Quick Guide to Change Notification for Registered Medical Devices

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

This application process will take approximately 30 minutes.

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

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

Please note that the time stated above excludes time taken for preparatory work in relation to filing the online form (e.g. scanning documents for file attachments.)

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

REFERENCES

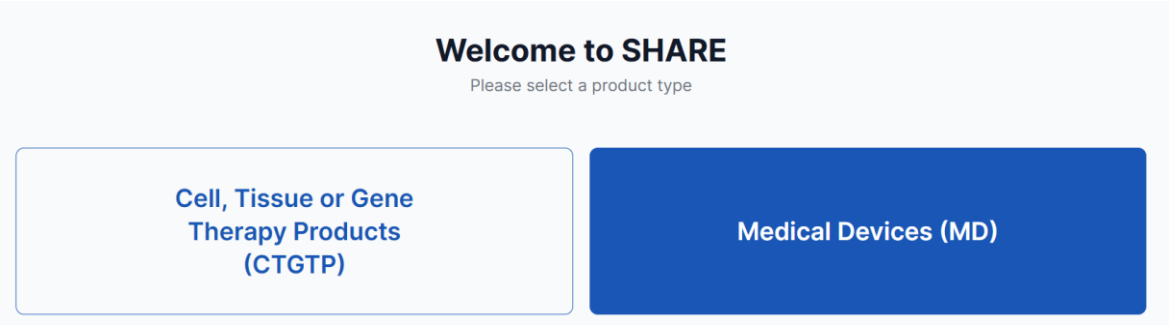
The information in the following guidance document is useful for the application:

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

INSTRUCTIONS

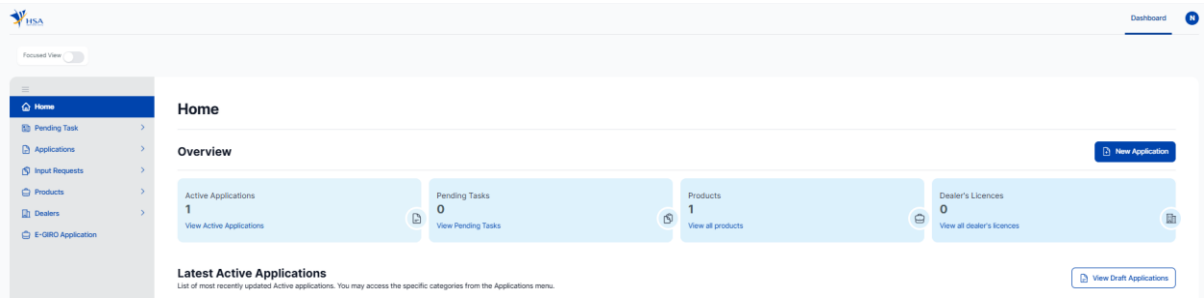
1. Logging into SHARE

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



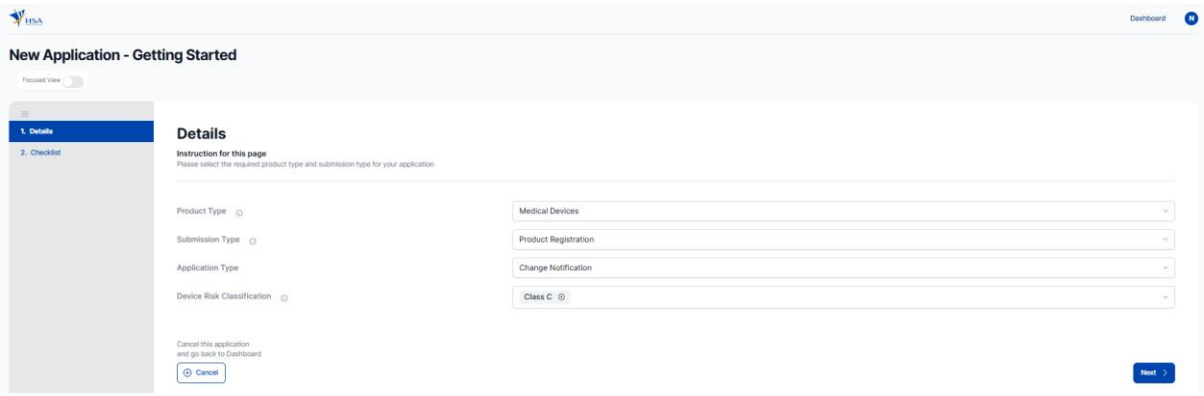
2. Creating a new Product Registration (Change Notification) application

