



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	<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) Functionalities in Trader User Interface



Trader - Todo Overview

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

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

Account Name and Last Login Time

Modules available for Trader

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

Notifications inbox

The dashboard provides an overview on application status and statistics

Click to view details

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"/>	View		Drafting	MD-C2&3&4	New	Experia Tech	
<input type="checkbox"/>	View		Drafting	MD-C2&3&4	New	Experia Tech	Test231231_1
<input type="checkbox"/>	View		Drafting	MD-C2&3&4	New	Experia Tech	Test231231_1
<input type="checkbox"/>	View		Drafting	MD-C2&3&4	New	Experia Tech	Name

(LAST UPDATED ON 15 APRIL 2024)

Modules available for Trader

Account Name and Last Login Time

Is Your Product A Medical Device?

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

Logout

Notifications inbox

The dashboard provides an overview on application status and statistics

Click to view details



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

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"/> View		Drafting	MD-C2&3&4	New	Experia Tech	
<input type="checkbox"/> View		Drafting	MD-C2&3&4	New	Experia Tech	Test231231_1
<input type="checkbox"/> View		Drafting	MD-C2&3&4	New	Experia Tech	Test231231_1
<input type="checkbox"/> View		Drafting	MD-C2&3&4	New	Experia Tech	Name

Bulk selection for export



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

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"/>	View		Drafting	MD-C2&3&4	New	Experia Tech	
<input type="checkbox"/>	View		Drafting	MD-C2&3&4	New	Experia Tech	Test231231_1
<input type="checkbox"/>	View		Drafting	MD-C2&3&4	New	Experia Tech	Test231231_1
<input type="checkbox"/>	View		Drafting	MD-C2&3&4	New	Experia Tech	Name

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"/>	View		Drafting	Experia Tech	New		

Trader - Todo 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"/> View		Drafting	MD-C2&3&4	New	Experia Tech	
<input type="checkbox"/> View		Drafting	MD-C2&3&4	New	Experia Tech	Test231231_1
<input type="checkbox"/> View		Drafting	MD-C2&3&4	New	Experia Tech	Test231231_1
<input type="checkbox"/> View		Drafting	MD-C2&3&4	New	Experia Tech	Name

Trader – 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 and a 'Reset Password' button. A green callout box labeled 'Reset Password' points to this button.

Below the 'Account Information' section is the 'Company Information' section, which includes fields for 'Company / Organization Name' (with 'English' and 'Chinese' language options), 'Registration Certification Type' (with 'Business Registration Certificate' selected), 'Upload BR' (with a file named 'Experia_BR_2023.pdf'), 'Business Registration Number' (with the value '62558875-000-12-22-3'), and 'Company Type' (with 'Main Company' selected). A 'Save' button is located at the bottom left of this section.

A 'Reset Password' modal window is open over the 'Company Information' section. It contains three input fields: 'Old Password', 'New Password', and 'Confirm Password'. Below these fields is a 'Confirm' button, which is highlighted by 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'. A 'Reset' button is located at the bottom right of the modal.

Trader – User Account Management

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** | Contact Info | Individual Accounts

Account

Login Name Reset Password

Company Information

Company / Organization Name

English

Chinese

Registration Certification Type

Business Registration Certificate

Certificate of Registration of a Society

Upload BR

Experia_BR_2023.pdf 21/11/2023 11:53:44 Delete Select files... Drop files here to upload

Business Registration Number Expiry Date

Company Type Main Company

Save Reset

View the Role, Contact Info and Individual Accounts under the Trader

Edit the account information, scroll down to edit other company information

Save



Trader – User Account Management – BR OCR

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 | Contact Info | Individual Accounts

Account

Login Name: [Redacted] Reset Password

Company Information

Company / Organization Name: English [Redacted] / Chinese [Redacted]

Registration Certification Type: Business Registration Certificate / Certificate of Registration of a Society

Upload BR: Experia_BR_2023.pdf 21/11/2023 11:53:44 Delete Select files... Drop files here to upload

Business Registration Number: 62558875-000-12-22-3 Expiry Date day/month/year

Save

Upload BR – the Business Registration Number and Expiry Date will be automatically recognized and filled. Validation check applies to the expiry date.

expiry date

Errors Encountered

- BR expired. Please upload the latest BR.



Trader – User Account Management

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** Contact Info Individual Accounts

Role

LRP Importer Distributor Local Manufacturer

LRP List

Listing no.	<input type="text"/>	Revision	<input type="text"/>	Application no.	<input type="text"/>
Issue Date	<input type="text" value="day/month/year"/>	Expiry Date	<input type="text" value="day/month/year"/>	Delist Date	<input type="text" value="day/month/year"/>

Remarks

View the Role, Contact Info and Individual Accounts under the Trader

The approved role is displayed under Role tab



Trader – User Account Management

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 **Contact Info** Individual Accounts

Primary Contact Update Contact Information Submit Company Contact Update

#	Contact Person	Post	Email	Mobile	Telephone	Fax
No record found						

Click to add Contact Update

LRP Contact

Public Phone Number

Urgent Mobile 24Hr

#	Responsibility	Contact Person	Post	Emergency Contact	Email	Mobile	Telephone
No record found							

Address of Storage / Maintenance / Other Facilities

Action	#	HK / Overs...	Name of Site	Address	Activity
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Trader – User Account Management

