

Training on Medical Device Information System (MDIS)

PART II: APPLICATION FOR LISTING



Agenda

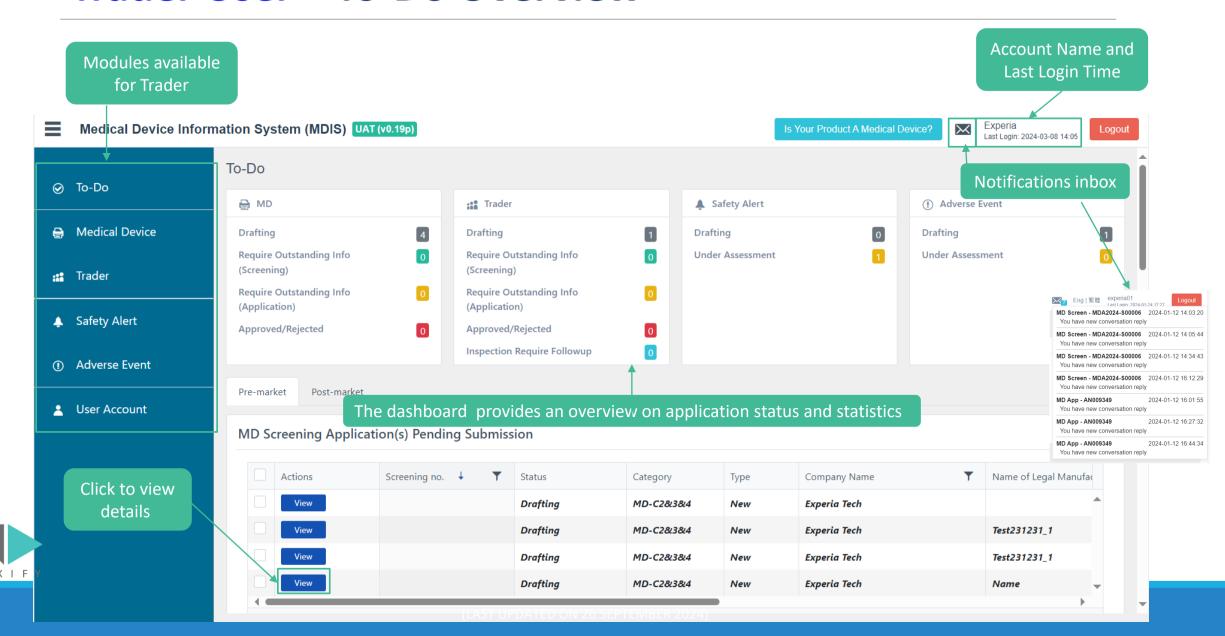
- 1) Functionalities in Trader User Interface
- 2) Functionalities in Individual User Interface
 - General functions
 - Submit MD applications
 - Submit Trader applications
 - Submit CAB applications
 - Submit NMPA applications
 - Other application-related matters



3) Enquiry and Support

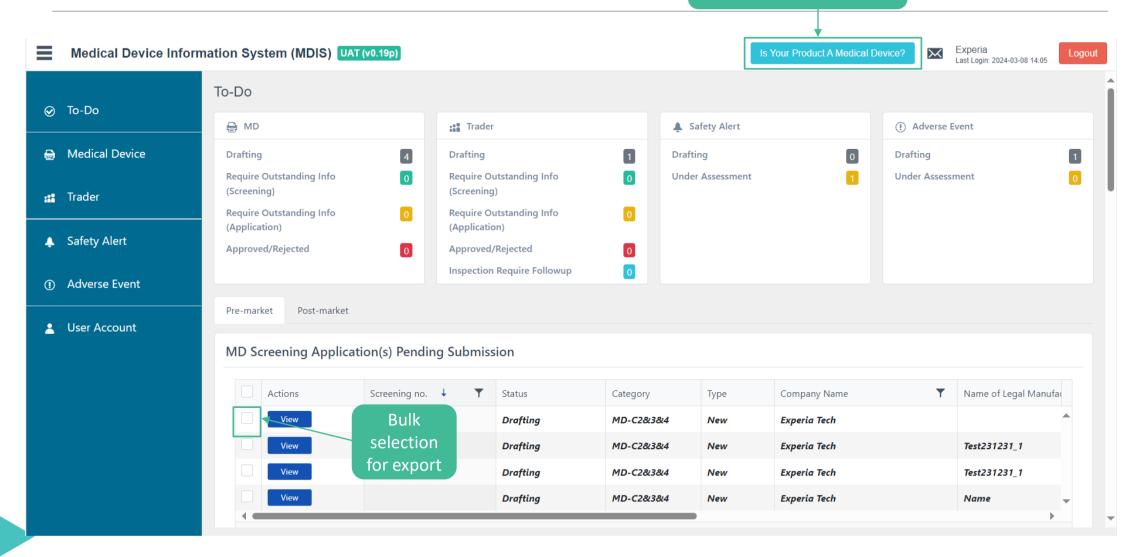
1) Functionalities in Trader User Interface

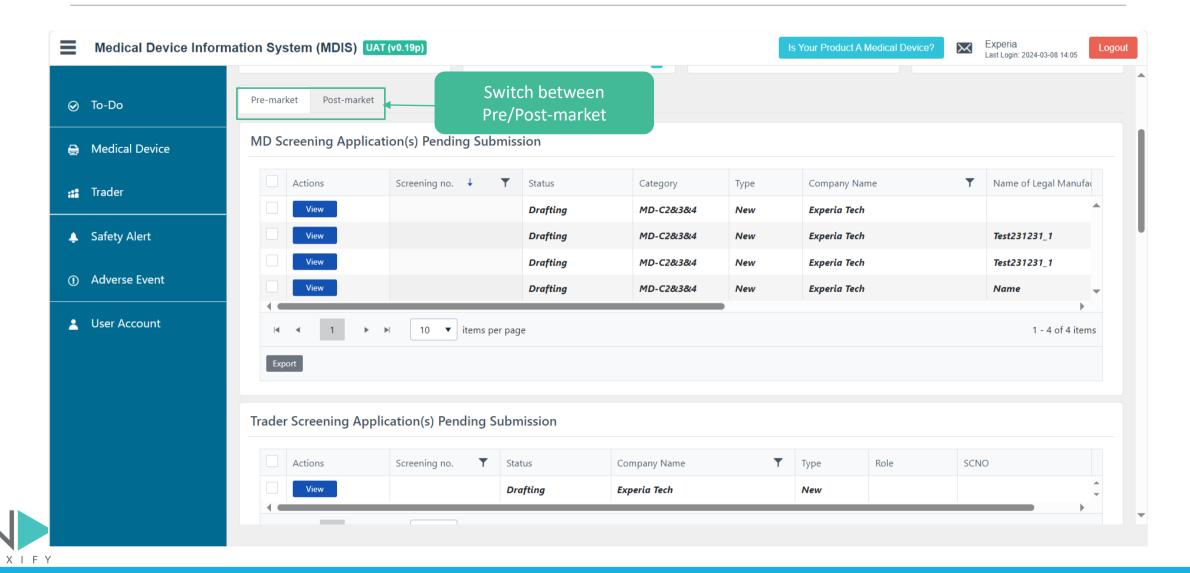


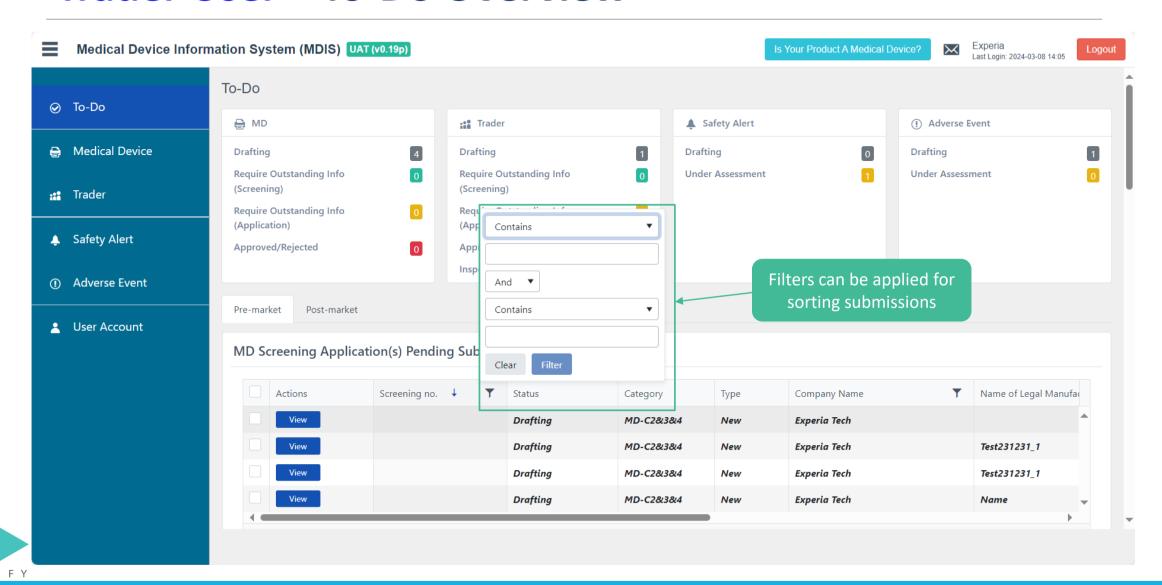


NEXIFY

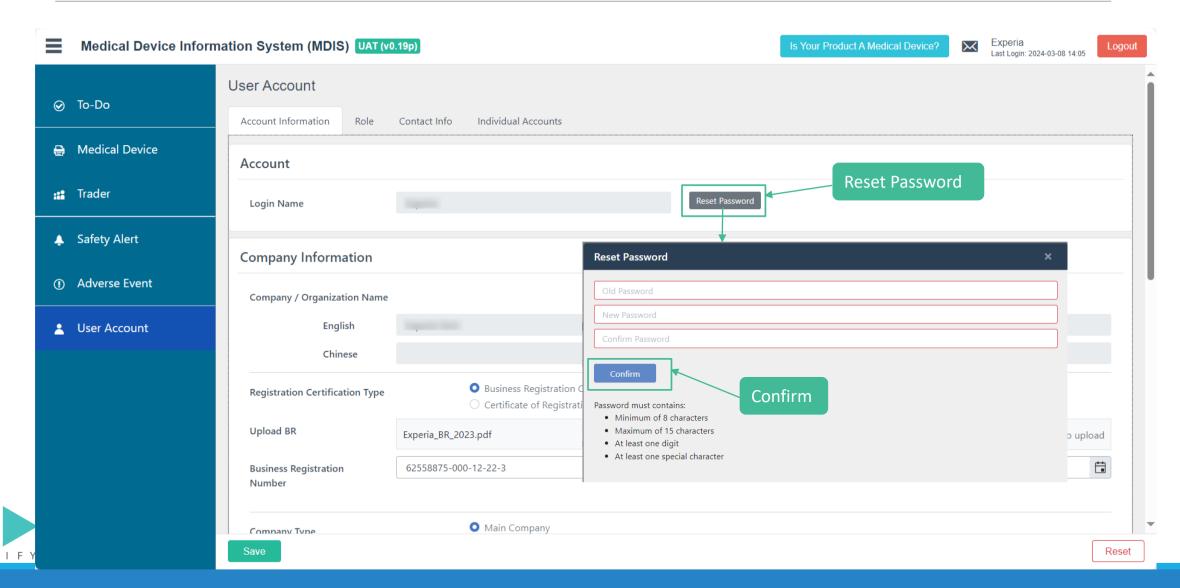
Link to external Q&A page for clarification



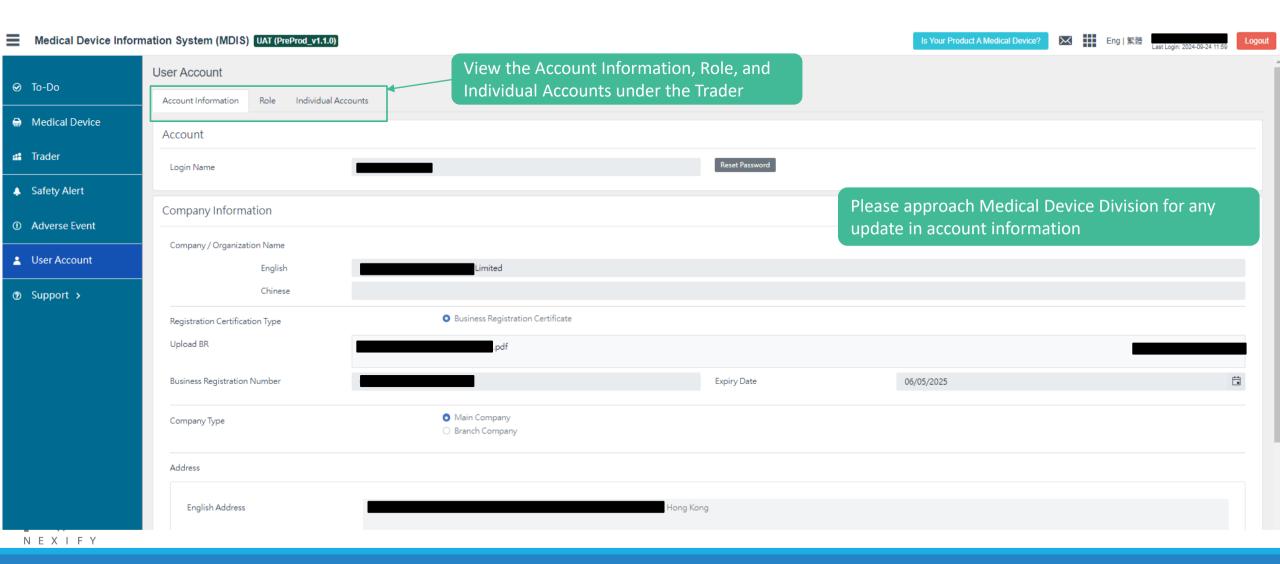




Trader User – User Account Management – Reset Password



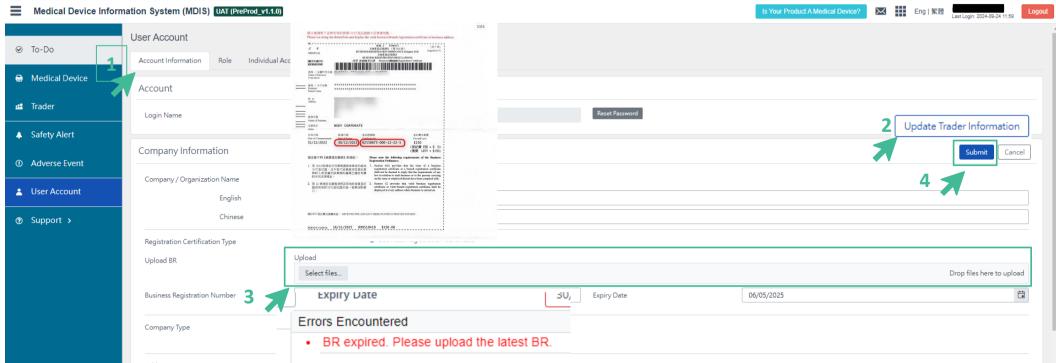
Trader User – User Account Management



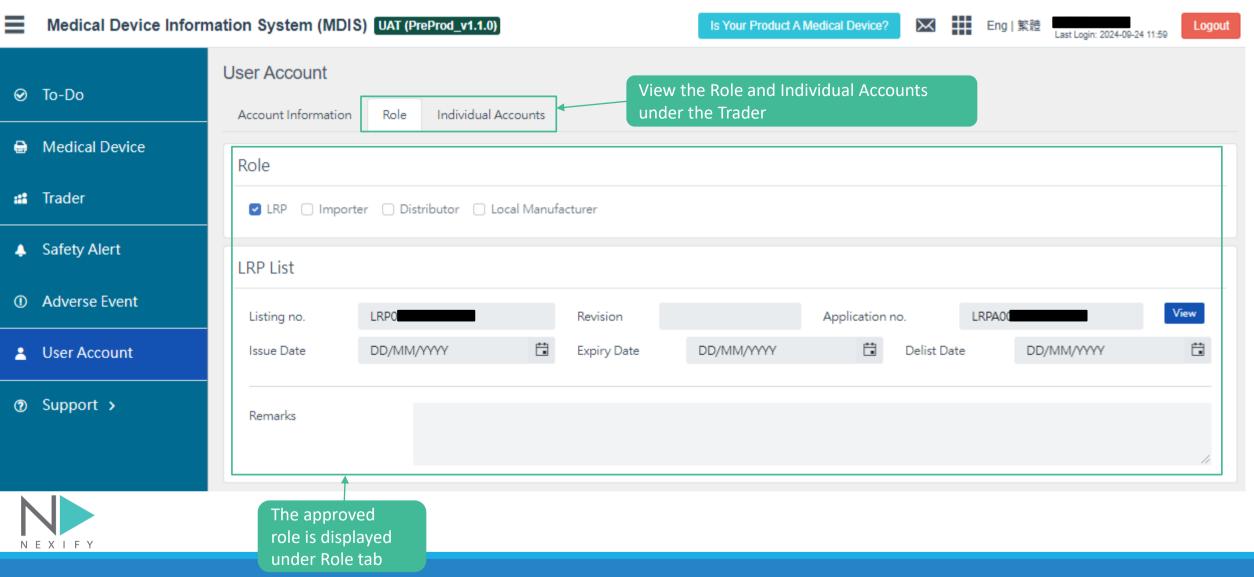
Trader User – User Account Management – Upload BR

To maintain account operation, you would need to upload latest BR regularly.

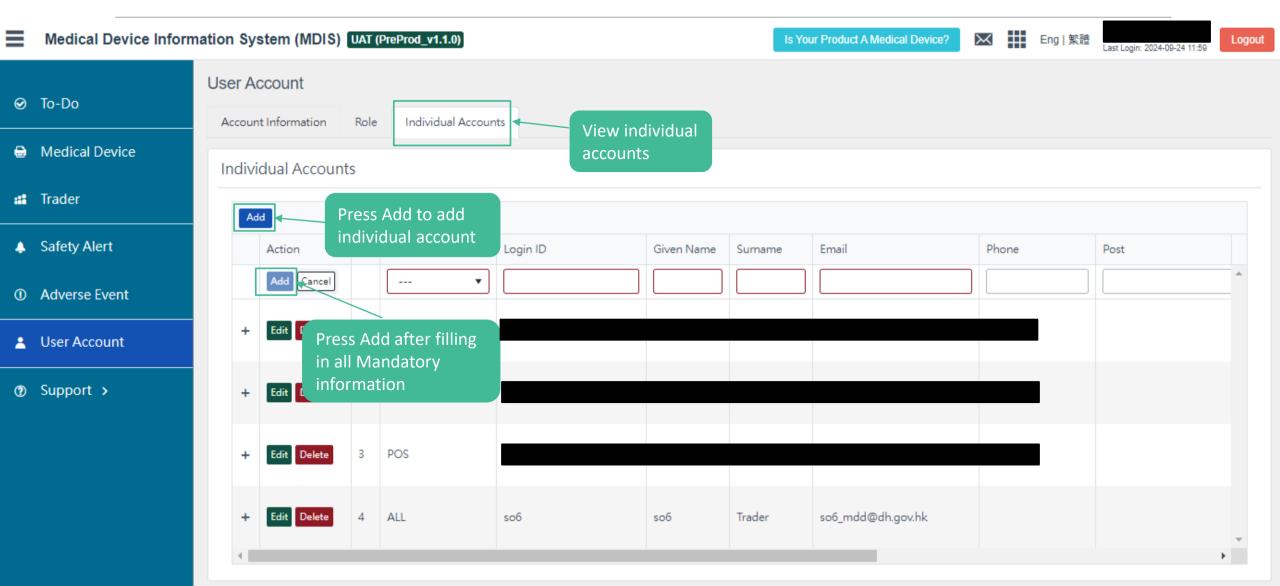
- Select "User Account" > "Account Information"
- 2. Click "Update Trader Information"
- 3. Upload BR file (The Business Registration Number and Expiry Date will be automatically recognized and filled. Validation check applies to the expiry date)
- 4. Click "Submit" to complete upload



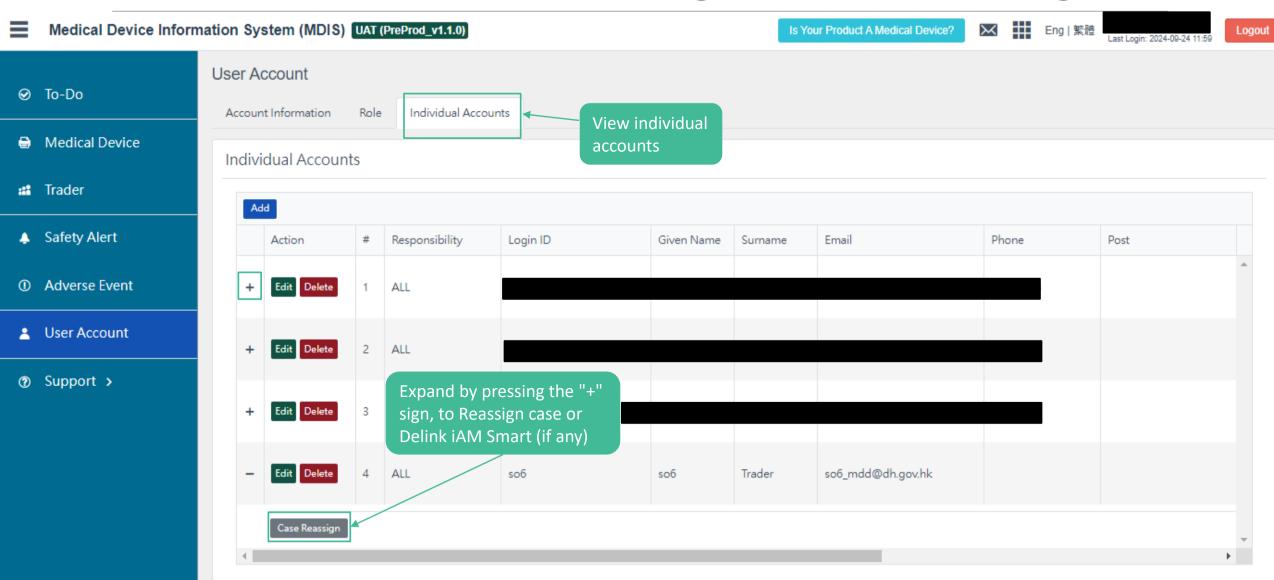
Trader User – User Account Management



Trader User – User Account Management – Add Individual Accounts

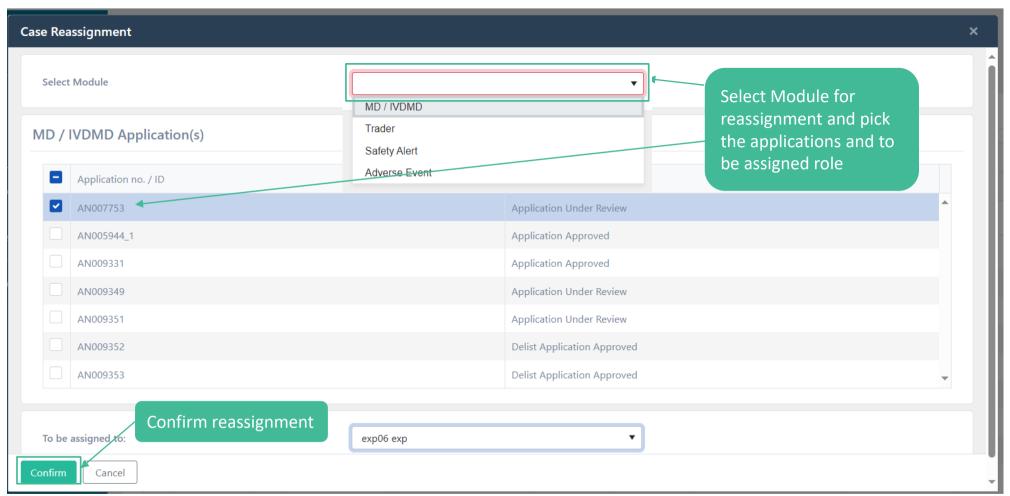


Trader User – User Account Management – Case Reassign



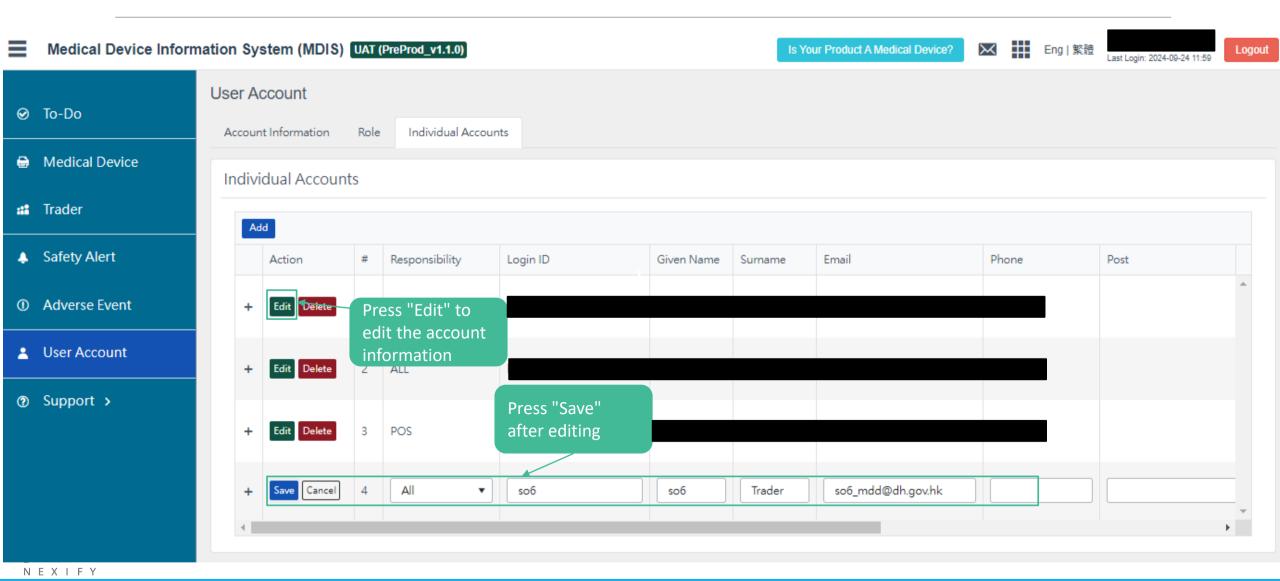
Trader User – User Account Management – Case Reassign (Cont.)

