PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mdb.gov.my
Email: mdb@mdb.gov.my

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 ³establishment´ according to the definition under Section 2 of Act 737.

If your organization/company is an ³establishment´ according to the definition under Section 2 of Act 737, please state ²

a) the type of your ³establishment´ according to the type of establishment in Section 2 Act 737

	Manufacturer		Authorized Representative		Distributor		Importer

b) status of your establishment license under Act 737

	Already submitted license application Please provide application form identification (Form ID) no « « « « « « « « « « « «		Already obtained establishment license Please provide license no « « « « « « « « « «

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

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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 Regulations2012 (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) [2]

(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:	

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APPENDIX A

MEDICAL DEVICE DETAILS (Repeat as needed)

No.	Medical Device name	Brand/ model	Manufacturer's name *(as it appears on the label)*	Description of Medical device	Intended use of Medical device	Class & classification rule *(according to First Schedule on Rules of Classification of Medical Device, MDR 2012):*	Site(s) details (name, address)	Quantity to be imported/ supplied	Marketing Approval Status in other country(-ies) *[Please state the name (s) of country (ies)]*		
									Registered/ licensed/ approved	Exempted/ notified/self-declared	*Others (please specify)*