



NOTIFICATION TO IMPORT OR SUPPLY MEDICAL DEVICES FOR CLINICAL INVESTIGATIONAL USE

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

All fields are mandatory unless stated otherwise.

PURPOSE OF NOTIFICATION: Importation Supply (Note: for locally manufactured medical device)

GENERAL INFORMATION

SECTION A: APPLICANT DETAILS

1. Please tick the appropriate box:

Local Sponsor

Manufacturer

An authorised person from a local organization (in case of foreign sponsor)/ Contract Research Organisation (CRO) (Note: shall have a permanent address in Malaysia)

Others (please specify):.....

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 B: SPONSOR DETAILS (to be filled if applicant details above is not sponsor)

1. Name of Contact Person:

2. Name & Address of Organisation:

3. Telephone No.:

4. Fax No.:

5. Email Address:

SECTION C: APPLICATION DETAILS

1. <input type="checkbox"/> First Application	
2. <input type="checkbox"/> Subsequent Application, please state: Previous MDA identification no.: Previous submission date :.....	
3. National Medical Research Registry (NMRR) Registration ID:	
4. Title of clinical investigation - as stated in in Clinical Investigation Plan (CIP) document (please attach a copy of Clinical Investigation Plan (CIP):	5. CIP No.:
	6. Checklist CIP review report (refer to Appendix A for template of checklist):
	7. Estimated duration of the clinical investigation :
	8. Proposed date of start of clinical investigation:
	9. Proposed date of completion of clinical investigation:

SECTION D: ENTRY POINT (Note: For Importation Only)

Please tick the appropriate box:

<input type="checkbox"/> Lapangan Terbang Antarabangsa Kuala Lumpur	<input type="checkbox"/> Lapangan Sultan Abdul Aziz Shah Subang
<input type="checkbox"/> Pelabuhan Klang	<input type="checkbox"/> Pelabuhan Pulau Pinang
<input type="checkbox"/> Pelabuhan Johor Bahru	<input type="checkbox"/> Others (please specify):

SECTION E: 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 F: FOR OFFICIAL USE

MDA Identification No.:	Date:	Valid Till:
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SECTION G: ATTESTATIONS & DECLARATION

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

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;
 Fully Partially
 - ii. Has/have met all the labeling requirements set out in the Sixth Schedule of the MDR 2012;
- b. I hereby confirm that/confirm on behalf of the sponsor (delete which is not applicable) that:
- the information provided is complete
 - the attached documents contain an accurate account of the information available
 - the clinical investigation will be conducted in accordance with the clinical investigation plan
 - serious adverse events and result-related information will be reported, in accordance with the applicable legislation
 - I confirm that the medical device(s) conform(s) to the essential requirements of all applicable directives and regulations except for those which are the scope of this CI
 - I confirm that appropriate safety measures have been taken for study participants/users
 - I accept the applicable fee(s)
- c. I shall be responsible to take the necessary actions should there be any adverse incident occurs during the period of investigation;
- d. I am aware this/these medical device(s) is/are permitted for clinical investigation purpose only. Therefore, the medical device(s) shall not be:
- placed/used at the trial site after the trial has ended;
 - placed in Malaysia;
- e. I shall ensure that this/these medical device (s) is/are disposed appropriately / exported out of Malaysia after the investigation 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 H: INVESTIGATOR BROCHURE: Device Identification

a. Is this study being conducted in First In Human (FIH) / First In Man (FIM)? Yes No

b. Does the device contain a drug? (Note: this question does not apply to IVDs) Yes No

If yes,

i. Brand/Trade Name of Drug:

ii. Active Ingredients:

iii. Manufacturer:

iv. Applicable Drug Identification Number (if any):

c. Device usage category (please tick the appropriate box)

<input type="checkbox"/> Obstetrics & Gynaecology	<input type="checkbox"/> Cardiovascular	<input type="checkbox"/> Ophthalmology	<input type="checkbox"/> Orthopaedics	<input type="checkbox"/> Physical Medicine
<input type="checkbox"/> Neurology	<input type="checkbox"/> Dental	<input type="checkbox"/> Ear, Nose & Throat	<input type="checkbox"/> Anaesthesiology	<input type="checkbox"/> Radiology/Imaging
<input type="checkbox"/> Gastroenterology & Urology	<input type="checkbox"/> General Hospital	<input type="checkbox"/> General & Plastic Surgery	<input type="checkbox"/> Others (please specify):.....	