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 **Contact Info** Individual Accounts

Primary Contact Click Submit Submit Cancel

Add Copy from LRP Copy from Importer Copy from Distributor Copy from Manufacturer

Action	#	Contact Person	Post	Email	Mobile	Telephone	Fax
Add Cancel		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

No record found

LRP Contact Add Contact Information

Public Phone Number

Urgent Mobile 24Hr

#	Responsibility	Contact Person	Post	Emergency Contact	Email	Mobile	Telephone
No record found							



Trader – User Account Management

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 **Contact Info** Individual Accounts

Primary Contact Click Submit Submit Cancel

Add Copy from LRP Copy from Importer Copy from Distributor Copy from Manufacturer

Action	#	Contact Person	Post	Email	Mobile	Telephone	Fax
Add Cancel		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Copy from sections below

LRP Contact

Public Phone Number

Urgent Mobile 24Hr

#	Responsibility	Contact Person	Post	Emergency Contact	Email	Mobile	Telephone
No record found							

Trader – User Account Management – Add Individual Accounts

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 Contact Info **Individual Accounts** View individual accounts

Individual Accounts

Add Press Add to add individual account

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

Press Add after filling in all Mandatory information

Trader – User Account Management – Add Individual Accounts

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 Contact Info **Individual Accounts** View individual accounts

Individual Accounts

Add Press Add to add individual account

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

Press Add after filling in all Mandatory information

Trader – User Account Management – Case Reassign

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 Contact Info **Individual Accounts** View individual accounts

Individual Accounts

Add

	Action	#	Responsibility	Login ID	Given Name	Surname	Email	Phone	Post
+	Edit Delete	1	ALL					91231234	
-	Edit Delete	2	ALL						
	Case Reassign Delink iAM Smart								
+	Edit Delete	3	ALL					12345678	

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

Trader – User Account Management

Case Reassignment

Select Module

MD / IVDMD Application(s)

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

To be assigned to: exp06 exp

Confirm Cancel

Select Module for reassignment and pick the applications and to-be assigned role

Confirm reassignment



Trader – User Account Management – Edit account information

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 Contact Info Individual Accounts

Individual Accounts

[Add](#)

Action	#	Responsibility	Login ID	Given Name	Surname	Email	Phone	Post
+ Edit Delete	1						91231234	
- Edit Delete								

[Case Reassign](#) [Delete](#)

+ [Save](#) [Cancel](#) 3 All 12345678

Press "Edit" to edit the account information

Press "Save" after editing

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

Medical Device Information System (MDIS) UAT (v0.19p) Is Your Product A Medical Device? Experia Last Login: 2024-03-08 17:52 Logout

User Account

Account Information Role Contact Info **Individual Accounts**

Individual Accounts

[Add](#)

Email	Phone	Post	Inactive	Too many failed Login	Receive Trader Account Notification	Last Login Time
o_laurence@nexify.com.hk	91231234		<input type="checkbox"/>		<input checked="" type="checkbox"/>	
.chan@nexify.com.hk			No		No	
oscar.li@nexify.com.hk	12345678		No		No	

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

Trader – User Account Management – Delink iAM Smart

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 indicator, a 'Is Your Product A Medical Device?' link, 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 'Individual Accounts' tab is selected and highlighted with a green box, with a callout bubble pointing to it that says 'View individual accounts'. Below this, the 'Individual Accounts' section features an 'Add' button and a table with columns: Action, #, Responsibility, Login ID, Given Name, Surname, Email, Phone, and Post. The table contains three rows. The first row has a '+' icon in the Action column, 'Edit' and 'Delete' buttons, and values '1', 'ALL', and '91231234'. The second row has a '-' icon, 'Edit' and 'Delete' buttons, and values '2', 'ALL'. The third row has a '+' icon, 'Edit' and 'Delete' buttons, and values '3', 'ALL'. A 'Delink iAM Smart' button is highlighted with a red box and a callout bubble that says 'Delink iAM Smart from the account'. A 'Please confirm' dialog box is open, asking 'Are you sure to delink with "iAM Smart"?', with 'No' and 'Yes' buttons.

Action	#	Responsibility	Login ID	Given Name	Surname	Email	Phone	Post
+ Edit Delete	1	ALL					91231234	
- Edit Delete	2	ALL						
+ Edit Delete	3	ALL						



4) Functionalities in Individual User Interface



Individual Users – User Account Management – reset Password

The screenshot displays the 'User Account' management page. On the left is a dark blue sidebar with navigation items: 'Todo', 'Medical Device', 'Trader', 'Safety Alert', 'Adverse Event', and 'User Account'. The main content area is titled 'User Account' and contains a form for account details. The 'Login Name' field is filled with 'experia01' and has a 'Reset Password' button next to it. Other fields include 'English Name' (test), 'Chinese Name' (Given Name), 'Post Title', 'Title', 'Email' (laurence@experia-tech.com), 'Office Phone' (12345678), and 'URL'. A 'Reset Password' modal is open, showing fields for 'Old Password', 'New Password', and 'Confirm Password', along with a 'Confirm' button. A green callout box with the text 'Reset Password' has an arrow pointing to the 'Reset Password' button in the main form. At the bottom left, a green callout box with the text 'Save after modification' has an arrow pointing to a 'Save' button in the form.



