## ESSENTIAL REQUIREMENT FOR NOTIFICATION OF SPECIAL ACCESS (SA)

### Information requirements are as outlined in the MeDC@St

| NO | MEDCAST NOTIFICATION FORM | EXPLANATION |
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| | **SECTION A : Applicant Details** | |
| 1. | **Applicant Type :** | Applicant is either:<br>- Local manufacturer license with Authority<br>- An authorised representative license with Authority |
| 2. | **Name of Applicant** | Person responsible name |
| 3. | **NRIC No. / Passport** | |
| 4. | **Designation** | |
| 5. | **Organisation Details** | Including<br>Name & Address |
| 6. | **Telephone No.** | Contact person number for efficient communication |
| 7. | **Email Address** | Contact person email for efficient communication |
| 8. | **Does The Company Already Holds Establishment License?** | If there is no establishment license, the application is not eligible |
| | **SECTION B : Healthcare Professional Details**<br>*(This Section Is for The Healthcare Professional Who or Which Takes Responsibilities for The Importation And/or Supply the Unregistered Medical Devices in Malaysia)* | |
| 1. | **Name** | The identity of the medical professional who initiated or acknowledge the device request. |
| 2. | **Title** | ➢ Hospital Director<br>➢ Head of Department<br>➢ Specialist /Physicians<br>➢ Medical Officer |
| 3. | **Annual Practicing Certificate Number** | Unique identification number issued to registered medical practitioners in Malaysia |
| 4. | **Telephone No.** | - |
| 5. | **Email Address** | - |
| 6. | **Healthcare Facility** | The site where the Special Access medical device will be placed or utilized.<br>***Each application corresponds to a single site.** |
| | **SECTION C : Medical Device Details** | |
| | **Name Of Medical Device**<br>**Grouping**<br>**Brief Description**<br>**Brand**<br>**Identifier**<br>**Intended use**<br>**Manufacturer's information**<br>**Risk-Based Classification**<br>**Quantity to be Imported**<br>**Marketing Approval Status in other country(-ies)** | ➢ A single application represents one group of medical devices only.<br>➢ The imported quantity solely pertains to the number intended for supply to the healthcare facility within the context of this application.<br>➢ The quantity are not for future supply. |

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| | **Supporting Documents** | 1) Manufacturer's QMS ISO 13485 Certificate<br>2) Pre-market Approval / Registration Certificate in other countries<br>3) Instruction for Use (IFU), Operations Manual or Product Brochure by Manufacturer<br>4) Clinical evidence demonstrating the device's safety and effectiveness for the intended use, if relevant.<br>5) Special Access Medical Device Label<br>6) Establishment License (AR & Manufacturer)<br>7) Letter of Authorization (LOA) from Legal Manufacturer. (if applicable)<br>8) A letter from the requesting medical practitioner detailing the clinical justification for the special access request and statement of undertaking. |
| | **SECTION C : Grouping List (for System, Family or Set)** | |
| | **Name of Device, Accessories as per label.**<br>**Intended Use**<br>**Identifier / Model**<br>**Brief description**<br>**Quantity to be imported.** | |
| | **SECTION D : Medical Rationale** | |
| **1** | **Please tick the appropriate box:** | |
| ☐ | **Medical devices on compassionate use basis** | A. Lack of Viable Treatment Alternatives: There must be a demonstrated absence of alternative treatment options available.<br>B. Failure or Unsuitability of Alternatives: Available alternative treatments should either have failed to produce the desired results or have been deemed ineffective or unsuitable based on the clinical judgment of the attending medical practitioner.<br>C. Clinical Imperative: It must be established that the patient's health would suffer significant clinical compromise in the absence of the requested treatment.<br>D. In the context of medical devices intended for use in emergency situations that present an imminent threat to a patient's life or long-term well-being, particularly in scenarios where the required medical equipment is unavailable within the Malaysian healthcare system. Such situations encompass individuals facing severe illness |

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| | | with a prognosis of imminent death within a few months or a heightened risk of premature death without prompt intervention. Additionally, this pertains to instances of declared health emergencies, including pandemic situations. |
| ☐ | **Alleviation of stock-out situation** | Medical device which essential to prevent any interruptions in the ongoing availability of a similar device. MDA will consider such requests when specific situations, like certain cases in registration process, ongoing change notifications or post-market actions, are in progress. |
| ☐ | **Design and/or operation that is likely to support or enhance the outcomes of the procedure or treatment for the patient.** | This pertains to the design and operation of a medical device, which should have the potential to positively influence and improve the results of a patient's procedure or treatment. |
| **1.** | **Provide the diagnosis, treatment or prevention for which the unregistered device is requested and the reasons why this unregistered device was chosen.** | Please include following information :<br><br>(1) Diagnosis / Medical Condition:<br>(2) Treatment / Procedure that involve:<br>(3) Reason why these products are to be exempted:<br>(4) Reason not used alternative treatment<br>(5) Registration Status<br>➢ Registration issue<br>➢ Medcast Submission ID (in draft/evaluation)<br>➢ CAB Assessment status<br>➢ Previous registration number and validity. If applicable |
| **2.** | **List the registered devices considered and provide a rationale as to why these registered devices would not adequately meet the requirements of the patient (registered with MDA).** | List any similar medical devices that are registered with MDA and were considered for use. Provide reasons why these registered devices are not sufficient or suitable for the patient's needs, and why the unregistered device is necessary for better treatment. |
| **3.** | **Identify and list the risks and benefits associated with the use of the unregistered device and indicate how the benefits obtained would outweigh the risks.** | Identify the potential risks and benefits associated with using the unregistered device. Explain how the expected benefits (e.g., improved patient outcomes) outweigh any potential risks involved in using a device that has not been officially registered. |
| **4.** | **Summarize the known safety and effectiveness information in respect of the device.** | Provide a summary of any known information regarding the safety and effectiveness of the unregistered device. This can include clinical data, research findings, or |

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| | | manufacturer information that demonstrates the device's reliability and suitability for the intended purpose. |
| **5.** | **In the event that conventional medical treatment has failed, is unavailable or unsuitable, Describe the condition for the treatment** | If conventional medical treatments have failed, are unavailable, or are unsuitable, describe the patient's condition and why these standard treatments are not effective. |
| **6.** | **In the case of emergency situation, Number of devices required for one month** | In case of an emergency, specify the number of devices required to treat the patient for a **one-month period**. This ensures that the correct number of devices is supplied during the special access period. |
| **7.** | **Please define quantity for batch release (if required).** | If batch release is needed for the unregistered device, define the total quantity of devices required for the release, ensuring it aligns with the needs of the treatment or procedure. |
| | **SECTION E : (Not Applicable)** | |
| | **SECTION F : Attestation & Declaration** | |