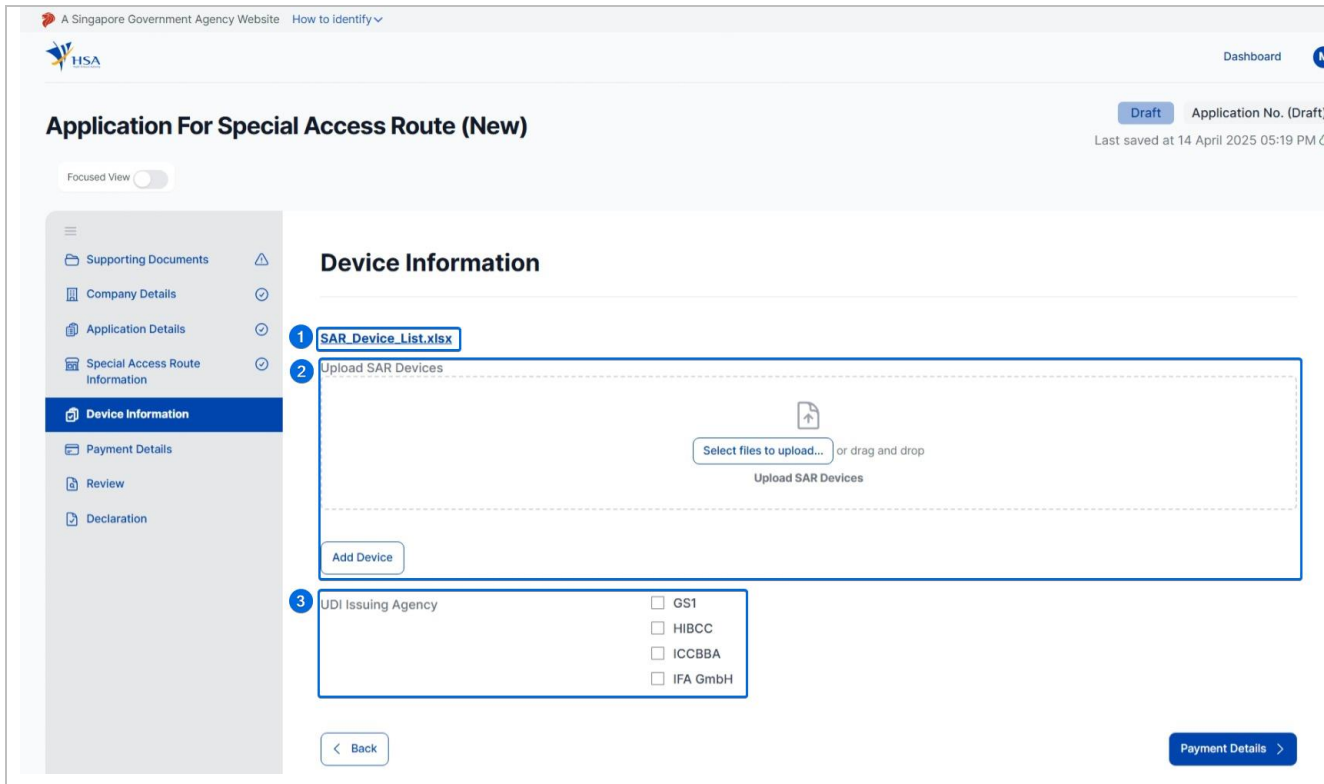
- 2) Applicants need to fill in the relevant licence information.

Application Information

- 3) Applicants need to fill in the application information.

Note: Fields to be filled and the applied rules may vary depending on the selected Purpose of Importation.

5.5.1.6. Device Information



This section is mandatory for GN-26, GN-27, GN-28 and GN-29. **This section will not be shown for GN-30.** It will capture information specific to the SAR Device.

- 1) Applicants can download an Excel template file to fill in device information.
- 2) Applicants can upload the Excel file to the system to add multiple devices at a time or add device by clicking 'Add Device'.
- 3) Applicants need to select UDI Issuing Agency if there are any devices with UDI-DI or DM-DI data.

5.5.1.7. Payment Details

A Singapore Government Agency Website

How to identify

HSA

Dashboard

M

Application For Special Access Route (New)

Draft

Application No. (Draft)

Last saved at 14 April 2025 05:21 PM

Focused View

Supporting Documents

Company Details

Application Details

Special Access Route Information

Device Information

Payment Details

Review

Declaration

Payment Details

Billing Information *

Client Code *

Select an option

Payment Information *

Preferred Payment Mode *

Online

Charge Code	Description	Quantity	Price
		Subtotal	\$0.00
		Tax	\$0.00
		Total	\$0.00

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

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

- 1) Applicants can select the client code from the dropdown list
- 2) Applicants will have two payment options, GIRO and Online payment. Applicants need to choose the preferred payment mode.

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HSA

Dashboard M

Application For Special Access Route (New)

Draft Application No. (Draft)

Last saved at 14 April 2025 05:22 PM

Focused View

Supporting Documents

Company Details

Application Details

Special Access Route Information

Device Information

Payment Details

Review

Declaration

Review

Supporting Documents

Supporting Documents Size: 0 Bytes

Download All Supporting Documents

▼ SAR Application Dossier

- ▼ 1. Instruction for Use
- ▼ 2. Device Label
- ▼ 3. PHMC or HCSA Licence (GN-27)
- ▼ 4. MCR Card (GN-26)
- ▼ 5. Doctor Declaration

5.5.1.9. Declaration

A Singapore Government Agency Website
How to identify



Dashboard

Application For Special Access Route (New)

Draft

Application No. (Draft)

Last saved at 14 April 2025 05:23 PM

Focused View

Supporting Documents

Company Details

Application Details

Special Access Route Information

Device Information

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 of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

On behalf of MD UAT Company 14,

a. I hereby attest that the information provided on this application and in any attached documentation is accurate, correct and complete.

b. I hereby attest that I have direct knowledge of the established procedures and systems in place in respect to distribution records, complaint handling, adverse event reporting and field safety corrective actions, including product recalls.

c. I hereby attest that the company has established procedure and system in place, where applicable, for handling, manufacturing, storage, delivery, installation, corrective action and servicing in respect to medical devices handled by the company, and

d. I understand that I will be liable to prosecution for an offence under section 24(6) of the Health Products Act (Cap.122D) if I make any statement or furnish any document that I know to be false or which I do not believe to be true; or if I intentionally suppress any material fact such that the information furnished is misleading.

1

☐ I acknowledge and confirm the above declarations

< Back

2

Submit

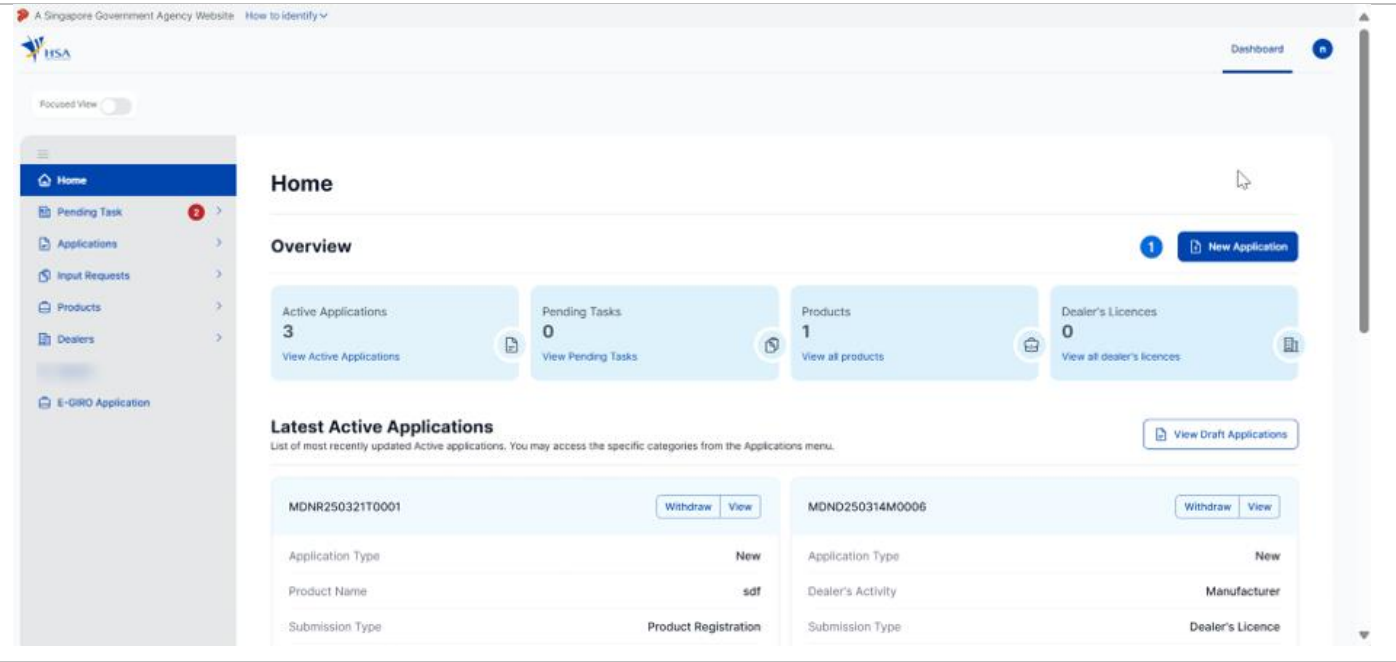
- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

Page 215 of 273

5.5.2. Distribution Record

The Applicant will need to submit the Distribution Records within 30 days after the date of expiry of the SAR licence or date of last export/supply, whichever is earlier.

5.5.2.1. Getting Started



- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard M

New Application - Getting Started

Focused View ☐

1. Details

2. Review

3. Checklist

Details

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

Product Type

Medical Devices

2 Submission Type

Special Access Route

3 Application Type

Distribution Records

Cancel this application
and go back to Dashboard

Cancel

Next

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Special Access Route' from the 'Submission Type' dropdown list
- 3) Applicants can select 'Distribution Record' from the 'Application Type' dropdown list

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard

New Application - Getting Started

Focused View ☐

- 1. Details
- 2. Review**
- 3. Checklist

Review

Instruction for this page
Please select the Licence which you wish to submit the Distribution Record for.

4

Licence Number

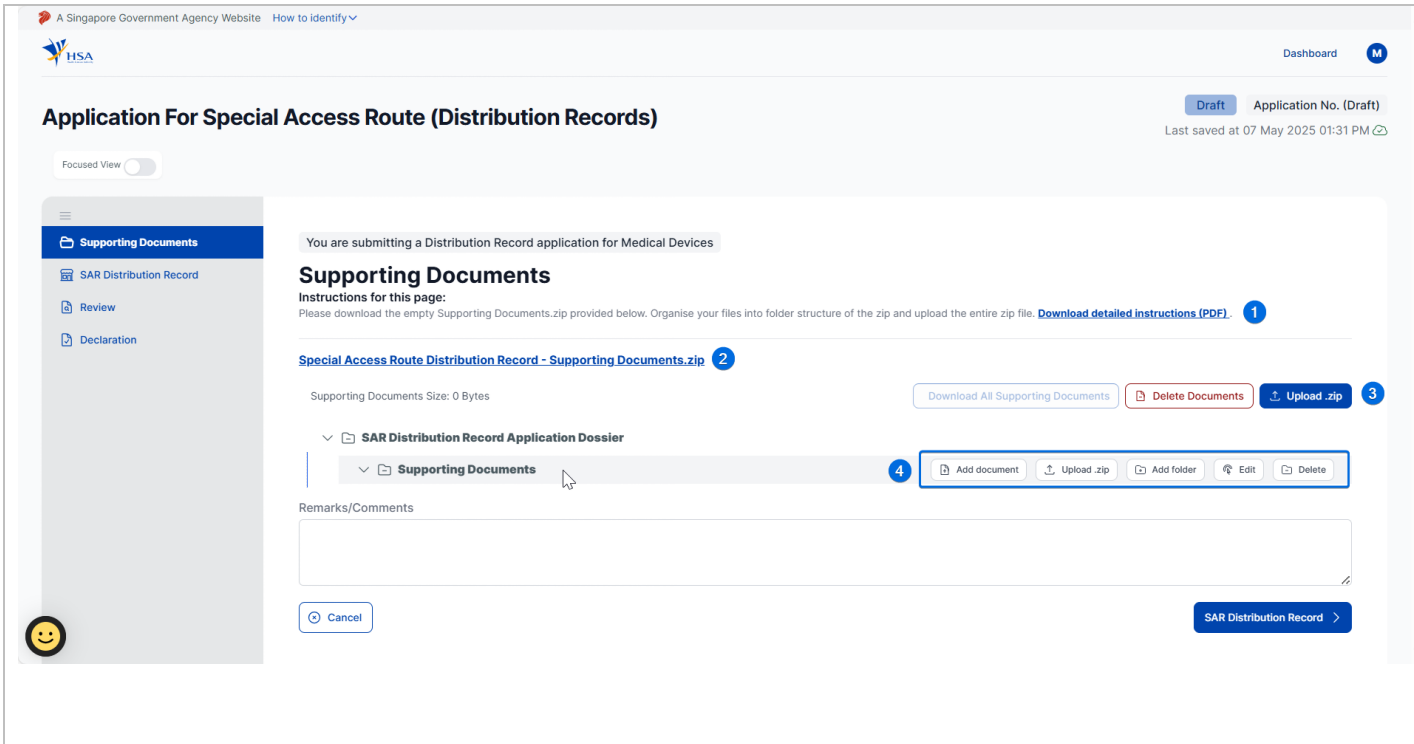
5

	Licence Number	Expiry Date	Type of Route
☐	MDS6250404H02	04-Apr-2026	GN-26

- 4) Applicants would be able to use the filter to find a specific Licence.
- 5) Applicants can select the licence that they would like to declare the distribution record

6) Applicants can create the application.