Only responsible Individual accounts can submit change / renewal / delist applications for their assigned application numbers

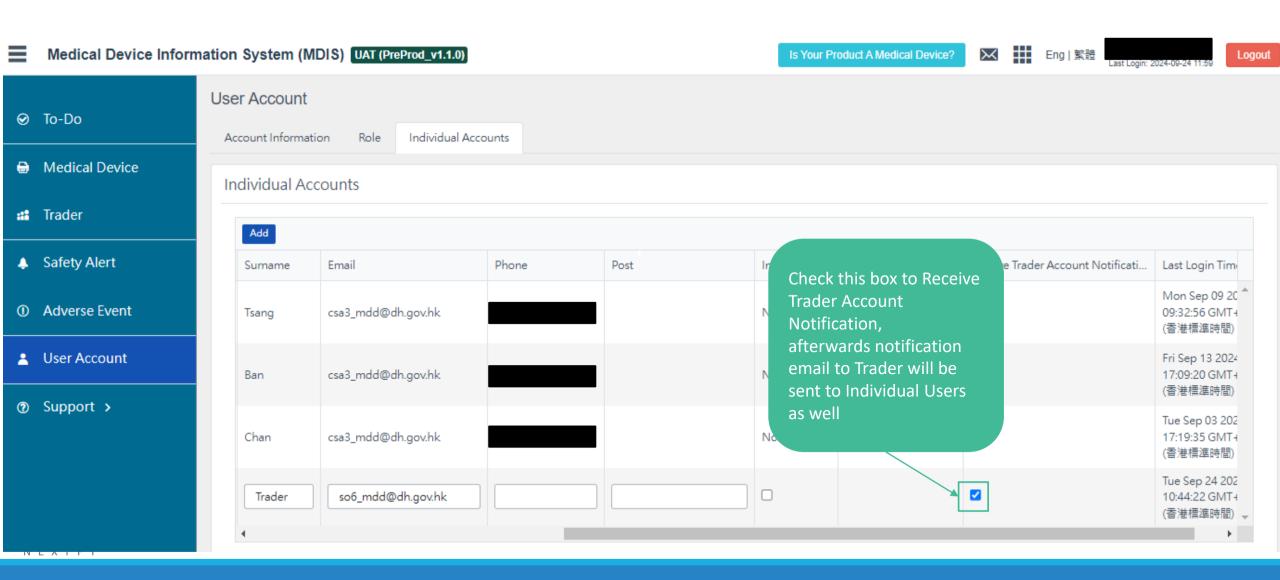




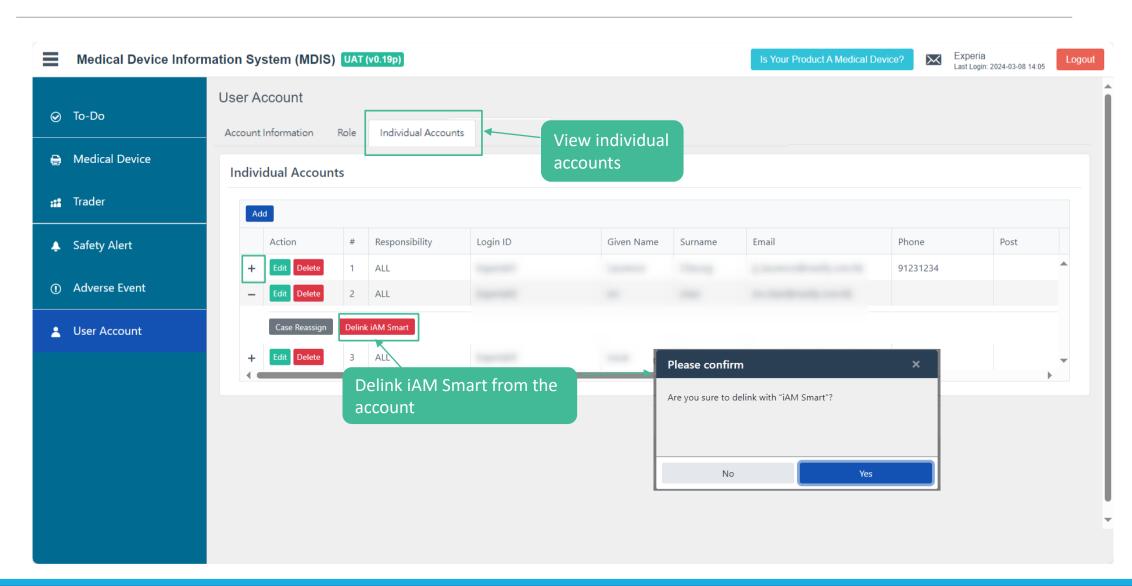
Trader User – User Account Management – Edit account information



Trader User – User Account Management – Edit account information (Cont.)



Trader User – User Account Management – Delink iAM Smart



2) Functionalities in Individual User Interface

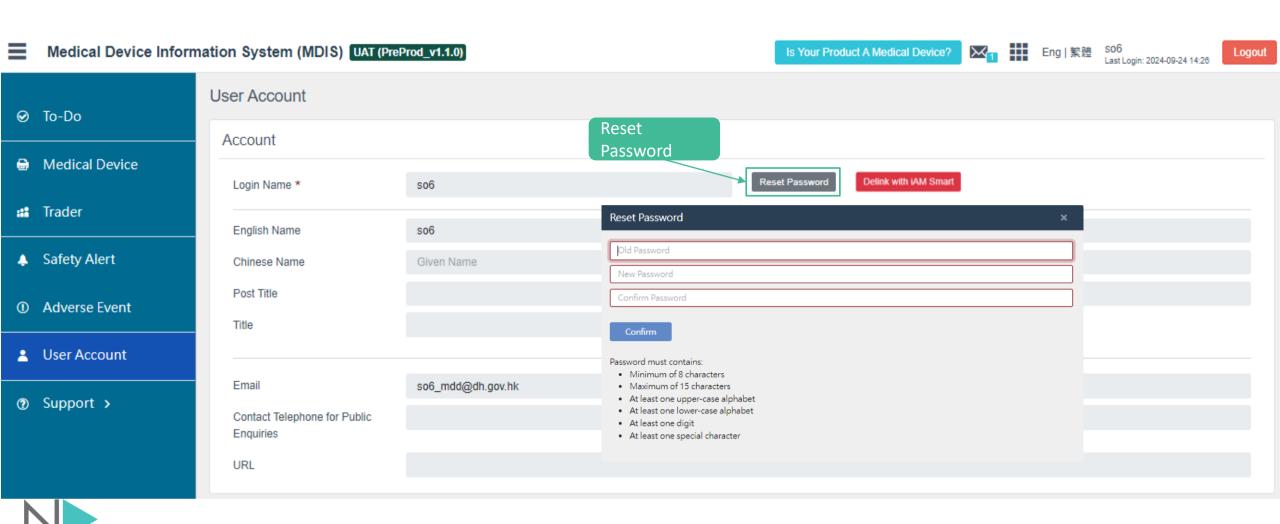


Functionalities in Individual User Interface

- General functions
 - User Account Management
 - > To-Do Overview
 - Medical Device Overview / Searching
 - Trader Overview / Searching

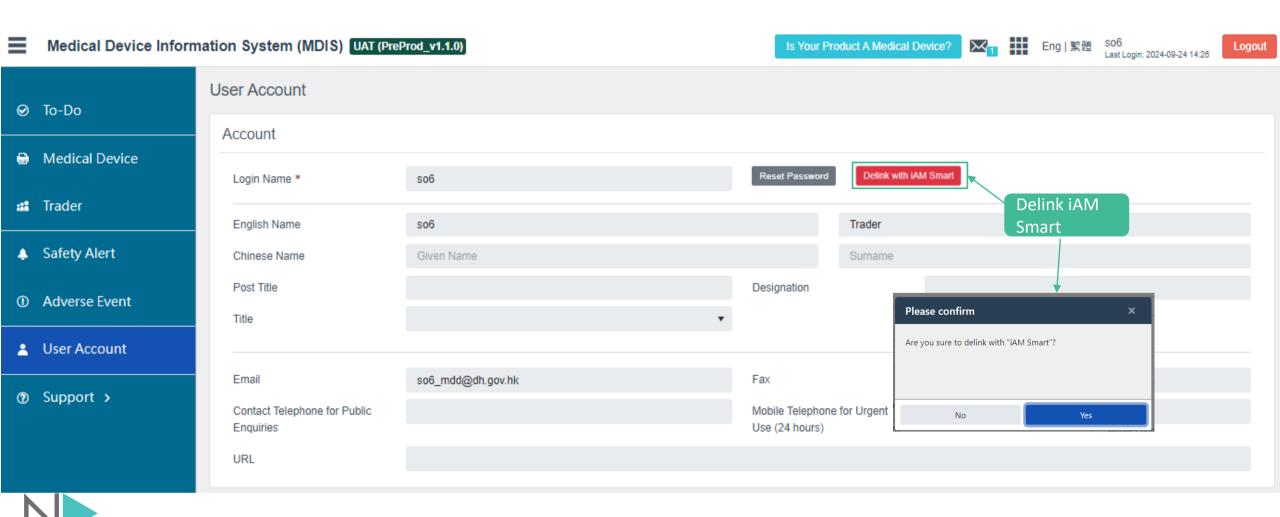


Individual Users – User Account Management – Reset Password



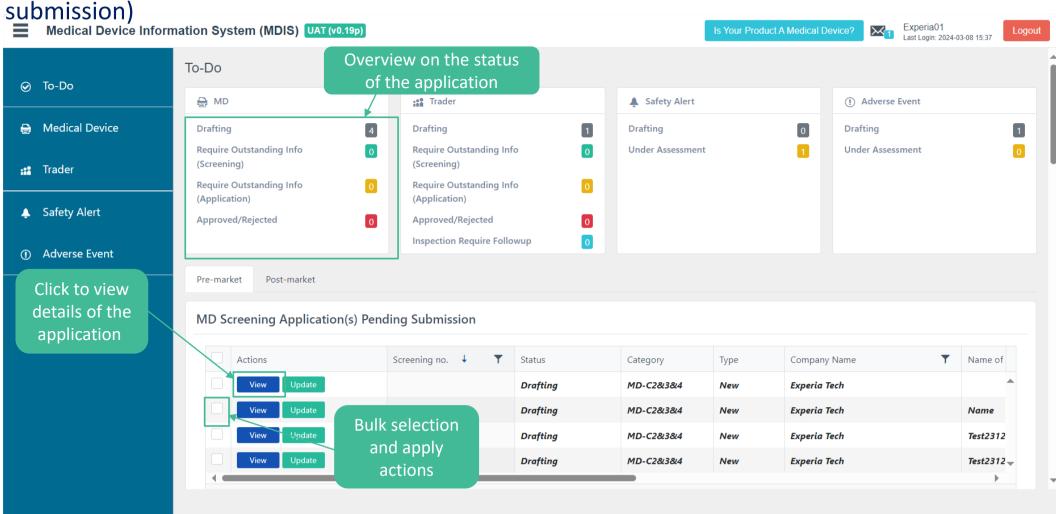
NEXIFY

Individual Users – User Account Management

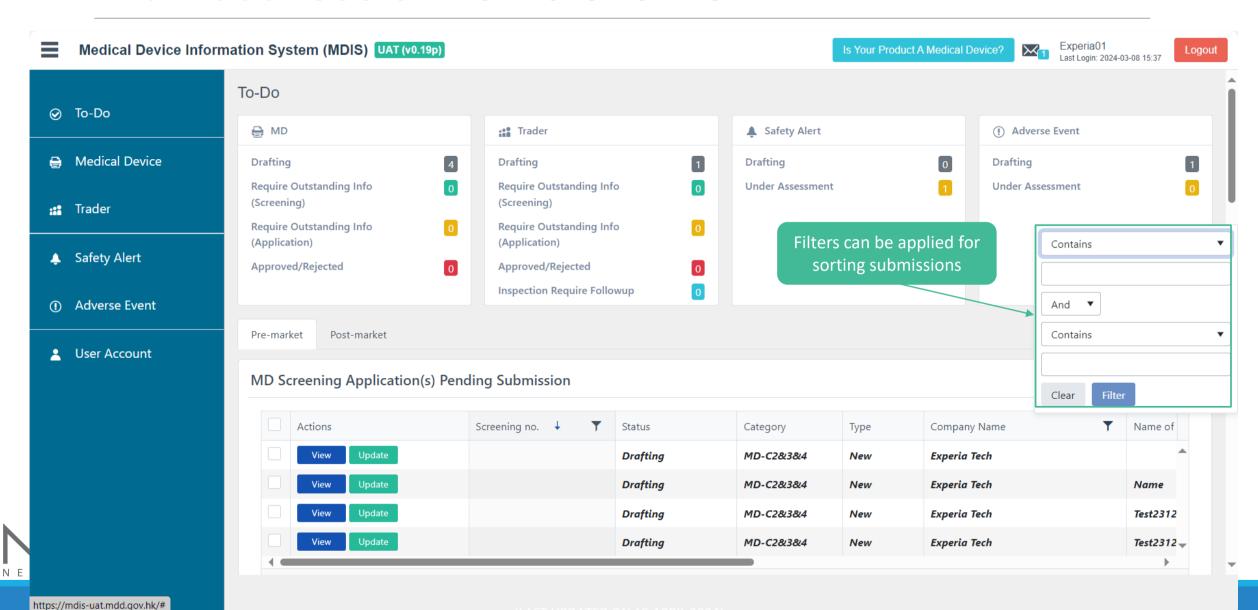


Individual Users – To-Do Overview

The To-Do list provides an overview of the tasks requiring further actions (e.g. pending for

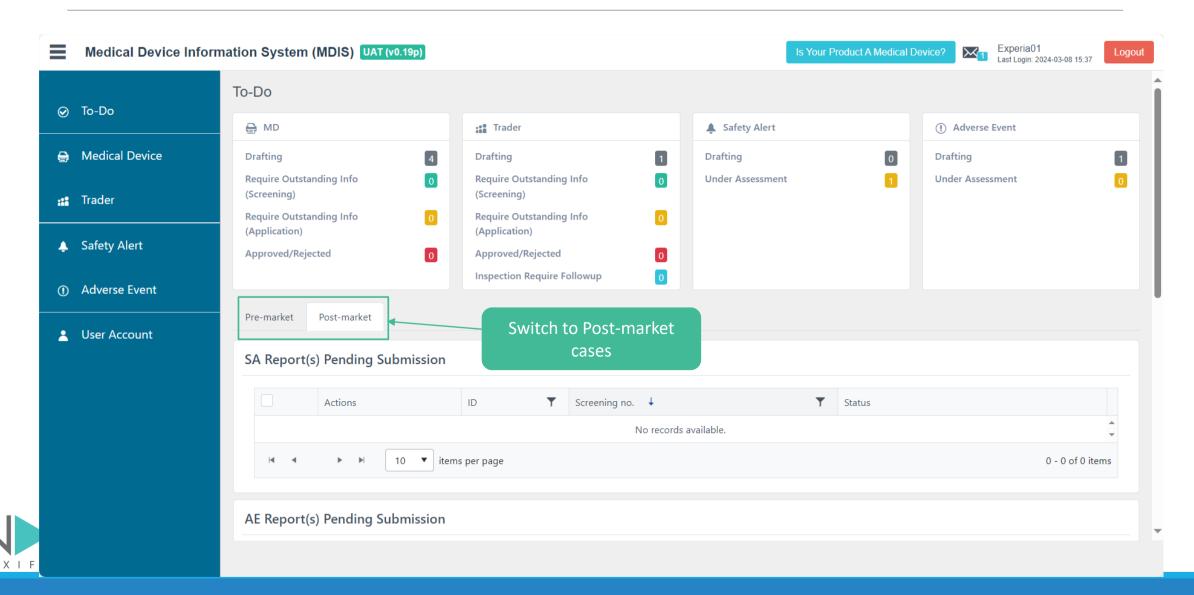


Individual Users – To-Do Overview

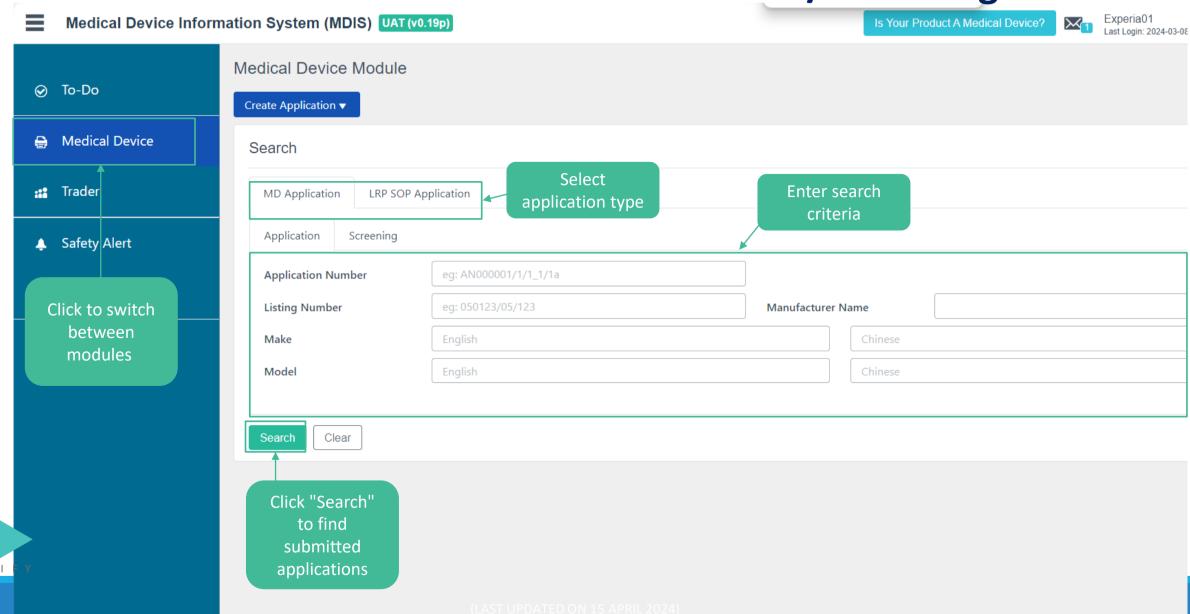


LAST OF DATED ON 13 AFKIL 2024

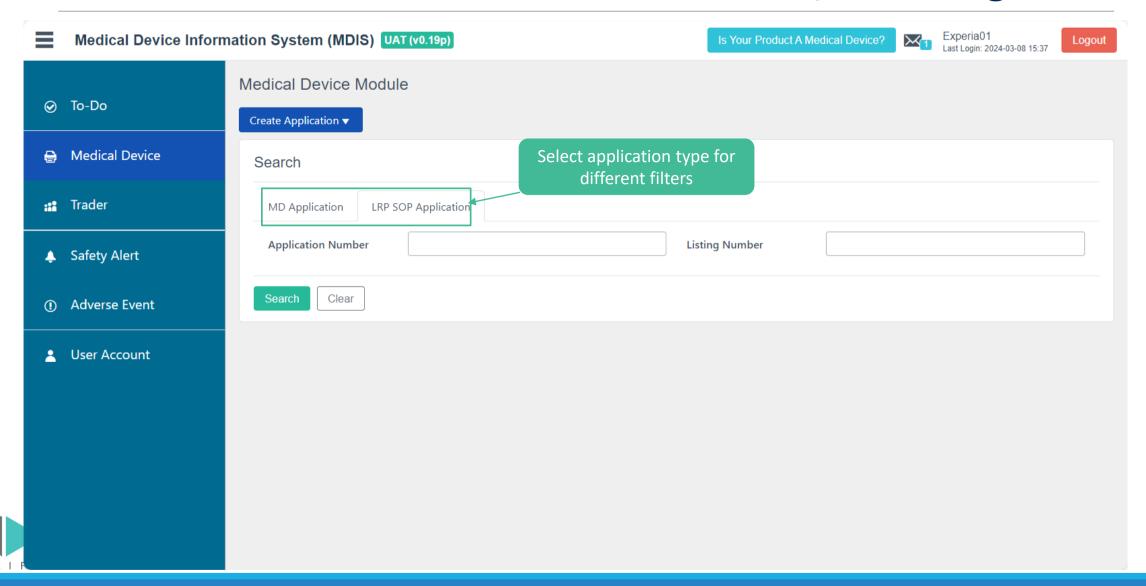
Individual Users – To-Do Overview



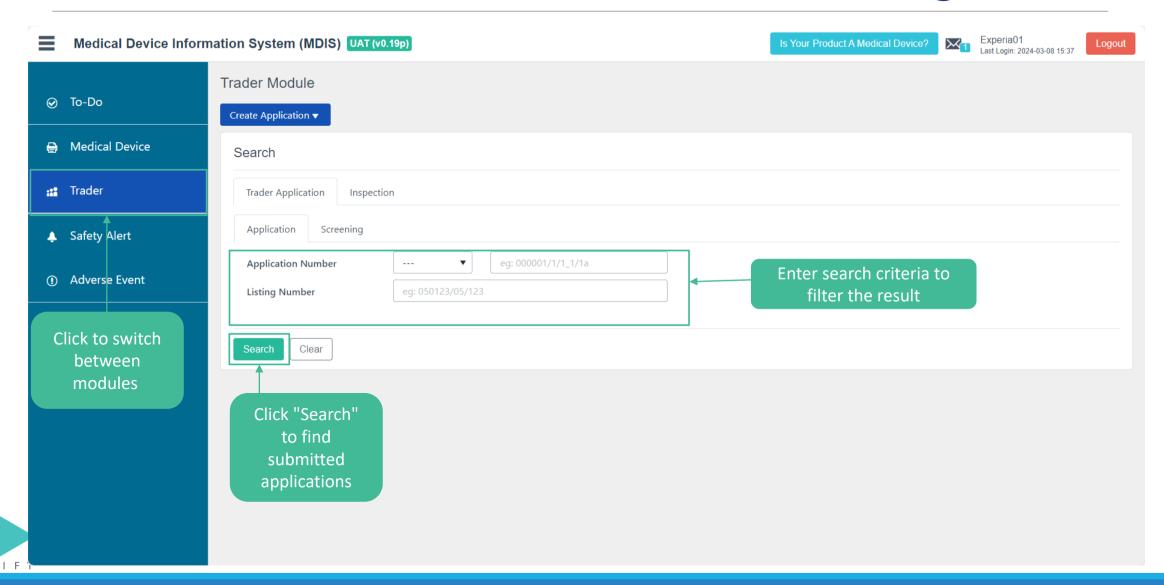
Individual Users – Medical Device Overview / Searching



