Guidance on Special Authorisation Routes (SAR)

Medical Devices Cluster

October 2019
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• Under the Health Products Act (Act) and Health Products (Medical Devices) Regulations 2010 (Regulations), all Class B, C and D medical devices are required to be registered with HSA prior to placing them on the Singapore market.

• In an emergency or in a case where all conventional therapies have failed, qualified practitioners (i.e. doctors and dentists) may need access to unregistered medical devices to meet special clinical needs (refer to Table 1) arising in the course of their practice.

• Special authorisation routes may be used to enable qualified practitioners to access unregistered medical devices for use on their patients.
Table 1: Definition of Special Clinical Needs

**Medical devices on compassionate use basis**

- Absence of alternative treatment option; or
- Available alternative treatments failed or deemed ineffective or unsuitable for the patient according to the doctor’s or the dentist’s clinical judgement;

and

- Patient’s health will be clinically compromised without the requested treatment

**Alleviation of stock-out situation**

- The unregistered medical device is needed to minimise disruption to the continued supply of a similar registered medical device

**Established medical devices with history of use**

- The unregistered medical device has been used
  - before 1 January 2012
  - in a licensed private hospital as approved by the relevant authority of that healthcare institution; or
  - in a licensed medical clinic as required by the doctor or dentist,

and

- There are no known safety issues related to the use of the device

**Novel or established medical device or upgraded version of established medical devices (new models/ new features)**

- Absence of registered alternatives or lack of a specific feature in registered medical device; or
- 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.
The following special authorisation routes may be used to facilitate the import and supply of unregistered medical devices for **clinical use**:

**GN-26**
- For licensed **qualified practitioners** to seek approval for the import and supply of **unregistered** medical devices for use on his patient(s).

**GN-27**
- For **laboratories and medical facilities licensed under the Private Hospital and Medical Clinics (PHMC) Act** to seek approval for the import and supply of **unregistered** medical devices for use on their patients.

**IMPORTANT**
- The safety, quality and performance of the device is **not assessed** by HSA during application review.
- As such, **the responsibility for prescribing an unregistered medical device rests with the qualified practitioner**.
- The qualified practitioner should also ensure the **patient has given appropriate informed consent prior to treatment**.
Special authorisation routes may also be used to facilitate the import and supply of unregistered medical devices for export, re-export or non-clinical purposes, as described below.

GN-28

• For the import of unregistered medical devices for the purposes of export or re-export

⚠️ Note:
- Companies with existing importer and wholesaler licences shall not require GN-28 authorisation for import for re-export.
- Dealers shall be required to maintain documentary evidence of import and supply (e.g. traceability records) as part of their mandatory device distribution records.
- Medical devices manufactured in Singapore and that are solely for export shall not require GN-28 authorisation from HSA for their export by the licensed manufacturer.

GN-29

• For the import of unregistered medical devices for non-clinical purposes

Note: Non-clinical purposes includes any form of use other than use or administration on humans e.g. training equipment (i.e. Not for use on humans); use on animals; or use of in-vitro diagnostic medical devices for research-use only.

GN-30

• For the import of registered medical devices on a consignment basis, by dealers not authorised by the Registrant

Note: The importation of a medical device which is already registered on the Singapore Medical Device Register (SMDR) shall be performed by a licensed importer authorised by the Registrant only. A dealer who has not been authorised by the Registrant to import a registered medical device may seek authorisation from HSA through this route.
The supporting documents to be submitted for each route is detailed below.

<table>
<thead>
<tr>
<th>Supporting documents</th>
<th>GN-26</th>
<th>GN-27</th>
<th>GN-28</th>
<th>GN-29</th>
<th>GN-30</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAR [Device List](Appendix 3)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Instructions for Use, Product Insert, or Operations Manual by the product owner</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Primary medical device label</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>A copy of the qualified practitioner’s registration under the Medical Registration Act (Cap. 174) or Dentists Act (Cap. 76) with the Medical Council Registration (MCR) Number or Dental Council Registration (DCR) Number clearly legible</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## APPLICATION REQUIREMENTS

### Supporting documents

<table>
<thead>
<tr>
<th>Supporting documents</th>
<th>GN-26</th>
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<th>GN-28</th>
<th>GN-29</th>
<th>GN-30</th>
</tr>
</thead>
<tbody>
<tr>
<td>A copy of the Clinical Laboratory’s, Medical Clinic's or Private Hospital’s licence under the Private Hospital and Medical Clinics (PHMC) Act (Cap. 248), with the PHMC Licence Number clearly legible</td>
<td></td>
<td>√</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A copy of quality management system certificate (e.g. Good Distribution Practice for Medical Devices (GDPMDS)) if a valid Importer licence with GDPMDS is unavailable</td>
<td>√</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Request form for unregistered medical device for use on patients by QP and PHMC Facility (Appendix 4)</td>
<td>√ by requesting qualified practitioner</td>
<td>√ by HOD or equivalent representing the PHMC facility</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: clinical justification shall reflect special clinical need (Table 1)*
## APPLICATION REQUIREMENTS

