

Training on Medical Device Information System (MDIS)

PART II: APPLICATION FOR NEW LISTING



Agenda

- 1) Introduction
- 2) Functionalities in Trader User Interface
- 3) Functionalities in Individual User Interface
- 4) Q&A



User Roles

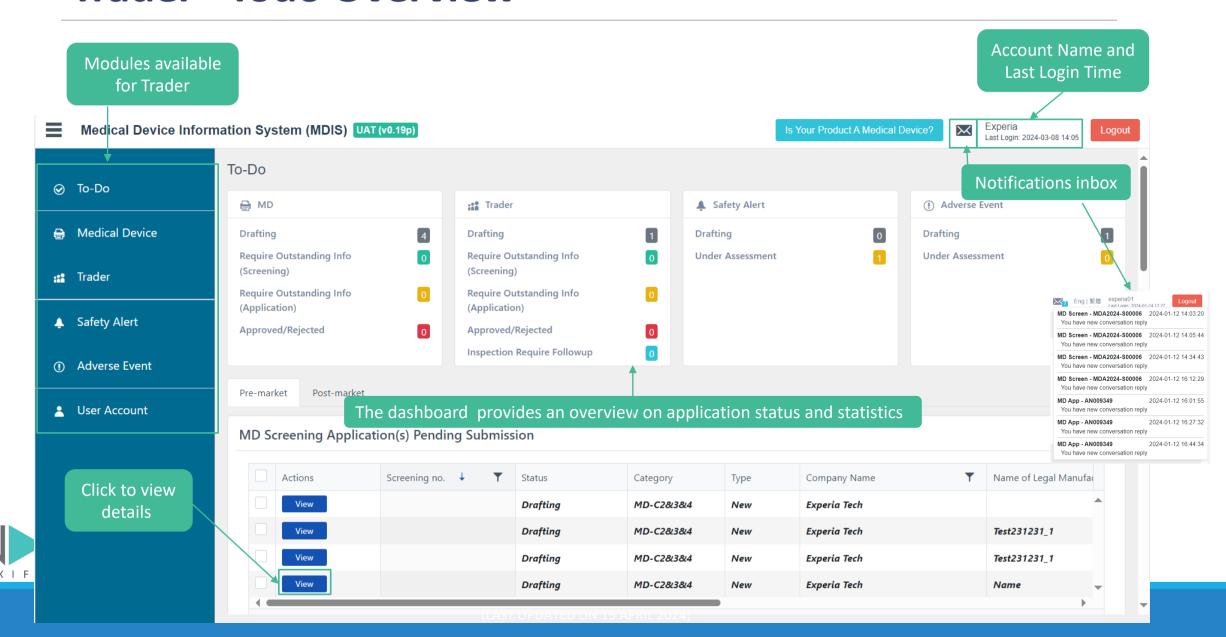
Two levels of accounts: External Trader User & External Individual User

Account Type	External Trader User (ETU)	External Individual User (EIU)
Pre-requisite	Valid BR certificate	Valid Trader User Account
Roles and Functions	 Maintain Individual User Accounts Oversee pre-market applications and post-market cases of all Individual Users Perform reassignment of applications / cases in case of staff turnover 	 Perform e-submission of premarket applications and e-reporting of post-market cases As direct contact during application / case processing stage

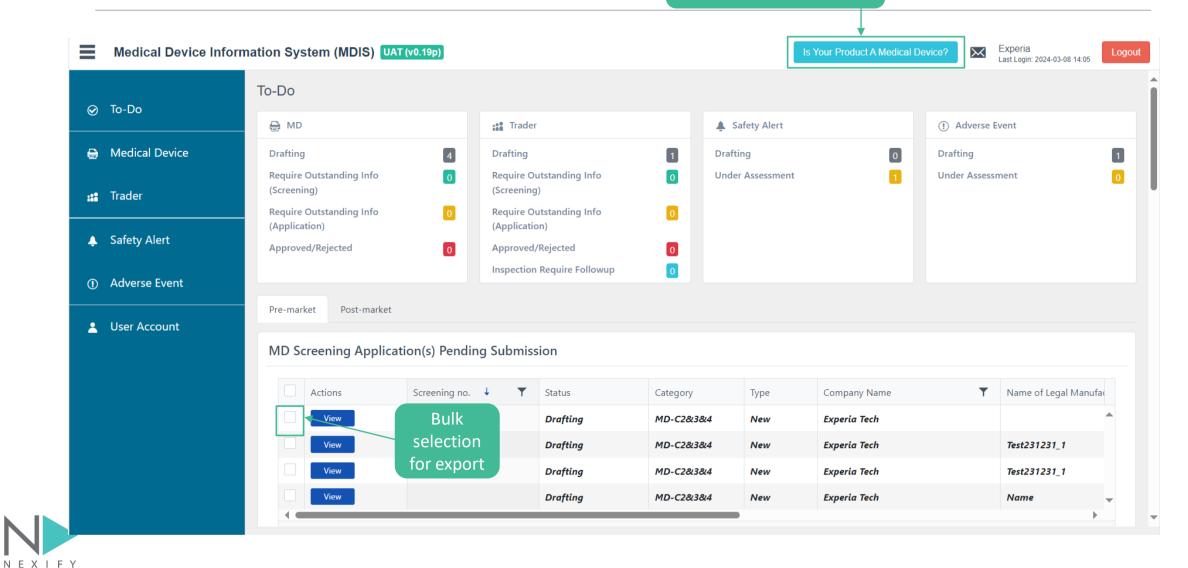


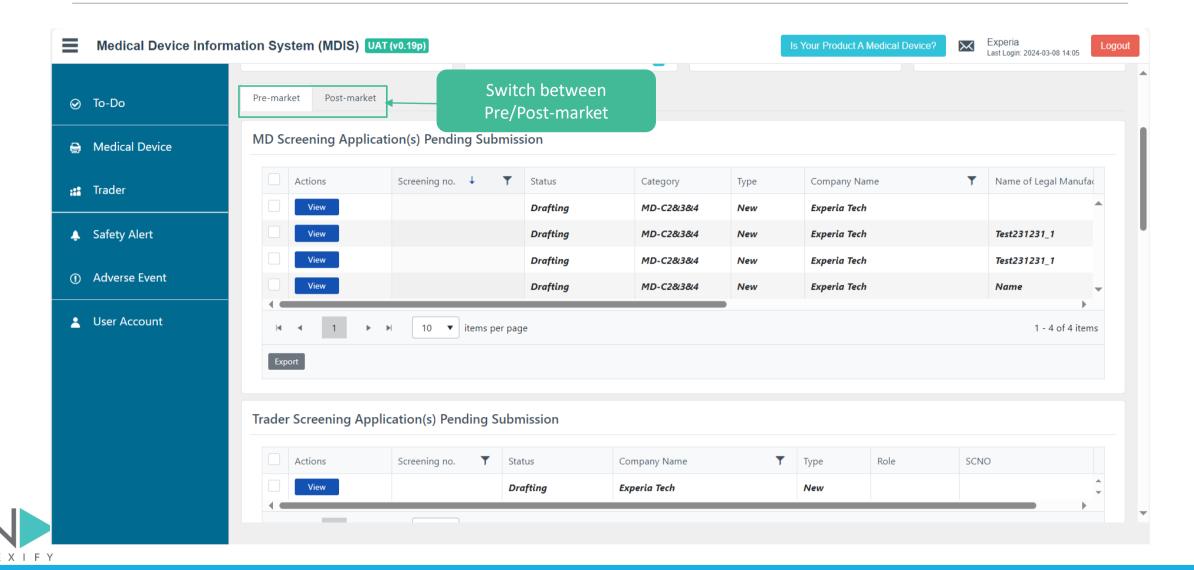
2) Functionalities in Trader User Interface

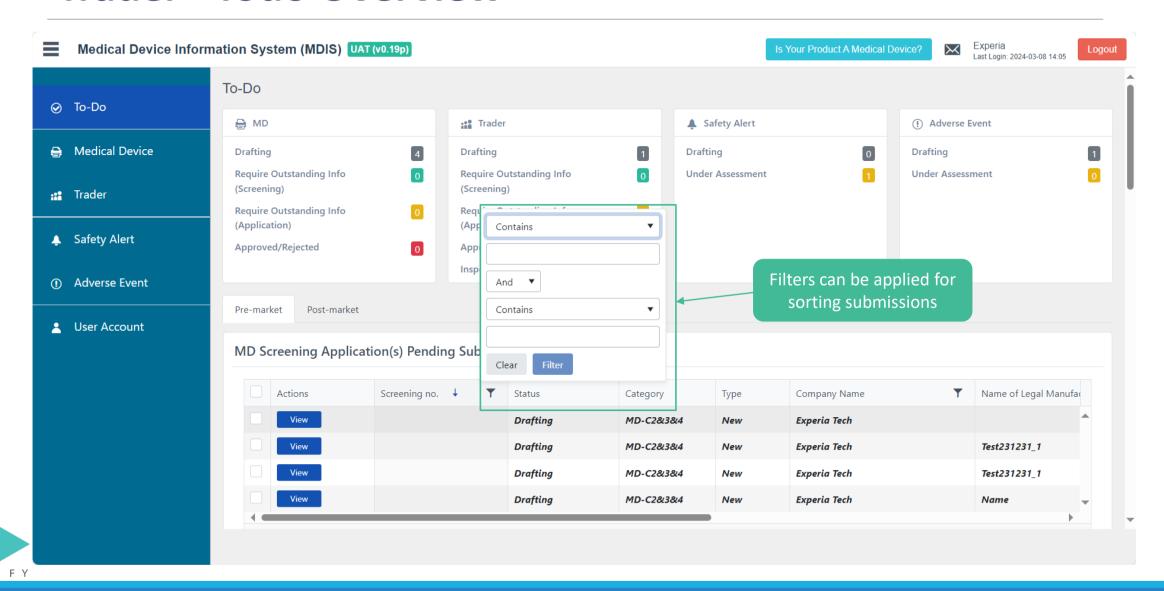




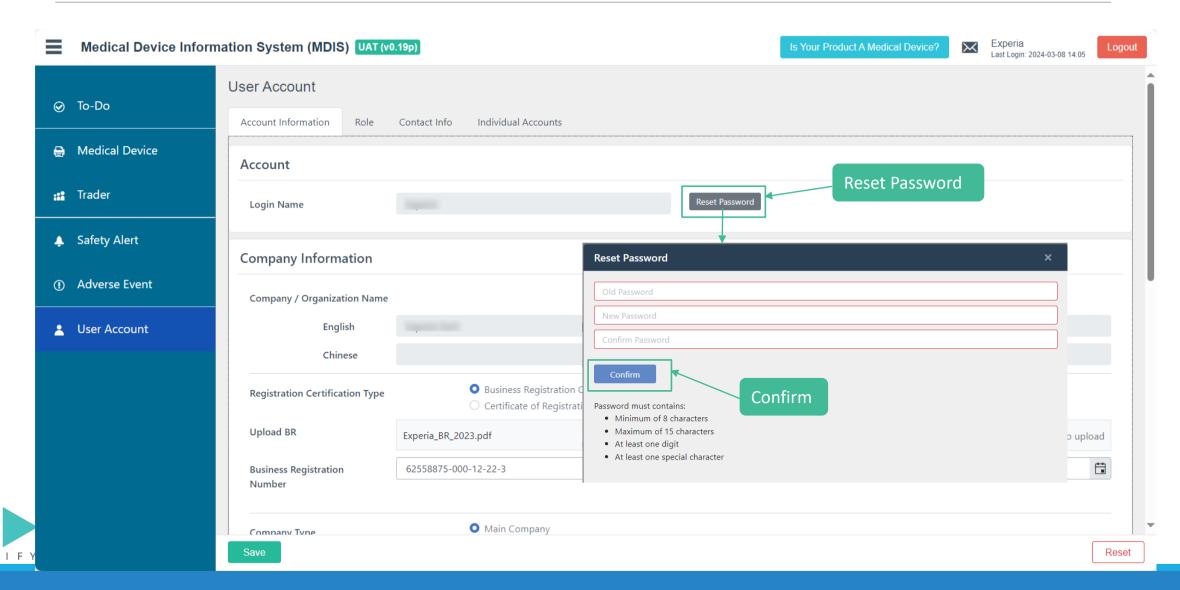
Link to external Q&A page for clarification

