



ACADEMY OF MEDICINE,
SINGAPORE

REQUEST FOR ENDORSEMENT

(Please complete this form to seek endorsement from Academy of Medicine, Singapore (AMS),
for unregistered medical devices under the
Health Sciences Authority (HSA) Special Access Route (SAR) Registration Support Initiative)

SECTION 1: REQUESTOR DETAILS

Please complete the fields accordingly.

Name of Qualified Practitioner (Receipt will be issued to this name)			
MCR or DCR Number		AMS Case No (to be assigned by AMS)	
Specialty/Subspecialty			
Designation			
Name of Hospital/Clinic			
Department (if applicable)			
Email			

SECTION 2: BILLING & PAYMENT DETAILS & APPLICATION FEE (Non-Refundable)

APPLICATION FEE (non-refundable)	\$300 + prevailing GST Please attach proof of payment with this form.	To be paid via PAYNOW at point of application to: UEN No: 197702012E (Academy of Medicine, Singapore) Reference Number: <Name of Qualified Practitioner>	
Application Fee Received (to be completed by AMS)		Date Received by AMS (to be completed by AMS)	
Please send the invoice to:			
Billing Institution / Name of Individual			
Billing Address			
Evaluation Fee Amount Payable* (See Section 4 for details – to be completed by AMS)		Date Received by AMS (to be completed by AMS)	
*AMS's endorsement on the Clinical Justification & Endorsement form will only be released to applicant upon settlement of evaluation fee.			
Billing Institution's Authorised Signature		Date	

PDPA DECLARATION

By submitting this application form, I agree to the terms and conditions stipulated above and that the Academy of Medicine, Singapore, may collect, use and disclose my personal data, as provided in this form, or (if applicable) obtained by our organisation as a result of your application in accordance with the Personal Data Protection Act 2012 and our data protection policy (available at our website www.ams.edu.sg)

SECTION 3: DECLARATION OF HSA CRITERIA FULFILMENT (Select and fill in the fields where relevant)

	HSA Qualification Criteria A: Essential and/or Life-saving device for rare clinical situations <i>Higher-risk medical devices that are critical for the diagnosis or treatment of rare diseases or life-threatening conditions, but which are supplied in small quantities such that the cost of registration may otherwise be difficult for companies to justify.</i>		HSA Qualification Criteria B: Legacy medical device without registered alternatives <i>Medical devices that:</i> - have been supplied and used in Singapore through SAR for at least 3 years; - have an established global track record of more than 10 years; and - have no registered equivalent available locally.
Name of unregistered medical device & HSA Qualification Criteria			
For HSA Qualification Criteria B Legacy Medical Devices, state the past SAR Licence Number			
I, the above Qualified Practitioner, hereby declare that the unregistered medical device requested above fulfilled the relevant HSA Qualification Criteria as stated in Section 2.			
Signature of above Qualified Practitioner		Date	

SECTION 4: EVALUATION FEES (For Official Use)

TYPES OF MEDICAL DEVICES	EVALUATION FEES (To be determined by AMS)						Turnaround Time (Working Days)
	Simple (Assessed by 1 Specialty/Subspecialty and/or 1-3 Reviewers)		Complex (Assessed by 2-3 Specialties/Subspecialties and/or 4-6 Reviewers)		Very Complex (Assessed by more than 3 Specialties/Subspecialties and/or more than 6 Reviewers)		
HSA Qualification Criteria A: Essential and/or Life-saving devices Essential and/or Life-saving devices with low-volume usage where manufacturers cite economic constraints that do not justify the applicable evaluation fees required for HSA registration	\$6,000 + prevailing GST		\$10,500 + prevailing GST		\$15,000 + prevailing GST		90 Days
	\$9,000 + prevailing GST		\$15,750 + prevailing GST		\$22,500 + prevailing GST		45 Days (50% surcharge)
HSA Qualification Criteria B: Legacy Devices Legacy devices with established clinical history facing disproportionate administrative burden relative to Singapore's market size	\$2,000 + prevailing GST		\$3,500 + prevailing GST		\$5,000 + prevailing GST		90 Days
	\$3,000 + prevailing GST		\$5,250 + prevailing GST		\$7,500 + prevailing GST		45 Days (50% surcharge)

SECTION 5: PROPOSED SPECIALTIES/SUBSPECIALTIES REQUIRED TO REVIEW APPLICATION *(For Official Use)*

COMPLEXITY OF REVIEW <i>(To be determined by AMS)</i>	
No. of Specialties/Subspecialties Required	
List of Specialties/Subspecialties Proposed to Review the Application	

SECTION 7: OUTCOME OF ENDORSEMENT FROM AMS *(For Official Use)*

(To be Completion by AMS official)		YES	NO
Application Endorsed			
Name of Certifying Officer			
Designation			
Signature		Date of Endorsement	

- END OF FORM -