



# Training on Medical Device Information System (MDIS)

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## PART I: ACCOUNT REGISTRATION





# Agenda

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## ➤ Introduction

### 1. **Trader Account**

#### ➤ Flow of Account Registration

#### ➤ Login

#### ➤ Forgot Password

### 2. **Individual Account**

#### ➤ Flow of Account Registration

#### ➤ Login

#### ➤ Forgot Password



# Introduction

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# Introduction

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The **Medical Device Information System (MDIS)** offers 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.



# Benefits of the MDIS

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## Streamlining Business Process

- Transition from paper-based to online submission of medical device and trader listing application
- Transition from paper-based certificate to electronic certificate

## Strengthening Communications

- Direct conversation with MDD officers in system

Starting from 1 January 2025, all listing applications must be submitted via MDIS






# Training Materials of the MDIS

Latest version of training materials are uploaded to the MDD Website (<https://www.mdd.gov.hk/en/information-publication/traders/index.html>)

[Home](#) > [Information, Video and Publication](#) > Traders

Thematic Pages

General Public

Traders 

• Briefing Webinar

Healthcare Professionals







Video

## Traders




### Briefing Webinar

- ▶ [Briefing Webinar on the Listing Application of Medical Devices under Medical Device Administrative Control System \(MDACS\)](#)

### Reference Materials for Briefing Seminar

- ▶ [Briefing for Updates of Guidance Notes on Adverse Event Reporting by Local Responsible Persons under the Medical Device Administrative Control System \(MDACS\).\(Chinese Version Only\)](#) 
- ▶ [Introduction of Medical Device Administrative Control System \(MDACS\).\(Chinese\)](#) 
- ▶ [Introduction of Medical Device Administrative Control System \(MDACS\).\(English\)](#) 
- ▶ [Briefing for Guidance Notes on Changes for Listed Medical Devices \(Chinese\)](#)  (For reference only)
- ▶ [Briefing for Guidance Notes on Changes for Listed Medical Devices \(English\)](#)  (For reference only)
- ▶ [Briefing for Technical References on Software Medical Devices and Cybersecurity and Artificial Intelligence Medical Devices \(AI-MD\).\(Chinese Version Only\)](#) 

### Training Materials on Medical Device Information System (MDIS)

- ▶ [Part I: Account Registration](#) 
- ▶ [Part II: Application for Listing](#) 
- ▶ [Part III: Reporting of Medical Device Safety Alerts and Adverse Events](#) 



# Feedback Survey of the MDIS

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Feedback Survey on MDIS (<https://www.mdd.gov.hk/en/mdis-survey/index.html>)



We value your opinion and  
suggestion



# Account Introduction

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There are two levels of accounts:

## 1. External Trader User (ETU)

- Go to [Registration of Trader Account](#)
- Go to [Trader Login](#)
- Go to [Forgot password](#)

## 2. External Individual User (EIU)

- Go to [Registration of Individual Account](#)
- Go to [Individual Login](#)
- Go to [Forgot password](#)

What are account pre-requisites?

1. External Trader User (ETU) – Valid BR certificate
2. External Individual User (EIU) – Valid Trader User Account



# User Roles & Functions

1. External Trader User (ETU)	2. External Individual User (EIU)
<ul style="list-style-type: none"><li>✓ Maintain Individual User Accounts</li><li>✓ Oversee pre-market (Medical device and trader) applications</li><li>✓ Oversee post-market (safety alert and adverse event) cases</li><li>✓ Perform reassignment of applications / cases in case of staff turnover</li></ul>	<ul style="list-style-type: none"><li>✓ Create pre-market (Medical device and trader) applications</li><li>✓ Create post-market (safety alert and adverse event) cases</li><li>✓ As direct contact during application / case processing stage</li></ul>



