



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 FOR EXPORT /DISPOSAL OF DEVICES UPON COMPLETION /TERMINATION OF CLINICAL INVESTIGATION /DRUG STUDY

All fields are mandatory unless stated otherwise.

Please state previous Notification ID to Import and/or Supply Unregistered Medical Devices Used in Clinical Trial:
.....

PURPOSE OF NOTIFICATION: Export Dispose locally

SECTION A: APPLICANT DETAILS

1. Please tick the appropriate box:

Local sponsor

Person or organization authorized by the sponsor to make the application

Others (please specify):

2. Name of Applicant:

3. NRIC No.:

4. Designation:

5. Name & Address of Organisation:

6. Telephone No.:

7. Fax No.:

8. Email Address:

SECTION B: SPONSOR DETAILS

1. Name of Contact Person:

2. Name & Address of Organisation:

3. Telephone No.:

4. Fax No.:

5. Email Address:

SECTION C: CLINICAL TRIAL DETAILS

1. Title of Clinical Trial (as stated in Protocol document):

2. Protocol No.:

3. Date of Study Completion:

4. Reason for Completion: (please tick)

Concluded normally

Premature termination – *safety reason**

Insufficient recruits

Premature termination – *other**

Directed by Authority/Ministry of Health

Directed by Ethics Committee

**Please give details below. Attach additional page if insufficient space.*

SECTION D: MEDICAL DEVICE DETAILS

Please provide medical device details in **Appendix A**

SECTION E: ATTESTATIONS & DECLARATION

I, the undersigned hereby declare that :

- 1. The information provided on this application form for export of unregistered medical device/s used in clinical trial is accurate, correct and complete;
- 2. Aware that any supply, other than export, of this medical device/s is/are prohibited;
- 3. Agree to comply with all relevant rules and regulations in the Medical Device Act 2012 (Act 737) and Medical Device Regulations 2012.

Signature:

Company Stamp:

Name:

Designation:

Date:

SECTION F: EXPORT POINT

Lapangan Terbang Antarabangsa Kuala Lumpur 1

Lapangan Sultan Abdul Aziz Shah Subang

Lapangan Terbang Antarabangsa Kuala Lumpur 2

Pelabuhan Pulau Pinang

Pelabuhan Klang

Pelabuhan Johor Pasir Gudang

Pelabuhan Tanjung Pelepas Johor

Others (please specify):

SECTION G: FOR OFFICIAL USE

Notification No.:

Date:

Notification to Import/Supply Medical Devices for Clinical Research Use

Name of Sponsor:		
Address:		
Name of Contact Person & Designation:		
Email Address & Tel. Number:	Clinical research Protocol Reference Number:	
	National Medical Research Registry ID (NMRR):	
Title of Approved Clinical research/Performance Evaluation:	Start Date of Clinical research/Clinical Research/Performance Evaluation	
	End Date of Clinical research/Clinical Research/Performance Evaluation	

S/N	Name as per Medical Device Label	Manufacturer	Product Identifier	Pre-market Clearance <i>[Please state the name (s) of country (s) and provide supporting documents as evidence if applicable]</i>	Quantity (UOM)

* Please attach separate sheets if more lines are required.

** This form is part of the notification to be submitted together with Attachment A

Date

Signature/Company stamp of Applicant