E-SUBMISSION GUIDE FOR NEW NOTIFICATION OF CLINICAL RESEARCH USE (CRU)

NO	MEDCAST NOTIFICATION FORM	EXPLANATION
	SECTION A : APPLICANT INFORMATION	
1.*	**Name of Applicant :**	Applicant can be : - Local sponsor or Local manufacturer, - An authorised person from a local organisation (in the case of foreign sponsor) - Local Contract Research Organisation (CRO)
2.*	**NRIC/Passport No. :**	Malaysian – ID Foreigner – Passport No.
3.*	**Designation :**	Applicant specific post in the organisation.
4.*	**Organisation Information**	Details of the applicant's organisation or company
	Organization Name : **Address of Organisation :** **State :** **City :** **Postcode :**	
5.	**Telephone No :**	At least 1 contact number is mandatory (Telephone / Mobile No)
6.	**Mobile No.:**	
7.	**Fax No.**	
8.*	**Email Address :**	Email correspondence
9.*	**Organization/Company role :** ☐ **Authorised representative of Foreign Sponsor** ☐ **Local Sponsor** ☐ **Contract Research Organization (CRO)**	Role or responsibilities of the applicant's organisation.

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	☐ **Others. Please specify**	
10.	**Foreign Sponsor Details**	Please fill in if applicable
10.1	**Name of contact person**	Name of person representing sponsor organisation.
10.2	**Organisation Details :** **Organisation Name :** **Organisation Address :** **State :** **City :** **Postcode :**	Sponsor's company or organisation name, address and contact details.
11.	**Importer Details**	If you appoint a 3rd Party Company to manage the Importation process
	Company Name : **Full Address :**	
12.	**EXTRA INFORMATION AND FILE UPLOAD**	This part allows the applicant to : 1. Provide summary about the application. 2. Submit any other information or documents related to this application (regardless of any Section), e.g. Proforma / commercial invoice / airway bill /purchase order. 3. You may also upload Study Protocol or Product brochure/ Intended for Use/ Pre-Market Approval (for devices other than laboratory consumable kits)
	• **Document upload** • **Freetext for any remarks or comments**	

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	SECTION B : RESEARCH INFORMATION	
1.*	**Purpose of Research :** ☐ **Companion diagnostic test (i.e. Clinical Drug Trial)** ☐ **Screening diagnostic test (i.e. Health survey)** ☐ **Clinical trial of a medical technique (i.e. surgical technique)** ☐ **Others. Please specify**	The type of research conducted for the purpose of this exemption application.
2.	**National Medical Research Registry (NMRR) Registration ID :**	Referring to National Medical Research Registry (NMRR) ID received after getting approval to conduct research from Medical Research & Ethics Committee (MREC). Compulsory for MOH study site.
3.*	**Protocol No :**	Reference number as stated in Study Protocol.
4.*	**Title of Research :**	Title as stated in Study Protocol.
5.*	**Proposed start date of research :**	Commencement date of the research.
6.*	**Proposed end date of research :**	Estimated Completion date of the research.
	Please upload research protocol document.	A document that describes the objectives, design, methodology, statistical considerations and organisation of a trial. This part is only mandatory for the following purpose of research: ☐ Clinical trial of a medical technique (i.e. surgical technique)

<table>
<tr><th>NO</th><th>MEDCAST NOTIFICATION FORM</th><th>EXPLANATION</th></tr>
<tr><td></td><td></td><td>☐ Others. Please specify</td></tr>
<tr><td></td><td colspan="2">SECTION C : RESEARCH SITE INFORMATION</td></tr>
<tr><td>1.*</td><td>+ Add site
<table><tr><th>No</th><th>Site Name</th><th>Full Address</th><th>Name of the Ethics Committee</th><th></th></tr><tr><td>1.</td><td></td><td></td><td></td><td>Update Delete</td></tr><tr><td>2.</td><td></td><td></td><td></td><td>Update Delete</td></tr><tr><td>3.</td><td></td><td></td><td></td><td>Update Delete</td></tr></table></td><td>The location(s) where trial-related activities are actually conducted. Please click +Add Site to key in research Site details.</td></tr>
<tr><td>2.*</td><td>Please upload authorisation research document (i.e. Ethical Approval) :</td><td>Please upload approval letter from MREC or Favourable opinion Letter from Independent Ethic Committee/Institutional Review Board (IEC/IRB) for trial site. This function allow multiple upload.</td></tr>
<tr><td></td><td colspan="2">SECTION D : MEDICAL DEVICE INFORMATION</td></tr>
<tr><td>1.*</td><td>List of Devices by Packaging (week/etc)</td><td>You can choose how to list the medical devices either based on group i.e. week,</td></tr>
</table>

