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 healthcare facility for use on their patients

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			
PHMC/ HCSA Licence No			
Address			

Section C: Clinical justification

Please select the appropriate clinical justification(s):

- ☐ Absence of alternative treatment option
- ☐ Available alternative treatments failed or deemed ineffective or unsuitable for patient according to professional judgement
- ☐ Unregistered medical device is needed to minimise disruption to the continued supply of a similar registered medical device
- ☐ Absence of registered alternatives or lack of a specific feature in registered medical device
- ☐ User's (doctor or dentist) familiarity or expertise
- ☐ Established medical device with history of safe use in a licensed private hospital or medical clinic

Please provide elaboration on the basis for the above selection:

☐ **Clinical Justification Review Form for unregistered Class D medical devices is included in this application**

Section D: Declaration

IMPORTANT

1. 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.
4. I undertake to maintain records of the patient including the contact details of the patient who received the above medical device(s) under my care/ the care of the licensed healthcare facility.
5. I will ensure that this medical device will be used or administered in accordance to its intended purpose and indications for use as stated in the product owner's instructions for use.
6. I undertake to indemnify the government against all actions, claims or proceedings in respect of any adverse event, injury to or death of any person whomsoever arising out of or in connection with the use of the above unregistered medical device.
7. 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 Qualified Practitioner/ Head of Department _____

MEDICAL DEVICES CLUSTER

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

Complete the below sections if the application is requested by a public healthcare instituition (PHI) and contain Class C and/ or Class D medical devices.

Section E: Endorsement by Chairman of Medical Board (CMB) or equivalent.

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

IMPORTANT

☐ I support the request of the unregistered Class C and/or Class D medical devices in this application

1. 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

Form No.: MDSA-HCP
Version No.: 3

Section F: SAR Device List

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

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

Record ID (To be generated by HSA System)	**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 UDI-DI per identifier)*	**Maximum Quantity** *(For each PHMC facility)*	**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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Name and Signature of QP/ HOD Date

Name and Signature of CMB or Equivalent Date