Individual Users – User Account Management

Medical Device Information System (MDIS) DEV (----) Is Your Product A Medical Device? Eng | 繁體 experia01 Last Login: 2024-01-24 17:46 Logout

User Account

Account

Login Name * Reset Password Delink with IAM Smart

English Name

Chinese Name

Post Title Designation

Title

Email Fax

Office Phone Mobile Phone

URL

Save

Delink iAM Smart

Please confirm

Are you sure to delink with "iAM Smart"?

No Yes

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

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

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

Bulk selection and apply actions

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



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

Filters can be applied for sorting submissions

Contains [] And [] Contains [] Clear Filter

MD Screening Application(s) Pending Submission

<input type="checkbox"/>	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

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

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 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



Individual Users – Medical Device Overview / Searching

- To-Do
- Medical Device**
- Trader
- Safety Alert

Click to switch between modules

Medical Device Module

Create Application ▼

Search

MD Application LRP SOP Application

Select application type

Enter search criteria

Application	Screening		
Application Number	eg: AN000001/1/1_1/1a		
Listing Number	eg: 050123/05/123	Manufacturer Name	
Make	English	Chinese	
Model	English	Chinese	

Search Clear

Click "Search" to find submitted applications



Individual Users – Medical Device Overview / Searching

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 Module

[To-Do](#) [Medical Device](#) [Trader](#) [Safety Alert](#) [Adverse Event](#) [User Account](#)

[Create Application](#)

Search

MD Application LRP SOP Application

Application Number Listing Number

[Search](#) [Clear](#)

Select application type for different filters

Individual Users - Create MD Application

Medical Device Information System (MDIS) **DEV** Is Your Product A Medical Device? ✉ 17 Experia01
Last Login: 2024-04-08 17:58 Logout

Medical Device Module

Create Application (Click to expand the drop-down menu and select the application type)

- MD101
- MD102

MD Application | LRP SOP Application

Application | Screening

Application Number

Listing Number Manufacturer Name

Make

Model

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



Individual Users – Submit MD Application (MD101)

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

Application for the Listing of Class II/III/IV General Medical Devices

* - Mandatory field
- Display in public

Part A | Part B | Part C | Part D | Part E | Declaration | PICS

The form is divided into different parts

Particulars of Manufacturer

A001 * **Manufacturer's Name #**

in English

in Chinese

Address of Head Office #

in English

in Chinese

Post Code Country

Contact Person Telephone

Fax Email

Save as draft

Save Submit Cancel Reset

Click "Submit" to apply form validation checking and submit

ON 15 APRIL 2024)

Individual Users – Submit MD Application (MD101)

Medical Device Information System (MDIS) **DEV** Is Your Product A Medical Device? Experia01 Last Login: 2024-04-08 18:41 Logout

Application for the Listing of Class II/III/IV General Medical Devices * - Mandatory field # - Display in public

Part A Part B ← Part C **Part B - Particulars of Local Responsible Person (LRP)**

Particulars of Local Responsible Person (LRP)

B001 * **LRP's Name #**

Address in Hong Kong (Please give the registered place of business, if any) #



Individual Users – Submit MD Application (MD101)

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

Application for the Listing of Class II/III/IV General Medical Devices * - Mandatory field # - Display in public

Part A Part B **Part C** Part D

Part C - Particulars of the Device

Particulars of the Device

C001 * **Make**

in English

in Chinese

Brand Name #

in English

in Chinese

Model #

Action	#	English	Chinese
No record found			



Individual Users – Submit MD Application (MD101)

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

Application for the Listing of Class II/III/IV General Medical Devices * - Mandatory field # - Display in public

Part A Part B Part C **Part D** Part E

Part D - Marketing Approvals and Essential Principles

Marketing Approvals and Essential Principles

D001 Marketing Approvals in Mainland China and/or Foreign Countries

- Approval(s) obtained for the medical device (with same make and model) to be placed on the market of the following countries:
 - Mainland China (National Medical Products Administration)
 - Australia (The Therapeutic Goods Administration)
 - Canada (Health Canada)
 - Member countries of European Union that have implemented relevant EU directives or regulations and a copy of the EC Declaration of Conformity is enclosed
 - Japan (Ministry of Health, Labour and Welfare)
 - Singapore (Health Sciences Authority)
 - South Korea (Ministry of Food and Drug Safety)
 - United States of America (U.S. Food and Drug Administration)
 - Others

No file(s) Select files... Drop files here to upload

Essential Principles

- Earliest approval obtained on or before 31 December 2004

Save Submit Cancel Reset



Individual Users – Submit MD Application (MD101)

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

Application for the Listing of Class II/III/IV General Medical Devices * - Mandatory field
- Display in public

Part A Part B Part C Part D **Part E** Declaration **Part E - Intention to join the Expedited Approval Scheme**

Intention to join the Expedited Approval Scheme

We would like to OPT-OUT from joining the Expedited Approval Scheme even if the medical device concerned is/are eligible# to join the scheme.

