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

Contents

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.
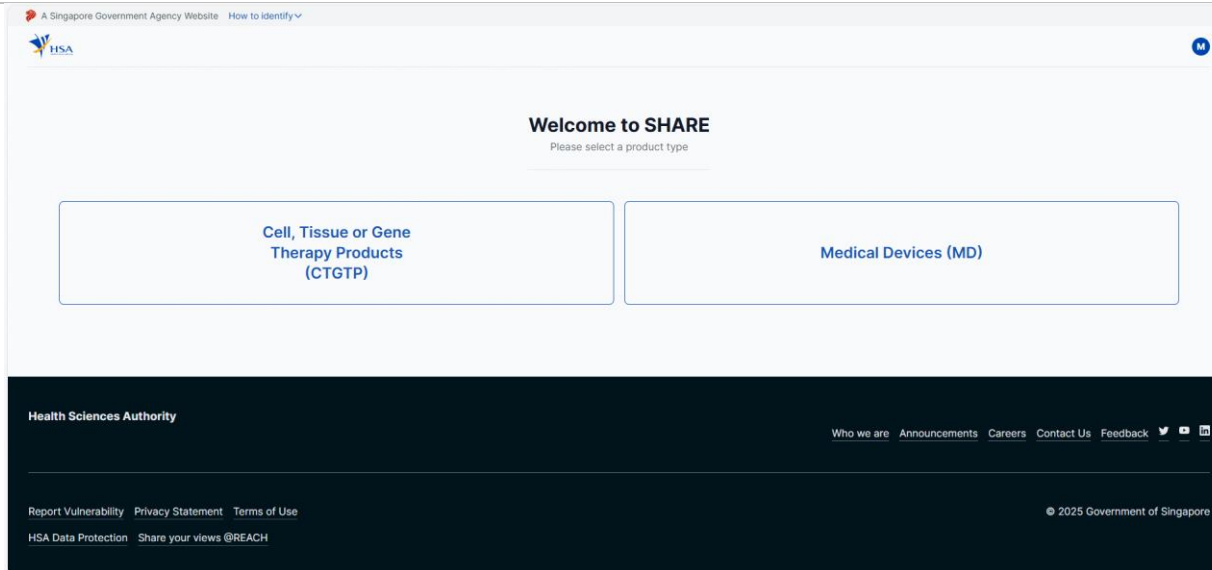
Terms	Definition
Applicant	An individual appointed by the company to make a submission to HSA
Class B/C/D Products	Products registered in SHARE. Class B/C/D/D (contains registrable therapeutic/medicinal product) indicates the product's risk classification. Class D (contains registrable therapeutic/medicinal 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. |
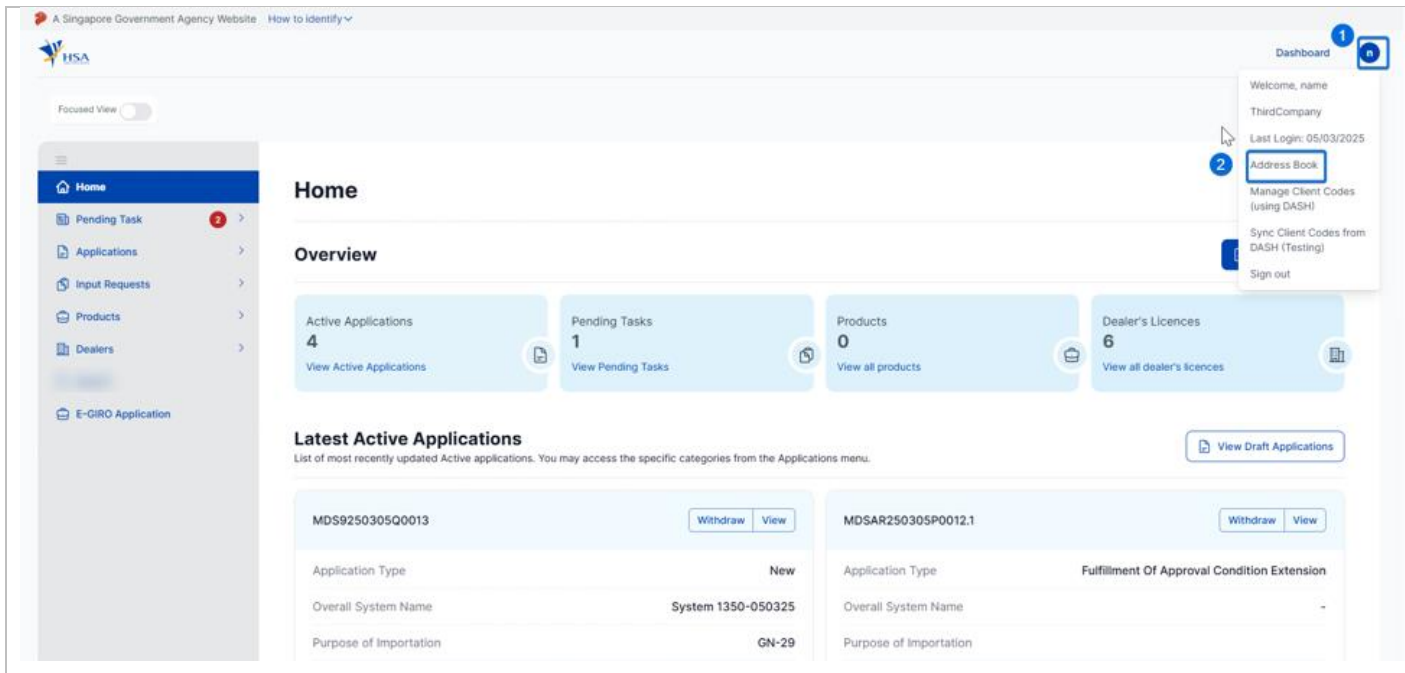
4. Overview

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.

Steps:
1) Select
2) Select 'Address Book'

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.

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.

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

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

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.

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

Health Sciences Authority

Report Vulnerability   Privacy Statement   Terms of Use

HSA Data Protection   Share your views @REACH

🙂

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.

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.
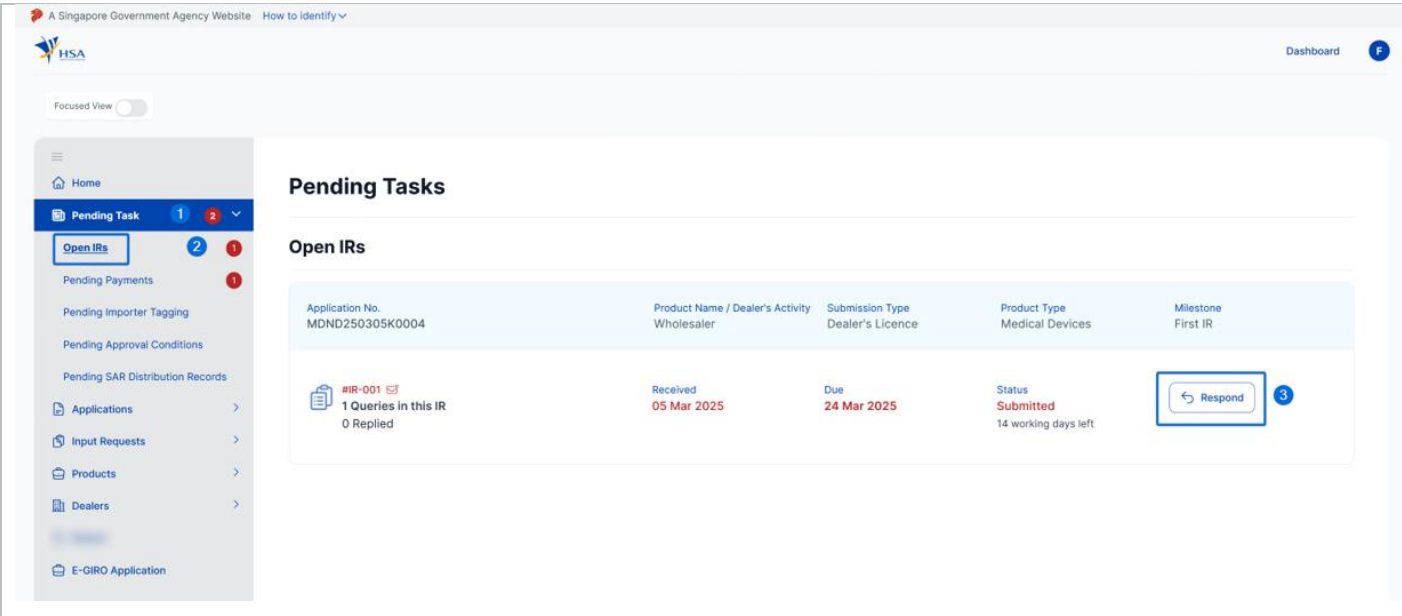
	Latest Active Applications:
	- Displays the latest active Applications submitted by the Applicant that are still in the review stage, along with key information about the Applications. The Applicant can perform actions such as viewing the details of the Application and initiating a withdrawal. Applicants 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

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

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

4.3.3. Pending Importer Tagging

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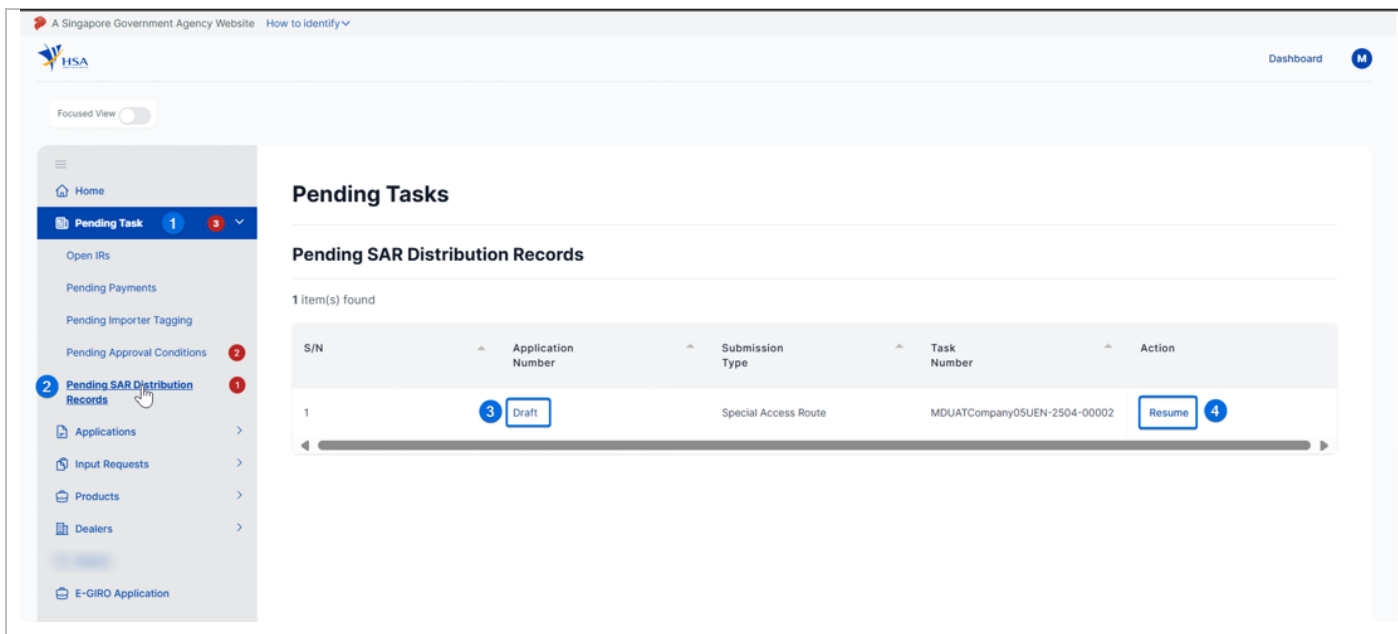
1) Navigate to 'Pending Tasks'
2) Select 'Pending Approval Conditons'
3) The system will automatically create the **Error! Not a valid result for table.** draft application 10 working days before the approval condition due date. Applicants would be able to review the Draft application of **Error! Not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

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

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

4.4.2. Active

1) Navigate to 'Applications'
2) Select 'Active'

Applicants can Withdraw the application. For more details, please refer to

3) Withdrawal
4) Applicants can view the application

4.4.3. Closed

1) Navigate to 'Application'
2) Select 'Closed'
3) Applicants can view the application
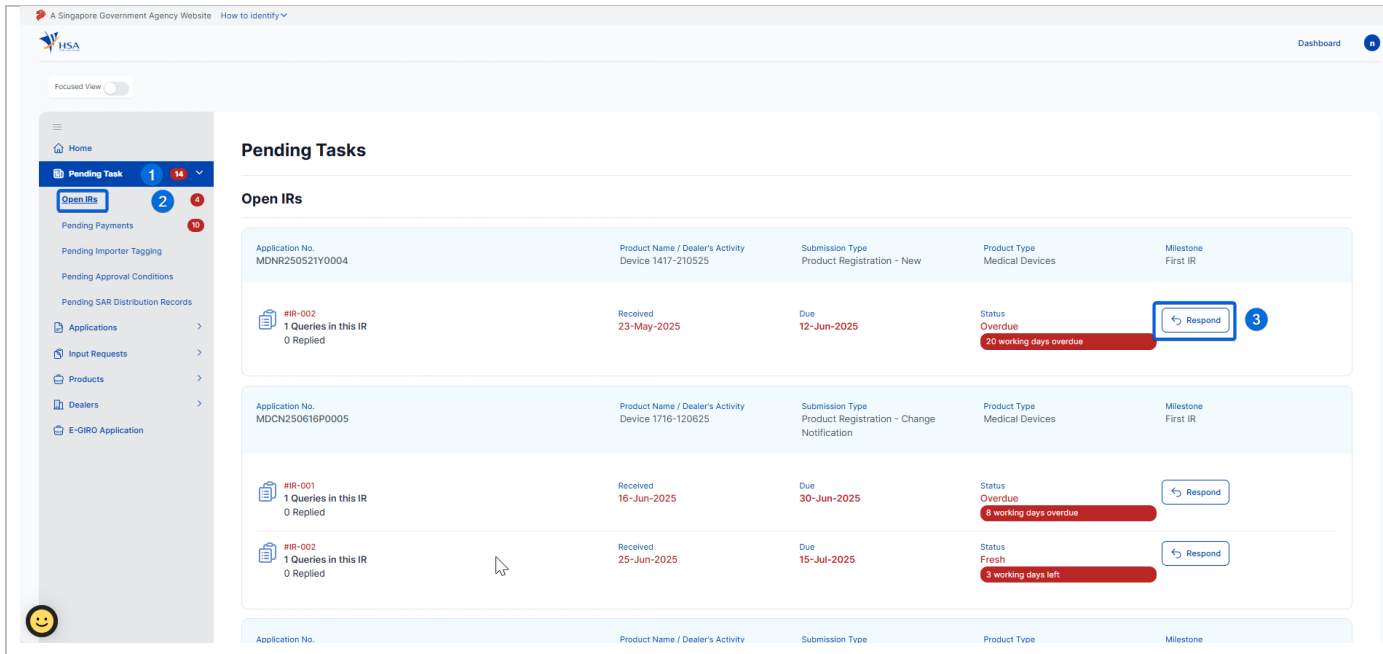
4.5. Input Requests

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

4.5.1. Open IRs

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

Applicants can

5) Request Extension for the selected IR.
6) Applicants can view the thread.

