VOLUNTARY REGISTRATION OF TECHNICAL PERSONNEL & TRAINING BODY UNDER MEDICAL DEVICE ACT 737

INTRODUCTION

In line with Section 43 of the Medical Device Act 737, the Medical Device Authority is developing a Medical Device Competency Regulatory Program. The voluntary registration of technical personnel and training body for medical device technical competency regulatory programme was launched in December 2016. This voluntary registration is to register technical personnels and training bodies undertaking activities and trainings related to installation, testing, commissioning, maintenance and disposal of medical devices. The technical competency of technical personnel will be assessed and assigned with a competency level accordingly.

This program consists of two phases. Phase 1 involves voluntary registration to capture data pertaining to technical personnel and training providers in the medical device sector. Phase 2 involves assessments of skills and assignment of competency level to the technical personnel.

OBJECTIVE

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

WHO HAS TO REGISTER

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.

HOW TO REGISTER MEDICAL DEVICE TECHNICAL PERSONNEL

Registration 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 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 Medical Device Technical Personnel (with supported documents) and Skill Assessment & Gap Analysis Matrix to email address **competencyregistration@mdb.gov.my**

HOW TO APPLY FOR MEDICAL DEVICE TRAINING BODY

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

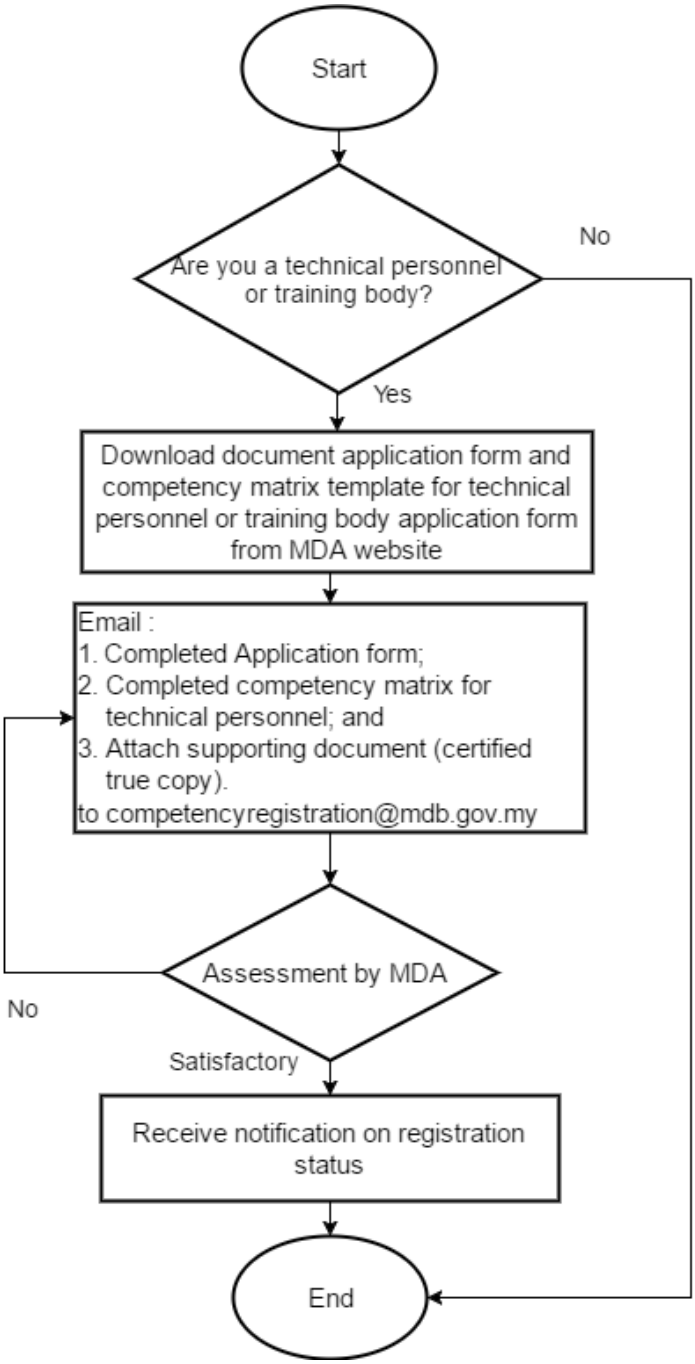
Step 1 : Click **here** to download **Application Form for Medical Device Training Body**

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 **competencyregistration@mdb.gov.my**

PROCESS FLOW

Process flow for voluntary registration of technical personnel & training body under medical device Act 737 is as follows:



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

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)