E-SUBMISSION GUIDE FOR NEW NOTIFICATION OF DEVICE STUDY

NO	MEDCAST NOTIFICATION FORM	EXPLANATION	REQUIREMENTS					
			CIU	PE	CU-GMD	CU-IVD	FS-GMD	FS-IVD
	DEVICE STUDY NOTIFICATION TYPE							
1.*	☐ **Clinical Investigational Use** ☐ **Performance Evaluation** ☐ **Clinical Use (GMD)** ☐ **Clinical Use (IVD)** ☐ **Feasibility Study (GMD)** ☐ **Feasibility Study (IVD)**	Please select the type of notification which appropriate to your research. You can refer to the document **C.1 Device Study Flow Chart Process** for more details.	√	√	√	√	√	√
2.*	**Purpose Of Notification** ☐ **Importation** ☐ **Supply**	Importation – if importing investigational devices from outside Malaysia Supply : if the investigational Device is locally manufactured	√	√	√	√	√	√
	SECTION A : APPLICANT INFORMATION							
1.*	**Role of Applicant** ☐ **Local Sponsor** ☐ **An Authorised person from a local organization (in case of foreign sponsor / manufacturer)** ☐ **Contract Research Organization (CRO)** ☐ **Others. Please specify**	Role or responsibilities of the applicant's organisation.	√	√	√	√	√	√
2.*	**Name of Applicant :**	Details of applicant who represents the company and is responsible for this application.	√	√	√	√	√	√
3.*	**NRIC/Passport No. :**		√	√	√	√	√	√
4.*	**Designation :**		√	√	√	√	√	√
5.*	**Organisation Information**		√	√	√	√	√	√
	Organization Name : **Address of Organisation :** **State :** **City :** **Postcode :**		√	√	√	√	√	√

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6.*	**Telephone No :**	At least 1 contact number is mandatory (Telephone / Mobile No)	√	√	√	√	√	√
7.	**Mobile No.:**	At least 1 contact number is mandatory (Telephone / Mobile No)	√	√	√	√	√	√
8.	**Fax No.**		√	√	√	√	√	√
9.*	**Email Address :**		√	√	√	√	√	√
	SECTION B : SPONSOR DETAILS (To be filled if applicant details above is not sponsor)							
1.*	**Name of contact person**	Name of person representing sponsor organisation.	√	√	√	√	√	√
2.*	**Organisation Details :** **Organisation Name :** ☐ **Non-Malaysia Address** ☐ **Malaysia Address** **Organisation Address :** **State :** **City :** **Postcode :**	Sponsor's company or organisation name, address and contact details.	√	√	√	√	√	√
3.*	**Telephone No :**	At least 1 contact number is mandatory (Telephone / Mobile No)	√	√	√	√	√	√
4.	**Mobile No.:**	At least 1 contact number is mandatory (Telephone / Mobile No)	√	√	√	√	√	√
5.	**Fax No.**		√	√	√	√	√	√
6.*	**Email Address :**		√	√	√	√	√	√
	SECTION C : NOTIFICATION DETAILS							
1.	**National Medical Research Registry (NMRR) Registration ID :**	Referring to National Medical Research Registry (NMRR) ID received after getting	√	√	√	√	√	√

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		approval to conduct research from Medical Research & Ethics Committee (MREC).						
2.*	**Title of Clinical Investigation / Study**	Title as stated in the Clinical Investigation Plan (CIP) document	√	√	√	√	√	√
3.*	**Please attach a copy of Clinical Investigation Plan (CIP)**	Document that states the rationale, objectives, design and pre-specified analysis, methodology, organization, monitoring, conduct and record-keeping of the clinical investigation.	√		√		√	
	PE – Clinical Performance Study Protocol (CPSP)			√		√		√
4.	**Date of Device Importation**	Estimated of the arrival date of the investigational device.	√	√	√	√	√	√
5.*	**CPSP/CIP/Study No.**	The unique identification code or short name assigned to the specific clinical investigation plan by the Sponsor (numeric, alphanumeric or acronym) should be indicated. / Protocol Number	√	√	√	√	√	√
6.*	**Estimated duration of Clinical Investigation / Study**	The duration of a study of a medical device should be such as to permit the demonstration of performance over a period of time sufficient to represent a realistic test of the device.	√	√	√	√	√	√
7.*	**Proposed date of Start of Clinical Investigation / Study**	Commencement date of the research.	√	√	√	√	√	√
8.*	**Proposed date of Completion of Clinical Investigation / Study**	Completion date of the research.	√	√	√	√	√	√
9.	**Clinical Investigation / Study Site :**							
	Investigator Site :							

