# CLINICAL JUSTIFICATIONS FOR CLASS D SPECIAL ACCESS ROUTES (SAR) APPLICATION

## Part 1: To be completed by Head of Department or equivalent

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

#### Institution Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

#### Specialty: *\_\_\_\_e.g. Cardiology\_\_\_\_\_\_*

#### Device Name:

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#### Description of Medical Device:

#### Please limit the write-up for this section to half a page only.

(Give a short description of the medical device, technical details of how it works and evidence of the device.)

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#### Describe the Clinical Service (in detail) which will require the use of the Medical Device:

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#### Describe the Levels of Medical Capability (LMC) for the above Clinical Service (in Q6):[[1]](#footnote-1)

|  |  |  |
| --- | --- | --- |
| **S/N** | **Service Code** | **Service Description[[2]](#footnote-2)** |
| 1 | *E.g. CO-A1 to CO-A6* | *All core services* |
| 2 | *E.g. EN-A1[[3]](#footnote-3)* | *Non-invasive diagnostic tests*   1. *Nuclear cardiology* 2. *Tilt table* |
| 3 | *E.g. EP-A3[[4]](#footnote-4)* | *Pulmonary thrombectomy (for acute pulmonary embolism), pulmonary balloon angioplasty (for chronic thromboembolic pulmonary hypertension)* |

#### Cross-checking with other hospitals and institutions (on a best effort basis):

|  |  |  |
| --- | --- | --- |
|  | **Which institutes were checked?** | **Results of check** |
| **Whether the Class D Medical Device has been used in other public healthcare institutions** |  | Which institution uses this Medical Device, if any?  Which clinical service?  Please provide more details of the use of medical device in other institutions. |

#### Target Patient Group (pls elaborate on the approximate patient numbers and the clinical indications for patients who will be selected to benefit from the use of this medical device):

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#### What are the resources required for the use of the Medical Device under the stated service?

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| --- | --- | --- |
| **Resource Type** | **Detailed Description** | **(A) Institution has the requisite resources[[5]](#footnote-5)** |
| Facilities & Equipment |  | Yes / No |
| Manpower & Training (Are there specific skills or procedure training or device training required for the use of this device? Please elaborate on these areas.) |  | Yes / No |
| Any other significant points that may present as patient safety and clinical care risk when this device is used and what are the mitigating measures to reduce such risks? (Please elaborate). |  | Yes / No / NA |

#### If answered “Yes” to 10(A) for Manpower & Training, please state the details of the specialist(s) who will be providing the service(s).

|  |  |  |
| --- | --- | --- |
| **Name** | **Specialty** | **Designation** |
| *e.g. Dr XXX* | *e.g. Cardiology* | *e.g. Senior Consultant* |
|  |  |  |

#### Other Comments (if any)

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**Contact Details**

(Please provide a contact number (daytime) and email that Hospital Services Division, MOH can approach for any clarification on the use of Medical Device.)

|  |  |
| --- | --- |
| **Name of Requestor** |  |
| **Designation** |  |
| **Department/Hospital** |  |
| **DID** |  |
| **HP No** |  |
| **Fax** |  |
| **E-mail Address** |  |
| **Signature of Requestor** |  |

**Submitted by:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name Designation Signature Date

### Part 2: To be completed by Chairman of Medical Board/Centre Director or equivalent

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| ***Supported / Put on Hold / Not Supported***[[6]](#footnote-6) |

#### Additional Comments

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Name Designation Signature Date

**Part 3: For MOH’s Internal Assessment and Endorsement**

#### *MOH’s comments*

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| ***Supported / Put on Hold / Not Supported***[[7]](#footnote-7) |

#### Other comments

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**Submitted by:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name Designation Signature Date

**Endorsed by:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name Designation Signature Date

1. Please input Service Code and Service Description according to the new LMC document for the specific specialty [↑](#footnote-ref-1)
2. Examples in this column are with respect to the services in the new Cardiology LMC document [↑](#footnote-ref-2)
3. Nomenclature for Enhanced service; Section A; Item 1 [↑](#footnote-ref-3)
4. Nomenclature for Enhanced Plus service; Section A; Item 3 [↑](#footnote-ref-4)
5. Delete where applicable [↑](#footnote-ref-5)
6. Delete where applicable [↑](#footnote-ref-6)
7. Delete where applicable [↑](#footnote-ref-7)