



# Training on Medical Device Information System (MDIS)

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## **PART III: REPORTING OF MEDICAL DEVICE SAFETY ALERTS AND ADVERSE EVENTS**



# Agenda

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- 1) Functionalities in **Trader User** Interface
- 2) Functionalities in **Individual User** Interface
  - General functions
  - Report Medical Device Safety Alerts
  - Report Medical Device Adverse Events
  - Other reporting-related matters
- 3) Enquiry and Support

# 1) Functionalities in **Trader User** Interface

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# Trader User – To-Do Overview

The dashboard provides an overview on application status and statistics

Modules available for Trader

Account Name and Last Login Time

Notifications inbox

Click to view details

Medical Device Information System (MDIS) UAT (v0.19p)

Is Your Product A Medical Device?

Experia  
Last Login: 2024-03-08 14:05

Logout

To-Do

| MD  | Trader                                    | Safety Alert        | Adverse Event       |
|---|---|---------------------|---------------------|
| Drafting: 4                               | Drafting: 1                               | Drafting: 0         | Drafting: 1         |
| Require Outstanding Info (Screening): 0   | Require Outstanding Info (Screening): 0   | Under Assessment: 1 | Under Assessment: 0 |
| Require Outstanding Info (Application): 0 | Require Outstanding Info (Application): 0 |                     |                     |
| Approved/Rejected: 0                      | Approved/Rejected: 0                      |                     |                     |
|   | Inspection Require Followup: 0            |                     |                     |

Pre-market Post-market

MD Screening Application(s) Pending Submission

| Actions                                       | Screening no. | Status   | Category  | Type | Company Name | Name of Legal Manufac |
|---|---------------|----------|-----------|------|--------------|-----------------------|
| <input type="checkbox"/> <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech |                       |
| <input type="checkbox"/> <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Test231231_1          |
| <input type="checkbox"/> <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Test231231_1          |
| <input type="checkbox"/> <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Name                  |

(LAST UPDATED ON 26 SEPTEMBER 2024)

# Trader User – To-Do Overview

Link to external Q&A page for clarification

Is Your Product A Medical Device?

Experia  
Last Login: 2024-03-08 14:05

Logout

Medical Device Information System (MDIS) UAT (v0.19p)

**To-Do**

- MD
  - Drafting: 4
  - Require Outstanding Info (Screening): 0
  - Require Outstanding Info (Application): 0
  - Approved/Rejected: 0
- Trader
  - Drafting: 1
  - Require Outstanding Info (Screening): 0
  - Require Outstanding Info (Application): 0
  - Approved/Rejected: 0
  - Inspection Require Followup: 0
- Safety Alert
  - Drafting: 0
  - Under Assessment: 1
- Adverse Event
  - Drafting: 1
  - Under Assessment: 0

Pre-market | Post-market

### MD Screening Application(s) Pending Submission

| <input type="checkbox"/> | Actions              | Screening no. | Status   | Category  | Type | Company Name | Name of Legal Manufac |
|--------------------------|----------------------|---------------|----------|-----------|------|--------------|-----------------------|
| <input type="checkbox"/> | <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech |                       |
| <input type="checkbox"/> | <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Test231231_1          |
| <input type="checkbox"/> | <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Test231231_1          |
| <input type="checkbox"/> | <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Name                  |

Bulk selection for export



# Trader User – To-Do Overview

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia Last Login: 2024-03-08 14:05 Logout

Pre-market Post-market Switch between Pre/Post-market

### MD Screening Application(s) Pending Submission

| <input type="checkbox"/> | Actions              | Screening no. ↓ | Status          | Category                 | Type       | Company Name        | Name of Legal Manufac |
|--------------------------|----------------------|-----------------|-----------------|--------------------------|------------|---------------------|-----------------------|
| <input type="checkbox"/> | <a href="#">View</a> |                 | <i>Drafting</i> | <i>MD-C2&amp;3&amp;4</i> | <i>New</i> | <i>Experia Tech</i> |                       |
| <input type="checkbox"/> | <a href="#">View</a> |                 | <i>Drafting</i> | <i>MD-C2&amp;3&amp;4</i> | <i>New</i> | <i>Experia Tech</i> | <i>Test231231_1</i>   |
| <input type="checkbox"/> | <a href="#">View</a> |                 | <i>Drafting</i> | <i>MD-C2&amp;3&amp;4</i> | <i>New</i> | <i>Experia Tech</i> | <i>Test231231_1</i>   |
| <input type="checkbox"/> | <a href="#">View</a> |                 | <i>Drafting</i> | <i>MD-C2&amp;3&amp;4</i> | <i>New</i> | <i>Experia Tech</i> | <i>Name</i>           |

1 10 items per page 1 - 4 of 4 items [Export](#)