5.5.2.2. Supporting Documents



A Singapore Government Agency Website How to identify

HSA Dashboard M

Application For Special Access Route (Distribution Records)

Draft Application No. (Draft)
Last saved at 07 May 2025 01:31 PM

Focused View

Supporting Documents

SAR Distribution Record

Review

Declaration

You are submitting a Distribution Record application for Medical Devices

Supporting Documents

Instructions for this page:
Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file. [Download detailed instructions \(PDF\)](#) 1

[Special Access Route Distribution Record - Supporting Documents.zip](#) 2

Supporting Documents Size: 0 Bytes

[Download All Supporting Documents](#) [Delete Documents](#) [Upload .zip](#) 3

▼ SAR Distribution Record Application Dossier

▼ Supporting Documents 4

Add document Upload .zip Add folder Edit Delete

Remarks/Comments

[Cancel](#) [SAR Distribution Record >](#)

- 1) Applicants can download detailed instructions for guidance
- 2) Applicants can download the Dossier Template as a zipped folder
- 3) Applicants can add the necessary files to the relevant folders within the Dossier Template and upload the zip file
- 4) Applicants can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - Add document
 - Upload zip file
 - Add folder
 - Edit folder
 - Delete folder

5.5.2.3. SAR Distribution Record

A Singapore Government Agency Website

How to identify

HSA

DashboardM

Application No. (Draft)

Last saved at 14 April 2025 09:46 PM

Application For Special Access Route (Distribution Records)

Focused View

Supporting Documents

SAR Distribution Record

Review

Declaration

You are submitting a Distribution Record application for Medical Devices

SAR Distribution Record

Distribution Record

Licence NumberMDS6250404H02

Expiry Date04-Apr-2026

Type of RouteGN-26

1

☒ I declare that there is no import and supply of the medical devices listed in the above mentioned licence

☐ I declare that there is import and/or supply of the medical devices listed in the above mentioned licence

< Back

Review >

A Singapore Government Agency Website
How to identify

HSA
Dashboard
M

Application For Special Access Route (Distribution Records)
Draft
Application No. (Draft)
Last saved at 23 April 2025 02:38 PM

Focused View

Supporting Documents
SAR Distribution Record
Review
Declaration

You are submitting a Distribution Record application for Medical Devices

SAR Distribution Record

Distribution Record

Licence Number: MDS7250423101
Expiry Date: 23-Apr-2026
Type of Route: GN-27

☐ I declare that there is no import and supply of the medical devices listed in the above mentioned licence
☒ I declare that there is import and/or supply of the medical devices listed in the above mentioned licence

Overall System Name	Name as per device label	Identifier	UDI-DI	DM-DI	Maximum Quantity	Quantity Imported	Quantity Supplied	Balance Stocks	Action
star	Cycle	890-			80				2 Edit

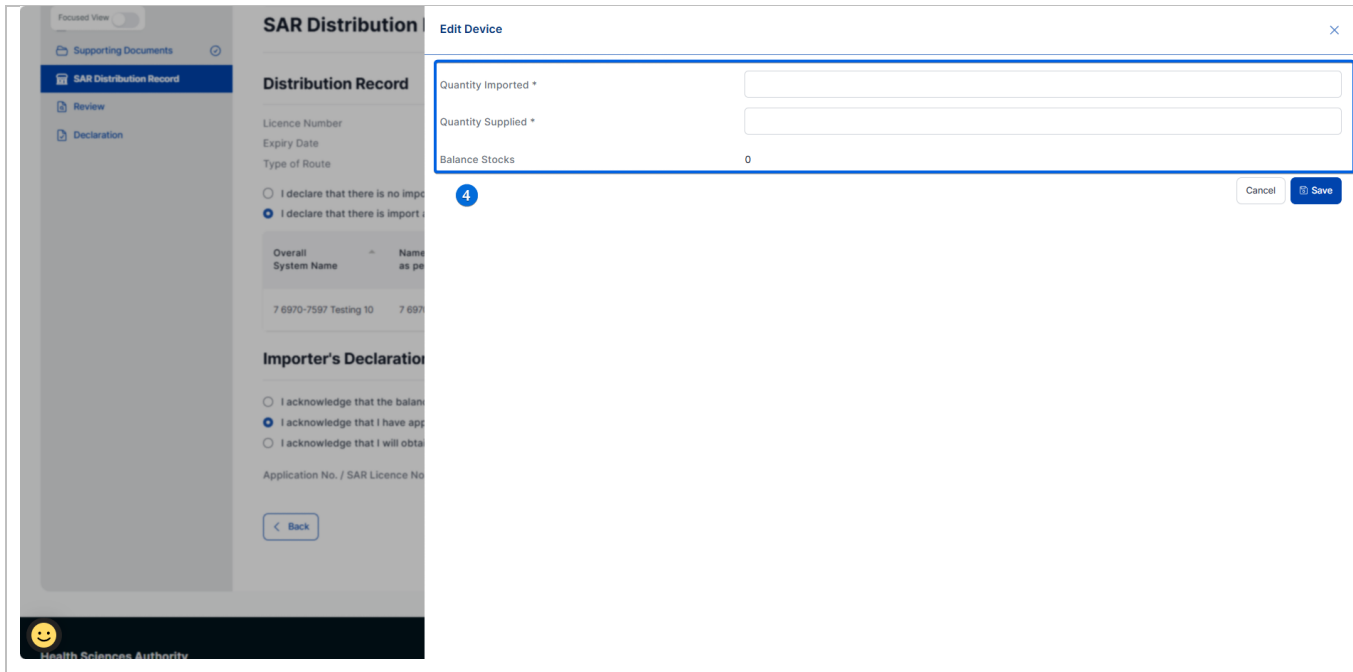
3
Importer's Declaration

☐ I acknowledge that the balance stocks will be destroyed / exported out of Singapore
☐ I acknowledge that I have applied for the relevant licences for the continued supply of the balance stocks in Singapore.
☐ I acknowledge that I will obtain the relevant licences for the continued supply of the balance stocks in Singapore.

Back
Review

If there is import and/or supply of the medical devices, Applicants need to provide more information.

- 2) Applicants need to click Edit to fill the necessary information.
- 3) Applicants need to select the appropriate declaration.



The screenshot shows the 'SAR Distribution Record' form. A blue box highlights the 'Quantity Imported *', 'Quantity Supplied *', and 'Balance Stocks' fields. A blue circle with the number 4 is next to the 'Quantity Supplied *' field. The form includes a 'Back' button and a 'Save' button.

- 4) Applicants need to fill the Device's Quantity Imported and Quantity Supplied.

Supporting Documents

SAR Distribution Record

Review

Declaration

You are submitting a Distribution Record application for Medical Devices

SAR Distribution Record

Distribution Record

Licence Number

MDS7250625M01

Expiry Date

25-Jun-2026

Type of Route

GN-27

☐ I declare that there is no import and supply of the medical devices listed in the above mentioned licence

☒ I declare that there is import and/or supply of the medical devices listed in the above mentioned licence

Overall System Name	Name as per device label	Identifier	UDI-DI	DM-DI	Action
NeuroVibe Harmonizer	GeneFusion Cartridge	Revitalizing interstellar beings	Hic explicabo voluptate deleniti.	Officia consectetur eum corporis minima accusantiu... Show More	Edit
BioSync Monitor	BioSync Monitor	Facilitating wound healing after surgical procedur... Show More	Ab a modi suscipit quidem esse at.	Nihil nostrum sequi consequuntur dignissimos tempo... Show More	Edit

Importer's Declaration

☐ I acknowledge that the balance stocks will be destroyed / exported out of Singapore

☒ I acknowledge that I have applied for the relevant licences for the continued supply of the balance stocks in Singapore.

☐ I acknowledge that I will obtain the relevant licences for the continued supply of the balance stocks in Singapore.

5

Application No. / SAR Licence No. / Product No.

Validate

Back

Review

5) If the Applicants declare that he has applied for the relevant licences for the continued supply of the balance stocks in Singapore, Applicants need to provide the relevant Application Number/SAR Licence Number/Product Number to be validated.

Page 224 of 273

5.5.2.4. Review

A Singapore Government Agency Website
How to Identify


Dashboard
M

Application For Special Access Route (Distribution Records)

Draft
Application No. (Draft)
Last saved at 14 April 2025 09:46 PM

Supporting Documents
SAR Distribution Record
Review
Declaration

You are submitting a Distribution Record application for Medical Devices

Review

Supporting Documents

Remarks/Comments

No remarks or comments

Distribution Record

Licence Number
MDS6250404H02

Expiry Date
04-Apr-2026

Type of Route
GN-26

☐ I declare that there is no import and supply of the medical devices listed in the above mentioned licence
☒ I declare that there is import and/or supply of the medical devices listed in the above mentioned licence

Review page displays the summary of all the sections filled before the declaration.

A Singapore Government Agency Website

How to identify

HSA

Dashboard

M

Application For Special Access Route (Distribution Records)

Draft

Application No. (Draft)

Last saved at 14 April 2025 09:47 PM

Focused View

Supporting Documents

SAR Distribution Record

Review

Declaration

1

I acknowledge and confirm the above declarations.

< Back

2 Submit

You are submitting a Distribution Record application for Medical Devices

Declaration

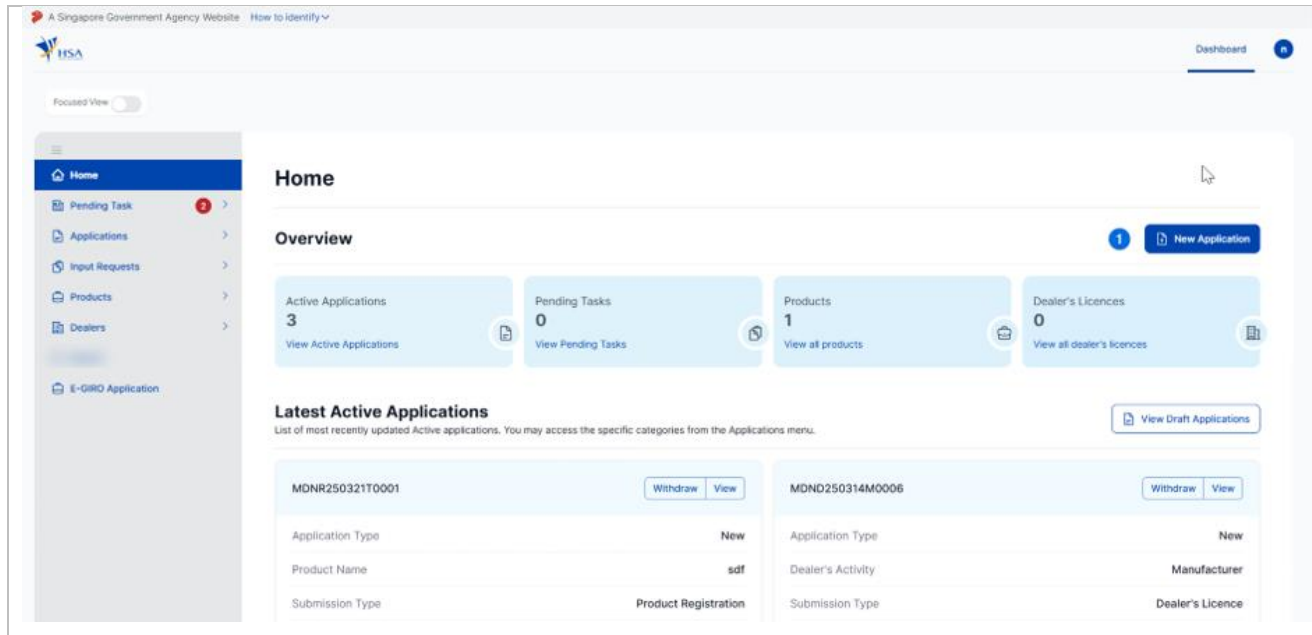
1. I, on behalf of my company, confirm that the information submitted is true and accurate.