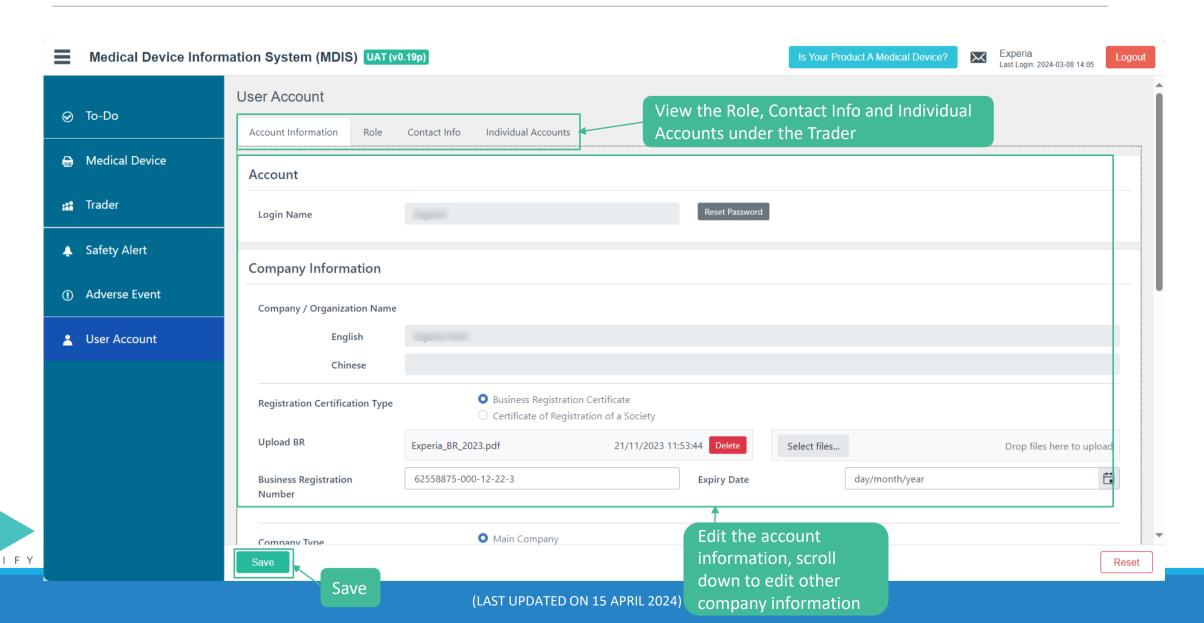




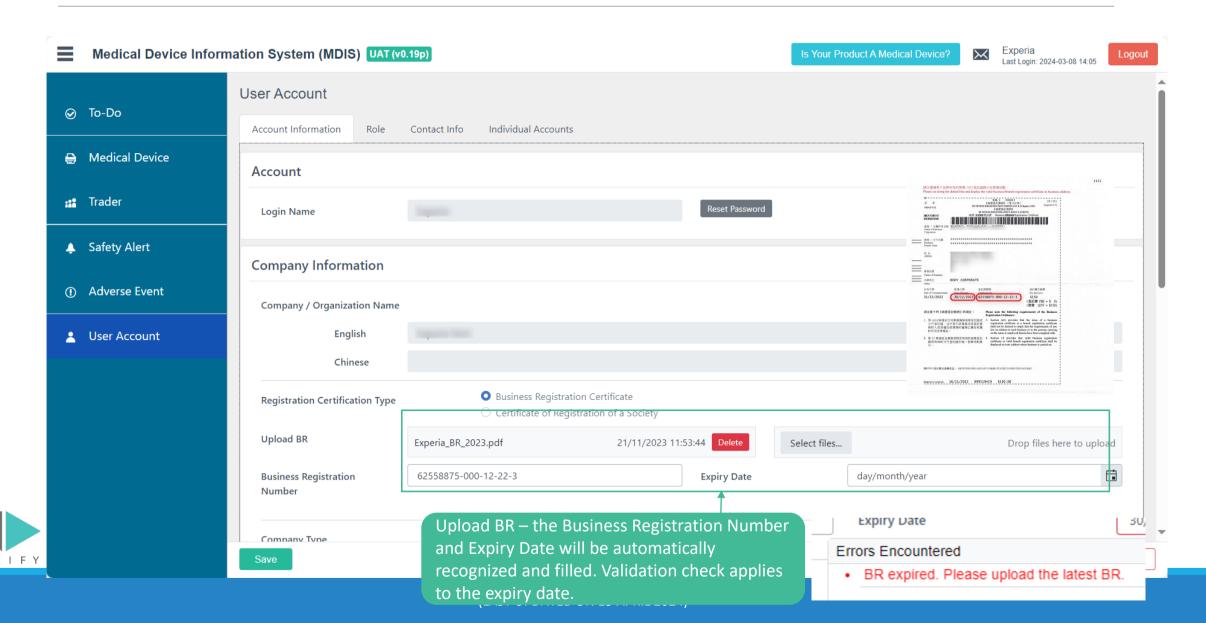


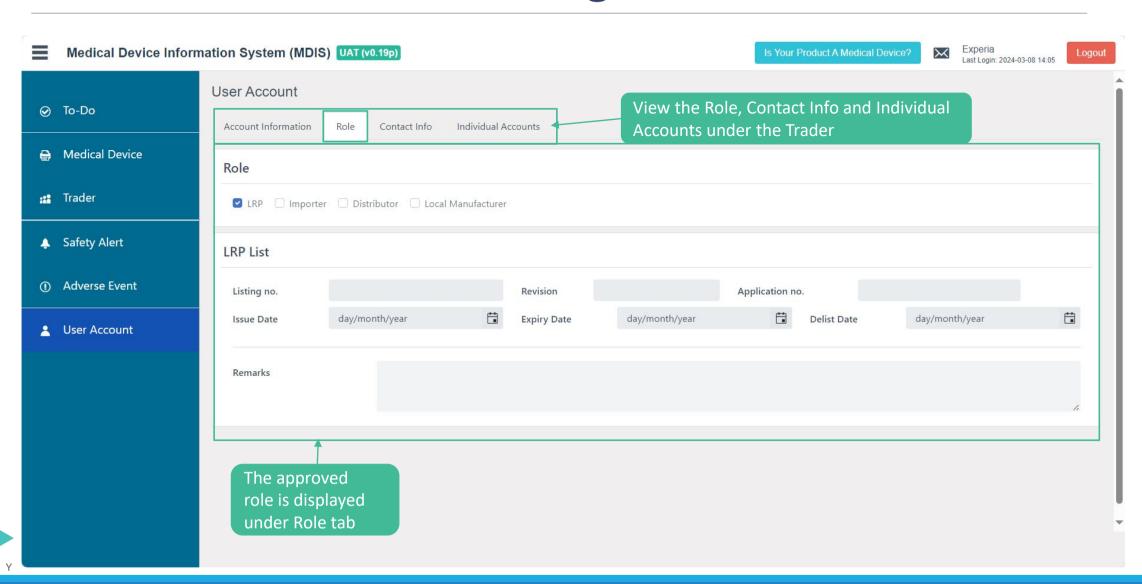
Trader – User Account Management – Reset Password

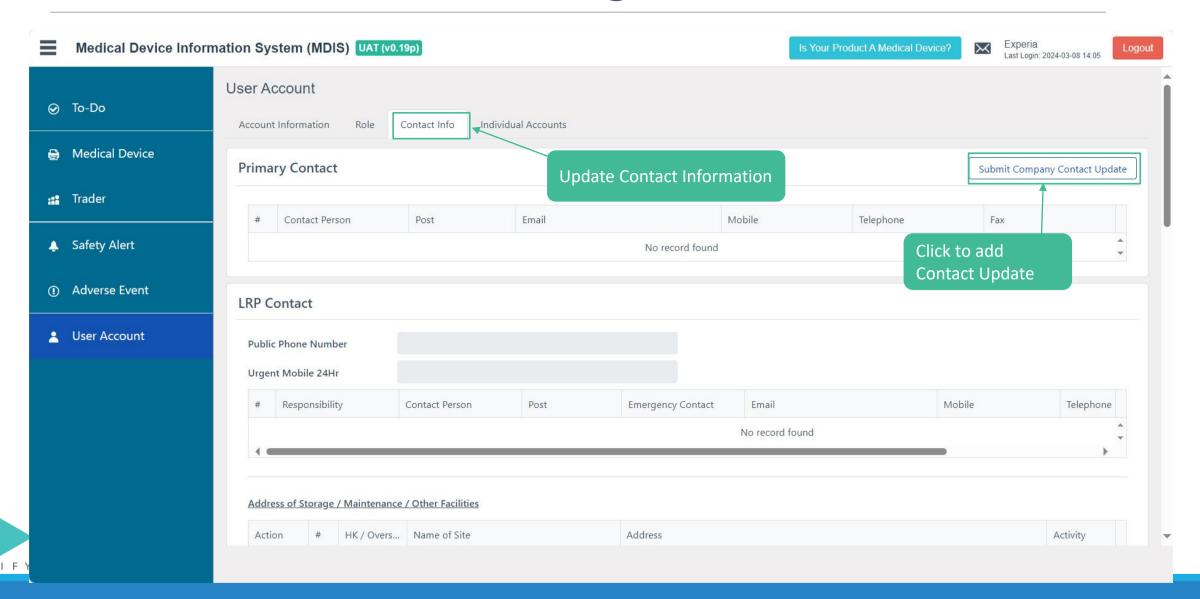


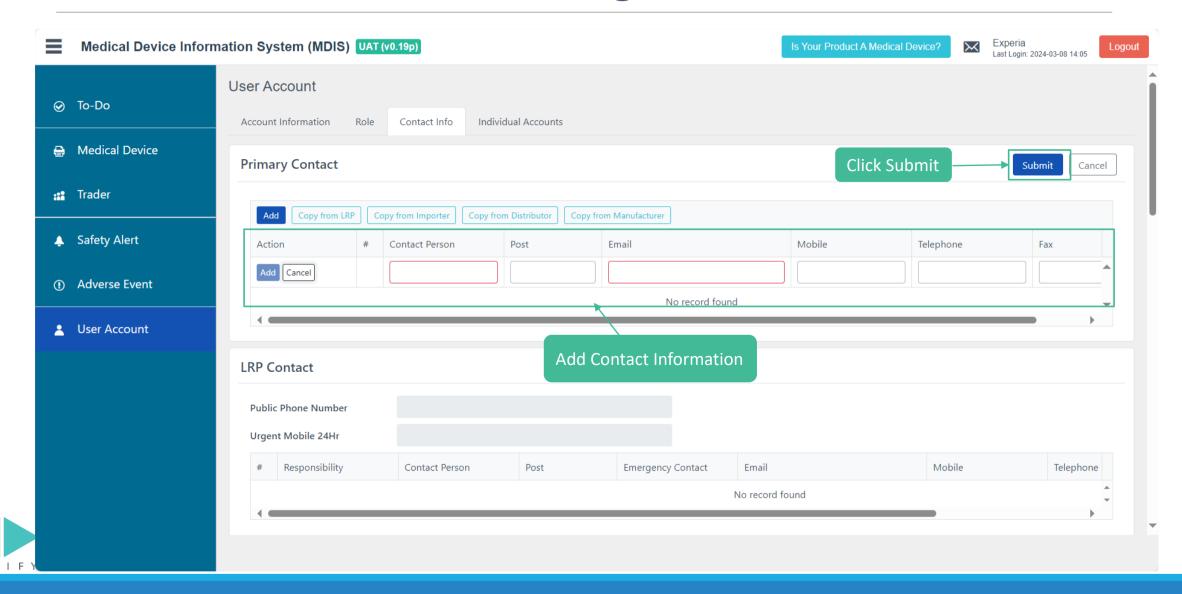


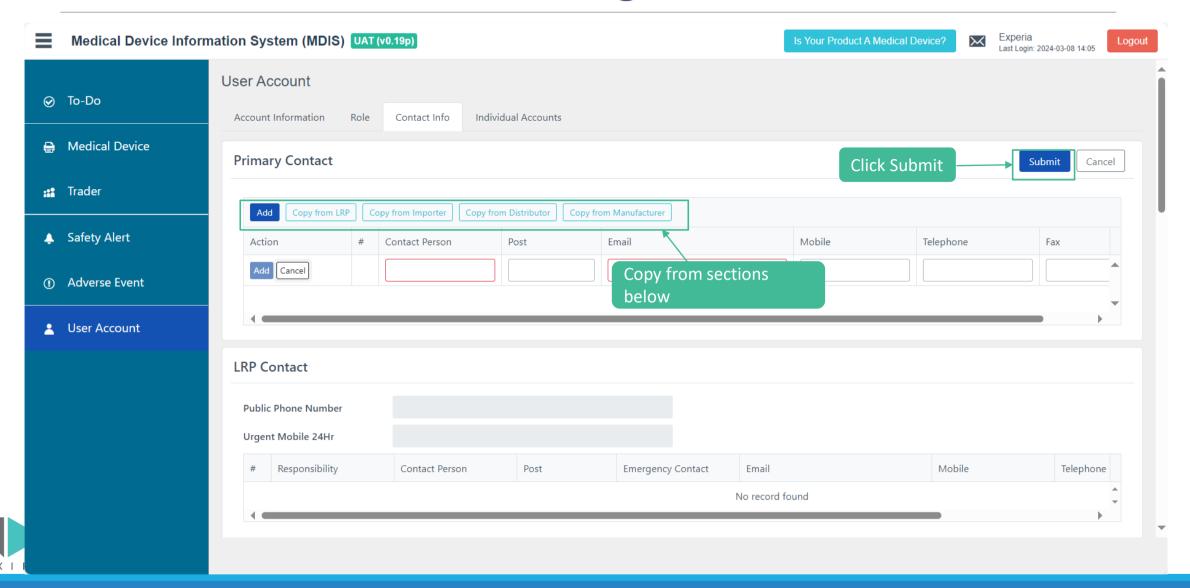
Trader – User Account Management – BR OCR



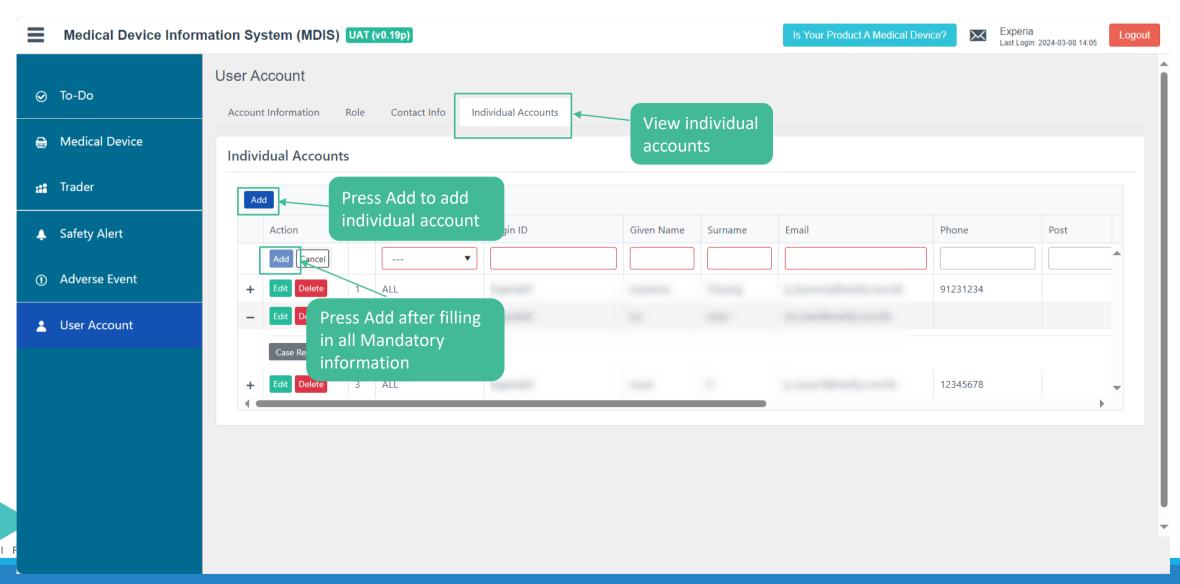




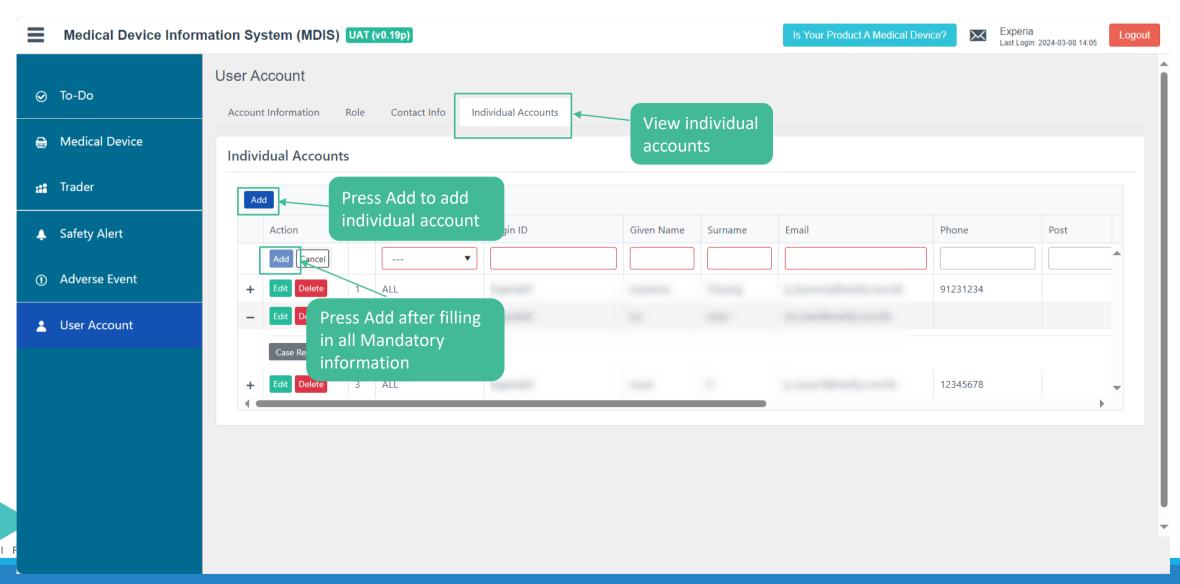




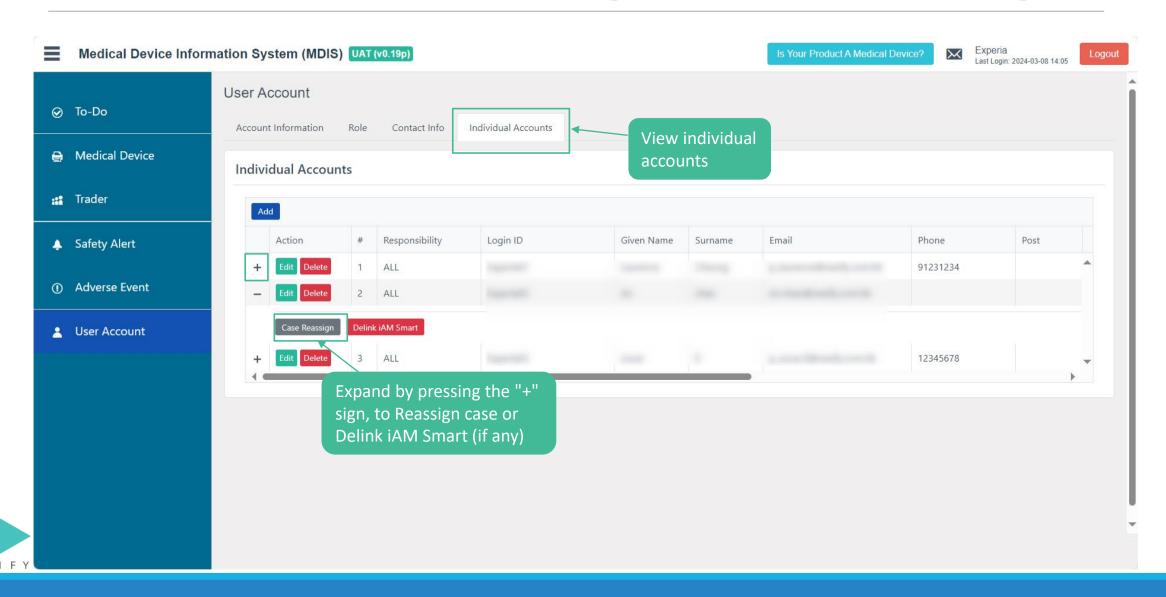
Trader – User Account Management – Add Individual Accounts