### Trader Screening Application(s) Pending Submission

| <input type="checkbox"/> | Actions              | Screening no. | Status          | Company Name        | Type       | Role | SCNO |
|--------------------------|----------------------|---------------|-----------------|---------------------|------------|------|------|
| <input type="checkbox"/> | <a href="#">View</a> |               | <i>Drafting</i> | <i>Experia Tech</i> | <i>New</i> |      |      |

# Trader User – To-Do Overview

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia Last Login: 2024-03-08 14:05 Logout

**To-Do**

- MD
  - Drafting: 4
  - Require Outstanding Info (Screening): 0
  - Require Outstanding Info (Application): 0
  - Approved/Rejected: 0
- Trader
  - Drafting: 1
  - Require Outstanding Info (Screening): 0
  - Require Outstanding Info (Application): 0
  - Approved/Rejected: 0
- Safety Alert
  - Drafting: 0
  - Under Assessment: 1
- Adverse Event
  - Drafting: 1
  - Under Assessment: 0

Pre-market Post-market

MD Screening Application(s) Pending Submissions

Filters can be applied for sorting submissions

| Actions                                       | Screening no. | Status   | Category  | Type | Company Name | Name of Legal Manufacturer |
|---|---------------|----------|-----------|------|--------------|----------------------------|
| <input type="checkbox"/> <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech |                            |
| <input type="checkbox"/> <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Test231231_1               |
| <input type="checkbox"/> <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Test231231_1               |
| <input type="checkbox"/> <a href="#">View</a> |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Name                       |

# Trader User – User Account Management – Reset Password

The screenshot displays the 'Medical Device Information System (MDIS) UAT (v0.19p)' interface. The top navigation bar includes a menu icon, the system name, a version tag, a 'Is Your Product A Medical Device?' button, a user profile for 'Experia' with a last login of '2024-03-08 14:05', and a 'Logout' button. The left sidebar contains navigation items: 'To-Do', 'Medical Device', 'Trader', 'Safety Alert', 'Adverse Event', and 'User Account' (which is highlighted). The main content area is titled 'User Account' and has tabs for 'Account Information', 'Role', 'Contact Info', and 'Individual Accounts'. The 'Account Information' tab is active, showing a 'Login Name' field with a 'Reset Password' button. A green callout box labeled 'Reset Password' points to this button. Below the 'Company Information' section, a 'Reset Password' modal window is open. It contains three input fields: 'Old Password', 'New Password', and 'Confirm Password'. A 'Confirm' button is highlighted with a green callout box labeled 'Confirm'. The modal also lists password requirements: 'Minimum of 8 characters', 'Maximum of 15 characters', 'At least one digit', and 'At least one special character'. The background form shows fields for 'Company / Organization Name' (with English and Chinese options), 'Registration Certification Type' (with 'Business Registration Certificate' selected), 'Upload BR' (with 'Experia\_BR\_2023.pdf'), 'Business Registration Number' (with '62558875-000-12-22-3'), and 'Company Type' (with 'Main Company' selected). A 'Save' button is at the bottom left, and a 'Reset' button is at the bottom right.





# Trader User – User Account Management

Medical Device Information System (MDIS) UAT (PreProd\_v1.1.0) Is Your Product A Medical Device? Eng | 繁體 Last Login: 2024-09-24 11:59 Logout

**User Account**

Account Information | Role | Individual Accounts

Account

Login Name: [Redacted] Reset Password

Company Information

Company / Organization Name

English: [Redacted] Limited

Chinese: [Redacted]

Registration Certification Type:  Business Registration Certificate

Upload BR: [Redacted].pdf

Business Registration Number: [Redacted] Expiry Date: 06/05/2025

Company Type:  Main Company  Branch Company

Address

English Address: [Redacted] Hong Kong

**View the Account Information, Role, and Individual Accounts under the Trader**

**Please approach Medical Device Division for any update in account information**

# Trader User – User Account Management – Upload BR

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

1. 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

The screenshot displays the 'Medical Device Information System (MDIS) UAT (PreProd\_v1.1.0)' interface. The left sidebar shows the navigation menu with 'User Account' selected. The main content area is titled 'User Account' and contains several sections: 'Account Information', 'Account', 'Company Information', and 'Registration Certification Type'. The 'Update Trader Information' form is visible, featuring an 'Upload' section with a 'Select files...' button and a 'Drop files here to upload' area. Below this, the 'Business Registration Number' field is highlighted with a green arrow and the number '3', and the 'Expiry Date' field is highlighted with a green arrow and the number '4'. A red error message is displayed at the bottom: 'BR expired. Please upload the latest BR.' The 'Submit' button is highlighted with a green arrow and the number '2'. The 'Cancel' button is also visible. The top right corner shows the user's name, 'Eng | 繁體', and the 'Logout' button.



