



Training on Medical Device Information System (MDIS)

PART I: ACCOUNT REGISTRATION



Agenda

- 1) Introduction**
- 2) Flow of Account Registration**
- 3) Q & A**

1) Introduction



Introduction

The **Medical Device Information System (MDIS)** will offer a one-stop e-service for the industry to submit online applications for listing of medical devices (MDs) and traders under the Medical Device Administrative Control System (MDACS), as well as to report safety alerts and adverse events related to MDs.

醫療儀器資訊系統支援業界一站式按照醫療儀器行政管理制
度申請醫療儀器和貿易商表列，並呈報與醫療儀器相關的安全
警示和醫療事件。

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Perform e-submission of pre-market applications and e-reporting of post-market cases• As direct contact during application / case processing stage

2) Flow of Account Registration




Registration

Medical Device Information System

Trader Login Individual Login

Experia01

...

Enter Captcha 

Login

Forgot Password Register

Click on Register

Tip: This web application is best viewed in landscape mode.

Registration (Cont.)



Register

Login Name

Company Information

Company / Organization Name

English

Chinese

Registration Certification Type Business Registration Certificate

Upload BR Drop files here to upload

Business Registration Number Expiry Date

Company Type Main Company Branch Company

Address

All Mandatory fields are indicated by red brackets and remains red after filled in

Select Type of registration certification

Upload BR image, The BR number and expiry date are auto-filled by OCR. Error message will be prompted if validation has failed

Select Company Type



- ### Errors Encountered
- BR No (5XXXXXXX-001-04-17-5) format invalid
 - BR expired. Please upload the latest BR.



Registration (Cont.)

Input by HK Address Lookup
Input by HK Address Lookup
Manual Input

The address can be entered by **HK Address Lookup** or **Manual Input**

Address

Input by HK Address Lookup

Tai Hong Street

Yat Hong Mansion, 47 Tai Hong Street, Eastern District, Hong Kong

香港, 東區, 太康街 47號, 逸康閣

Floor Unit

Enter your **building name** or **street name** to search for full address

English Address	Chinese Address
Yat Hong Mansion, 47 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 47號, 逸康閣
Kwun Fai Mansion, 53 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 53號, 觀輝閣
Lai Wan Building, 1 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 1號, 麗灣大廈
Sai Wan Ho Health Centre, 28 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 28號, 西灣河健康中心
Yee Yun Mansion, 31 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 31號, 怡雲閣
Yee Hoi Mansion, 33 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 33號, 怡海閣
35 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 35號
Yee Qun Mansion, 37 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 37號, 怡坤閣
38 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 38號
38 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 38號
38 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 38號
38 Tai Hong Street, Eastern District, Hong Kong	香港, 東區, 太康街 38號

Choose an address and click **Select**

(LAST UPDATED ON

Registration (Cont.)

Address

Formatted

Estate / Building / Street Name

Floor Unit

Contact Information of Management Representative

English Name

Chinese Name

Post Title Designation

Title

Email Fax

Office Phone Mobile Phone

URL

Fill in mandatory information with a red bracket, and click **Submit** to submit registration request to MDD for review.

After successful registration, confirmation email will be sent to the registered email address with title "Please setup your password for login to the Medical Device Information System"

Registration (Cont.)

The registrant will receive an email, and can proceed to completing the registration of their user account by clicking on the link embedded. **The link will expire after 15 minutes.**

Please be reminded to apply strong password combining special character, upper-case letter and numbers. The password should be updated every 3 months.

[MDIS] Please setup your password for login to the Medical Device Information System ...



To



Sat 13/04/2024 22:59

(This email is sent automatically by the computer system. Please do not reply to this email. 此乃電腦系統自動發出的通知，請勿回覆此電子郵件。)

Dear [REDACTED] (Login ID: [REDACTED]),

You have just created a new Trader User Account in the Medical Device Information System (MDIS)! Please click the below link to setup your password for login to the MDIS.

<https://mdis.mdd.gov.hk/reset-password?code=eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9.eyJleHAiOiJlE3MTI5OTk0MzMsImhhdCI6MTcxMjAzMywiaXNzKklxqLDUAATGd3XtktKpFsc>

Please reach out to our dedicated MDIS technical support team at 3702 5356 or email at mdis_support@nexify.com.hk whenever necessary.