2. I, on behalf of my company, must comply where applicable, with the Health Products Act and its corresponding regulations. I must also comply with other applicable laws and their regulations.

- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

5.5.3. Fulfilment Of Approval Conditions

5.5.3.1. Getting Started



- 1) Applicants would be able to create a new application by clicking on the “**New Application**” button.

A Singapore Government Agency Website [How to identify](#)

HSA [Dashboard](#) **M**

New Application - Getting Started

Focused View ☐

1. Details

2. Review

3. Checklist

Details

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

Product Type ⓘ

Medical Devices

2 Submission Type ⓘ

Special Access Route

3 Application Type ⓘ

Fulfilment Of Approval Conditions

Cancel this application and go back to Dashboard

Applicants would be able to select the type of application they want to submit.

- 2) Applicants would be able to select 'Special Access Route' from the 'Submission Type' dropdown list.
- 3) Applicants would be able to select 'Fulfilment Of Approval Conditions' from the 'Application Type' dropdown list.

A Singapore Government Agency Website [How to Identify](#)

HSA

Dashboard M

New Application - Getting Started

Focused View ☐

- 1. Details
- 2. Review
- 3. Checklist

Review

Instruction for this page
Please select the fulfillment of conditions.

4

SAR Number Application Number

Reset Filter

5

MDS6250625004 Application Number MDSA250625Q0021

Approval Conditions	Date
☐ add specific condition	10-Jul-2025
☐ OD edited	04-Jul-2025

6 Request Extension

< Back

Next >

- 4) Applicants would be able to use the filter to find a specific Licence.
- 5) Applicants would be able to select the approval conditions to fulfil by checking the respective approval condition's checkbox.
- 6) Applicant can 'Error! Not a valid result for table.'

A Singapore Government Agency Website [How to identify](#)

HSA [Dashboard](#) **M**

New Application - Getting Started

Focused View ☐

1. Details

2. Review

3. Checklist

Checklist

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

Product Type	Medical Devices
Submission Type	Special Access Route
Application Type	Fulfilment Of Approval Conditions

 **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 to fulfil an approval condition for your Special Access Route Licence.

Submission Instructions

Please select the approval condition you wish to fulfil and submit the relevant supporting documents.

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

Change Product or Submission Type

[< Back](#)

7

Create Application 

7) Applicants would be able to create the application.

5.5.3.2. Fulfilment of Approval Conditions

A Singapore Government Agency Website [How to identify](#)

HSA

Dashboard M

Application For Fulfilment Of Approval Condition

Draft Application No. (Draft)

Last saved at 14 April 2025 11:09 PM

Focused View

Fulfilment of Approval Condition

Review

Declaration

1 Upload Files for All Conditions

MDS6250410I24

Approval Conditions	Date	Actions
custom		
Uploaded files:	30-Apr-2025	2 Upload Files
3 9B86D1C1ACFC4DA3963B2F2F3F38536E (1).pdf		

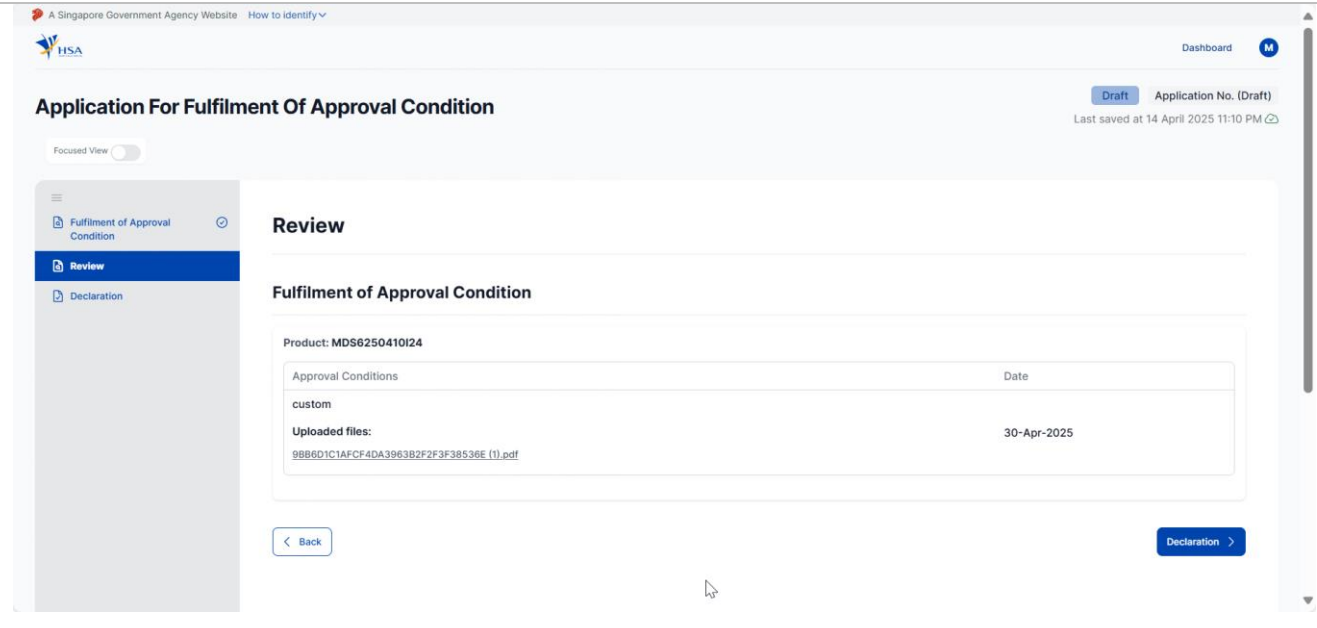
Cancel

Review

- 1) Applicants would be able to upload files for all conditions
- 2) Applicants would be able to upload files for specific condition
- 3) Applicants would be able to download and delete files

- 1) Applicants would be able to upload files for all conditions
- 2) Applicants would be able to upload files for specific condition
- 3) Applicants would be able to download and delete files

5.5.3.3. Review



A Singapore Government Agency Website How to identify

HSA Dashboard M

Application For Fulfilment Of Approval Condition

Draft Application No. (Draft)
Last saved at 14 April 2025 11:10 PM

Focused View

Fulfilment of Approval Condition

Review

Declaration

Review

Fulfilment of Approval Condition

Product: MDS6250410124

Approval Conditions	Date
custom	

Uploaded files:

9BB6D1C1AFCF4DA3963B2F2F3F38536E (1).pdf	30-Apr-2025
--	-------------

< Back Declaration >

Review page displays the summary of all the sections filled before the declaration.

A Singapore Government Agency Website | How to identify

HSA

Dashboard M

Draft Application No. (Draft)

Last saved at 14 April 2025 11:44 AM

Application For Fulfilment Of Approval Condition

Focused View

Fulfilment of Approval Condition

Review

Declaration

Declaration

1. I, on behalf of my company, confirm that the information submitted is true and accurate.
2. I, on behalf of my company, must comply where applicable, with the Health of Products Act and its corresponding regulations. I must also comply with other applicable laws and their regulations.

1 ☐ I acknowledge and confirm the above declarations.

< Back

2 Submit

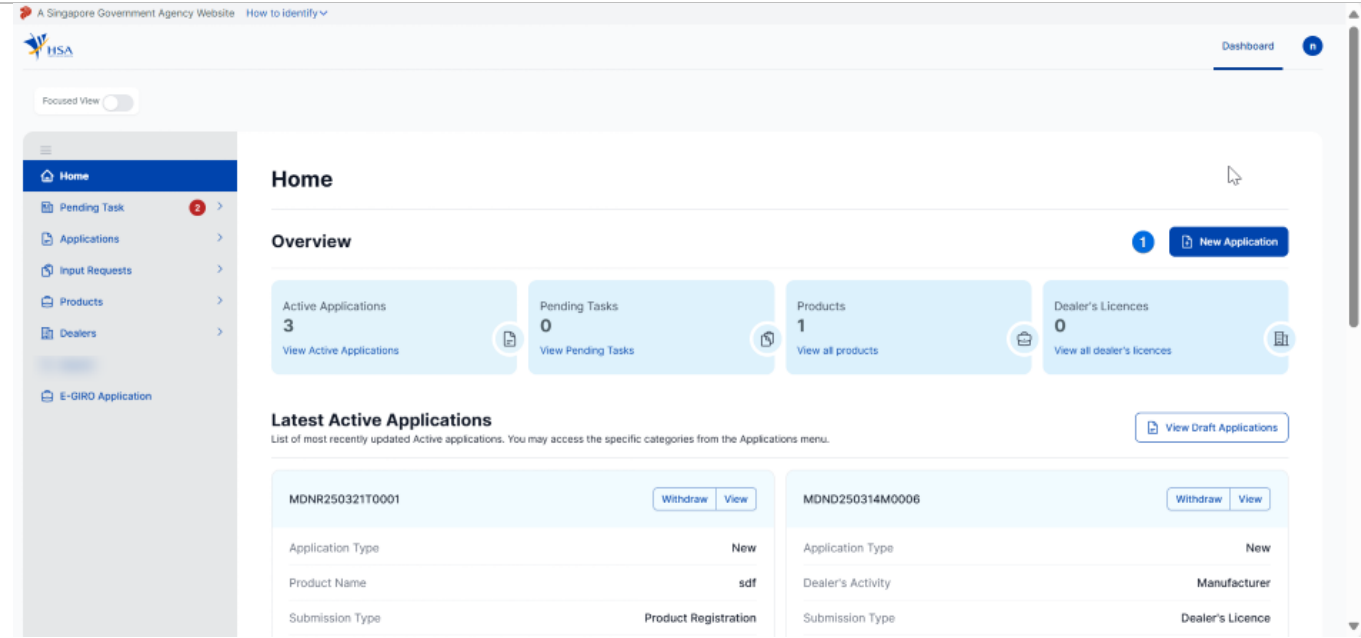
- 1) Applicants need to acknowledge and confirm the declaration.
- 2) Applicants can submit the application.

- 1) Applicants need to acknowledge and confirm the declaration.
- 2) Applicants can submit the application.

5.6. Free Sale Certificate

A Free Sale Certificate (FSC) can be issued by HSA to companies requiring the certificate for medical devices that are registered on the SMDR or notified on the Class A Medical Device Database to fulfil import requirements of foreign regulatory authorities.

5.6.1. Getting Started – Details



- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard M

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

2 Submission Type Free Sale Certificate

3 Application Type New

4 Device Risk Classification Class B, C, D

5 Product Owner Select Product Owner

Search
Hane

Cancel this application
and go back to Dashboard

Cancel
Next

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Free Sale Certificate' from the 'Submission Type' dropdown list
- 3) Applicants can select 'New' from the 'Application Type' dropdown list
- 4) Applicants can select the device risk classification they would like to apply for from the 'Device Risk Classification' dropdown list.
- 5) Applicant can search and select the related product owner they would like to apply for from the 'Product Owner' dropdown list.

A Singapore Government Agency Website
How to identify


Dashboard
M

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	Free Sale Certificate
Application Type	New
Device Risk Classification	Class B, C, D



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 Free Sale Certificate for Class B, C, D Medical Devices.

Submission Instructions

Please read and understand the requirements and information presented on the [certificate website](#) before proceeding with your application. This will ensure a smooth submission process.
Kindly note that once an application has been submitted and processed, no refunds will be provided.