# Trader User – User Account Management

Medical Device Information System (MDIS) UAT (PreProd\_v1.1.0) Is Your Product A Medical Device? Eng | 繁體 Last Login: 2024-09-24 11:59 Logout

**User Account**

Account Information **Role** Individual Accounts

**Role**

LRP  Importer  Distributor  Local Manufacturer

**LRP List**

|             |                 |             |            |                 |                   |                      |
|-------------|-----------------|-------------|------------|-----------------|-------------------|----------------------|
| Listing no. | LRP0 [REDACTED] | Revision    | [REDACTED] | Application no. | LRPA00 [REDACTED] | <a href="#">View</a> |
| Issue Date  | DD/MM/YYYY      | Expiry Date | DD/MM/YYYY | Delist Date     | DD/MM/YYYY        |                      |
| Remarks     |                 |             |            |                 |                   |                      |

View the Role and Individual Accounts under the Trader

The approved role is displayed under Role tab



# Trader User – User Account Management – Add Individual Accounts

Medical Device Information System (MDIS) UAT (PreProd\_v1.1.0) Is Your Product A Medical Device? Eng | 繁體 Last Login: 2024-09-24 11:59 Logout

**User Account**

Account Information Role **Individual Accounts** View individual accounts

**Individual Accounts**

Add Press Add to add individual account

| Action  | Login ID             | Given Name           | Surname              | Email                | Phone                | Post                 |
|---|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| <span>Add</span> <span>Cancel</span> <span>---</span> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| + <span>Edit</span> <span>Delete</span>               | [Redacted]           | [Redacted]           | [Redacted]           | [Redacted]           | [Redacted]           | [Redacted]           |
| + <span>Edit</span> <span>Delete</span>               | [Redacted]           | [Redacted]           | [Redacted]           | [Redacted]           | [Redacted]           | [Redacted]           |
| + <span>Edit</span> <span>Delete</span>               | 3                    | POS                  | [Redacted]           | [Redacted]           | [Redacted]           | [Redacted]           |
| + <span>Edit</span> <span>Delete</span>               | 4                    | ALL                  | so6                  | so6                  | Trader               | so6_mdd@dh.gov.hk    |

Press Add after filling in all Mandatory information

# Trader User – User Account Management – Case Reassign

## User Account

Account Information

Role

Individual Accounts

View individual accounts

### Individual Accounts

[Add](#)

| Action  | # | Responsibility | Login ID   | Given Name | Surname    | Email             | Phone      | Post       |
|---|---|----------------|------------|------------|------------|-------------------|------------|------------|
| <a href="#">+</a> <a href="#">Edit</a> <a href="#">Delete</a> | 1 | ALL            | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED]        | [REDACTED] | [REDACTED] |
| <a href="#">+</a> <a href="#">Edit</a> <a href="#">Delete</a> | 2 | ALL            | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED]        | [REDACTED] | [REDACTED] |
| <a href="#">+</a> <a href="#">Edit</a> <a href="#">Delete</a> | 3 | [REDACTED]     | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED]        | [REDACTED] | [REDACTED] |
| <a href="#">-</a> <a href="#">Edit</a> <a href="#">Delete</a> | 4 | ALL            | so6        | so6        | Trader     | so6_mdd@dh.gov.hk |            |            |

[Case Reassign](#)

Expand by pressing the "+" sign, to Reassign case or Delink iAM Smart (if any)

# Trader User – User Account Management – Case Reassign

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

The screenshot displays the 'Case Reassignment' interface. At the top, there is a 'Select Module' dropdown menu with a red border. Below it, a table lists 'MD / IVDM Application(s)'. The first row is selected, showing application number 'AN007753' and status 'Application Under Review'. At the bottom, there is a 'To be assigned to:' dropdown menu with 'exp06 exp' selected, and a 'Confirm reassignment' button. A green callout box points to the 'Select Module' dropdown with the text: 'Select Module for reassignment and pick the applications and to-be assigned role'. Another green callout box points to the 'Confirm' button with the text: 'Confirm reassignment'.

| Application no. / ID                         | Status                      |
|--|-----------------------------|
| <input checked="" type="checkbox"/> AN007753 | Application Under Review    |
| <input type="checkbox"/> AN005944_1          | Application Approved        |
| <input type="checkbox"/> AN009331            | Application Approved        |
| <input type="checkbox"/> AN009349            | Application Under Review    |
| <input type="checkbox"/> AN009351            | Application Under Review    |
| <input type="checkbox"/> AN009352            | Delist Application Approved |
| <input type="checkbox"/> AN009353            | Delist Application Approved |



# Trader User – User Account Management – Edit account information

- To-Do
- Medical Device
- Trader
- Safety Alert
- Adverse Event
- User Account
- Support >

