

INFORMATION ON



WHAT IS MeDC@St?

MeDC@St is a web-based Online Application System for Establishment Licensing, Medical Device Registration and Export Permit. It is a centralized system where only one account needs to be created by an applicant to apply for establishment licensing, medical device registration or Export Permit.

It consists of three modules on:

- i- Establishment licensing,
- ii- Medical device registration,
- iii- Export Permit.

WHO SHOULD USE THE SYSTEM?

The following parties who deal with medical devices and operate their businesses in Malaysia:

- Manufacturers of medical devices
- Importers or exporters of medical devices
- Distributors of medical devices
- Authorized Representative of medical devices

WHEN?

When the Medical Device Act 2012 (Act 737) and Medical Device Registration 2012 become effective on 1st July 2013, all application for establishment licence, medical device registration or export permit should be done using an online application form that is provided in MeDC@St.

WHY MeDC@St?

- MeDC@St supports the implementation of Medical Device Act 2012 (Act 737) and its regulation.
- MeDC@St consists of application forms for establishment licence, medical device registration and export permit.

- MeDC@St is an integrated, secured and user friendly system.
- MeDC@St can be accessed anywhere and anytime as long as there is internet connection
- MeDC@St application is supported by Windows, Mac or Linux.

HOW TO CREATE AN ACCOUNT?

Step 1:

Applicant need to create an account using MeDC@St Account Creation Form. Information on Business Registration, Establishment Name and valid email address need to be provided in the form. Applicant must also provide user name and password for security purposes. Applicant must reconfirm the password. Once the form is completed, applicant must click “create account” button to proceed to next step.

Step 2:

Applicant need to validate the email address that is provided in the MeDC@St Account Creation Form to activate the MeDC@St account.

Step 3:

After email validation is done, applicant need to login to MeDC@St system by providing the User Name and Password given in the MeDC@St Account Creation Form during account creation.

Applicant can choose what application he wants to do by clicking to the relevant to make an application. Applicant can refer to the guidelines below for further information;

- i- Guideline on How to Apply Establishment Licence
- ii- Guideline on How to Apply Medical Device Registration
- iii- Guideline on How to Apply Export Permit

HELP DESK

All inquiries regarding MedC@St, can be addressed at <http://www.mdb.gov.my/medcast/feedback/> or at the Hunting Line, 03-88850778.

Medical Device Authority,
Ministry of Health Malaysia,
Level 5, Menara Prisma,
No. 26, Jalan Persiaran Perdana, Precint 3
62675 Putrajaya, MALAYSIA