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

Change Product or Submission Type

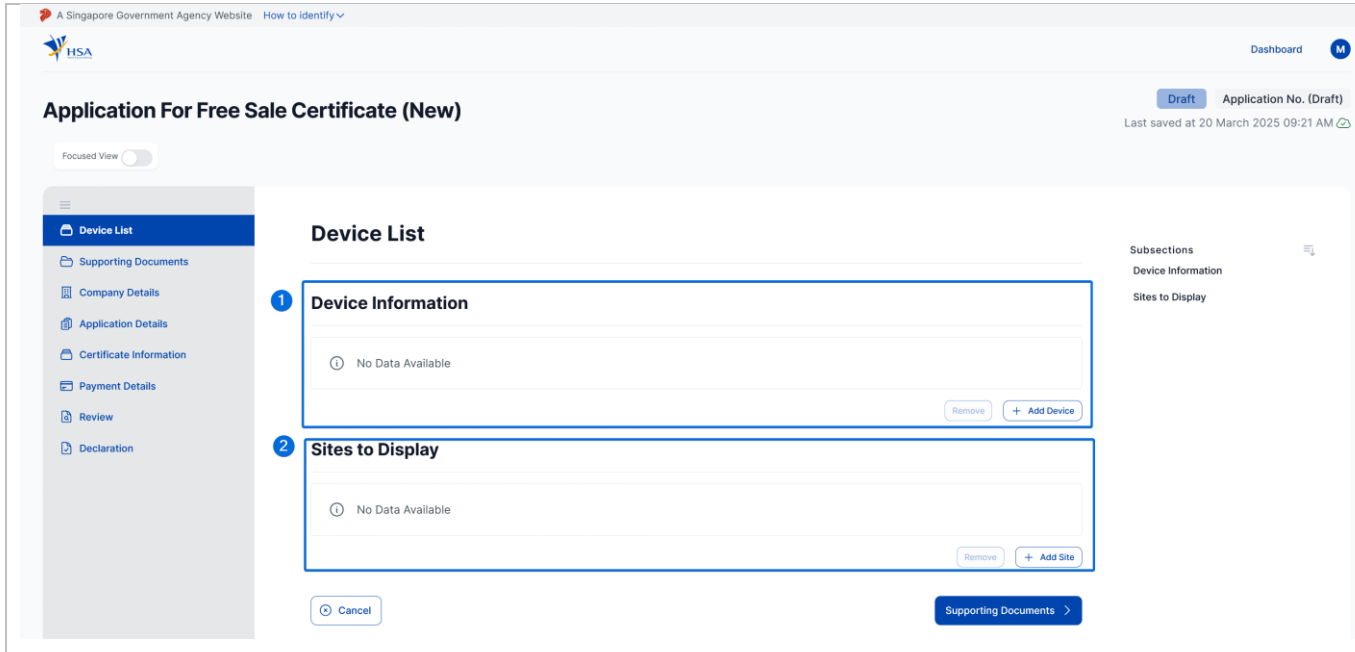
< Back

6 Create Application

6) Applicants can create the application.

5.6.2. Device List

Class A



A Singapore Government Agency Website [How to identify](#)

HSA

Dashboard **M**

Application For Free Sale Certificate (New)

Draft Application No. (Draft)
Last saved at 20 March 2025 09:21 AM

Focused View ☐

Device List

Supporting Documents

Company Details

Application Details

Certificate Information

Payment Details

Review

Declaration

Device List

1 Device Information

① No Data Available

Remove + Add Device

2 Sites to Display

① No Data Available

Remove + Add Site

Cancel

Supporting Documents >

Subsections

Device Information

Sites to Display

Device Information

- 1) Based on the Product Owner and Risk Classification selected, the system will provide a list of available products for selection. Applicants can add the products they intend to register by clicking on 'Add Device'.

Sites to Display

- 2) Applicants need to select the sites that they would like to apply for by clicking on 'Add Site'.

A Singapore Government Agency Website [How to identify](#)

HSA

Application For Free Sale Certificate (N)

Focused View ☐

- Device List
- Supporting Documents
- Company Details
- Application Details
- Certificate Information
- Payment Details
- Review
- Declaration

Device List

Device Inform

No Data Avail

Manufacturin

No Data Avail

Cancel

Select Models

Device Name *

Intended Use *

Select Class A Products

Device Identifier (Model No.) Name as per Device Label

Reset Filter

Select	Name as per Device Label	Device Identifier (Model No.)	Brief Description of Item	Site	
☐	Device Sterile 1	MDPN250321U0004	Intended 1	OM 12 Mar 2025 UAT 2035	Mark as Primary
☒	Device 2	MDPN250321T0003	Intended 2	OM 12 Mar 2025 UAT 2035	Mark as Primary
☐	Device Non Sterile 1	MDPN250321V0005	Intended 2	Luciana Company	Mark as Primary

Cancel Add Device

- Applicants need to fill the device name
- Search for results by entering the required data in the search table and clicking 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results
- Applicants can select the device by checking the box.
- Applicants can mark the device as primary to indicate the intended use for the list of models.

Class B, C, D

A Singapore Government Agency Website

How to identify

HSA

Dashboard

M

Application For Free Sale Certificate (New)

Draft

Application No. (Draft)

Last saved at 20 March 2025 09:21 AM

Focused View

Device List

Supporting Documents

Company Details

Application Details

Certificate Information

Payment Details

Review

Declaration

1

Device Information

No Data Available

Remove + Add Device

2

Sites to Display

No Data Available

Remove + Add Site

Cancel

Supporting Documents

Subsections

Device Information

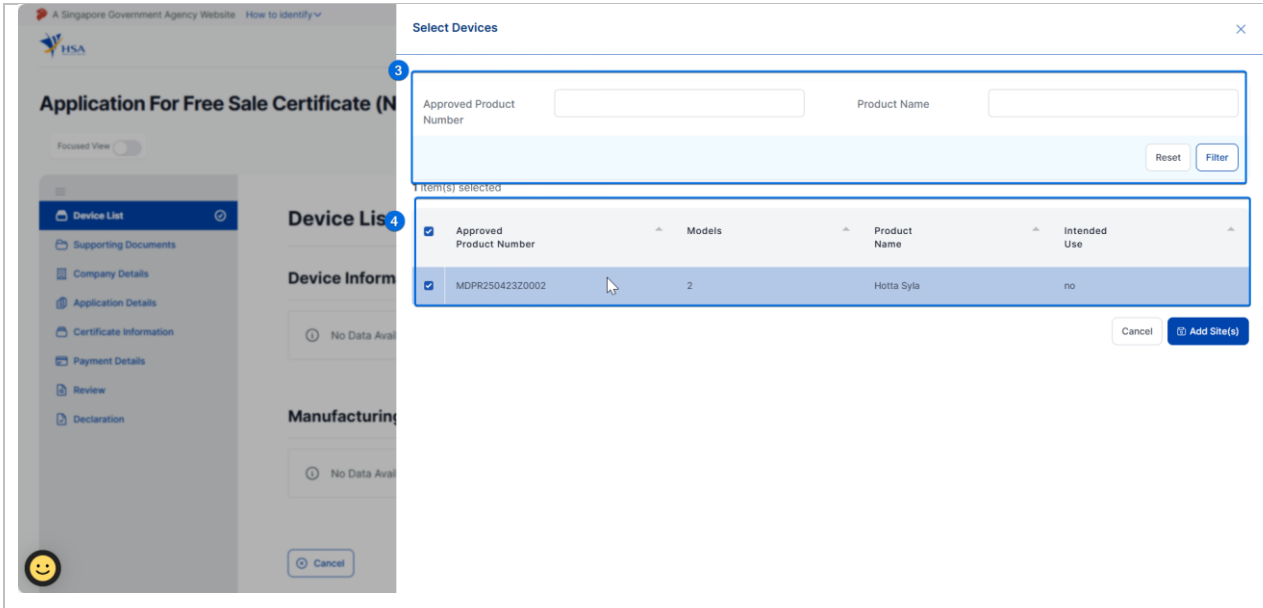
Sites to Display

Device Information

- 1) Based on the Product Owner and Risk Classification selected, the system will provide a list of available products for selection. Applicants can add the products they intend to register by clicking on 'Add Device'.

Sites to Display

- 2) Applicants need to select the sites that they would like to apply for by clicking on 'Add Site'.



Select Devices

Approved Product Number Product Name

1 item(s) selected

☒	Approved Product Number	Models	Product Name	Intended Use
☒	MDPR25042320002	2	Hotta Sylia	no

- 3) Search for results by entering the required data in the search table and clicking 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results
- 4) Applicants can select the device by checking the box.

Application for Free Sale Certificate (new)

Last saved at 07 May 2025 01:41 PM

Focused View

Device List

Supporting Documents

Company Details

Application Details

Certificate Information

Payment Details

Review

Declaration

Device List

Device Information

1 item(s) selected

☒	Approved Product Number	Models	Product Name	Intended Use	Action
☒	MDPR250423Z0002	5 selected	Hotta Sylva	no	Delete

Remove

+ Add Device

Manufacturing Sites to Display

No Data Available

Remove

+ Add Site

Cancel

Supporting Documents

5) Applicants can select the model

Application For Free Sale Certificate (FSC)

Focused View

Device List

Supporting Documents

Company Details

Application Details

Certificate Information

Payment Details

Review

Declaration

Device List

Device Information

0 item(s) selected

Approved Product Number

MDPR2504232

Manufacturing

No Data Available

Cancel

Select Models

1 item(s) selected

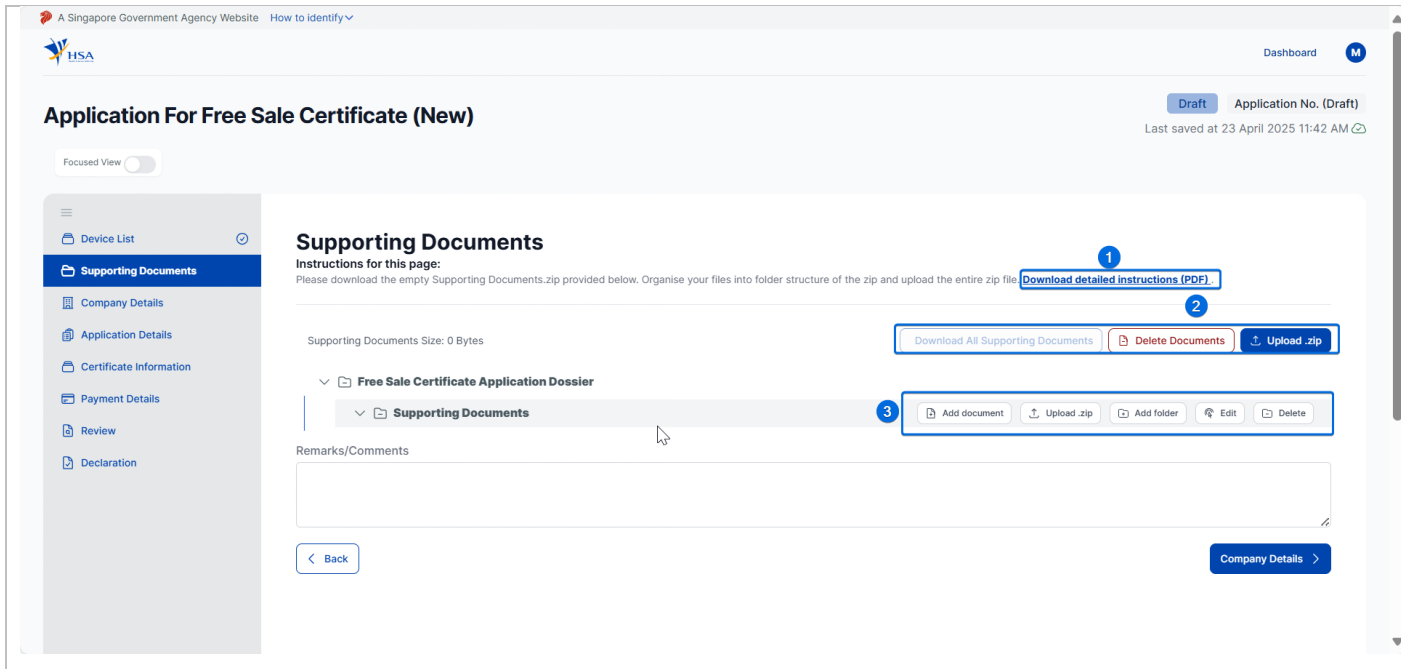
	Name as per Device Label	Device Identifier (Model No.)	Site
☒	Star Vital	890763	MD UAT Company 05
☐	Star Vital	890763	Sea M

Cancel

Update Model(s)

6) Applicants can select the models by checking the box

5.6.3. Supporting Documents



A Singapore Government Agency Website [How to Identify](#)

HSA

Dashboard **M**

Application For Free Sale Certificate (New)

Draft Application No. (Draft)
Last saved at 23 April 2025 11:42 AM

Focused View ☐

Device List

Supporting Documents

Company Details

Application Details

Certificate Information

Payment Details

Review

Declaration

Supporting Documents

Instructions for this page:
Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file

Supporting Documents Size: 0 Bytes

[Download detailed instructions \(PDF\)](#)

[Download All Supporting Documents](#) [Delete Documents](#) [Upload .zip](#)

Free Sale Certificate Application Dossier

Supporting Documents

Add document Upload .zip Add folder Edit Delete

Remarks/Comments

[Back](#) [Company Details](#)

- 1) Applicants can download detailed instructions for guidance
- 2) Applicants can upload the zip file
- 3) Applicants can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - a. Add document
 - b. Upload zip file
 - c. Add folder
 - d. Edit folder
 - e. Delete folder

5.6.4. Company Details

A Singapore Government Agency Website [How to Identify](#)

HSA Dashboard M

Application For Free Sale Certificate (New) Draft Application No. (Draft) Saving ...

