



PIHAK BERKUASA PERANTI PERUBATAN  
*Medical Device Authority*  
KEMENTERIAN KESIHATAN MALAYSIA  
*Ministry of Health Malaysia*  
Portal: [www.mda.gov.my](http://www.mda.gov.my)  
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**APPLICATION FORM FOR CONDITIONAL APPROVAL FOR SELF TEST COVID-19 TEST KITS  
(LOT TO LOT VARIATION TEST)  
FORM C**

*All field are mandatory unless stated otherwise*

**SECTION A : APPLICANT / COMPANY DETAILS**

1. Name of Applicant:

2. NRIC No./Passport:

3. Designation:

4. Name & Address of Organization:

5. Telephone No.:

6. Email Address:

**SECTION B: MEDICAL DEVICE DETAILS**

Please provide details of the medical device in **Appendix 1.**

## MEDICAL DEVICE DETAILS

<b>Name of Medical Device:</b>			
<b>Brief Description:</b>			
<b>Reference Number Conditional Approval Letter:</b>			
<b>Brand:</b>			
<b>Identifier (catalogue or model number):</b>			
<b>New Batch/Lot Number: (more than one)</b>			
<b>Sample Type:</b>			
<b>Intended use of the device:</b>			
<b>Manufacturer's Information:</b>	<p>Manufacturer's Name: <i>(as it appears on the label)</i></p> <p>Contact Name and Title:</p> <p>Address (Number , Street, City, Country)</p> <p>Postal Code:</p> <p>Telephone : <span style="float: right;">Email:</span></p>		
<b>Grouping List :</b>			
No.	Name of device, accessories, constituent components, or articles as per product label:	Model	Brief Description

Note: If more than one (1) medical device, please fill up in a separate sheet.