# Flow of Account Registration – **Trader Account**

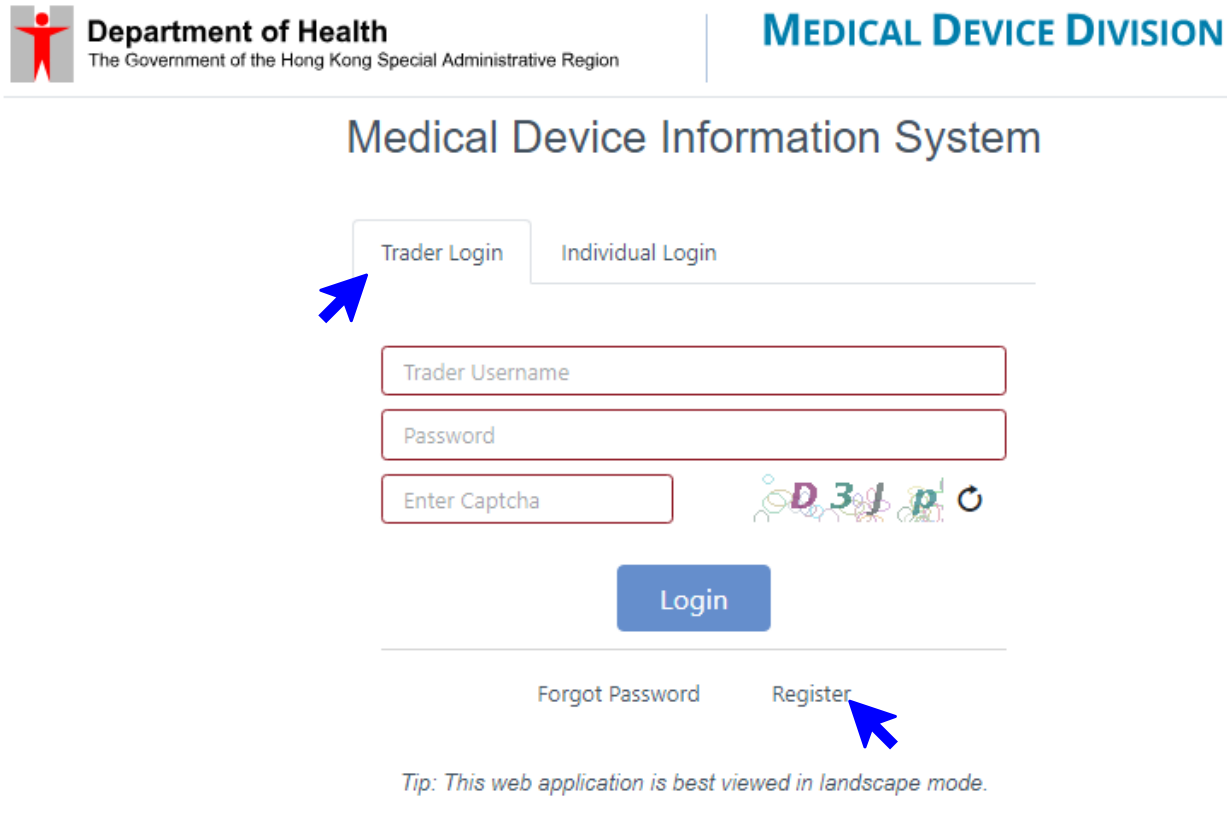
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# Registration of Trader Account (P. 1-7)

1. Access the Medical Device Information System home page
2. Click “**Trader Login**” tab
3. Click “**Register**” option



The screenshot shows the Medical Device Information System registration page. At the top, there is a header with the Department of Health logo and the Medical Device Division name. Below the header, the title "Medical Device Information System" is centered. The main content area contains a registration form. The form has two tabs: "Trader Login" and "Individual Login". A blue arrow points to the "Trader Login" tab. Below the tabs, there are three input fields: "Trader Username", "Password", and "Enter Captcha". A blue arrow points to the "Enter Captcha" field. To the right of the "Enter Captcha" field is a captcha image showing the characters "D 3 J p" with a refresh button. Below the input fields is a blue "Login" button. Below the "Login" button, there are two links: "Forgot Password" and "Register". A blue arrow points to the "Register" link. At the bottom of the form, there is a tip: "Tip: This web application is best viewed in landscape mode."