Focused View ☐

Company Details

Company Information
This sub-section is pre-filled from your login and requires no action on your part.

Company Name: Franata Company
UEN: FranataCompanyUEN

Company Address *

[Clear ACRA Address](#)

Postal Code *: 549880
Block / Number *: 18
Level - Unit: 5 - 9
Street Name *: CHIAP GUAN AVENUE
Building Name:

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	Fran	+65-23456789	

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

Applicants can navigate to other sections within the application form by clicking the section name on the left panel.

Company Information

This information is **auto populated based on the Corppass login**.

Applicants cannot edit any of the information for this section

Company Address

This field is automatically populated based on the ACRA address.

However, applicants can clear the pre-filled address and manually enter it if needed.

***Do note that changing the address field in the application form **does not** change/update any address in ACRA.**

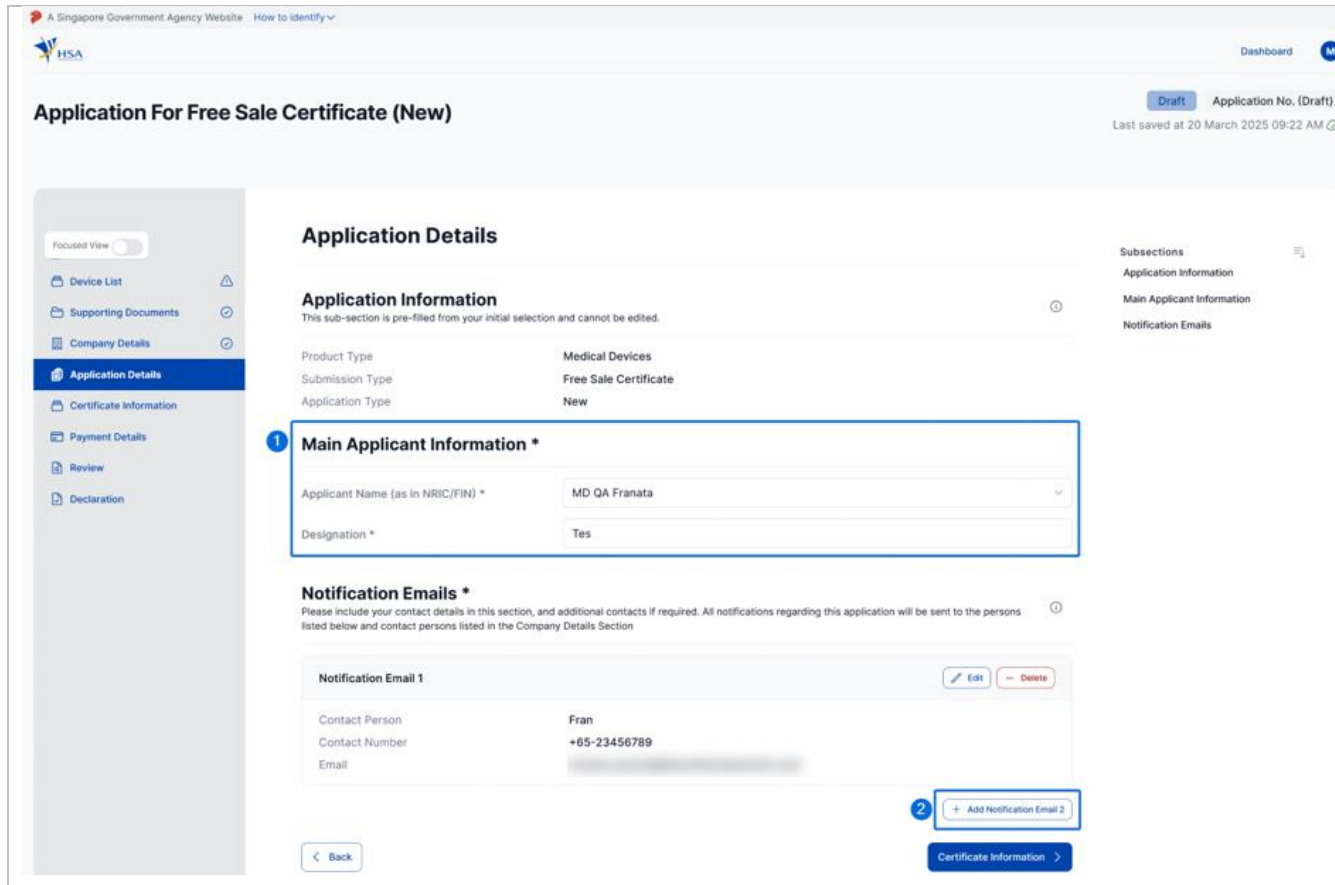
Contact Information

The contact Information refers to a global list of company's default contact details that would be notified for all Applications within the Company.

- 1) Applicants can click on the company address book, opening a new tab that allows them to update the company's address

book. For more details, please refer to 4.1.1 Address book.

5.6.5. Application Details



Main Application Information

- 1) The **applicant's name** is automatically 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.

Notification Emails

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.

- 2) The applicant can update the notification email by selecting 'Add Notification Email.'

5.6.6. Certificate Information

A Singapore Government Agency Website [How to Identify](#)

HSA Dashboard M

Application For Free Sale Certificate (New) Draft Application No. (Draft)
Last saved at 14 April 2025 03:51 PM

Certificate Information

Device Information

Device Name	Intended Use Selected	Models
Device	Intended 2	1 selected

Manufacturing Sites to Display

Site Name	Address
OM 12 Mar 2025 UAT 2035	91318 Parisian Skyway, Bolivia

Importing Country/Region
Please provide device information for your products.

No Data Available

Additional Information

1 [+ Add Importing Country/Region](#)

2 ☐ I declare that additional information to be appended to the certificate has been uploaded to Supporting Documents

☒ I declare that no additional information or modifications will be added to the certificate

[< Back](#) [Payment Details >](#)

Subsections

- Device Information
- Manufacturing Sites to Display
- Importing Country/Region
- Additional Information

Left Sidebar:

- Device List
- Supporting Documents
- Company Details
- Application Details
- Certificate Information**
- Payment Details
- Review
- Declaration

- 1) Applicants need to enter the Importing Country/Region by clicking on 'Add Importing Country/Region'.
- 2) Applicants need to acknowledge and confirm the declaration

5.6.7. Payment Details

A Singapore Government Agency Website
How to Identify

Dashboard
M

Draft
Application No. (Draft)
Last saved at 20 March 2025 09:23 AM

Application For Free Sale Certificate (New)

Focused View

Device List
Supporting Documents
Company Details
Application Details
Certificate Information
Payment Details
Review
Declaration

Payment Details

Subsections
Billing Information
Payment Information

Billing Information *

1
Client Code *
WC-372604

Postal Code
123123
Block / House No.
123
Level / Unit
4 - 3
Street Name
6838 Grimes-Howe Lane
Building Name
Furman Upton

Payment Information *

2
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
GIRO

Online

Charge Code	Description	Quantity	Price
MEDAPPFSC	Free Sale Cert - App Fee	1	\$57.00
MEDAPPFSCDEVFEE	FSC - Per Device & 1 Ctry/an Add'l Device (Afghanistan)	1	\$57.00
	Subtotal		\$104.59
	Tax		\$9.41
	Total		\$114.00

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

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

- 1) Applicants can select the client code from the dropdown list
- 2) Applicants will have two payment options, GIRO and Online payment. Applicants need to choose the preferred payment mode.

5.6.8. Review

A Singapore Government Agency Website

How to Identify

HSA

Health Service Authority

Dashboard

M

Application For Free Sale Certificate (New)

Draft Application No. (Draft)

Last saved at 14 April 2025 04:03 PM

Focused View

Device List

Supporting Documents

Company Details

Application Details

Certificate Information

Payment Details

Review

Declaration

Review

Supporting Documents

Supporting Documents Size: 0 Bytes

Download All Supporting Documents

Free Sale Certificate Application Dossier

Supporting Documents

Remarks/Comments

No remarks or comments

Company Information

Company Name

Luciana Company

UEN

LucianaCompanyUEN

Review page displays the summary of all the sections filled before the declaration.

5.6.9. Declaration

A Singapore Government Agency Website
How to identify



Dashboard
M

Application For Free Sale Certificate (New)

Draft
Application No. (Draft)
Last saved at 20 March 2025 09:23 AM

Focused View

Device List
Supporting Documents
Company Details
Application Details
Certificate Information
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 of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

On behalf of Franata Company,

a. I hereby attest that the information provided on this application is accurate, correct and complete.

b. I am informed and I understand that it is a serious offence under Section 30(10) of the Health Products Act 2007 to make any statement or furnish any information which I know to be false or does not believe to be true in support of this application.

I have thoroughly reviewed and verified the accuracy, correctness, and completeness of this application for the issuance of the requested certificate.

☒ I acknowledge and confirm the above declarations

Back

2
Submit

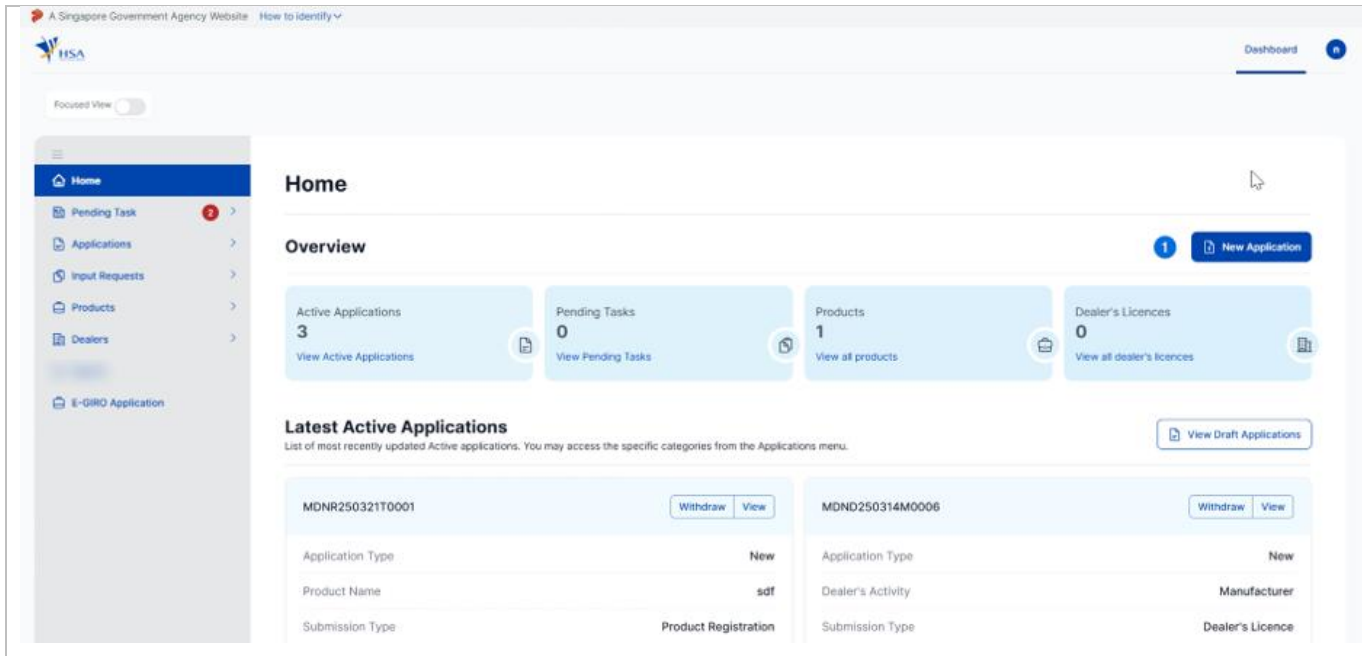
- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

Page 249 of 273

5.7. Export Certificate

An Export Certificate (EXC) can be issued by HSA to local, licensed manufacturers requiring the certificate for medical devices that are not registered with HSA.

5.7.1. Getting Started – Details



The screenshot shows the HSA dashboard interface. On the left is a sidebar menu with options: Home, Pending Task (with a red notification badge), Applications, Input Requests, Products, Dealers, and E-GIRO Application. The main content area is titled 'Home' and 'Overview'. It features four summary cards: 'Active Applications' (3), '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 summary cards is a section titled 'Latest Active Applications' with a list of two applications. Each application entry includes a unique ID, application type, product name, submission type, and buttons for 'Withdraw' and 'View'.