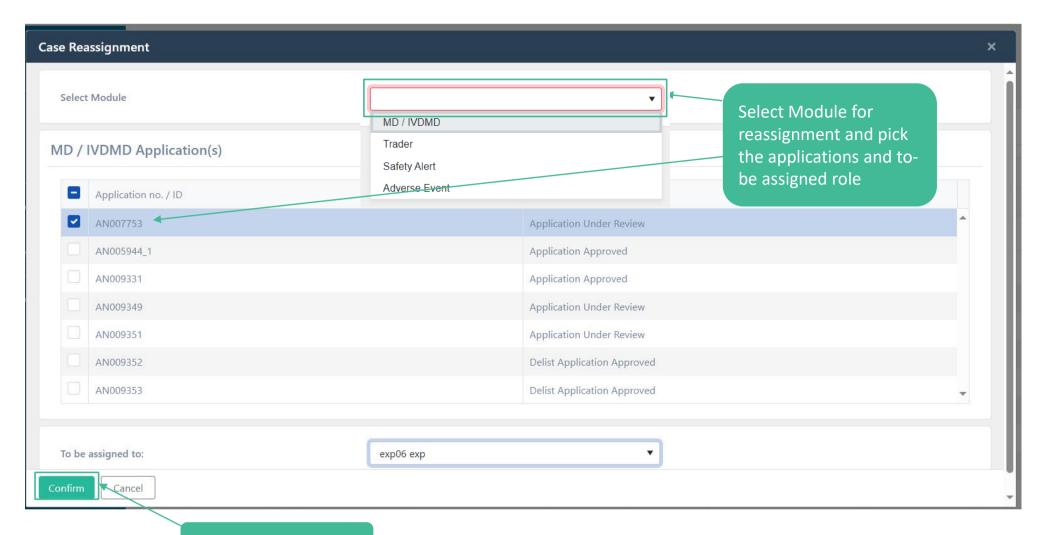


Trader – User Account Management – Add Individual Accounts



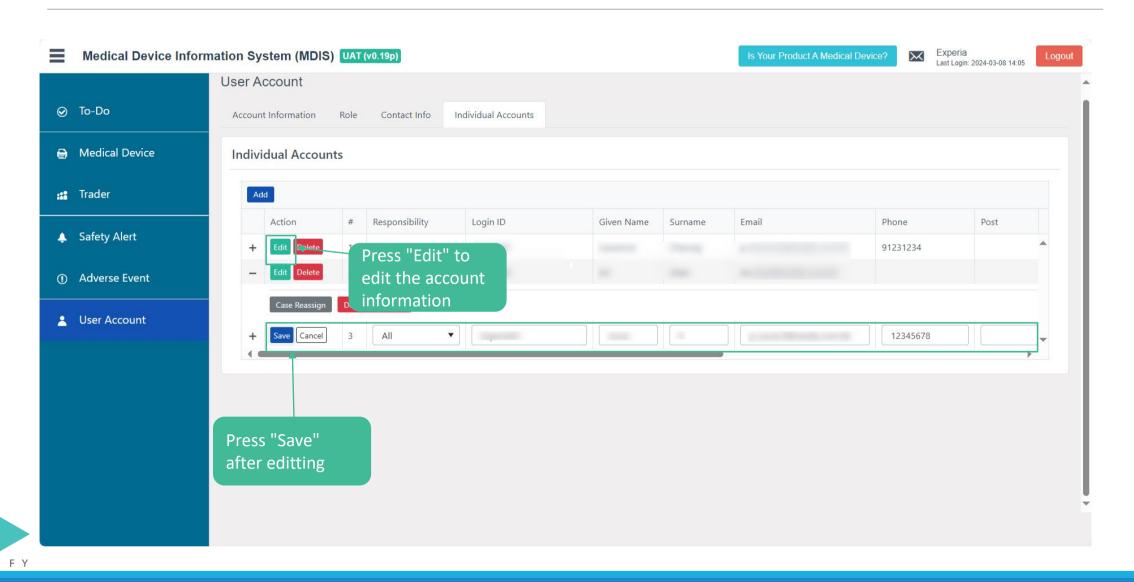
Trader – User Account Management – Case Reassign



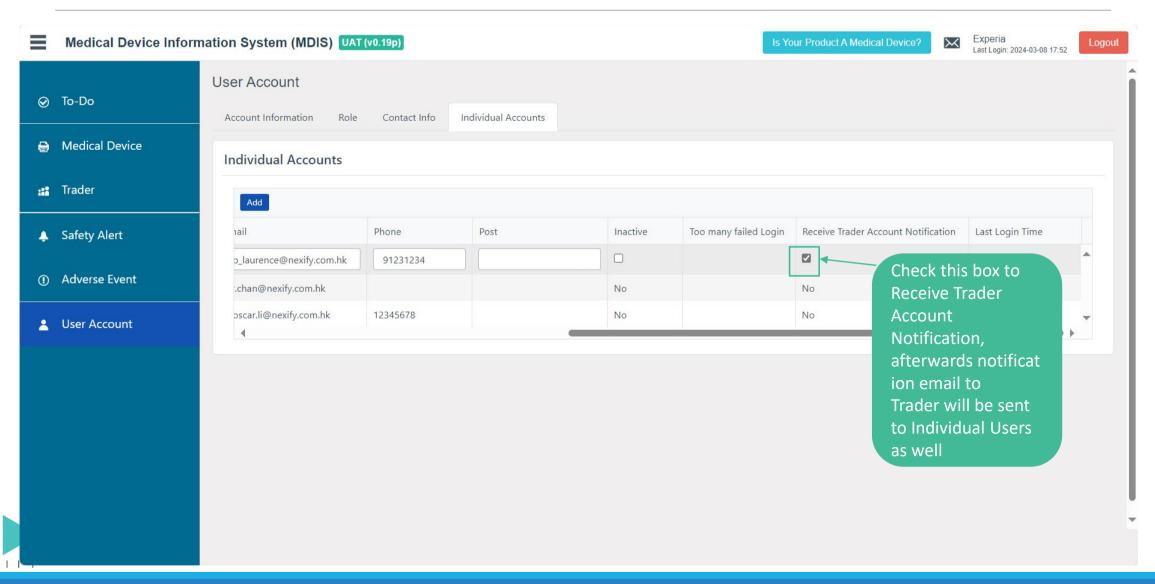




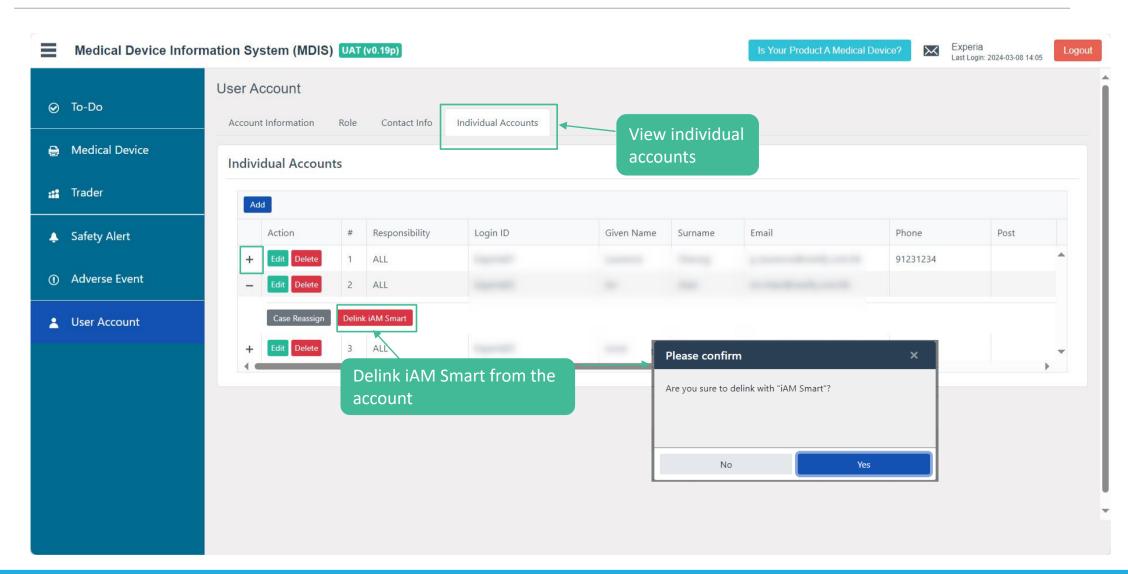
Trader – User Account Management – Edit account information



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



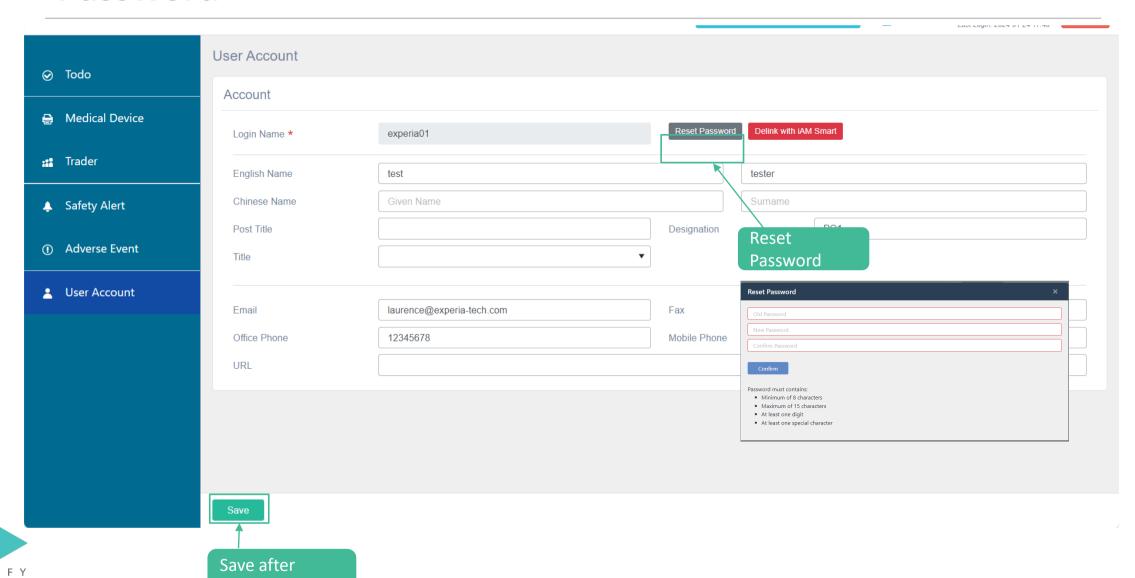
Trader – User Account Management – Delink iAM Smart



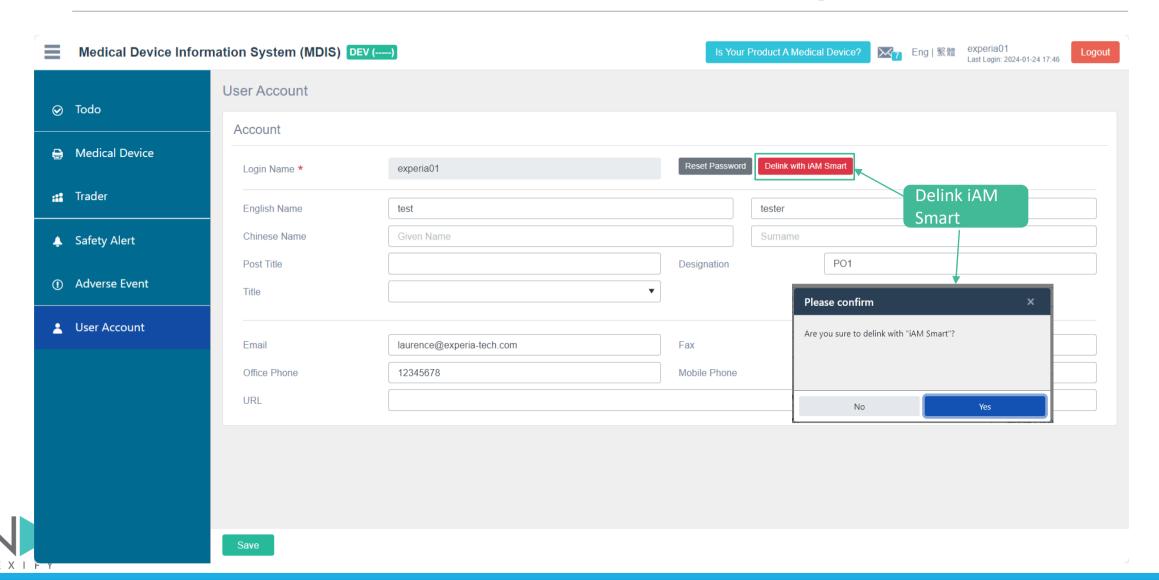
4) Functionalities in Individual User Interface



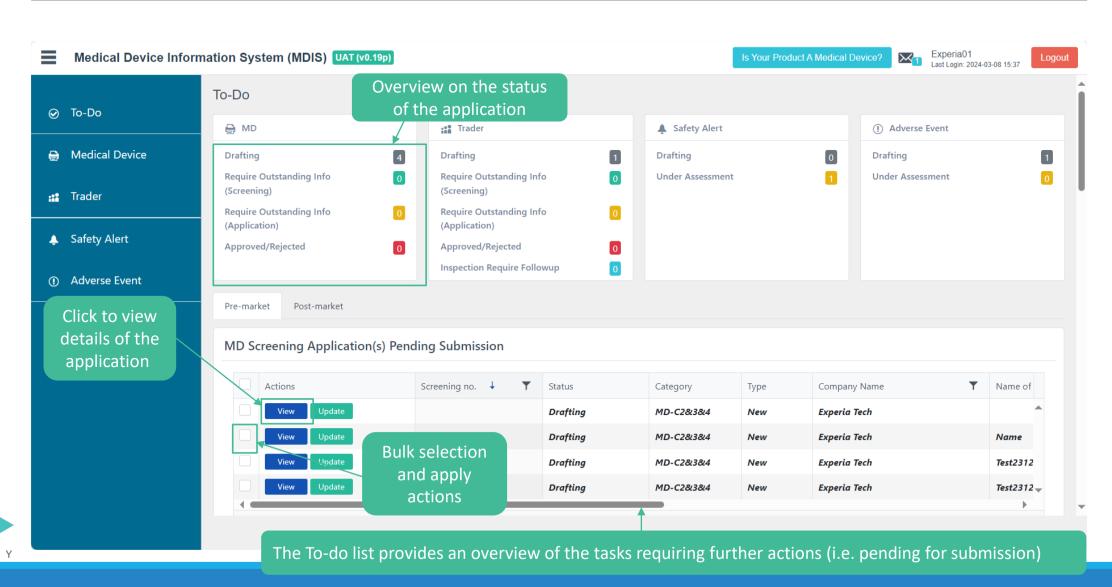
Individual Users – User Account Management – reset Password