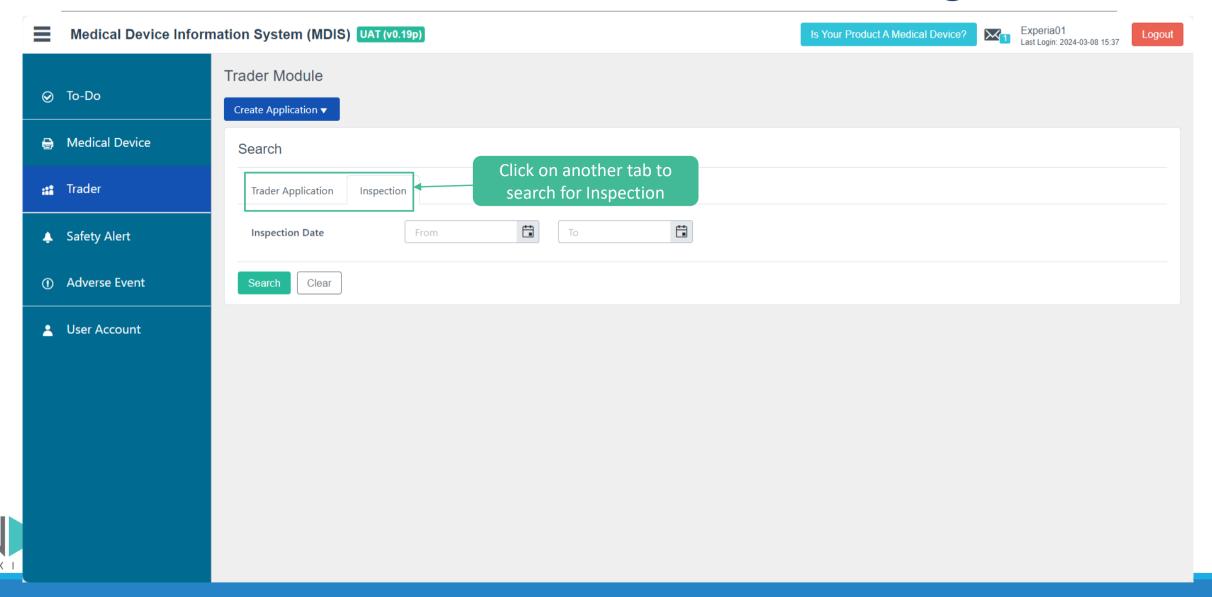
Individual Users – Medical Device Overview / Searching



Individual Users – Trader Overview / Searching



Individual Users – Trader Overview / Searching



Functionalities in Individual User Interface

- Submit MD Application
 - New Application
 - Change Application
 - Renewal Application
 - Delist Application
 - > Taking Over Application

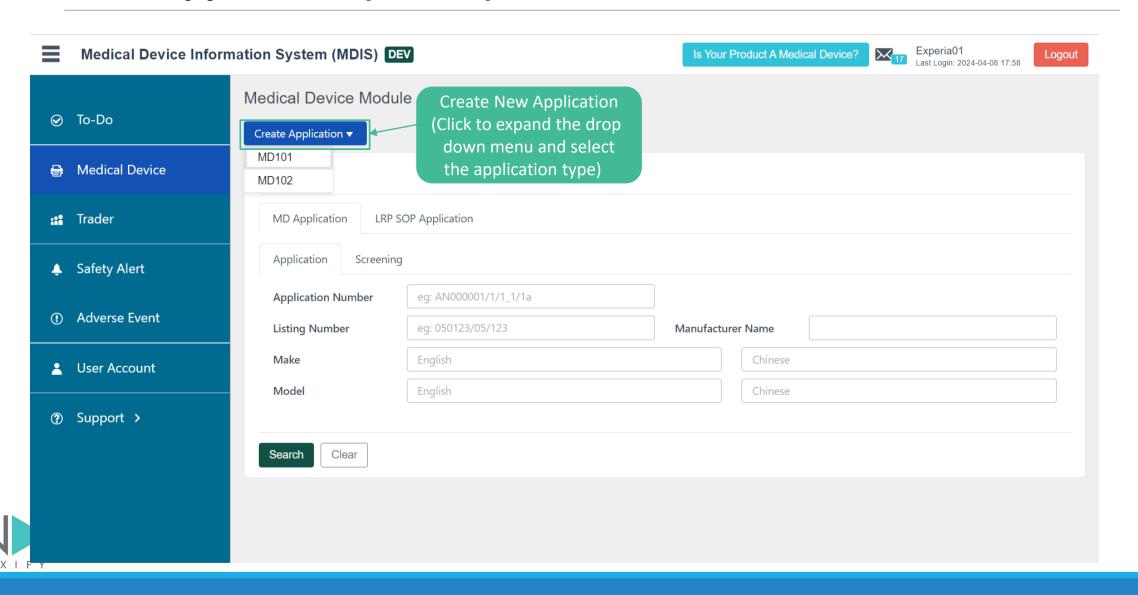


Individual User – Submit MD Application – Preparation of application documents

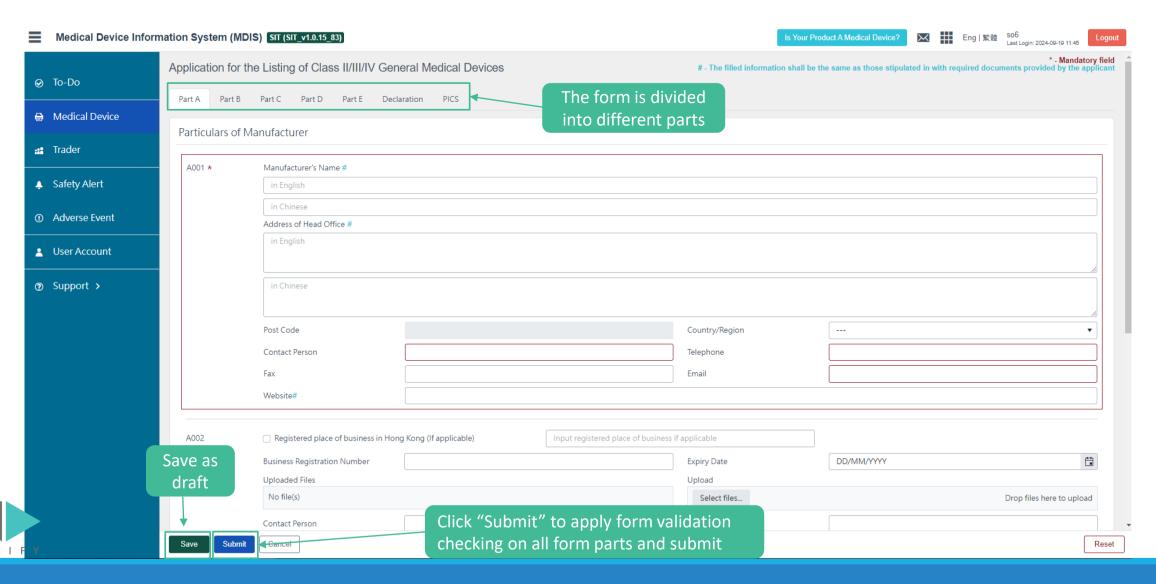
- Requirements, application procedures, guidance for completing the application form and information required for application for listing of MDs, you may refer to:
 - the Guidance Notes for Listing Class II/III/IV Medical Devices (GN-02)
 - the Guidance Notes for Listing Class B/C/D In Vitro Diagnostic Medical Device (GN-06)
- Application Forms: MD101 (GMD) / MD102 (IVDMD)
 - Part A: Particulars of Manufacturer
 - Part B: Particulars of Local Responsible Person
 - Part C: Particulars of the Device
 - Part D: Marketing Approvals and Essential Principles
 - > Part E: Intention to join the Expedited Approval Scheme
 - Declaration
 - > PICS



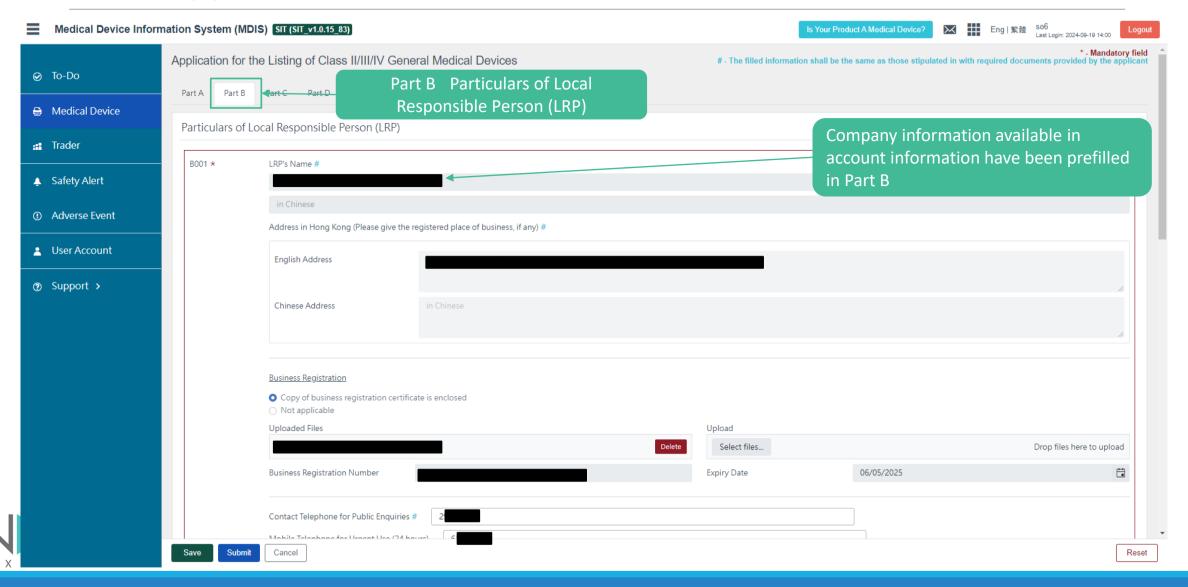
Individual User – Submit MD Application – New Application (P. 1-17)



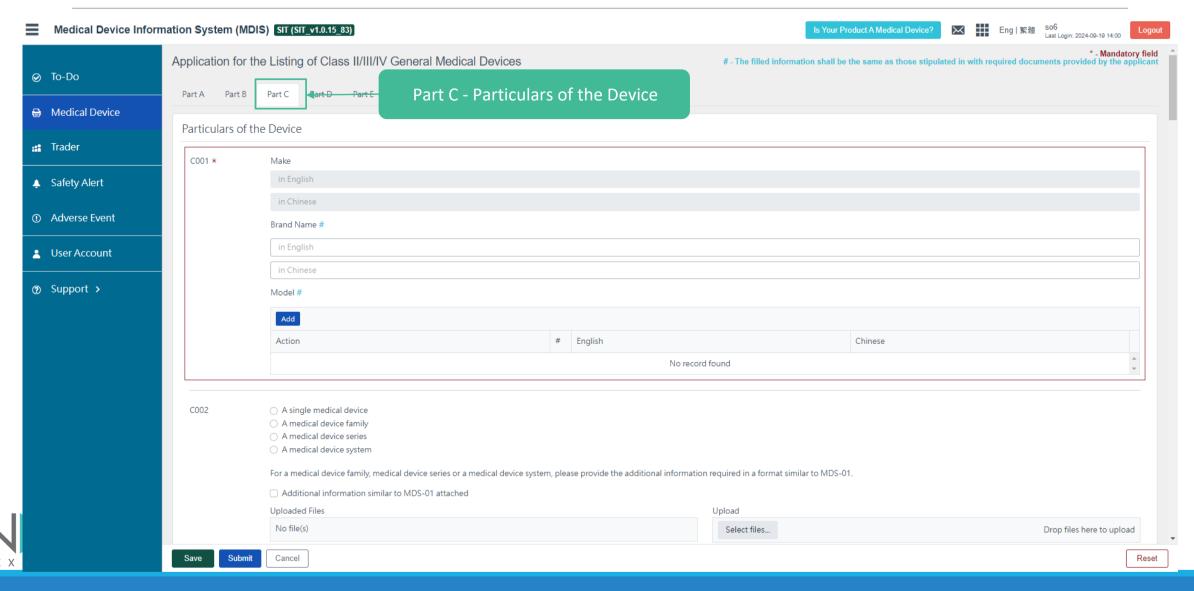
Individual User – Submit MD Application – New Application (MD101) (P. 2-17)



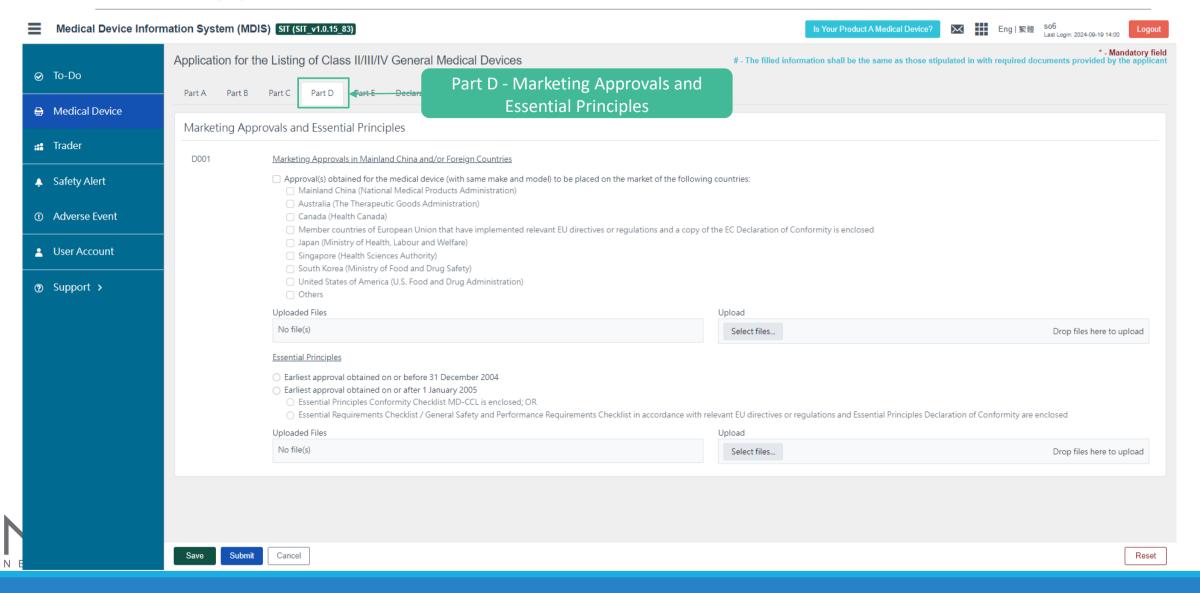
Individual User – Submit MD Application – New Application (MD101) (P. 3-17)



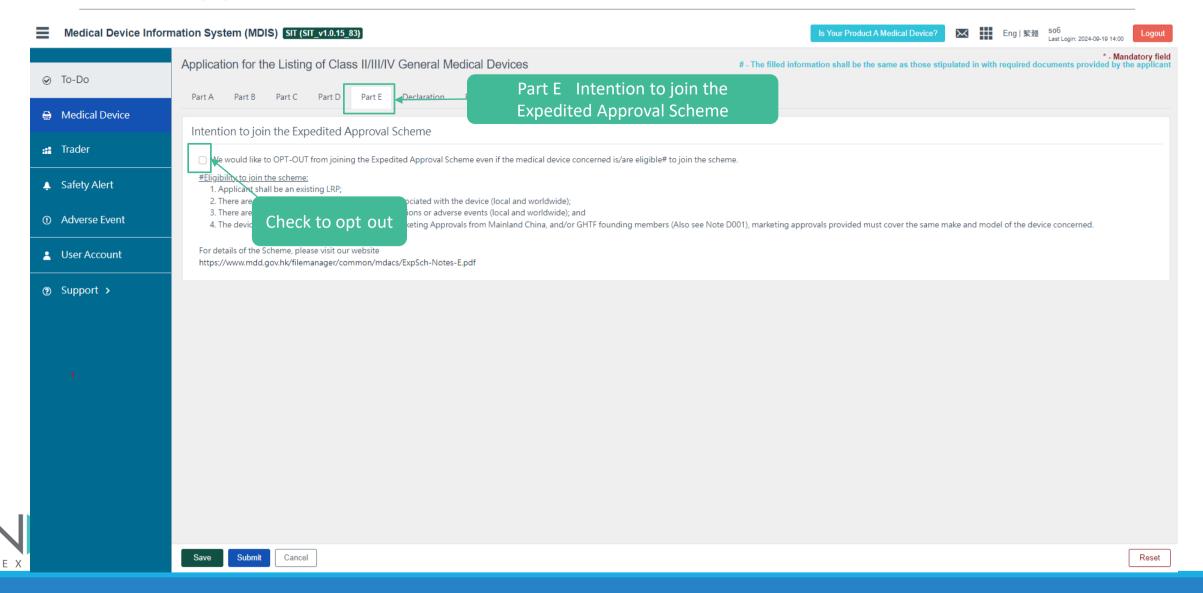
Individual User – Submit MD Application – New Application (MD101) (P. 4-17)



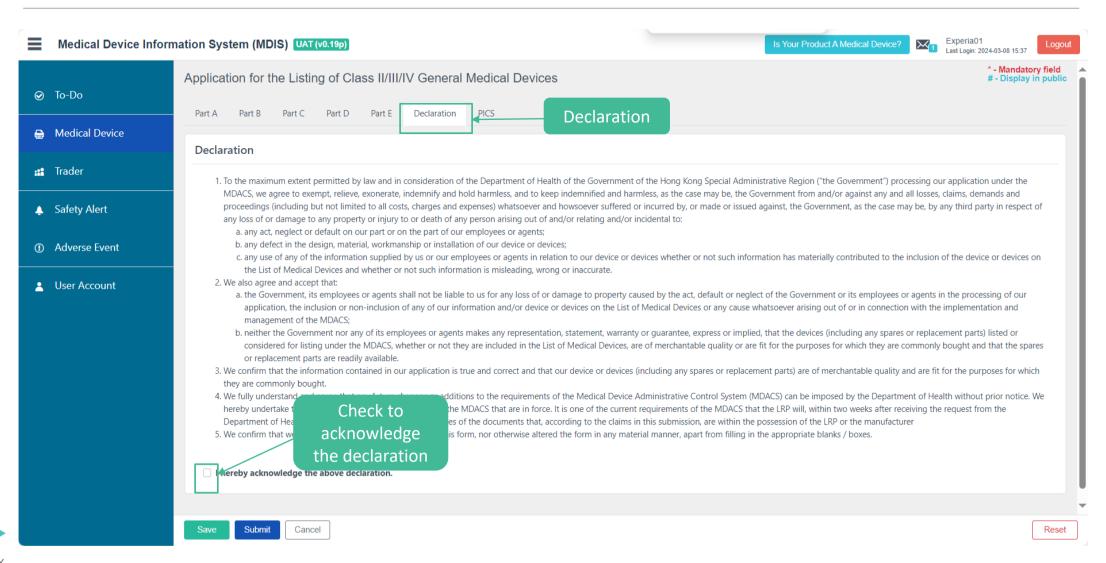
Individual User – Submit MD Application – New Application (MD101) (P. 5-17)



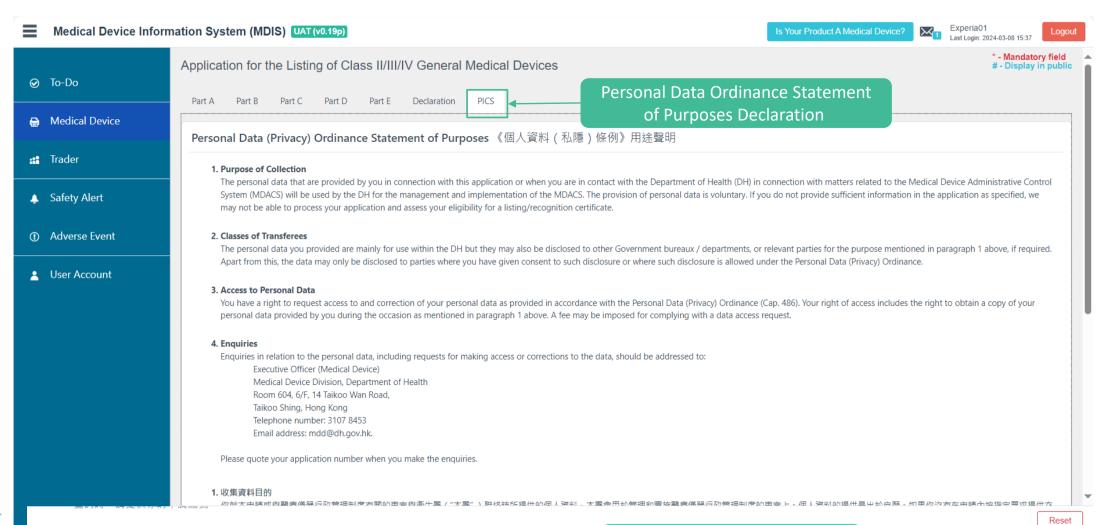
Individual User – Submit MD Application – New Application (MD101) (P. 6-17)



Individual User – Submit MD Application – New Application (MD101) (P. 7-17)



Individual User – Submit MD Application – New Application (MD101) (P. 8-17)