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

Password

Enter Captcha

D 3 J p

Login

Forgot Password Register

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



# Registration of Trader Account (P. 2-7)

All **mandatory fields** are hinted by red brackets



## MEDICAL DEVICE DIVISION

### Register

Login Name

**!** Login Name is unique and not changeable once registered.  
*Keep your account safe and secure.*

Company Information

Company / Organization Name

English

Chinese

Select Type of registration certification

Registration Certification Type

☒ Business Registration Certificate

Upload BR

Upload

Select files...

Drop files here to upload

Business Registration Number

Expiry Date

DD/MM/YYYY



Select Company Type

Company Type

☐ Main Company  
☐ Branch Company

Branch entity should indicate “Branch Company” under **Company Type** and upload both valid Business Registration and Branch Registration Certificates

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

#### Errors Encountered

- Invalid entries detected for BR number
- Invalid entries detected for BR Expiry Date
- BR expired. Please upload the latest BR.
- A company with the same Business Registration Number has already registered

請將此表格填妥後，將有效之商業/分行登記證書顯示在營業地點。  
Please fill out along the dotted line and display the valid business/branch registration certificate at business address.

表號: FORM 2 [第 1 頁]  
BUSINESS REGISTRATION ORDINANCE Chapter 316 [Regulation 5]  
《商業登記條例》第 316 章  
BUSINESS REGISTRATION REGULATIONS  
《商業登記規例》  
商業 X0000 登記證 Business X00000/Registration Certificate

名稱 / 法團中文名稱  
Name of Business / Corporation

地址  
Address

業務性質  
Nature of Business

法團地位  
Status

BOOY CORPORATE

生效日期  
Date of Commencement

31/12/2022

失效日期  
Date of Expiry

30/12/2023

登記證號碼  
Certificate No.

62558875-000-12-22-3

登記費及雜費  
Fee and Levy

\$150  
(登記費 FEE = \$ 0)  
(雜費 LEVY = \$150)

請注意下列《商業登記條例》的規定：  
Please note the following requirements of the Business Registration Ordinance:

1. 第 6(1) 條規定任何獲發給商業登記證或分行登記證，並不表示該獲發或該證註冊的人或受僱於該業務的僱員已遵從有關的任何法律規定。  
1. Section 6(1) provides that the issue of a business registration certificate or a branch registration certificate shall not be deemed to imply that the requirements of any law in relation to such business or to the persons carrying on the same or employed therein have been complied with.

2. 第 12 條規定若獲發給其有效之商業登記證或有效之分行登記證於每一營業地點展示。  
2. Section 12 provides that valid business registration certificate or valid branch registration certificate shall be displayed at every address where business is carried on.

商業/分行登記證號碼: BR/REGD FIRM AND LEVY HERE PRINTED IN PRINTED FIGURES

BR/REGD FIRM AND LEVY: 16/11/2022 899519419 \$150.00



# Registration of **Trader Account** (P. 3-7)

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## Requirements on format of Business Registration (BR) Certificates