d. For IVDs only (please tick the appropriate box)

<input type="checkbox"/> Chemistry	<input type="checkbox"/> Microbiology	<input type="checkbox"/> Immunology	<input type="checkbox"/> Clinical Toxicology
<input type="checkbox"/> Haematology	<input type="checkbox"/> Pathology	<input type="checkbox"/> Others (please specify):.....	

e. Will the device be marketed in Malaysia? Yes No

f. Medical Device Grouping:

Single Family Set System IVD Test Kit IVD Cluster

g. Please provide following supporting document for investigational medical device:

Sample of packaging label for the device

No.	Device Identification	Trade Name	Generic Name	Model Name	Model number(s) (if any)	Manufacturer name and address	Device Classification	Total Cost of Devices (MYR)

h. Please provide the Investigator Brochure containing other device details as specified in 5.1.3 in the Guidance Document – Notification of Exemption From Registration of Medical Devices For The Purpose Of Clinical Research or Performance Evaluation

SECTION I: CLINICAL INVESTIGATIONAL PLAN (CIP): General Information

No.	Name & address of the investigation site	Name and professional position of Principal Investigator	Address, contact number and email of Principal Investigator	Name and professional positions of Coordinating Investigator	Address, contact number and email of Coordinating Investigator	Name of the Ethics Committee	Authorisation/Opinion of Ethics Committee <small>(please attach the approval letter)</small>
							<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

SECTION J: SUPPORTING DOCUMENTS			
DOCUMENTS	CHECKLIST (Please tick if the document is attached)	REQUIRED FOR	REMARKS
Clinical Investigation Plan (CIP) (Including a copy of informed consent or the draft informed consent submitted in parallel to the Ethics Committee)		Section C	
Sample of device packaging label		Section H	
EC Approval Letter		Section I	Ethics Committee (EC) Approval Letter for each local investigation institution is required.

Note: Additional documents or information may be requested by MDA, if deemed necessary

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.*

9	ASSESSMENT OF SAFETY <ul style="list-style-type: none"> - Specification for safety parameters - Methods and timing for assessment, recording and analysis - Procedures for getting reports and reporting of adverse events and intercurrent illnesses - Type and duration of follow-up after adverse events 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
10.	DATA MANAGEMENT <ul style="list-style-type: none"> - Procedures <ul style="list-style-type: none"> i. Used for data review, database cleaning, issuing and resolving data queries ii. Verification, validation and securing electronic clinical data systems iii. Data retention - Specific data retention - Other aspects of clinical quality assurance - Direct access to source data / documents - Permit trial related monitoring, audits, IEC review and regulatory inspection by the investigator 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
11.	AMENDMENTS TO CIP <ul style="list-style-type: none"> - Procedures to amend the CIP 	<input type="checkbox"/>	
12.	DEVIATIONS FROM CIP <ul style="list-style-type: none"> - Statement to specify that investigator cannot deviate from the CIP - Procedures for recording, reporting and analysing CIP deviations - Notifications requirements and time frames - Corrective and preventive actions and principal investigator disqualification criteria 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
13.	DEVICE ACCOUNTABILITY <ul style="list-style-type: none"> - Procedures for the accountability of investigational devices 	<input type="checkbox"/>	
14.	STATEMENTS OF COMPLIANCE <ul style="list-style-type: none"> - Clinical investigations shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki - Compliance to International Standard and any regional or national regulations, as appropriate - Clinical investigations shall not begin until the required approval / favourable opinion from the EC or regulatory authority have been obtained - Any additional requirements imposed by the EC or regulatory authority shall be followed - Type of insurance that shall be provided for subjects 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	

19.	PUBLICATION POLICY - Statement i. Indication of results of the clinical investigation will be submitted for publication ii. Indication of the conditions under which results of the clinical investigations will be offered for publication	<input type="checkbox"/> <input type="checkbox"/>	
20.	QUALITY CONTROL AND ASSURANCE	<input type="checkbox"/>	
21.	ETHICS	<input type="checkbox"/>	
22.	DATA HANDLING AND RECORD KEEPING	<input type="checkbox"/>	
23.	FINANCE AND INSURANCE	<input type="checkbox"/>	
24.	SUPPLEMENTS	<input type="checkbox"/>	

