INTRODUCTION

In line with Section 43 of the Medical Device Act 737, the Medical Device Authority is developing the Medical Device Competency Regulatory Program. The voluntary listing of technical personnel and training body for medical device technical competency regulatory programme was launched in December 2016. This voluntary application is to list technical personnel, training bodies, and Competency Certification Bodies (CCBs) related to installation, testing, commissioning, maintenance and disposal of medical devices.

During this voluntary phase, MedTComp is a platform that will list technical personnel and training bodies via online system. For the MedTComp system, MDA will issue auto-generated acknowledgement letter for the technical personnel, and training body accordingly. For Competency Certification Bodies (CCBs) application will be processed manually. No fee will be incurred for this application process during voluntary phase.

The training body and competency certification body shall be independent, not related to its client and shall not be involved in activities relating to maintenance, testing, installation, commissioning and disposal of medical devices. All voluntary applications (biomedical technical personnel, training body and competency certification body) will be listed with MDA.

OBJECTIVE

- To familiarize all stakeholders with the medical device technical competency regulatory programme;
- To assess the competency of technical personnel;
- To assess readiness of training bodies and competency certification bodies in conforming to regulatory requirements;
- To develop and maintain a registry of technical personnel, training bodies, competency certification bodies and relevant regulatory documents; and
- To provide a smooth transition into mandatory phase before the enforcement of 2nd medical devices regulation.

WHO HAS TO BE LISTED

The following parties who undertake the said activities in Malaysia are invited to participate in this voluntary scheme.

- Technical personnel undertaking installation, testing, commissioning, maintenance and disposal of medical device (Example: Service Engineer, Biomedical Engineer, Technician or etc.)
- Training body providing trainings related to installation, testing, commissioning, maintenance and disposal of a medical device.
- Competency certification body certify technical personnel related to installation, testing, commissioning, maintenance and disposal of a medical device.
HOW TO APPLY BIOMEDICAL TECHNICAL PERSONNEL (BTP)

Application may be made using MeDTComp (Medical Device Technical Competency Online System). This is a web-based online application system for biomedical technical personnel.

**Step 1**: Click [here](#) to view MeDTComp webpage

**Step 2**: In MeDTComp webpage, click New Registration for account creation and select drop-down menu, Registration as Biomedical Technical Personnel. Fill in required details and click Register. A validation email will be sent to the email address provided to activate the account.

**Note**: A validation email may be received in the SPAM or TRASH folder because of filtering by receiving email server. If the validation email is not received in the inbox, please check in the SPAM or Trash folder.

**Step 3**: Log in to your account using validated email address and password.

**Step 4**: Fill in all required information and please ensure all information entered are correct.

**Note**: Please refer user manual for MeDTComp Biomedical Technical Personnel (BTP) for detail instructions. Click [here](#) for User Manual For Biomedical Technical Personnel.

**Step 5**: Download your Acknowledgement Letter for Biomedical Technical Personnel at your MeDTComp dashboard.

Any enquiry pertaining to the system please email to support.medtcomp@mda.gov.my

HOW TO APPLY MEDICAL DEVICE TRAINING BODY (TB)

Application may be made using MeDTComp (Medical Device Technical Competency Online System). This is a web-based online application system for Medical Device Training Body.

**Step 1**: Click [here](#) to view MeDTComp webpage

**Step 2**: In MeDTComp webpage, New Registration for account creation and select drop-down menu, Registration as Training Body. Fill in required details and click Register. A validation email will be sent to the email address provided to activate the account.

**Note**: A validation email may be received in the SPAM or TRASH folder because of filtering by receiving email server. If the validation email is not received in the inbox, please check in the SPAM or Trash folder.

**Step 3**: Log in to your account using validated email address and password.
Step 4 : Fill in all required information and please ensure all information entered are correct.

Note: Please refer user manual for MeDTComp Training Body (TB) for detail instructions. Click here for User Manual For Training Body.

Step 5 : Download your Acknowledgement Letter for Training Body at your MeDTComp dashboard.

Any enquiry pertaining to the system please email to support.medtcomp@mda.gov.my

HOW TO APPLY FOR MEDICAL DEVICE COMPETENCY CERTIFICATION BODY (CCB)

Application is manual and only pertinent relevant information will be required. It consists of three main steps, namely;

Step 1 : Click here to download Application Form for Medical Device Competency Certification Body

Step 2 : Fill in all required information and please ensure all information entered are correct.

Step 3 : Submit completed Application Form for Medical Device Competency Certification Body (with supported documents) to email address : voluntarycompetencylistingccb@mdb.gov.my

ENQUIRY

Enquiries can be sent to Medical Device Authority (MDA) at the following address:

Chief Executive  
Medical Device Authority (MDA), Ministry of Health Malaysia  
Level 6, Prima 9, Prima Avenue II  
Block 3547, Persiaran APEC  
63000 Cyberjaya, Selangor, Malaysia  
(Attention to: Director Policy, Code and Standard Division)

Note : The above requirements will be subject to change from time to time.

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