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

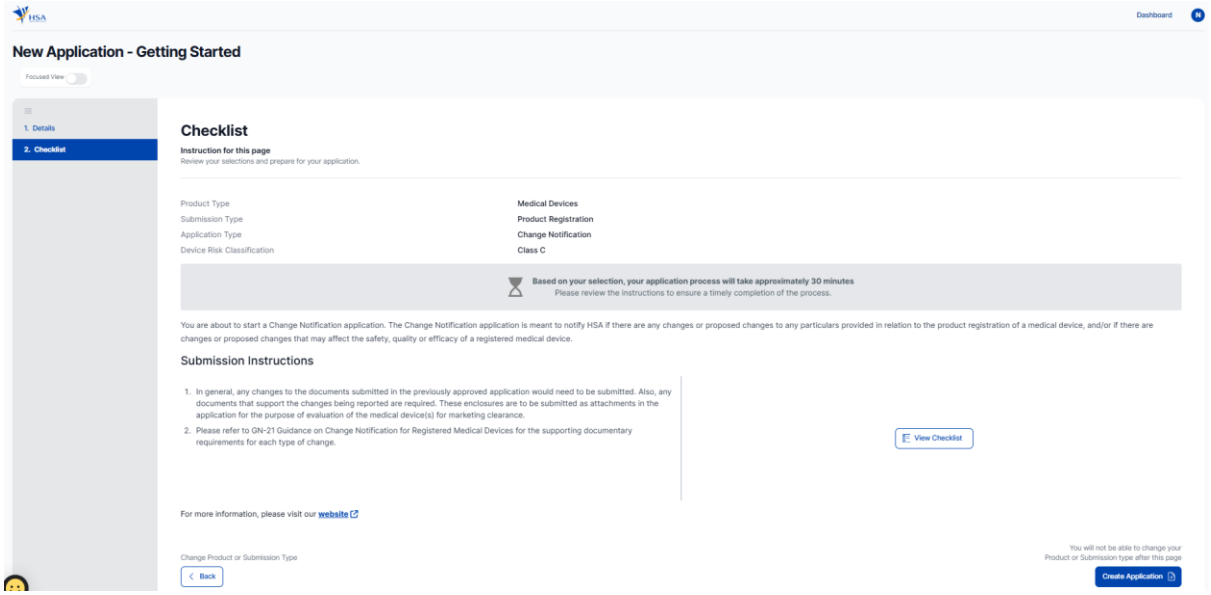


Under Details page, applicants can select

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



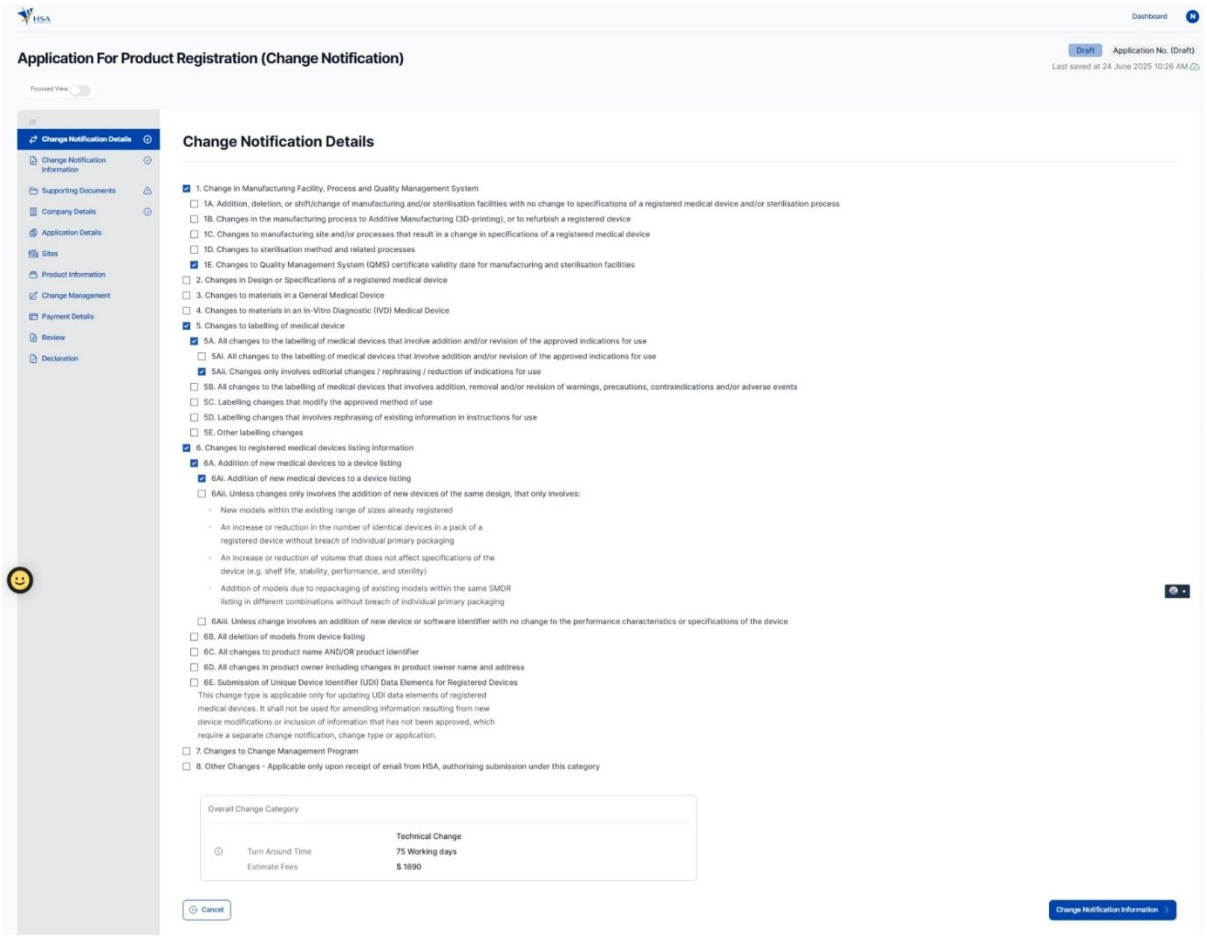
Under Checklist page, applicants can review their selections and Instructions before proceeding to Create Application.



