# CLINICAL JUSTIFICATIONS FOR SPECIAL ACCESS ROUTES (SAR) APPLICATION

## Part 1: To be completed by Head of Department (or equivalent) of requesting healthcare institution

#### Cluster: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

#### Healthcare institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

#### Specialty: *e.g. Cardiology*

#### Name of medical device (as per device label): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Clinical services requiring the use of the medical device**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. **Intended start date of medical device usage**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

#### Technical details of medical device:

#### *Please limit the write-up for this question to half a page.*

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| Intended use, key features and implementation information of the medical device: |
| Key evidence supporting the clinical safety and clinical efficacy of the medical device: |

#### Explain why the use of the unregistered, higher risk Class D medical device is necessary.

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| *One key consideration is whether registered alternatives are available to perform the intended clinical procedure(s), and if so, why the registered alternatives are not used instead. Please focus your justifications on this aspect.*  |

#### Describe the Levels of Medical Capability[[1]](#footnote-1) (LMC) for the clinical services requiring the use of the medical device:

|  |  |
| --- | --- |
| **Service Code** | **Service Description** |
| *E.g. EN-A1d* | *Neurosurgery: Carotid endarterectomy and stenting.* |
| *E.g. EP-A1a(i)* | *Radiology: Specialised interventional radiology services**(i) Neuroradiology - endovascular treatment for aneurysms, AVM, AVF, tumour, head & neck haemorrhages.* |

#### Target patient group:

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| List all the procedures and corresponding clinical indications of patients who would be selected to benefit from the use of the medical device.*E.g. Orthopaedic surgery, for patients with segmental deficient meniscus.* |
| Estimated number of patients per year who would be using the medical device: |

#### What are the resources required for the use of the medical device under the stated clinical services?

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| --- | --- | --- |
| **Resource type** | **Description** | **Remarks** |
| Facilities and equipment | *When using the medical device for stated clinical services, what other facilities and equipment are required?* | *Does the institution have the requisite resources?* |
| Manpower and training | *Describe any additional device / skills / procedure training required for the use of the medical device.* | *Please state the number and designation of medical staff required to undergo training.**e.g. 2 Cardiology Senior Consultants, 2 NICU nurses.* |
| Risk mitigation  | *Describe any major risks arising from the use of the medical device under the stated clinical services.* | *State the mitigating measures to reduce these risks.* |

#### Other comments (if any)

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**Contact details**

Provide a contact number and email that the Hospital Services Division, MOH can approach for any clarification on the use of the medical device.

|  |  |
| --- | --- |
| **Name** |  |
| **Designation** |  |
| **Department** |  |
| **Contact number** |  |
| **Fax** |  |
| **E-mail address** |  |

**Submitted by:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Name |  | Designation |  | Signature |  | Date |

### Part 2: To be completed by Chairman of Medical Board / Centre Director (or equivalent) of requesting healthcare institution

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| **Supported / Put on Hold / Not Supported** *Please delete accordingly* |

#### Additional Comments

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|  |  |  |  |  |  |  |
| Name |  | Designation |  | Signature |  | Date |

1. The Head of Department or the Qualified Practitioner may approach the healthcare institution’s clinical services department to obtain the list of approved LMCs specific to the institution. [↑](#footnote-ref-1)