ESSENTIAL REQUIREMENT FOR NOTIFICATION OF SPECIAL ACCESS (SA)

NO	MEDCAST NOTIFICATION FORM	EXPLANATION
	SECTION B : HEALTHCARE PROFESSIONAL DETAILS	
1.	Name	The identity of the medical professional who initiated or acknowledge the device request.
2.	Title	➢ Hospital Director ➢ Head of Department ➢ Specialist /Physicians ➢ Medical Officer
3.	Annual Practicing Certificate Number :	Unique identification number issued to registered medical practitioners in Malaysia
4.	Health Care Facility Name : Address :	The site where the SA medical device will be placed or utilized. *Each application corresponds to a single site.
	SECTION C : MEDICAL DEVICE DETAILS	
	Name Of Medical Device Grouping Brief Description Brand Identifier Intended use Manufacturer's information Risk-Based Classification Quantity to be Imported Marketing Approval Status in other country(-ies)	➢ A single application represents one group of medical devices only. ➢ The imported quantity solely pertains to the number intended for supply to the healthcare facility within the context of this application.
	SECTION D : MEDICAL RATIONALE	
1.	Provide the diagnosis, treatment or prevention for which the unregistered device is requested and the reasons why this unregistered device was chosen.	Please include following information : (1) Diagnosis / Medical Condition: (2) Treatment / Procedure that involve: (3) Reason why these products are to be exempted: (4) Reason not used alternative treatment (5) Re-registration Status ➢ Re-registration issue ➢ New Re-Registration Submission ID (in draft/evaluation) ➢ CAB Verification Assessment status ➢ Previous/current registration number and validity
2.	Healthcare Professional Undertaking	Upload statement. See example. *Please upload at Section C

EXAMPLE HEALTHCARE PROFESSIONAL UNDERTAKING

SPECIAL ACCESS MEDICAL DEVICE NOTIFICATION REQUEST

Device Name :
Quantity :

I acknowledge that the special access medical device is granted under exceptional circumstances and that I will comply with all relevant regulations, guidelines, and policies. I will cooperate with regulatory authorities and provide any necessary information or data as required.

By signing this undertaking statement, I certify my commitment to the responsible and ethical use of the requested special access medical device. I understand the gravity of this request and the importance of upholding patient safety and quality of care.

Signature: _____
Date: _____
Official Stamp: _____