Applicants can

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 In

Product Ow

Product Owner

Product Owner
Address

Device Listin

Device 1

Device Type

Device Name

Intended Use

Is Standalone

Machine Learni

If the device co
interfacing cap
that apply

Risk Class

Medical Specia

Is the device fo

Is the In Vitro D

Edit Data for Product Owner Informatio

Product Owner Information *

Please provide product owner information for each

Product Owner (Local)

Product Owner Name

Address

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

Request Extension

Applicants can request to extend due date for IR.

Edit

Product Information

Product Owner Information ⓘ   ① 1 Queries   ② Edit   ③ Edit History

Subsections

Product Owner Information

Device Listing

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
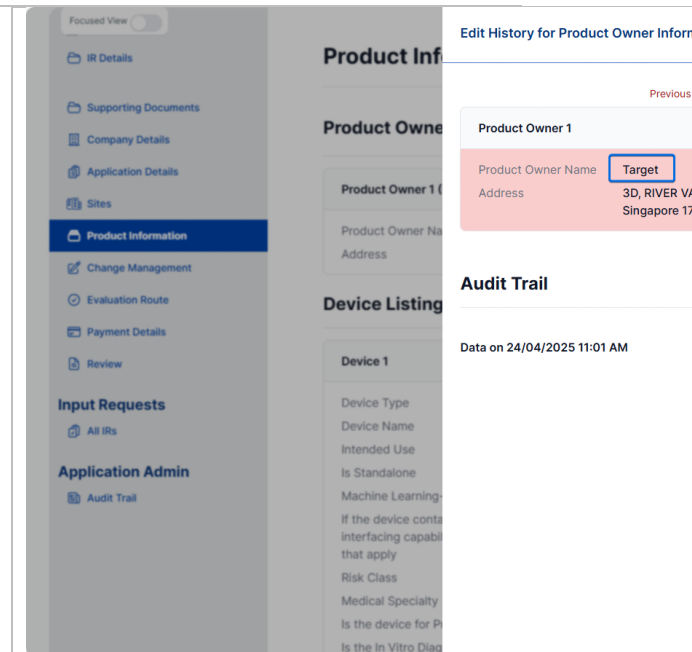
Sidebar navigation:

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

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

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

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

Input Requests initiated by officers to which the applicant has already responded are displayed here.
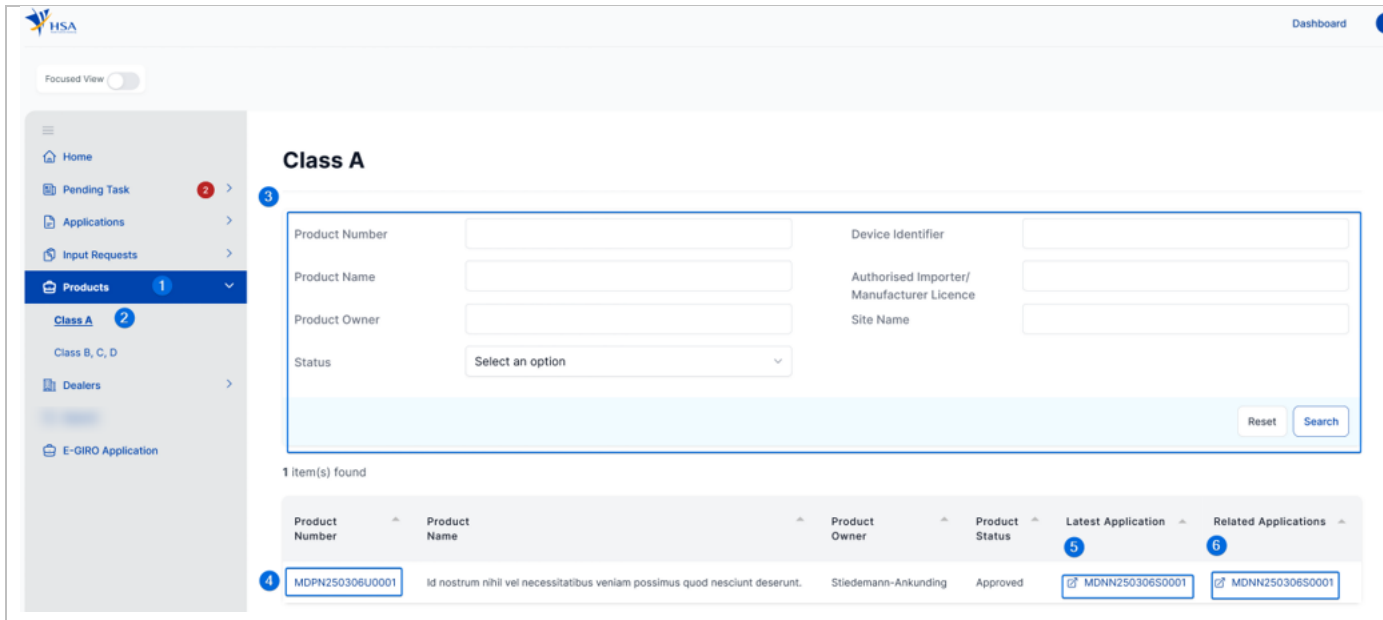
The Responded IRs list displays the number of queries in the IR, received date, due date, status, and a view button.

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

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

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

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

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

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

	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.

2) Applicants have the option to select various products within a given application.
3) Applicants will review the withdrawal
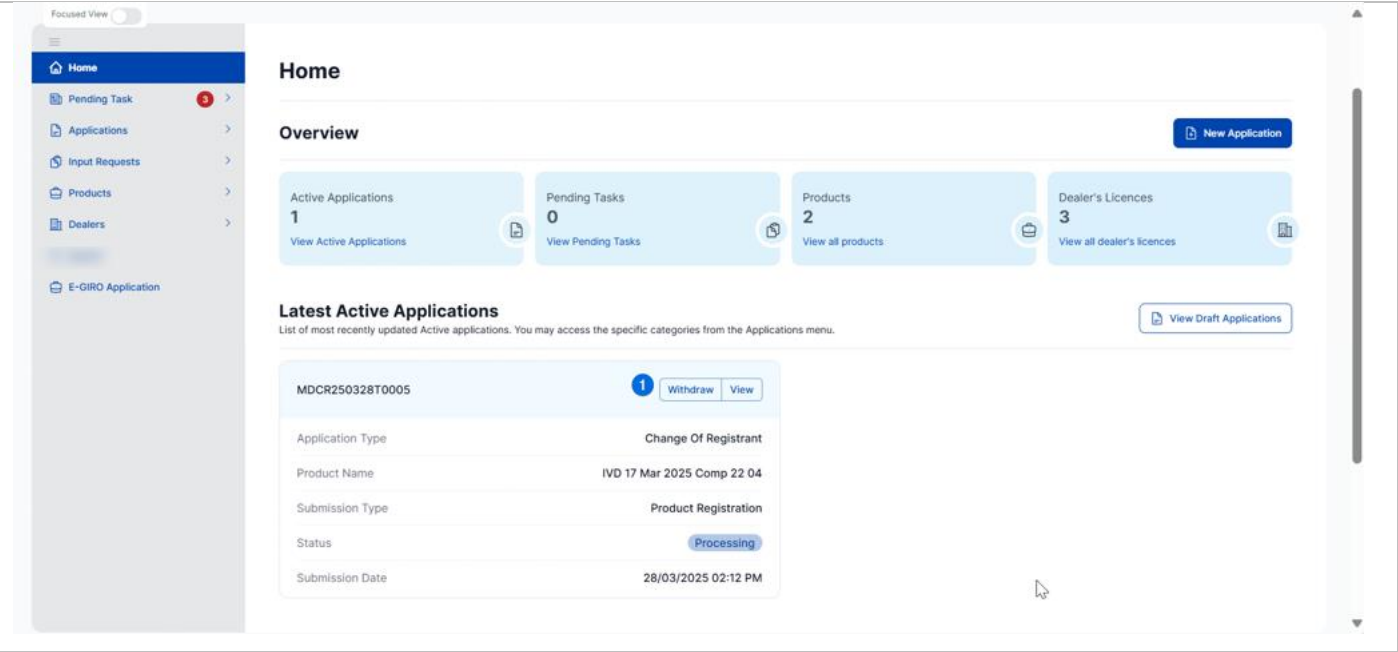
4) (Optional) Add remarks
5) Applicants need to confirm the required product they want to withdraw.
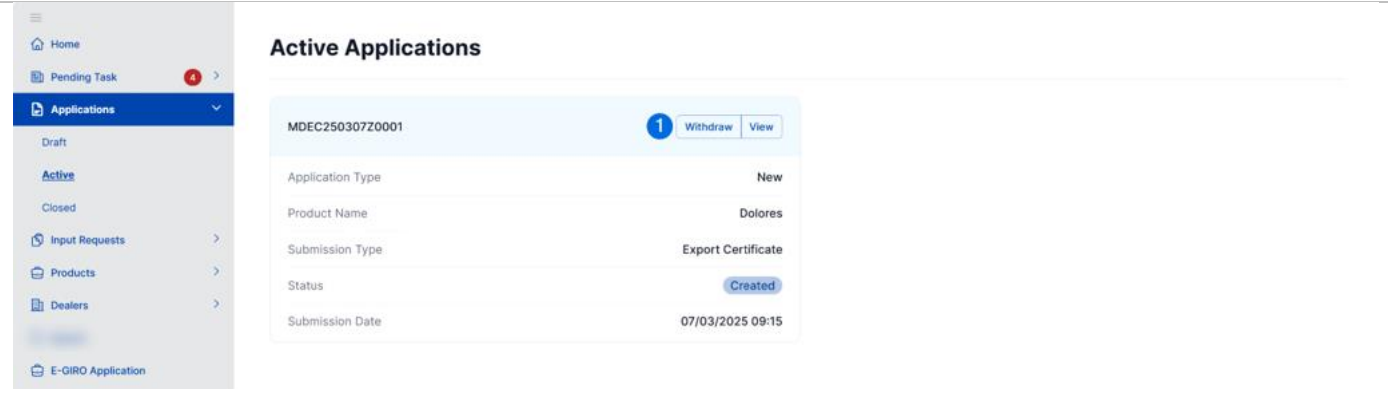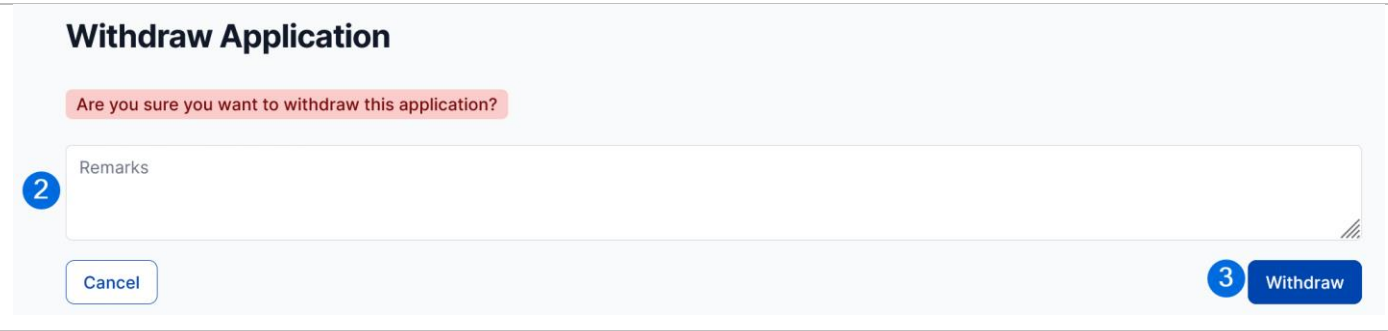
4.8.2. Change Notification

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

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 ⌄

Withdraw Application

Are you sure you want to withdraw this application?

