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.	√	√	√	√	√	√
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**	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.	√	√	√	√	√	√
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.	√	√	√	√	√	√

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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**		√	√	√	√	√	√
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**	Class of medical device based on the classification rules of medical device as specified in Second Schedule of Medical Device Regulation 2012. e.g Class A, Class B, Class C or Class D	√	√	√	√	√	√
6.9*	**Brief Description & Indented 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	√	√	√	√	√	√
7	**Update Quantity**							

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	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 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**	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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	• 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; 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;							

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	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**							