Form No.: MDSA-HCP Version No.: 4



MEDICAL DEVICES CLUSTER

REQUEST FOR UNREGISTERED MEDICAL DEVICE FOR USE ON PATIENTS BY QUALIFIED PRACTITIONER/ LICENSED HEALTHCARE FACILITY

* Please complete all fields below. All fields are mandatory.

Section A: Purpose of application

| GN-26: On request by Qualified Practitioner for use on his patient GN-27: On request by licensed healt their patients |
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Section B: Requesting Qualified Practitioner (QP) information

To be completed by Head of Department (or equivalent) of licensed healthcare facility for GN-27.

| | • | |
|-------------------------|-------------------|--|
| Full name | MCR or DCR Number | |
| Department | Designation | |
| Email | Tel no | |
| Name of Hospital/Clinic | | |
| HCSA Licence No | | |
| Address | | |

Section C: Clinical justification

| Please select the appropriate clinical justification(s): |
|--------------------------------------------------------------------------------------------------------------------------------|
| Compassionate use basis: |
| ☐ Absence of alternative treatment option |
| □ Available alternative treatments failed or deemed ineffective or unsuitable for patient according to professional judgement |
| AND patient's health will be clinically compromised without the requested treatment |
| Alleviation of out-of-stock situation: |
| ☐ Unregistered medical device is needed to minimise disruption to the continued supply of a similar registered medical |
| device |
| Novel or established medical device or upgraded version of established medical device: |
| □ Absence of registered alternatives or lack of a specific feature in registered medical device |
| □ User's (doctor or dentist) familiarity or expertise in terms of device technology, design and/or operation that is likely to |
| support or enhance the safety outcomes of the procedure or treatment for the patient |
| AND patient's health will be clinically compromised without the requested medical device |
| Please provide elaboration on the basis for the above selection: |
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| Clinical Justification Review Form for unregistered Class D medical devices is included in this application |

Section D: Declaration



- I am fully aware that the medical device(s) specified in attached SAR Device List has not been evaluated by the Authority for the required quality, safety and efficacy standards for supply in Singapore.
- 2. The import and/or supply of the unregistered medical device(s) are required for the use of the patient(s) under my care/ patients of the licensed healthcare facility and I undertake to assume full responsibility for such use.
- 3. I undertake to ensure the patient is appropriately informed prior to treatment and consents to the treatment.

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MEDICAL DEVICES CLUSTER

REQUEST FOR UNREGISTERED MEDICAL DEVICE FOR USE ON PATIENTS BY QUALIFIED PRACTITIONER/ LICENSED HEALTHCARE FACILITY

| me | | of the patient including the contact details of the patient who received the above e/ the care of the licensed healthcare facility. | | | | | |
|-------------------------------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--|
| | indications for use as stated in the product owner's instructions for use. | | | | | | |
| inj | | | | | | | |
| of | = | rmation provided by me in this form is true and accurate. I acknowledge that if any ne in this form is false or inaccurate, I will be liable to prosecution for providing false de. | | | | | |
| | | | | | | | |
| | Date | Signature of Qualified Practitioner/ Head of Department | | | | | |
| nd/or C | e the below section if the a lass D medical devices. | Signature of Qualified Practitioner/ Head of Department pplication is requested by a Public Healthcare Instituition (PHI) and contain Class nan of Medical Board (CMB) or equivalent. | | | | | |
| nd/or C | e the below section if the a lass D medical devices. n E: Endorsement by Chair | oplication is requested by a <u>Public Healthcare Instituition (PHI</u>) and contain <u>Class</u> | | | | | |
| nd/or C | e the below section if the a lass D medical devices. n E: Endorsement by Chair me | oplication is requested by a <u>Public Healthcare Instituition (PHI)</u> and contain <u>Class</u> | | | | | |
| Section Full na | e the below section if the a lass D medical devices. n E: Endorsement by Chair me | pplication is requested by a <u>Public Healthcare Instituition (PHI)</u> and contain <u>Class</u> nan of Medical Board (CMB) or equivalent. MCR or DCR Number | | | | | |
| Section Full na Depart Email | e the below section if the a lass D medical devices. n E: Endorsement by Chair me | pplication is requested by a Public Healthcare Instituition (PHI) and contain Class nan of Medical Board (CMB) or equivalent. MCR or DCR Number Designation | | | | | |
| Section Full na Depart Email Name o | e the below section if the a lass D medical devices. n E: Endorsement by Chair me | pplication is requested by a Public Healthcare Instituition (PHI) and contain Class nan of Medical Board (CMB) or equivalent. MCR or DCR Number Designation | | | | | |

- I am fully aware that the medical device(s) specified in attached SAR Device List has not been evaluated by the Authority for the required quality, safety and efficacy standards for supply in Singapore.
- 2. The import and/or supply of the unregistered medical device(s) are required for the use of the patients of the licensed healthcare facility.
- 3. I hereby declare that all the information provided by me in this form is true and accurate. I acknowledge that if any of the information provided by me in this form is false or inaccurate, I will be liable to prosecution for providing false information under the Penal Code.

| Date | Signature of CMB or Equivalent |
|------|--------------------------------|

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Section F: SAR Device List

Note: The device information in this SAR Device List must be identical to the excel device list uploaded in SHARE. For GN-27 with multiple healthcare facilities, the maximum quantity for each facility must add up to the total consolidated quantity in the excel device list uploaded in SHARE.

This section is to be endorsed by the requesting QP listed in section B. If the SAR Device List is requested by a Public Healthcare Institution (PHI) and contain Class C and/or Class D medical devices, this section is to be endorsed by the CMB listed in section E. If the SAR device list exceeds one page, all pages shall be endorsed by the requesting QP listed in section B and CMB listed in section E.

| | SPECIAL ACCESS ROUTE DEVICE LIST | | | | | | | | | |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| Medical Speciality | Overall System Name (If the MDs do not have any overall system name, enter the name as per device label as indicated in Column D.) | Name as per device label (To include software version number, if applicable, for supply in Singapore) | Identifier | UDI-DI (To use "," if there are multiple UDI-DI per identifier) | DM-DI (Only if DM-DI is available and is different from UDI-DI) (To use "," if there are multiple DM-DI per identifier) | Quantity (For each HCSA licensed | Unit of Measurement (UOM) (pieces, units, vials, boxes etc. If the UOM is in boxes, please state the quantities found in each box) | Any Approval from Reference Agencies? Y/N (US FDA, EU, Health Canada, Australia TGA, Japan MHLW) | Filenames of labels (Please identify all variable fields if representatives label was submitted. For GN-28: Indicate NA.) | Filenames of Instructions for Use (For GN-28: Indicate NA.) |
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