2 Remarks

Cancel   **3** Withdraw

Health Sciences Authority
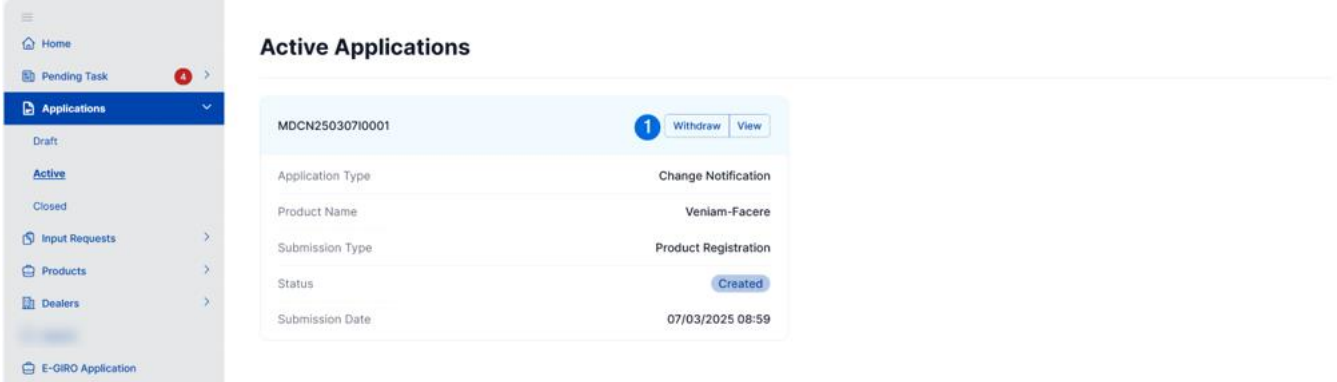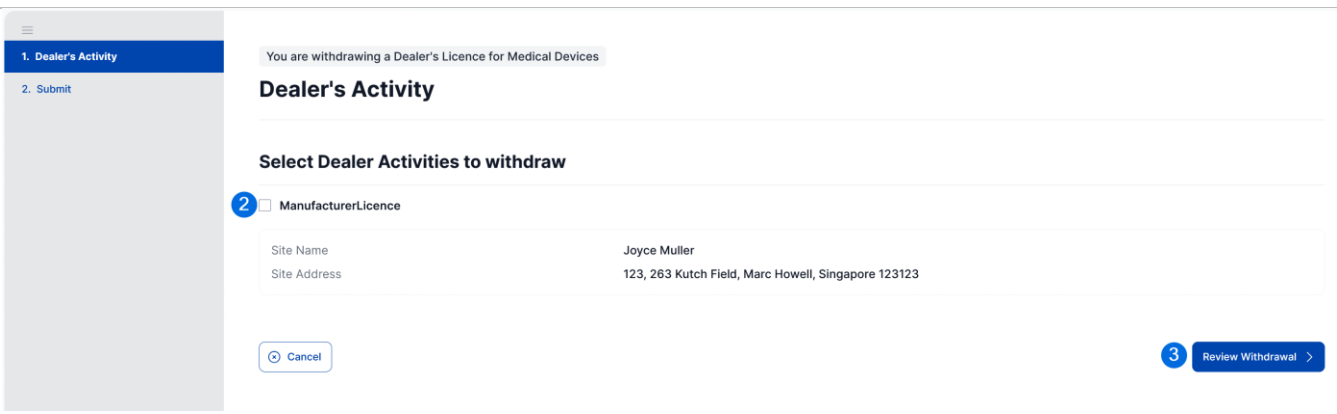
Who we are   Announcements   Careers   Contact Us   Feedback

Report Vulnerability   Privacy Statement   Terms of Use

HSA Data Protection   Share your views @REACH

© 2025 Government of Singapore

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
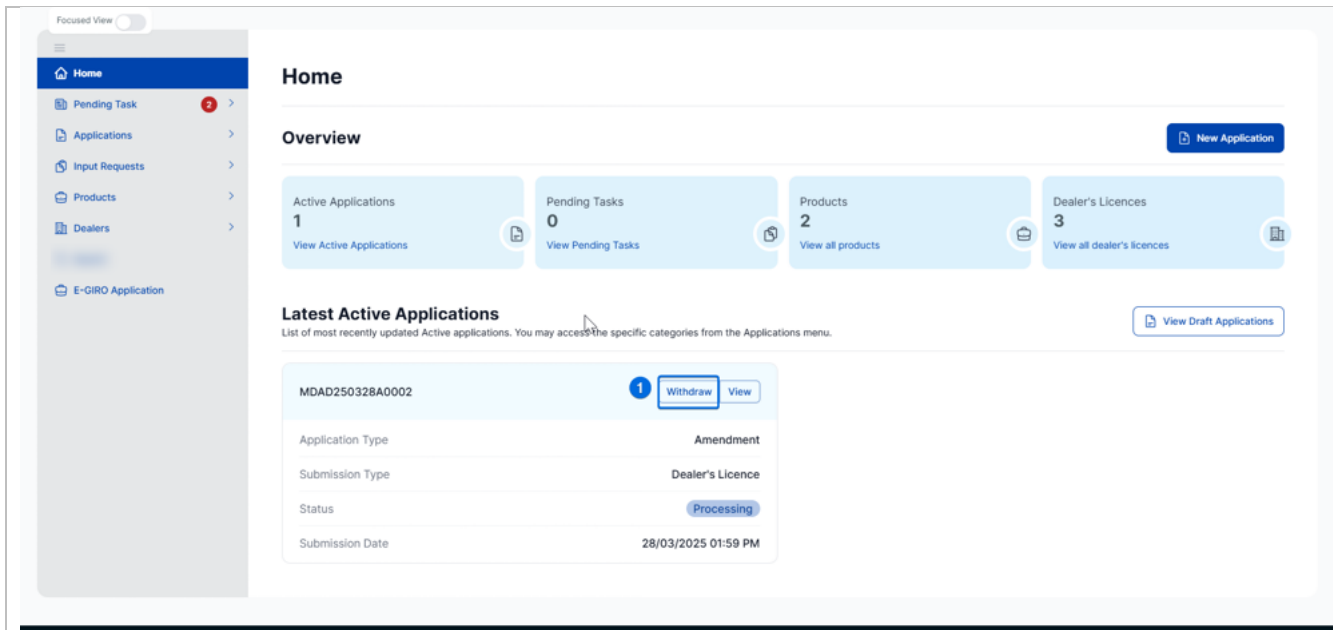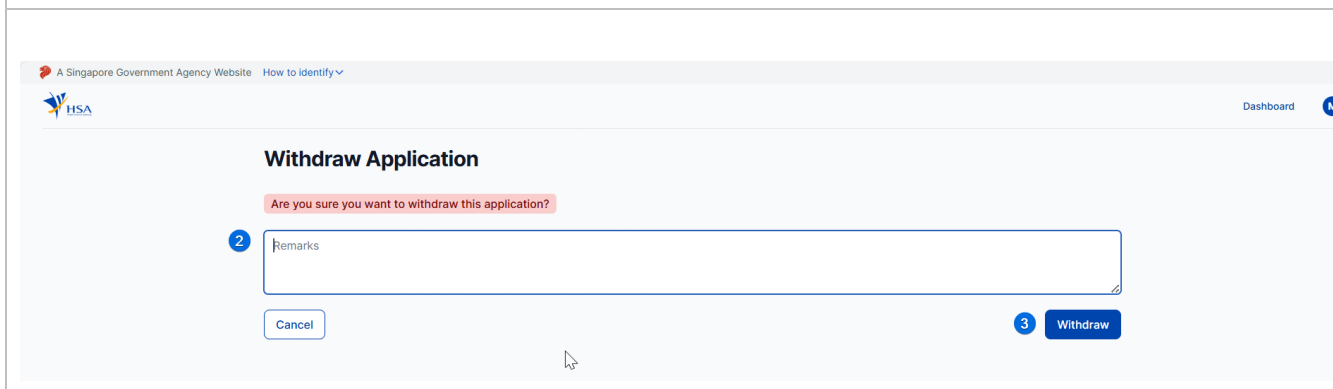
4) (Optional) Add remarks

5) Applicants need to confirm the required dealer they want to withdraw.

4.8.5. Dealer's Licence (Amendment)
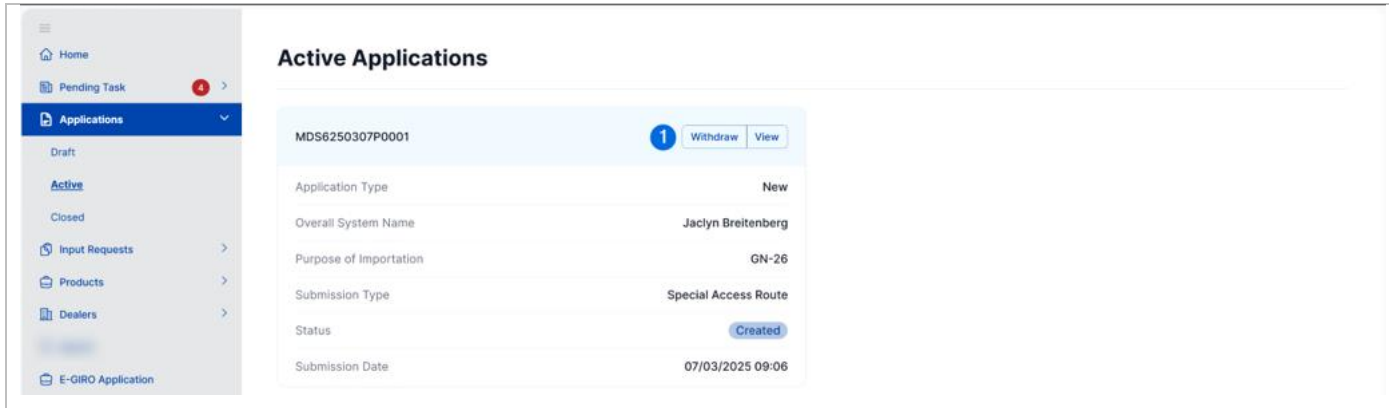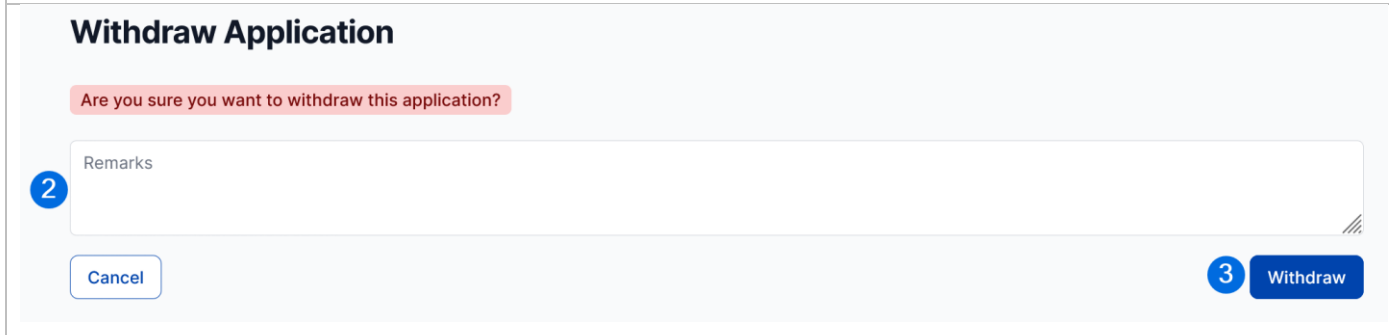
1) Applicants can select the '**Withdraw'** option to withdraw application while the application is pending HSA approval.

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. Cancellation

4.9.1. Product Notification

1) Create new application

HSA   Dashboard   F

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

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

You are cancelling a Product Notification for Medical Devices

Device Selection

Select Devices to Cancel

Notification Number

Product Name

Product Owner Name

Intended Use

Identifier

Reset | Filter

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

Cancellation Reasons

☐ Quality and/or Safety Issue(s)
☐ Business Decision
☐ Product Discontinued
☐ Others, please specify

Cancel

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

4.9.2. Product Registration

1) Create new application

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

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

Cancel Application For Product Registration

You are cancelling a Product Registration for Medical Devices

Submit

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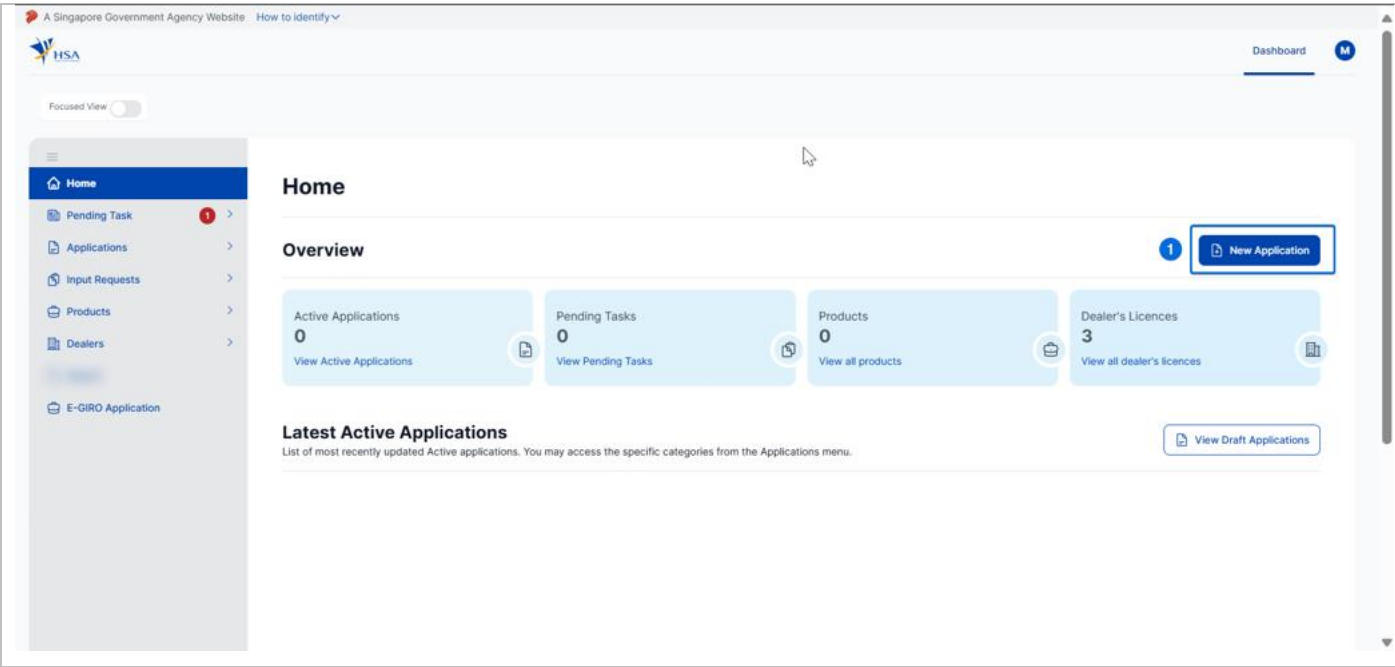
○ I am no longer registered with Accounting and Corporate Regulatory Authority of Singapore (ACRA) as a business entity. I attest that I have transferred records of supply and records of complaints of the registered medical device(s) to the Product Owner.