### Supporting documents

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<th>GN-29</th>
<th>GN-30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label with a statement to the effect of ‘for supply for non-clinical purpose only’</td>
<td></td>
<td></td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>SMDR listing number of the original registered medical device</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Documentary evidence to show that the medical device is registered in the exporting country e.g. free sale certificate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Certified true copy of ISO 13485 certificate for each of the manufacturing sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>√</td>
</tr>
</tbody>
</table>

### APPLICATION REQUIREMENTS

- Introduction
- Application Requirements
- Application Process
- Post-market Obligation
- Distribution Records
- Appendix
## Application Requirements

### Supporting documents

<table>
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<th>GN-28</th>
<th>GN-29</th>
<th>GN-30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copy of invoice from exporting company indicating the lot number/serial number of each of the medical device to be imported</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Attestation</strong> from product owner that the medical device is identical to registered medical device in Singapore, including the manufacturing site, packaging and labelling (Appendix 5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Undertaking by importer to take responsibility for quality, safety and performance of the medical device to be imported</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
All **Special Authorisation Route (SAR)** transactions are conducted through the Medical Device Information and Communication System (MEDICS).

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**Importer to apply for CRIS Company Account**
- A CRIS account allows companies to carry out electronic transactions with HSA
- Refer to Client Registration and Identification Service (CRIS) [here](#)

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**Prepare and Apply for SAR via MEDICS**
- Obtain **all** required supporting documents
- Refer to Table 2 for importer pre-requisite requirements
- Refer to MEDICS application guide for Special Authorisation Route

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**Review of application by HSA**
- Turn-around-time: 14 working days

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**Application Process**

**Online Procedure**

**Points to note**

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Table 2: Importer requirements for SAR

<table>
<thead>
<tr>
<th>GN-26</th>
<th>A certified quality management system (e.g. to the requirement of Good Distribution Practice for Medical Devices (GDPMDS))</th>
</tr>
</thead>
<tbody>
<tr>
<td>GN-27</td>
<td>A valid importer and wholesaler licence with Good Distribution Practice for Medical Devices (GDPMDS) or ISO 13485</td>
</tr>
</tbody>
</table>

The full application fees will be charged upon submission of the application in MEDICS. Payment is to be made by the applicant (i.e. importer).

- Acceptable payment modes: Credit card or GIRO
- Download the GIRO application form [here](#) if you wish to set up a GIRO account with HSA
- Refer to the [fee schedule](#) on HSA website for the applicable fees

**NOTE:**

- There shall be **no refund of application fees**, once the application has been submitted. This includes any incorrect or withdrawn applications.
- There shall be **no amendments** to the application, including the quantity requested for use, once the application has been approved.
• It is the responsibility of the licence holder, PHMC and qualified practitioner/user to ensure the medical device(s) complies with any other applicable regulatory requirements of other regulatory bodies in Singapore prior to its supply or for its use.
  ➢ E.g. for medical devices also subject to control under the Radiation Protection Act, a licence from the Radiation Protection and Nuclear Science Department (RPNSD) of the National Environment Agency (NEA) may be required.

• The safety and performance of the device is **not assessed** by HSA during application review.

• The authorisation shall only be valid for a period of **12 months** from the date of approval, and permits **multiple** import consignments within the validity period (except GN-30 which only permits a **single** import consignment).

• The unregistered medical device shall only be imported by the importer authorised in the approval.

• **No further import and supply of the medical devices is permitted after expiry of the authorisation.** Unauthorised supply of an unregistered medical device is an offence under the Act and penalties of a fine of up to $50,000 or imprisonment for a term not exceeding 2 years, or both will apply.
GN-26 & GN-27 applications

- HSA requires that applications be **substantiated with a clinical justification**, reflecting the **special clinical need** (Table 1) for the unregistered devices by the qualified practitioner (for GN-26) or Head of Department or equivalent representing the PHMC facility (for GN-27) in place of registered products.

- Capital equipment **shall not** be authorised via GN-26 and GN-27. Product registration will be required.
  - *Refers to medical devices that are installed as part of the PHMC’s fixed infrastructure e.g. X-ray machines, CT scanners, MRI machines.*

- Records on the particulars of patients are to be maintained and kept on file by the requesting qualified practitioner or PHMC facility and to be submitted upon request by the Authority.
The responsibility for reporting field safety corrective actions (FSCA) and adverse events for medical devices that are supplied through the special authorisation route lies primarily with the importer who arranged for its supply.

It is a condition of approval that the importer reports the details of any FSCA or adverse event to the Authority according to applicable timelines.
• The importer shall be required to submit a declaration on the distribution records via MEDICS within 30 days after expiry of authorisation, or within 30 days after date of last export/supply*, whichever is earlier.