Application ID	Application Type	Product Name	Submission Type
MDNR250321T0001	New	sdf	Product Registration
MDND250314M0006	New		Dealer's Licence

- 1) Applicants would be able to create a new application by clicking on the 'New Application' button.

A Singapore Government Agency Website [How to identify](#)

HSA [Dashboard](#) **M**

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

2

Submission Type ⓘ

Export Certificate

3

Application Type

New

Cancel this application
and go back to Dashboard

[Cancel](#)

[Next >](#)

Applicants can select the type of application they want to submit.

- 2) Applicants can select 'Export Certificate' from the 'Submission Type' dropdown list
- 3) Applicants can select 'New' from the 'Application Type' dropdown list

A Singapore Government Agency Website

How to Identify

HSA

Health Science Authority

Dashboard

M

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

Submission Type

Application Type

Medical Devices

Export Certificate

New

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 an Export Certificate for unregistered Medical Devices.

Submission Instructions

Please read and understand the requirements and information presented on the [certificate website](#) before proceeding with your application. This will ensure a smooth submission process.

Kindly note that once an application has been submitted and processed, no refunds will be provided.

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

Change Product or Submission Type

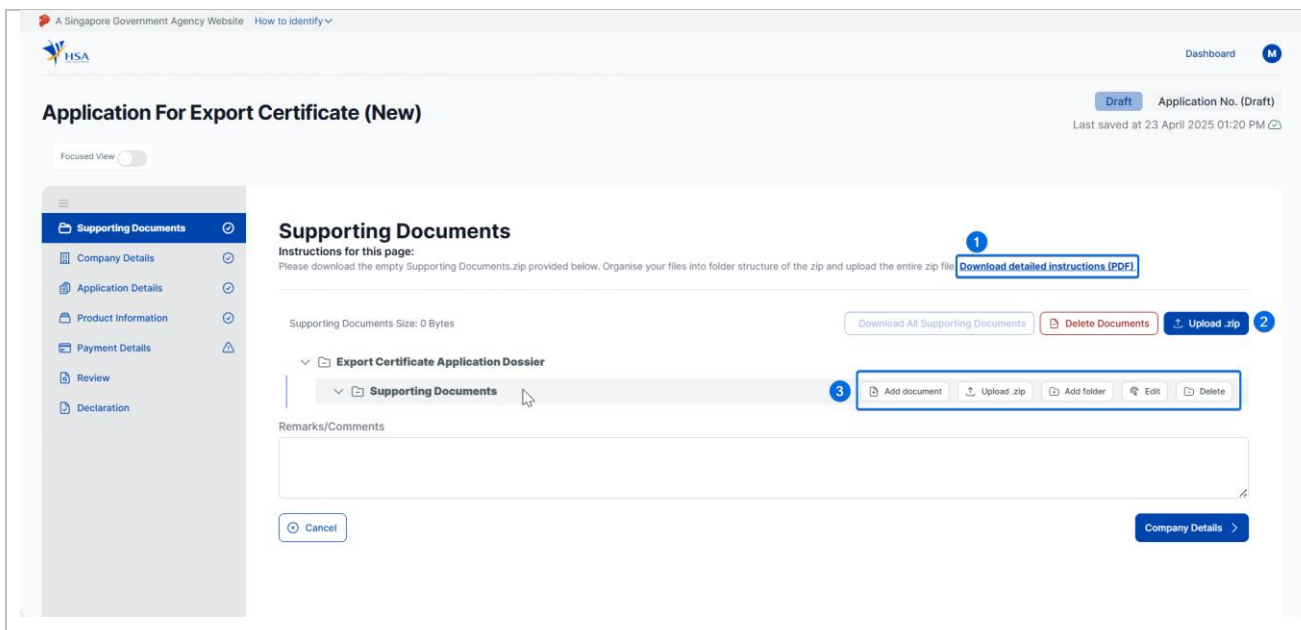
< Back

4 Create Application

4) Applicants can create the application.

Page 252 of 273

5.7.2. Supporting Documents



A Singapore Government Agency Website [How to Identify](#)

HSA

Dashboard **M**

Application For Export Certificate (New)

Draft Application No. (Draft)
Last saved at 23 April 2025 01:20 PM

Focused View ☐

Supporting Documents

Instructions for this page:
Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file.

Supporting Documents Size: 0 Bytes

[Download All Supporting Documents](#) [Delete Documents](#) [Upload .zip](#)

Export Certificate Application Dossier

Supporting Documents

Remarks/Comments

[Cancel](#) [Company Details](#)

- 1) Applicants can download detailed instructions for guidance
- 2) Applicants can upload the zip file
- 3) Applicants can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - a. Add document
 - b. Upload zip file
 - c. Add folder
 - d. Edit folder
 - e. Delete folder

5.7.3. Company Details

A Singapore Government Agency Website [How to Identify](#)

HSA Dashboard

Application For Export Certificate (New) Draft Application No. (Draft)
Last saved at 20 March 2025 10:16 AM

Company Details

Company Information
This sub-section is pre-filled from your login and requires no action on your part.

Company Name: Franata Company
UEN: FranataCompanyUEN

Company Address *

[Clear ACRA Address](#)

Postal Code *: 549880
Block / Number *: 18
Level - Unit: 5 - 9
Street Name *: CHIAP GUAN AVENUE
Building Name:

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	Fran	+65-23456789	

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

Subsections:
Company Information
Company Address
Contact Information

Focused View: ☐

Supporting Documents: [+](#)

Company Details
Application Details
Product Information
Payment Details
Review
Declaration

Applicants can navigate to other sections within the application form by clicking the section name on the left panel.

Company Information

This information is **auto populated based on the Corppass login**. Applicants cannot edit any of the information for this section

Company Address

This field is automatically populated based on the ACRA address. However, applicants can clear the pre-filled address and manually enter it if needed.

*Do note that changing the address field in the application form **does not change/update any address in ACRA**.

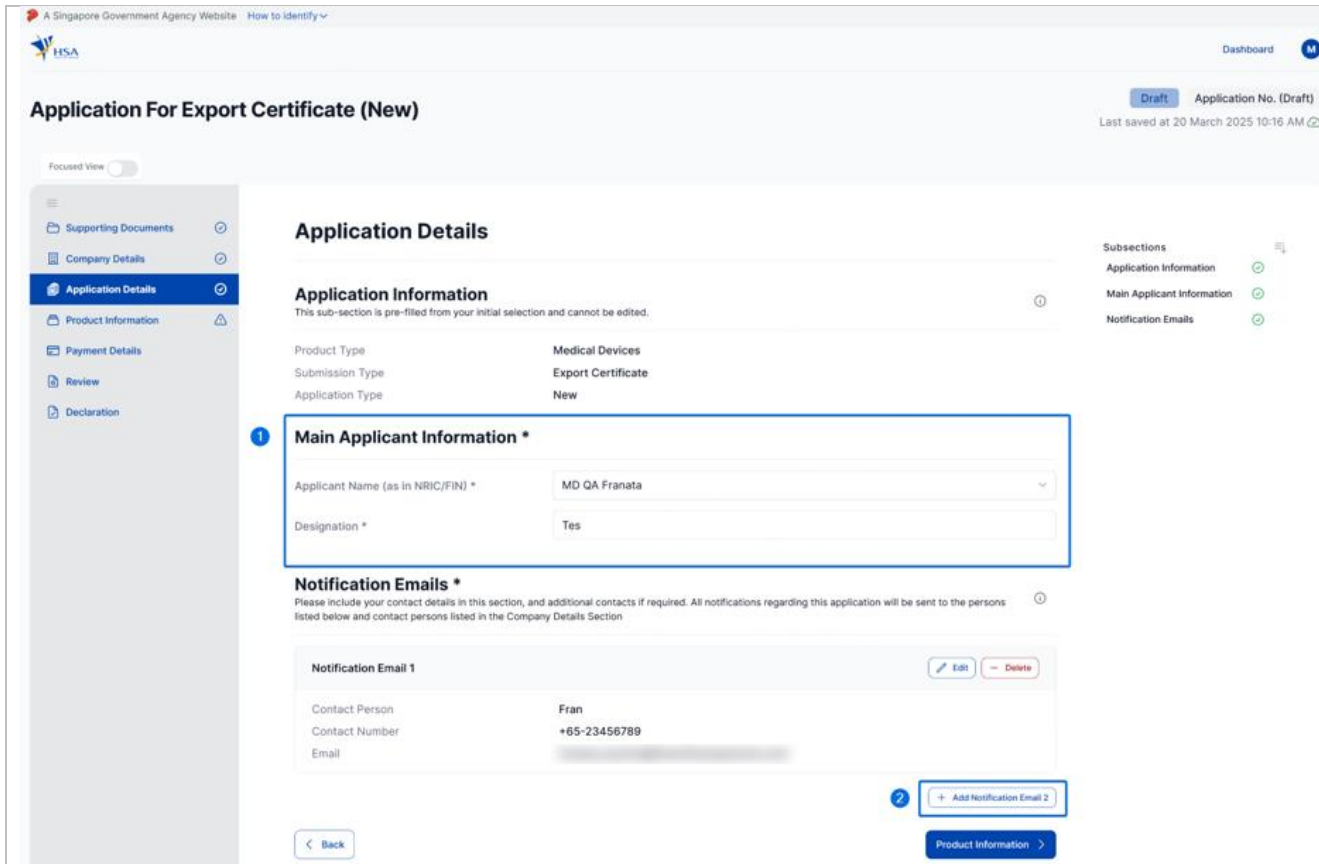
Contact Information

The contact Information refers to a global list of company's default contact details that would be notified for all Applications within the Company.

- 1) Applicants can click on the company address book, opening a new tab that allows them to update the company's address

book. For more details, please refer to 4.1.1 Address book

5.7.4. Application Details



Application For Export Certificate (New)

Application Details

Application Information
This sub-section is pre-filled from your initial selection and cannot be edited.

Product Type: Medical Devices
Submission Type: Export Certificate
Application Type: New

Main Applicant Information *

Applicant Name (as in NRIC/FIN) *: MD QA Franata
Designation *: Tes

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

Notification Email 1

Contact Person: Fran
Contact Number: +65-23456789
Email: [Redacted]

Subsections

- Application Information
- Main Applicant Information
- Notification Emails

Buttons: Back, Add Notification Email 2, Product Information

Main Application Information

- 1) The **applicant's name** is automatically 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.

Notification Emails

- The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.
- 2) The applicant can update the notification email by selecting 'Add Notification Email'.

5.7.5. Product Information

A Singapore Government Agency Website [How to identify](#)

HSA

Dashboard **M**

Application For Export Certificate (New)

Draft Application No. (Draft)
Last saved at 20 March 2025 10:16 AM

Focused View ☐

Overview - Product Information

1 Product Owner Information *
Please provide the product owner information for your products in this application.

No Data Available

+ Add Product Owner

2 Device Information *
Please provide device information for your products.

No Data Available

+ Add Device

3 Importing Country/Region
Please provide device information for your products.

No Data Available

+ Add Importing Country/Region

[< Back](#) [Payment Details >](#)

Subsections

Product Owner Information ☒

Device Information ☐

Importing Country/Region ☐

Product Owner Information

- 1) Applicants enter relevant information about the owner of the product, such as their name and address by clicking on 'Add Product Owner'. There will be only **one Product Owner** for the Products in this Application. Product Owner can be either Overseas or Local.

Device Information

- 2) Applicants enter the device information that they want to include in the Export Certificate by clicking on 'Add Device'.

Importing Country/Region

- 3) Applicants need to enter the Importing Country/Region by clicking on 'Add Importing Country/Region'.

5.7.6. Payment Details

A Singapore Government Agency Website [How to identify](#)

HSA

Dashboard **M**

Application For Export Certificate (New)

Draft Application No. (Draft)

Last saved at 20 March 2025 10:57 AM

Payment Details

Billing Information *

1 Client Code * WC-372604

Postal Code 123123

Block / House No. 123

Level / Unit 4 - 3

Street Name 6838 Grimes-Howe Lane

Building Name Furman Upton

Payment Information *

2 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
MEDAPPEXP	Export Cert - App Fee	1	\$57.00
MEDAPPEXPDEVFEE	EXC - Per Device & 1 Ctry/an Add'l Device (Burkina Faso)	1	\$57.00
	Subtotal		\$104.59
	Tax		\$9.41
	Total		\$114.00

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 >](#)

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

- 1) Applicants can select the client code from the dropdown list
- 2) Applicants will have two payment options, GIRO and Online payment. Applicants need to choose the preferred payment mode.