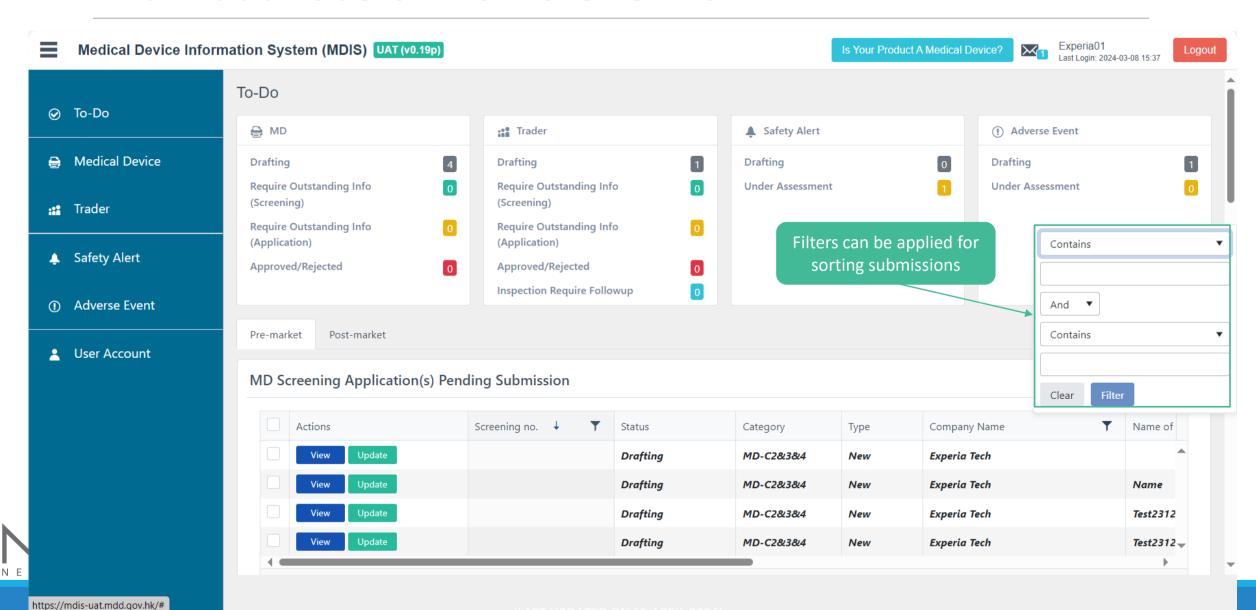
Individual Users – User Account Management



Individual Users – To Do Overview

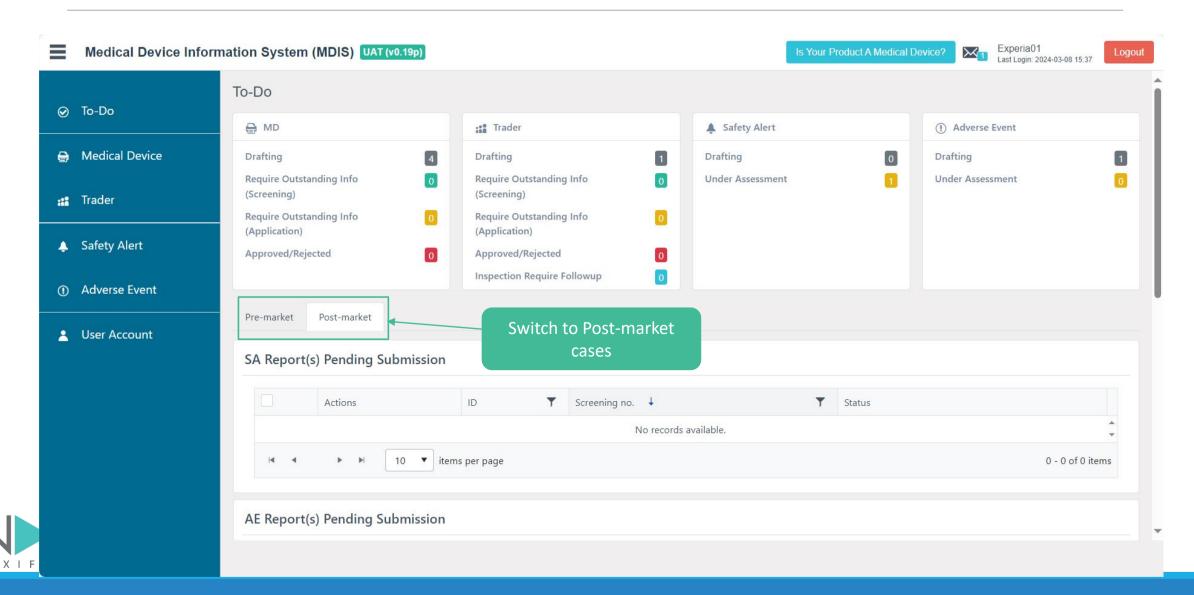


Individual Users – To Do Overview

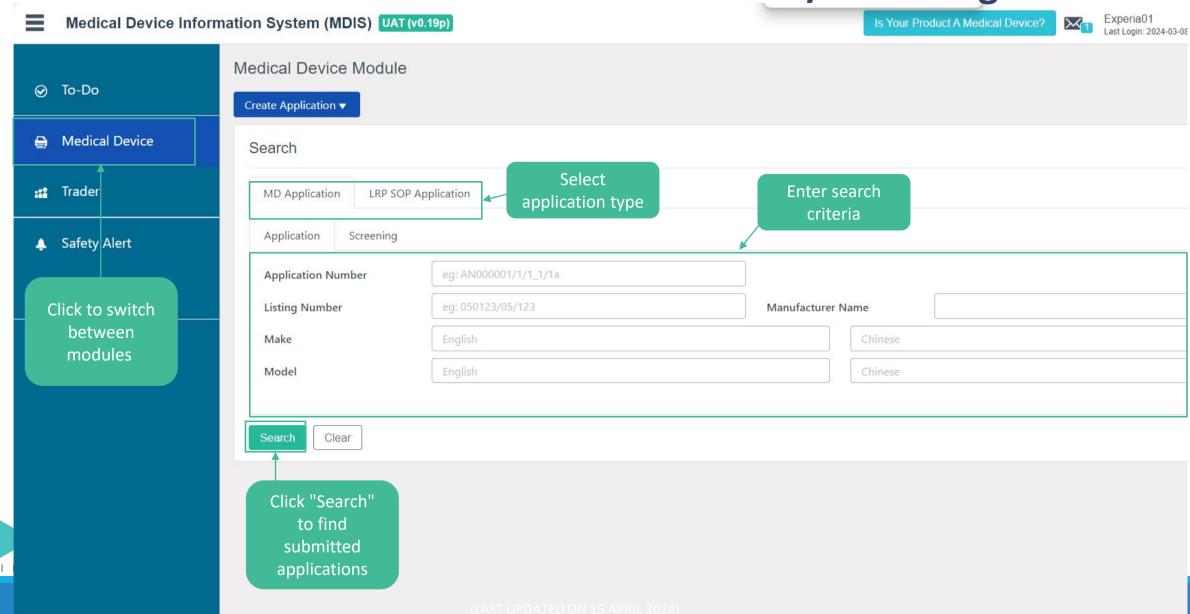


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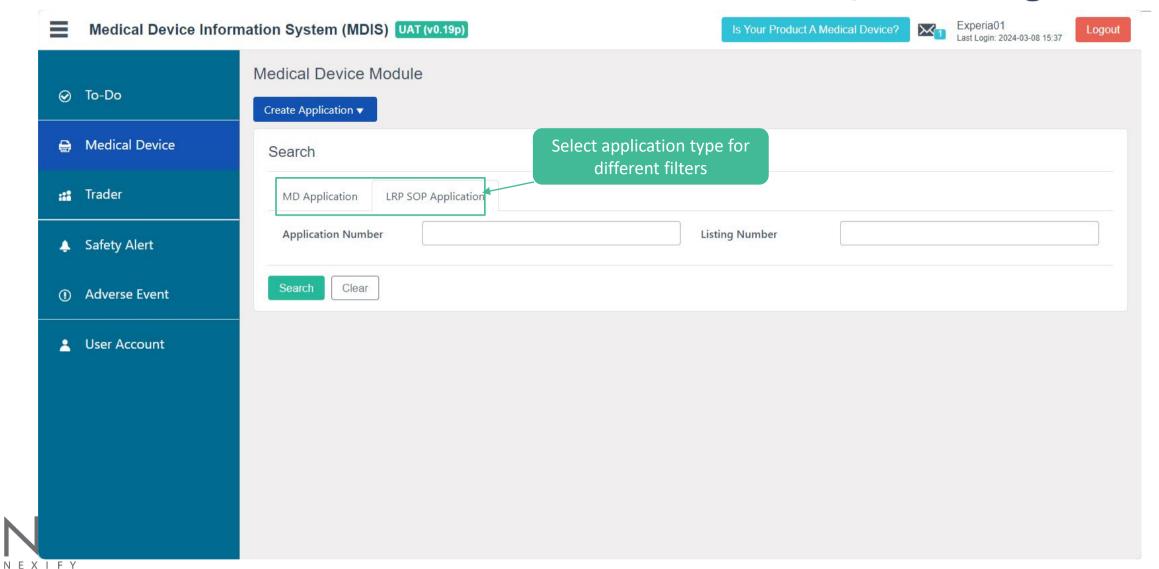
Individual Users – To Do Overview



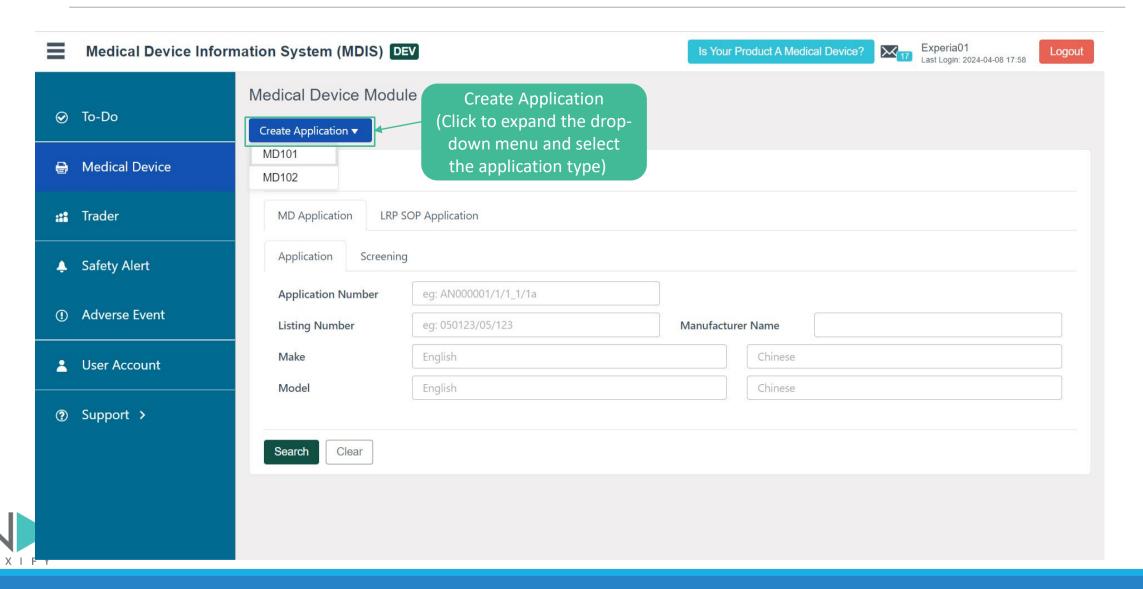
Individual Users – Medical Device Overview / Searching

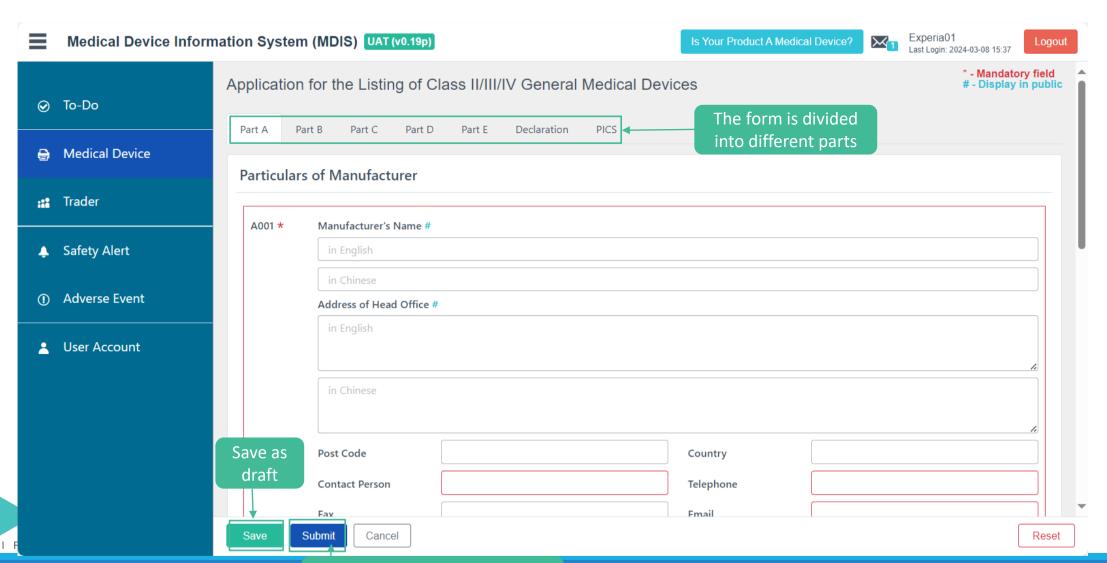


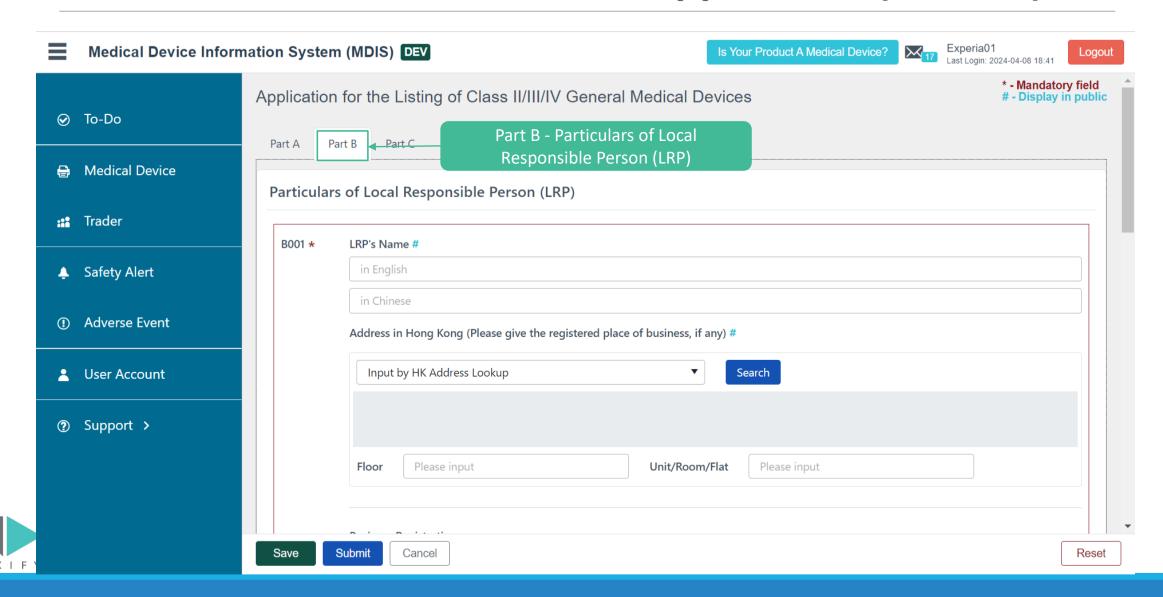
Individual Users – Medical Device Overview / Searching