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<tr><th>NO</th><th>MEDCAST NOTIFICATION FORM</th><th>EXPLANATION</th></tr>
<tr><td></td><td></td><td>event type, packing list etc, or on a regular list basis.</td></tr>
<tr><td></td><td>○ Yes ○ No</td><td>Yes – To list medical devices based on group, i.e. week, packing list, event type etc
No – For normal medical device listing</td></tr>
<tr><td></td><td>If you Click No</td><td>If choose no, your table will be view as this.</td></tr>
<tr><td></td><td>Upload Medical Device (XLSX) Add Manually Devices
<table>
<tr><th>No</th><th>Device Name</th><th>Brief Description</th><th>Identifier</th><th>Manufacturer Name</th><th>UOM</th><th>Total Qty</th><th>Total Importation</th></tr>
<tr><td>1.</td><td>Adult SpO2</td><td>To estimate the oxygen saturation of the blood and the pulse rate</td><td>A123</td><td>XYZ Corp.</td><td>Set</td><td>1</td><td>2</td></tr>
<tr><td>2.</td><td>Patient Thermometer</td><td>To measure temperature of body</td><td>B123</td><td>XYZ Corp.</td><td>Set</td><td>1</td><td>2</td></tr>
</table></td><td>You can either
1. Add manuall the medical devices, or
2. Upload in bulk using Excel. However you must follow the instruction as prescribed.
a. Download the excel template
b. Fill in the excel and save.
c. Upload.
d. Strictly did not change the given template format.
e. Mandatory to fill-up all column</td></tr>
<tr><td></td><td>If you Click Yes</td><td>If you click yes, you can add the title and your device list will be view as this</td></tr>
<tr><td></td><td>Package Name
Week 1 Add Package</td><td>You can create a Package title first.</td></tr>
<tr><td></td><td>Upload Medical Device (XLSX) Add Manually Devices</td><td>You can either
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<tr><td>1.</td><td>Week 1</td><td>Urine Cup</td><td>Specimen Kits for IVD diagnostics</td><td>QWE</td><td>XYZ Corp.</td><td>Box</td><td>1</td><td>2</td></tr>
<tr><td>2.</td><td>Week 1</td><td>Vacutainer Plastic Tube w/ Sodium Citrate, Blue Top</td><td>Specimen Kits for IVD diagnostics</td><td>ASD</td><td>ABC Corp</td><td>Box</td><td>1</td><td>2</td></tr>
<tr><td>3.</td><td>Week 2</td><td>Urine Cup</td><td>Specimen Kits for IVD diagnostics</td><td>QWE</td><td>XYZ Corp.</td><td>Box</td><td>1</td><td>2</td></tr>
<tr><td>4.</td><td>Week 2</td><td>Vacutainer Plastic Tube w/ Sodium Citrate, Blue Top</td><td>Specimen Kits for IVD diagnostics</td><td>ASD</td><td>ABC Corp</td><td>Box</td><td>1</td><td>2</td></tr>
</table>
</td><td>2. Upload in bulk using Excel. However you must follow the instruction as prescribed.
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e. Mandatory to fill-up all column</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>2.</td><td>Please upload medical device supporting document (i.e. marketing approval status):</td><td>Supporting documents can be Product IFU, brochure, marketing approval status etc.
This part is only mandatory for the following purpose of research:</td></tr>
</table>

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		☐ Clinical trial of a medical technique (i.e. surgical technique) ☐ Others. Please specify
	SECTION E : IMPORTATION ENTRY POINT	
*	☐ **Lapangan Terbang Antarabangsa Kuala Lumpur 1** ☐ **Lapangan Terbang Antarabangsa Kuala Lumpur 2** ☐ **Lapangan Sultan Abdul Aziz Shah Subang** ☐ **Pelabuhan Klang** ☐ **Pelabuhan Tanjung Pelepas Johor** ☐ **Pelabuhan Pulau Pinang** ☐ **Pelabuhan Johor Pasir Gudang** ☐ **Others. Please specify**	Location where importation medical device(s) entering Malaysia. Please tick where appropriate.
	SECTION F : MULTIPLE SHIPMENT (DISABLE)	
	SECTION G : ATTESTATION & IMPORTAION	
*	**I, the undersigned, on behalf of the company hereby attest and declare that:** ✓ **I shall not import and/or supply any unregistered medical device prior to obtaining Acknowledgement on Notification from the Authority.** ✓ **I shall used the medical device only in accordance with the purpose as declared in the Notification.** ✓ **I shall ensure the medical device conform to the relevant essential principles for safety and performance as stipulated in Appendix 1 of Third Schedule of the MDR 2012.** ✓ **I shall ensure proper handling of the medical device and responsible to take the necessary actions if there be any occurrence of adverse incident occurs during the period of research.** ✓ **I shall appropriately label the medical device according to the labeling requirements as prescribe in the Sixth Schedule of the MDR 2012.** ✓ **I shall ensure that the medical device will properly disposed of or destroyed or exported out of Malaysia after the research has ended or the research being terminated.** ✓ **I shall comply fully with the terms and conditions imposed in the Acknowledgement on Notification by the Authority.** ✓ **I am fully aware and acknowledge of the penal consequences for a false declaration in respect of the above, I may be punishable under Penal Code [Act 574] for dishonestly or**	A sworn declaration which recites duties, responsibilities and obligations of applicant and shall be made by person responsible. Please read, understand and agree to the conditions.

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	fraudulently makes, signs, seals, or executes any declaration, or other document which is untrue, inaccurate or misleading. ☐ **I Have Read and Agree to The Above Terms and Conditions**	