



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 TO IMPORT MEDICAL DEVICES FOR CLINICAL USE AND RESEARCH SUPPORTIVE USE

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

All fields are MANDATORY unless stated otherwise.

First Application

Subsequent Application, please state the previous **notification no.:**
MDA/_____

SECTION A: PURPOSE OF RESEARCH

Clinical Use

Research Supportive Use (for other studies)

Research Supportive Use (clinical drug trial)

SECTION B: APPLICANT DETAILS

1. Please tick the appropriate box:

Local Sponsor

Manufacturer

An authorised person from a local organisation / company / Contract Research Organisation (CRO)
(Note: must have a permanent address in Malaysia)

2. Name of Applicant:

3. NRIC No./Passport:

4. Designation:

5. Name & Address of Organisation:

6. Telephone No.:

7. Fax No.:

8. Email Address:

SECTION C: SPONSOR DETAILS

1. Name of Contact Person:

2. Name & Address of Organisation:

3. Telephone No.:

4. Fax No.:

5. Email Address:

SECTION D: CLINICAL RESEARCH DETAILS

1. National Medical Research Registry (NMRR) Registration ID:	
2. Title of Clinical Trial - as stated in Protocol document	3. Protocol No.:
	4. Estimated duration of the clinical trial:
	5. Proposed date of start of trial:

SECTION E: TRIAL SITE DETAILS

For multiple sites, please refer **Appendix A**

1. Name & Address of the trial site:	
2. Name of Principal Investigator:	
3. Name of the Ethics Committee:	
4. Authorisation / Opinion of Ethics Committee (please attach the approval letter):	<input type="checkbox"/> To be requested <input type="checkbox"/> Pending <input type="checkbox"/> Authorisation accepted/favourable opinion

SECTION F: MEDICAL DEVICE DETAILS

Please provide medical device details according to the following:
1. **Appendix B** Details of Medical Device

SECTION G: ENTRY POINT

Please tick the appropriate box:

<input type="checkbox"/> Lapangan Terbang Antarabangsa Kuala Lumpur 1	<input type="checkbox"/> Lapangan Terbang Sultan Abdul Aziz Shah Subang
<input type="checkbox"/> Lapangan Terbang Antarabangsa Kuala Lumpur 2	<input type="checkbox"/> Pelabuhan Pulau Pinang
<input type="checkbox"/> Pelabuhan Klang	<input type="checkbox"/> Pelabuhan Pasir Gudang, Johor
<input type="checkbox"/> Pelabuhan Tanjung Pelepas, Johor	<input type="checkbox"/> Others (please specify):

SECTION H: MULTIPLE SHIPMENT *(tick the appropriate box & kindly state the total no. of devices per shipment if this trial requires multiple shipment – Repeat if necessary)*

<input type="checkbox"/> First shipment : Total number of devices _____
<input type="checkbox"/> Second shipment : Total number of devices _____
<input type="checkbox"/> Third shipment : Total number of devices _____

SECTION I: ATTESTATIONS & DECLARATION

I, the undersigned, on behalf of the company hereby declare that :

- a. This/These medical device (s) indicated on this application:
 - i. Conform(s) to all relevant essential principles for safety and performance as set out in the Appendix 1 of Third Schedule of the Medical Device Regulations (MDR) 2012;
 - ii. Has/have met all the labeling requirements set out in the Sixth Schedule of the MDR 2012;
- b. I shall be responsible to take the necessary actions should there be any adverse incident occurs during the period of trial;
- c. I am aware this/these medical device(s) is/are permitted for clinical research purpose only. Therefore, the medical device(s) shall not be:
 - i. placed/used at the trial site after the trial has ended;
 - ii. placed in Malaysia;
- d. I shall ensure that this/these medical device (s) is/are disposed appropriately / exported out of Malaysia after the trial has ended;

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:	Company Stamp:
Name:	
Designation:	Date:

SECTION J: FOR OFFICIAL USE

Notification No.:	Date:
-------------------	-------

APPENDIX A

TRIAL SITE DETAILS (For multiple sites in Malaysia – Repeat as needed)				
No.	Name & Address of the trial site	Name of Principal Investigator	Name of the Ethics Committee	Authorisation/Opinion of Ethics Committee (please attach the approval letter)
				<input type="checkbox"/> To be requested <input type="checkbox"/> Pending <input type="checkbox"/> Authorisation accepted/favourable opinion
				<input type="checkbox"/> To be requested <input type="checkbox"/> Pending <input type="checkbox"/> Authorisation accepted/favourable opinion
				<input type="checkbox"/> To be requested <input type="checkbox"/> Pending <input type="checkbox"/> Authorisation accepted/favourable opinion
				<input type="checkbox"/> To be requested <input type="checkbox"/> Pending <input type="checkbox"/> Authorisation accepted/favourable opinion

APPENDIX B

DETAILS OF MEDICAL DEVICES – (Kindly list down medical devices ONLY. All fields are mandatory)

Is the packing list for Study-Visits Specific Kits attached as part of the supporting documents? Yes No

No.	Device Name	Identifier (e.g. Model/ Lot/Batch Number)	Description & Intended Purpose (description must be precisely in details)	Risk Class	Product Owner / Manufacturer	Total Quantity <u>per site</u> (Units)	Total Quantity (Units)	Total Cost of devices (MYR)

SECTION K: SUPPORTING DOCUMENTS			
DOCUMENTS	CHECKLIST (Please tick if the document is attached)	REQUIRED FOR	REMARKS
IRB / EC Approval Letter		Section E or Appendix A	Institutional Review Board (IRB) / Ethics Committee (EC) Approval Letter for each local trial institution is required.
Packing List for Study-Visits Specific Kits		Appendix B	A complete packing list of the items in the Study-Visits Specific Kits can be attached to facilitate the submission for Appendix B (Non-Investigational Medical Devices). Study protocol number should be indicated on the packing list for reference

Note: Additional documents or information may be requested by MDA, if deemed necessary. Any insufficient / incomplete information provided upon submission will be returned to the applicant.

The form and supporting documents can be sent either via email (*Please convert the form to PDF Format*) to ci@mdb.gov.my OR via posts to:

*Pengarah
Bahagian Penilaian Teknikal
Pihak Berkuasa Peranti Perubatan
Level 5, Menara Prisma,
Persiaran Perdana, Presint 3
62675 Putrajaya.*