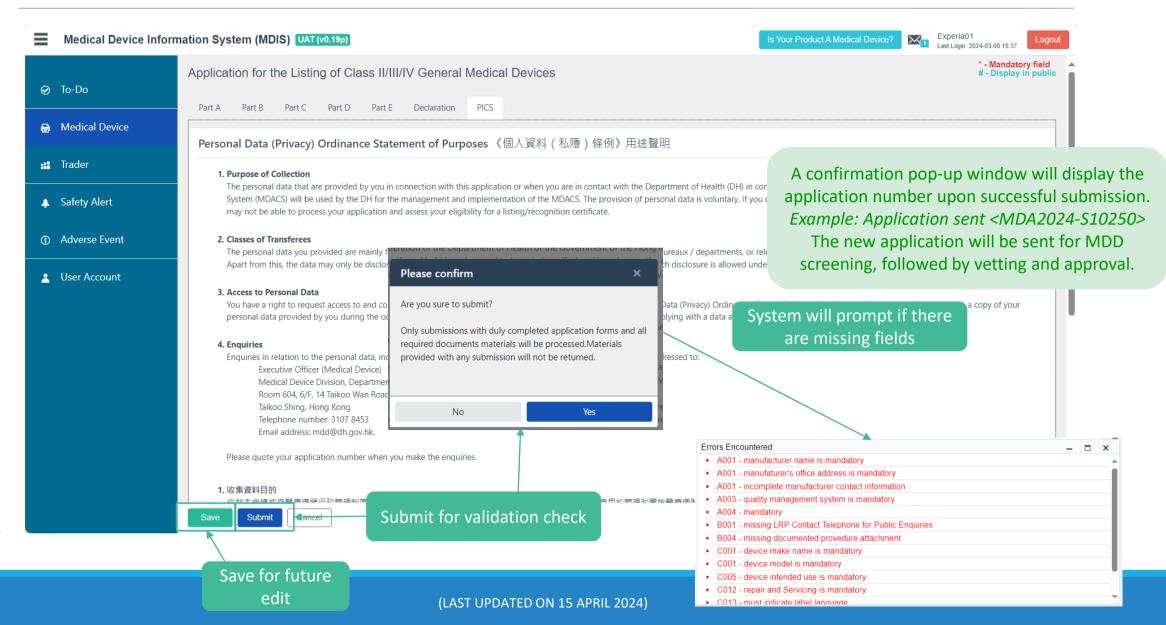


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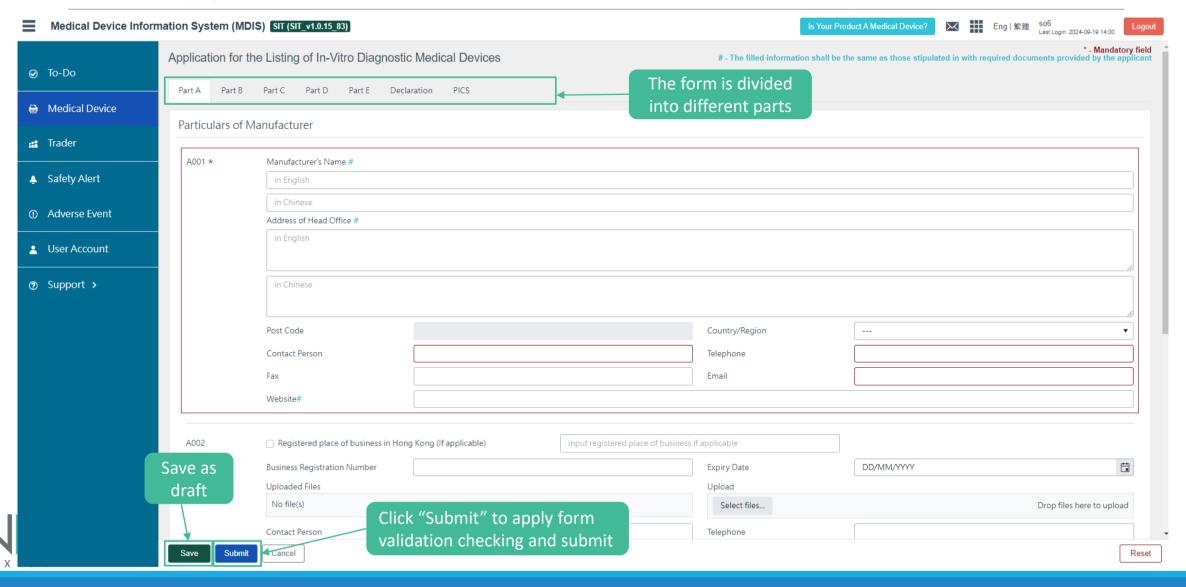
Lhereby acknowledge the above statement. 本人已閱讀及完全明白並同意以上聲明。

Scroll down to check the box

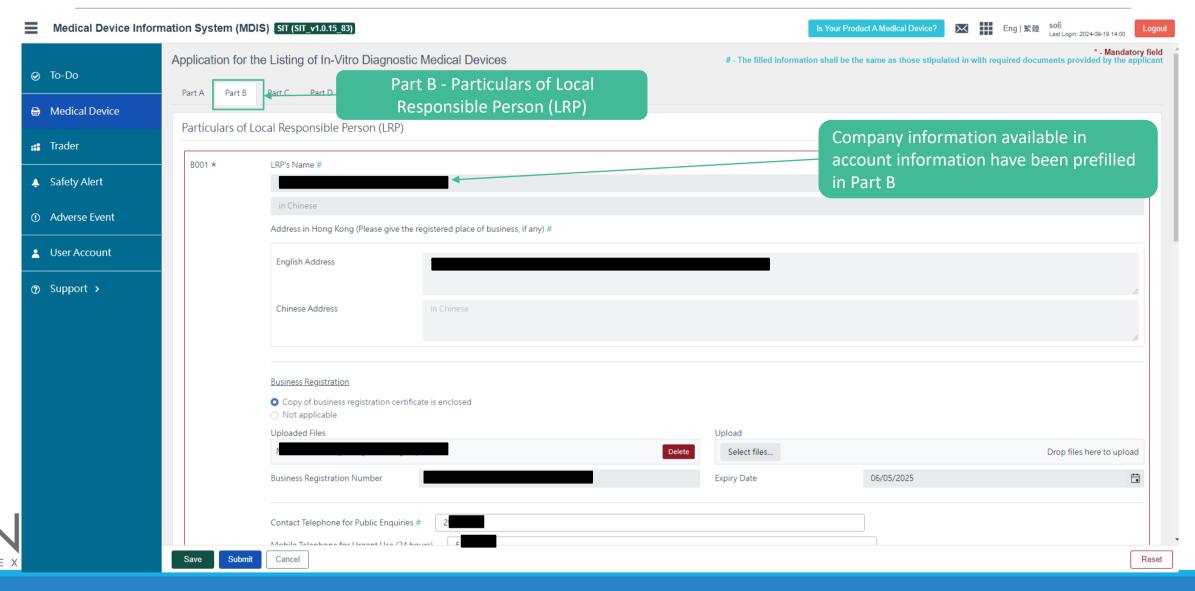
Individual User – Submit MD Application – New Application (MD101) (P. 9-17)



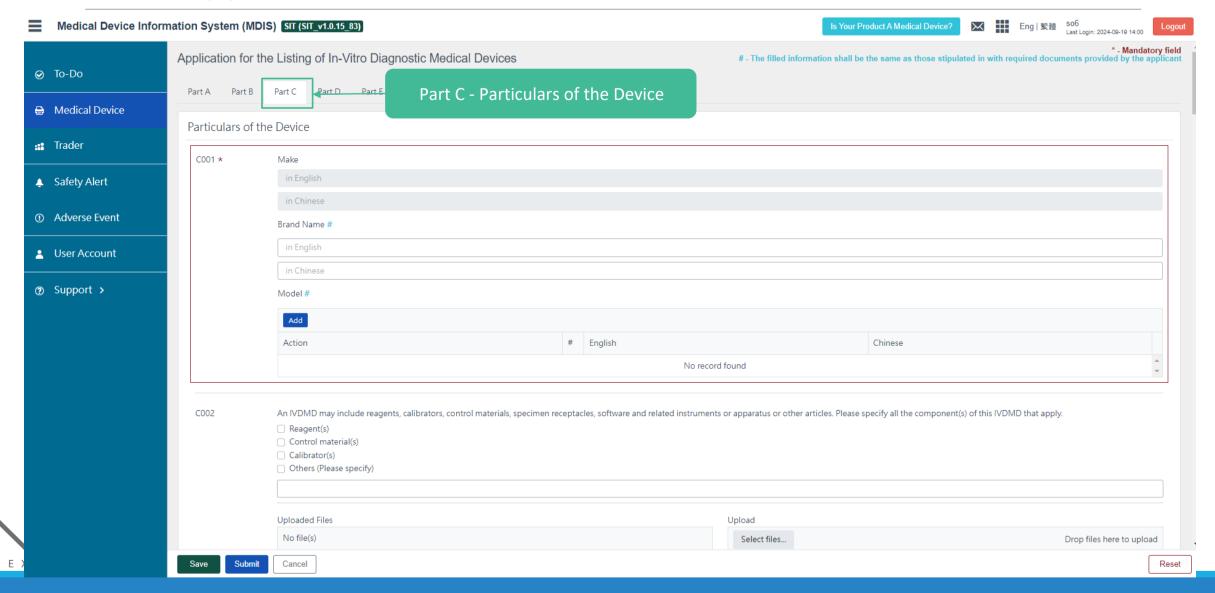
Individual User – Submit MD Application – New Application (MD102) (P. 10-17)



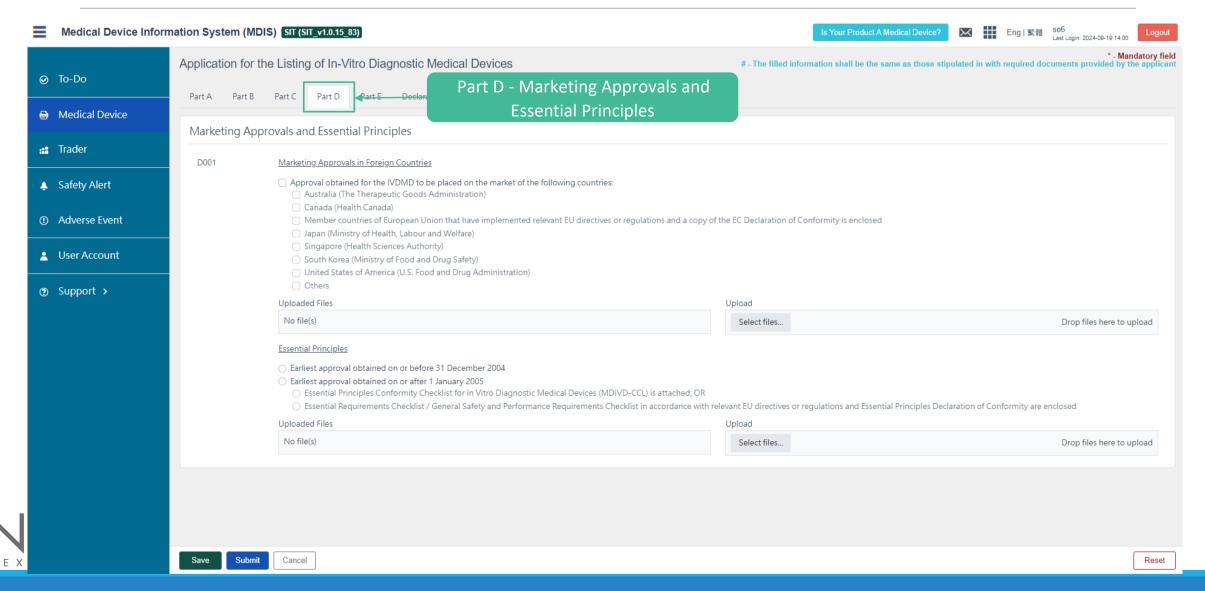
Individual User – Submit MD Application – New Application (MD102) (P. 11-17)



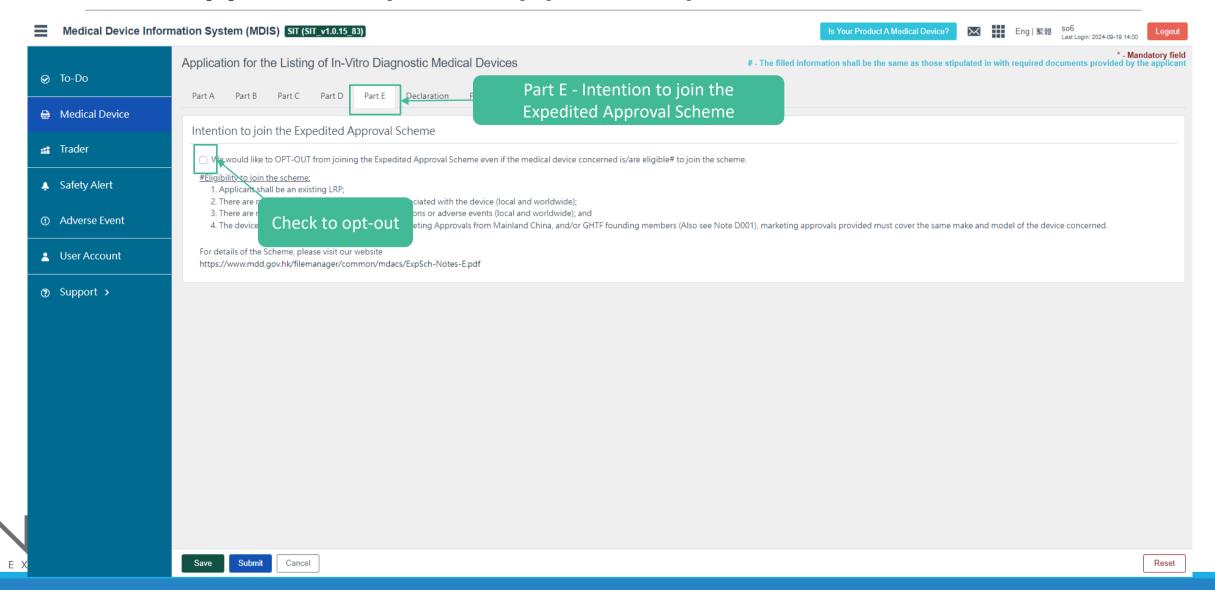
Individual User – Submit MD Application – New Application (MD102) (P. 12-17)



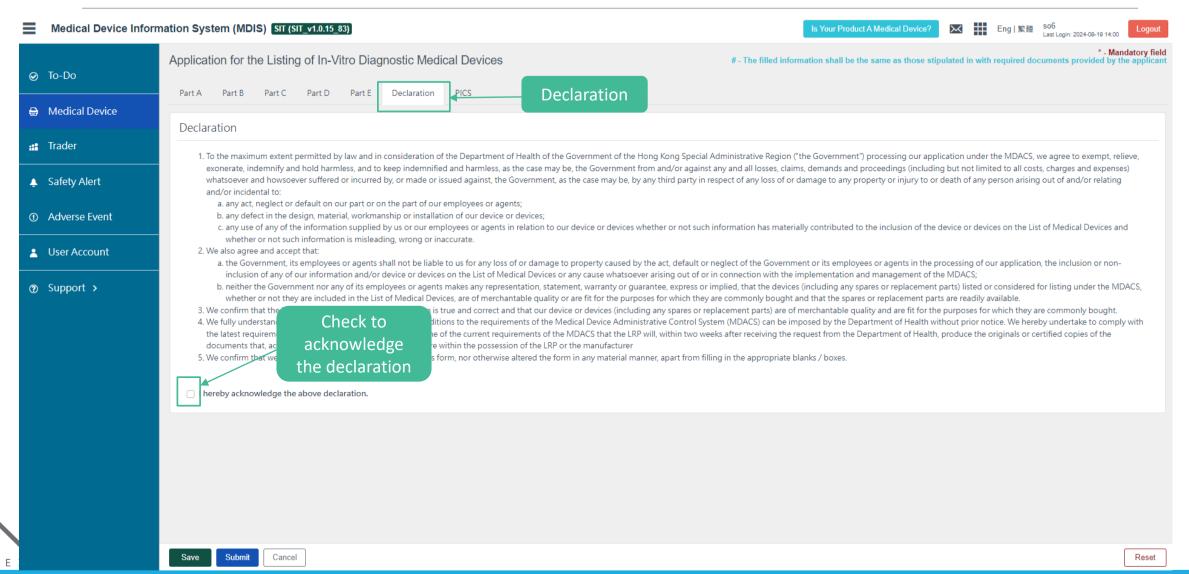
Individual User – Submit MD Application – New Application (MD102) (P. 13-17)



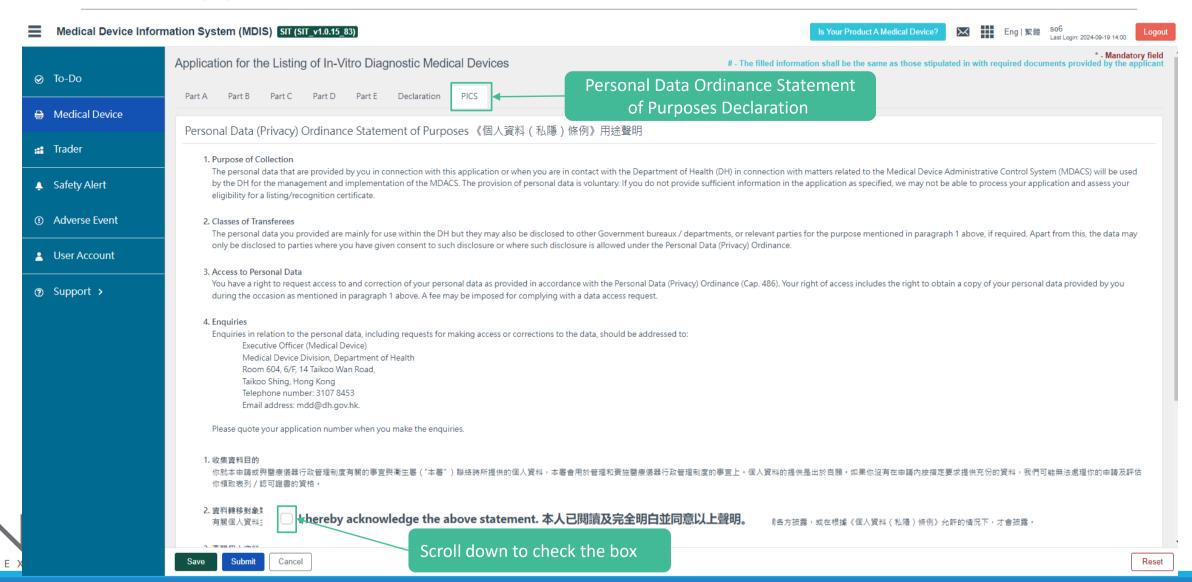
Individual User – Submit MD Application – New Application (MD102) (P. 14-17)



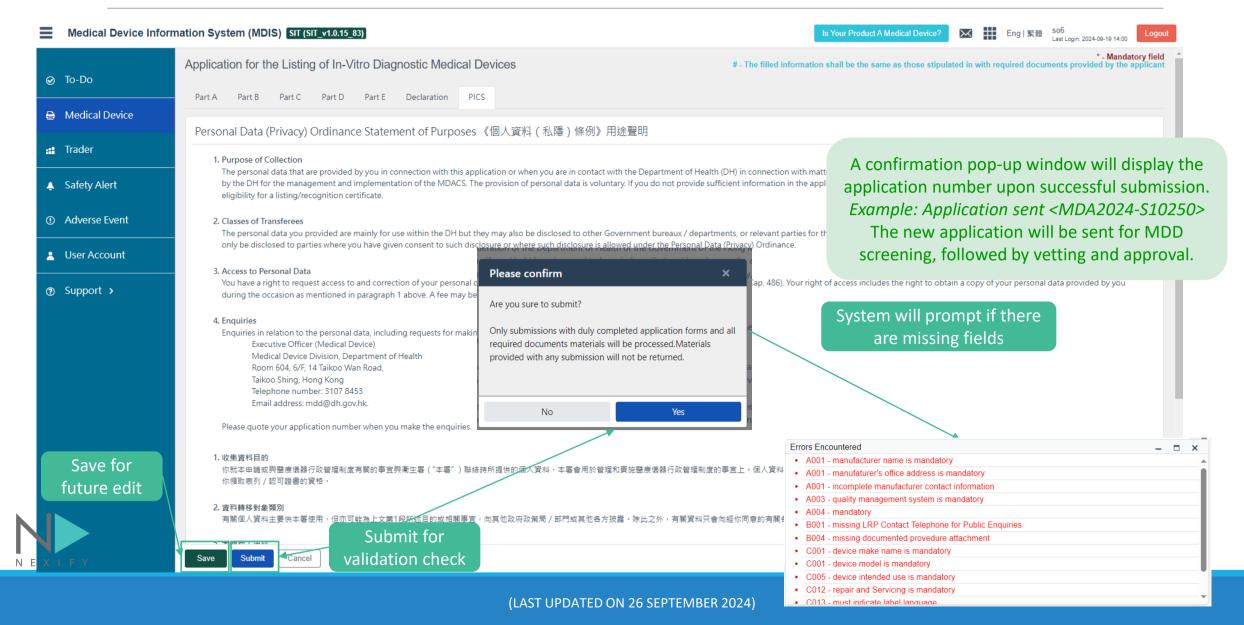
Individual User – Submit MD Application – New Application (MD102) (P. 15-17)



Individual User – Submit MD Application – New Application (MD102) (P. 16-17)



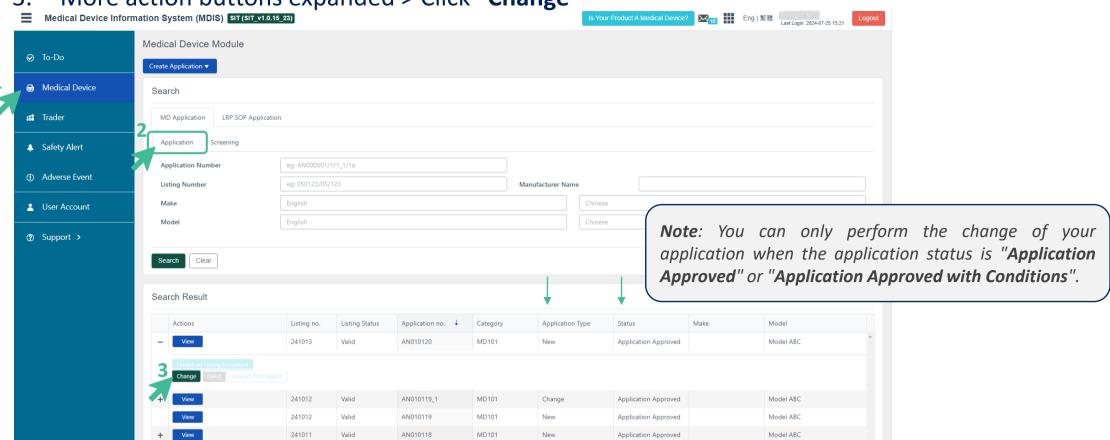
Individual User – Submit MD Application – New Application (MD102) (P. 17-17)



Individual User – Submit MD Application – Change Application (P. 1-6)

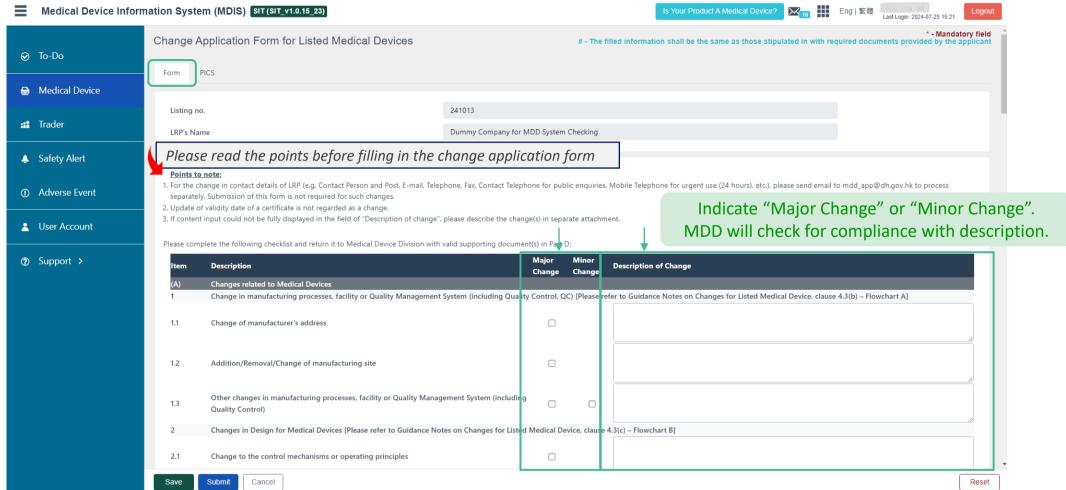
- 1. After logging into the MDIS System, click "Medical Device" to view or update applications of your individual account.
- 2. Select "MD Application" > "Application" > "Search" > Click "+"

3. More action buttons expanded > Click "Change"



Individual User – Submit MD Application – Change Application (P. 2-6)

In the "Change Application Form for Listed Medical Devices", input the item(s) you would like to change in the "Form" tab.

