



## PIHAK BERKUASA PERANTI PERUBATAN MEDICAL DEVICE AUTHORITY

### STEP BY STEP INSTRUCTION TO OBTAIN ESTABLISHMENT LICENSE UNDER MEDICAL DEVICE ACT 2012 (ACT 737)

#### INTRODUCTION

Medical Device Act 2012 (Act 737) is passed by the Parliament in 2012 and is made effective on 30<sup>th</sup> Jun 2013. In accordance with section 15 of the Act, it is a mandatory requirement stated by law for establishments (manufacturer, authorised representative, distributor and importer) to obtain establishment license for them to conduct activities related to medical devices.

Section 80(1) of Act 737 provides for a one year transition period for establishments to apply for establishment license under Section 15 of the Act. The transition period to apply for establishment license will end on 30<sup>th</sup> June 2014. Section 80(3) of the same Act specifies that establishments that **have already applied** for an establishment license before the end of transitional period are allowed to continue conducting their business activities pending determination of its application for the establishment license by the Authority.

#### WHAT WILL HAPPEN AFTER 30<sup>th</sup> JUNE 2014

1. Establishments that **have not applied** for establishment license by 30<sup>th</sup> Jun 2014 **are prohibited** from conducting medical device related activities come 1<sup>st</sup> July 2014.
2. In accordance with Section 16(2) which requires establishment license application to be accompanied with the prescribed application fee, establishments that have submitted establishment license application **but have yet to pay the prescribed application fee** are required to do so before 30<sup>th</sup> Jun 2014.

#### INSTRUCTION FOR APPLYING ESTABLISHMENT LICENSE

1. Visit the official portal of Medical Device Authority at <http://www.mdb.gov.my> through any modern web browser. A link to MeDC@St (Medical Device Computerized Application System) can be accessed through the link provided . Application for establishment license shall be done online through the MeDC@St system.
2. First, applicant must create an account prior continuing with the system. Once the account has been set up, an activation email will be sent by the system to the applicant. The applicant must click on the link provided to activate his/her account.
3. Once activated, applicant can start to login to his/her account. Upon successful login, applicant is greeted with the dashboard view of the system.

4. Applicant can continue to make an application for establishment license by clicking the establishment license link located in the menu. An establishment license form will be prompted.
5. Complete the form and attach any documents that are needed. Applicant may refer to Guidelines on How to Apply for Establishment License under Medical Device Act 2012 (Act 737) found [here](#). The document will assist and familiarize the applicant on each fields found in the application form.
6. Upon completion, press the submit button to submit the application.
7. A payment advice slip will be available once the application is submitted. Applicant is required to pay the amount of RM 250.00 based on the payment instruction prescribed in the slip. **(This step is vital for establishment to complete to ensure them the added benefits of transitional period as stipulated under Section 80(3) of Medical Device Act 737. Failure to complete the application as instructed up until this point would result with the prohibition for the establishment to continue with medical devices related activities).**
8. Once the payment is cleared, the Authority will start to evaluate the application (this will takes some time).
9. Only applications that are in compliance with the regulatory requirements are approved by the Authority.
10. Applications that are found to be incomplete or unsatisfactory during evaluation shall be returned back to the applicant.
11. Returned applications must be resubmitted with additional information, particulars or documents by the applicant within thirty days from the date of request. If this condition is not being honoured by applicant, the application shall be deemed to be withdrawn and shall not be further proceeded with by the Authority.
12. Applicant will be asked to pay registration fee once the establishment licensed is approved based on the instruction given in the payment advice slip.
13. Upon full payment of the registration fee, the Authority will issue the Establishment License certificate.

## ENQUIRIES

Any enquiries relating to this instruction can be forwarded to :

Chief Executive  
Medical Device Authority  
Ministry of Health Malaysia  
Level 5, Menara Prisma, No. 26  
Jalan Persiaran Perdana, Presint 3  
62675 Putrajaya  
Tel : 03-88922400 Fax : 03-88922500  
Email : [mdb@mdb.gov.my](mailto:mdb@mdb.gov.my)

Thank you