3. Selecting Change Notification Details

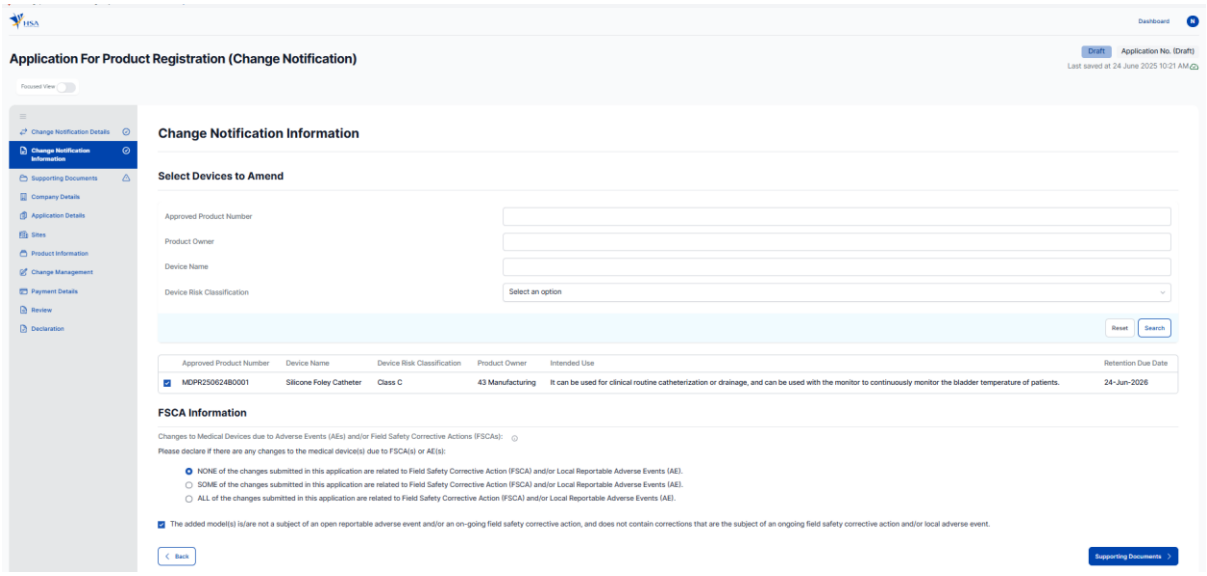
Applicants will need to select the applicable change type(s) for the application.

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



4. Selecting Change Notification Information

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



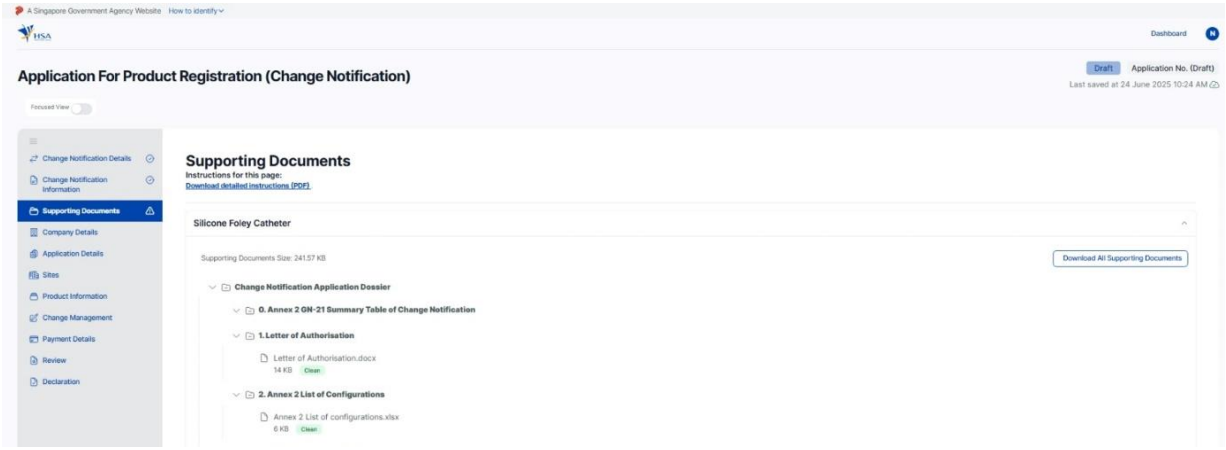
5. Preparing supporting documents

To upload supporting documents, applicants can

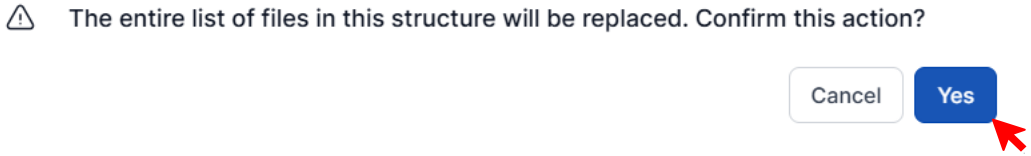
a) Applicants can download the empty Supporting Documents Template zip file
b) Unzip the downloaded zip file
c) Add in supporting documents into the folder
d) Compress (zip) the completed folder to the standard zip format – the extension of the compressed file should be '.zip'. Please do not compress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

6. Uploading files into Supporting Documents

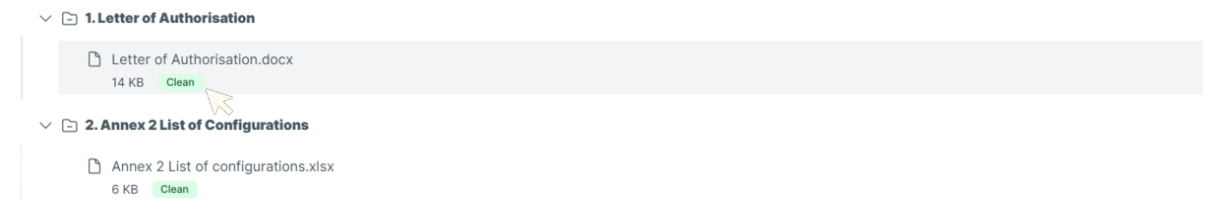
a) Click on the Upload.zip button



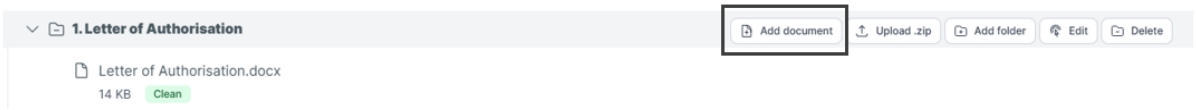
b) Click on the Yes button when confirmation message appears asking to replace the existing file structure.



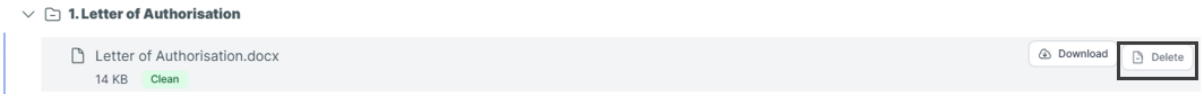
c) The system will start processing the files as indicated by the "Processing" tag. You may continue with the rest of the application while the file(s) is/are processing. After the file(s) is/are processed, the file(s) will be tagged with the "Clean" tag.



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

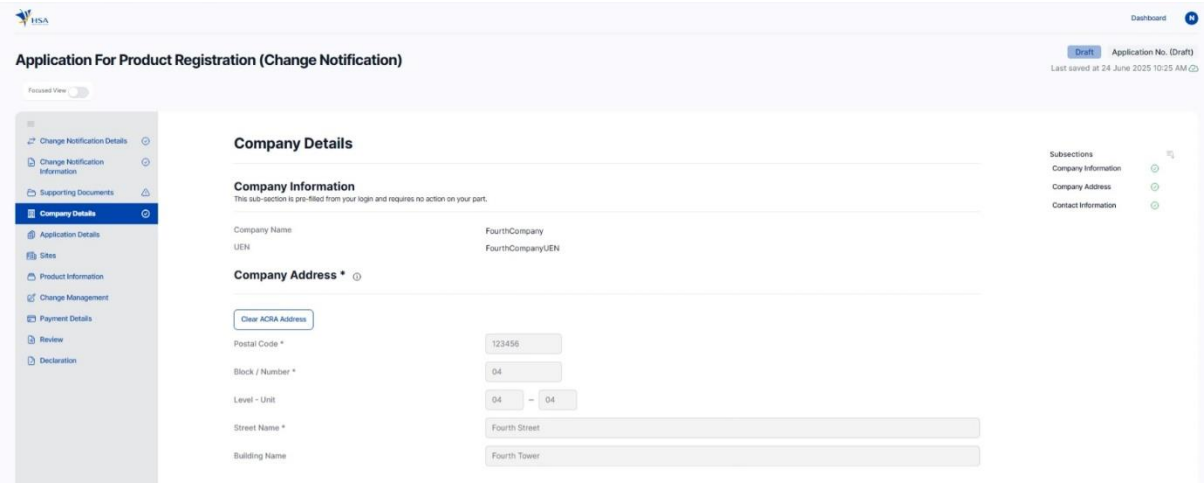


e) To delete a file in the existing folder structure. Hover the mouse over the file and click on the Delete button

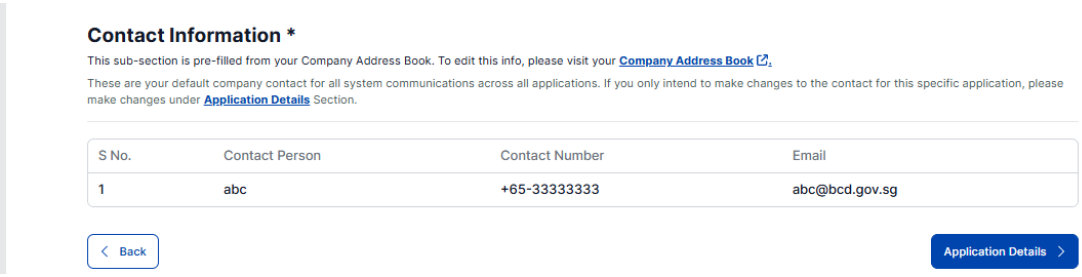


7. Company and application details

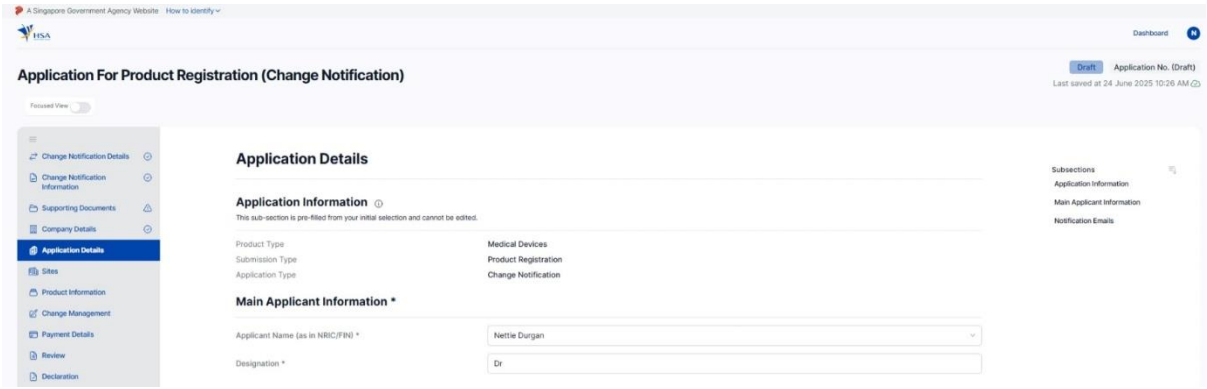
Company details is auto populated based on ACRA information. Applicants may enter the company address if needed.