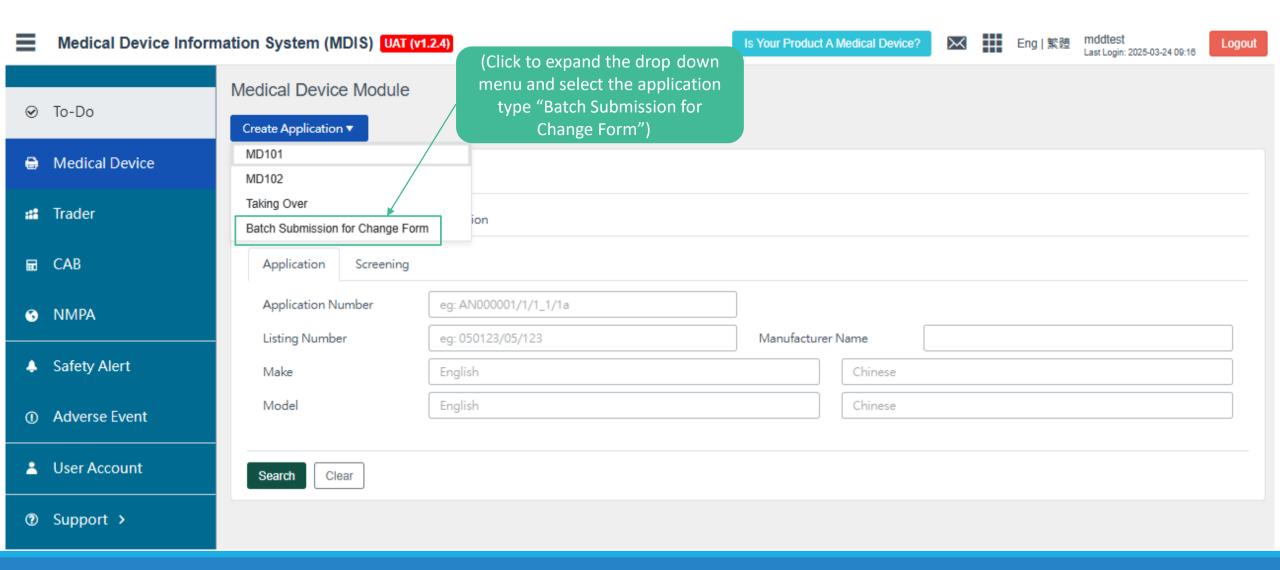


Individual User – Submit MD Application – Change Application (P. 3-6)

Check acknowledge "**PICS**" statement before submit > Click "**Submit**" to save and submit the application.

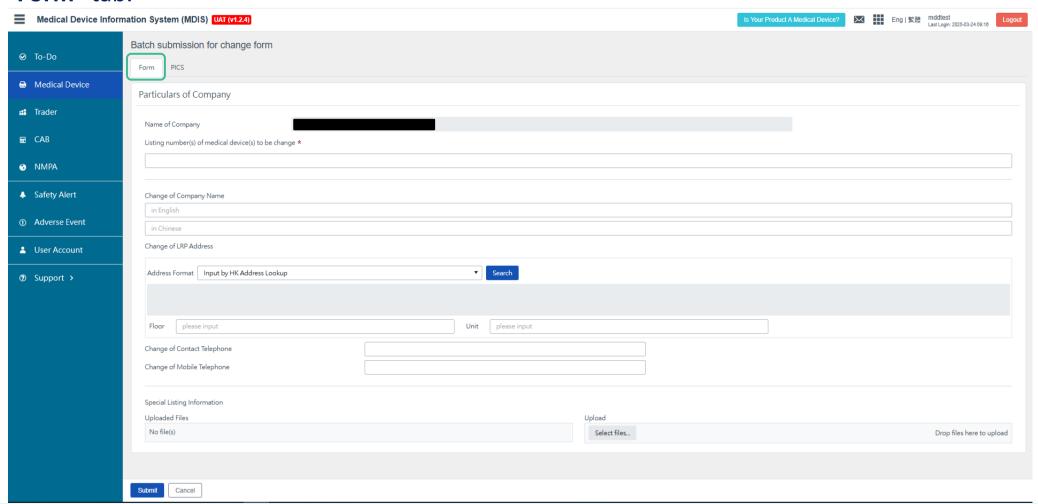


Individual User – Submit MD Application – Change Application (Batch submission) (P. 4-6)



Individual User – Submit MD Application – Change Application (Batch submission) (P. 5-6)

In the "Batch Submission for Change Form", input the item(s) you would like to change in the "Form" tab.



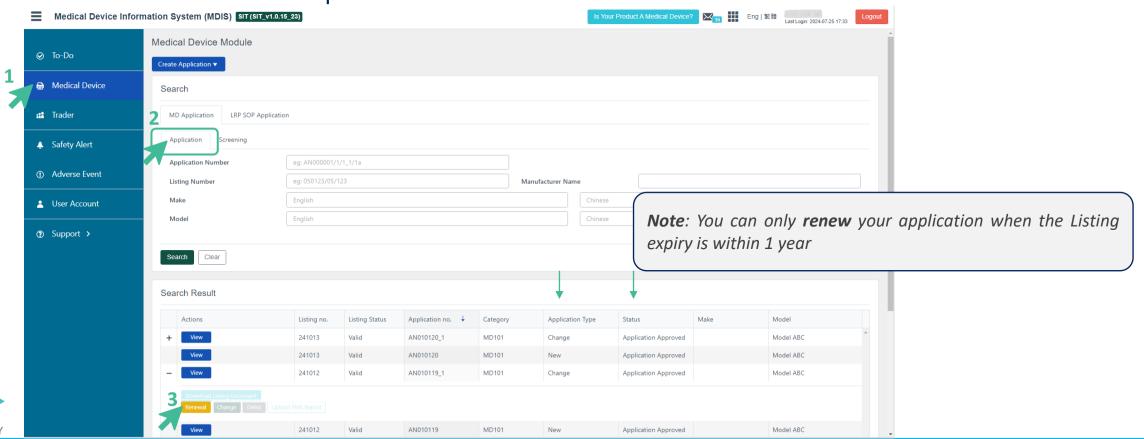
Individual User – Submit MD Application – Change Application (Batch submission) (P. 6-6)

Check acknowledge "PICS" statement before submit > Click "Submit" to save and submit the application.



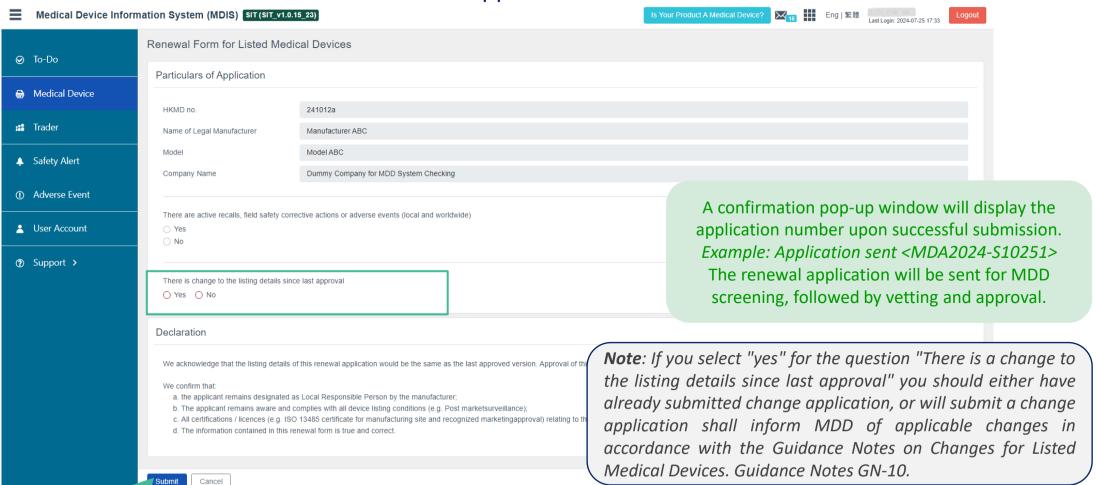
Individual User – Submit MD Application – Renewal Application (P. 1-2)

- 1. After logging into the MDIS System, click "Medical Device" to view or update applications of your individual account.
- 2. Select "MD Application" > "Application" > "Search" > Click "+"
- 3. More action buttons expanded > Click "Renewal"



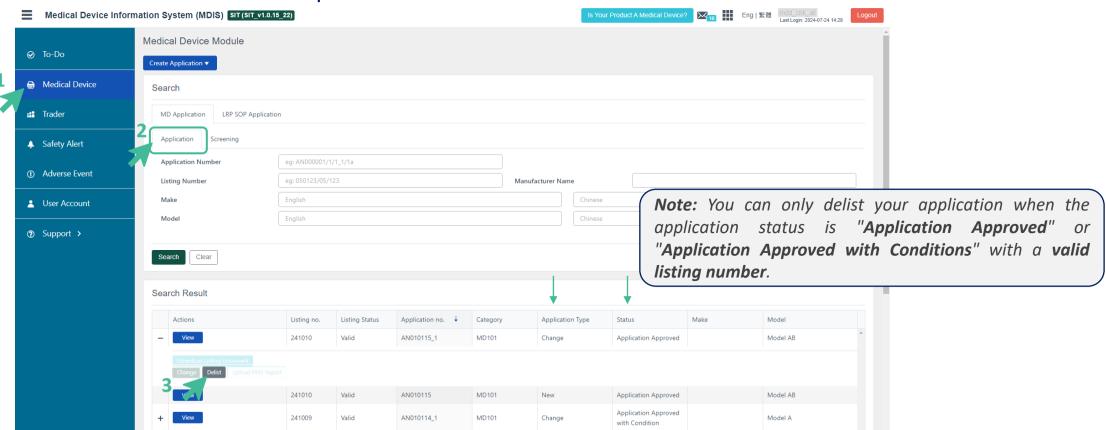
Individual User – Submit MD Application – Renewal Application (P. 2-2)

- 1. In the "Renewal Form for Listed Medical Devices", fill in all mandatory fields.
- 2. Click "Submit" to save and submit the application.



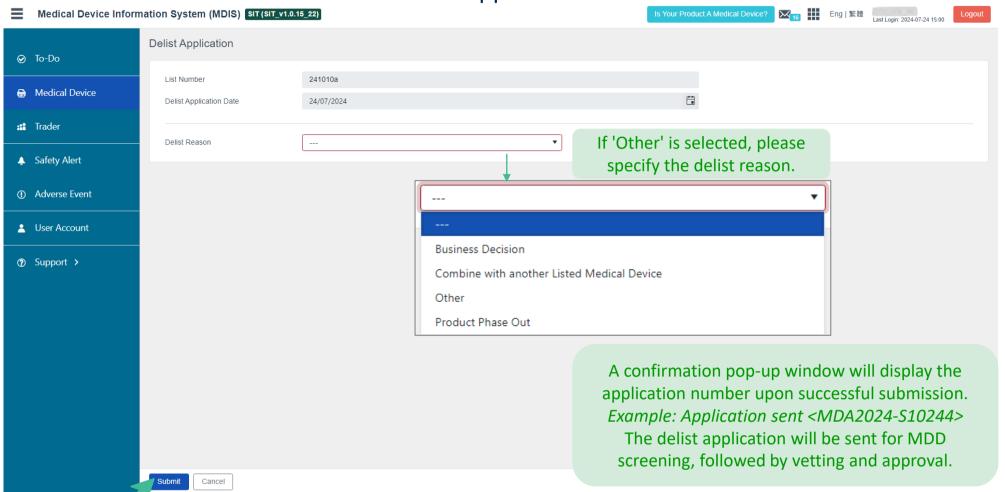
Individual User – Submit MD Application – Delist Application (P. 1-2)

- 1. After logging into the MDIS System, click "Medical Device" to view or update applications of your individual account.
- 2. Select "MD Application" > "Application" > "Search" > Click "+"
- 3. More action buttons expanded > Click "Delist"



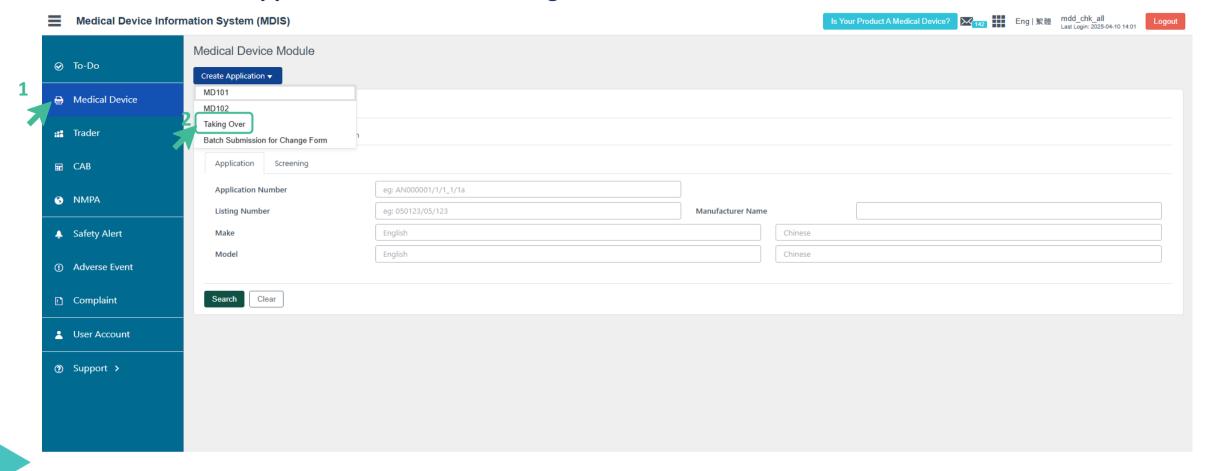
Individual User – Submit MD Application – Delist Application (P. 2-2)

- 1. In the "Delist Application", select the delist reason from drop-down.
- 2. Click "Submit" to save and submit the application.



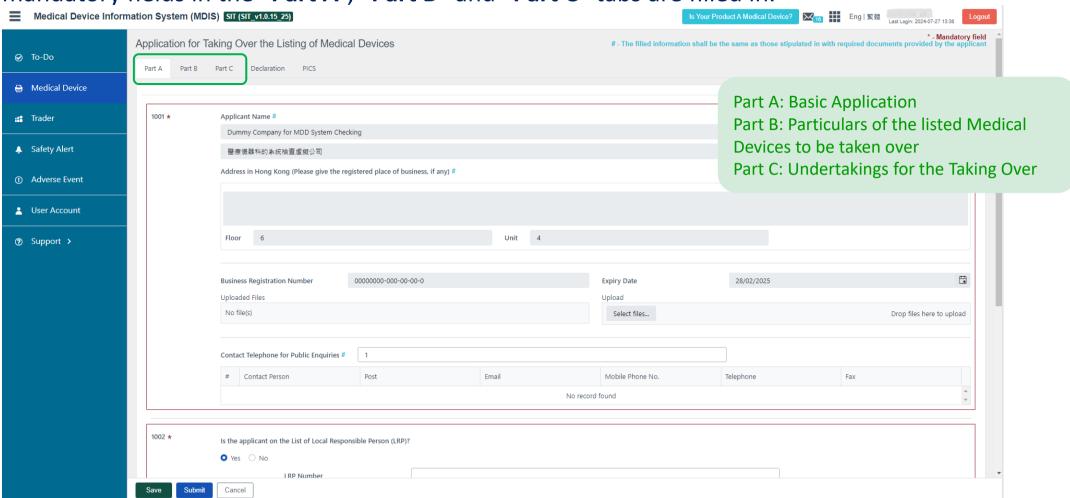
Individual User – Submit MD Application – Taking Over Application (P. 1-4)

- 1. After logging into the MDIS System, click "Medical Device" module.
- 2. Click "Create Application" > Select "Taking Over"



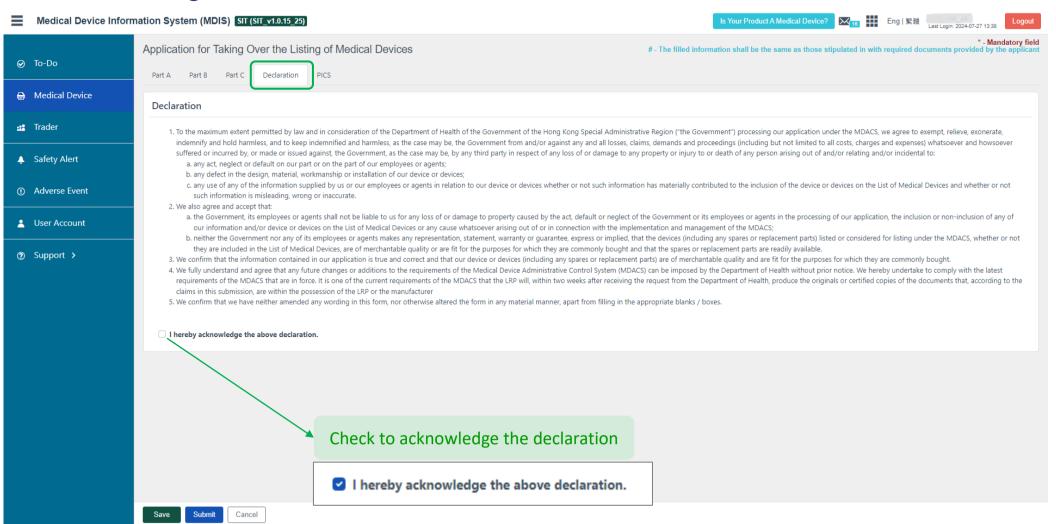
Individual User – Submit MD Application – Taking Over Application (P. 2-4)

In the "Application for Taking Over the Listing of Medical Devices", please ensure that all mandatory fields in the "Part A", "Part B" and "Part C" tabs are filled in.



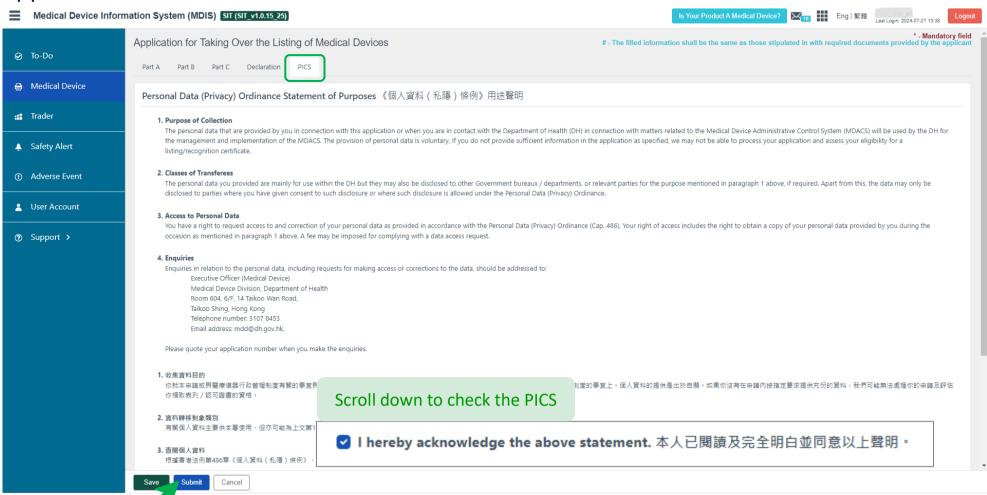
Individual User – Submit MD Application – Taking Over Application (P. 3-4)

Check acknowledge the declaration in "Declaration" tab



Individual User – Submit MD Application – Taking Over Application (P. 4-4)

Check acknowledge "PICS" statement before submit > Click "Submit" to save and submit the application.



Functionalities in Individual User Interface

- Submit Trader Application
 - New Application
 - Change Application
 - Renewal Application
 - Delist Application

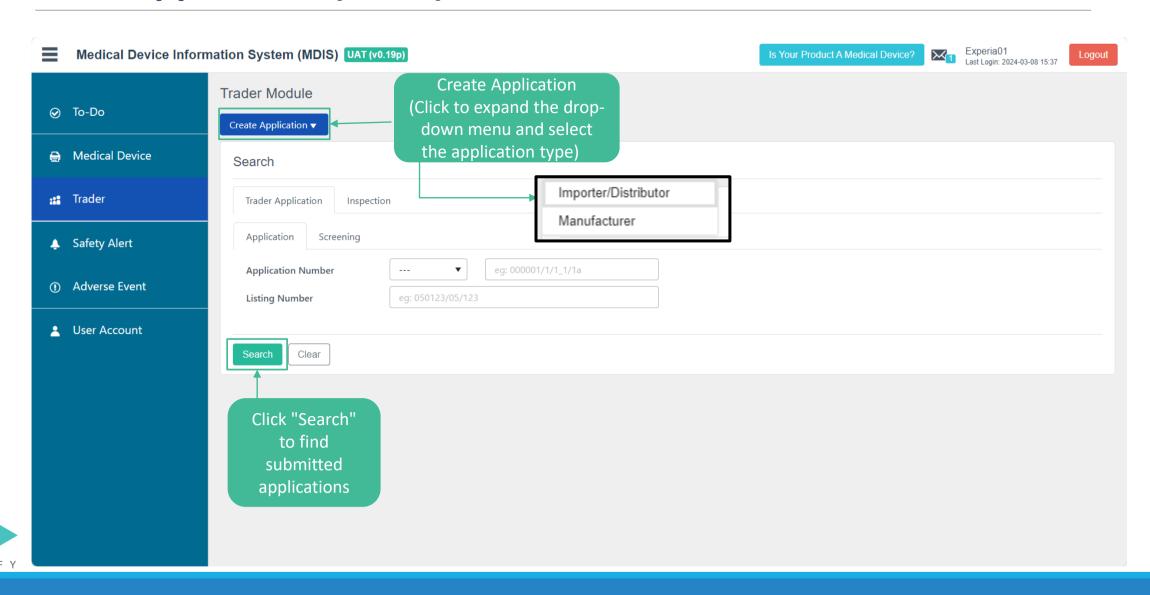


Individual User – Submit Trader Application – Preparation of application documents

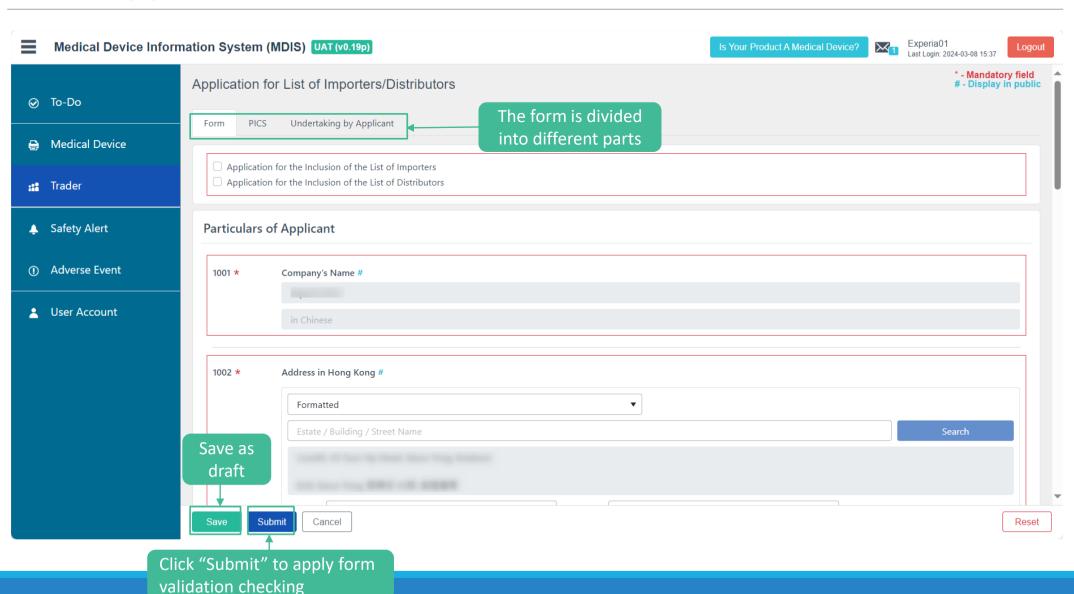
- Requirements, application procedures, guidance for completing the application form and information required for application for listing of traders, you may refer to:
 - the Guidance Notes for Listing of Importers of Medical Devices (GN-07)
 - the Guidance Notes for Listing of Local Manufacturers (GN-08)
 - the Guidance Notes for Listing of Distributors (GN-09)
- Application Forms: Importer/Distributor/ Local Manufacturer
 - Form
 - > PICS
 - Undertaking by Applicant