#Eligibility to join the scheme:

1. Applicant shall be an existing LRP;
2. There are no serious injuries associated with the device (local and worldwide);
3. There are no corrective actions or adverse events (local and worldwide); and
4. The device has not received Independent Marketing Approvals from Mainland China, and/or GHTF founding members (Also see Note D001), marketing approvals provided must cover the same make and model of the device concerned.

For details of the Scheme, please visit our website
<https://www.mdd.gov.hk/filemanager/common/mdacs/SchExp-Note-for-Applicant-202201-E.pdf>

Check to opt-out

Save Submit Cancel Reset

Individual Users – Submit MD Application (MD101)

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

Application for the Listing of Class II/III/IV General Medical Devices

* - Mandatory field
- Display in public

Part A Part B Part C Part D Part E **Declaration** PICS Declaration

Declaration

- To the maximum extent permitted by law and in consideration of the Department of Health of the Government of the Hong Kong Special Administrative Region ("the Government") processing our application under the MDACS, we agree to exempt, relieve, exonerate, indemnify and hold harmless, and to keep indemnified and harmless, as the case may be, the Government from and/or against any and all losses, claims, demands and proceedings (including but not limited to all costs, charges and expenses) whatsoever and howsoever suffered or incurred by, or made or issued against, the Government, as the case may be, by any third party in respect of any loss of or damage to any property or injury to or death of any person arising out of and/or relating and/or incidental to:
 - any act, neglect or default on our part or on the part of our employees or agents;
 - any defect in the design, material, workmanship or installation of our device or devices;
 - any use of any of the information supplied by us or our employees or agents in relation to our device or devices whether or not such information has materially contributed to the inclusion of the device or devices on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.
- We also agree and accept that:
 - the Government, its employees or agents shall not be liable to us for any loss of or damage to property caused by the act, default or neglect of the Government or its employees or agents in the processing of our application, the inclusion or non-inclusion of any of our information and/or device or devices on the List of Medical Devices or any cause whatsoever arising out of or in connection with the implementation and management of the MDACS;
 - neither the Government nor any of its employees or agents makes any representation, statement, warranty or guarantee, express or implied, that the devices (including any spares or replacement parts) listed or considered for listing under the MDACS, whether or not they are included in the List of Medical Devices, are of merchantable quality or are fit for the purposes for which they are commonly bought and that the spares or replacement parts are readily available.
- We confirm that the information contained in our application is true and correct and that our device or devices (including any spares or replacement parts) are of merchantable quality and are fit for the purposes for which they are commonly bought.
- We fully understand and agree that any future changes or additions to the requirements of the Medical Device Administrative Control System (MDACS) can be imposed by the Department of Health without prior notice. We hereby undertake to comply with the MDACS that are in force. It is one of the current requirements of the MDACS that the LRP will, within two weeks after receiving the request from the Department of Health, provide copies of the documents that, according to the claims in this submission, are within the possession of the LRP or the manufacturer.
- We confirm that we have not, and will not, copy, reproduce, disseminate, or otherwise use or disclose the information in this form, nor otherwise altered the form in any material manner, apart from filling in the appropriate blanks / boxes.

I hereby acknowledge the above declaration.

Save Submit Cancel Reset



Individual Users – Submit MD Application (MD101)

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 indicator, a 'Is Your Product A Medical Device?' button, a user profile for 'Experia01' with a last login of '2024-03-08 15:37', and a 'Logout' button. The left sidebar contains navigation options: 'To-Do', 'Medical Device', 'Trader', 'Safety Alert', 'Adverse Event', and 'User Account'. The main content area is titled 'Application for the Listing of Class II/III/IV General Medical Devices' and features a breadcrumb trail: 'Part A > Part B > Part C > Part D > Part E > Declaration > PICS'. A green callout box points to the 'PICS' tab with the text 'Personal Data Ordinance Statement of Purposes Declaration'. Below the breadcrumb, the section is titled 'Personal Data (Privacy) Ordinance Statement of Purposes 《個人資料 (私隱) 條例》用途聲明'. The content is organized into four numbered sections: 1. Purpose of Collection, 2. Classes of Transferees, 3. Access to Personal Data, and 4. Enquiries. A 'Reset' button is located at the bottom right of the content area. At the bottom of the page, a green callout box points to a checkbox with the text 'I hereby acknowledge the above statement. 本人已閱讀及完全明白並同意以上聲明。' and another green callout box says 'Scroll down to check the box'. The footer includes the 'NEXIFY' logo and the text '(LAST UPDATED ON 15 APRIL 2024)'.

Individual Users – Submit MD Application (MD101)



Individual Users – Submit MD Application (MD102)

* - Mandatory field
- Display in public

Application for the Listing of In-Vitro Diagnostic Medical Devices

Part A Part B Part C Part D Declaration PICS

The form is divided into different parts

Particulars of Manufacturer

A001 *

Manufacturer's Name #

in English

in Chinese

Address of Head Office #

in English

in Chinese

Post Code

Contact Person

Fax

Country

Telephone

Email

Save as draft

Save

Submit

Cancel

Reset

Click "Submit" to apply form validation checking and submit

15 APRIL 2024)

Individual Users – Submit MD Application (MD102)

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

Application for the Listing of In-Vitro Diagnostic Medical Devices

Part B - Particulars of Local Responsible Person (LRP)

Part A **Part B** ← Part C

Particulars of Local Responsible Person (LRP)