1. File size within 3MB
2. Document size within A4
3. Content should be clear and legible



## Examples of unacceptable BR Certificates

- ✘ Blurred/Obscured fonts

- ✗ Slanted fonts

- ✘ Distorted fonts



# Registration of Trader Account (P. 5-7)

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

**Input by HK Address Lookup**

Address

Address Format **Input by HK Address L...** **Search** 1

Input by HK Address Lookup

Manual Input

Floor  Unit

**Manual Input**

Address

Address Format **Manual Input**

English Address

Chinese Address

**Address Lookup**

2  **Search** 3

English Address	Chinese Address
Wong Nai Chung Reservoir Workmen's Quarters Water Supplies Department Hong Kong, 12 Tai Tam Reservoir Road, Southern District, Hong Kong	香港, 南區, 大潭水塘道 12號, 香港水務署黃泥涌水塘工人宿舍
Hong Kong Parkview, Block 1, 88 Tai Tam Reservoir Road, Southern District, Hong Kong	香港, 南區, 大潭水塘道 88號, 第 1 座, 隱明山莊
Cemeteries And Crematoria Section (Hong Kong), Cemeteries And Crematoria Hong Kong Office, 1j Wong Nai Chung Road, Wan Chai District, Hong Kong	香港, 灣仔區, 黃泥涌道 1j號, 墳場及火葬場香港區辦事處, 灣仔區墳場及火葬場辦事處
Hong Lok Yuen, International College Hong Kong Hong Lok Yuen (Primary Section), 3 Hong Lok Yuen Twentieth Street, Tai Po District, New Territories	新界, 大埔區, 康樂園第二十街 3號, INTERNATIONAL COLLEGE HONG KONG HONG LOK YUEN (PRIMARY SECTION), 康樂園
Hong Lok Yuen, International College Hong Kong Hong Lok Yuen (Kindergarten Section), 5 Hong Lok Yuen Twentieth Street, Tai Po District, New Territories	新界, 大埔區, 康樂園第二十街 5號, INTERNATIONAL COLLEGE HONG KONG HONG LOK YUEN (KINDERGARTEN SECTION), 康樂園
World Wide Fund For Nature Hong Kong, 51 Tam Kon Chau Road, Yuen Long District, New Territories	新界, 元朗區, 担竿洲路 51號, 世界自然 (香港) 基金會
Dorsett Mongkok Hong Kong, 88 Tai Kok Tsui Road, Yau Tsim Mong District, Kowloon	九龍, 油尖旺區, 大角咀道 88號, 香港旺角帝盛酒店
Hong Kong Institute Of Construction Tai Po Training Ground, Cic Tp Training Ground Substation, 13 Dai Wah Street, Tai Po District, New Territories	新界, 大埔區, 大華街 13號, 建造業大埔訓練場變電站, 香港建造學院大埔訓練場
The Hong Kong Polytechnic University, Mong Man Wai Building, 11 Yuk Choi Road, Yau Tsim Mong District, Kowloon	九龍, 油尖旺區, 窩才道 11號, 康民樓, 香港理工大學

**Select** 4

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

Choose an address and click **Select** button. The address will be auto filled.

The address inputted must be consistent with the address shown on the Business Registration (BR) Certificate. If trader cannot identify the exact BR address via HK Address Lookup, please input the address manually.



# Registration of **Trader Account** (P. 6-7)

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

Contact Information of Management Representative

English Name	<input type="text" value="Given Name"/>	<input type="text" value="Surname"/>
Chinese Name	<input type="text" value="Given Name"/>	<input type="text" value="Surname"/>
Post Title	<input type="text"/>	Designation <input type="text"/>
Title	<input type="text" value="▼"/>	
Email	<input type="text"/>	Fax <input type="text"/>
Contact Telephone for Public Enquiries	<input type="text"/>	Mobile Telephone for Urgent Use (24 hours) <input type="text"/>
URL	<input type="text"/>	
<div><input type="button" value="Submit"/> <input type="button" value="Cancel"/></div>		

The **Submit** button will be enabled after filling in all mandatory information, click **Submit** to submit registration request to MDD for review.



## Registration of Trader Account (P. 7-7)

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

Please remember to apply a strong password that combines special characters, uppercase letters, and numbers. The password should be updated every 3 months.

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

To

Reply

Reply All

Forward

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  (Login ID: ),

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.eyJleHAiOjE3MTI5OTk0MzMslmlhdCI6MTcxMjkxMzAzMywiaXNkIixqLDUAATGd3XtktKpFsc>

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.

Medical Device Division

Medical Device Information System

Reset Password

Login Name

New Password

Confirm Password

Reset

After inputting the Login Name, New Password and Confirm Password, the **Reset** button will be enabled. Click **Reset** to proceed.