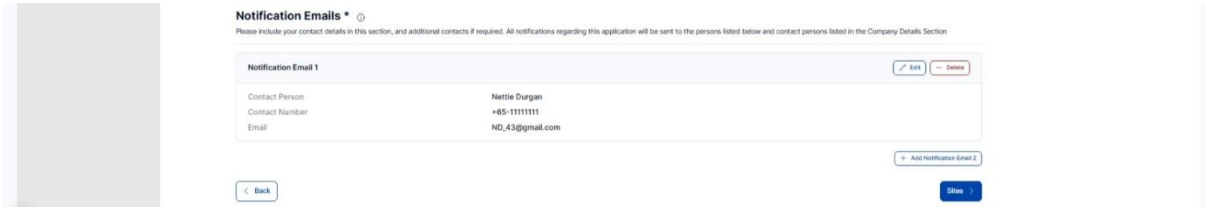
Company Contact Information refers to the company's default contact for all applications within the company. If applicant intend to make changes to the contact for this specific application, please include additional contact details in the 'Notification Emails' field under the Application Details page.



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



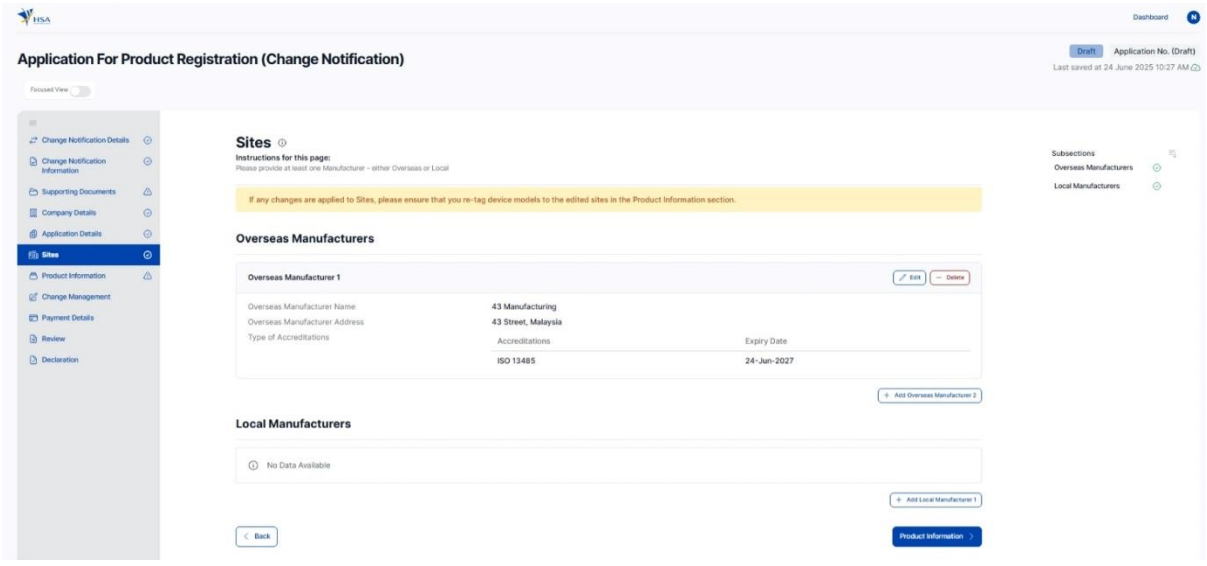
The contact details entered under Notification Emails are specific to the application. Notification Emails can be added to receive notifications exclusively for updates related to the application.



8. Adding or editing manufacturing sites

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

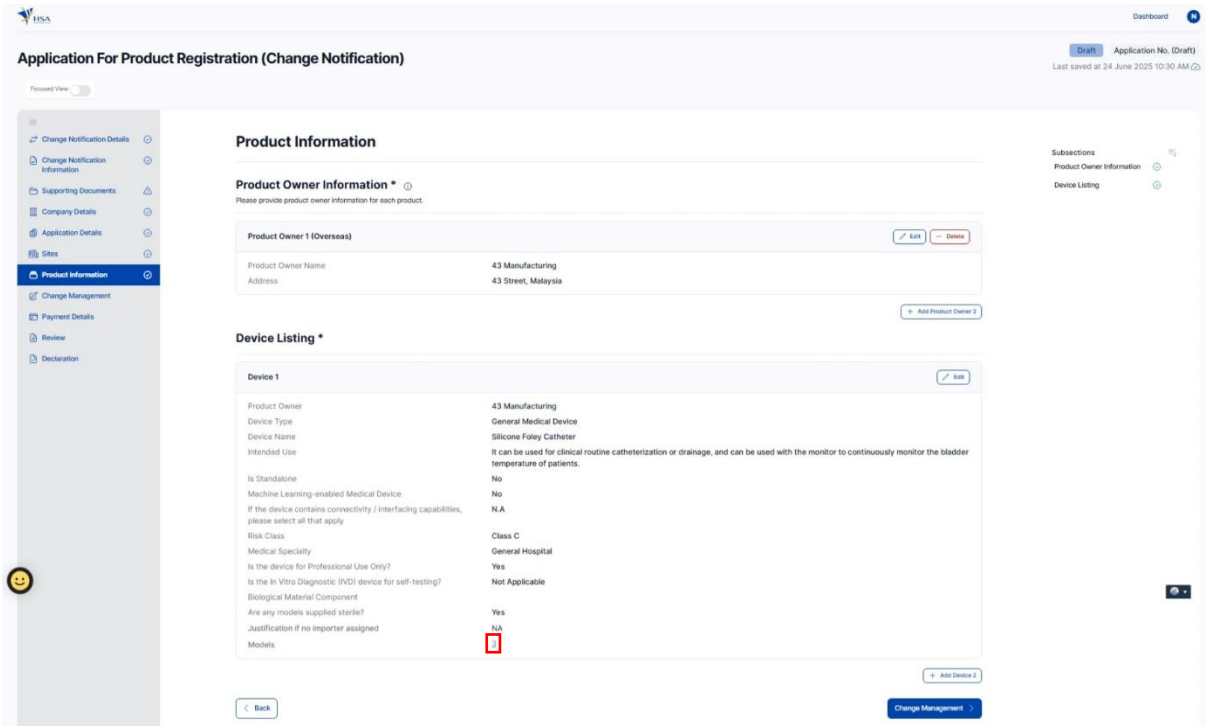
Applicants are to update existing manufacturer and/or sterilisation site details (e.g., ISO 13485 certificate expiry date) by clicking on 'Edit' button.