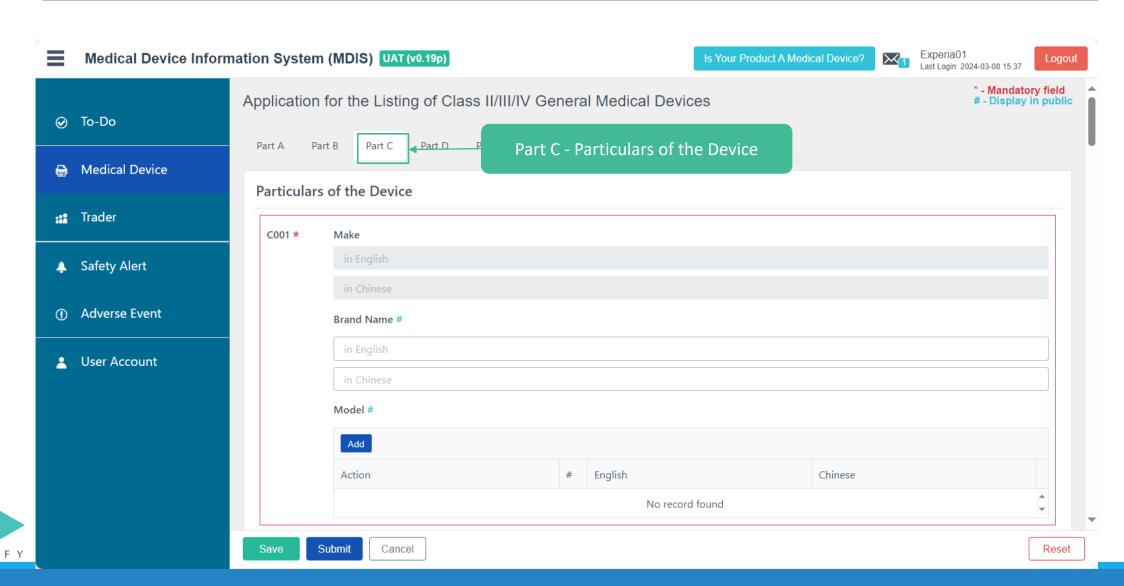


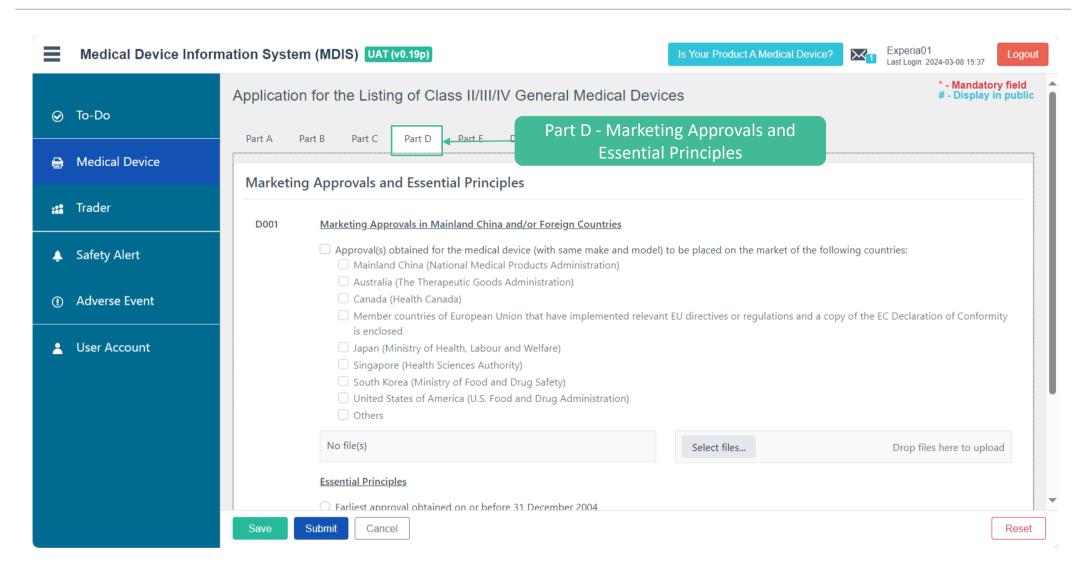
Individual Users - Create MD Application