Reset

Password must contains:

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

*Keep your account safe and secure.*



# Login – Trader Account

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# Accessing MDIS – Trader Account

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



MEDICAL DEVICE DIVISION

➤ Login by Username, Password, Captcha

➤ All **Mandatory Fields** are hinted by red brackets

➤ Click Login to proceed

Login

**Note:** If you attempt to log into your account with the incorrect password in **5 times**, the system will automatically lock your account as a safety precaution. Please click “Forgot Password” to reset your password and regain access to the system.

Medical Device Information System

Trader Login Individual Login

Trader Username

Password

Enter Captcha

Login

Forgot Password Register

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

## Errors Encountered

- Incorrect user name or password
- Account locked due to too many failed login



# Forgot password – **Trader Account**

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# Forgot Password – Trader Account (P. 1-2)

1. Click “**Forgot Password**” option in Login page
2. Enter Trader Username, Email Address to **Request a reset link**



MEDICAL DEVICE DIVISION

## Medical Device Information System

Trader Login Individual Login

Trader Username

Password

Enter Captcha

Login

Forgot Password Register

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

Forgot password

Trader Username

Email Address

Request a reset link

Click “**Request a reset link**” after filling mandatory information, reset password email will be sent.

Request a reset link



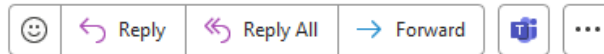
# Forgot Password – Trader Account (P. 2-2)

The User will receive a reset password email with the title "[MDIS] Please reset your password for login to the Medical Device Information System" and can proceed to reset by clicking the embedded link. **The link will expire after 15 minutes.** Please remember to apply a strong password that combines special characters, uppercase letters, and numbers. The password should be updated every 3 months.

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



mdis@egismail.gov.hk  
To [redacted]



19/07/2024 (週五) 17:52

(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 requested to change password for your account in the Medical Device Information System (MDIS)! Please click the below link to reset your password for login to the MDIS within 15 minutes.

<https://mdis.mdd.gov.hk/reset-password?code=eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9.eyJleHAiOiJlE3MjE0NDUsImh0dCI6MTcyMTM4Mjc0NSwiaXNzIjpc>

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.

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, the **Reset** button will be enabled. Click **Reset** to proceed.

Reset



# Flow of Account Registration – Individual Account

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# Registration of Individual Account (P. 1-3)

1. Login by **Trader Account**
2. Click “**User Account**” on sidebar menu
3. Click “**Individual Accounts**” tab

To-Do

Medical Device

Trader

Safety Alert

Adverse Event

User Account

Support >

Medical Device Information System (MDIS) (v1.0.23)

Is Your Product A Medical Device?

Eng | 繁體

Last Login: 2024-07-19 12:34

Logout

User Account

Account Information

Role

Contact Info

Individual Accounts

Individual Accounts

Add

Action	#	Responsibility	Login ID	Given Name	Surname	Email	Phone	Post	Inactive	Too many failed Login	Receive Trader A
+ Edit Delete	1	ALL	mdd_cheng123456789@meddevice.com.tw	Mach	Cheng	macheng@mdd.com.tw			No		No
+ Edit Delete	2	PRE	mdd_cheng123456789@meddevice.com.tw	Mach	Cheng	macheng@mdd.com.tw			No		No
+ Edit Delete	3	ALL	mdd_cheng123456789@meddevice.com.tw	Mach	Cheng	macheng@mdd.com.tw			No		No



# Registration of Individual Account (P. 2-3)

All **mandatory fields** are hinted by red brackets

Medical Device Information System (MDIS) (v1.0.23)

Is Your Product A Medical Device?