5.7.7. Review

A Singapore Government Agency Website

How to identify

HSA

Health Sciences Authority

Dashboard

M

Application For Export Certificate (New)

Draft

Application No. (Draft)

Last saved at 20 March 2025 10:57 AM

Focused View

Supporting Documents

Company Details

Application Details

Product Information

Payment Details

Review

Declaration

Review

Supporting Documents

Remarks/Comments

Company Information

No remarks or comments

Company Name
UEN

Franata Company
FranataCompanyUEN

Review page displays the summary of all the sections filled before the declaration.

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A Singapore Government Agency Website

How to identify

HSA

DashboardM

DraftApplication No. (Draft)

Last saved at 20 March 2025 10:58 AM

Application For Export Certificate (New)

Focused View

Supporting Documents

Company Details

Application Details

Product Information

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 of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

On behalf of Franata Company,
a. I hereby attest that the information provided on this application is accurate, correct and complete.
b. I am informed and I understand that it is a serious offence under Section 30(10) of the Health Products Act 2007 to make any statement or furnish any information which I know to be false or does not believe to be true in support of this application.
I have thoroughly reviewed and verified the accuracy, correctness, and completeness of this application for the issuance of the requested certificate.

I acknowledge and confirm the above declarations.

< Back

Submit

- 1) Applicants need to acknowledge and confirm the declaration
- 2) Applicants can submit the application

5.8.1. Class A

- 1) Applicants will redirect to view all active SMDR.
- 2) Search for results by entering the required data in the search table and clicking 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.

5.8.2. Class B, C, D

Singapore Medical Device Register (SMDR)

Advanced Search
Multiple criteria search is always AND condition

Product Name: Contains - Like

Registration: Contains - Like

Product Owner: Contains - Like

Product Owner Location: Select an option

Local Manufacturer: Contains - Like

Importer: Contains - Like

Product Number: Contains - Like

Model Name: Contains - Like

Model Identifier: Contains - Like

UDI-DI: Contains - Like

UDI-PI: Contains - Like

Device Class/IVD Category: Select an option

Medical Specialty Area: Select an option

Intended Use: Contains - Like

Hide Reset Search

188 item(s) found

Product Number	Product Name	Product Owner	Device Risk Classification	Intended Use
MDPE2024142010	GMD 14 Apr 2025 Invalid M1 1703	Overseas 12 Mar 2025 PD 2127	Class B	For invalid M1 testing
MDPE2024020002	IVD 2 April 2025 Auto Renewal 1302	Overseas 12 Mar 2025 PD 2127	Class D	Auto retention testing
MDPE2023262812	FaceMask	Samsat Tan and Solicitors	Class B	The blood glucose monitor is intended for the quantitative measurement of glucose. The device is suitable for self-testing and provides fast, accurate results to help users make informed decisions about their diabetes care.
MDPE2023170018	IVD 17 Mar 2025 CUI 04	Overseas 17 Mar 2025 Comp 21 PD 01	Class C	For CUI testing
MDPE2023090017	EEG Machine	Samsat Tan and Solicitors	Class B	The blood glucose monitor is intended for the quantitative measurement of glucose. The device is suitable for self-testing and provides fast, accurate results to help users make informed decisions about their diabetes care.
MDPE2024052002	GMD 5 Apr 2025 Auto Retention 1243	Local 25 Mar 2025 PD 0711	Class C	For auto retention testing
MDPE2023170013	GMD 17 Mar 2025 Comp 22 04	MD URT Company 19	Class B	For CUI testing
MDPE2023042005	GMD 24 Mar 2025 C 1804	Local 12 Mar 2025 PD 2025 Updated	Class C	For PR testing
MDPE2023030010	CT Scanner	Jack Ng and Solicitors	Class B	The blood glucose monitor is intended for the quantitative measurement of glucose. The device is suitable for self-testing and provides fast, accurate results to help users make informed decisions about their diabetes care.
MDPE2023170003	GMD 17 Mar 2025 Comp 21 CUI 01	Local 17 Mar 2025 Comp 21 PD 01	Class C	For CUI URT testing

Showing 1 to 10 of 188 results

Page Size: 10

1 2 3 4 5 Next Last

URL:

<https://share.hsa.gov.sg/medics/PublicListing/Smdr>

This page will show the list of all active Class B/C/D Products registered in SHARE. There will be advanced search provided to ease user when searching for specific product.

- 1) Applicants will redirect to view all active Class A products.
- 2) Search for results by entering the required data in the search table and clicking 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 3) For each Product, the user will be able to click the Product Number to see the Product's information in more detail.

5.8.3. Dealer's Licence

A Singapore Government Agency Website [How to identify](#)

Dealer's Licence

[View SMDR](#)

Advanced Search

Multiple criteria search is always AND condition

Licence Number		Contains - Like
Company Name		Contains - Like
Dealer's Activity	Select an option	Equal

[Hide](#) [Reset](#) [Search](#)

125 item(s) found

Licence Number	Company Name	Licence Type
MDML250314W01	FifteenthCompany	Manufacturer
MDML250405Y02	Luciana Company	Manufacturer
MDWL250123L08	Stiedemann - Rutherford	Wholesaler
MDML250123W03	FifthCompany	Manufacturer
MDWL250318N04	MD UAT Company 09	Wholesaler
MDIL250411R02	Franata Company	Importer
MDWL250317M31	MD UAT Company 22	Wholesaler
MDML250317H18	MD UAT Company 03	Manufacturer
MDML250319D03	FifteenthCompany	Manufacturer
MDWL250317O15	MD UAT Company 17	Wholesaler

Showing 1 to 10 of 125 results

Page Size: 10 [First](#) [Prev](#) [1](#) [2](#) [3](#) [4](#) [5](#) [Next](#) [Last](#)

URL:

<https://share.hsa.gov.sg/medics/PublicListing/DealerLicence>

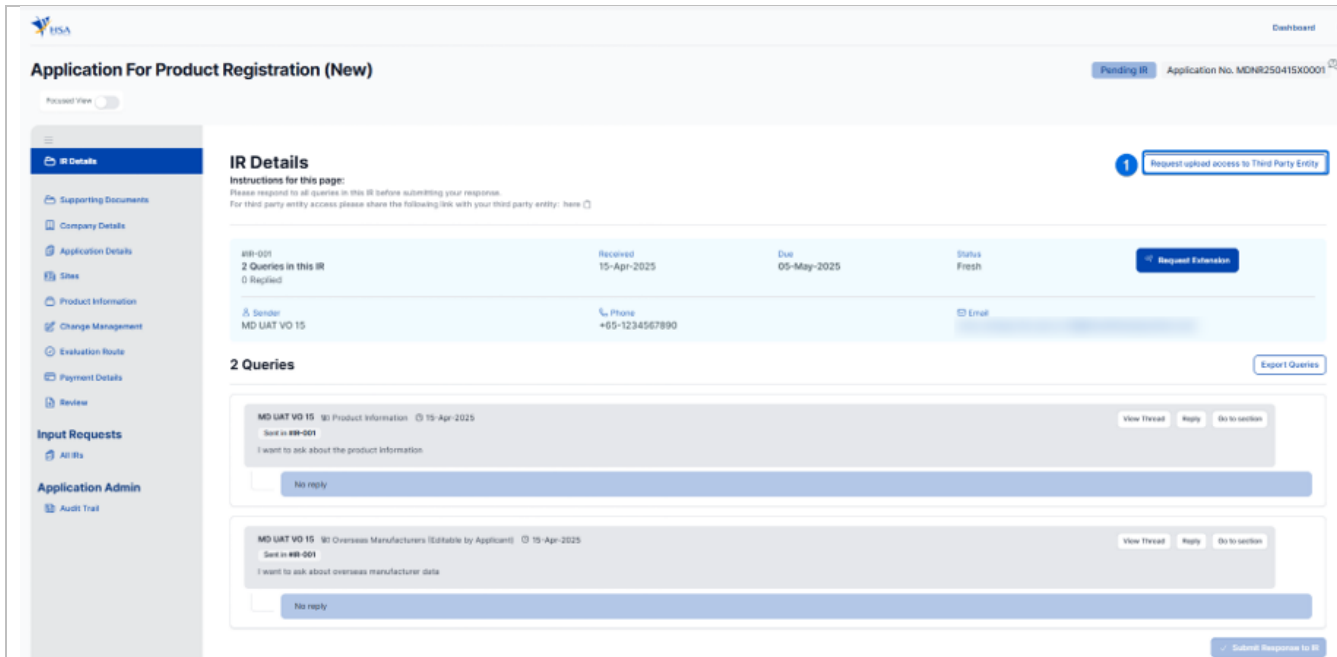
This page will show the list of all active Manufacturer, Importer, and Wholesaler Licences registered in SHARE. There will be advanced search provided to ease user when searching for a specific Licence.

- 1) Applicants will redirect to view all active SMDR.
- 2) Search for results by entering the required data in the search table and clicking 'Search' button. If the applicant enters multiple search criteria, the system will apply an 'AND' search to refine the results.
- 3) For each Licence, the user will be able to click the Licence Number to see the Licence's information in more detail.

5.9. Overseas Entity Login

Local applicant is able to request overseas entity to submit additional documents to support his application. The request is done through an open IR. The applications that support this function are Product Registration (New) and Product Registration (Change Notification).

5.9.1. Local Applicant Request Access for Overseas Entity



The screenshot shows the 'Application For Product Registration (New)' page. The top navigation bar includes the HSA logo, a 'Dashboard' link, and a 'Pending IR' status indicator. The main header displays 'Application No. MDNR250415X0001'. The left sidebar contains a menu with options: Supporting Documents, Company Details, Application Details, Sites, Product Information, Change Management, Evaluation Route, Payment Details, Review, Input Requests, and Application Admin. The main content area is titled 'IR Details' and includes instructions for responding to queries. Below this, there is a table with columns for 'Received', 'Due', and 'Status'. The table shows one query received on 15-Apr-2025, due on 05-May-2025, with a status of 'Fresh'. A 'Request Extension' button is visible next to the query. Below the table, there are two queries listed, each with a 'View Thread', 'Reply', and 'Go to section' button. The first query is from MD UAT VO 15, asking for product information. The second query is from MD UAT VO 15, asking for overseas manufacturer data. A 'Submit Response to IR' button is at the bottom right.

In the application IR Details page.

- 1) Applicants would be able to request access for overseas entity by clicking on the **“Request upload access to Third Party Entity”** button.



Application For Product Registration (New)

Focused View

- IR Details
- Supporting Documents
- Company Details
- Application Details
- Sites
- Product Information
- Change Management
- Evaluation Route
- Payment Details
- Review
- Input Requests
- Application Admin
- Audit Trail

IR Details

Instructions for this page:
Please respond to all queries in this IR before submit.
For third party entity access please share the follow

#IR-001
2 Queries in this IR
0 Replied

Sender
MD UAT VO 15

2 Queries

MD UAT VO 15 | Product Information

Sent in #IR-001

I want to ask about the product information

No reply

MD UAT VO 15 | Overseas Manufacturers

Sent in #IR-001

I want to ask about overseas manufacturer

No reply

Request upload access to Third Party Entity

Email *

Remarks *

We need overseas third party entity to address your query

Section	Created On	Query
☐ Product Information	15-Apr-2025	I want to ask about the product information
☒ Overseas Manufacturers	15-Apr-2025	I want to ask about overseas manufacturer data

Cancel Save

2) Applicants would be able to fill in the details of the request.

- Email
 - Remarks
 - Select the related IR queries by using the checkbox
- 3) Submit the request by clicking on the “**Save**” button.

Application For Product Registration (New)

Pending IR Application No. MDNR250415X0001

IR Details

Instructions for this page:
Please respond to all queries in this IR before submitting your response.
For third party entity access please share the following link with your third party entity: [Link](#)

IR ID	Received	Due	Status	Action
IR-001	15-Apr-2025	05-May-2025	Responded	Request Extension

2 Queries

MD UAT VO 15: [Product Information](#) 15-Apr-2025
Sent to IR-001
I want to ask about the product information

MD UAT VO 15: [Product Information](#) 15-Apr-2025
Sent to IR-001
reply here

MD UAT VO 15: [Overseas Manufacturer \(Subtable by Applicant\)](#) 15-Apr-2025
Sent to IR-001
I want to ask about overseas manufacturer data

MD UAT VO 15: [Overseas Manufacturer \(Subtable by Applicant\)](#) 15-Apr-2025
Sent to IR-001
We need overseas third party entity to address your query

After officer grant the access to the overseas entity.

- 4) Applicants would be able to see additional text added for third party entity access.
- 5) Applicants need to copy the link and share it to the overseas entity for him to access the system. Applicants also need to provide the application number to the overseas entity for his verification process.

Note: A new IR will be generated for the query pending input from the overseas entity. Once the overseas entity has responded, the IR will be marked as “Responded” and no action is required from the applicants. The applicants may continue addressing the rest of the queries concurrently.