## User Account

Account Information Role Individual Accounts

### Individual Accounts

[Add](#)

| Action  | # | Responsibility | Login ID | Given Name | Surname | Email             | Phone | Post |
|---|---|----------------|----------|------------|---------|-------------------|-------|------|
| + <a href="#">Edit</a> <a href="#">Delete</a> |   |                |          |            |         |                   |       |      |
| + <a href="#">Edit</a> <a href="#">Delete</a> | 2 | ALL            |          |            |         |                   |       |      |
| + <a href="#">Edit</a> <a href="#">Delete</a> | 3 | POS            |          |            |         |                   |       |      |
| + <a href="#">Save</a> <a href="#">Cancel</a> | 4 | All            | so6      | so6        | Trader  | so6_mdd@dh.gov.hk |       |      |

Press "Edit" to edit the account information

Press "Save" after editing

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

Medical Device Information System (MDIS) UAT (PreProd\_v1.1.0) Is Your Product A Medical Device? Eng | 繁體 Last Login: 2024-09-24 11:59 Logout

**User Account**

Account Information Role Individual Accounts

### Individual Accounts

[Add](#)

| Surname                             | Email  | Phone                | Post                 | Individual Account       | Receive Trader Account Notification | Last Login Time                         |
|-------------------------------------|--|----------------------|----------------------|--------------------------|-------------------------------------|---|
| Tsang                               | csa3_mdd@dh.gov.hk                             | [REDACTED]           |                      | N                        | <input type="checkbox"/>            | Mon Sep 09 2024 09:32:56 GMT+8 (香港標準時間) |
| Ban                                 | csa3_mdd@dh.gov.hk                             | [REDACTED]           |                      | N                        | <input type="checkbox"/>            | Fri Sep 13 2024 17:09:20 GMT+8 (香港標準時間) |
| Chan                                | csa3_mdd@dh.gov.hk                             | [REDACTED]           |                      | No                       | <input type="checkbox"/>            | Tue Sep 03 2024 17:19:35 GMT+8 (香港標準時間) |
| <input type="text" value="Trader"/> | <input type="text" value="so6_mdd@dh.gov.hk"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Tue Sep 24 2024 10:44:22 GMT+8 (香港標準時間) |

**Check this box to Receive Trader Account Notification, afterwards notification email to Trader will be sent to Individual Users as well**



# Trader User – User Account Management – Delink iAM Smart

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia Last Login: 2024-03-08 14:05 Logout

**User Account**

Account Information Role **Individual Accounts** View individual accounts

**Individual Accounts**

Add

| Action   | # | Responsibility | Login ID | Given Name | Surname | Email | Phone    | Post |
|--|---|----------------|----------|------------|---------|-------|----------|------|
| + <span>Edit</span> <span>Delete</span>                  | 1 | ALL            |          |            |         |       | 91231234 |      |
| - <span>Edit</span> <span>Delete</span>                  | 2 | ALL            |          |            |         |       |          |      |
| <span>Case Reassign</span> <span>Delink iAM Smart</span> | 3 | ALL            |          |            |         |       |          |      |
| + <span>Edit</span> <span>Delete</span>                  |   |                |          |            |         |       |          |      |

Delink iAM Smart from the account

**Please confirm**

Are you sure to delink with "iAM Smart"?

No Yes



## 2) Functionalities in **Individual User** Interface

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# Functionalities in **Individual User** Interface

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

# Individual Users – User Account Management – reset Password

Medical Device Information System (MDIS) UAT (PreProd\_v1.1.0) Is Your Product A Medical Device? Eng | 繁體 S06 Last Login: 2024-09-24 14:26 Logout

**User Account**

Account

Login Name \*  Reset Password Delink with IAM Smart

English Name

Chinese Name

Post Title

Title

Email

Contact Telephone for Public Enquiries

URL

Reset Password

Old Password

New Password

Confirm Password

Confirm

Password must contains:

- Minimum of 8 characters
- Maximum of 15 characters
- At least one upper-case alphabet
- At least one lower-case alphabet
- At least one digit
- At least one special character



# Individual Users – User Account Management

Medical Device Information System (MDIS) UAT (PreProd\_v1.1.0) Is Your Product A Medical Device? Eng | 繁體 S06 Last Login: 2024-09-24 14:26 Logout

**User Account**

Account

Login Name \*  Reset Password Delink with IAM Smart

English Name

Chinese Name

Post Title  Designation

Title

Email  Fax

Contact Telephone for Public Enquiries  Mobile Telephone for Urgent Use (24 hours)

URL

**Delink iAM Smart**

Please confirm  
Are you sure to delink with "iAM Smart"?