B001 * **LRP's Name #**

Experia Tech

in Chinese

Address in Hong Kong (Please give the registered place of business, if any) #

Floor Unit/Room/Flat

Business Registration

Copy of business registration certificate is enclosed
 Not applicable

[Save](#) [Submit](#) [Cancel](#) [Reset](#)



Individual Users – Submit MD Application (MD102)

Medical Device Information System (MDIS) **DEV** Is Your Product A Medical Device? 17 Eng | 繁體 Experia01 Last Login: 2024-04-13 00:01 Logout

Application for the Listing of In-Vitro Diagnostic Medical Devices * - Mandatory field
- Display in public

Part A Part B **Part C** ← Part D **Part C - Particulars of the Device**

Particulars of the Device

C001 *

Make

in English

in Chinese

Brand Name #

in English

in Chinese

Model #

Add

Action	#	English	Chinese
No record found			

Save **Submit** **Cancel** **Reset**



Individual Users – Submit MD Application (MD102)

Medical Device Information System (MDIS) **DEV** Is Your Product A Medical Device? 17 Eng | 繁體 Experia01 Last Login: 2024-04-13 00:01 Logout

Application for the Listing of In-Vitro Diagnostic Medical Devices * - Mandatory field
- Display in public

Part A Part B Part C **Part D** ← Declaration **Part D - Marketing Approvals and Essential Principles**

Marketing Approvals and Essential Principles

D001 Marketing Approvals in Foreign Countries

- Approval obtained for the IVDMD to be placed on the market of the following countries:
 - Australia (The Therapeutic Goods Administration)
 - Canada (Health Canada)
 - Member countries of European Union that have implemented relevant EU directives or regulations and a copy of the EC Declaration of Conformity is enclosed
 - Japan (Ministry of Health, Labour and Welfare)
 - Singapore (Health Sciences Authority)
 - Korea (Ministry of Food and Drug Safety)
 - United States of America (U.S. Food and Drug Administration)
 - Others

No file(s) Select files... Drop files here to upload

Essential Principles

- Earliest approval obtained on or before 31 December 2004
- Earliest approval obtained on or after 1 January 2005
- Essential Principles Conformity Checklist for In-Vitro Diagnostic Medical Devices (MDIVD-CCL) is attached: OR

Save Submit Cancel Reset



Individual Users – Submit MD Application (MD102)

Medical Device Information System (MDIS) **DEV** Is Your Product A Medical Device? Eng | 繁體 Experia01 Last Login: 2024-04-13 00:01 Logout

Application for the Listing of In-Vitro Diagnostic Medical Devices * - Mandatory field
- Display in public

Part A Part B Part C Part D **Declaration** ← PICS Declaration

Declaration

1. To the maximum extent permitted by law and in consideration of the Department of Health of the Government of the Hong Kong Special Administrative Region ("the Government") processing our application under the MDACS, we agree to exempt, relieve, exonerate, indemnify and hold harmless, and to keep indemnified and harmless, as the case may be, the Government from and/or against any and all losses, claims, demands and proceedings (including but not limited to all costs, charges and expenses) whatsoever and howsoever suffered or incurred by, or made or issued against, the Government, as the case may be, by any third party in respect of any loss of or damage to any property or injury to or death of any person arising out of and/or relating and/or incidental to:

- a. any act, neglect or default on our part or on the part of our employees or agents;
- b. any defect in the design, material, workmanship or installation of our device or devices;
- c. any use of any of the information supplied by us or our employees or agents in relation to our device or devices whether or not such information has materially contributed to the inclusion of the device or devices on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.

2. We also agree and accept that:

- a. the Government, its employees or agents shall not be liable to us for any loss of or damage to property caused by the act, default or neglect of the Government or its employees or agents in the processing of our application, the inclusion or non-inclusion of any of our information and/or device or devices on the List of Medical Devices or any cause whatsoever arising out of or in connection with the implementation and management of the MDACS;
- b. neither the Government nor any of its employees or agents makes any representation, statement, warranty or guarantee, express or implied, that the devices (including any spares or replacement parts) listed or considered for listing under the MDACS, whether or not they are included in the List of Medical Devices, are of merchantable quality or are fit for the purposes for which they are commonly bought and that the spares or replacement parts are readily available.

3. We confirm that the information contained in our application is true and correct and that our device or devices (including any spares or replacement parts) are of merchantable quality and are fit for the purposes for which they are commonly bought.

4. We fully understand and agree that any future changes or additions to the requirements of the Medical Device Administrative Control System (MDACS) can be imposed by the Department of Health. We undertake to comply with the latest requirements of the MDACS that are in force. It is one of the current requirements of the MDACS that, upon receiving the request from the Department of Health, produce the originals or certified copies of the documents that, according to the requirements of the MDACS, are in the possession of the LRP or the manufacturer.

5. We confirm that this form is filled in this form, nor otherwise altered the form in any material manner, apart from filling in the appropriate blanks / boxes.

hereby acknowledge the above declaration.