9. Editing product owner and device listing information

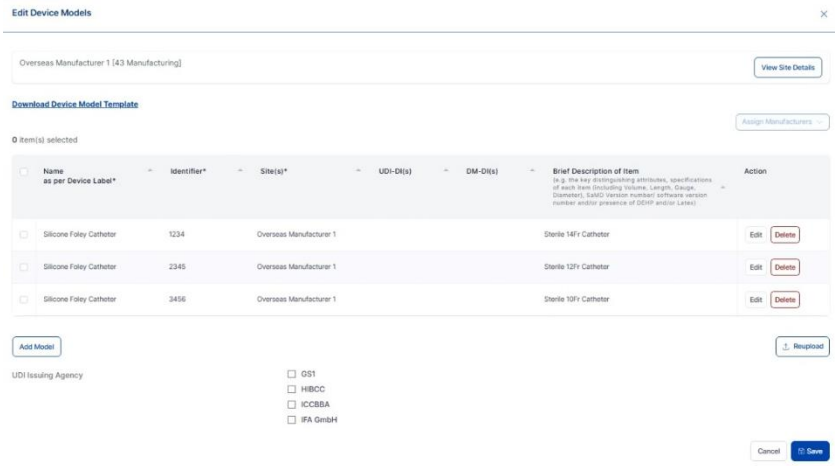
Applicant can edit product owner and device listing information by clicking 'Edit' button of the respective sections.

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



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

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



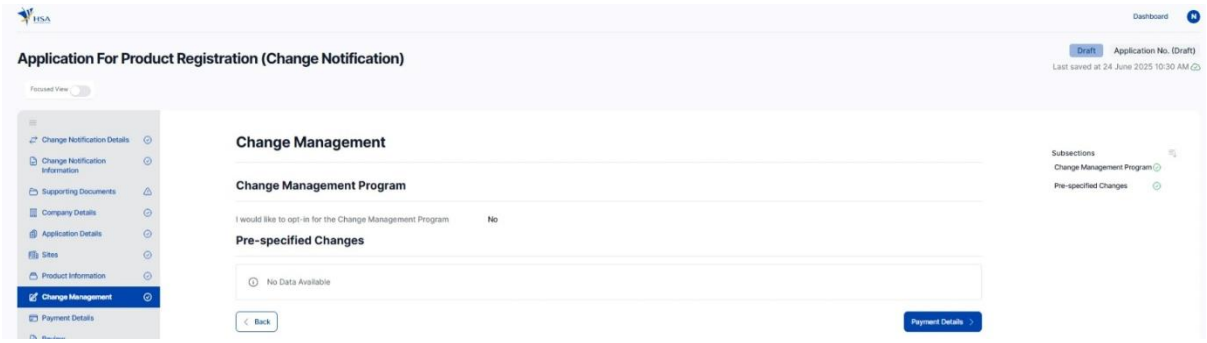
In the "Edit Device Models" section, applicants can add new models by clicking "Add Model" button and/or amend the following information of existing models:

a) Name as per device listing
b) Identifier
c) UDI-DI & DM-DI
d) Brief Description of Item
e) Site(s)

11. Change Management

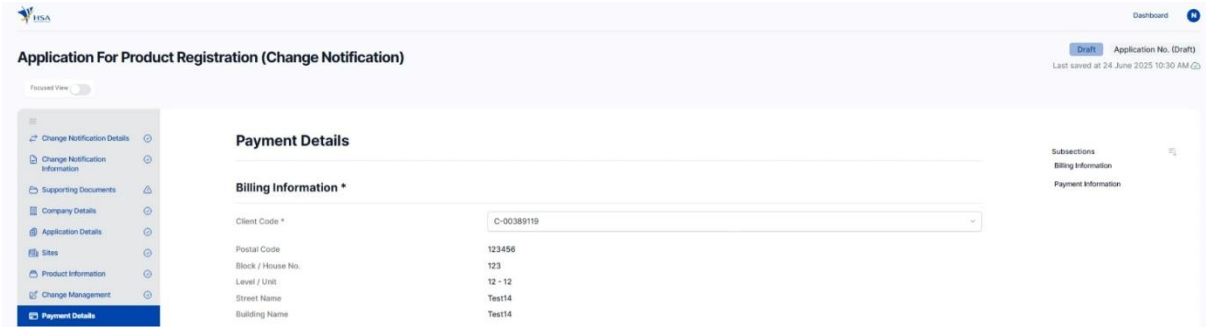
Change Management Program is a voluntary program to facilitate timely implementation of software changes for Software as a Medical Device (SaMD).