Medical Device Division

Medical Device Information System

Reset Password

Reset

Password must contains:

- Minimum of 8 characters
- Maximum of 15 characters
- At least one digit
- At least one special character

After inputting the Login Name, New Password and Confirm Password, click Reset to proceed.



Accessing MDIS - Trader

URL: <https://mdis.mdd.gov.hk/>

- Login by Username, Password, Captcha
- All **Mandatory Fields** are hinted by red brackets



Department of Health
The Government of the Hong Kong Special Administrative Region

MEDICAL DEVICE DIVISION

Medical Device Information System

Trader Login Individual Login

Experia

....

Enter Captcha

Login

Forgot Password Register

Tip: This web application is best viewed in landscape mode.

Create Individual Users Accounts

The screenshot displays the Medical Device Information System (MDIS) interface. The top navigation bar includes a menu icon, the system name 'Medical Device Information System (MDIS)', a link 'Is Your Product A Medical Device?', a user profile 'Experia' with 'Last Login: 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' (highlighted). The main content area is titled 'User Account' and has tabs for 'Account Information', 'Role', 'Contact Info', and 'Individual Accounts' (selected). Below the tabs is a table titled 'Individual Accounts' with columns for 'Action', 'Login ID', 'Given Name', 'Surname', 'Email', 'Phone', and 'Post'. The table contains three rows of data. A green callout box points to the 'Add' button in the top left of the table area, stating 'Press Add to add individual account'. Another green callout box points to the 'Add' button in the first row of the table, stating 'Press Add after filling in all Mandatory information'. A third green callout box points to the 'Individual Accounts' tab, stating 'View individual accounts'. A fourth green callout box points to the 'User Account' module in the sidebar, stating 'Click on User Account module'.

Medical Device Information System (MDIS)

Is Your Product A Medical Device? Experia Last Login: 2024-03-08 14:05 Logout

User Account

Account Information Role Contact Info Individual Accounts

Individual Accounts

Press Add to add individual account

Press Add after filling in all Mandatory information

View individual accounts

Click on User Account module

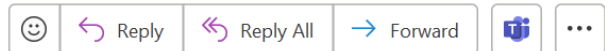
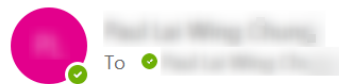
Action	Login ID	Given Name	Surname	Email	Phone	Post
+ Add Cancel	---					
+ Edit Delete	1	ALL			91231234	
- Edit Delete						
Case Re						
+ Edit Delete	3	ALL			12345678	

Create Individual Users Accounts – email notification to EIU

The added individual user will receive an email, and can proceed to completing the registration of their individual user account by clicking on the link embedded. **The link will expire after 15 minutes.**

Please be reminded to apply strong password combining special character, upper-case letter and numbers. The password should be updated every 3 months.

[MDIS] Please setup your password for login to the Medical Device Information System ...



Sat 13/04/2024 22:59

(This email is sent automatically by the computer system. Please do not reply to this email. 此乃電腦系統自動發出的通知，請勿回覆此電子郵件。)

Dear [REDACTED] (Login ID: [REDACTED]),

Your trader has just created a new Individual User Account for you in the Medical Device Information System (MDIS)! Please click the below link to setup your password for login to the MDIS.

<https://mdis.mdd.gov.hk/reset-password?code=eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9.eyJleHAiOiJlE3MTI5OTk0MzMsImhhdCI6MTcxMjAzMywiaXNzKklxqLDUAATGd3XtktKpFsc>

Please reach out to our dedicated MDIS technical support team at 3702 5356 or email at mdis_support@nexify.com.hk whenever necessary.

Medical Device Division

Medical Device Information System

Reset Password

Reset

Password must contains:

- Minimum of 8 characters
- Maximum of 15 characters
- At least one digit
- At least one special character

After inputting the Login Name, New Password and Confirm Password, click **Reset** to proceed.