Check to acknowledge the declaration

Save Submit Cancel Reset



Individual Users – Submit MD Application (MD102)

MDIS DEV

Is Your Product A Medical Device? 17 Eng | 繁體 Experia01 Last Login: 2024-04-13 00:01 Logout

Application for the Listing of In-Vitro Diagnostic Medical Devices * - Mandatory field # - Display in public

Part A Part B Part C Part D Declaration PICS Personal Data Ordinance Statement of Purposes Declaration

Personal Data (Privacy) Ordinance Statement of Purposes 《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 application or when you are in contact with the Department of Health (DH) in connection with matters related to the Medical Device Administrative Control System (MDACS) will be used by the DH for the management and implementation of the MDACS. The provision of personal data is voluntary. If you do not provide sufficient information in the application as specified, we may not be able to process your application and assess your eligibility for a listing/recognition certificate.

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 (Cap. 486). Your right of access includes the right to obtain a copy of your personal data provided by you

I hereby acknowledge the above statement. 本人已閱讀及完全明白並同意以上聲明. Scroll down to check the box

Save Submit Cancel Reset

Individual Users – Submit MD Application

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

<input type="checkbox"/>	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

For saved case, the pending submission for future edit will appear on Todo list. Click "Update" to continue editing, or press "View" to view the submission

Individual Users – MD Application Enquiries

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

Export

MD Screening Application(s) Outstanding Enquiries

<input type="checkbox"/>	Actions	Screening no. ↓	Status	Category	Type	Company Name	Name of Legal Manufac
No records available.							

10 items per page 0 - 0 of 0 items

Trader Screening Application(s) Outstanding Enquiries

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

10 items per page 0 - 0 of 0 items

MD Application(s) Outstanding Enquiries

<input type="checkbox"/>	Actions	Application no. ↓	Status	Application Type	Manufacturer	LRP
--------------------------	---------	-------------------	--------	------------------	--------------	-----

Inquiries from MDD at Initial Screening and Application stage will be displayed in Todo list for user's response



Individual Users – Trader Application Enquiries

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

Actions	Screening no.	Status	Category	Type	Company Name	Name of Legal Manufac
No records available.						

10 items per page 0 - 0 of 0 items

Trader Screening Application(s) Outstanding Enquiries

Actions	Screening no.	Status	Company Name	Type	Role	SCNO
No records available.						

10 items per page 0 - 0 of 0 items

MD Application(s) Outstanding Enquiries

Actions	Application no.	Statu
No records available.		

10 items per page 0 - 0 of 0 items

Inquiries from MDD about Trader Application at Initial Screening and Application stage will be displayed in Todo list for user's response (Screening To-Do captured for illustration)



Individual Users – MD Application Status

The screenshot displays the 'Individual Users – MD Application Status' interface. On the left is a dark blue sidebar with navigation options: To-Do, Medical Device, Trader, Safety Alert, Adverse Event, and User Account. The main content area is divided into three sections:

- Trader Application(s) Outstanding Enquiries:** A table with columns: Actions, Application no., Status, Application Type, and VO. It shows 'No records available.' and a pagination of '0 - 0 of 0 items'.
- Approved / Rejected MD Application(s):** A table with columns: Actions, Application no., Status, Application Type, Manufacturer, and LRP. It contains one record:

Actions	Application no.	Status	Application Type	Manufacturer	LRP
<input type="checkbox"/> View Update	AN005944_1	Application Approved	Delist	St. Jude Medical Cardiac Rhythm Management Division	Abbott Me Kong) Lim

The 'Status' column is highlighted in green. Below the table is a pagination of '1 - 1 of 1 items' and an 'Export' button.
- Approved / Rejected Trader Application(s):** A table with columns: Actions and Application. It is currently empty.

A green callout box with an arrow pointing to the 'Status' column of the second table contains the text: 'The Approval/Rejection result of the application will be displayed in the Todo list. User can update Conversation in the case for communication with MDD.'

Individual Users – Create Trader Application

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

Trader Module

Create Application

Search

Trader Application Inspection

Application Screening

Application Number

Listing Number

Click to switch between modules

Click "Search" to find submitted applications

Enter search criteria to filter the result

Individual Users – Create Trader Application

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

Trader Module

[Create Application](#)

Search

Trader Application Inspection

Inspection Date From To

[Search](#) [Clear](#)

Click on another tab to search for Inspection

Navigation Menu:

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

Individual Users – Create Trader Application

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

Trader Module

Create Application ▼

Search

Trader Application Inspection

Application Screening

Application Number --- eg: 000001/1/1_1/1a

Listing Number eg: 050123/05/123

Search Clear

Importer/Distributor
Manufacturer

Create Application (Click to expand the drop-down menu and select the application type)

Click "Search" to find submitted applications

Individual Users – Create Trader Application

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

Application for List of Importers/Distributors * - Mandatory field
- Display in public

Form PICS Undertaking by Applicant

Application for the Inclusion of the List of Importers
 Application for the Inclusion of the List of Distributors

Particulars of Applicant

1001 * **Company's Name #**

in Chinese

1002 * **Address in Hong Kong #**

Formatted

Estate / Building / Street Name

The form is divided into different parts

Save as draft

Click "Submit" to apply form validation checking



Individual Users – Create Trader Application

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

Application for List of Importers/Distributors

Form PICS Undertaking by Applicant

Personal Data (Privacy) Ordinance Statement of Purposes

Personal Data (Privacy) Ordinance Statement of Purposes (《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 application or when you are in contact with the Department of Health (DH) in connection with matters related to the Medical Device Administrative Control System (MDACS) will be used by the DH for the management and implementation of the MDACS. The provision of personal data is voluntary. If you do not provide sufficient information in the application as specified, we may not be able to process your application and assess your eligibility for a listing/recognition certificate.