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



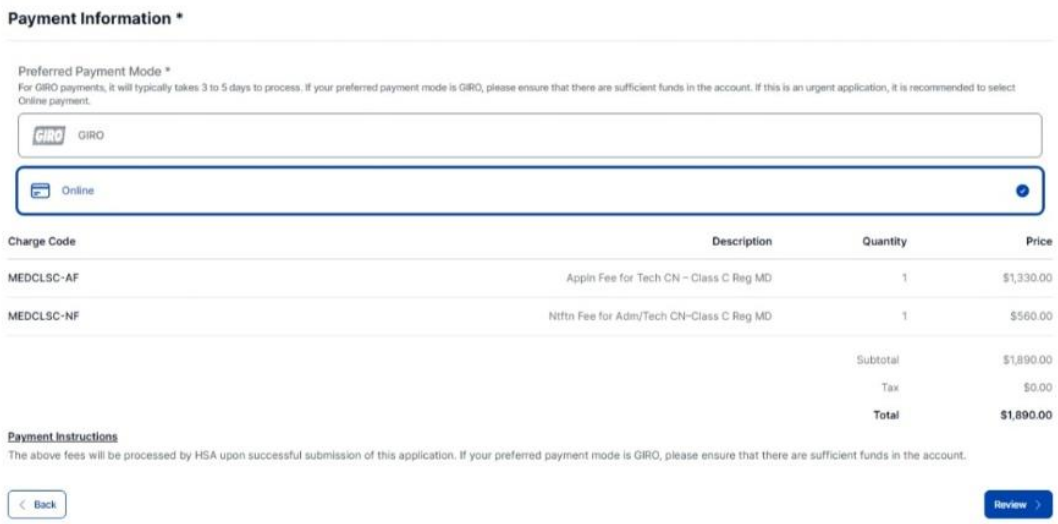
12. Choosing Payment Method

Applicants can select the client code from the dropdown list.



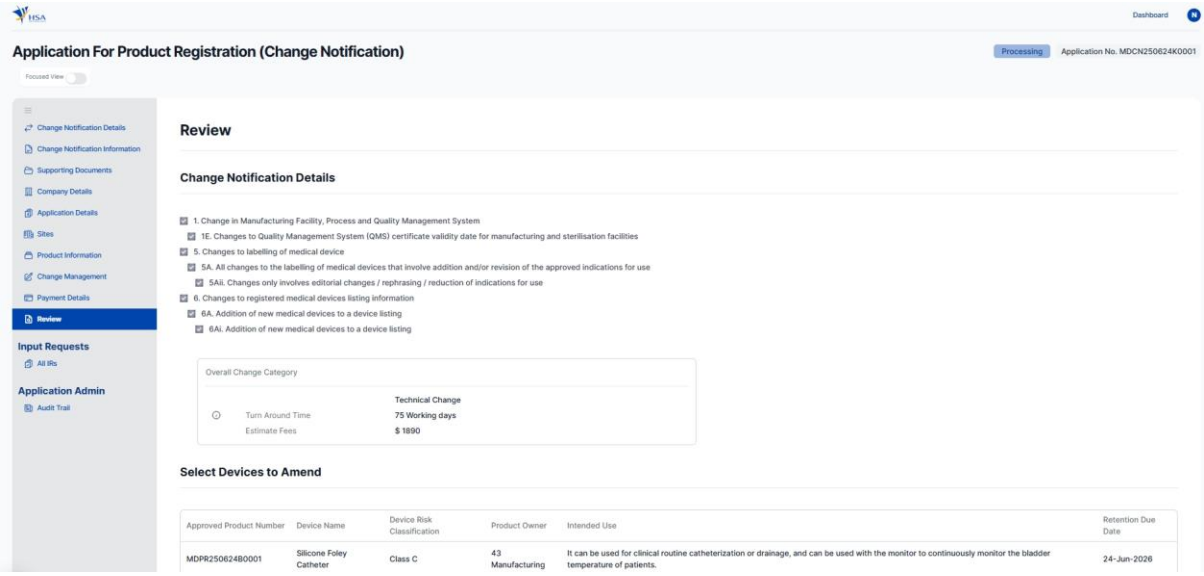
Applicants may choose the preferred payment mode, GIRO or Online payment.

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



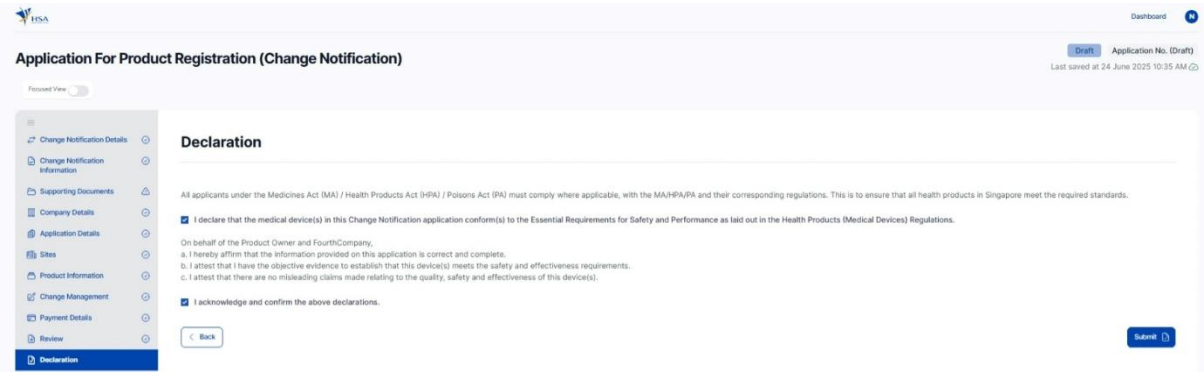
13. Review Application

Applicants to review the summary of all sections filled.