Accessing MDIS – Individual Users

- For individual users, Trader Username and Individual Username are required
- The system also supports iAM Smart login
- All **Mandatory Fields** are hinted by red brackets



Department of Health
The Government of the Hong Kong Special Administrative Region

MEDICAL DEVICE DIVISION

Medical Device Information System

Trader Login Individual Login

Select Individual Login

Trader Username

Experia

...

Enter Captcha

g b o v c

Login Login with iAM Smart

[More Info](#)

[Forgot Password](#)

Tip: This web application is best viewed in landscape mode.

Accessing MDIS – Forgot Password



Department of Health

The Government of the Hong Kong Special Administrative Region

MEDICAL DEVICE DIVISION

Medical Device Information System

Trader Login Individual Login

Trader Username

Experia

....

Enter Captcha

Login Login with iAM Smart

[More Info](#)

Forgot Password

Tip: This web application is best viewed in landscape mode.

Forgot password

Trader Username

Individual Username

Email Address

Request a reset link

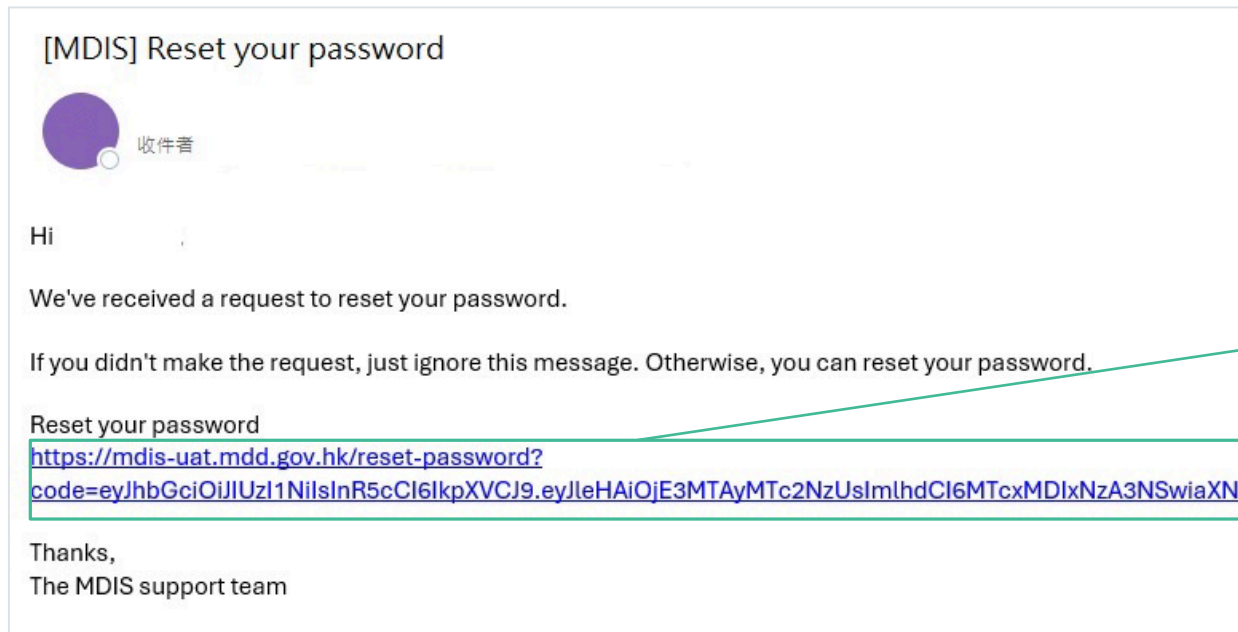
Click **Forgot Password** and enter Trader Username, Individual Username, Email Address to request a reset link

Click to request for link after filling mandatory information, confirmation email with title "[MDIS] Reset your password" will be sent



Accessing MDIS – Forgot Password (Con't)

The user will receive a reset password email, and can proceed to reset by clicking the link embedded. Please be reminded to apply strong password combining special character, upper-case letter and numbers. The password should be updated every 3 months.



Medical Device Information System

Reset Password

Login Name

New Password

Confirm Password

Reset

Password must contains:

- Minimum of 8 characters
- Maximum of 15 characters
- At least one digit
- At least one special character

After inputting the Login Name, New Password and Confirm Password, click Reset to proceed.

3) Q & A