Back   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

2) Select 'Dealer's Licence' 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

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

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

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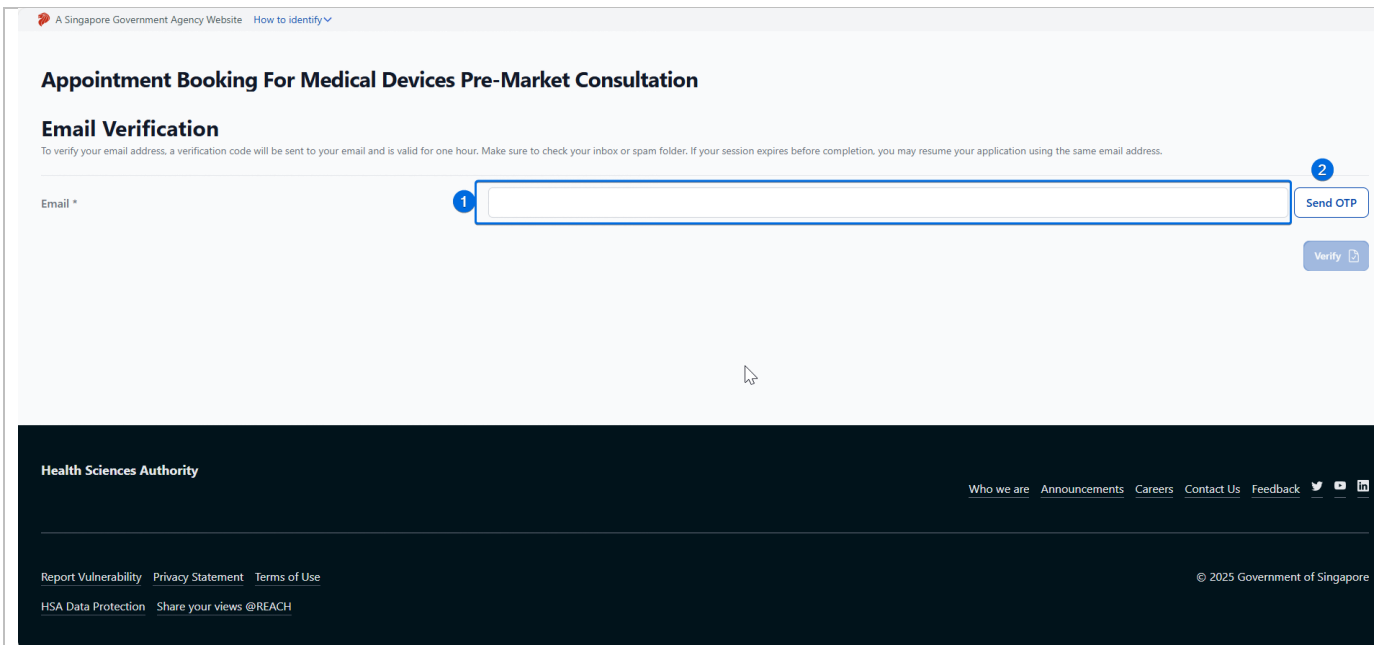
7) Applicants need to confirm the licence(s) that they would like to cancel

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

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.

3) Applicants can enter the verification code in their email and then select "**Verify**".

5.1.2. Applicant 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.

Booking Information

Booking Details

Consultation Type *

○ Device Development   ○ Device Pre-Submission

February 2025

Sun	Mon	Tue	Wed	Thu	Fri	Sat
		11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	1

Selected Slot *   N/A

List of Attendees
Please add at least one attendee.

ⓘ No Data Available

Add Attendee

‹ Back   Device Information ›

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

Device Development'.

Device Pre-Submission

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'.

4) Applicants need to fill out the device information.

Device Development

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.

Appointment Booking For Medical Devices Pre-Market Consultation

5) **Device Information**

Have you enquired on this medical device previously? *   ○ Yes   ○ No

Device Name *

Device Type * ⓘ   ○ General Medical Device   ○ In-Vitro Diagnostic Device

Medical Specialty *   Select an option

Proposed Intended Use/Indications for Use * ⓘ

Device/Technology Description * ⓘ

Focused View

Applicant Information
Booking Information
Device Information
Supporting Documents
Review
Declaration

Overview of Device Development
Please select accordingly based on current development progress of the device

Concept Feasibility completed? *   ○ Yes   ○ No   ○ Ongoing

Invention & Prototyping completed? *   ○ Yes   ○ No   ○ Ongoing

Design Validation (Pre-Clinical) completed? *   ○ Yes   ○ No   ○ Ongoing

Clinical Studies completed? *   ○ Yes   ○ No   ○ Ongoing
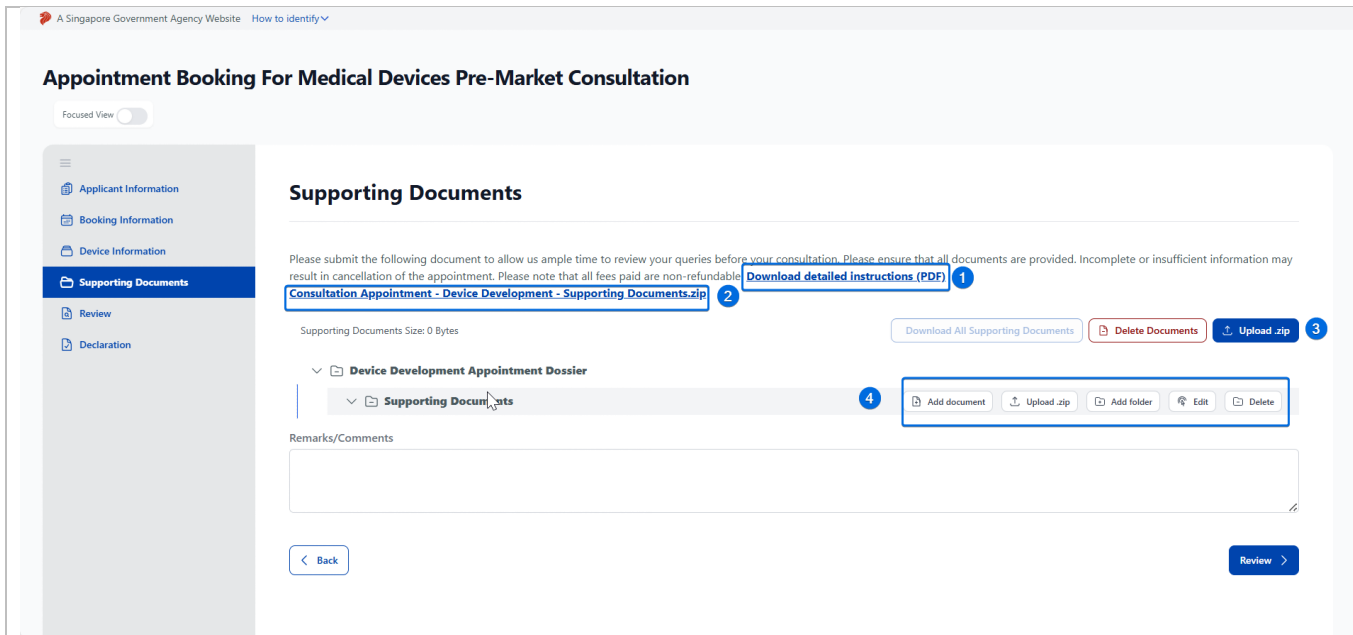
Has the Product been launched? *   ○ Yes   ○ No

‹ Back   Supporting Documents ›

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

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

5.1.6. Declaration

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

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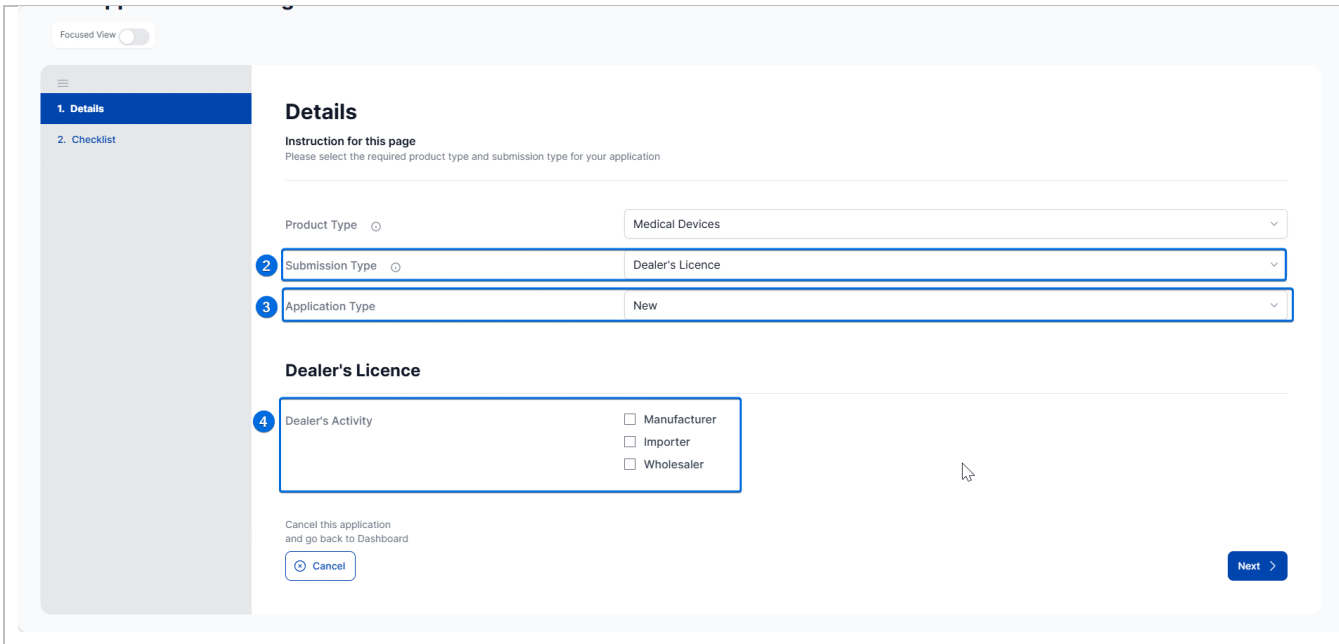
Dealer's Licence(s) are required for companies that intend to manufacture, import or wholesale medical devices in Singapore.

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.

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.

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

5.2.1.3. Company 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.

5.2.1.4. 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

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 (Nev

Add Site Details 1   ×

Manufacturer   Delete

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 * ⓘ
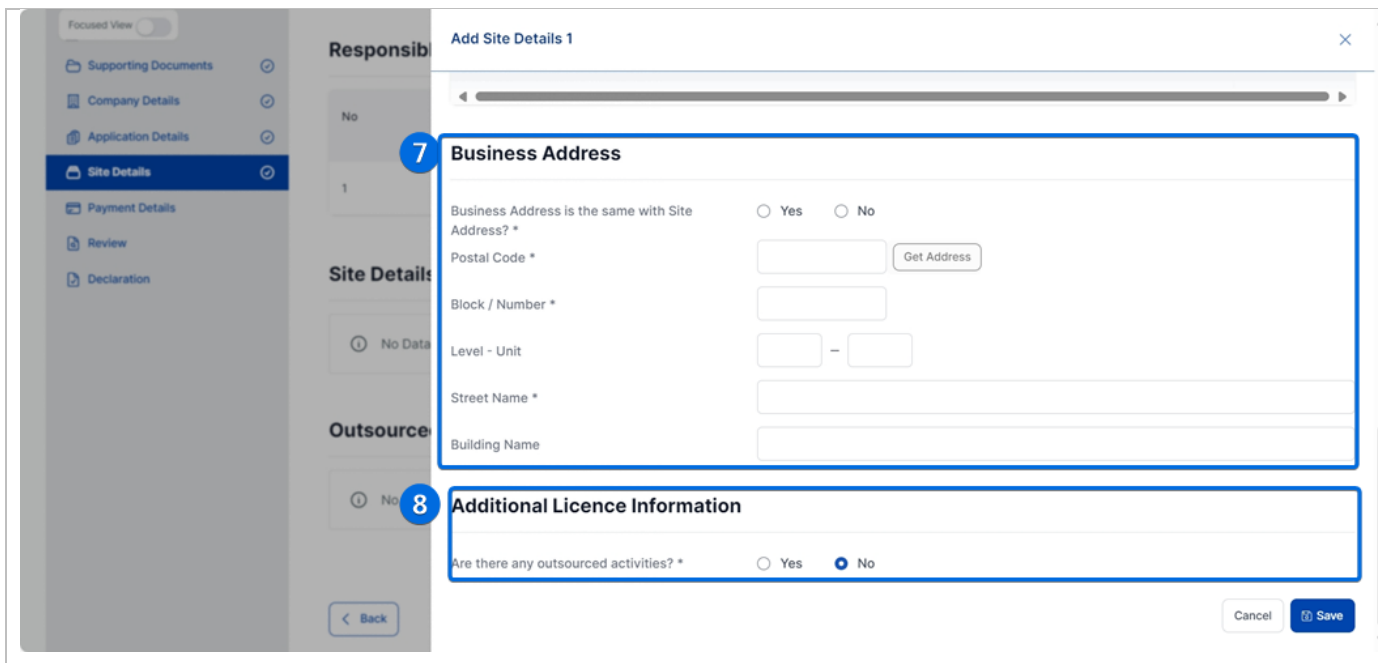
                                                                                Add Certification

No Data Available

                                                                    Cancel   💾 Save

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

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

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

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

5.2.1.8. Declaration

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

1) Applicants would be able to create a new application by clicking on the "**New Application**" 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

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 ① 🗂 Licence Details 🗔 Payment Details 📄 Review 📄 Declaration **Amendment Information** ☐ 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	Select licence type ⌄	Risk Classification	Select risk classification ⌄
Licence Number	[ ]		
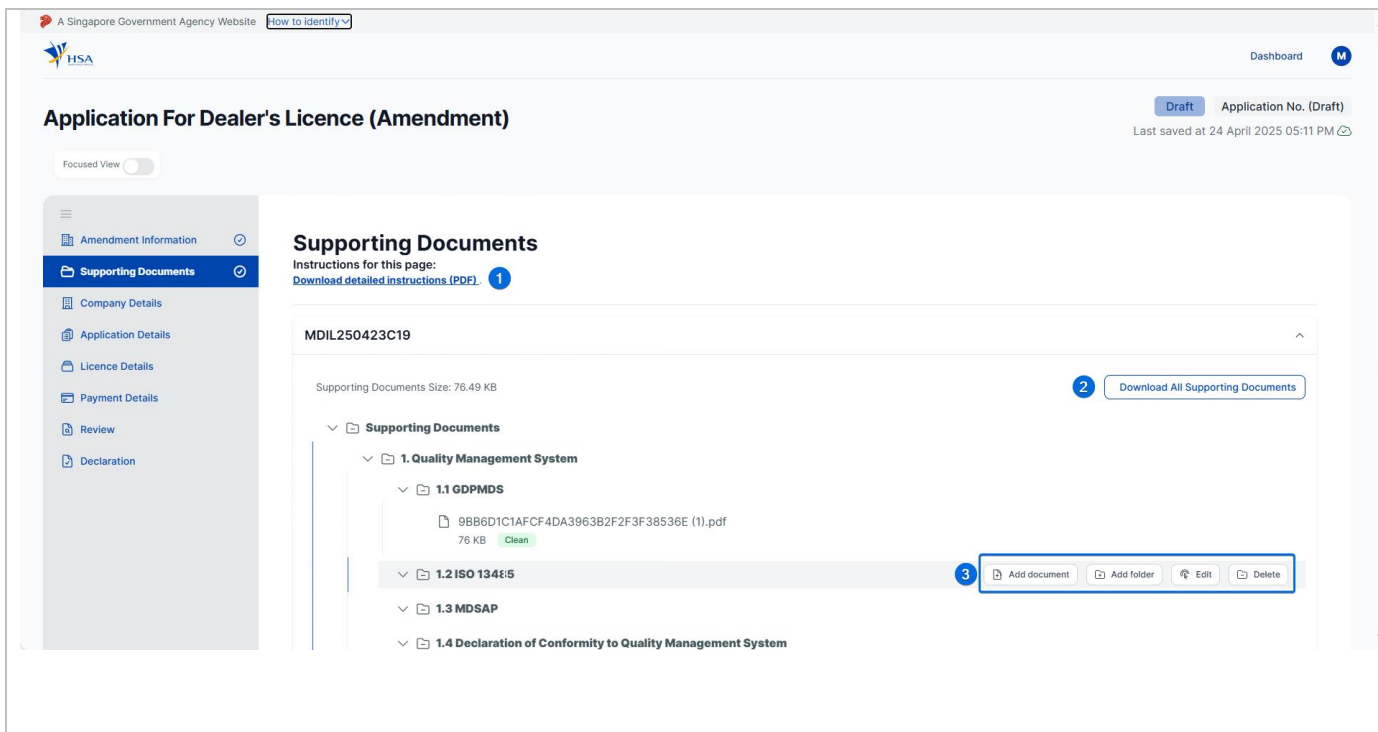
Reset   Filter

	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

Focused View

- 🏢 Amendment Information ⊘
- 📁 Supporting Documents ⊘
- 📋 Company Details
- 📄 Application Details
- 🗂 Licence Details
- 💳 Payment Details
- 📄 Review
- 📄 Declaration

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

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

Subsections

Company Information ⊘
Company Address ⊘
Contact Information ⊘

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
① **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-	

[< 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.