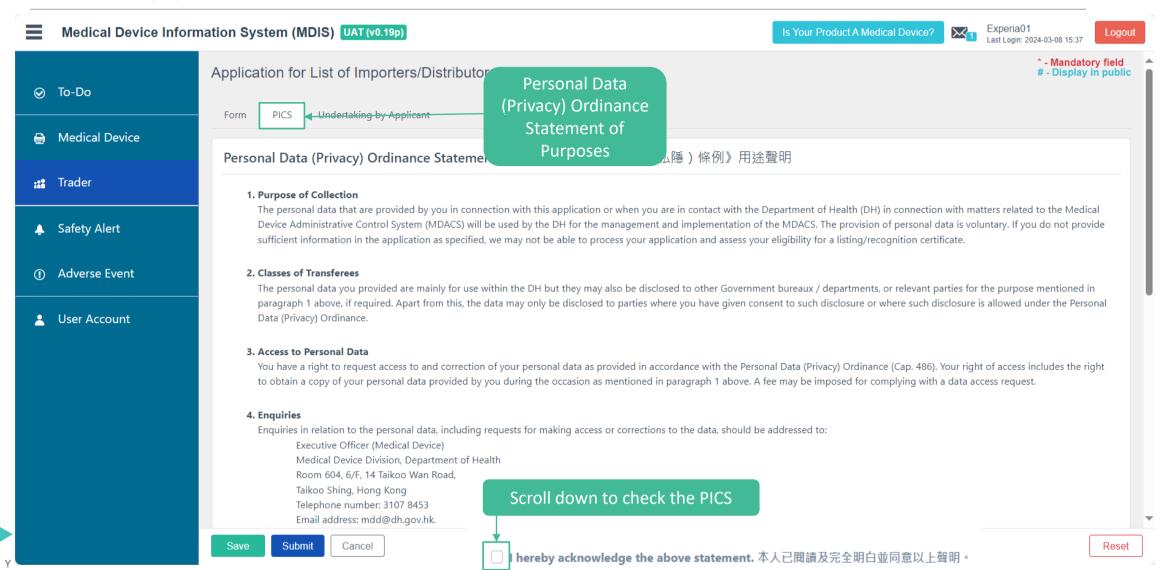
Individual User – Submit Trader Application – New Application (P. 1-5)



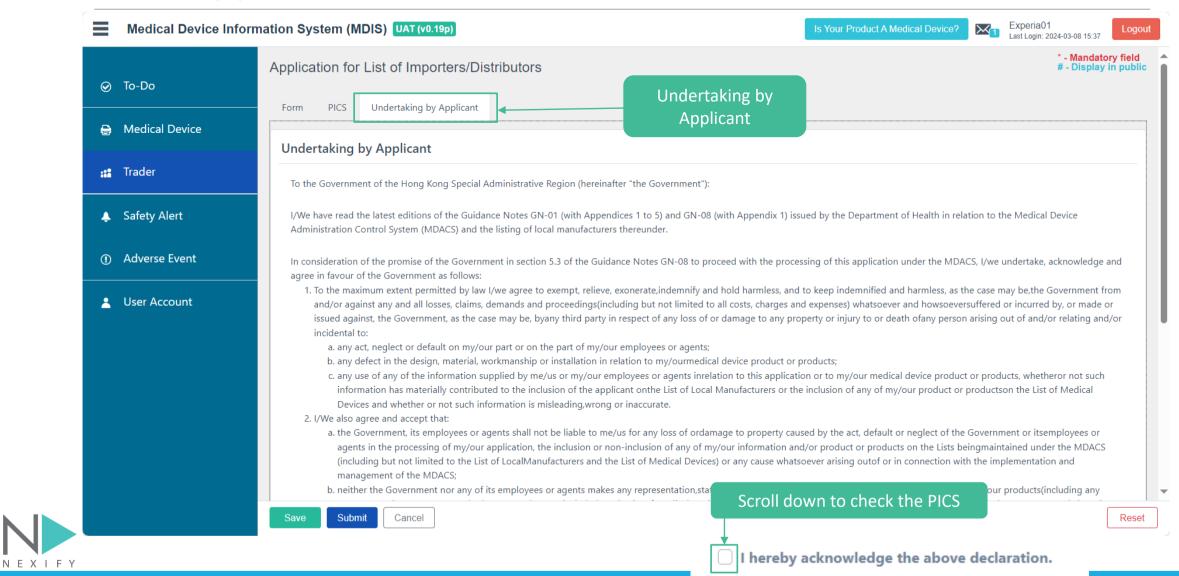
Individual User – Submit Trader Application – New Application (P. 2-5)



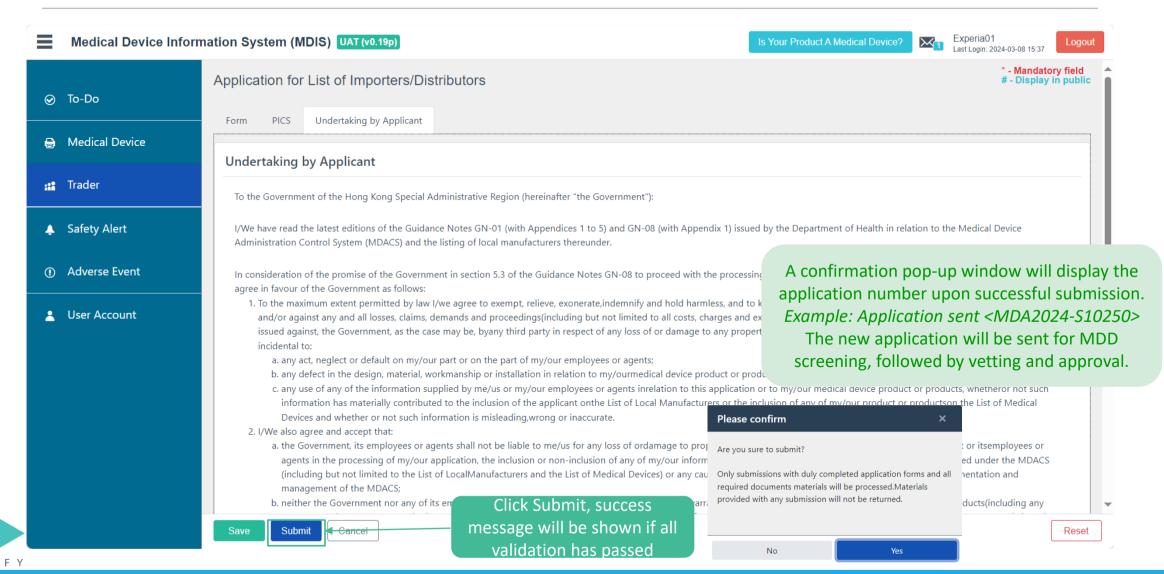
Individual User – Submit Trader Application – New Application (P. 3-5)



Individual User – Submit Trader Application – New Application (P. 4-5)



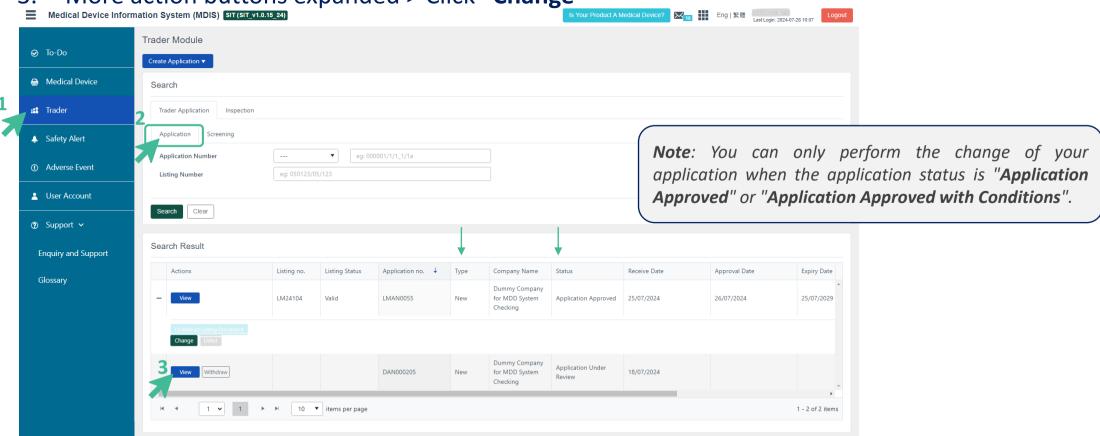
Individual User – Submit Trader Application – New Application (P. 5-5)



Individual User – Submit Trader Application – Change Application (P. 1-4)

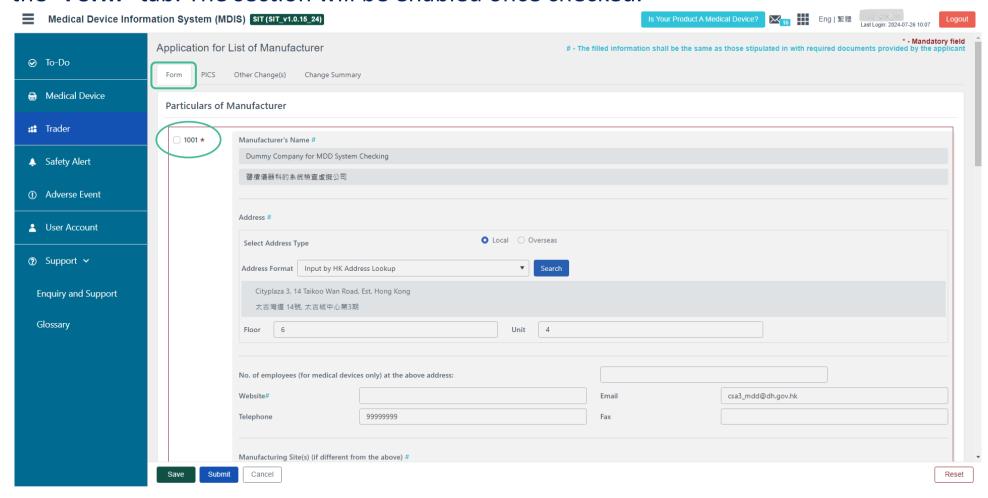
- 1. After logging into the MDIS System, click "**Trader**" to view or update applications of your individual account.
- 2. Select "Trader Application" > "Application" > "Search" > Click "+"

3. More action buttons expanded > Click "Change"



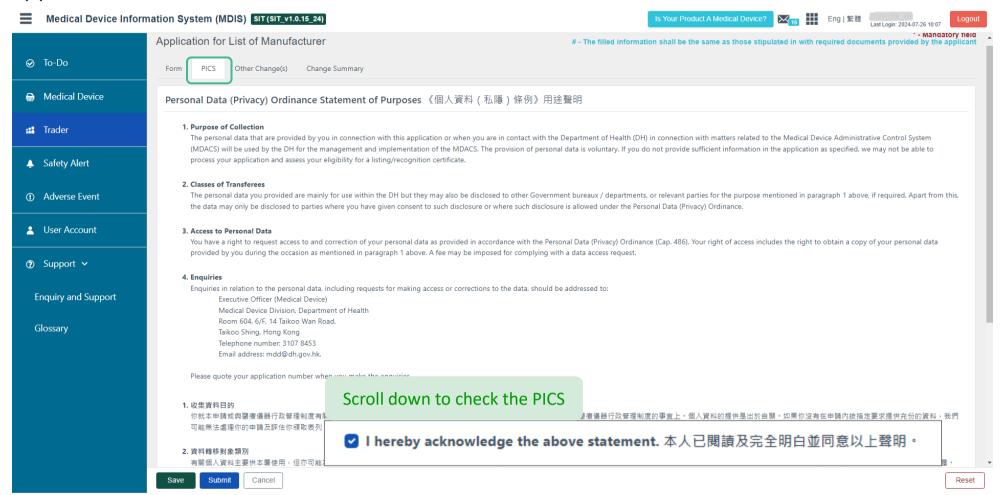
Individual User – Submit Trader Application – Change Application (P. 2-4)

The previous form content will be displayed. Check the section(s) you would like to change in the "Form" tab. The section will be enabled once checked.



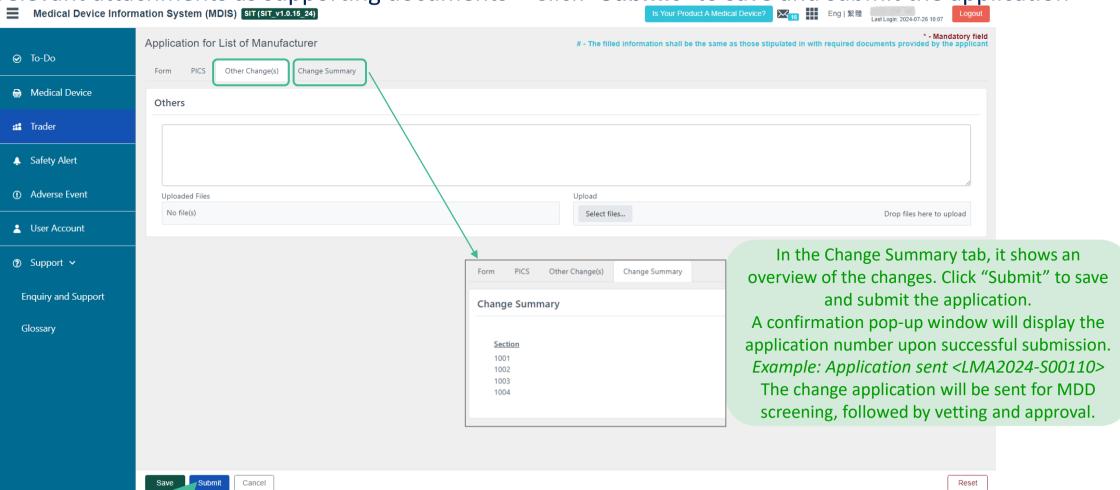
Individual User – Submit Trader Application – Change Application (P. 3-4)

Check acknowledge "PICS" statement before submit > Click "Submit" to save and submit the application.



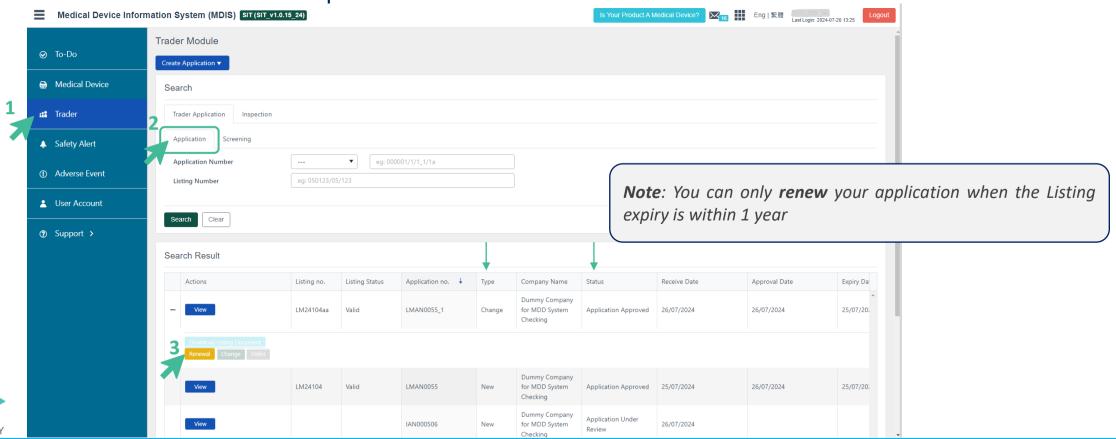
Individual User – Submit Trader Application – Change Application (P. 4-4)

If there is additional information to be changed, please fill in "Other Change(s)" tab and upload any relevant attachments as supporting documents > Click "Submit" to save and submit the application



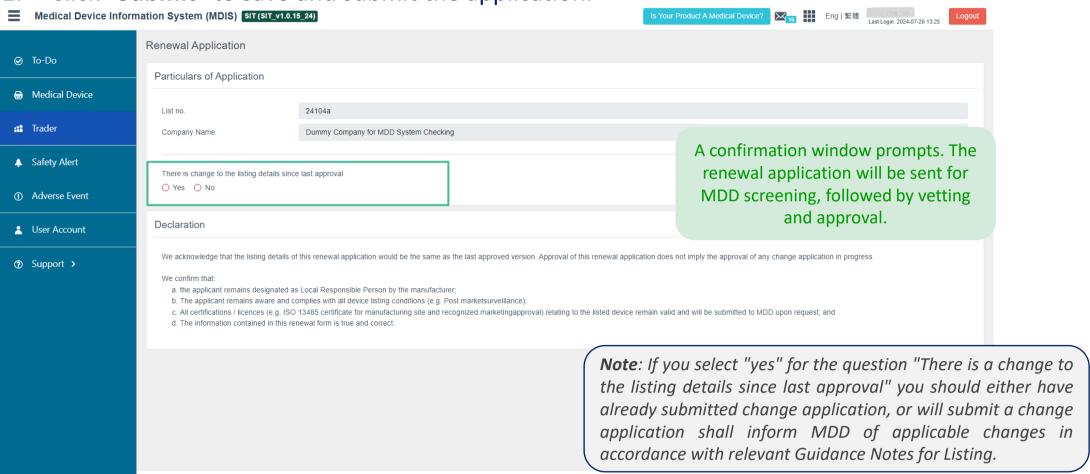
Individual User – Submit Trader Application – Renewal Application (P. 1-2)

- 1. After logging into the MDIS System, click "**Trader**" to view or update applications of your individual account.
- 2. Select "Trader Application" > "Application" > "Search" > Click "+"
- More action buttons expanded > Click "Renewal"



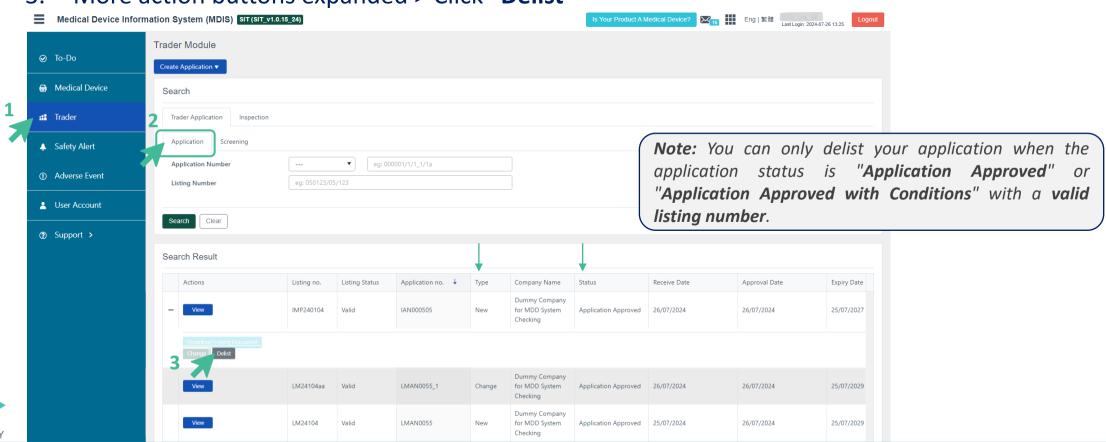
Individual User – Submit Trader Application – Renewal Application (P. 2-2)

- 1. In the Renewal Form, fill in all mandatory fields.
- 2. Click "Submit" to save and submit the application.



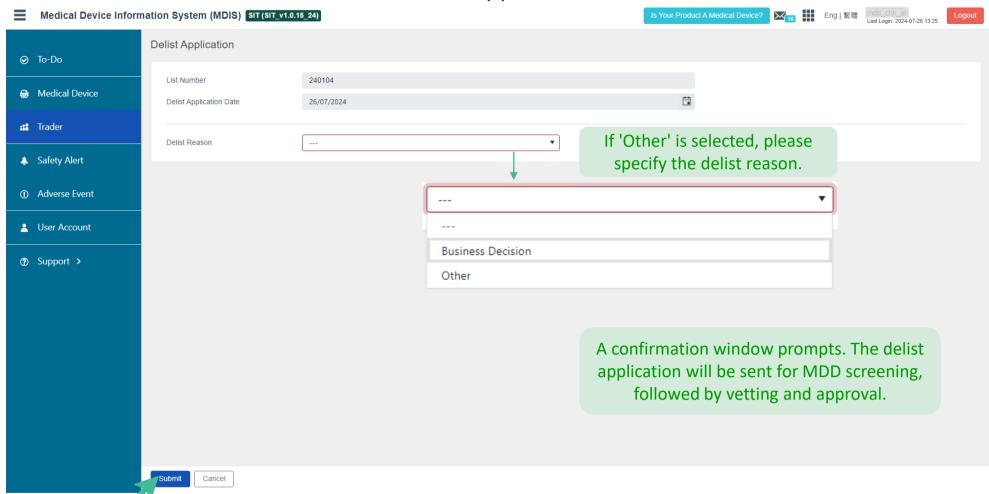
Individual User – Submit Trader Application – Delist Application (P. 1-2)

- 1. After logging into the MDIS System, click "**Trader**" to view or update applications of your individual account.
- 2. Select "Trader Application" > "Application" > "Search" > Click "+"
- More action buttons expanded > Click "Delist"



Individual User – Submit Trader Application – Delist Application (P. 2-2)

- 1. In the "Delist Application", select the delist reason from drop-down.
- 2. Click "Submit" to save and submit the application.



Functionalities in Individual User Interface

- Submit CAB Application
 - New Application
 - Change Application
 - Cease Recognition Application

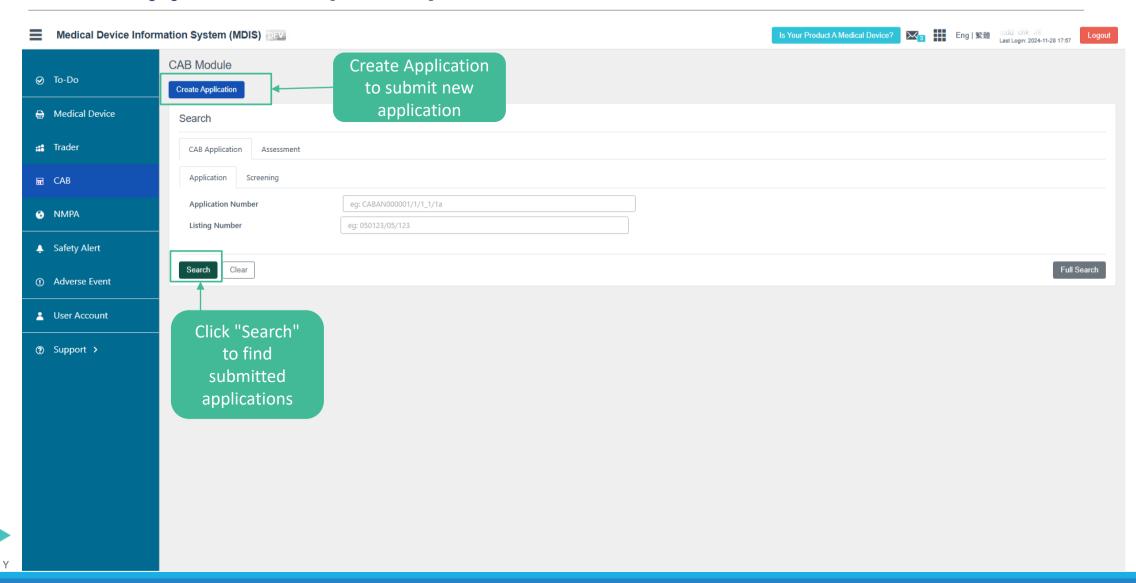


Individual User – Submit CAB Application – Preparation of application documents

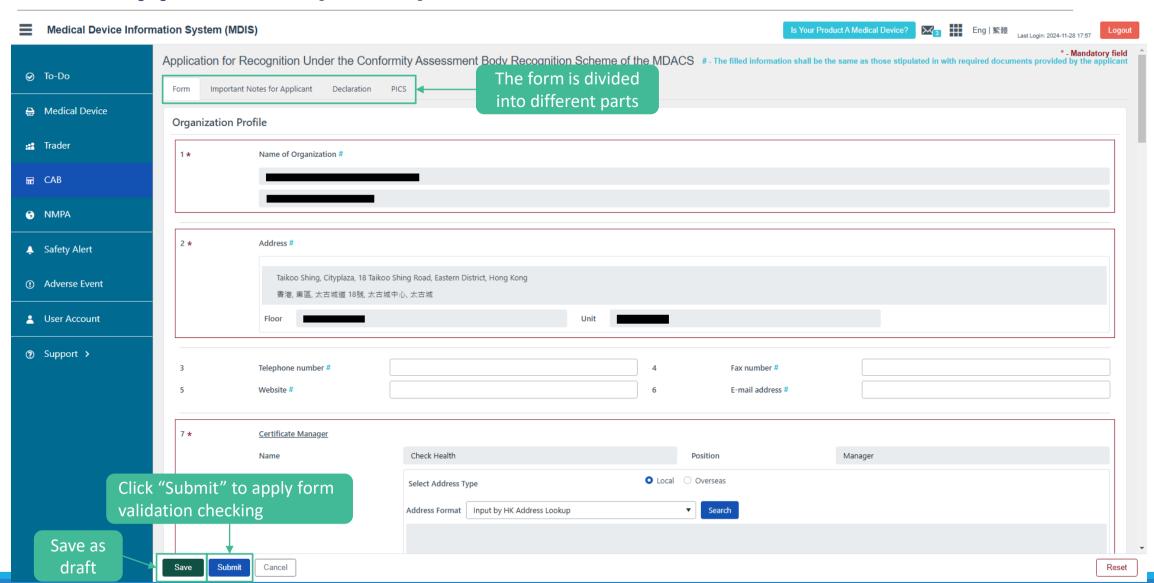
- Requirements, application procedures, guidance for completing the application form and information required for application for recognition of CAB, you may refer to:
 - the Conformity Assessment Framework and Conformity Assessment Bodies (GN-04)
- Application Form:
 - > Form
 - Important Notes for Applicant
 - Declaration
 - > PICS