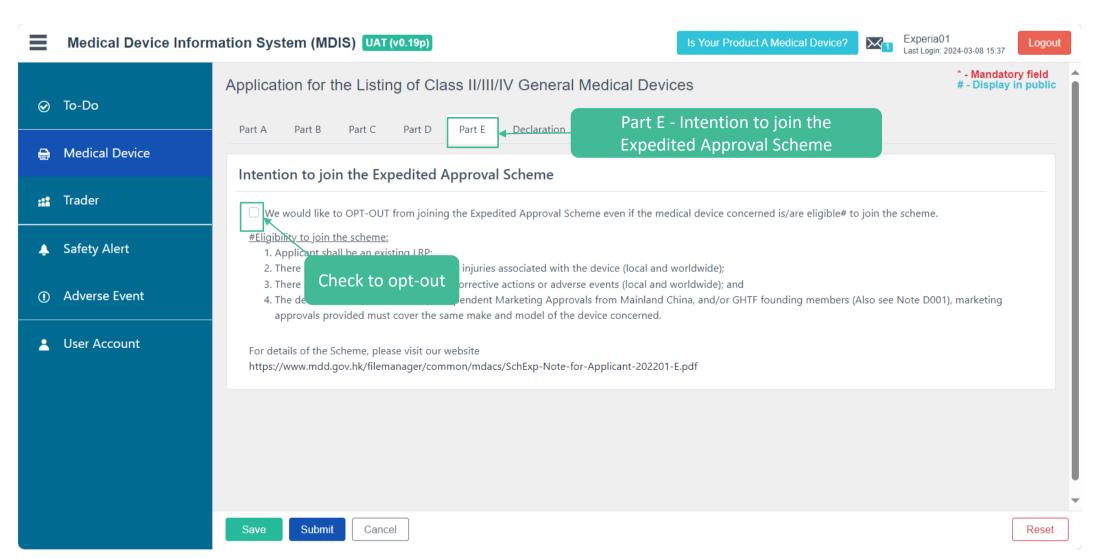


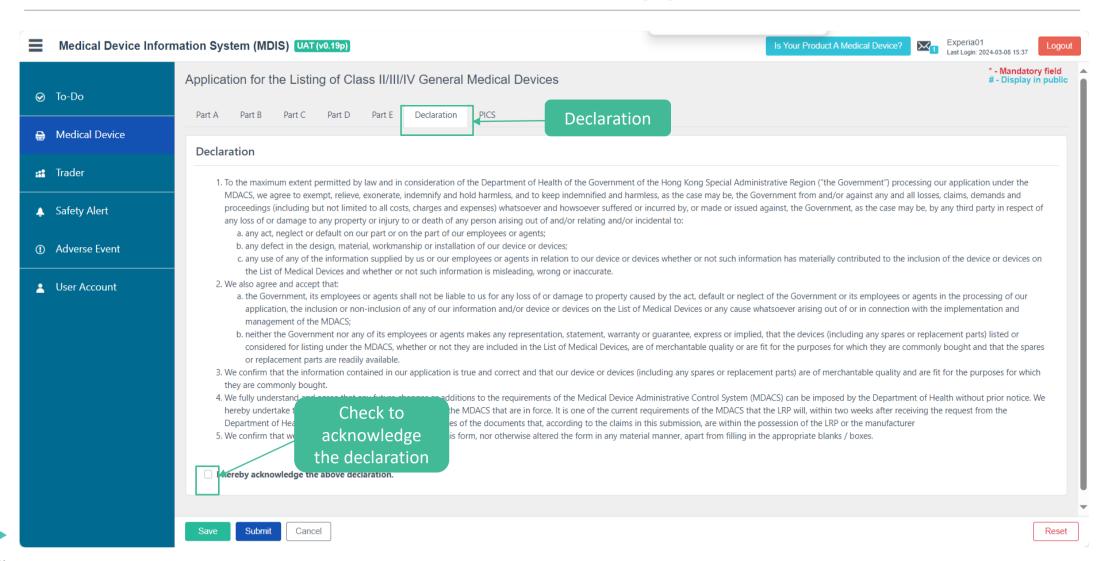


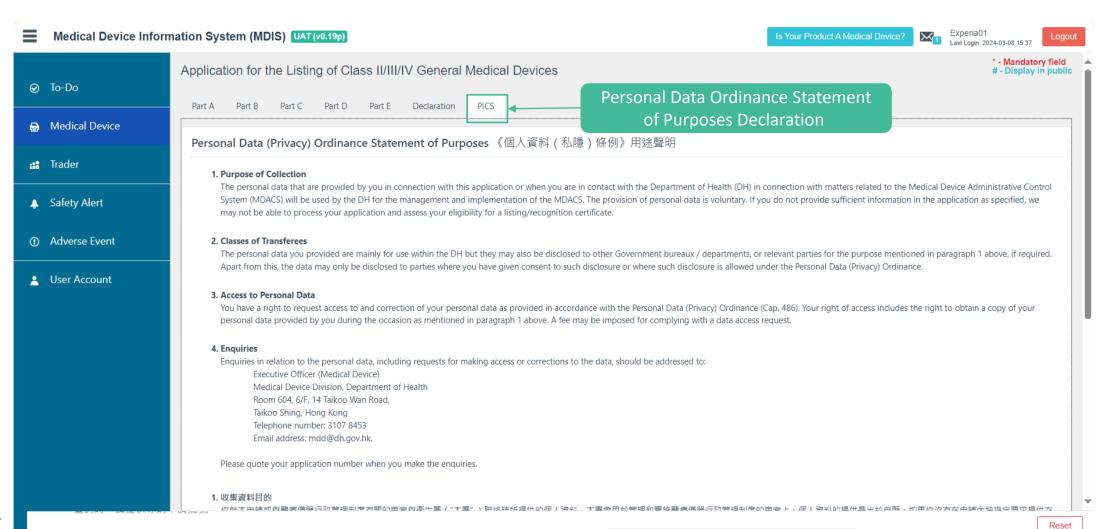








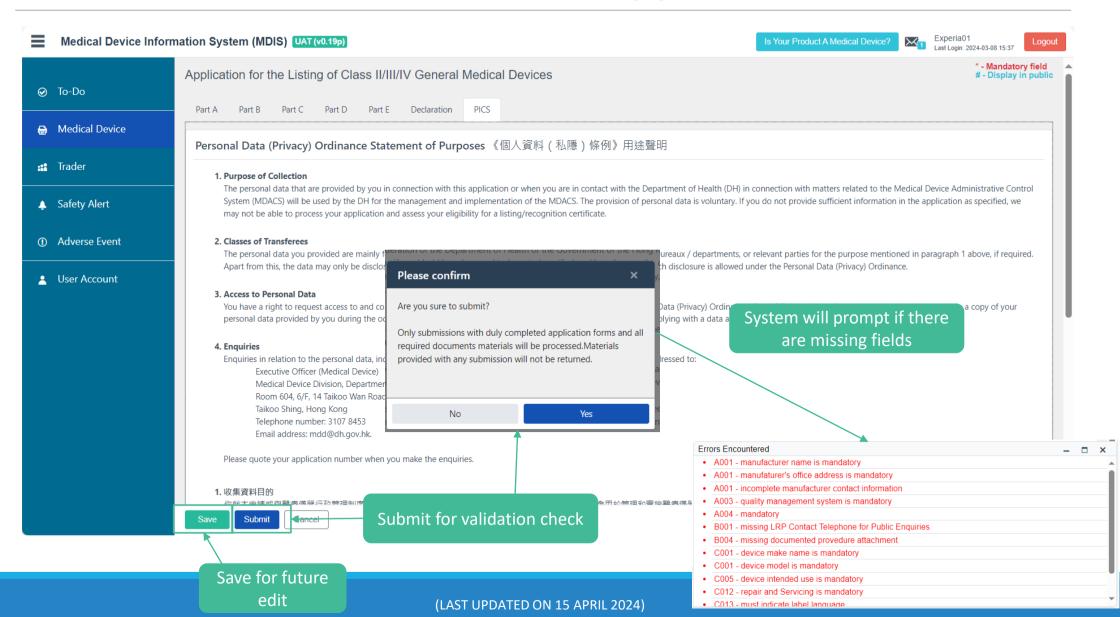


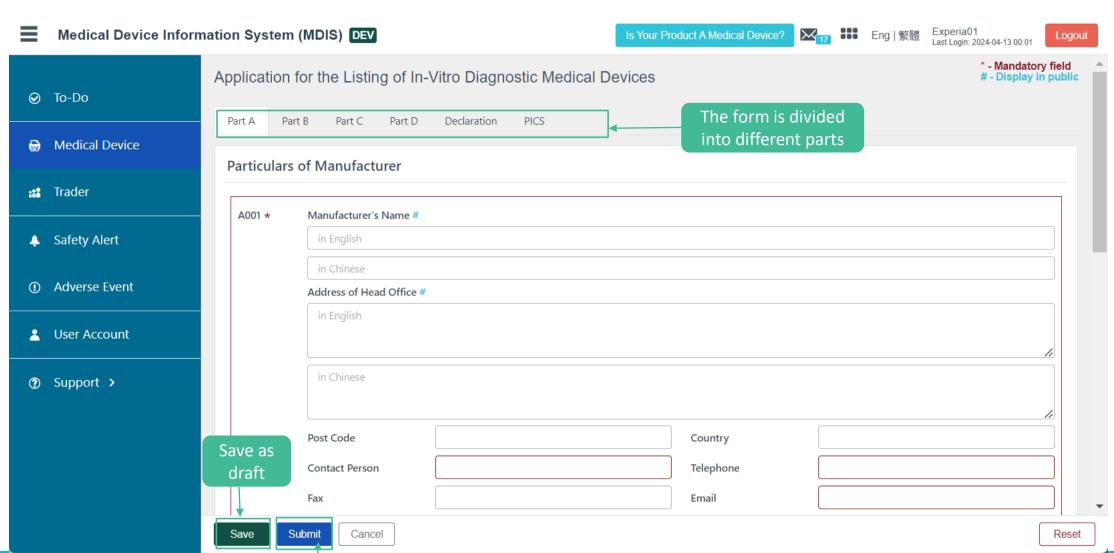


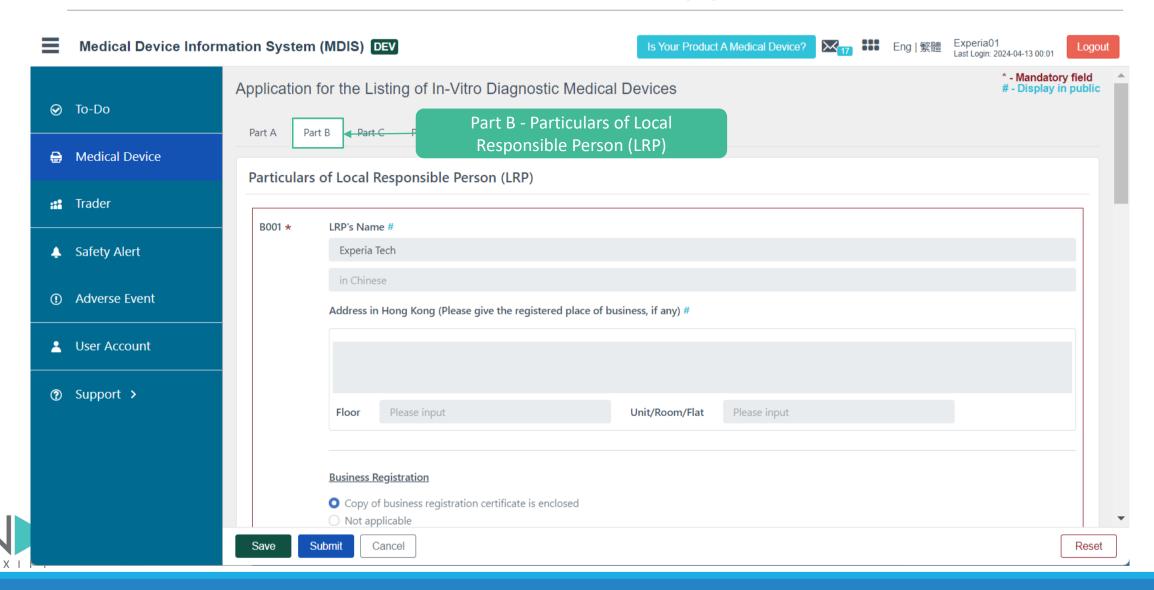
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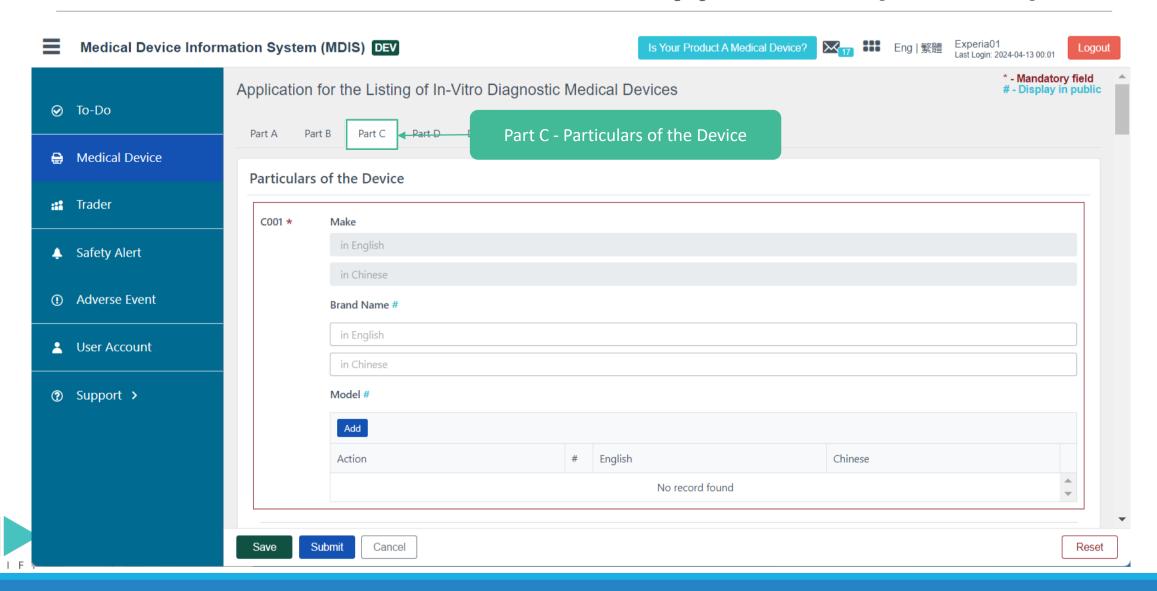
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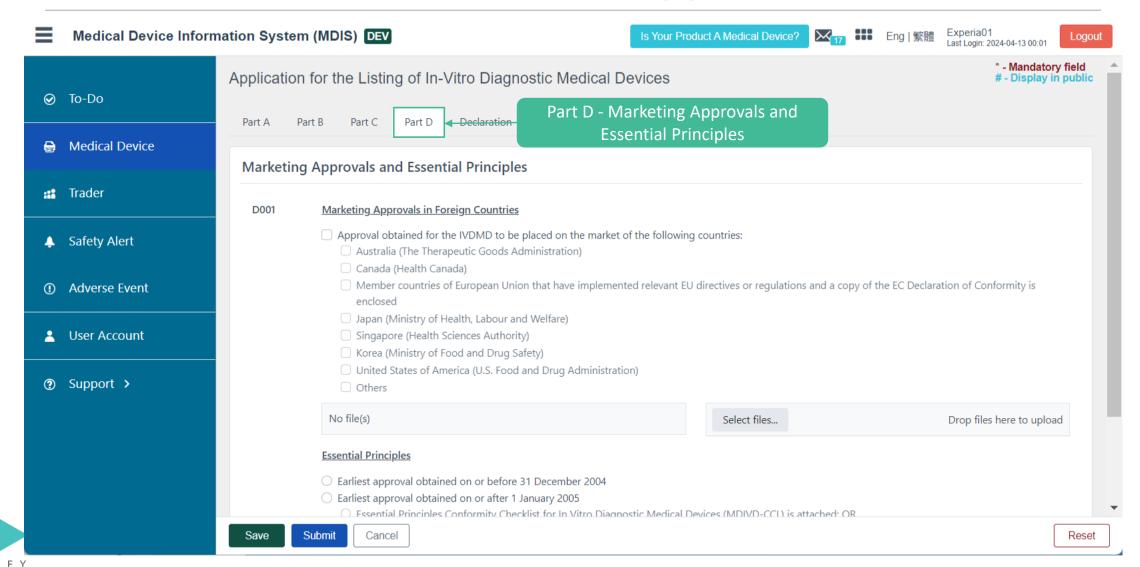
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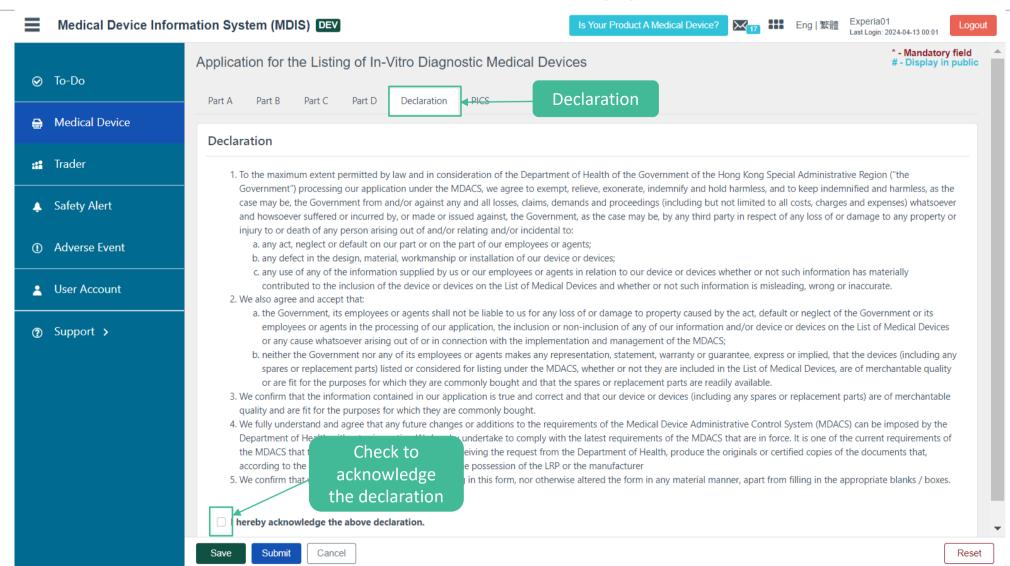




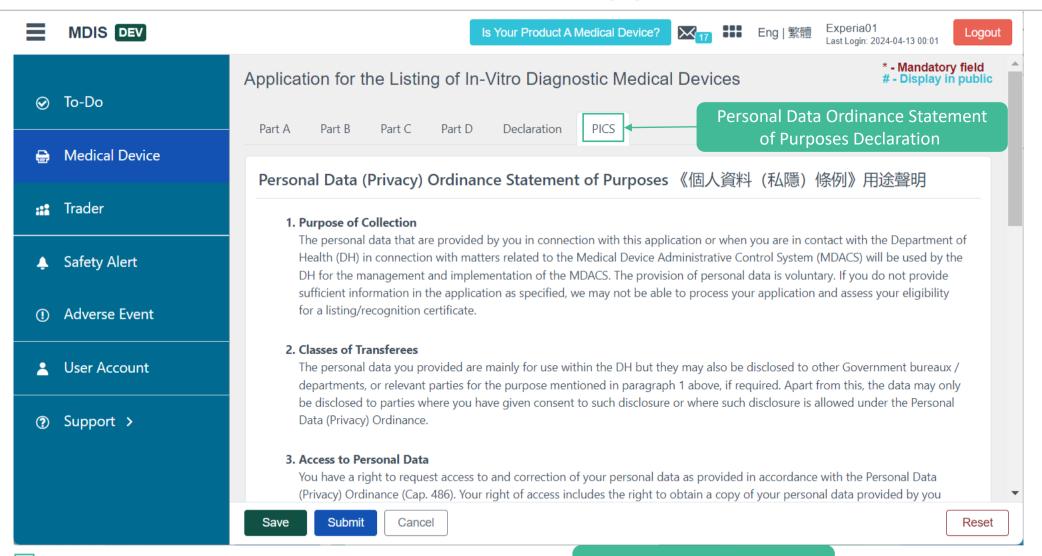








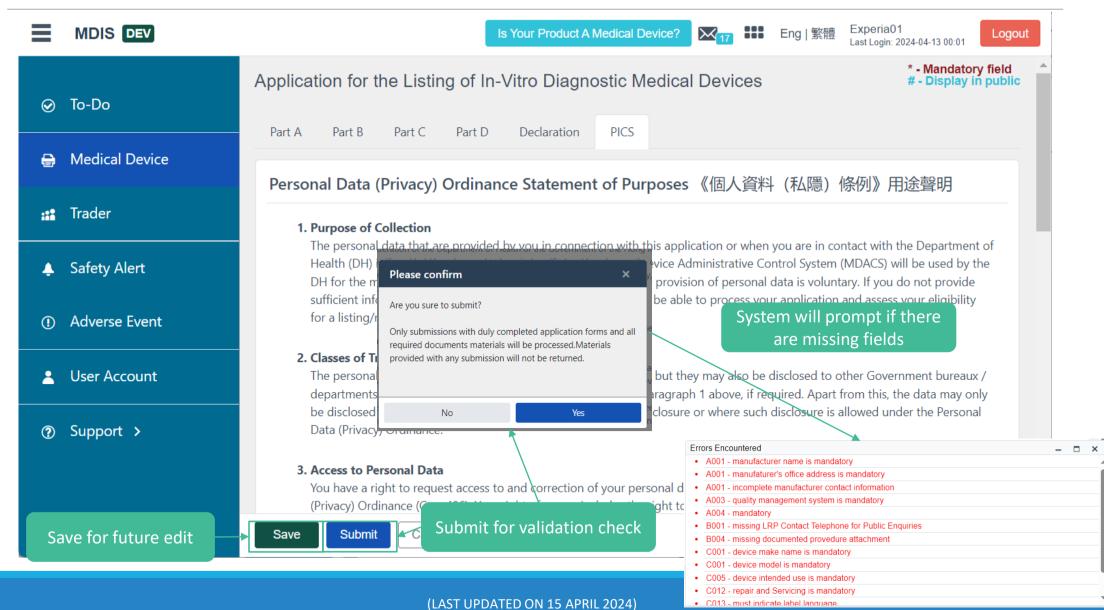


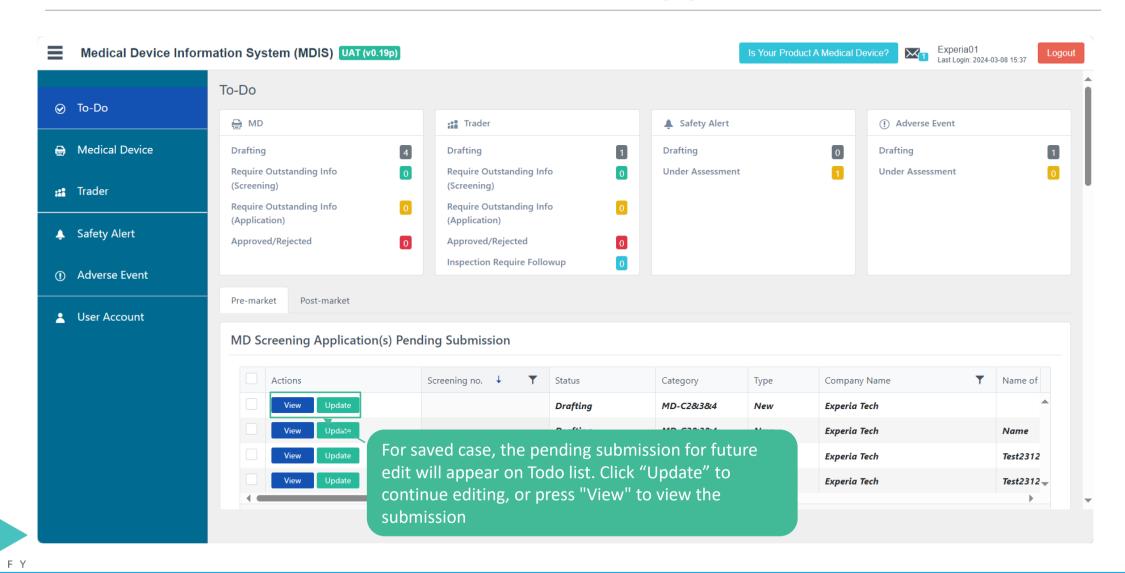




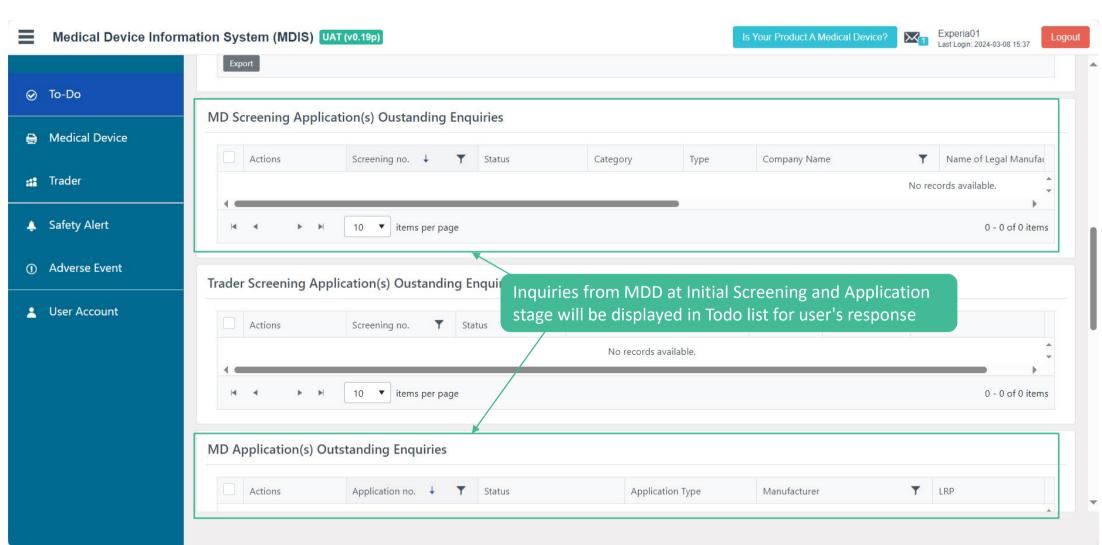
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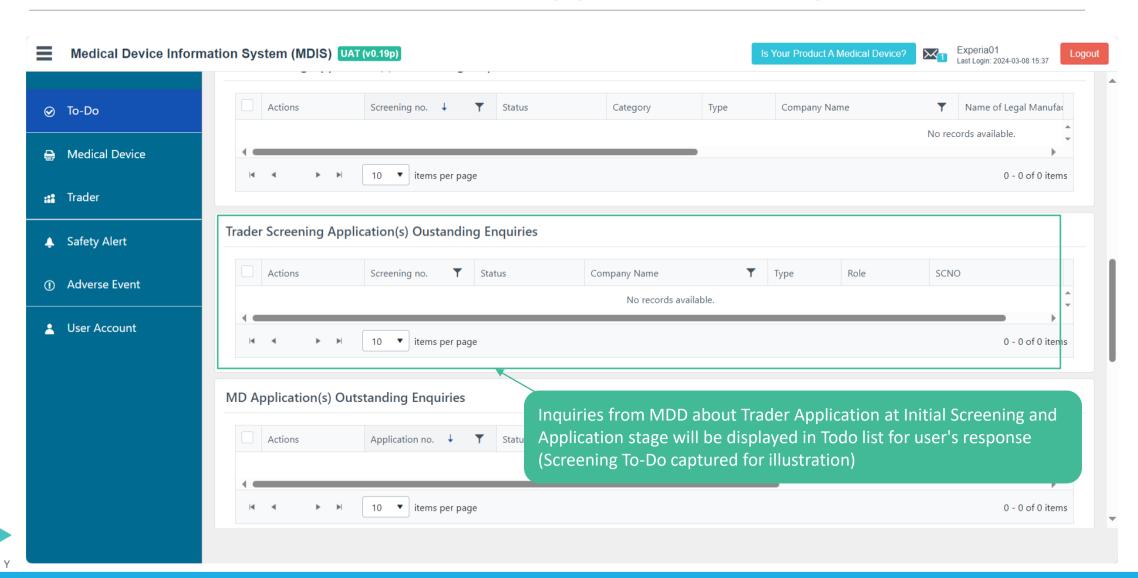