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9.1*	Name of Clinical Investigation / Study Site	Institution or site where the clinical investigation is carried out.	√	√	√	√	√	√
9.2*	Address of Clinical Investigation / Study Site		√	√	√	√	√	√
	Principal Investigator :	Refer to qualified person responsible for conducting the clinical investigation at an investigation site.						
9.3*	Name of Principal Investigator		√	√	√	√	√	√
9.4*	Professional of Position Principal Investigator		√	√	√	√	√	√
9.5*	Address of Principal Investigator		√	√	√	√	√	√
9.6*	Contact Number of Principal Investigator		√	√	√	√	√	√
9.7*	Email of Principal Investigator		√	√	√	√	√	√
10.	Update List Coordinating Investigator	Refer to investigator who is appointed by the sponsor to assist in coordinating the work in a multicentre clinical investigation.						
	Name		√	√	√	√	√	√
	Position		√	√	√	√	√	√
	Address		√	√	√	√	√	√
	Contact		√	√	√	√	√	√
	Email		√	√	√	√	√	√
11.	Update EC/IRB	Refer to independent body whose responsibility it is to review clinical investigation in order to protect the rights, safety and well-being of human subjects participating in a clinical investigation.						
*	Ethics Committee (EC) / Institutional Review Board (IRB)		√	√	√	√	√	√
*	Authorisation / Opinion Of Ethics Committee ☐ TO BE REQUESTED ☐ PENDING ☐ AUTHORISATION ACCEPTED/FAVOURABLE OPINION		√	√	√	√	√	√
	Upload approval Letter	EC Approval Letter	√	√	√	√	√	√
	SECTION D : INVESTIGATOR BROCHURE : Device Identification							
1.*	Is this Clinical Investigation / Study being conducted in First In Human (FIH) / First In Man (FIM)?	FIM – A clinical investigation in which a medical device for a specific indication is evaluated for the first time in human subjects.	√	√	√	√	√	√

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2.	**Does the device contain a drug?(Note: this question does not apply to IVDs)?**		√	X	√	X	√	X
3.	**Device usage category** ☐ Obstetrics & Gynaecology ☐ Cardiovascular ☐ Ophthalmology ☐ Orthopaedics ☐ Physical Medicine ☐ Neurology ☐ Dental ☐ Ear, Nose & Throat ☐ Anaesthesiology ☐ Radiology/Imaging ☐ Gastroentology & Urology ☐ General Hospital ☐ General & Plastic Surgery ☐ Others ☐ Oncology	Medical device usage category refers to classifying device according to its speciality.	√	√	√	√	√	√
	IVD ☐ Chemistry ☐ Microbiology ☐ Immunology ☐ Clinical Toxicology ☐ Haematology ☐ Pathology ☐ Others							
4.	**Medical Device Grouping** ■ **Single** ■ **System** ■ **Family** ■ **Set**	Various components / accessories can be used as a separate component, individual customized pack or group and can be categorized as SINGLE, FAMILY, SYSTEM, and SET. The grouping of medical device should be done according to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulation 2012.	√	√	√	√	√	√

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5.*	**Please provide the following supporting document for investigational medical device : Investigator's Brochure (IB)**	IB refer to compilation of the current clinical and non-clinical information on the investigational medical device(s), relevant to the clinical investigation.	√	√	√	√	√	√
6.	**Add Investigational Medical Device**	Refer to device being assessed for clinical performance, effectiveness, or safety in a clinical investigation. You can choose how to list the medical devices either individually key-in or bulk upload using excel.	√	√	√	√	√	√
6.1*	**Device Name (As Per Label)**		√	√	√	√	√	√
6.2*	**Trade Name**	A unique name given by the manufacturer to identify a medical device as a whole product, also known as the brand name.	√	√	√	√	√	√
6.3*	**Generic Name**	Generic naming systems i.e. referring to GMDN etc	√	√	√	√	√	√
6.4*	**Identifier**	Can be product code.	√	√	√	√	√	√
6.5	**Model Name (If any)**		√	√	√	√	√	√
6.6*	**Manufacturer Name**	A person who own or responsible for the design, production, fabrication, assembly, processing, packaging and labelling of the device.	√	√	√	√	√	√
6.7*	**Manufacturer Address**		√	√	√	√	√	√
6.8*	**Risk Classification**	A risk-based system considering the vulnerability of the human body and the potential risks associated with the devices. Please refer to the classification rules as specified in Second Schedule of Medical Device Regulation 2012. e.g Class A, Class B, Class C or Class D	√	√	√	√	√	√

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6.9*	**Brief Description & Indented purpose**	Description : to address the device physical characteristic or features in general. Intended Purpose : The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer (labelling, brochure, pamphlet etc)	√	√	√	√	√	√
7	**Update Quantity**							
	Quantity	Quantity supply per site	√	√	√	√	√	√
*	**SECTION E : 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 : ATTESTATION & IMPORTAION							
	I, the undersigned, on behalf of the company hereby declare that: **a. This/These medical device (s) indicated on this notification:** • **Conform(s) to all relevant essential principles for safety and performance as set out in the**	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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	Appendix 1 of Third Schedule of the Medical Device Regulations (MDR) 2012 * ☐ Fully ☐ Partially • Has/have met all the labeling requirements set out in the Sixth Schedule of the MDR 2012; b. I hereby confirm that/confirm on behalf of the sponsor (delete which is not applicable) that: • the information provided is complete • the attached documents contain an accurate account of the information available • the clinical investigation will be conducted in accordance with the clinical investigation plan • serious adverse events and result-related information will be reported, in accordance with the applicable legislation • I confirm that the medical device(s) conform(s) to the essential requirements of all applicable directives and regulations except for those which are the scope of this CI • I confirm that appropriate safety measures have been taken for study participants/users • I accept the applicable fee(s) c. I shall be responsible to take the necessary actions should there be any adverse incident occurs during the period of investigation;							

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	d. I am aware this/these medical device(s) is/are permitted for clinical investigation purpose only. Therefore, the medical device(s) shall not be: • **placed/used at the trial site after the trial has ended;** • **placed in Malaysia;** **e. I shall ensure that this/these medical device (s) is/are disposed appropriately / exported out of Malaysia after the investigation has ended;** **f. 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 notification 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).** ☐ **I Have Read And Agree To The Above Terms And Conditions**							