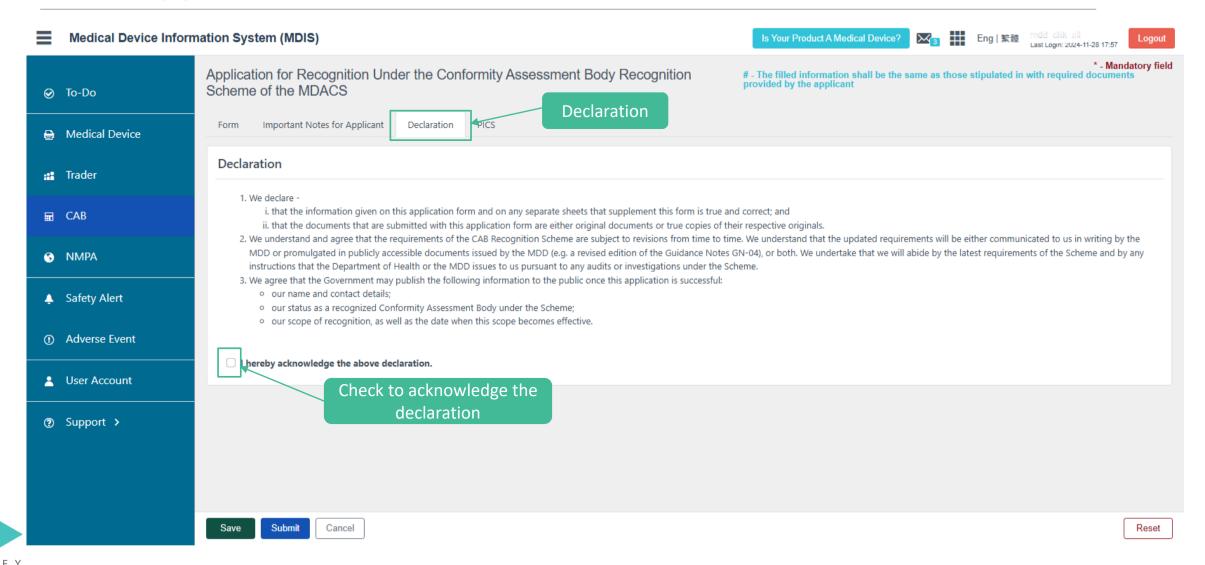
Individual User – Submit CAB Application – New Application (P. 1-5)



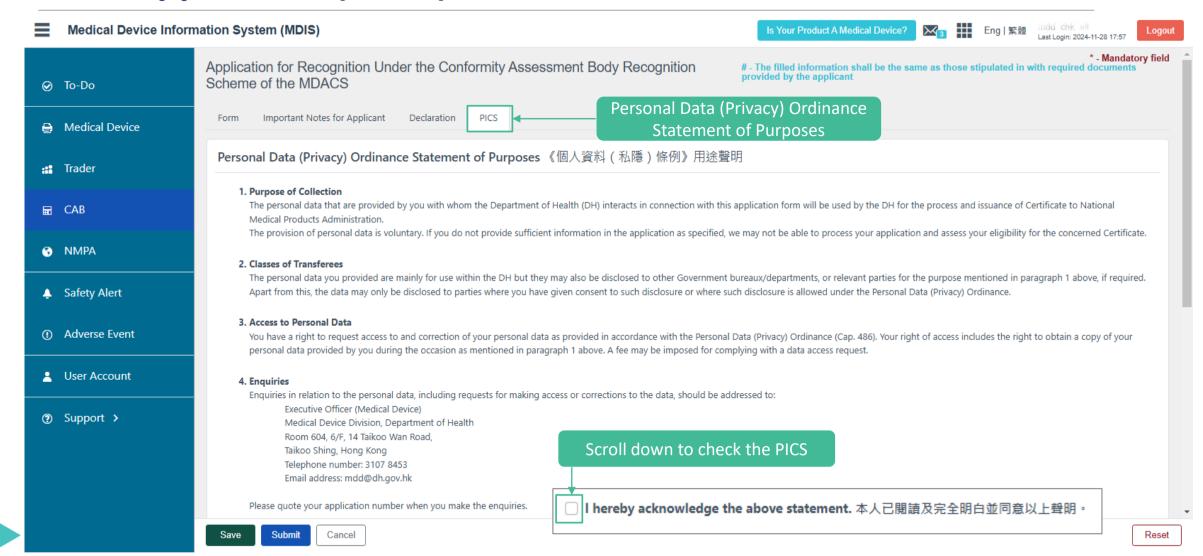
Individual User – Submit CAB Application – New Application (P. 2-5)



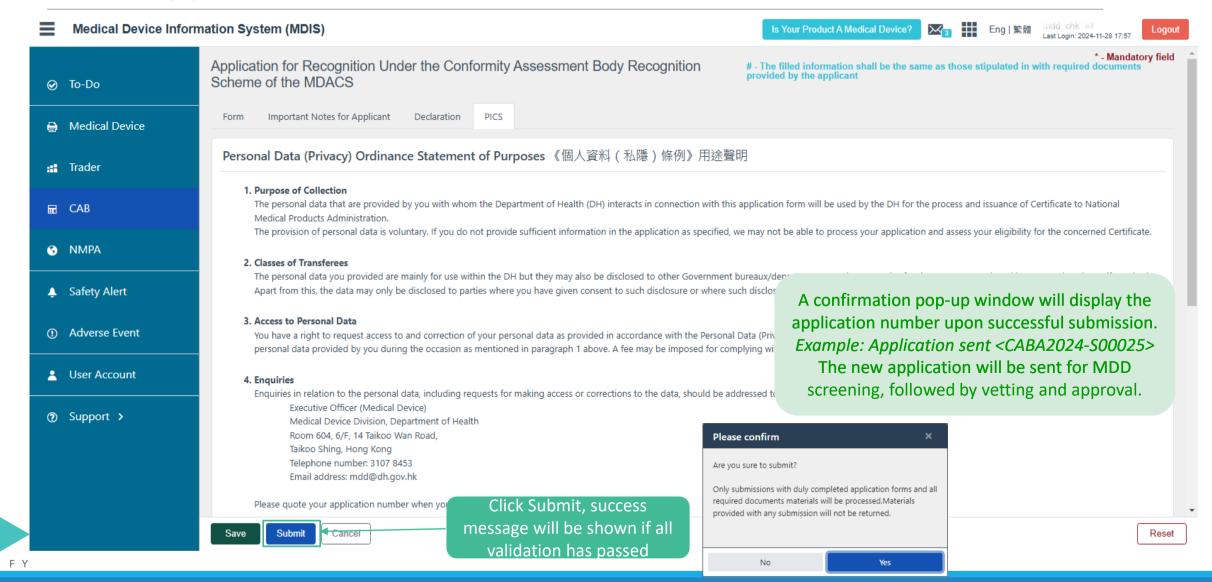
Individual User – Submit CAB Application – New Application (P. 3-5)



Individual User – Submit CAB Application – New Application (P. 4-5)

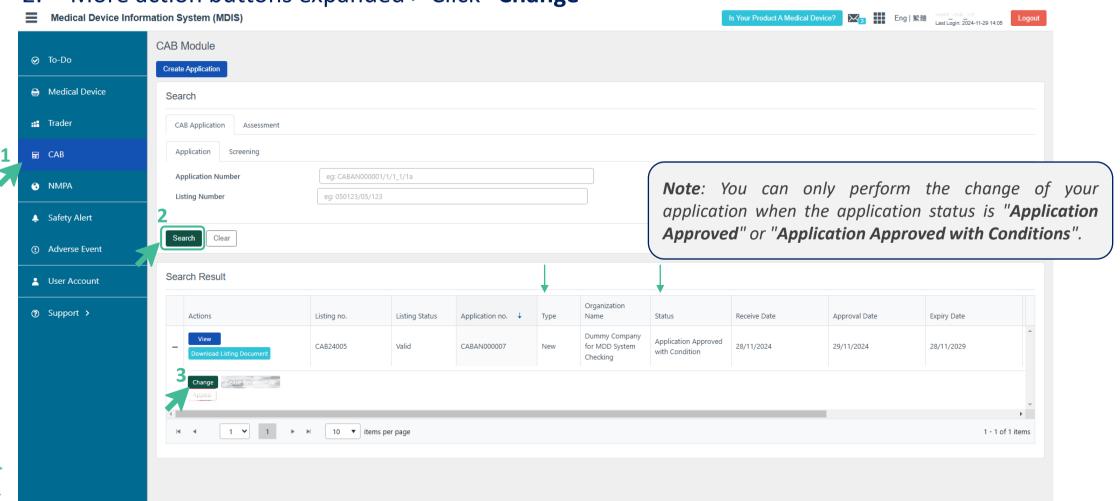


Individual User – Submit CAB Application – New Application (P. 5-5)



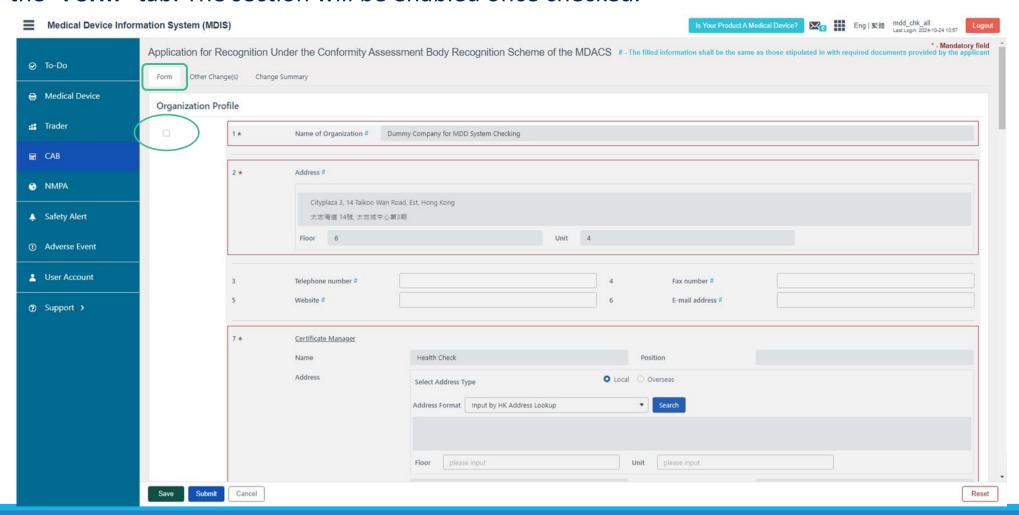
Individual User – Submit CAB Application – Change Application (P. 1-3)

- 1. In "CAB" module, select "CAB Application" > "Application" > "Search" > Click "+"
- 2. More action buttons expanded > Click "Change"



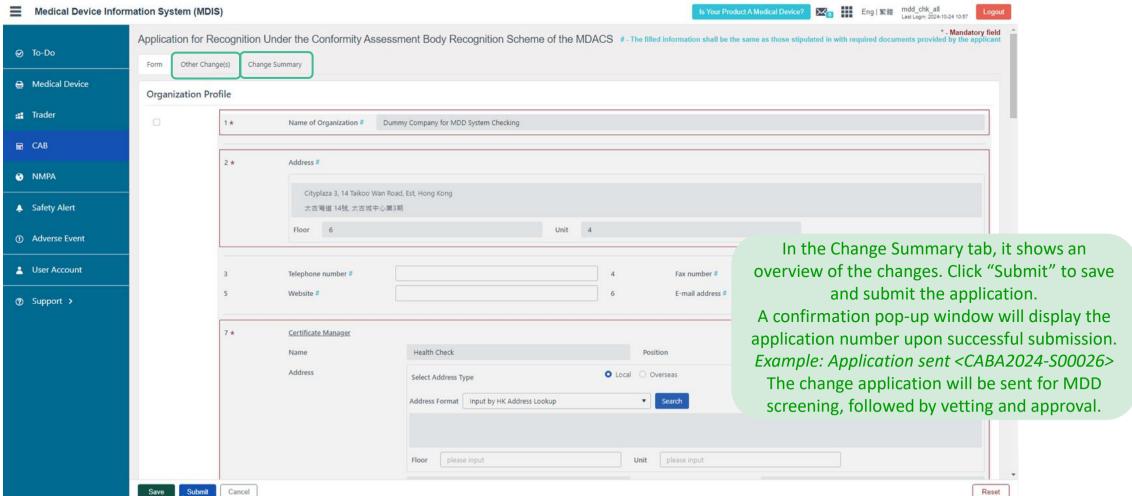
Individual User – Submit CAB Application – Change Application (P. 2-3)

The previous form content will be displayed. Check the section(s) you would like to change in the "Form" tab. The section will be enabled once checked.



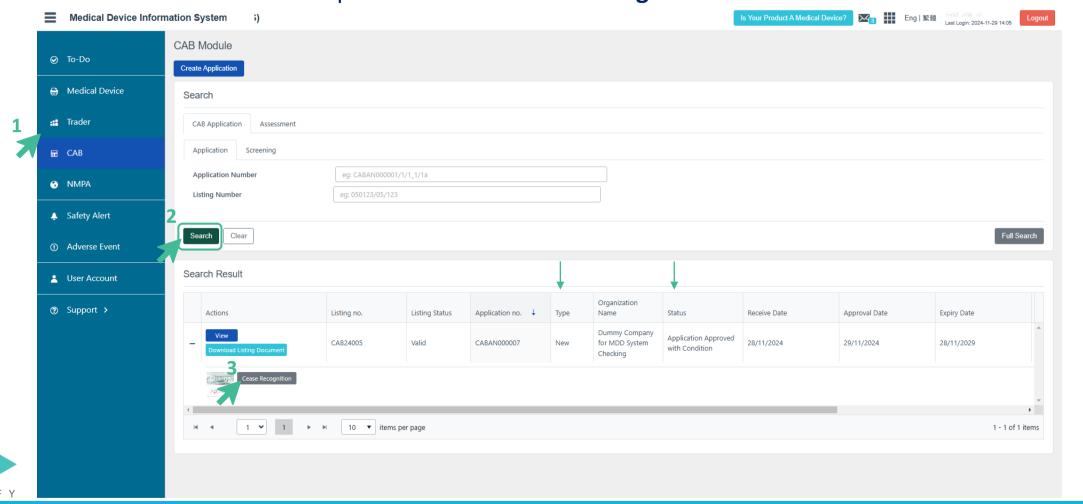
Individual User – Submit CAB Application – Change Application (P. 3-3)

If there is additional information to be changed, please fill in "Other Change(s)" tab and upload any relevant attachments as supporting documents > Click "Submit" to save and submit the application



Individual User – Submit CAB Application – Cease Recognition Application (P. 1-2)

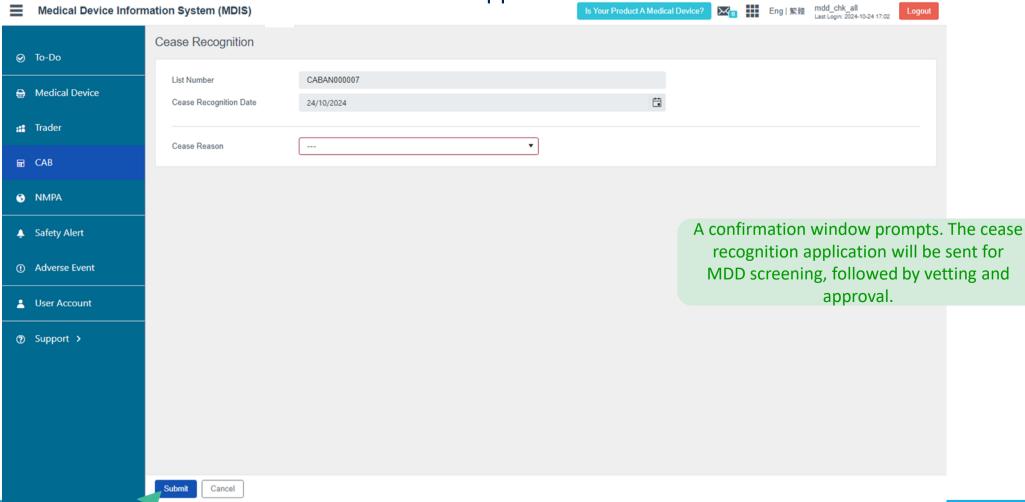
- 1. In "CAB" module, select "CAB Application" > "Application" > "Search" > Click "+"
- 2. More action buttons expanded > Click "Cease Recognition"



Individual User – Submit CAB Application – Cease Recognition Application (P. 2-2)

1. In the "Cease Recognition", select the cease reason from drop-down.

2. Click "**Submit**" to save and submit the application.

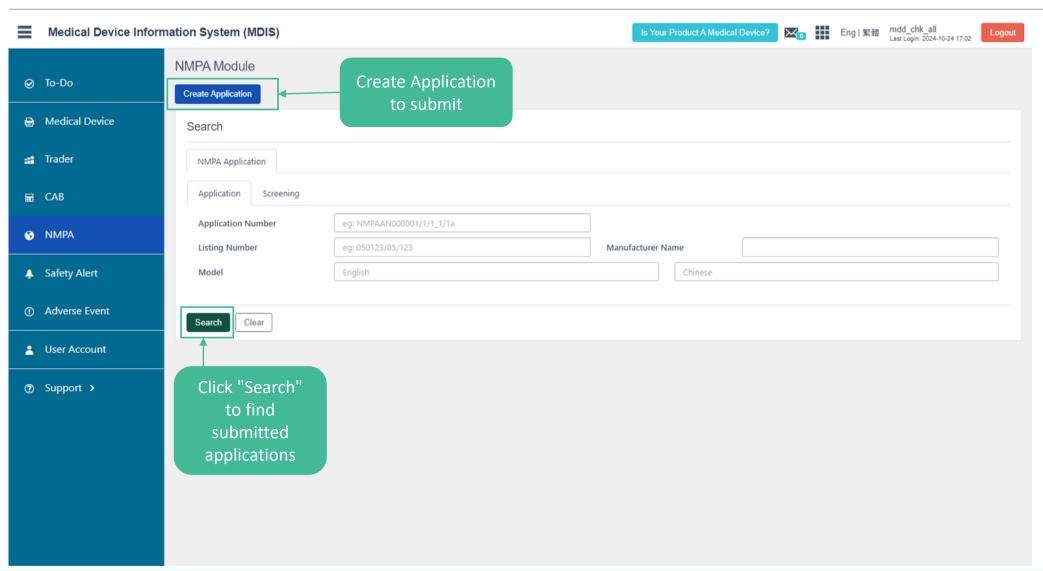


Functionalities in Individual User Interface

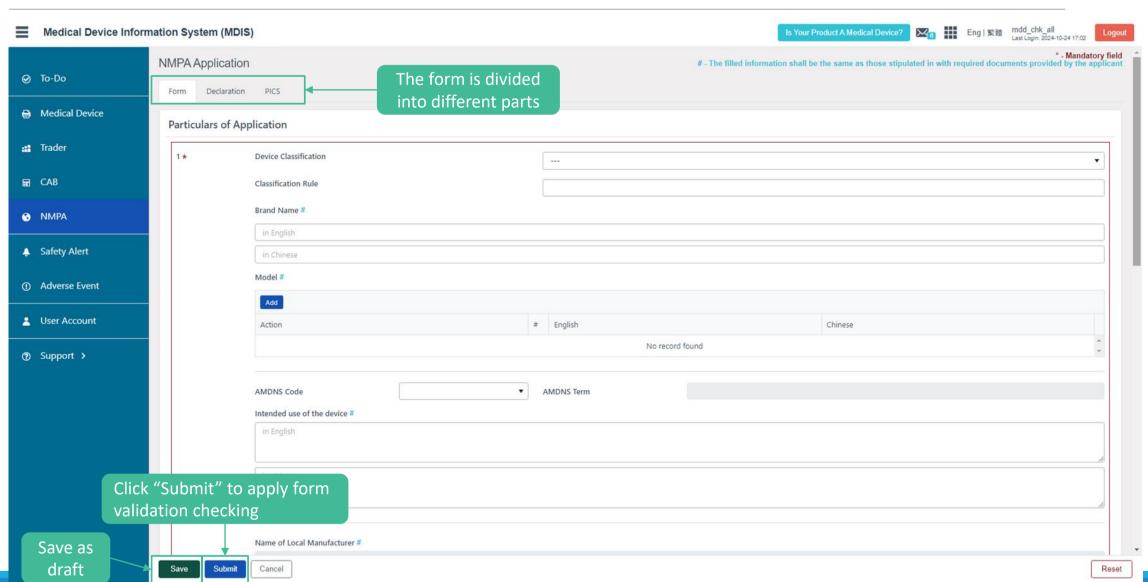
Submit NMPA Application



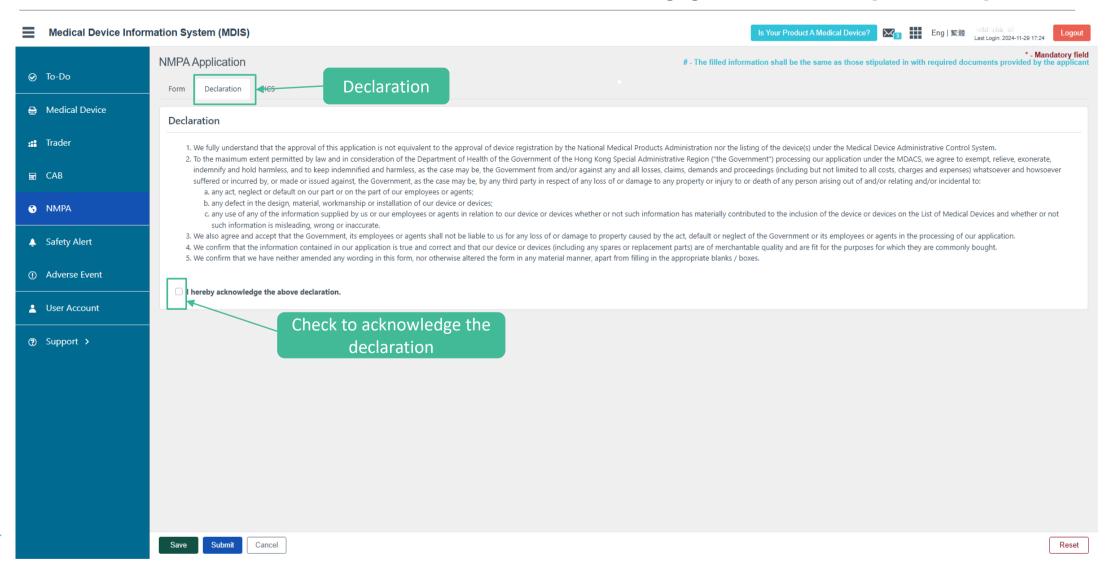
Individual User – Submit NMPA Application (P. 1-5)