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 (Cap. 486). Your right of access includes the right to obtain a copy of your personal data provided by you during the occasion as mentioned in paragraph 1 above. A fee may be imposed for complying with a data access request.

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

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

* - Mandatory field
- Display in public

Individual Users – Create Trader Application

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

Application for List of Importers/Distributors * - Mandatory field
- Display in public

Form PICS **Undertaking by Applicant** **Undertaking by Applicant**

Undertaking by Applicant

To the Government of the Hong Kong Special Administrative Region (hereinafter "the Government"):

I/We have read the latest editions of the Guidance Notes GN-01 (with Appendices 1 to 5) and GN-08 (with Appendix 1) issued by the Department of Health in relation to the Medical Device Administration Control System (MDACS) and the listing of local manufacturers thereunder.

In consideration of the promise of the Government in section 5.3 of the Guidance Notes GN-08 to proceed with the processing of this application under the MDACS, I/we undertake, acknowledge and agree in favour of the Government as follows:

- To the maximum extent permitted by law I/we agree to exempt, relieve, exonerate, indemnify and hold harmless, and to keep indemnified and harmless, as the case may be, the Government from and/or against any and all losses, claims, demands and proceedings (including but not limited to all costs, charges and expenses) whatsoever and howsoever suffered or incurred by, or made or issued against, the Government, as the case may be, by any third party in respect of any loss of or damage to any property or injury to or death of any person arising out of and/or relating and/or incidental to:
 - any act, neglect or default on my/our part or on the part of my/our employees or agents;
 - any defect in the design, material, workmanship or installation in relation to my/our medical device product or products;
 - any use of any of the information supplied by me/us or my/our employees or agents in relation to this application or to my/our medical device product or products, whether or not such information has materially contributed to the inclusion of the applicant on the List of Local Manufacturers or the inclusion of any of my/our product or products on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.
- I/We also agree and accept that:
 - the Government, its employees or agents shall not be liable to me/us for any loss of or damage to property caused by the act, default or neglect of the Government or its employees or agents in the processing of my/our application, the inclusion or non-inclusion of any of my/our information and/or product or products on the Lists being maintained under the MDACS (including but not limited to the List of Local Manufacturers and the List of Medical Devices) or any cause whatsoever arising out of or in connection with the implementation and management of the MDACS;
 - neither the Government nor any of its employees or agents makes any representation, statement or warranty in relation to the processing of my/our application, the inclusion or non-inclusion of any of my/our information and/or product or products on the Lists being maintained under the MDACS or our products (including any

Save Submit Cancel Reset

Scroll down to check the PICS

I hereby acknowledge the above declaration.

Individual Users – Create Trader Application

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

Application for List of Importers/Distributors

* - Mandatory field
- Display in public

Form PICS Undertaking by Applicant

Undertaking by Applicant

To the Government of the Hong Kong Special Administrative Region (hereinafter "the Government"):

I/We have read the latest editions of the Guidance Notes GN-01 (with Appendices 1 to 5) and GN-08 (with Appendix 1) issued by the Department of Health in relation to the Medical Device Administration Control System (MDACS) and the listing of local manufacturers thereunder.

In consideration of the promise of the Government in section 5.3 of the Guidance Notes GN-08 to proceed with the processing of this application under the MDACS, I/we undertake, acknowledge and agree in favour of the Government as follows:

- To the maximum extent permitted by law I/we agree to exempt, relieve, exonerate, indemnify and hold harmless, and to keep indemnified and harmless, as the case may be, the Government from and/or against any and all losses, claims, demands and proceedings (including but not limited to all costs, charges and expenses) whatsoever and howsoever suffered or incurred by, or made or issued against, the Government, as the case may be, by any third party in respect of any loss of or damage to any property or injury to or death of any person arising out of and/or relating and/or incidental to:
 - any act, neglect or default on my/our part or on the part of my/our employees or agents;
 - any defect in the design, material, workmanship or installation in relation to my/our medical device product or products;
 - any use of any of the information supplied by me/us or my/our employees or agents in relation to this application or to my/our medical device product or products, whether or not such information has materially contributed to the inclusion of the applicant on the List of Local Manufacturers or the inclusion of any of my/our product or products on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.
- I/We also agree and accept that:
 - the Government, its employees or agents shall not be liable to me/us for any loss of or damage to property or loss of business or income or any other loss or damage suffered or incurred by me/us or my/our employees or agents in the processing of my/our application, the inclusion or non-inclusion of any of my/our information on the List of Local Manufacturers and the List of Medical Devices) or any cause of action in relation to the management of the MDACS;
 - neither the Government nor any of its employees or agents shall be liable to me/us for any loss of or damage to property or loss of business or income or any other loss or damage suffered or incurred by me/us or my/our employees or agents in the processing of my/our application, the inclusion or non-inclusion of any of my/our information on the List of Local Manufacturers and the List of Medical Devices) or any cause of action in relation to the management of the MDACS;

Save Submit Cancel

Click Submit, success message will be shown if all validation has passed

Please confirm

Are you sure to submit?

