

GUIDE TO MEDICS WORKBENCH

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a company to manage their MEDICS transactions and Licences with HSA.

The online [Workbench](#) in MEDICS is a one-stop Application and Licence Management Module.

INSTRUCTIONS

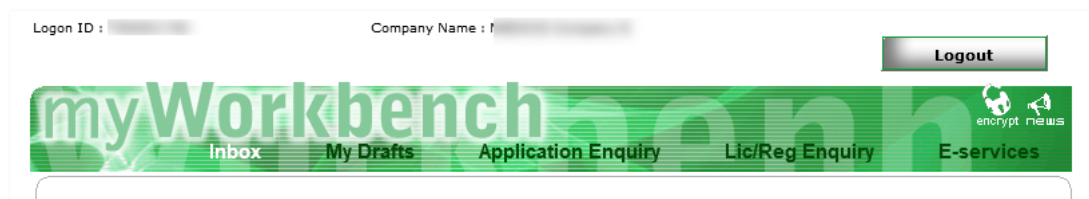
In order to use this e-Service in MEDICS, you must have all of the following:

1. Personal Access Authentication to log on

- [CorpPass](#) (Singapore Corporate Access), a corporate digital identity for business and other entities to transact with Government online services, OR
- [HSA PIN](#) (HSA Personal Identification Number), password for overseas individual, supplied by HSA

2. A CRIS Company Account for MEDICS (Client Registration & Identification Services), an account to enable a local company to gain access to MEDICS. See details at cris@hsa.

ONLINE ENQUIRY IN WORKBENCH



There are 5 tabs for the company to manage their applications and licence/Registration in MEDICS (via Inbox; My Drafts; Application Enquiry; Lic/Reg Enquiry; E-Services).

Encryption Tool

An on-line encryption tool is available for companies who wish to encrypt their files before submission on-line.

1. Click on the “encrypt logo” and a new window will pop up.
2. Browse for the file to encrypt using the browse button and click on “Encrypt File” to start encryption.
3. The encrypted file will be created in the same folder as the original file. The file will have .sec extension.
4. The file is now encrypted and ready for submission as attachment in any MEDICS e-application.

TAB 1 – Inbox

This tab serves as an inbox between company users and MDB regarding any application. The Inbox holds the following:

- Applications that are approved or rejected by MDB forwarded to the company;
- Applications that are send back by MDB to the company for input-request, principally for the company to provide further information;
- Registration of Higher Risk Medical Device Form created by MDB for the company to complete and return for listing on the Singapore Medical Device Register, upon approval of Product Registration (Market Clearance) Application.

The following fields are displayed to identify the applications in the Inbox:

1. *Transaction No.*
2. *Job Reference No.*
3. *Dossier No.*
4. *Job Type*
5. *Received Date*
6. *Submitted Date*
7. *App. Status*

The default sorting is by <Transaction No.>. Click on the column name to sort the listing of that column. The sorting order will alternate between ascending and descending by repeated clicking on the column name.

Item 1: Click on the <Transaction No.> will display the following application form:

For Approved, rejected or withdrawn – display the application form and outcome

For Input Request – open a form for user to complete

For Registration for Higher Risk Medical Device (Draft) - open a form for user to complete

Item 3: Click on <Dossier No.> to view the summary of the dossier:

- Dossier Summary
 - Dossier No.
 - Pre-market App. Job Ref. No.
 - Submission Date
 - Approval Date
 - Status
 - Submission Grade
 - TAT (Turnaround Time (Actual/Target))
- Device Info
 - Device Proprietary / Brand Name
 - Device Class/Category
 - Status
 - Transaction No.
 - Job Ref. No.

Click on the <Pre-market App. Job Ref. No.> to display a read-only version of the original application form. The payment advice for the original application can be access there.

Click on the <Transaction No.> to display a read-only version of the Registration of Higher Risk Medical Device form.

Item 7: App Status – if the Registration for higher risk medical device is completed by a drafter, the status will be “Ready to Submit”

Note: Users who are submitter can view all applications. Users who are drafters can only see those applications (Market clearance application for higher risk medical device and registration of higher risk medical devices) that they are assigned to handle.

TAB 2 – My Drafts

This tab displays the draft applications for any jobs that are created by any submitter or users representing the company but not yet submitted to MDB.

The following fields are displayed:

1. *Transaction No.*
2. *App. Type*
3. *Job Type*
4. *Applicant Name*
5. *Last Updated Date*
6. *Status*

The default sorting is by <Transaction No.>. Click on the column name to sort the listing of that column. The sorting order will alternate between ascending and descending by repeated clicking on the column name.

Item 1: Click on the <Transaction No.> open the form for user to complete

Item 6: Status – if the Product Registration (Market Clearance) Application for Higher Risk Medical Device is completed by a drafter, the status will be “Ready to Submit”

Note: Users who are submitter can view all drafts created by all users. Users who are drafters can only see those applications (Market clearance application for higher risk medical device and registration of higher risk medical devices) that they are assigned to handle.

TAB 3 – Application Enquiry

This tab allows users to search any of the applications accessible to him using a query mode.

The following search criteria are available:

1. *Job Reference No.*
2. *Dossier No.*
3. *Transaction No.*
4. *Application Type*
5. *Job Type*
6. *Application Status*
7. *Submission Date*
8. *Last Updated Date*
9. *Order by*

Item 4: Four Application Type can be selected from a dropdown list (leaving it blank will search for all):

- New Application
- New Application (withdrawal)
- Cancellation of Licence/Notification
- Amendment of Licence/Notification

Item 5: Select job type from a list of all MEDICS e-Applications. Leaving it blank will search for all.

Item 6: Select the Status of the applications from a drop down list:

- Draft*
- Pending*
- Approved*
- Closed*
- Rejected*
- Withdrawn*
- Input Request*

The Search result will be displayed as:

- *Transaction No.*
- *Job Reference No.*
- *Application Type*
- *Dossier No.*
- *Job Type*
- *Last Updated Date*
- *Submitted Date*
- *Application Status*

TAB 4 - Application Enquiry

This tab allows users to search any of the licences / device registrations accessible to the user using a query mode.

The following search criteria are available:

1. *Licence/Registration Type*
2. *Device Proprietary/Brand Name*
3. *GMDN*
4. *Authorised Rep*
5. *Brand Owner*
6. *Licence/ Registration No*
7. *Device Class/ IVD Category*
8. *Specialty Category*
9. *Biological Material Component*
10. *Status*

The search results is a list of licence / registrations that meets the search criteria and displays the following fields:

- *Licence/ Registration No.*
- *Licence/ Registration Type*
- *Approved Date*
- *Expiry Date*
- *Licence Status*

The user may click on the icon for licence / registration to view / print the history of the licence / registration. The information displayed will include:

- Transaction history (including amendment and supplementary)
- Renewal History (including date and Fees charged)
- Other Changes (such as transfer of AR, suspension, revoke, etc)

TAB 5 – E-Services

This section allows the user to access the other MEDICS E-service modules that are available.

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