No Yes



# Individual Users – To-Do Overview

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

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia01 Last Login: 2024-03-08 15:37 Logout

**To-Do**

Overview on the status of the application

| MD  | Trader                                    | Safety Alert        | Adverse Event       |
|---|---|---------------------|---------------------|
| Drafting: 4                               | Drafting: 1                               | Drafting: 0         | Drafting: 1         |
| Require Outstanding Info (Screening): 0   | Require Outstanding Info (Screening): 0   | Under Assessment: 1 | Under Assessment: 0 |
| Require Outstanding Info (Application): 0 | Require Outstanding Info (Application): 0 |                     |                     |
| Approved/Rejected: 0                      | Approved/Rejected: 0                      |                     |                     |
| Inspection Require Followup: 0            | Inspection Require Followup: 0            |                     |                     |

Pre-market Post-market

Click to view details of the application

Bulk selection and apply actions

MD Screening Application(s) Pending Submission

| Actions                              | Screening no. | Status   | Category  | Type | Company Name | Name of  |
|--------------------------------------|---------------|----------|-----------|------|--------------|----------|
| <input type="checkbox"/> View Update |               | Drafting | MD-C2&3&4 | New  | Experia Tech |          |
| <input type="checkbox"/> View Update |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Name     |
| <input type="checkbox"/> View Update |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Test2312 |
| <input type="checkbox"/> View Update |               | Drafting | MD-C2&3&4 | New  | Experia Tech | Test2312 |

# Individual Users – To-Do Overview

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia01 Last Login: 2024-03-08 15:37 Logout

**To-Do**

- MD
  - Drafting: 4
  - Require Outstanding Info (Screening): 0
  - Require Outstanding Info (Application): 0
  - Approved/Rejected: 0
- Trader
  - Drafting: 1
  - Require Outstanding Info (Screening): 0
  - Require Outstanding Info (Application): 0
  - Approved/Rejected: 0
  - Inspection Require Followup: 0
- Safety Alert
  - Drafting: 0
  - Under Assessment: 1
- Adverse Event
  - Drafting: 1
  - Under Assessment: 0

Pre-market | Post-market

MD Screening Application(s) Pending Submission

Filters can be applied for sorting submissions

Contains [ ] And [ ] Contains [ ] Clear Filter

| <input type="checkbox"/> | Actions                                     | Screening no. ↓ | Status   | Category  | Type | Company Name | Name of  |
|--------------------------|---|-----------------|----------|-----------|------|--------------|----------|
| <input type="checkbox"/> | <a href="#">View</a> <a href="#">Update</a> |                 | Drafting | MD-C2&3&4 | New  | Experia Tech |          |
| <input type="checkbox"/> | <a href="#">View</a> <a href="#">Update</a> |                 | Drafting | MD-C2&3&4 | New  | Experia Tech | Name     |
| <input type="checkbox"/> | <a href="#">View</a> <a href="#">Update</a> |                 | Drafting | MD-C2&3&4 | New  | Experia Tech | Test2312 |
| <input type="checkbox"/> | <a href="#">View</a> <a href="#">Update</a> |                 | Drafting | MD-C2&3&4 | New  | Experia Tech | Test2312 |

# Individual Users – To-Do Overview

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia01 Last Login: 2024-03-08 15:37 Logout

**To-Do**

- Medical Device
- Trader
- Safety Alert
- Adverse Event
- User Account

**To-Do Summary:**

| Category      | Sub-category                           | Count |
|---------------|--|-------|
| MD            | Drafting                               | 4     |
|               | Require Outstanding Info (Screening)   | 0     |
|               | Require Outstanding Info (Application) | 0     |
|               | Approved/Rejected                      | 0     |
| Trader        | Drafting                               | 1     |
|               | Require Outstanding Info (Screening)   | 0     |
|               | Require Outstanding Info (Application) | 0     |
|               | Approved/Rejected                      | 0     |
| Safety Alert  | Drafting                               | 0     |
|               | Under Assessment                       | 1     |
| Adverse Event | Drafting                               | 1     |
|               | Under Assessment                       | 0     |

Pre-market  Post-market  Switch to Post-market cases

**SA Report(s) Pending Submission**

| <input type="checkbox"/> | Actions | ID | Screening no. | Status |
|--------------------------|---------|----|---------------|--------|
| No records available.    |         |    |               |        |

10 items per page 0 - 0 of 0 items

**AE Report(s) Pending Submission**





## 2) Functionalities in **Individual User** Interface -Report Medical Device Safety Alerts

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# Individual Users – Report Medical Device Safety Alert (P. 1-3)

MDIS UAT (PreProd\_v1.1.0)

Is Your Product A Medical Device?

