REQUIREMENT FOR NOTIFICATION OF CUSTOM MADE (CM)

Important Notice : The Custom Made Notification System is activated using earlier version of Medcast 2.0. Users may face system bugs, but rest assured, it won't impact your application's submission. If you encounter unresolved issues, please reach out to the MDA officer for assistance.

NO	MEDCAST NOTIFICATION FORM	EXPLANATION (All field are Mandatory. Please state NA if not applicable)
	SECTION A : APPLICANT DETAILS	
1.	Role Of Applicant :	Applicant can be either establishment, healthcare practitioner, government department, government or private healthcare facility
2.	Name Of Applicant :	
3.	NRIC No/Passport :	
4.	Designation :	
Organisation		
1.	Name Of Organisation	Kindly fulfil the requested information.
2.	Address Of Organisation	
3.	State	
4.	District	
5.	Postcode	
6.	Telephone No / Mobile No.	Kindly furnish the contact details including the phone number and email of the applicant accountable for submitting the application.
7.	Email Address	
	SECTION B : PRESCRIBER DETAILS	
1.	Name	Medical practitioner, dental practitioner, pharmacist, clinical psychologist, nurse, midwife, medical assistant, physiotherapist, occupational therapist and other allied healthcare professional
2.	Annual Practicing Certificate Number	State NA if not applicable
3.	Contact details	Kindly fulfil the requested information.
4.	Health Care Facility Name : Address :	
	SECTION C : CUSTOM MADE MEDICAL DEVICE MANUFACTURER DETAILS	
	Organisation Details	For foreign manufacturer information – State : choose as OTHERS City : choose as OTHERS Remark : The details provided here will not be reflected in the letter.
	Contact Person details	
	Name Telephone Email	
	SECTION D : CUSTOM MADE MEDICAL DEVICE DETAILS	
1.	Please provide following supporting document:	A copy of statements for custom-made medical device that contain : (1) Specific design characteristic which are unique to the particular patient's anatomic-physiological features and/or pathological condition. i.e. models (physical or 3D model data); moulds (e.g. for dental or orthotic purposes) or dental impressions.

NO	MEDCAST NOTIFICATION FORM	EXPLANATION (All field are Mandatory. Please state NA if not applicable)
		(2) Written prescriptions from healthcare professional which contain the name of the particular patient and planned surgery date or medical device application date (where applicable). **Important**: Please ensure that you provide accurate information in your initial submission, as the system may not permit any modifications afterward.
	SECTION E : PATIENT DETAILS	
	Patient's ref No (MRN /HIS)	Kindly fulfil the requested information.
	SECTION F : ATTESTATION AND DECLARATION	
	Attestation	
	ANNEX A : MEDICAL DEVICE DETAILS FOR CUSTOM MADE MEDICAL DEVICE	
	Name Of Medical Device	Kindly fulfil the requested information.
	Grouping	
	Description	**The content should consist of a maximum of 255 characters.**
	Brand	Kindly fulfil the requested information.
	Model	
	Intended use	**The content should consist of a maximum of 255 characters.**
	Manufacture's name	**The manufacturer's name & address should match the label exactly.** **Important**: The details provided here will be reflected in the letter.
	Class	**Categorize the device in accordance with the guidelines outlined in the First Schedule of the Medical Device Classification Rules, as per MDR 2012.**
	Classification Rule	
	Marketing Approval Status in other country(-ies)	**Kindly submit the following documents in this designated section:** **(1) Instructions for Use (IFU)** **(2) Product Brochure** **(3) Product Label** **(4) Statement of custom-made medical device from manufacturer (Refer Annex B of the Guidance Document)** **Important**: Please ensure that you provide accurate information in your initial submission, as the system may not permit any modifications afterward.