

## **VOLUNTARY LISTING OF TECHNICAL PERSONNEL, TRAINING BODY OR COMPETENCY CERTIFICATION BODY UNDER MEDICAL DEVICE ACT 737**

### **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 personnels, training bodies, and Competency Certification Bodies (CCBs) related to installation, testing, commissioning, maintenance and disposal of medical devices.

During this voluntary phase, MDA will issue notification letter for the technical personnel, training body or CCB accordingly. 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, disposal of medical devices and all voluntary applications 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, and competency certification bodies relevant regulatory documents; and
- To provide a smooth transition into mandatory phase before the enforcement of 2<sup>nd</sup> 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 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 Biomedical Technical Personnel**;

Click [here](#) to download **Skill Assessment & Gap Analysis Matrix**; and

Click [here](#) for **instructions to fill in skill assessment & gap analysis matrix**

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

**Step 3** : Submit completed Application Form for Biomedical Technical Personnel (with supported documents) and Skill Assessment & Gap Analysis Matrix to email address : [voluntarycompetencylistingtp@mdb.gov.my](mailto:voluntarycompetencylistingtp@mdb.gov.my)

## HOW TO APPLY FOR MEDICAL DEVICE TRAINING BODY (TB)

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 Training 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 Training Body** (with supported documents) to email address : [voluntarycompetencylistingtb@mdb.gov.my](mailto:voluntarycompetencylistingtb@mdb.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](mailto: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 5, No. 26, Menara Prisma, Precinct 3  
62675 Putrajaya, MALAYSIA.  
(Attention to: Director Policy, Code and Standard Division)

Note : The announcement titled VOLUNTARY REGISTRATION OF TECHNICAL PERSONNEL & TRAINING BODY UNDER MEDICAL DEVICE ACT 737 will no longer effective. Announcement of VOLUNTARY LISTING OF TECHNICAL PERSONNEL, TRAINING BODY OR COMPETENCY CERTIFICATION BODY UNDER MEDICAL DEVICE ACT 737 effective on 26 January 2018. All applications submitted is still remain valid. The above requirements will be subject to change from time to time.