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

5.2.2.6. Licence Details

Responsible Person(s) for Licence(s)

1) Applicants can do the following:
   a. Input responsible person(s) for the selected dealer's activity during the application creation process by clicking on '+ Add Responsible Person'
   b. Edit existing responsible person(s) by clicking on 'Edit'
   c. 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

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:
   a. Input outsourced provider for the selected dealer's activity during the application creation process by clicking on "Add Outsourced provider".
   b. Edit existing outsourced provider by clicking "Edit"
   c. Delete existing outsourced provider by clicking "Delete"

5.2.2.7. Payment Details

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.

5.2.2.8. Review

Application For Dealer's Licence (Amendment) [Draft] Application No. (Draft) Last saved at 25 March 2025 02:54 PM	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.

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 Typ
Jurong	In-vitro Diagnostic Device (IVD), General Medical Device	Class A/B/C/D	1, Ave 1, #01-01, Singapore 123456	,

Existing Site

Previous values | Current Value

Site Details 1

Site Name	Franecki LLC
Site Address	280B, SENGKANG EAST AVENUE, COMPASSVALE ANCILLA, Singapore 542280
Device Type(s)	General Medical Device, In-vitro Diagnostic Device (IVD)
Risk Classification	Class A

Site Details 1

Site Name	Franecki Edit LLC 01
Site Address	280B, SENGKANG EAST AVENUE, COMPASSVALE ANCILLA, Singapore 542280
Device Type(s)	General Medical Device, In-vitro Diagnostic Device (IVD)
Risk Classification	Class A

Licence Information

Licence Type	Licence Number
(MDIL250505W03) Importer	MDIL250505W03
(MDML250505C05) Manufacturer	MDML250505C05
(MDWL250505L04) Wholesaler	MDWL250505L04

Licence Information

Licence Type	Licence Number
(MDIL250505W03) Importer	MDIL250505W03
(MDML250505C05) Manufacturer	MDML250505C05
(MDWL250505L04) Wholesaler	MDWL250505L04

Certification(s)

Licence Type	Licence Number	Type of Quality Management System (QMS) Certification	Certification Body	Expiry Date	Scope of Quality Management System
(MDIL250505W03) Importer	MDIL250505W03	Declaration of Conformity to Quality Management System (QMS): GDPMDS	N/A	N/A	N/A
(MDML250505C05) Manufacturer	MDML250505C05	Declaration of Conformity to Quality Management System: ISO13485	N/A	N/A	N/A
(MDWL250505L04) Wholesaler	MDWL250505L04	Declaration for Exemption from GDPMDS Certification	N/A	N/A	N/A

Certification(s)

Licence Type	Licence Number	Type of Quality Management System (QMS) Certification	Certification Body	Expiry Date	Scope of Quality Management System
(MDIL250505W03) Importer	MDIL250505W03	Declaration of Conformity to Quality Management System (QMS): GDPMDS	N/A	N/A	N/A
(MDIL250505W03) Importer	MDIL250505W03	Declaration of Conformity to Quality Management System: ISO13485	N/A	N/A	N/A
(MDML250505C05) Manufacturer	MDML250505C05	Declaration of Conformity to Quality Management System: ISO13485	N/A	N/A	N/A
(MDWL250505L04) Wholesaler	MDWL250505L04	Declaration for Exemption from GDPMDS Certification	N/A	N/A	N/A
(MDWL250505L04) Wholesaler	MDWL250505L04	Declaration of Conformity to Quality Management System (QMS): GDPMDS	N/A	N/A	N/A

5.2.2.9. Declaration

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

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.

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 'Renewal' from the 'Application Type' dropdown list.

4) Applicants would be able to create the application.

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

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

1) Applicants would be able to 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.

5.2.3.4. Review

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

5.2.3.5. Declaration

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.

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

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

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".

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

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

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
9BB6D1C1AFCF4DA3963B2F2F3F38536E.pdf	

[Back] [Declaration >]

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

5.2.4.5. Declaration

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.

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

6) Applicants can create the application.

5.3.1.2. 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

5.3.1.3. Company 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. |

5.3.1.4. 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'.

5.3.1.5. Sites

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

1) 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:
   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 add and edit the device's information of the product
3) The applicant can add the device's models

Add Device

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

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 Inf

Product Owne

Please provide product o

Product Owner (Lo

Product Owner Na

Address

Device Listing

No Data Avai

< 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]
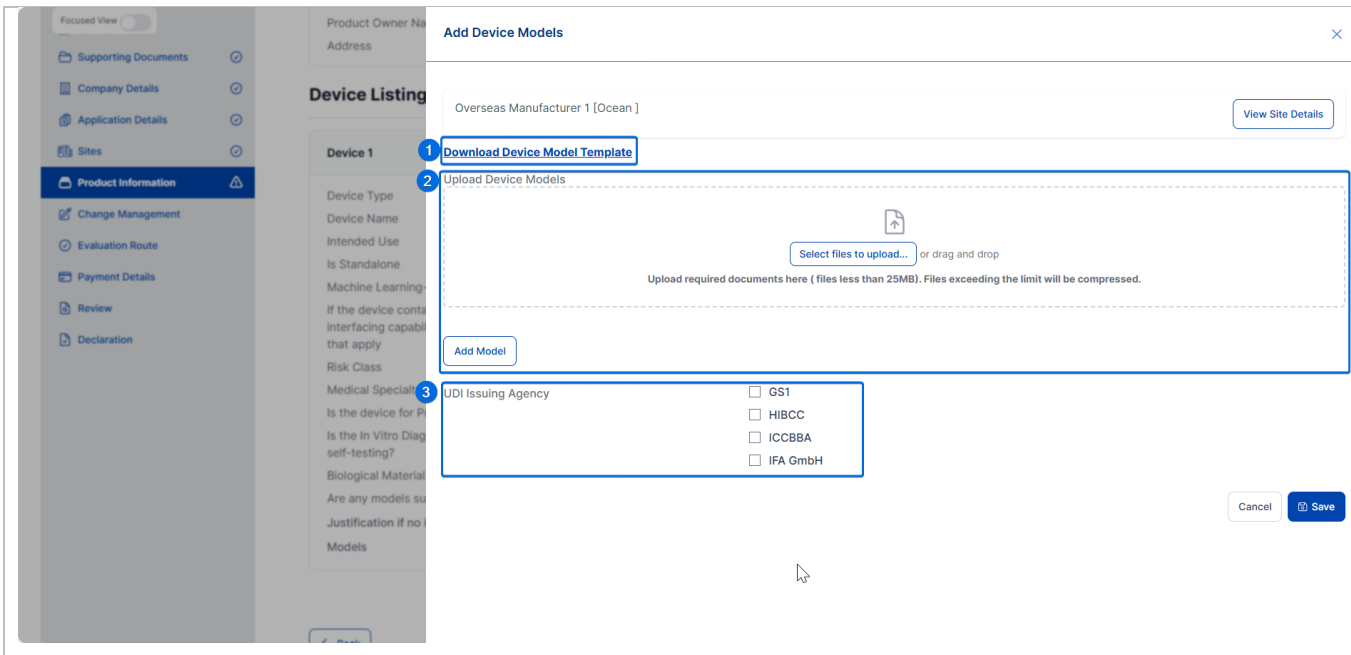
Local Authorised Importer Name

[_____]

[+ Add Dealer]

Justification if no importer assigned *

[_____]

[Cancel] [💾 Save]

Add Device Model

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

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

5.3.1.8. Evaluation Route

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

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

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

5.3.1.11. Declaration

	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

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

4) Applicants can create the application.

5.3.2.2. Product List

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 select the products to retain by checking the respective product's checkbox.

5.3.2.3. Payment Details

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

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

5.3.2.5. Declaration

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

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

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 Devie 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

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).
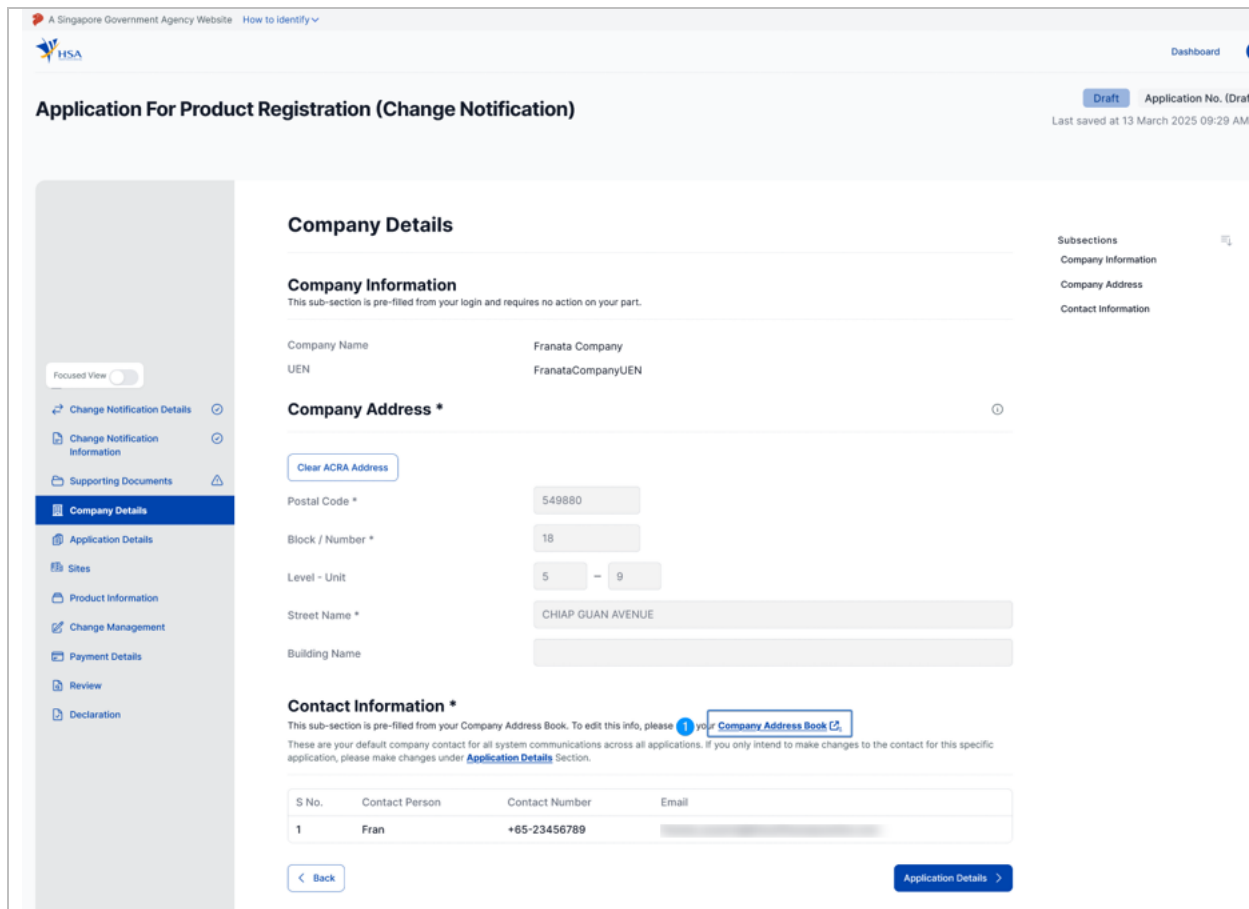
5.3.3.4. Supporting Documents

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

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

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

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.

5.3.3.9. Change Management

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

5.3.3.10. Payment Details

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

![Review page screenshot] 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 **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.

5.3.3.12. Declaration

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

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

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

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

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.

5.3.4.5. Company 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. |

5.3.4.6. 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'.

5.3.4.7. Payment Details

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.

