

MEDICAL DEVICES CLUSTER
CLINICAL JUSTIFICATION AND ENDORSEMENT OF UNREGISTERED MEDICAL
DEVICES TO QUALIFY AS ESSENTIAL/LIFE-SAVING OR LEGACY DEVICE

Please complete all applicable fields below.

Section A: To be completed by Requesting Doctor

• Name of Qualified Practitioner:	
• MCR or DCR Number:	
• Department:	
• Designation:	
• Email:	
• Name of Hospital/Clinic:	

Qualification Criteria:

- ☐ A: Essential life-saving devices for rare clinical situations
☐ B: Legacy medical devices without registered alternatives

Name of unregistered medical devices requested:

- *For system: To state overall system name (ABC Generator System), without consumables*
- *For implant: To state overall implant name (DEF Stent), without listing all sizes*
- *For test kits: To state overall test kit name (GHI test kit)*

Unregistered medical devices fulfilled Qualification Criteria A:

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Unregistered medical devices fulfilled Qualification Criteria B:

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Clinical Justification:

For Qualification Criteria A: Please ensure all pointers are addressed.

- *Clinical elaboration on how the medical devices are essential and/or life-saving in nature, detailing the consequences of device unavailability on patient outcome and*
- *Describe the rare clinical circumstances requiring use of device (i.e. limited use circumstance).*

For Qualification Criteria B:

- *Clinical elaboration on legacy device necessity and*
- *Confirming absence of registered alternatives*

Should space be insufficient, clinical justification may be furnished in a separate document signed, stamped and dated by the requesting Qualified Practitioner.

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Date

Signature of Qualified Practitioner

LIST OF UNREGISTERED MEDICAL DEVICES		
<i>Qualification Criteria A: Essential/life-saving MDs for rare clinical situations</i>		
S/N	Name as per device label	Identifier

LIST OF UNREGISTERED MEDICAL DEVICES		
<i>Qualification Criteria B: Legacy Medical Device</i>		
S/N	Name as per device label	Identifier

Section B: Endorsement by Chairman Medical Board/Academy of Medicine Singapore	
• Name of Qualified Practitioner:	
• MCR or DCR Number:	
• Department:	
• Designation:	
• Email:	
☐ I support the unregistered medical devices listed above as meeting the qualification criteria.	
_____ Date	_____ Signature of CMB/AMS