5.9.2. Overseas Entity Verification



A Singapore Government Agency Website How to identify

HSA

Singapore Health Product Access and Regulatory E-System (SHARE)

Singapore Health Product Access and Regulatory E-System (SHARE)

Third Party Entity Log in

1 Email

Application Reference Number

2 Send OTP

URL:

<https://share.hsa.gov.sg/medics/thirdparty/login>

As the system does not require login to access this feature, to ensure secure access, overseas entity must verify their email through a 2-factor authentication process.

- 1) Overseas entity needs to type in the correct email address and the related application number.
- 2) Overseas entity needs to click **“Send OTP”** to proceed to the next page.

A Singapore Government Agency Website | How to identify

 Singapore Health Product Access and Regulatory E-System (SHARE)

✓ Your request was successful. Please check your inbox and also your spam or junk folder for the OTP. ✕

Singapore Health Product Access and Regulatory E-System (SHARE) ³

Third Party Entity Log in

853- Code

Resend OTP in 0' ⁴

- 3) Overseas entity needs to fill in the OTP. The OTP must be used within **the validity period of 1 hour**. However, the overseas entity can **request a new OTP after 10 minutes**, invalidating the previous OTP. After 1 Hour the OTP expires, the overseas entity will need to request a new OTP.
- 4) Overseas entity needs to click **“Login”** to submit the OTP.

5.9.3. Overseas Entity Accessing Application

A Singapore Government Agency Website
How to identify



View Application

Application No. MDNR250415X0001

Focused View

All IRs

#IR-002

1 Queries in this IR

0 Replied

Sender

MD UAT VO 15

Received

15-Apr-2025

Due

01-May-2025

Status

Fresh

11 working days left

1

Response

Overseas entity would be able to only see his assigned IRs in the application. Overseas entity would **not** be able to see other details of the application.

Overseas entity would be able to see the list of IRs he has access to in the application.

- Overseas entity would be able to click 'Response' button to see the IR Details.

A Singapore Government Agency Website [How to identify](#)

HSA

View Application

Application No. MDNR250415X0001

Focused View ☐

IR Details

Supporting Documents 3

Input Requests

All IRs

IR Details

#IR-002	Received	Due	Status
1 Query in this IR 1 Replied	15-Apr-2025	01-May-2025	Fresh

Sender MD UAT VO 15

Phone +65-1234567890

Email

1 Queries

Export Queries

MD UAT VO 15 Overseas Manufacturers 15-Apr-2025

Sent in #IR-002

I want to ask about overseas manufacturer data

Applicant Overseas Manufacturers 15-Apr-2025

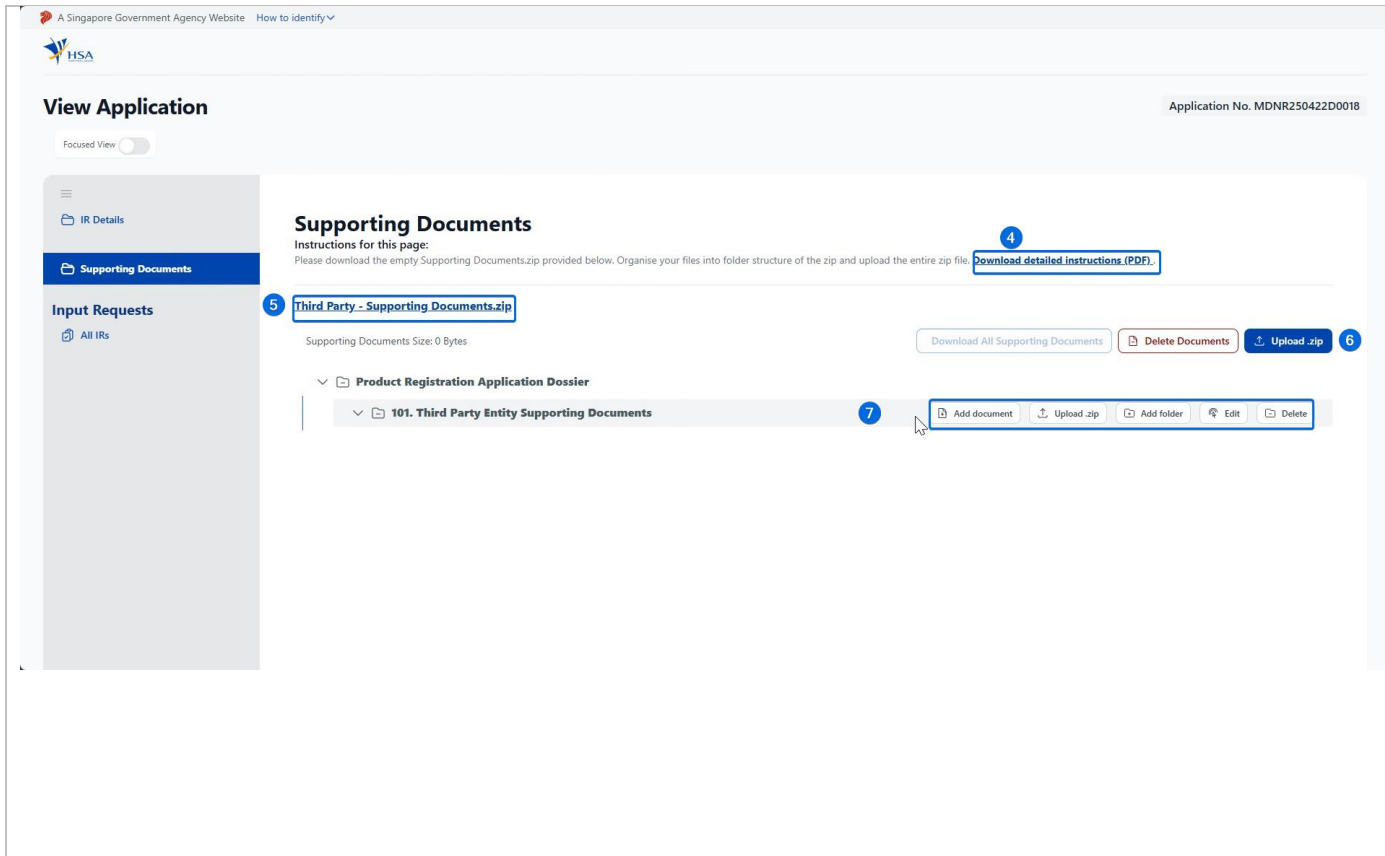
Sent in #IR-002

reply from third party (I added the overseas manufacturer documents)

Edit Reply

Submit Response to IR

- 2) Overseas entity would be able to see the list of queries he is assigned to.
- 3) Overseas entity would be able to see the Supporting Documents section.



View Application Application No. MDNR250422D0018

Supporting Documents

Instructions for this page:
Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file.

[Download detailed instructions \(PDF\).](#)

Third Party - Supporting Documents.zip

Supporting Documents Size: 0 Bytes

[Download All Supporting Documents](#) [Delete Documents](#) [Upload.zip](#)

Product Registration Application Dossier

101. Third Party Entity Supporting Documents

[Add document](#) [Upload.zip](#) [Add folder](#) [Edit](#) [Delete](#)

In Supporting Documents section, overseas entity can only see the “Third Party Entity Supporting Documents” folder and his own uploaded files.

- 4) Overseas entity can download detailed instructions for guidance
- 5) Overseas entity can download the Dossier Template as a zipped folder
- 6) Overseas entity can add the necessary files to the relevant folders within the Dossier Template and upload the zip file
- 7) Overseas entity can update Supporting Documents from an existing Dossier by performing any of the following actions:
 - a. Add document
 - b. Upload zip file
 - c. Add folder
 - d. Edit folder
 - e. Delete folder

A Singapore Government Agency Website [How to Identify](#)

HSA

View Application Application No. MDNR250415X0001

☐ Focused View

IR Details

#IR: 002 1 Query in this IR 1 Replied	Received 15-Apr-2025	Due 01-May-2025	Status Fresh
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Sender: MD UAT VO 15 | Phone: +65-1234567890 | Email: [Redacted]

1 Queries Export Queries

MD UAT VO 15 | Overseas Manufacturers | 15-Apr-2025
Sent in #IR-002
I want to ask about overseas manufacturer data

Applicant | In Manufacturers | 15-Apr-2025
Sent in #IR-002
reply from third party (I added the overseas manufacturer documents)

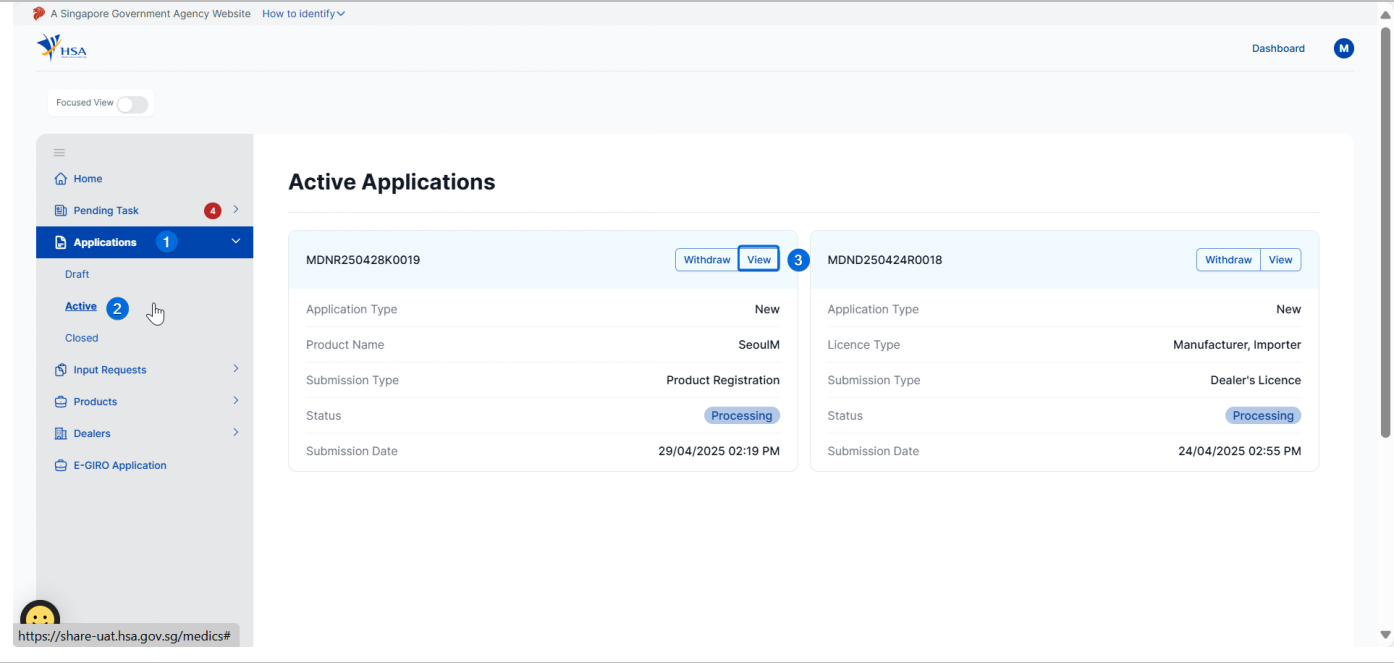
8 [Edit Reply](#)

9 [Submit Response to IR](#)

- 8) Overseas entity would be able to reply to the query.
- 9) Overseas entity would be able to submit response to IR.

5.10. Update Notification Emails

For active or closed applications, Applicant can update the Notification Emails in the Application Details section.



- 1) Navigate to 'Applications'
- 2) Select 'Active' or 'Closed'
- 3) Applicants can access the application which they would like to update the notification emails by clicking 'View'

Focused View

Supporting Documents

Company Details

Application Details 4

Sites

Product Information

Change Management

Evaluation Route

Payment Details

Review

Input Requests

All IRs

Application Admin

Audit Trail

Application Details

Application Information

Product Type

Medical Devices

Submission Type

Product Registration

Application Type

New

Device Type

General Medical Device

Main Applicant Information

Applicant Name (as in NRIC/FIN)

MD UAT Company 05 User 01

Designation

ba

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

Notification Email 1

Contact Person

Sarah

Contact Number

+65-12345678

Email

5

Edit

Delete

6

7

+ Add Notification Email 2

8

Save

Subsections

Application Information

Main Applicant Information

Notification Emails

4) Navigate to 'Application Details'

5) Applicants can edit the current Notification email

6) Applicants can delete the current Notification email

7) Applicants can add one more Notification email

8) Applicants need to save their changes made in the 'Notification Emails' section

Note: Applicants need to at least provide one notification email.