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ID No:
IMD-EDR/
IMD-PCR/

PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Blok 3547, Persiaran APEC,
63000 Cyberjaya, Selangor, Malaysia



INNOVATIVE MEDICAL DEVICE REVIEW APPLICATION FORM

PART A: INSTRUCTIONS

1. This form is intended to be used for **INNOVATIVE MEDICAL DEVICE** applications **ONLY**.
2. One application form is for **ONE** medical device **ONLY**.
3. Inaccurate/unsatisfactory/incomplete data may result in rejection of this application and new application shall be submitted if intended by applicant.
4. This evaluation helps MDA assess the safety, effectiveness, and overall performance of the device.
5. Please fill in the form as completely as possible and submit it via email to innovative-md@mda.gov.my

PART B: APPLICANT INFORMATION

1. Company's Name:			
2. Contact Person:			
3. Phone No:	4. Email Address:		
5. Position:			
6. Address:			
Postcode:	City:	State:	Country:
7. Role of Applicant: <i>(Role related to this specific product being applied for)</i>			
<input type="checkbox"/> Medical Device Industry	<input type="checkbox"/> Health Institutions	<input type="checkbox"/> University	
<input type="checkbox"/> Research Institutions	<input type="checkbox"/> Innovation & Technology Company	<input type="checkbox"/> Other (specify):	
8. For Companies: <i>MDA License Number (if applicable)</i>			
9. Name of Main & Research Team: <i>(List the name of the applicant and involved research team members)</i>			

PART C: PROJECT INFORMATION

1. Project Title: <i>(Provide the full and clear title of the project)</i>
2. Project Summary: <i>(Brief overview of the device, its purpose, and its innovative features)</i>
3. Patent Search/ Prior Art Search Report: <i>(Please attach)</i>
4. Technology Readiness Level (TRL): <i>(Please select the appropriate TRL stage based on the description below)</i> <ul style="list-style-type: none">• <input type="checkbox"/> TRL 3: Proof of Concept (POC)• <input type="checkbox"/> TRL 4: Early Prototype Tested• <input type="checkbox"/> TRL 5: Laboratory Testing• <input type="checkbox"/> TRL 6: Prototype Tested in Relevant Environment

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- TRL 7: Field Testing
- TRL 8: Ready for Market Use
- TRL 9: Fully Operational in the Market Use

5. Proof of Concept (POC) Information:

- Available *(Please attach POC report)*
- Not Available

6. Problem Statement:

(Provide a statement of the problem the device aims to address, supported by relevant data)

7. Proposed Solution:

(Briefly explain how the device will address the stated problem)

8. Project Objectives & Milestones:

(Illustrative milestone examples are provided below)

a. Milestone 1:

- Objective:
- Activities:
- Deliverables:

b. Milestone 2:

- Objective:
- Activities:
- Deliverables:

c. Milestone 3:

- Objective:
- Activities:
- Deliverables:

PART D: DEVICE DETAILED INFORMATION

1. Name of Device: *(Please list any brand name/s, synonyms, etc.)*

2. Model Number *(if applicable)*:

3. Type of Device:

- General Medical Device (GMD) In-Vitro Diagnostic Medical Device (IVD)

4. Description of device:

- a. Design: *(Describe the physical design, including dimensions and components)*
- b. Materials: *(List all materials used in the construction of the device)*
- c. Functionality: *(Explanation of the working mechanism)*
- d. Key Features: *(Highlight innovative or unique features that distinguish it from existing devices)*
- e. Device characteristics:

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5. Choose the applicable Innovative Medical Device Designation Criteria <i>(Please tick and justify)</i>	
<input type="checkbox"/>	Feature a new mode of action as their main principle <i>[Explanation]</i>
<input type="checkbox"/>	Provide a significant improvement or represent a highly novel application over existing practices as an alternative, including devices designed to treat serious illnesses, life-threatening diseases, and address unmet patient needs <i>[Explanation]</i>
<input type="checkbox"/>	Utilize novel materials for medical devices <i>[Explanation]</i>
<input type="checkbox"/>	Other: <i>(Please state and explain any other innovation criteria below)</i> <i>[Explanation]</i>
6. Common Intended Use/ Purpose: <i>(Specific to the device, system, etc. which may include):</i> <ul style="list-style-type: none">- <i>The indication of the device (treat/prevent/diagnose/monitor)</i>- <i>Patient population (age/gender/disease)</i>- <i>Body parts affected</i>- <i>Intended user</i>	
7. Market Competition Analysis <i>(Analysis may include innovation advantages)</i>	
8. Who is the potential commercial developer/IP new ownership/IP license holder?	
9. Technical Drawing of the Prototype <i>(If Available):</i> <ul style="list-style-type: none">• <input type="checkbox"/> Available <i>(Please attach technical drawing or prototype diagram)</i>• <input type="checkbox"/> Not Available	
10. Device Classification: <i>(According to the medical device classification system)</i> <ul style="list-style-type: none">• <input type="checkbox"/> Class A• <input type="checkbox"/> Class B• <input type="checkbox"/> Class C• <input type="checkbox"/> Class D	

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PART E: DOCUMENT CHECKLIST

Please ensure the following documents are attached with your application (if applicable)

Documents Checklist:

- Proof of Concept (POC) Report* *(Please attach report)*

- Safety & Efficacy Testing Report: *(Please tick and attach applicable report)*
 - Biocompatibility Testing
 - Electrical/ Engineering Testing
 - Performance Testing (clinical)
 - Software Vallidation
 - Sterilization
 - Usability
 - Other (please specify):

- Risk Management and Analysis: *(Example: ISO 14971) (please attach report)*

- Clinical Investigation Report: *(Please attach report)*

- Academic Papers *(Published clinical trials, unpublished completed clinical trials, expert opinions)*

- Standard Compliance Certificates/Report

- Device Design and Technical Specifications *

- Additional Documents *(Please list and attach the documents indicated):*

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PART F: ATTESTATIONS & DECLARATIONS

I, < Name of Applicant >, ID < NRIC No./ Passport No. >, on behalf of < Name of Company >, as the applicant of this **evaluation for innovative medical devices**, with this declare that:

- i. This innovation/ product meets the definition of medical device as in Section 2, Medical Device Act 2012 (Act 737); and
- ii. This innovative medical device is only for evaluation of the safety, effectiveness, and performance of the device.
- iii. Only submit one product per application form.
- iv. I understand this is a non-refundable application once the acceptance of the innovative medical devices product evaluation proposal.

I, the undersigned, hereby attest that the information and attached documents provided on this application are accurate, correct, complete, and current to this date. I understand that any declaration made by me in this application that is untrue, inaccurate, or misleading is an offense under Section 76(1) Act 737 and shall, upon conviction be liable to a fine not exceeding RM 100,000 or imprisonment for a term not exceeding 2 years or to both and may result in the cancellation/ rejection of this evaluation.

**(please strikethrough accordingly)*

Signature:

Company stamp:

Applicant's Name:

Designation:

Date:

For further information please contact:

Strategic Planning Coordination Unit
Policy and Strategic Planning Division
Medical Device Authority (MDA)
Ministry of Health
Level 6, Prima 9, Prima Avenue II,
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Note:

All information submitted is strictly protected and shall be handled in full compliance with the Official Secrets Act 1972 [Act 88] and Section 6, Personal Data Protection Act 2010 [Act 709]. Such information is classified as confidential and shall not be disclosed, shared or otherwise made accessible to any unauthorised party, except where disclosure is required or permitted by law.