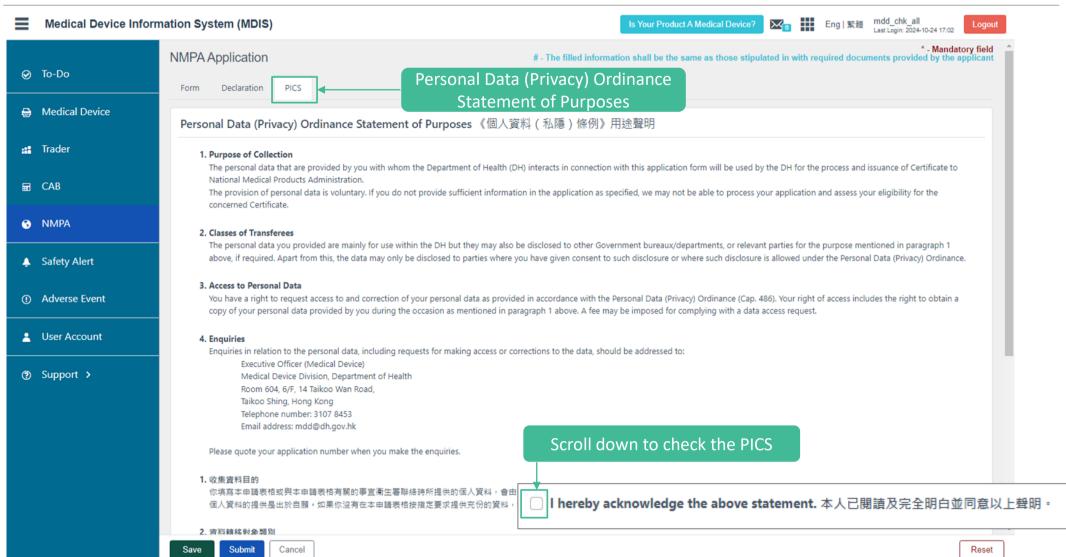
Individual User – Submit NMPA Application (P. 2-5)



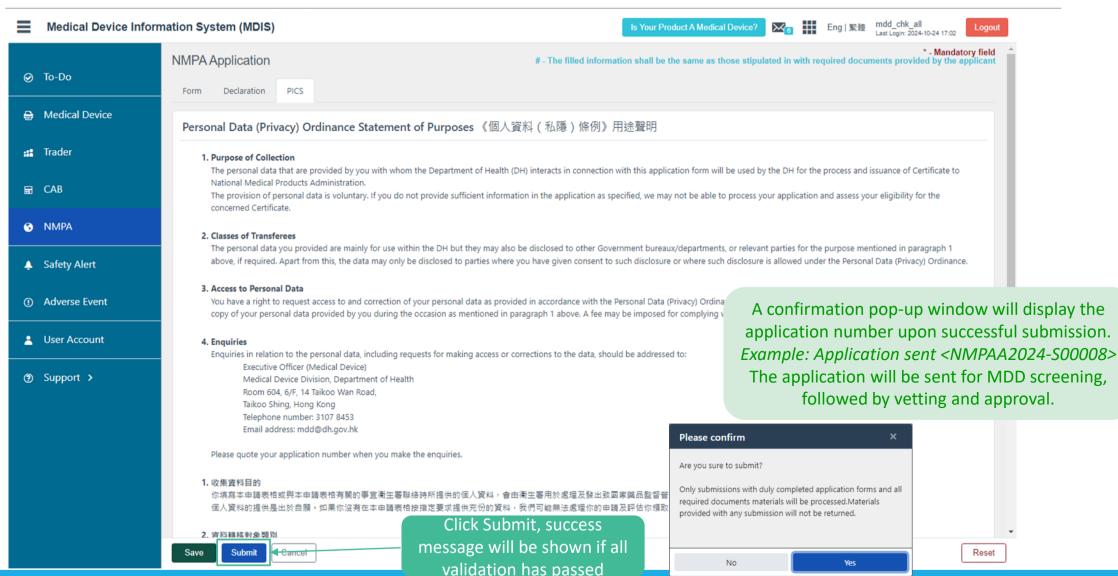
Individual User - Submit NMPA Application (P. 3-5)



Individual User - Submit NMPA Application (P. 4-5)



Individual User - Submit NMPA Application (P. 5-5)

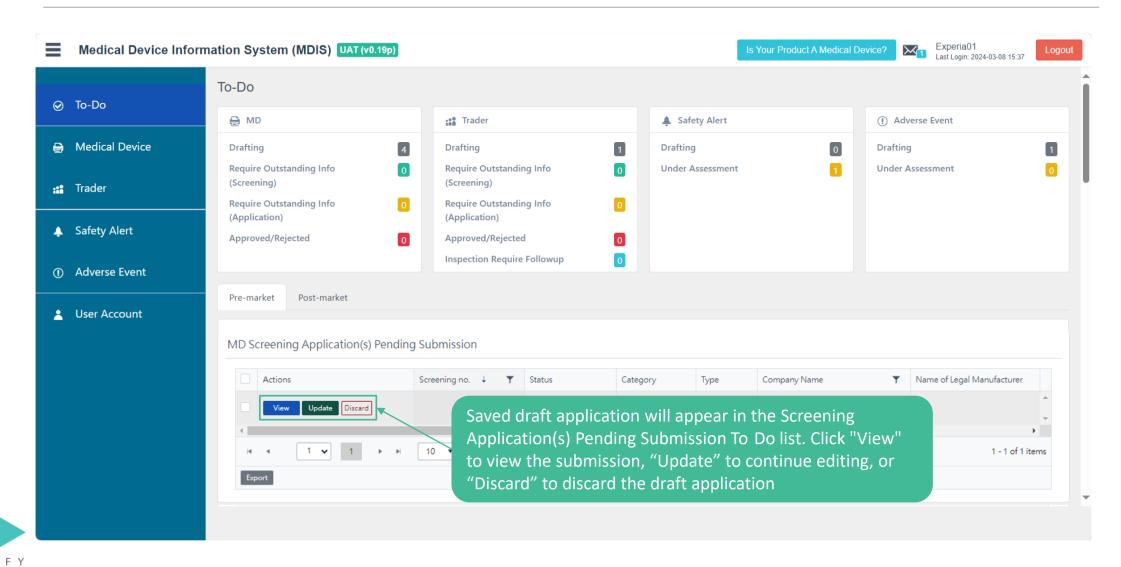


Functionalities in Individual User Interface

- Other application-related matters
 - Access draft application
 - Check application status
 - Responding to Application Enquiries
 - Withdraw application
 - Download Listing Certificates

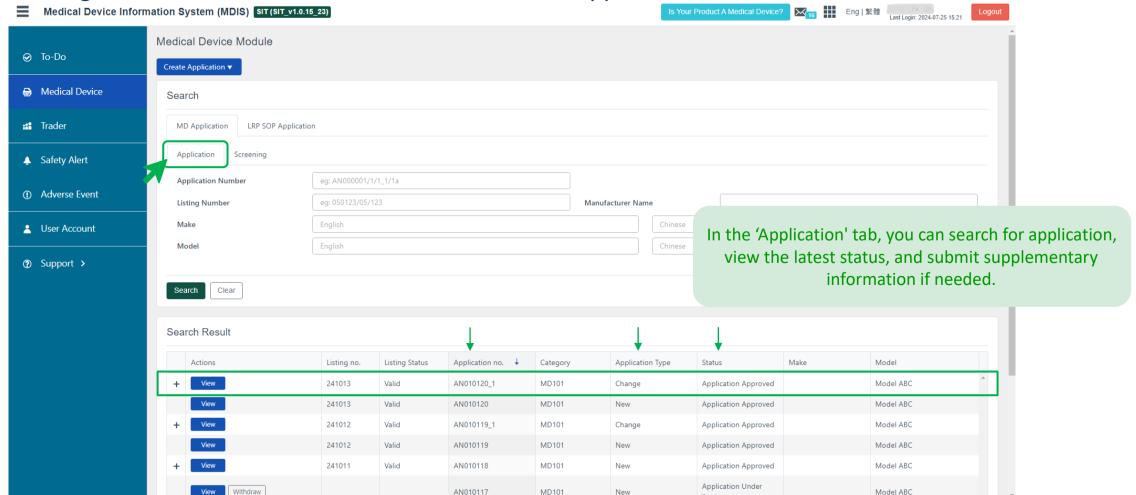


Individual Users – Access draft Application



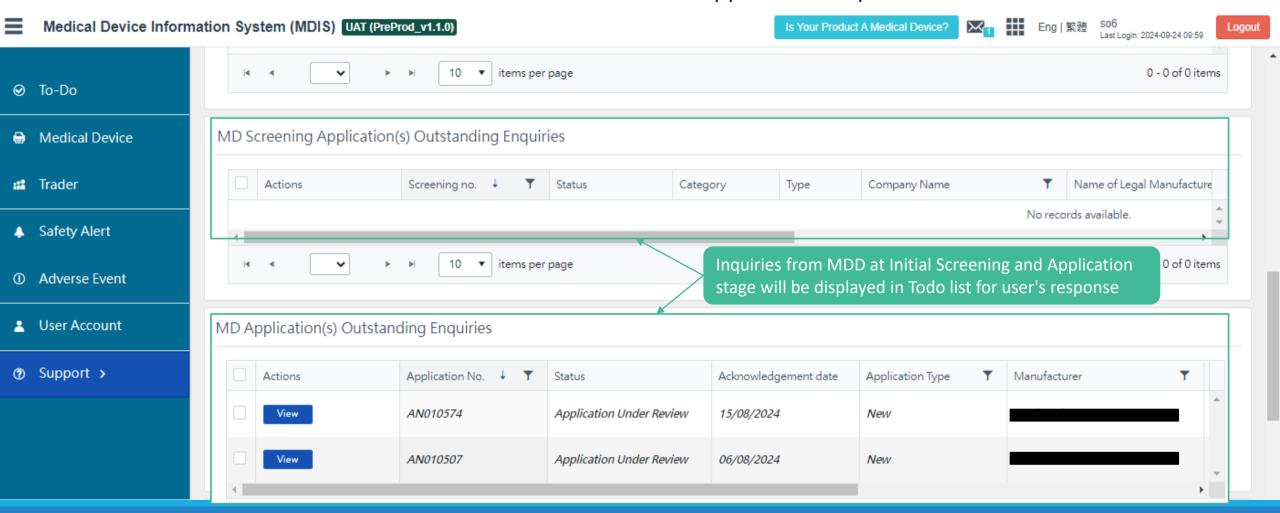
Individual Users – Check Application status

The status will be updated according to MDD's procedures. You can check the latest status by clicking "Medical Device" / "Trader" and search the application record of interest.



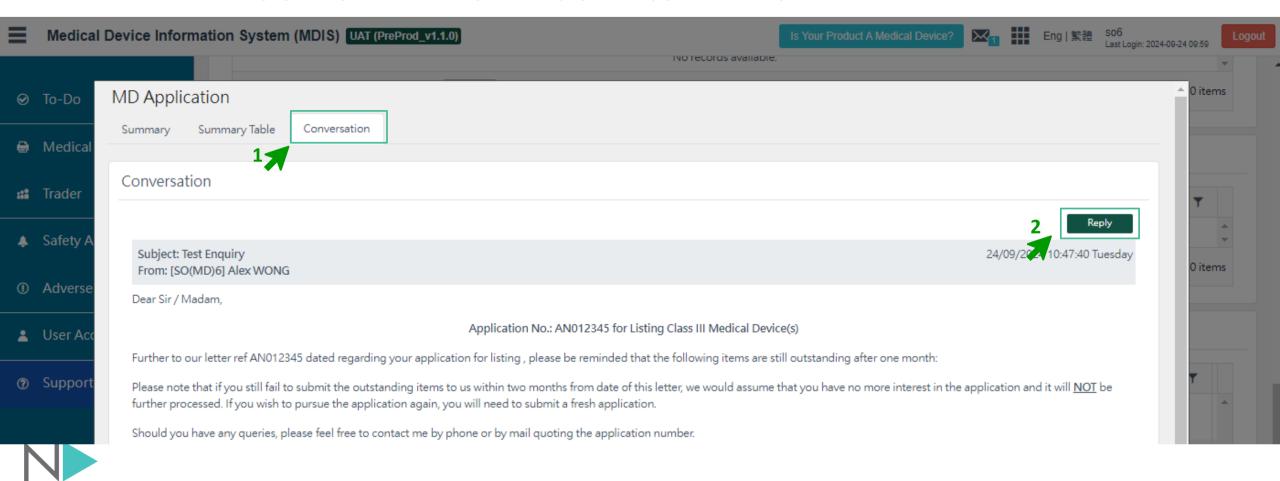
Individual Users – Responding to Application Enquiries

After receiving notification email for new message from a particular application number, you can access the To-Do list in the Individual account for the application required action



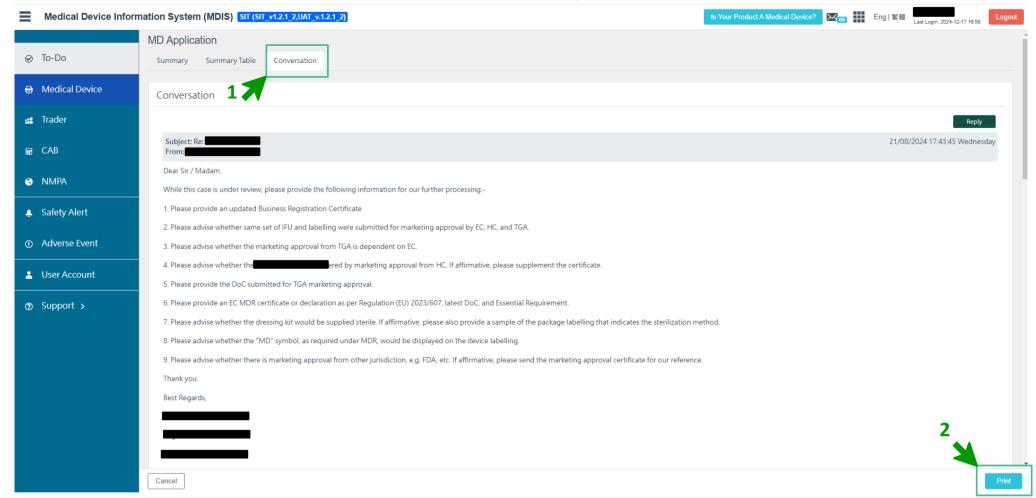
Individual Users – Responding to Application Enquiries

- 1. Access "Conversation" tab for the application to view the enquiry from MDD
- 2. Click "Reply" to provide complete reply or supplementary information



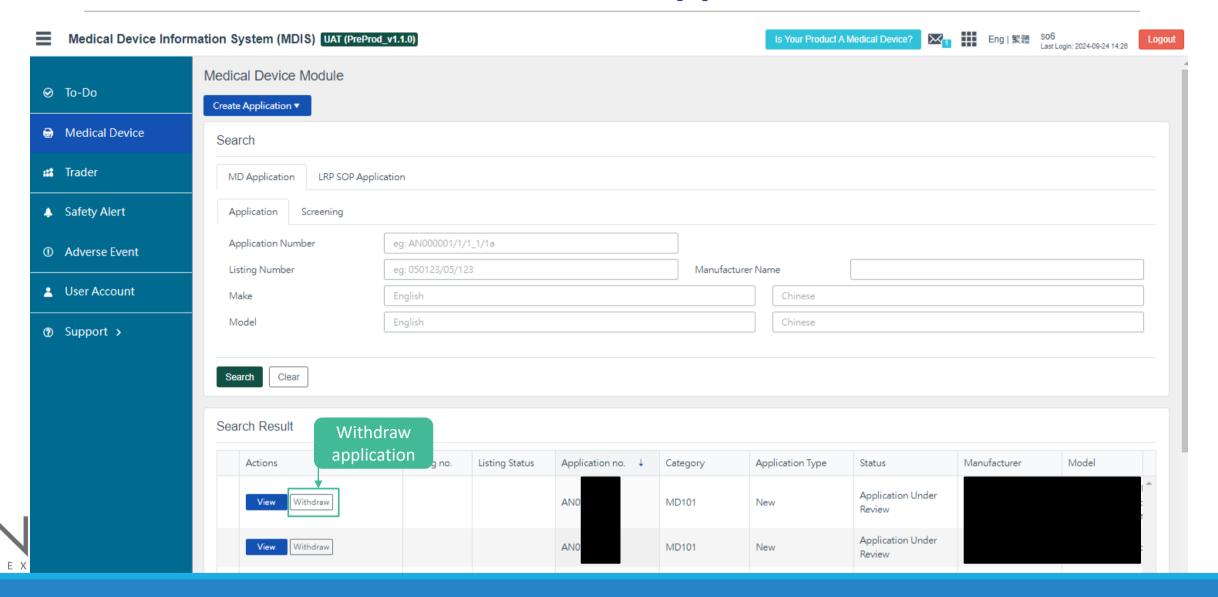
Individual Users – Export Application Enquiries

- 1. Access "Conversation" tab for the application to view the enquiry from MDD
- 2. Click "Print" to export all conversations for the application



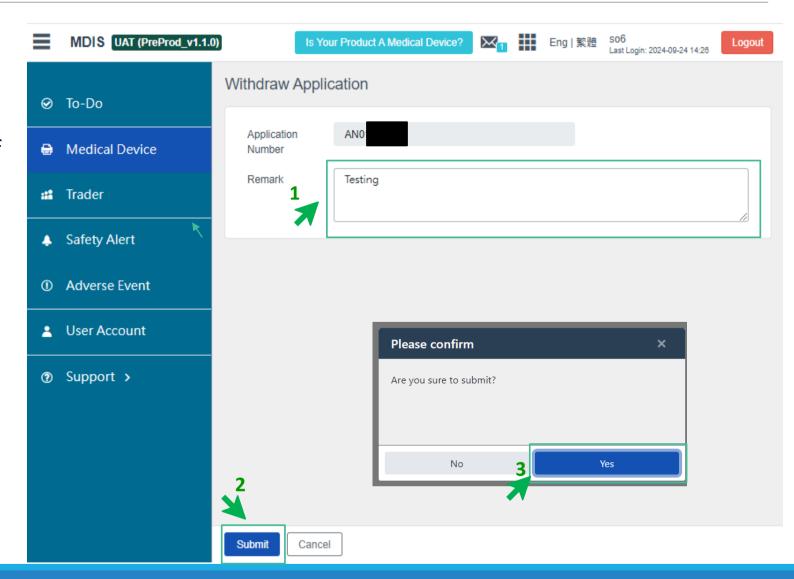


Individual Users – Withdraw Application



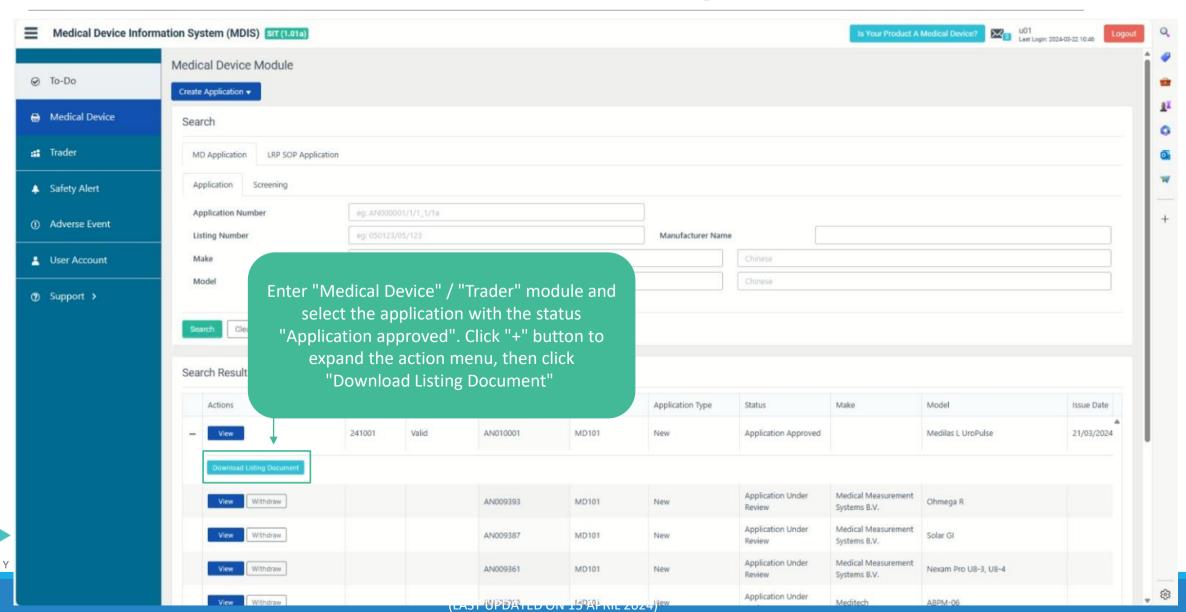
Individual Users – Withdraw Application

- 1. Enter remarks
- 2. Click "Submit"
- 3. Press "Yes" and confirm dialog box to confirm submission of withdrawal request





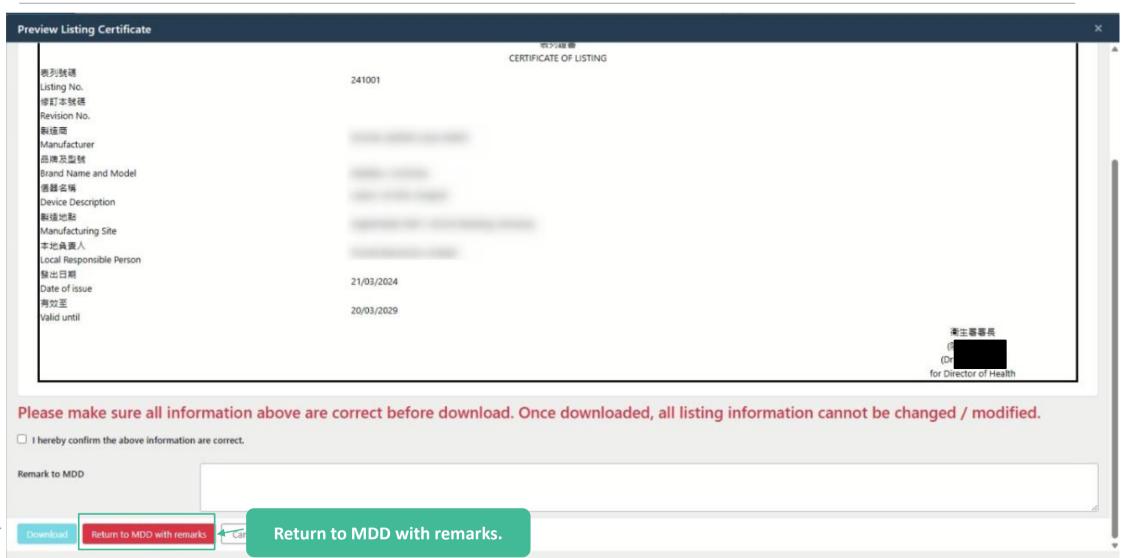
Individual Users – Download Listing Certificates (P. 1-3)



Individual Users – Download Listing Certificates (P. 2-3)



Individual Users – Download Listing Certificates (P. 3-3)



Overview of Application Status (Initial Screening stage)

Application Status	Interpretation
Drafting	When the applicant clicked "Save" to a created application before submit. Drafting applications can be stored in MDIS for up to 3 months
Application submitted	The applicant clicked "Submit" and the application has been successfully submitted
Application Acknowledged	The application has been screened by MDD
Application Closed	The application has been closed by MDD
Withdraw request submitted	The applicant clicked "withdraw" and submitted the withdrawal request
Application withdrawn	MDD confirmed the applicant's withdrawal request



Overview of Application Status (Application stage)

Application Status	Interpretation
Application Under Review	The application is being reviewed by MDD's vetting officer
Application Closed	The application has been closed by MDD
Withdraw request submitted	The applicant clicked "withdraw" and submitted the withdrawal request
Application withdrawn	MDD confirmed the applicant's withdrawal request
Application Approved	The application is approved. The applicant can download the certificate from the MDIS.
Application Approved with Condition	The application is approved with conditions given by MDD. The applicant can download the certificate from the MDIS.
Application Rejected	The application is rejected. The applicant can download the reject letter from the MDIS.
Delist Application Approved	The delist application is approved. The applicant can download the delist letter from the MDIS.



Enquiry and Support

- Please reach out to our dedicated MDIS technical support team at 3702 5356 or email at mdis_support@nexify.com.hk whenever necessary.
- For other general enquiries related to applications under MDACS, please contact Medical Device Division at 3107 8484 or email at mdd@dh.gov.hk.

