



NOTIFICATION OF MEDICAL DEVICE FOR DEMONSTRATION OR EDUCATION PURPOSE

(In accordance with Medical Device (Exemption) Order 2016)

Please complete all information requested on this form. *(All fields are mandatory unless stated otherwise)*

1. GENERAL INFORMATION

Period of Demonstration//training (education):

2. DETAILS OF APPLICANT AND COMPANY

Name of Person Responsible:

NRIC/Passport Number:

Designation:

Organization/Company Name:

Organization/Company Address:

City:

State:

Telephone No.:

Email Address:

Please skip this question if your organization/company is not an “establishment” according to the definition under Section 2 of Act 737.

If your organization/company is an “establishment” according to the definition under Section 2 of Act 737, please state—

a) the type of your “establishment” according to the type of establishment in Section 2 Act 737

<input type="checkbox"/>	Manufacturer	<input type="checkbox"/>	Authorized Representative	<input type="checkbox"/>	Distributor	<input type="checkbox"/>	Importer
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b) status of your establishment license under Act 737

<input type="checkbox"/>	Already submitted license application Please provide application form identification (Form ID) no	<input type="checkbox"/>	Already obtained establishment license Please provide license no
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3. MEDICAL DEVICE INFORMATION

- Please provide details of the medical device according to **Appendix A**
- Please provide supporting document for medical device: Sample of the medical device packaging label/promotional material (such as brochure, pamphlet or catalogue) that contain information



about the intended use/general description/mode of action of the medical device.

4. ATTESTATIONS & DECLARATION

I, the undersigned hereby declare that:

a. The product(s) indicated on this application:

- (i) Is/are a medical device(s) according to the definition of "medical device" set out in Section 2, Medical Device Act 2012 (Act 737);
- (ii) Has/have been classified according to Rules of Classification of Medical Device, as set out in the First Schedule of the Medical device Regulations 2012 (MDR 2012); and
- (iii) Has/have met all the labelling requirements set out in the Sixth Schedule of the MDR 2012.

b. I shall be responsible for the establishment and implementation of a system to monitor safety and performance of this/these medical device(s) and take the necessary actions should there be any occurrence of adverse incident during the period of the demonstration, exhibition or training involving the medical device;

c. I am aware that the permission is restricted to the importation and/or supply for the unregistered medical device(s) for the purpose of demonstration, exhibition or training *only*. Therefore, I shall undertake that the medical device(s)—

- (i) **Shall be removed from** the demonstration, exhibition or training site soonest possible after the demonstration, exhibition or training has ended;
- (ii) **Shall not be placed** in the Malaysian market;
- (iii) **Shall not be used** on a human or a patient.

I, the undersigned, hereby attest that the information and attachment provided on this notification is/are accurate, correct, complete and current to this date. I understand that any declaration by me in this application that is untrue, inaccurate or misleading shall be liable to a fine not exceeding **RM 500,000.00** or to imprisonment for a term not exceeding **3 years** or to both. (S.76 Act 737 refers).

Signature:

Name:

Designation:

Date:

Company stamp:

