

## **MEDICAL DEVICE AUTHORITY (MDA) REGULATORY INFORMATION SUBSCRIPTION**

### **INTRODUCTION**

This program of e-mail notification subscription is an initiative of MDA to provide the latest information to stakeholders and general public who wish to subscribe to this service. This is one of the initiatives that MDA is offering to promote effective dissemination of information to individuals and companies that values on time and direct access to pertinent regulatory information and activities related to medical devices.

### **OBJECTIVE**

- MDA publishes/ issues new regulatory information on medical device; and
- With this program, updated pertinent information from MDA is directly accessible to the stakeholders such information are including but not limited to the following:
  - a. Gazettement orders;
  - b. Regulations;
  - c. Policies;
  - d. Guidance documents;
  - e. Guidelines;
  - f. Programs;
  - g. Trainings; and
  - h. Others related to regulatory information.

### **WHO HAS TO SUBSCRIBE**

The target group for the implementation of MDA e-mail notification subscription is as follows:

- Manufacturers, authorized representatives, importers, and distributors;
- Conformity Assessment Bodies (CABs);
- Medical device associations;
- Healthcare institutions or universities;
- Healthcare professionals (HCPs);
- Testing labs;
- Students; and
- Interested individual.

### **HOW TO SUBSCRIBE**

Applicants shall apply and submit an application fee to the MDA.

Only pertinent relevant information will be required. The application process consists of five main steps, namely:

**Step 1** : Click on the [Application Form](#) to subscribe/ unsubscribe E-mail subscription.

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

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**Step 3** : Submit completed Application Form by clicking on the submit button.

**Step 4** : Tax invoice will be issued MDA to the applicant via email supplied in the application form.

**Step 5** : All applications will be charged **RM 106 per application including 6% GST**. The validity of e-mail notification subscription is valid for one (1) year. The subscriber will receive an e-mail reminder 30 days before the expiration date for renewal. Payment shall be made through bank draft, payable to:

"KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN" and courier to;

KETUA EKSEKUTIF  
PIHAK BERKUASA PERANTI PERUBATAN,  
KEMENTERIAN KESIHATAN MALAYSIA, ARAS 6, PRIMA 9, PRIMA AVENUE  
II, BLOCK 3547, PERSIARAN APEC, 63000 CYBERJAYA, SELANGOR.

Note:

1. CASH WILL NOT BE accepted. We will not be responsible for the cash sent or brought to MDA.
2. Kindly be informed that payment can be combined for a maximum of 5 applications only.
3. Payment to be made after issuance of payment advice from MDA.
4. A statement "MDA Regulatory Information Subscription" and Phone No. of the applicant shall be written at the back of the bank draft outside table section.
5. A receipt of payment will be issued once the bank draft is accepted by the MDA.
6. Processing time will normally take up to 7 working days after payment is made.

## ENQUIRY

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

Medical Device Authority, Ministry of Health Malaysia.  
Aras 6, Prima 9, Prima Avenue II,  
Block 3547, Persiaran APEC,  
63000 Cyberjaya, Selangor.  
Email: [mdasubscription@mdb.gov.my](mailto:mdasubscription@mdb.gov.my)  
Tel: 03-82300300  
Faks: 03-82300200