5.3.4.8. Review

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

5.3.4.9. Declaration
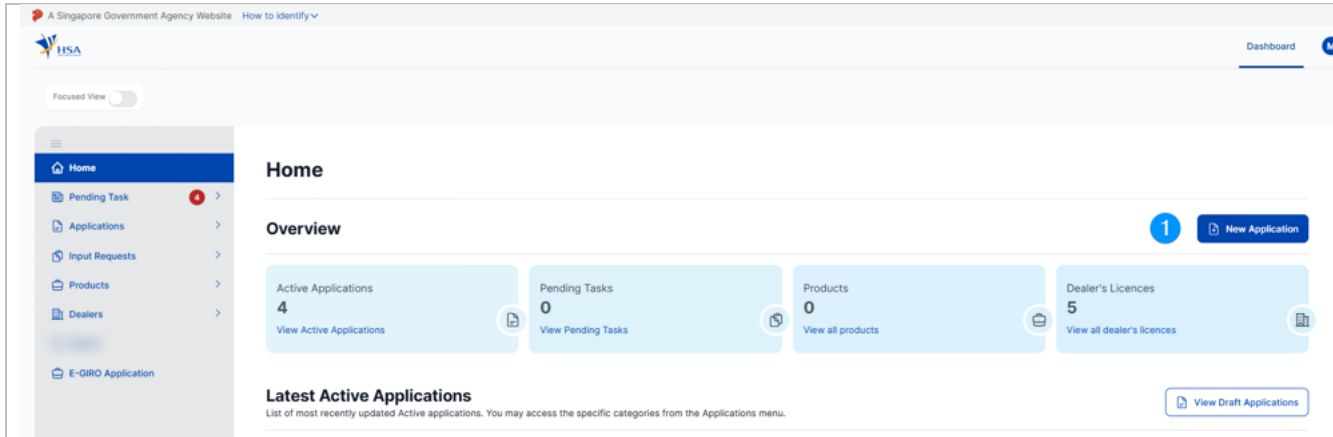

1) Applicants need to acknowledge and confirm the declaration
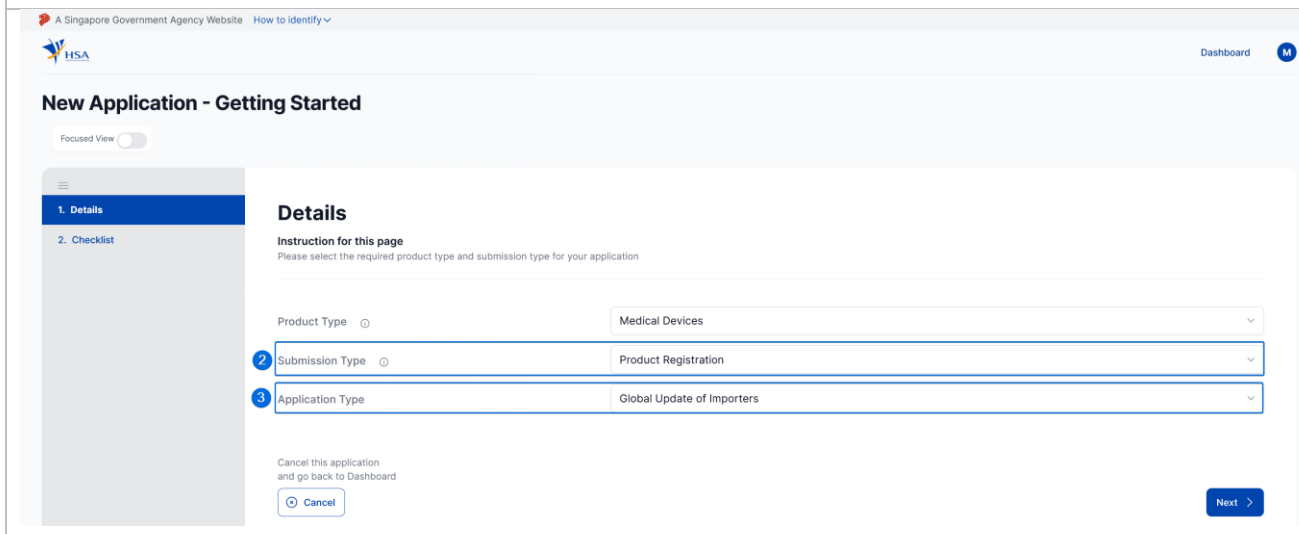2) Applicants can submit the application

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.

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

2) Applicants would be able to select 'Product Registration' from the 'Submission Type' dropdown list.

3) Applicants would be able to select 'Fulfilment Of Approval Conditions' from the 'Application Type' dropdown list.

5.3.5.2. Getting Started- Review

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.**'

4) Applicants would be able to create the application.

Request Extension

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

📄 Review

📄 Declaration

Review

❹

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.

Request Extension

Focused View

1. Details

Review

Declaration

Declaration

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   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

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

5.3.5.4. Review

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

5.3.5.5. Declaration

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

1) Applicants would be able to create a new application by clicking on the 'New Application' 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 'Global Update of Importers' from the 'Application Type' dropdown list

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	Global Update of Importers

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 assign or update your previous assignment of an Importer to your registered products.

Submission Instructions

Please ensure that you assign the correct Importer to the relevant product(s). The assigned Importer will then receive a notification to accept or reject your assignment.

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

4 Create Application

4) Applicants can create the application.

5.3.6.2. Company 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

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

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

5.3.6.6. Declaration

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

5.3.6.7. Tagged Importer Company's Actions

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.

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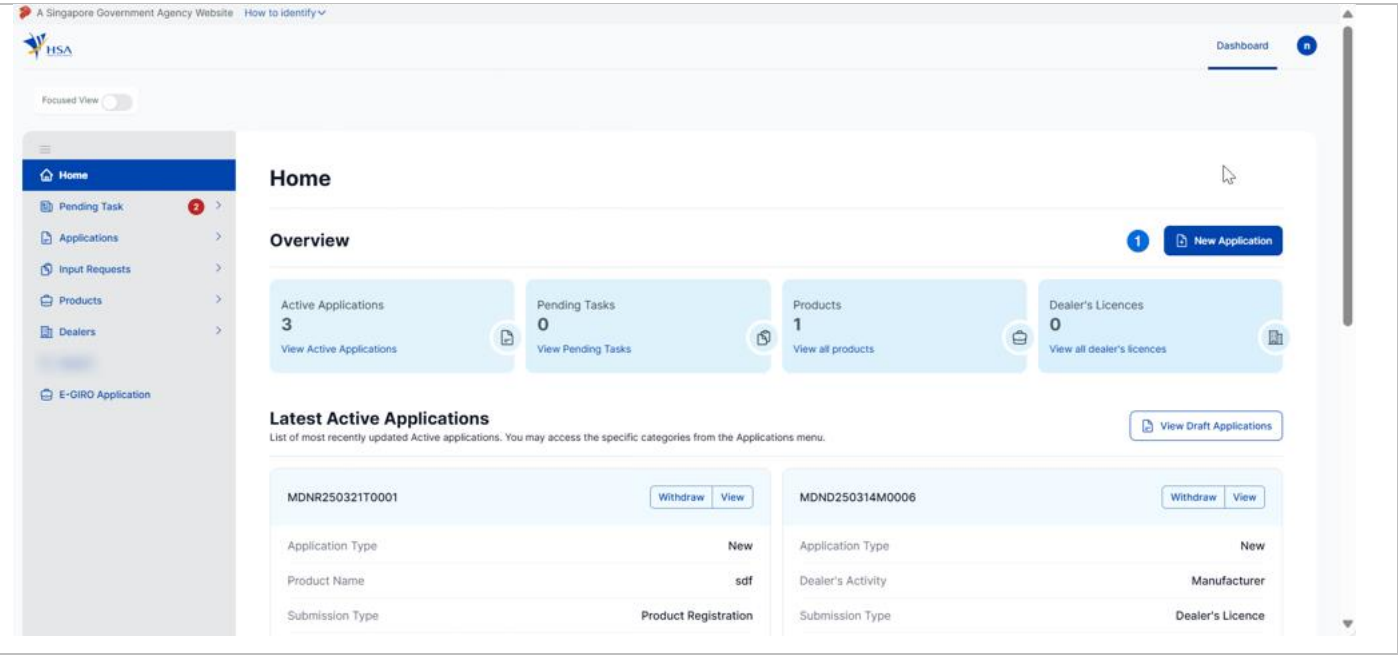
1) Applicants would be able to create a new application by clicking on the 'New Application' button.

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.

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

‹ Back

5 Create Application

5) Applicants can create the application.

5.4.1.2. Company 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.

5.4.1.3. 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

Subsections

Overseas Manufacturers

Local Manufacturers

Overseas Manufacturers

Overseas Manufacturer 1		Edit	Delete
Overseas Manufacturer Name	Ocean		
Overseas Manufacturer Address	415 Thomas Street, Algeria		

+ Add Overseas Manufacturer 2

Local Manufacturers

ⓘ No Data Available

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. 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.

5.4.1.5. Product Information

Product Information
1) 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
2) Applicants need to declare if there are any sterile Medical Devices being notified.

Device Listing
3) 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

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

5.4.1.7. Declaration

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

5.4.2. Amendment

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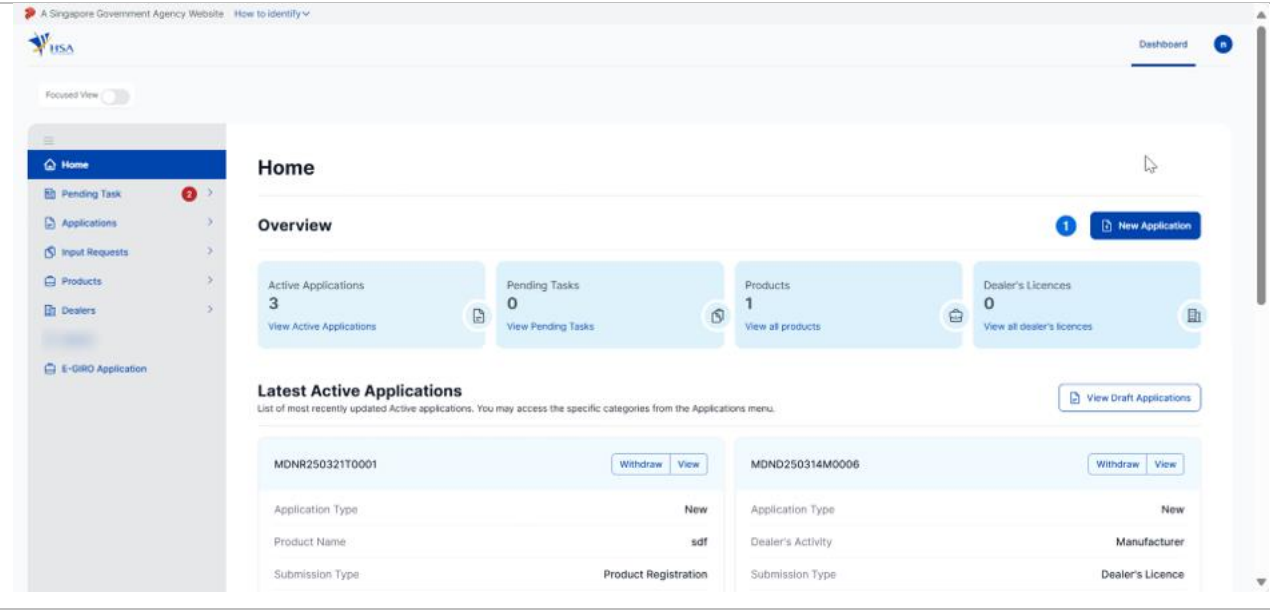
1) Applicants would be able to create a new application by clicking on the 'New Application' button.

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.

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

⑤ Create Application 🗋

---

5) Applicants can create the application.

5.4.2.2. Device Selection

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

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.

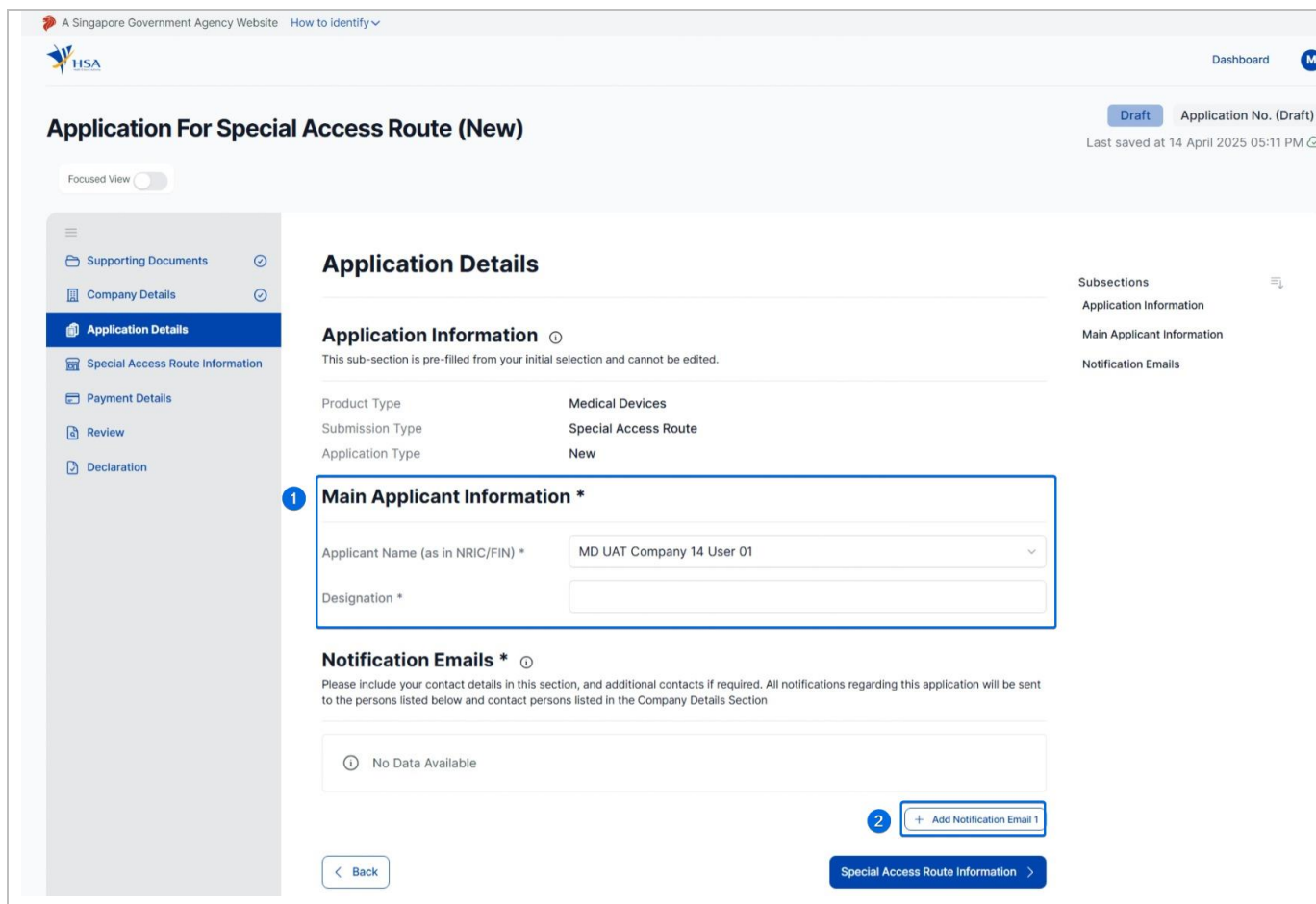*Do note that changing the address field in the application form **does not change/update any address in ACRA.**

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

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

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

Product Information

1) 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

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

Device Listing

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

5.4.2.7. Review

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

5.4.2.8. Declaration

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

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.

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

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   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.