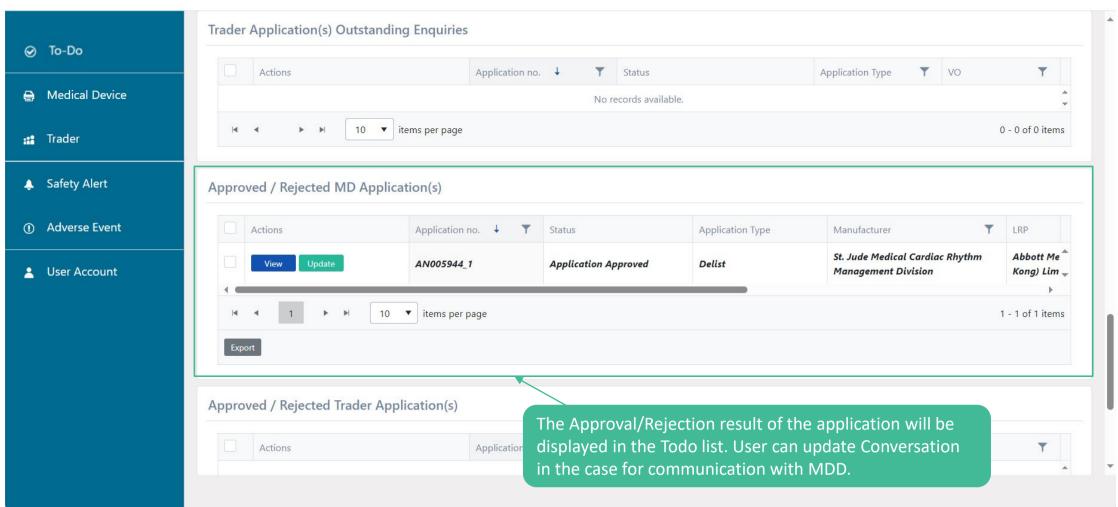
Individual Users – MD Application Enquiries

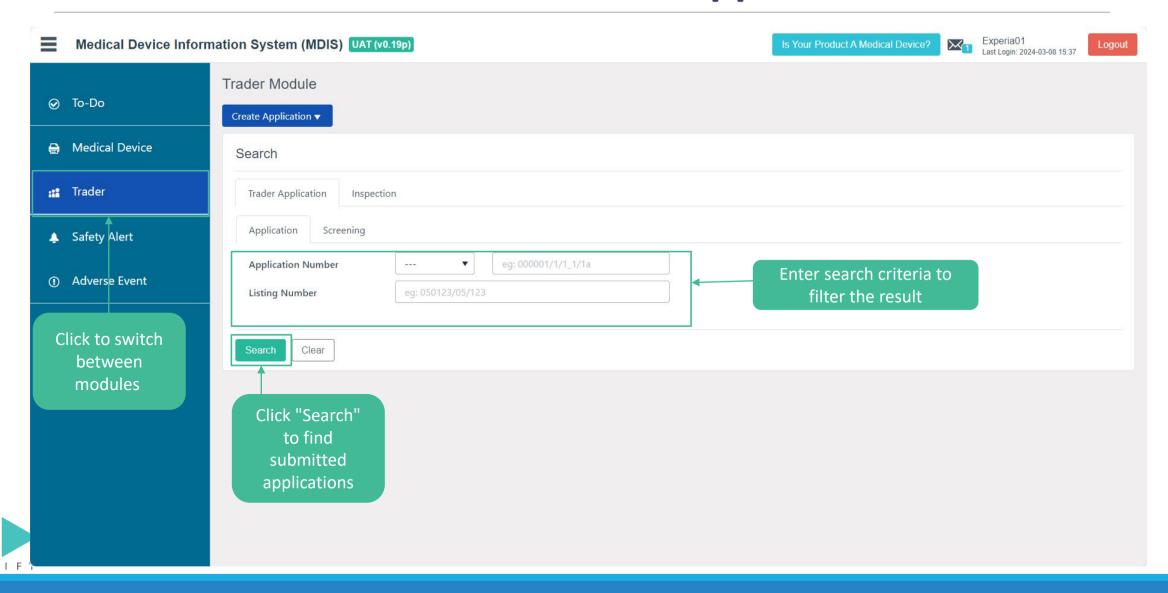


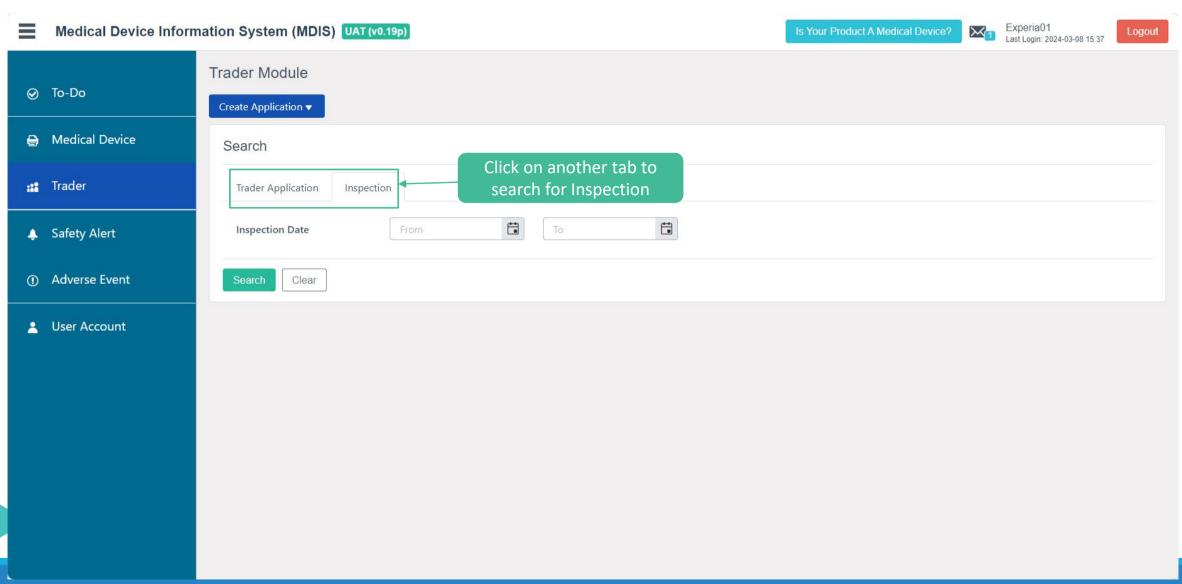
Individual Users – Trader Application Enquiries

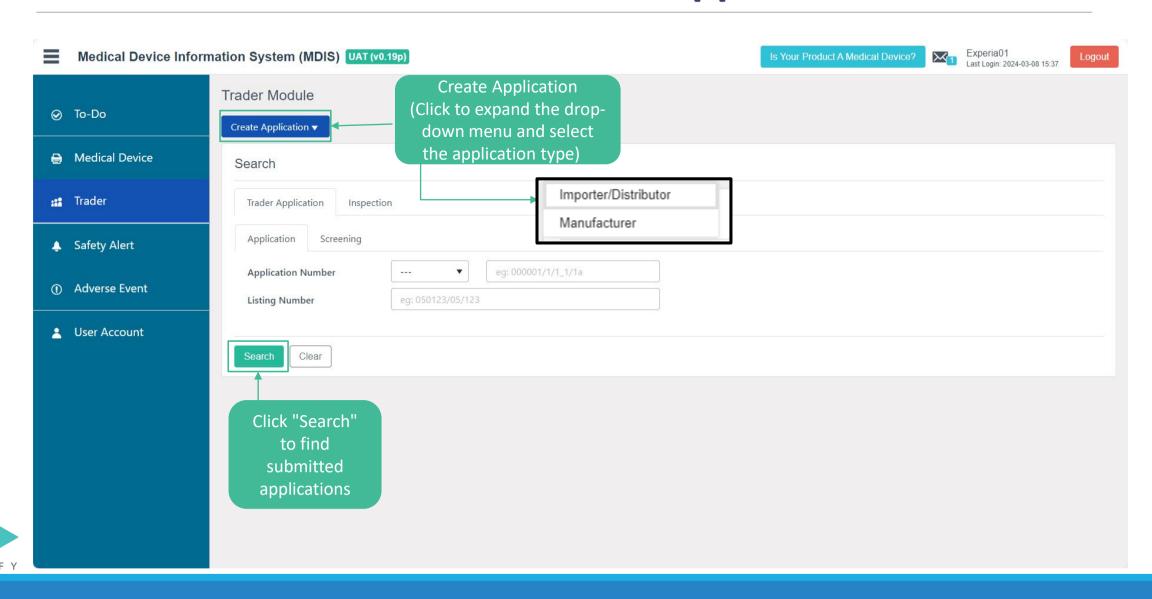


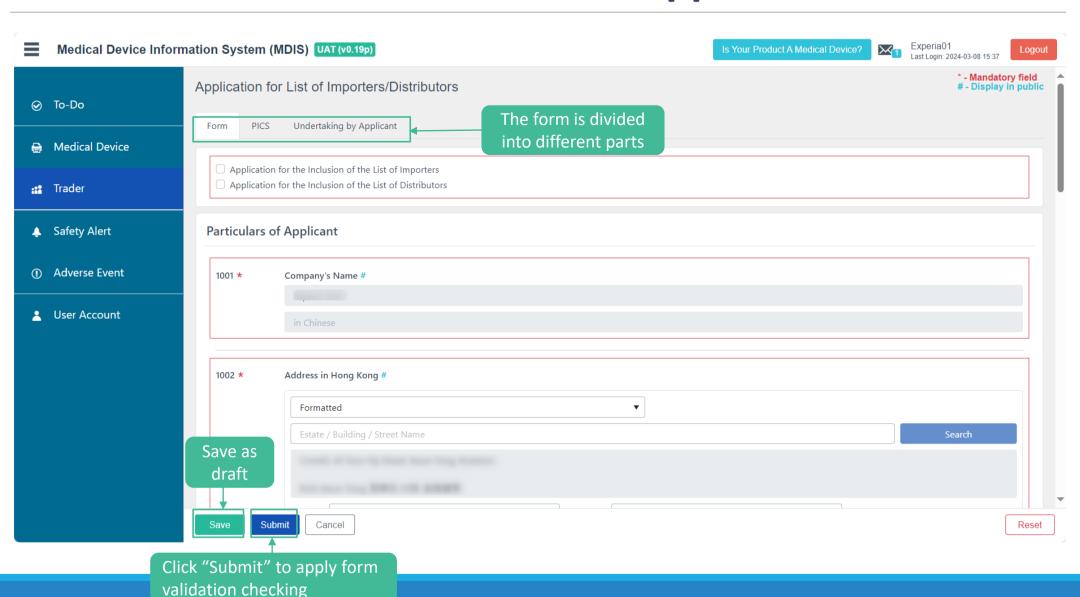
Individual Users – MD Application Status