Eng | 繁體 S06 Last Login: 2024-09-24 14:28 Logout

Safety Alert Module

Create Alert

Search

Case Screen Case

Case no. eg: HK-2018-0001/0001/2018

Alert Reference Model

Search Clear

Click to switch between modules

Click "Search" to find submitted alerts

# Individual Users – Report Medical Device Safety Alert (P. 2-3)

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia01 Last Login: 2024-03-08 15:37 Logout

**Safety Alert** \* - Mandatory field

Form PICS

**Safety Alert Identification**

Safety Alert Identification Date \*   Alert Reference

**Reporter Contact Information**

Role  Company Name

Contact Person  Post

Telephone  Fax  Mobile

Email

**Device Information**

Device Name \*

| # | Listed | HKMD no. | Make | Model | Status |
|---|--------|----------|------|-------|--------|
|   |        |          |      |       |        |

**Annotations:**

- Mandatory fields are highlighted in red
- Save as draft
- Click "Submit" to apply form validation checking



# Individual Users – Report Medical Device Safety Alert (P. 3-3)

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia01 Last Login: 2024-03-08 15:37 Logout

Safety Alert \* - Mandatory field

Form PICS

It is Mandatory to check the PICS

Personal Data (Privacy) Ordinance 個人資料 (私隱) 條例 用途聲明

**1. Purpose of Collection**  
The personal data that are provided by you in connection with this Report Form or when you are in contact with the Department of Health (DH) in connection with in this Report Form will be used by the DH for medical device safety alert monitoring and management. The provision of personal data is voluntary. If you do not provide sufficient information in the Report Form as specified, we may not be able to provide assistance to you.

**2. Classes of Transferees**  
The personal data you provided are mainly for use within the DH but they may also be disclosed to other Government bureaux / departments, or relevant parties for the purpose mentioned in paragraph 1 above, if required. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

**3. Access to Personal Data**  
You have a right to request access to and correction of your personal data as provided in accordance with the Personal Data (Privacy) Ordinance to obtain a copy of your personal data provided by you during the occasion as mentioned in paragraph 1 above. A fee may be charged for such access or correction.

**4. Enquiries**  
Enquiries in relation to the personal data, including requests for making access or corrections to the data, should be addressed to:  
Executive Officer (Medical Device)  
Medical Device Division, Department of Health  
Room 604, 6/F, 14 Taikoo Wan Road  
Taikoo Shing, Hong Kong  
Telephone number: 3107 8453  
Email address: mdd@dh.gov.hk.

Scroll down to check the PICS

A confirmation pop-up window will display the case number upon successful reporting.  
Example: Report sent <SA2024-S10250>  
The safety alert will be sent for MDD assessment.

Save Submit Cancel

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

## 2) Functionalities in **Individual User** Interface -Report Medical Device Adverse Events

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# Individual Users – Report Medical Device Adverse Event (P. 1-3)

The screenshot displays the Medical Device Information System (MDIS) User Acceptance Test (UAT) interface. The top navigation bar includes the system name 'Medical Device Information System (MDIS) UAT (v0.19p)', a link 'Is Your Product A Medical Device?', user information 'Experia01 Last Login: 2024-03-08 15:37', and a 'Logout' button. The left sidebar contains navigation items: 'To-Do', 'Medical Device', 'Trader', 'Safety Alert', 'Adverse Event' (highlighted), and 'User Account'. The main content area is titled 'Adverse Event Module' and features a 'Create Adverse Event Report' button with a dropdown arrow. A callout box points to this button with the text 'Create AE report, Click to expand drop down'. Below this is a search section with a 'Search' button and a 'Clear' button. A callout box points to the 'Search' button with the text 'Click "Search" to find submitted AE reports'. The search form includes a 'Case' dropdown menu (with 'MD User' and 'LRP' options visible), a 'Screen Case' checkbox, a 'Case no.' input field (with the example 'eg: AEC-2023-0001/0001/2023'), and a 'Model' input field.



# Individual Users – Report Medical Device Adverse Event (P. 2-3)

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia01 Last Login: 2024-03-08 15:37 Logout

Medical Device Adverse Event Report Form - for Local Responsible Persons \* - Mandatory field

Form PICS

**Mandatory fields are highlighted in red**

**I. Administrative Information**

|                              |                |                       |                |                    |                |
|------------------------------|----------------|-----------------------|----------------|--------------------|----------------|
| ReportType                   | ---            | LRP Report no.        |                | Classification     | ---            |
| Date of this Report          | day/month/year | Date of Adverse Event | day/month/year | LRP Awareness Date | day/month/year |
| Expected Date of Next Report | day/month/year |                       |                |                    |                |