View Checklist

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
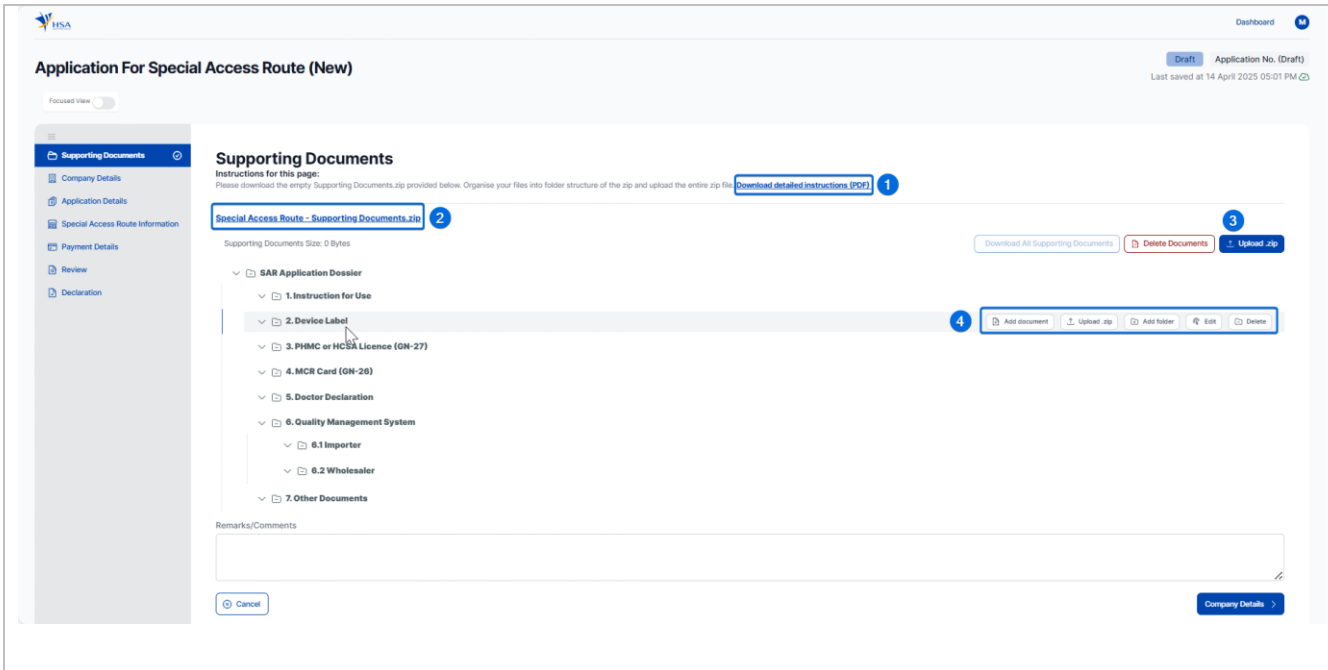
④ Create Application
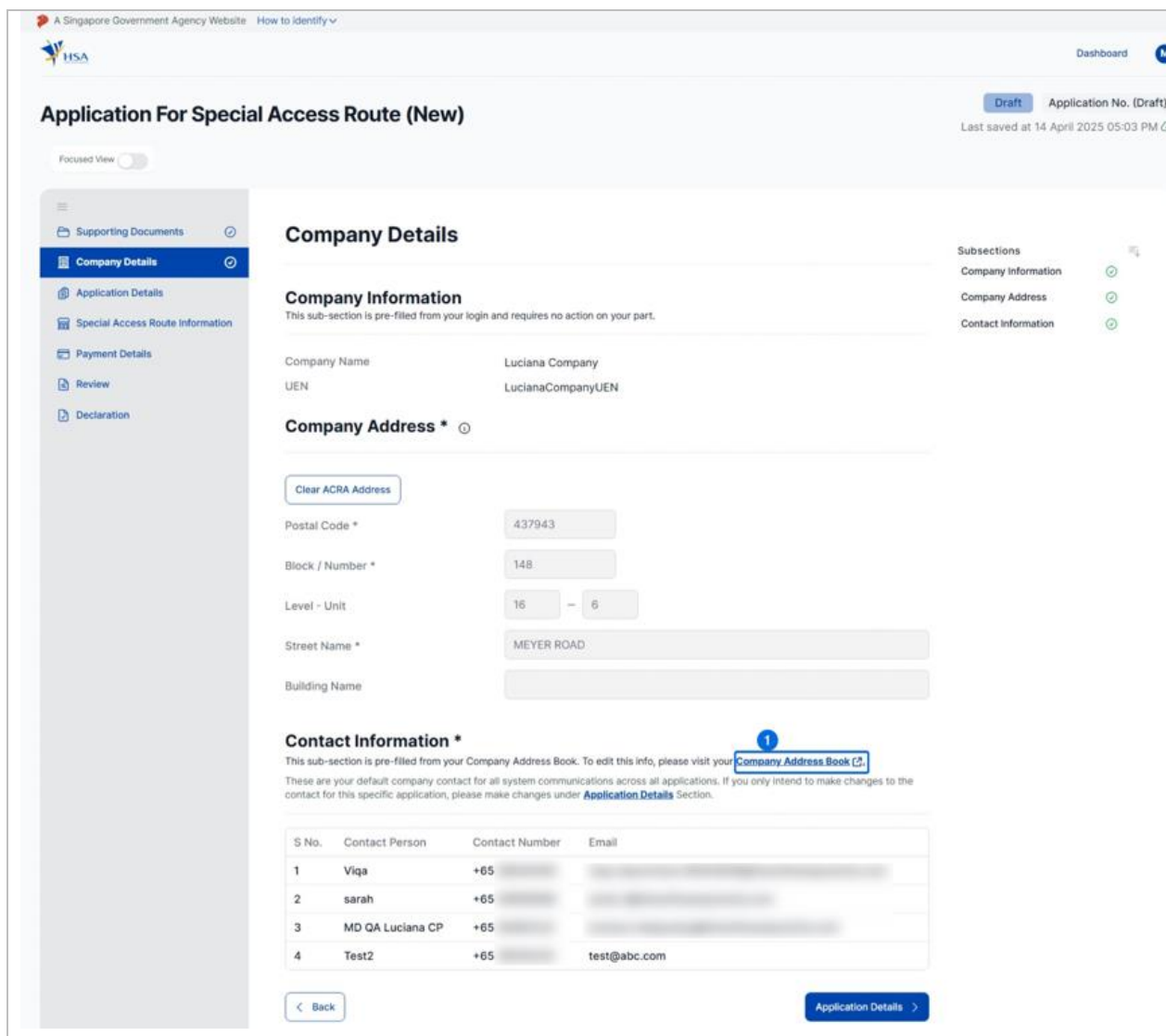
4) Applicants can create the application.

5.5.1.2. 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

5.5.1.3. Company 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.

5.5.1.4. 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

Purpose of Importation

1) Applicants need to select the purpose of importation.

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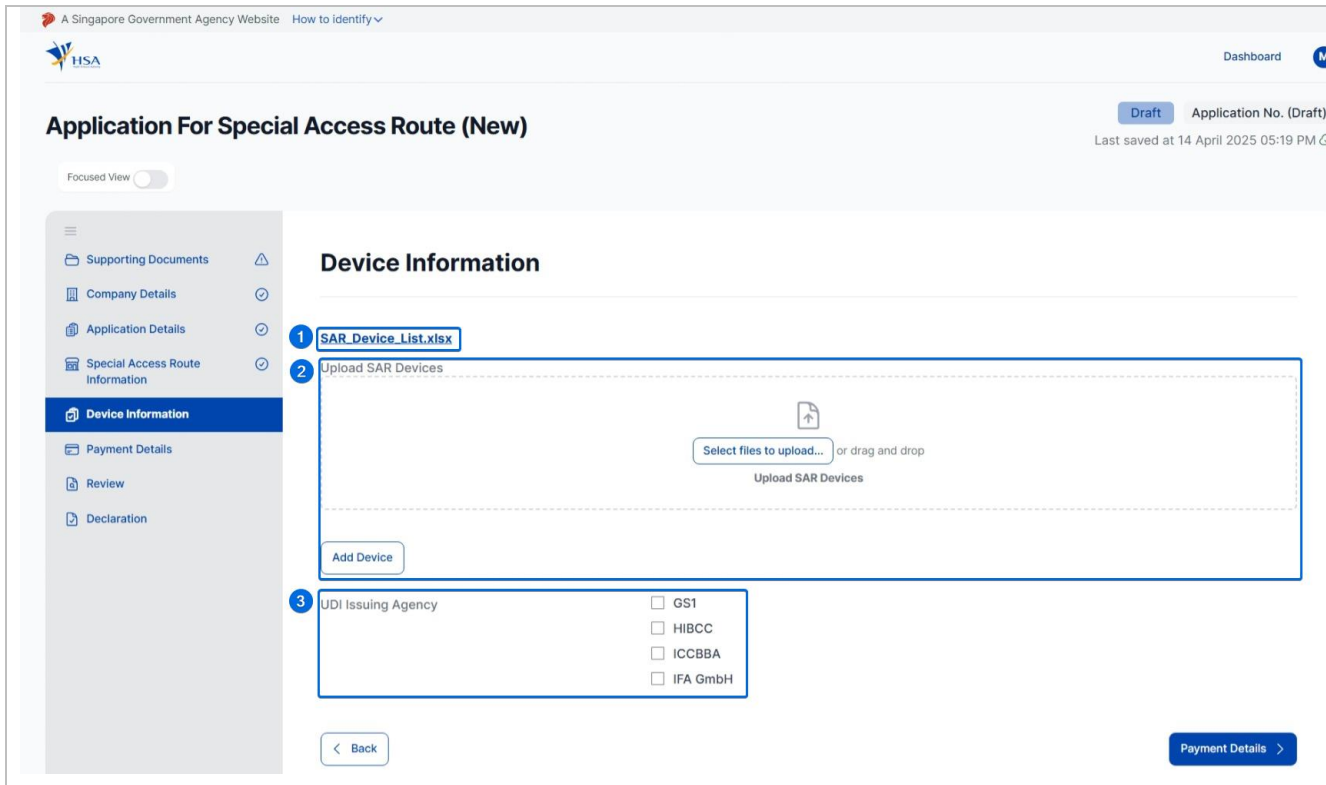
2) Applicants need to fill in the relevant licence information.

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

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.

5.5.1.8. Review

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

5.5.1.9. Declaration

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

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.

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

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

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

1) Applicants need to select the appropriate declaration

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.

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.

5.5.2.4. Review

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

5.5.2.5. Declaration

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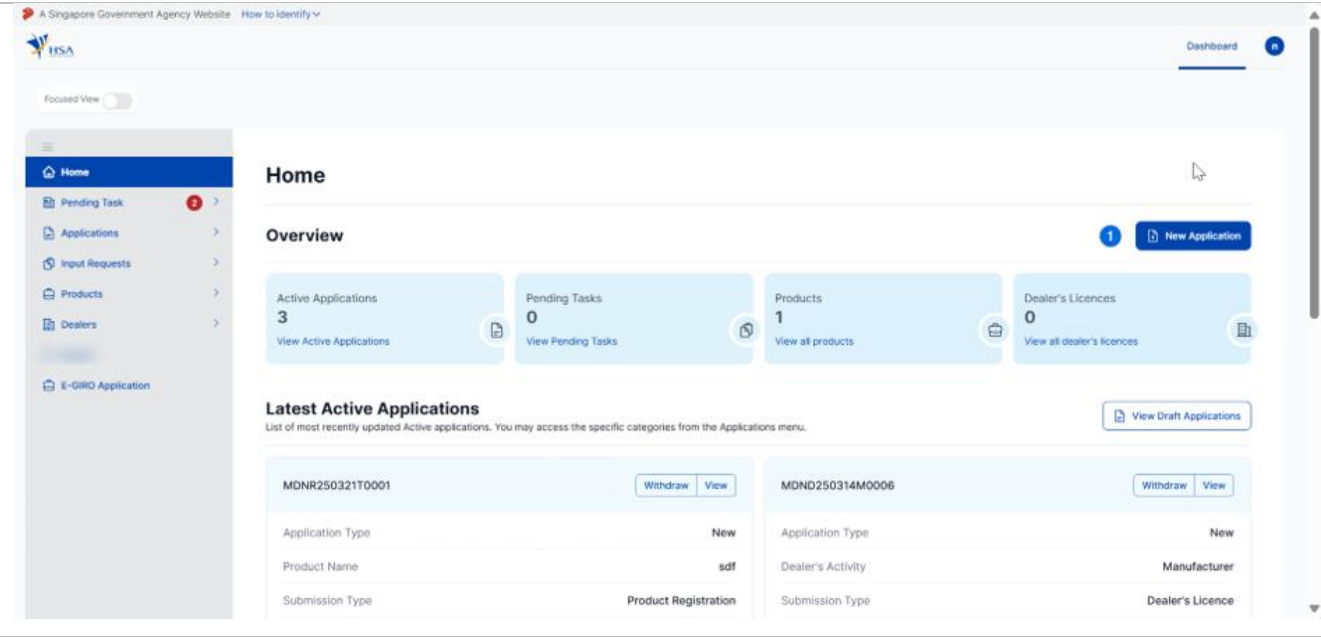
1) Applicants would be able to create a new application by clicking on the "**New Application**" button.

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

2) Applicants would be able to select 'Special Access Rute' from the 'Submission Type' dropdown list.

3) Applicants would be able to select 'Fulfilment Of Approval Conditions' from the 'Application Type' dropdown list.

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.**'

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

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

< Back

7) Create Application

---

7) Applicants would be able to create the application.

5.5.3.2. Fulfilment of Approval Conditions

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

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

5.5.3.4. Declaration

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.

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.