Eng | 繁體

mdd\_chk  
Last Login: 2024-07-19 12:34

Logout

To-Do

Medical Device

Trader

Safety Alert

Adverse Event

User Account

Support >

User Account

Account Information

Role

Contact Info

Individual Accounts

Individual Accounts

Add

Action	#	Responsibility	Login ID	Given Name	Surname	Email	Phone	Post	Inactive	Too many failed Login	Receive Trader A
<div>Add</div> <div>Cancel</div>		<div>---</div>							<input type="checkbox"/>		<input type="checkbox"/>
<div>+</div> <div>Edit</div> <div>Delete</div>	1	ALL	mdd_chk						No		No
<div>+</div> <div>Edit</div> <div>Delete</div>	2	PRE	mdd_chk_012						No		No
<div>+</div> <div>Edit</div> <div>Delete</div>	3	ALL	mdd_chk_012						No		No

The new row is shown.  
Click **Add** after filling in all mandatory information.

Add

Cancel

Suggest to set unique Login ID. System will validate if the Login ID exist.  
*Keep your account safe and secure.*

Errors Encountered

User already exist

NEXIFY

(LAST UPDATED ON JULY 2024)



# Registration of Individual Account (P. 3-3)

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

Please remember to apply a strong password that combines special characters, uppercase letters, and numbers. The password should be updated every 3 months.

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



mdis@egismail.gov.hk

To



Reply

Reply All

Forward



19/07/2024 (週五) 17:45

(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 [Name] (Login ID: [ID]),

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 within 15 minutes.

<https://mdis.mdd.gov.hk/reset-password?code=eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9.eyJleHAiOiJlE0Njg2NzEsImh0dCI6MTcyMTM4MjI3MSwiaXNzIjoqjousSjDgSLCZ7VVo>

Please note if you are from an existing LRP or trader listed in MDACS, please expect at least 3 working days lead time for establishing correlation to your LRP or trader role in the MDIS before you can submit a fresh application with your existing LRP or trader role.

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.

Medical Device Division



## 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

Reset

After inputting the Login Name, New Password and Confirm Password. The **Reset** button will be enabled, click **Reset** to proceed.

*Keep your account safe and secure.*



# Login – Individual Account

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# Accessing MDIS – Individual Account

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



MEDICAL DEVICE DIVISION

➤ Login by Trader Username, Individual Username, Password, Captcha

➤ Also supports Login with iAM Smart

➤ All **Mandatory Fields** are hinted by red brackets

➤ Click Login to proceed



**Note:** If you attempt to log into your account with the incorrect password in **5 times**, the system will automatically lock your account as a safety precaution. Please click "[Forgot Password](#)" to reset your password and regain access to the system.

Medical Device Information System

Trader Login

Individual Login

Trader Username

Individual Username

Password

Enter Captcha



Login

Login with iAM Smart

[More Info](#)

[Forgot Password](#)

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

## Errors Encountered

- Incorrect user name or password
- Account locked due to too many failed login



# Forgot password - Individual Account

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# Forgot Password – Individual Account (P. 1-2)

1. Click “Forgot Password” option in Login page
2. Enter Trader Username, Email Address to Request a reset link



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

Individual Username

Password

Enter Captcha



Login



Login with iAM Smart

[More Info](#)



1 Forgot Password

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

### Forgot password

Trader Username

Email Address



2 Request a reset link

Click “Request a reset link”  
after filling mandatory  
information, reset password  
email will be sent.

Request a reset link



# Forgot Password – Individual Account (P. 2-2)

The user will receive a reset password email with the title "[MDIS] Please reset your password for login to the Medical Device Information System" and can proceed to reset by clicking the embedded link. **The link will expire after 15 minutes.** Please remember to apply a strong password that combines special characters, uppercase letters, and numbers. The password should be updated every 3 months.

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



mdis@egismail.gov.hk  
To [redacted]



19/07/2024 (週五) 17:52

(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 requested to change password for your account in the Medical Device Information System (MDIS)! Please click the below link to reset your password for login to the MDIS within 15 minutes.

<https://mdis.mdd.gov.hk/reset-password?code=eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9.eyJleHAiOiJlE3MjE0NDUsImh0dCI6MTcyMTM4Mjc0NSwiaXNzIjpc>

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.

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, the **Reset** button will be enabled. Click **Reset** to proceed.

Reset



# 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).