

REQUEST FOR UNREGISTERED MEDICAL DEVICE FOR USE ON PATIENTS BY
QUALIFIED PRACTITIONER/ LICENSED HEALTHCARE FACILITY



	MEDICAL DEVICES CLUSTER REQUEST FOR UNREGISTERED MEDICAL DEVICE FOR USE ON PATIENTS BY QUALIFIED PRACTITIONER/ LICENSED HEALTHCARE FACILITY
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4. I undertake to maintain records of the patient including the contact details of the patient who received the above medical device(s) under my care/ the care of the licensed healthcare facility. 5. I will ensure that this medical device will be used or administered in accordance to its intended purpose and indications for use as stated in the product owner's instructions for use. 6. I undertake to indemnify the government against all actions, claims or proceedings in respect of any adverse event, injury to or death of any person whomsoever arising out of or in connection with the use of the above unregistered medical device. 7. I hereby declare that all the information provided by me in this form is true and accurate. I acknowledge that if any of the information provided by me in this form is false or inaccurate, I will be liable to prosecution for providing false information under the Penal Code.	_____ Date	_____ Signature of Qualified Practitioner/ Head of Department
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Complete the below section if the application is requested by a **Public Healthcare Institution (PHI)** and contain **Class C and/or Class D** medical devices.

Section E: Endorsement by Chairman of Medical Board (CMB) or equivalent.

Full name		MCR or DCR Number	
Department		Designation	
Email		Tel no	
Name of Hospital/Clinic			
HCSA Licence No			
Address			

! IMPORTANT

I support the request of the unregistered Class C and/or Class D medical devices in this application

1. I am fully aware that the medical device(s) specified in attached SAR Device List has not been evaluated by the Authority for the required quality, safety and efficacy standards for supply in Singapore. 2. The import and/or supply of the unregistered medical device(s) are required for the use of the patients of the licensed healthcare facility. 3. I hereby declare that all the information provided by me in this form is true and accurate. I acknowledge that if any of the information provided by me in this form is false or inaccurate, I will be liable to prosecution for providing false information under the Penal Code.	_____ Date	_____ Signature of CMB or Equivalent
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