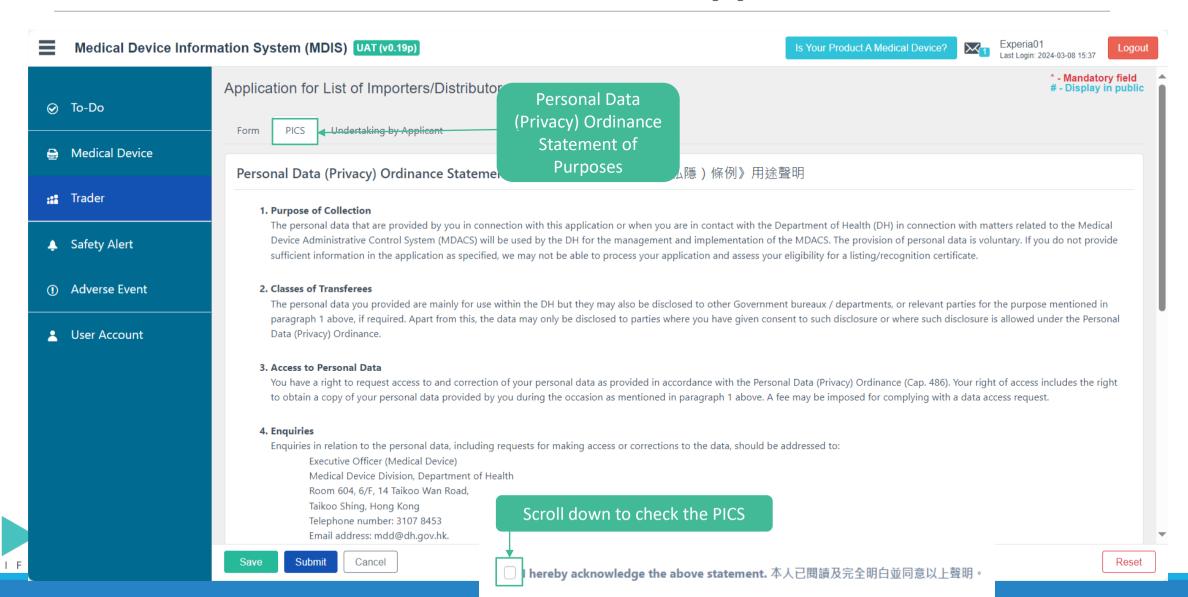




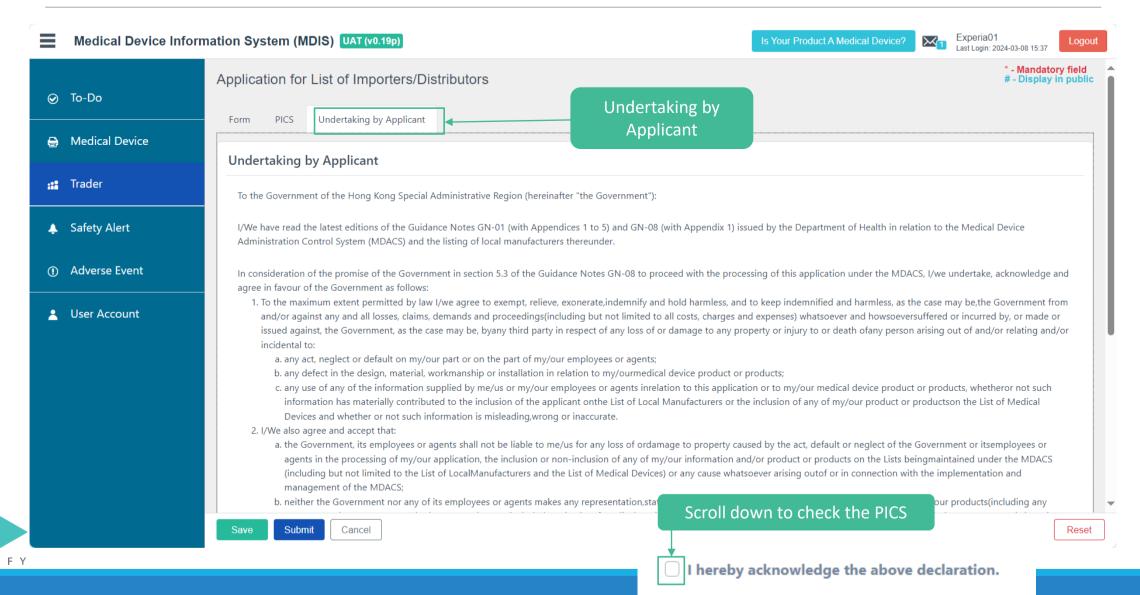


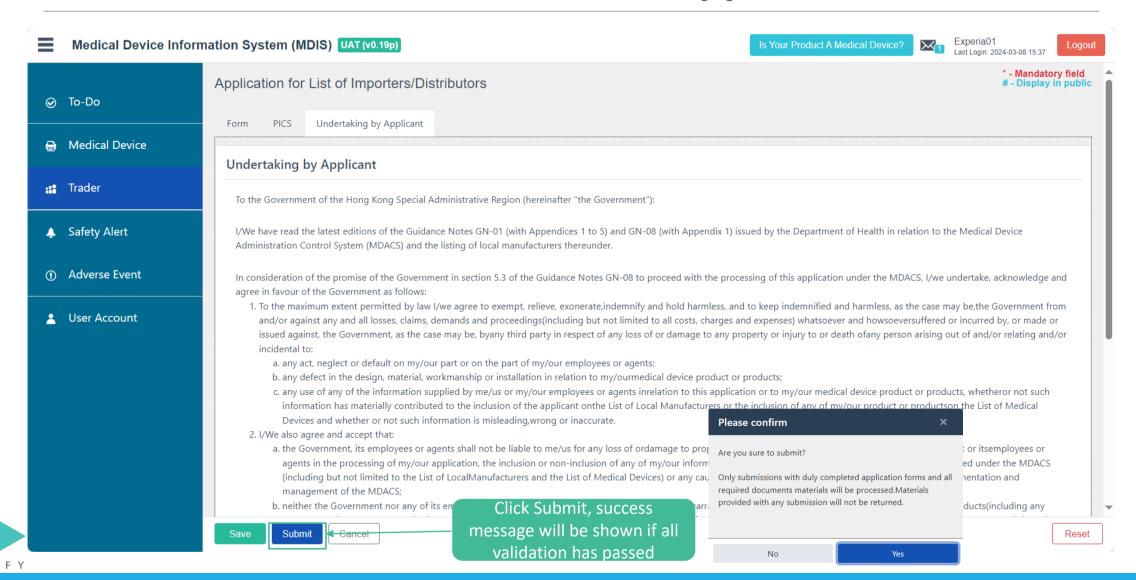




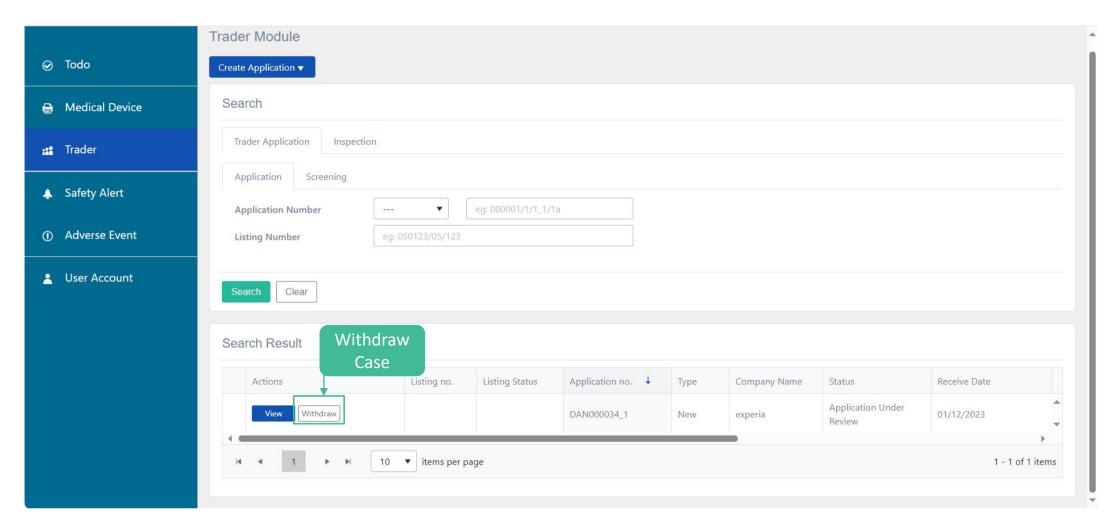


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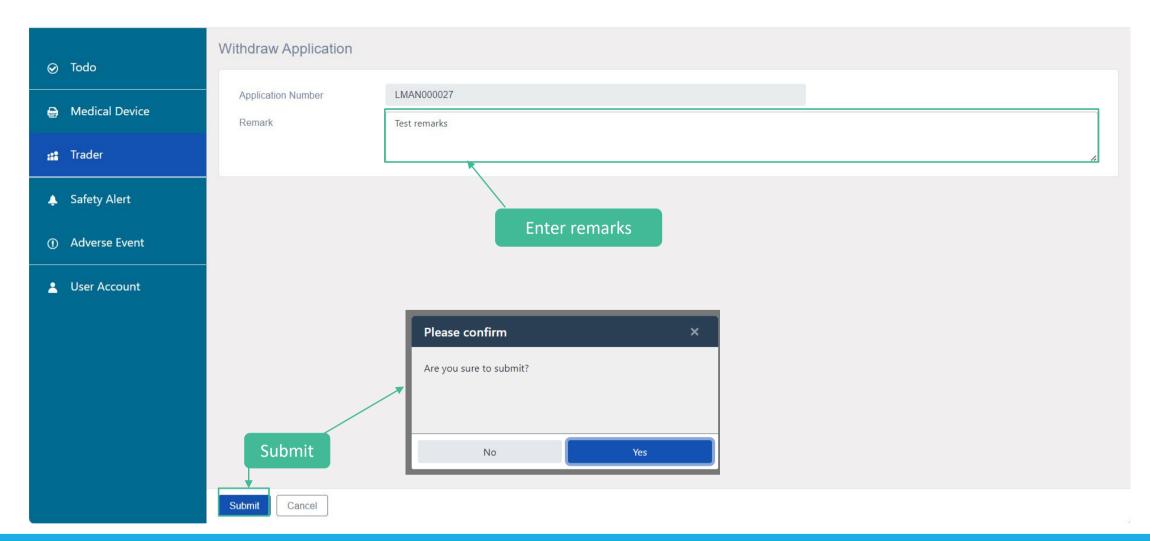


Individual Users – Withdraw Application



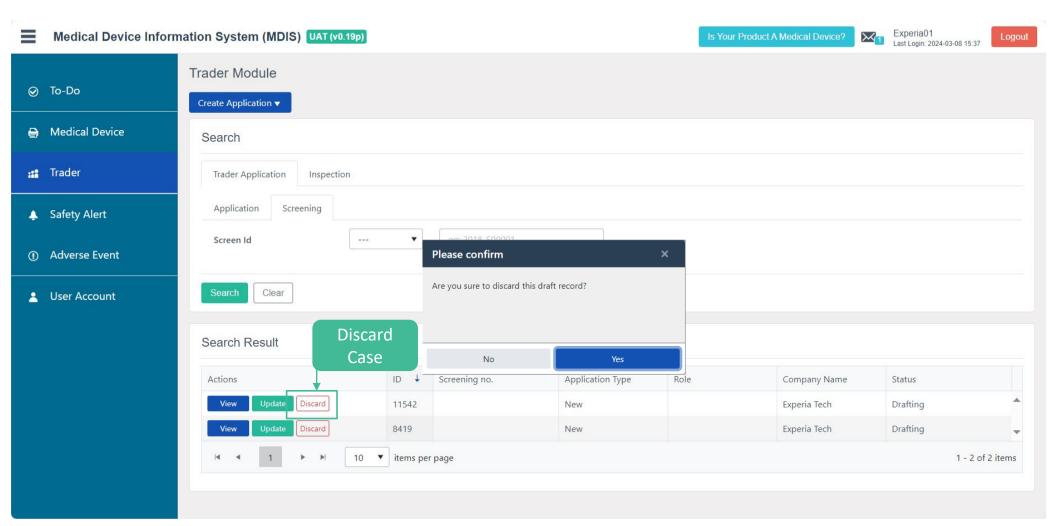


Individual Users – Withdraw Application

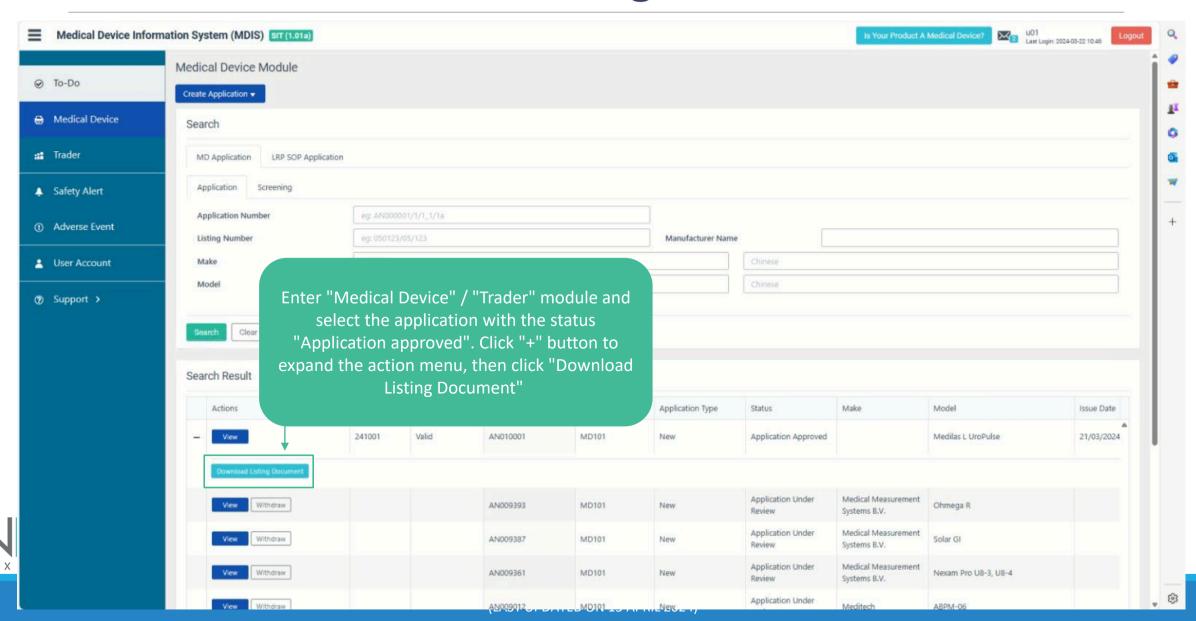




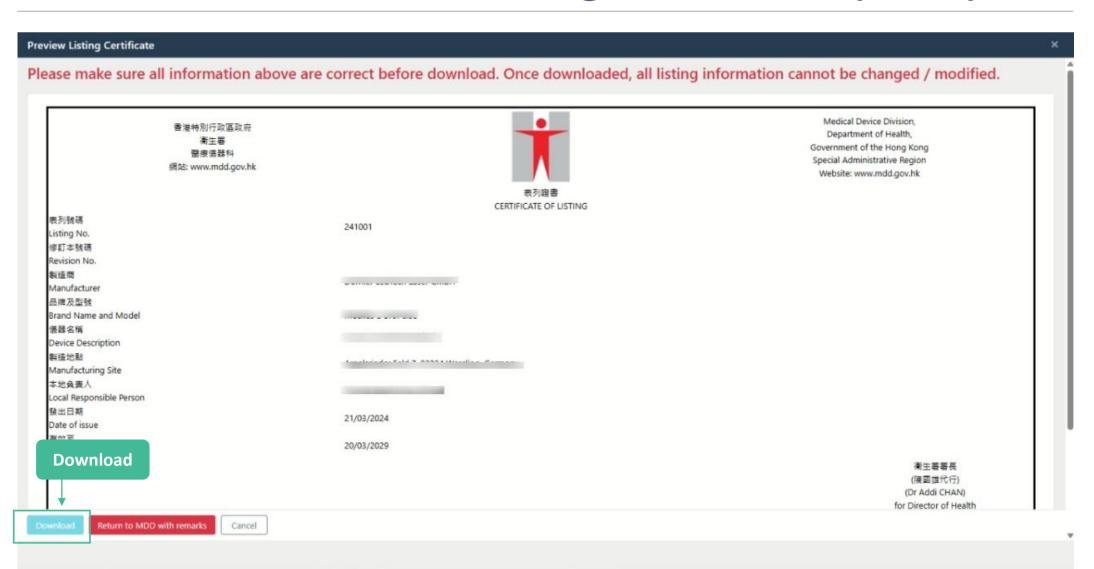
Individual Users – Discard drafted Application



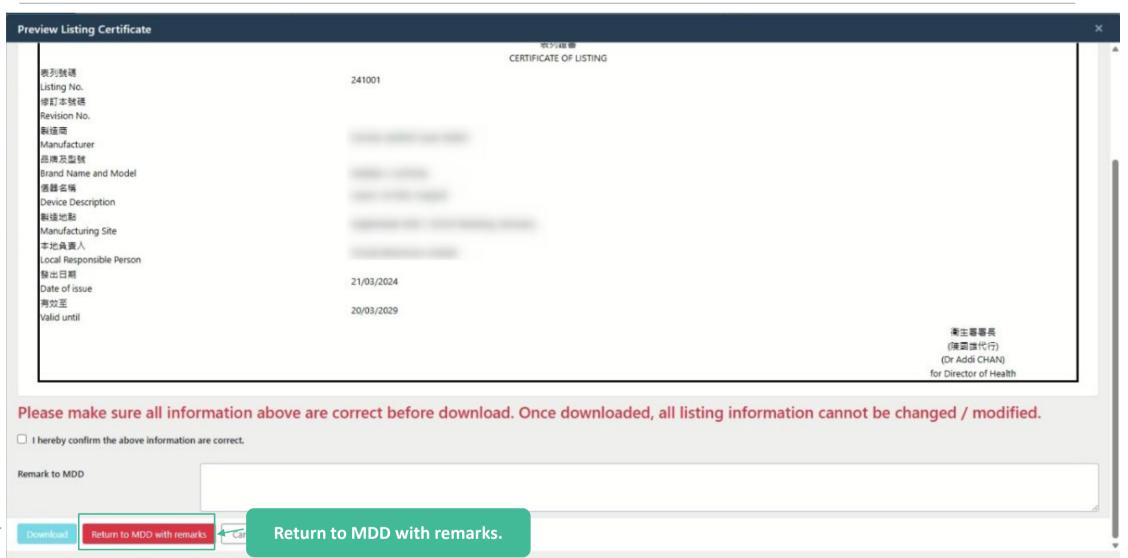
Individual Users – Print Listing e-certificate



Individual Users – Print Listing e-certificate (Cont.)



Individual Users – Print Listing e-certificate (Cont.)



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 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.
Application Appealing	The applicant clicked "Submit" and the appeal application has been successfully submitted



4) Q & A

