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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 LOW RISK MEDICAL DEVICES

(In accordance with Circular Letter of Medical Device Authority No. 3 Year 2014 : Exemption of Medical Device From Registration Requirements)

Please complete all information requested on this form. *(All fields are mandatory unless stated otherwise)*

1. LOCAL MANUFACTURER / AUTHORIZED REPRESENTATIVE DETAILS

Name of Establishment:	
Address :	
City:	State:
Type of establishment : ☐ Manufacturer ☐ Authorized Representative	Establishment License Number or Form Identification (Form ID) :
Name of Person Responsible:	Designation:
Telephone No.:	Email Address:

2. MEDICAL DEVICE DETAILS

*(The maximum number of medical device is **limited to 10** per notification)*

Please provide details of the medical device according to the following:

- **Appendix A** for single medical device

- **Appendix B** for medical devices that are grouped as Family / System / Set / IVD Test Kit / IVD Cluster

Please provide following supporting document for this low risk medical device claim :

Sample of product packaging label and promotional material (such as brochure, pamphlet or catalogue) that contain information about the intended use, general description, sterility condition and mode of action of the device.

3. ATTESTATIONS & DECLARATION

Part 1 : Applicable to local manufacturer only

I, < Name of responsible person >, ID <IC No. _____>, **the manufacturer** of this/these device/s, 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. This/These medical device(s) is/are classified as Class A according to Rules of Classification of Medical Device, as set out in the First Schedule of the Medical device Regulations 2012 (MDR 2012).

iii. This/These medical device(s) is/are supplied non sterile, with no measuring function and/or non-active.

iv. 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.

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

I shall be responsible for the establishment and implementation of post-market surveillance and vigilance system to monitor safety and performance of this/these medical device(s).

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I hereby attest that the information and attachment provided on this notification is/are accurate, correct, complete and current to this date.
I understand and acknowledge that it is an offence under Section 76, of Act 737 to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.

Signature:

Person Responsible Name:

Designation :

Date :

Company stamp :

Part 2 : Applicable to Authorized Representative only

I, < Name of responsible person >, ID <IC No. _____>, **the Authorized Representative** of this/these device(s), has/ have obtained the objective evidence from the foreign manufacturer that :

i. This/These product(s) is/are according to the definition of medical device set out in Section 2 Act 737.
ii. This/These medical device(s) is/are classified as Class A according to Rules of Classification of Medical Device, as set out in the First Schedule of the MDR 2012.
iii. This/These medical device(s) is/are supplied non sterile, with no measuring function and/or non-active.
iv. 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.
v. The medical device(s) has/have met all the labeling requirements set out in the Sixth Schedule of the MDR 2012.

I shall be responsible for the establishment and implementation of post-market surveillance and vigilance system to monitor safety and performance of this/these medical device(s).

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

I understand and acknowledge that it is an offence under Section 76, of Act 737 to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.

Signature:

Person Responsible Name:

Designation :

Date :

Company stamp :

APPENDIX A

MEDICAL DEVICE DETAILS FOR SINGLE MEDICAL DEVICE *(Repeat As Needed)*

No.	Device Name	Brand / Model	Manufacturer's Name *(as it appears on the label)*	Description of Device	Intended Use of Device	Class & Classification Rule *(according to First Schedule on Rules of Classification of Medical Device, MDR 2012):*	Marketing Approval Status in other country(-ies) *[Please state the name (s) of country (ies) and provide supporting documents as evidence]*		
							Registered/ Licensed/ Approved	**Exempted/ Notified/ Self-Declared**	***Others (please specify)***

***Note** : The technical documentation of the low risk device shall be in the* format *as specified in Appendix 2 of Schedule 3 of MDR 2012 and shall be made available upon request by the Authority.*

APPENDIX B

MEDICAL DEVICE DETAILS FOR MEDICAL DEVICE GROUPED AS :

☐ **FAMILY** ☐ **SET** ☐ **SYSTEM** ☐ **IVD TEST KIT** ☐ **IVD CLUSTER**

Brand :

Intended Use of the device :

Manufacturer's Name
(as it appears on the label)

Class & Classification Rule: :
(according to First Schedule on Rules of Classification of Medical Device, MDR 2012)

Marketing Approval Status in other country(-ies) :
(Please state the name (s) of country (ies) and provide supporting documents as evidence)

☐ Registered /Licensed .....

☐ Exempted/Notified/Self-Declared .....

☐ Others (please specify) .....

No.	Name of device, components, reagents and/or articles as per product label:	Model	Medical Device Description

Note :

i. If more than one (1) medical device grouping, please fill out in a separate **Appendix B**.
ii. The technical documentation of the low risk device shall be in the format as specified in Appendix 2 of Schedule 3 of MDR 2012 and shall be made available upon request by the Authority