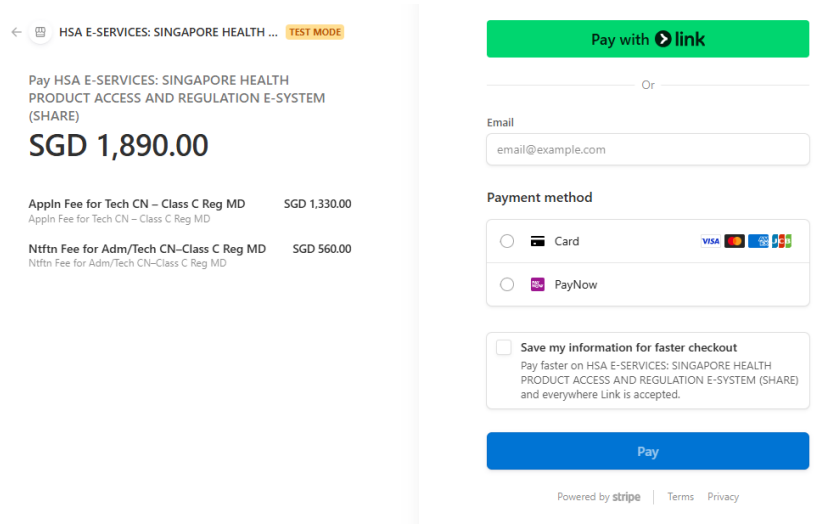
14. Declaration

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

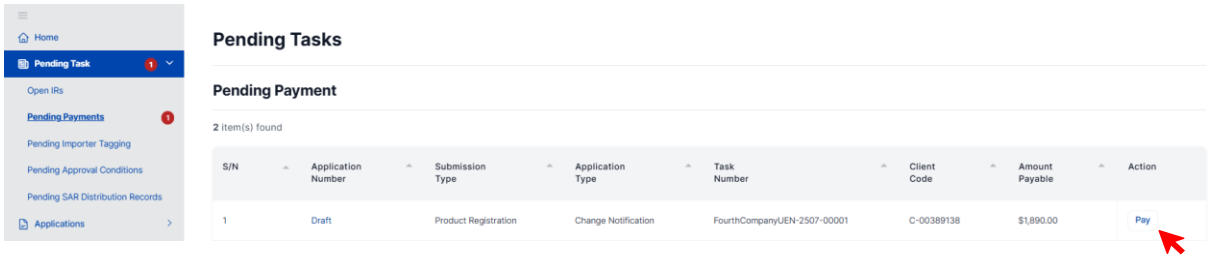


15. Online Payment

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

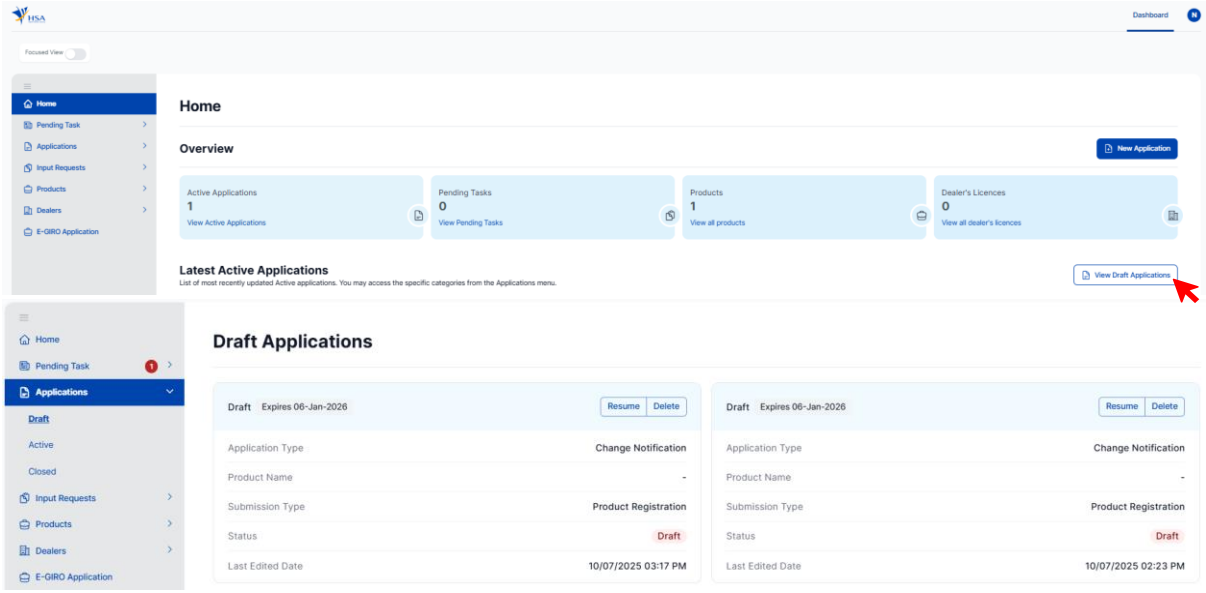


If you encounter any issues with the online payment, please check the Pending Tasks page to locate and complete any outstanding payments.



16. Accessing and Managing Drafts

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



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