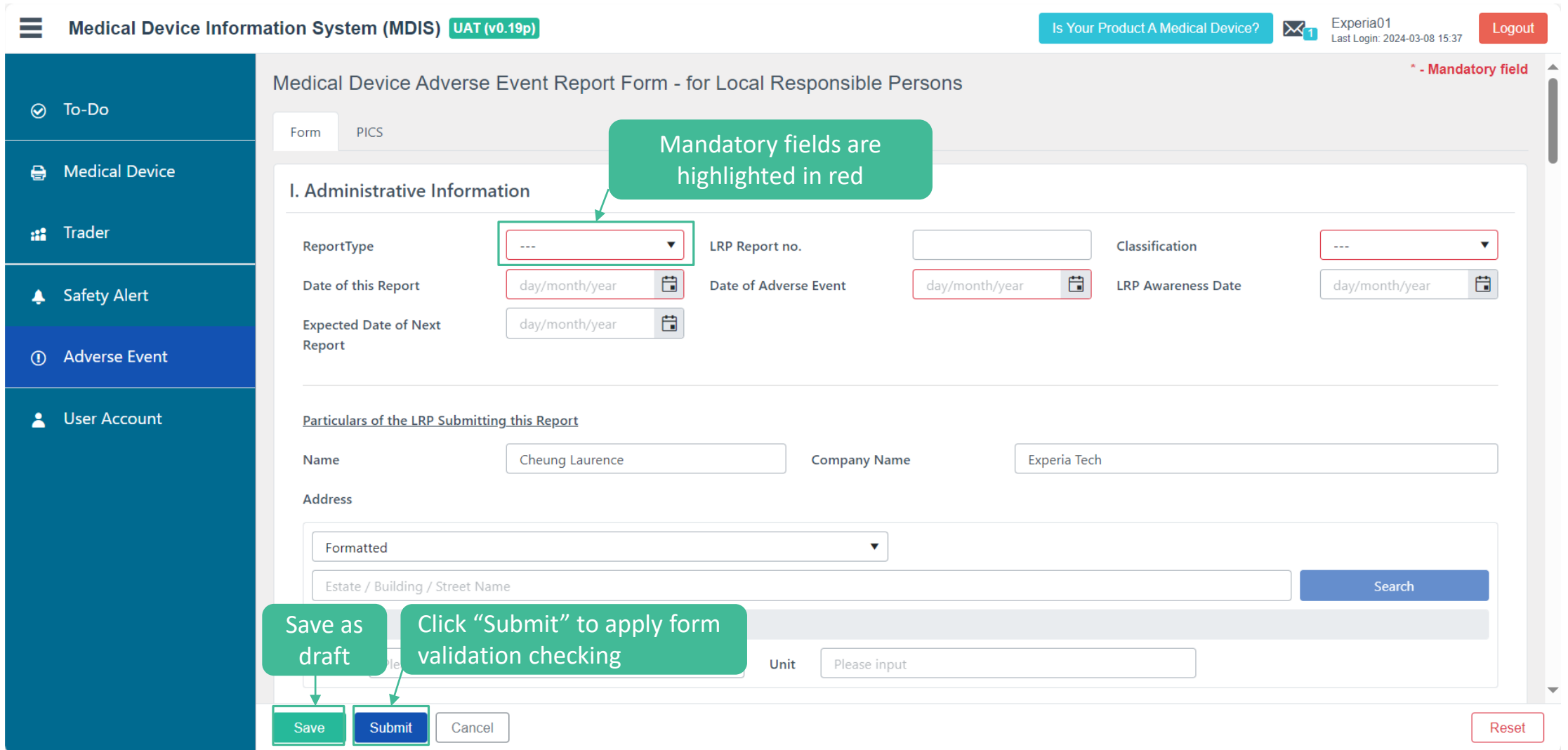
Particulars of the LRP Submitting this Report

|         |  |              |              |
|---------|--|--------------|--------------|
| Name    | Cheung Laurence                              | Company Name | Experia Tech |
| Address | Formatted<br>Estate / Building / Street Name |              |              |

Unit Please input

**Save as draft** **Click "Submit" to apply form validation checking**

Save Submit Cancel Reset



# Individual Users – Report Medical Device Adverse Event (P. 3-3)

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia01 Last Login: 2024-03-08 15:37 Logout

Medical Device Adverse Event Report Form - for Local Responsible Persons \* - Mandatory field

Form  It is Mandatory to check the PICS

Personal Data (Privacy) Ordinance (個人資料 (私隱) 條例) 用途聲明

**1. Purpose of Collection**  
The personal data that are provided by you in connection with this Report Form or when you are in contact with the Department of Health (DH) in connection with in this Report Form will be used by the DH for medical device adverse event investigation and management. The provision of personal data is voluntary. If you do not provide sufficient information in the Report Form as specified, we may not be able to provide assistance to you.

