PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mdb.gov.my
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NOTIFICATION OF UNREGISTERED MEDICAL DEVICES FOR SPECIAL ACCESS

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

All field are mandatory unless stated otherwise

SECTION A : APPLICANT / COMPANY DETAILS

(This section is for the individual, institution or organization who or which takes responsibilities for the importation and/or supply the unregistered medical devices in Malaysia)

1. Please Tick The Appropriate Box:

- ☐ Local manufacturer
- ☐ Local Health Professional *(obtains directly from the manufacturer for supply the unregistered medical device to his/her patient)*
- ☐ An Authorised Person from a Local Organisation / Company *(Note: Must Have A Permanent Address In Malaysia)*
- ☐ Others (Please Specify):.....

2. Name of Applicant:

3. NRIC No./Passport:

4. Designation:

5. Name & Address of Organization:

6. Telephone No.:

7. Email Address:

8. Does the company already holds Establishment License?

☐ Yes

If Yes, please state the company Establishment License Number:

.....

Company's Role :

- ☐ Local Manufacturer
- ☐ Authorized Representative
- ☐ Distributor
- ☐ Importer

☐ No

SECTION B : HEALTHCARE PROFESSIONAL DETAILS

(*This section is for the healthcare professional who or which takes responsibilities for the importation and/or supply the unregistered medical devices in Malaysia)*

1. Name:

2. Title:

3. Annual Practicing Certificate Number:

4. Telephone No.:

5. Email Address:

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6. Health Care Facility Name & Address:

SECTION C: MEDICAL DEVICE DETAILS

Please provide details of the medical device in **Appendix A.**

SECTION D : MEDICAL RATIONALE

1. Provide the diagnosis, treatment or prevention for which the unregistered device is requested and the reasons why this unregistered device was chosen.

2. List the licensed devices considered and provide a rationale as to why these licensed devices would not adequately meet the requirements of the patient.

Device Name	Medical Device License Number	Rationale as to why this licensed device would not adequately meet the requirements of the patient

Remark: Please attach additional page if space insufficient

3. Identify and list the risks and benefits associated with the use of the unregistered device and indicate how the benefits obtained would outweigh the risks.

4. Summarize the known safety and effectiveness information in respect of the device.

5. In the case of a request for Batch Release,

(a) describe the emergency condition requiring treatment, and

(b) provide the number of devices required for one month: _____

SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING

(Health care professionals are required to make an undertaking that they will inform the patient for whom the device is intended of the risks and benefits associated with its use)

I, < Name of Healthcare Professional >, ID <IC No. _____>,

i. undertake to inform the patient, < Patient's Initials or Identifier _____>, who is to be treated with the device of the risks and benefits associated with the use of this unregistered medical device.

ii. confirm that I have informed the patient, < Patient's Initials or Identifier _____>, who is to be diagnosed or treated with the device of the risks and benefits associated with the use of this unregistered medical device.

iii. declare that the unregistered medical device to be used on the patient is to save the life of a patient , to help a

patient suffering from a serious disease or condition when existing registered medical device have failed, unavailable or are unsuitable to provide a diagnosis, treatment or prevention for patients under my care

iv. have obtained the informed consent of the patient, or the patient's legal representative, to the proposed diagnose/treatment

v. will take full responsibility for the use of this unregistered medical device on the named patient listed above and shall adhere to the conditions of approval

vi. will ensure that this medical device will be used or administered in accordance to its intended purpose and indications for use as stated in the product owner's instructions for use.

In the case of a batch release request (if applicable)

(Note : In the case of a Batch Release, (a) it is sponsor's responsibility to maintain a distribution record in respect of the device; (b) Health care professionals are requested to return any unused devices to the sponsor)

I, < Name of Healthcare Professional >, ID <IC No. _____>,

i. undertake to inform the patients who are to be treated with the device of the risks and benefits associated with the use of this unregistered medical device.

ii. confirm that I cannot inform the patients, who are to be diagnosed or treated with the device of the risks and benefits associated with the use of this unregistered medical device. I attest that institutional policies will be followed.

Date :

Health Care Facility Stamp :

SECTION F : ATTESTATIONS & DECLARATION

I, the undersigned hereby declare that :

i. This/These product(s) is/are according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737).

ii. The device(s) conform(s) to all relevant essential principles for safety and performance, set out in the Appendix 1 of Third Schedule of the MDR 2012.

iii. The medical device(s) has/have met all the labeling requirements set out in the Sixth Schedule of the MDR 2012.

iv. The technical documentation of the unregistered device(s) is/are prepared in accordance with the format as specified in Appendix 2 of Schedule 3 of MDR 2012 and is/are available upon request by the Authority.

Remark: Any kind of deletion in Section F please provide justification

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 adverse incident occurs for the purpose of making available this/these unregistered medical device(s) for use for special access;

I hereby attest that the information and attachment provided on this notification is/are accurate, correct, complete and current to this date.

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)

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Signature:

Person Responsible Name:

Designation :

Date :

Company stamp :

APPENDIX 1

MEDICAL DEVICE DETAILS

Name of Medical Device:			
Grouping :	☐ Single ☐ System ☐ Family ☐ Set		
Brief Description:			
Brand:			
Identifier (catalogue or model number):			
Intended use of the device:			
Manufacturer's Information:	Manufacturer's Name: *(as it appears on the label)* Contact Name and Title: Address (Number , Street, City, Country) Postal Code: Telephone : Email :		
Risk-Based Classification :		**Classification Rule:** (according to First Schedule on Rules of Classification of Medical Device, MDR 2012)	
Quantity to be Imported:			
Marketing Approval Status in other country(-ies) (Please : i. state the name (s) of country (ies) ii. provide evidence such as Declaration of Conformity/Device Licence/Registration Certificate/510k/etc)	☐ Registered /Licensed	☐ Exempted/ Notified	☐ Others (please specify) ....
Grouping List :	***Not Applicable to single medical device***		

No.	Name of device, accessories, constituent components, or articles as per product label:	Model	Brief Description	Quantity to be Imported

Note : If more than one (1) medical device, please filled out in a separate sheet of **Appendix A**.