Only submissions with duly completed application forms and all required documents materials will be processed. Materials provided with any submission will not be returned.

No Yes

Reset



Individual Users – Withdraw Application

The screenshot displays the 'Trader Module' interface. On the left is a navigation sidebar with options: Todo, Medical Device, Trader (selected), Safety Alert, Adverse Event, and User Account. The main content area is titled 'Trader Module' and includes a 'Create Application' button. Below this is a search section with tabs for 'Trader Application' and 'Inspection', and sub-tabs for 'Application' and 'Screening'. Search filters include 'Application Number' (with a dropdown and text input 'eg: 000001/1/1_1/1a') and 'Listing Number' (with text input 'eg: 050123/05/123'). 'Search' and 'Clear' buttons are present. The 'Search Result' section shows a table with one item. A green callout box labeled 'Withdraw Case' points to the 'Withdraw' button in the 'Actions' column of the table row.

Actions	Listing no.	Listing Status	Application no. ↓	Type	Company Name	Status	Receive Date
View Withdraw			DAN000034_1	New	experia	Application Under Review	01/12/2023

1 - 1 of 1 items

Individual Users – Withdraw Application

Withdraw Application

Application Number: LMAN000027

Remark: Test remarks

Enter remarks

Submit

Submit | Cancel

Please confirm

Are you sure to submit?

No | Yes



Individual Users – Discard drafted Application

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

Trader Module

Create Application ▾

Search

Trader Application Inspection

Application Screening

Screen Id

Please confirm

Are you sure to discard this draft record?

Search Result

Discard Case

Actions	ID	Screening no.	Application Type	Role	Company Name	Status
<input type="button" value="View"/> <input type="button" value="Update"/> <input type="button" value="Discard"/>	11542		New		Experia Tech	Drafting
<input type="button" value="View"/> <input type="button" value="Update"/> <input type="button" value="Discard"/>	8419		New		Experia Tech	Drafting

1 10 items per page 1 - 2 of 2 items



Individual Users – Print Listing e-certificate

The screenshot shows the Medical Device Information System (MDIS) interface. The top navigation bar includes the system name, version (SIT 1.01a), a user account menu (u01, Last Login: 2024-03-22 10:45), and a Logout button. A sidebar on the left contains navigation options: To-Do, Medical Device, Trader, Safety Alert, Adverse Event, User Account, and Support. The main content area is titled "Medical Device Module" and features a search section with filters for "MD Application" (LRP SOP Application), "Application" (Screening), "Application Number" (eg: AN000001/1/1_1/1a), "Listing Number" (eg: 050123/05/123), "Manufacturer Name", "Make" (Chinese), and "Model" (Chinese). Below the search filters is a "Search Result" table with columns for Actions, Application Type, Status, Make, Model, and Issue Date. The first row in the table is highlighted, and a green callout box points to the "Download Listing Document" button in the Actions column.

Enter "Medical Device" / "Trader" module and select the application with the status "Application approved". Click "+" button to expand the action menu, then click "Download Listing Document"

Actions	Application Type	Status	Make	Model	Issue Date
View Download Listing Document	New	Application Approved		Medilas L UroPulse	21/03/2024
View Withdraw	New	Application Under Review	Medical Measurement Systems B.V.	Ohmega R	
View Withdraw	New	Application Under Review	Medical Measurement Systems B.V.	Solar GI	
View Withdraw	New	Application Under Review	Medical Measurement Systems B.V.	Nexam Pro U8-3, U8-4	
View Withdraw	New	Application Under Review	Meditech	ABPM-06	

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

Preview Listing Certificate

Please make sure all information above are correct before download. Once downloaded, all listing information cannot be changed / modified.

香港特別行政區政府
衛生署
醫療器械科
網站: www.mdd.gov.hk



表列證書
CERTIFICATE OF LISTING

Medical Device Division,
Department of Health,
Government of the Hong Kong
Special Administrative Region
Website: www.mdd.gov.hk

表列號碼 Listing No.	241001
修訂本號碼 Revision No.	
製造商 Manufacturer	
品牌及型號 Brand Name and Model	
儀器名稱 Device Description	
製造地點 Manufacturing Site	
本地負責人 Local Responsible Person	
發出日期 Date of issue	21/03/2024
有效期至 Valid until	20/03/2029

Download

Download Return to MDD with remarks Cancel

衛生署署長
(陳國雄代行)
(Dr Addi CHAN)
for Director of Health

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

Preview Listing Certificate

表列證書
CERTIFICATE OF LISTING

表列號碼 Listing No.	241001
修訂本號碼 Revision No.	
製造商 Manufacturer	
品牌及型號 Brand Name and Model	
儀器名稱 Device Description	
製造地點 Manufacturing Site	
本地負責人 Local Responsible Person	
發出日期 Date of issue	21/03/2024
有效至 Valid until	20/03/2029

衛生署署長
(陳國強代行)
(Dr Addi CHAN)
for Director of Health

Please make sure all information above are correct before download. Once downloaded, all listing information cannot be changed / modified.

I hereby confirm the above information are correct.

Remark to MDD

[Download](#) [Return to MDD with remarks](#) [Cancel](#)

Return to MDD with remarks.

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