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Medical Device Division, Department of Health  
Room 604, 6/F, 14 Taikoo Wa Road  
Taikoo Shing, Hong Kong  
Telephone number: 3107 8453  
Email address: mdd@dh.gov.hk

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

Save Submit Cancel

Click "Submit" to apply form validation checking & submit



# Functionalities in **Individual User** Interface

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- **Other reporting-related matters**
  - Access draft reports
  - Checking report status
  - Responding to Case Enquiries

# Individual Users – Access draft Reports

Medical Device Information System (MDIS) UAT (PreProd\_v1.1.0) Is Your Product A Medical Device? Eng | 繁體 s06 Last Login: 2024-09-24 17:21 Logout

**To-Do**

- Safety Alert
  - Drafting: 1
  - Under Assessment: 1
- Adverse Event
  - Drafting: 0
  - Under Assessment: 1

Post-market

SA Report(s) Pending Submission

| <input type="checkbox"/> | Actions   | ID     | Screening no. | Status   |
|--------------------------|---|--------|---------------|----------|
| <input type="checkbox"/> | <a href="#">View</a> <a href="#">Update</a> <a href="#">Discard</a> | 107539 |               | Drafting |

1 - 1 of 1 items

Export

AE Report(s) Pending Submission

No records available.

0 - 0 of 0 items

**View** **Update** **Discard**

Saved draft reports will appear in the Report(s) Pending Submission To-Do list. Click "View" to view the submission, "Update" to continue editing, or "Discard" to discard the draft reports



# Individual Users – Check Report status

The status will be updated according to MDD's procedures. You can check the latest status by clicking “**Safety Alert**” / “**Adverse Event**” and search the case record of interest.

Medical Device Information System (MDIS) UAT (PreProd\_v1.1.0) Is Your Product A Medical Device? Eng | 繁體 Last Login: 2024-09-24 17:21 Logout

Safety Alert Module

Create Alert

Search

Case Screen Case

Case no. eg: HK-2018-0001/0001/2018

Alert Reference Model

Search Clear

Search Result

| Actions              | ID ↓  | Case no.     | Source | Open Date  | File Closing D... | Status           | CO      |
|----------------------|-------|--------------|--------|------------|-------------------|------------------|---------|
| <a href="#">View</a> | 48913 | HK-2024-0103 | FSCA   | 24/09/2024 |                   | Work in progress | SO(MD)2 |

1 10 items per page 1 - 1 of 1 items

In the 'Case' tab, you can search for case, view the latest status, and submit supplementary information if needed.

# Individual Users – Responding to Case Enquiries

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

The screenshot displays a user interface with a sidebar on the left and a main content area. The sidebar contains the following menu items: To-Do, Medical Device, Trader, Safety Alert, Adverse Event, User Account, and Support. The main content area is divided into three sections:

- AE Report(s) Pending Submission:** A table with columns: Actions, ID, Screening no., and Status. It contains one row with ID 107539 and Status Drafting. Below the table are pagination controls (1 of 1 items) and an Export button.
- SA Case(s) Under Assessment:** A table with columns: Actions, ID, Case no., and Status. It contains one row with ID 48913 and Case no. HK-2024-0103, Status Pending Assessment. Below the table are pagination controls (1 of 1 items) and an Export button.
- AE Case(s) Under Assessment:** A table with columns: Actions, S/F, Case no., and Status. It contains one row with S/F 1756 and Case no. AEC-2024-0029, Status Pending Assessment. Below the table are pagination controls (1 of 1 items) and an Export button.

A green callout box with an arrow pointing to the 'SA Case(s) Under Assessment' section contains the text: "Inquiries from MDD in safety alert and adverse event cases will be displayed in To-Do list for user's response".

# Individual Users – Responding to Case Enquiries

1. Access “**Conversation**” tab for the case to view the enquiry from MDD
2. Click “**Reply**” to provide complete reply or supplementary information

The screenshot displays the Medical Device Information System (MDIS) interface. At the top, the system name and version (UAT (PreProd\_v1.1.0)) are visible, along with a navigation menu on the left. The main content area shows a "Safety Alert - HK-2024-0103" case. A "Report" tab is selected, and a "Conversation" tab is highlighted with a green box and a green arrow labeled "1". Below the tabs, the conversation details are shown, including the subject, from, and date. A "Reply" button is highlighted with a green box and a green arrow labeled "2".

Medical Device Information System (MDIS) UAT (PreProd\_v1.1.0)

Is Your Product A Medical Device? Eng | 繁體 Last Login: 2024-09-24 17:21 Logout

SA Report(s) Pending Submission

Safety Alert - HK-2024-0103 \* - Mandatory field

Report Conversation

1 Conversation

Subject: [Our ref no.: HK-2024-0103] [REDACTED]  
From: [SO(MD)2] Marcus NG 24/09/2024 17:12:59 Tuesday

2 Reply

Our ref no.: HK-2024-0103

Dear Sir/Madam,

Manufacturer: Test Manufacturer

Model: ABC

Model Identifier:

With reference to the Medical Device Safety Alert (FSCA Ref: Testing 20240924) (Link: <->) concerning the captioned product, I should be grateful if you would confirm with us the followings:

# Enquiry and Support

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- Please reach out to our dedicated MDIS technical support team at 3702 5356 or email at [mdis\\_support@nexify.com.hk](mailto: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](mailto:mdd@dh.gov.hk).