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

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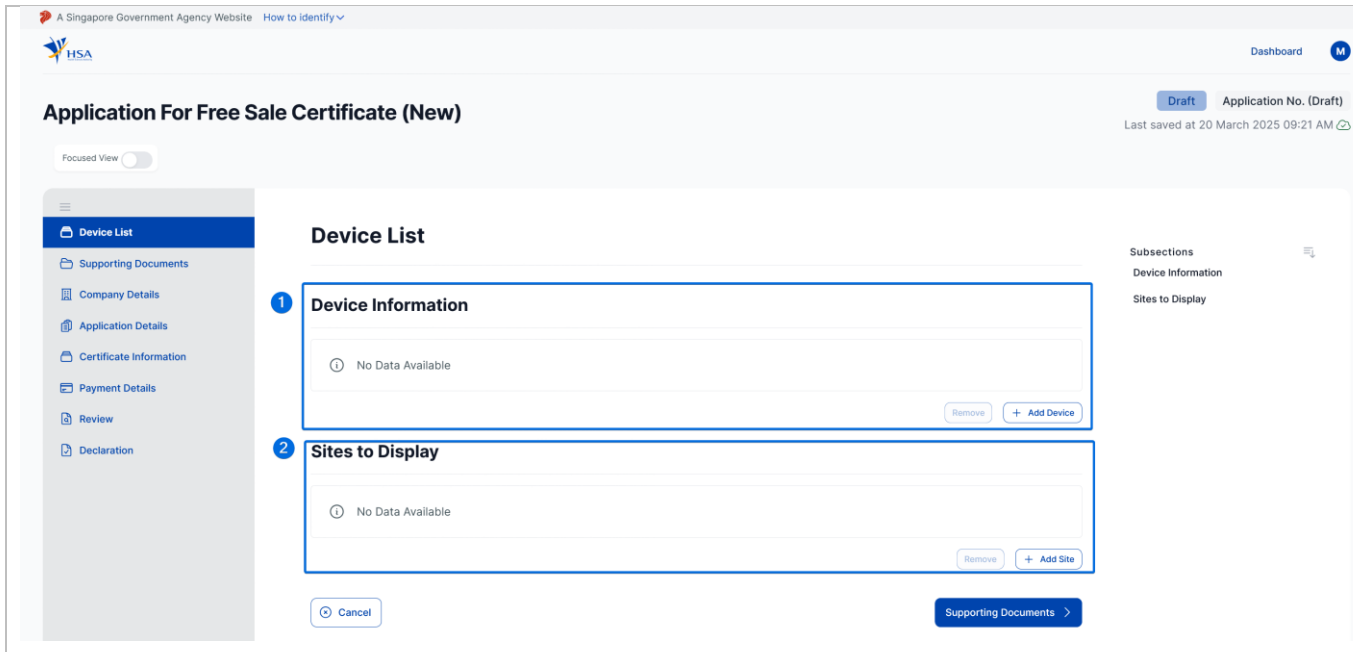
‹ Back

6 Create Application 📄

6) Applicants can create the application.

5.6.2. Device List

Class A

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'.

3) Applicants need to fill the device name
4) 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) Applicants can select the device by checking the box.
6) Applicants can mark the device as primary to indicate the intended use for the list of models.

Class B, C, D

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'.

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

Device Information

1 item(s) selected

	Approved Product Number	Models	Product Name	Intended Use	Action
☑	MDPR250423Z0002	5 0 selected	Hotta Syla	no	Delete

Remove   + Add Device

Manufacturing Sites to Display

ⓘ No Data Available

Remove   + Add Site

⊗ Cancel   Supporting Documents >
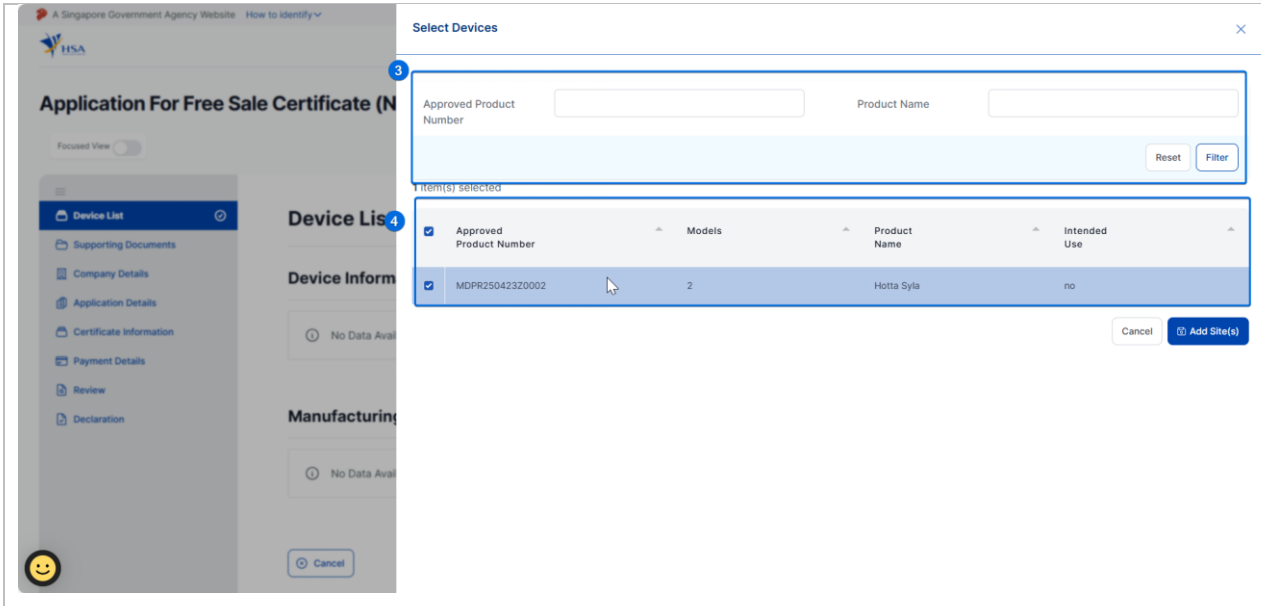
Subsections

Device Information

Manufacturing Sites to Display
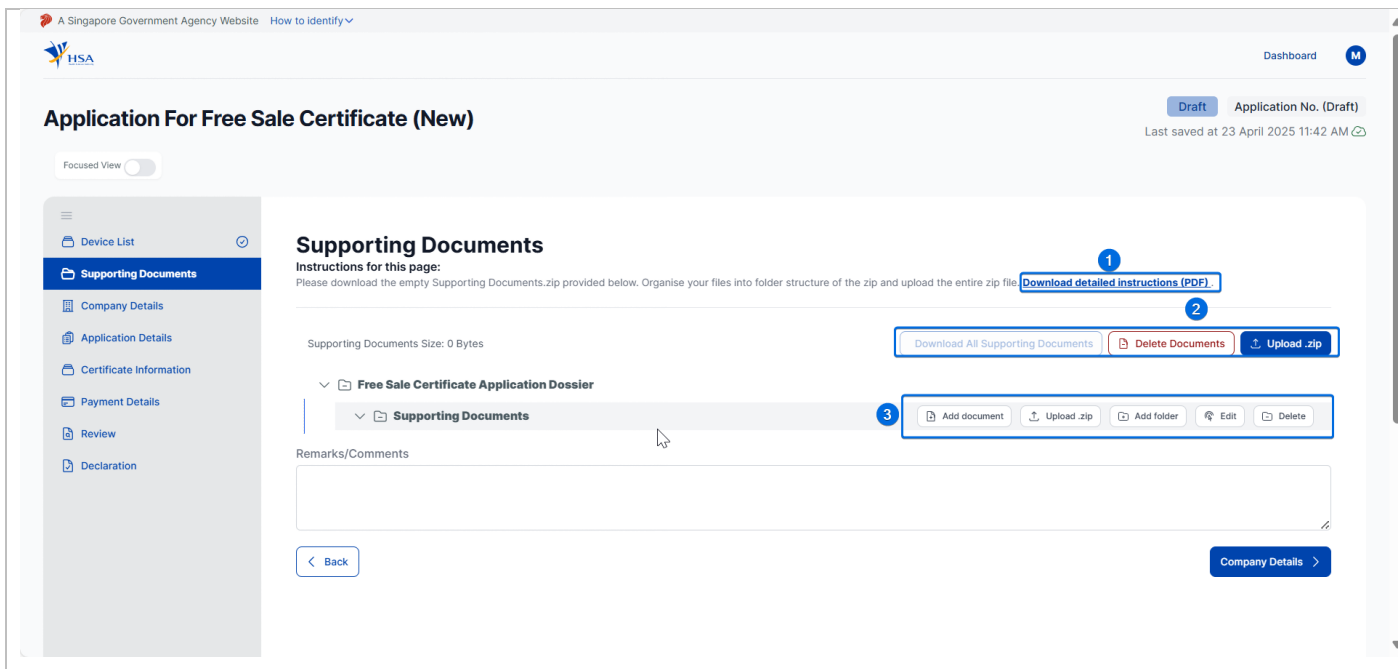
5) Applicants can select the model

6) Applicants can select the models by checking the box

5.6.3. Supporting Documents

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

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

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

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

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

5.6.9. Declaration

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

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

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

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

4) Applicants can create the application.

5.7.2. Supporting Documents

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

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

	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

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

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

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

5.7.8. Declaration

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

5.8. Public Portal

Public portal is accessible by all public users and login is not required.

5.8.1. Class A

URL:
https://share.hsa.gov.sg/medics/PublcListing/ClassA

This page will show the list of all active Class A products registered in SHARE, allowing users to search for specific products.

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

	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

URL:
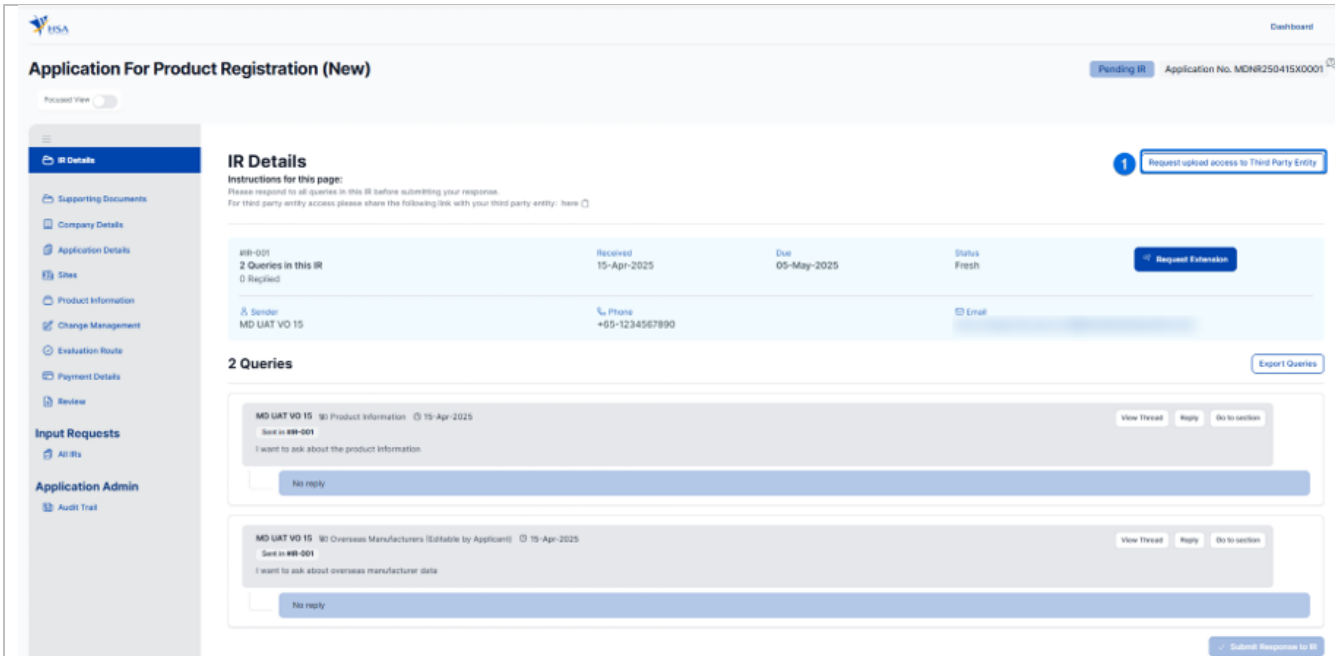https://share.hsa.gov.sg/medics/PublicListing/DealerLicence

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

<table>
<tr>
<td>

</td>
<td>

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.

</td>
</tr>
</table>

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.
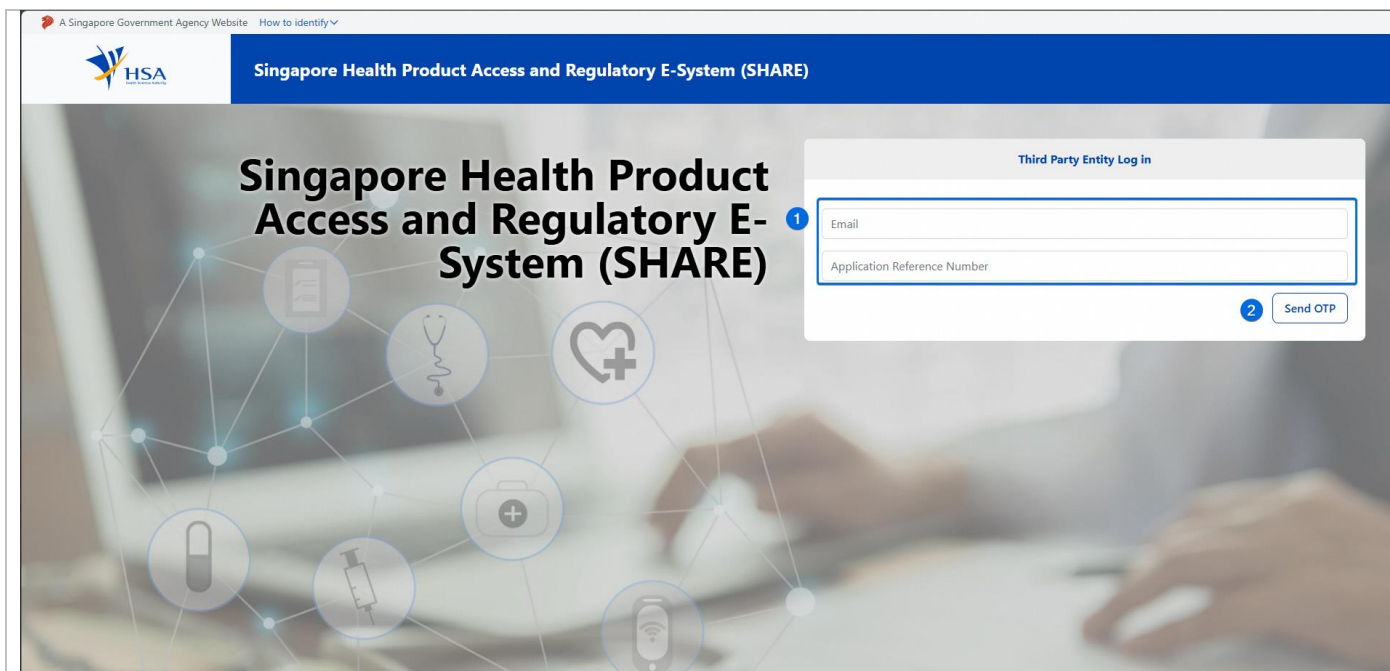
After officer grant the access to the overseas entity.

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

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.

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

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.

1) Overseas entity would be able to click 'Response' button to see the IR Details.

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.

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

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'

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.