• Importer shall be required to maintain documentary evidence of supply (e.g. traceability records) as part of their mandatory device distribution records for the devices imported under this authorisation. This information shall be submitted to the Authority upon request.

*refers to delivery of the medical device to qualified practitioner, PHMC facility or the consignee using it for non-clinical purpose.
## APPENDIX 1

### Summary of routes

<table>
<thead>
<tr>
<th>Description</th>
<th>GN-26</th>
<th>GN-27</th>
<th>GN-28</th>
<th>GN-29</th>
<th>GN-30</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>For licensed qualified practitioners to seek approval for the import and supply of unregistered medical devices for use on his patient(s).</td>
<td>For laboratories and medical facilities licensed under the PHMC Act to seek approval for the import and supply of unregistered medical devices for use on their patients.</td>
<td>For the import of unregistered medical devices for the purposes of export or re-export</td>
<td>For the import and supply of unregistered medical devices for non-clinical purpose</td>
<td>For the import of registered medical devices on a consignment basis, by dealers not authorized by the Registrant</td>
</tr>
<tr>
<td><strong>Pre-requisite requirement for the importer</strong></td>
<td>A certified quality management system (e.g. to the requirement of Good Distribution Practice for Medical Devices (GDPMDS))</td>
<td>A certified quality management system (e.g. to the requirement of Good Distribution Practice for Medical Devices (GDPMDS))</td>
<td></td>
<td></td>
<td>A valid importer and wholesaler licence with Good Distribution Practice for Medical Devices (GDPMDS) or ISO 13485</td>
</tr>
<tr>
<td><strong>Validity period</strong></td>
<td>12 months</td>
<td>12 months</td>
<td>12 months</td>
<td>12 months</td>
<td>12 months</td>
</tr>
<tr>
<td><strong>No. of import consignments allowed</strong></td>
<td>Multiple</td>
<td>Multiple</td>
<td>Multiple</td>
<td>Multiple</td>
<td>Single</td>
</tr>
<tr>
<td><strong>Fees</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Refer to the <a href="#">fee schedule</a> on HSA website for the applicable fees</td>
</tr>
</tbody>
</table>

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**Introduction**

**Application Requirements**

**Application Process**

**Post-market Obligation**

**Distribution Records**

**Appendix**

**Appendix 1**

**Appendix 2**

**Appendix 3**

**Appendix 4**

**Appendix 5**

**Definitions**

**Summary**
**IMPORT**: with its grammatical variations and cognate expressions, means to bring or cause to be brought into Singapore by land, sea or air.

**MEDICAL DEVICE**: means a medical device as described in the First Schedule of the Act. This includes IN VITRO DIAGNOSTIC (IVD) PRODUCT (as set out in the Regulations).

**PRODUCT OWNER** (as set out in the Regulations):

• in relation to a health product, means a person who —
• (a) supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
• (b) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

**QUALIFIED PRACTITIONER (as set out in the Regulations)**: means:-

• a person registered under the Medical Registration Act (Cap. 174), when acting in the course of providing medical treatment to a patient under his care; or
• a person registered under the Dentists Act (Cap. 76) whose name appears in the first division of the dentists register kept under that Act, when acting in the course of providing dental treatment to a patient under his care.
# SPECIAL AUTHORISATION ROUTES

## DEVICE LIST

<table>
<thead>
<tr>
<th>Record ID</th>
<th>Medical Speciality</th>
<th>Overall System Name</th>
<th>Name as per device label</th>
<th>Identifier</th>
<th>Maximum Quantity</th>
<th>Unit of Measurement</th>
<th>Any Approval from Reference Agencies? Y/N</th>
<th>Filenames of labels</th>
</tr>
</thead>
<tbody>
<tr>
<td>(To be generated by HSA System)</td>
<td></td>
<td>(If the MUs do not have any overall system name, enter the name as per device label as indicated in Column D.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Application**

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- Application Requirements
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- Post-market Obligation
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- Appendix

**Appendix**

- Appendix 3
- Appendix 4
- Appendix 5

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**Definitions**

- Summary

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APPENDIX 4

Request form for unregistered medical device for use on patients by QP and PHMC Facility

MEDICAL DEVICES BRANCH
REQUEST FOR UNREGISTERED MEDICAL DEVICE FOR USE ON PATIENTS BY QUALIFIED PRACTITIONER/PHMC 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 PHMC facility for use on their patients

Section B: Requesting Qualified Practitioner (QP) information
To be completed by Head of Department (or equivalent) of PHMC for GN-27.

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full name</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td>MCR or DCR Number</td>
</tr>
<tr>
<td>Email</td>
<td>Designation</td>
</tr>
<tr>
<td>Name of Hospital/Clinic</td>
<td>Tel no</td>
</tr>
<tr>
<td>PHMC Licence No</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
</tbody>
</table>

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:
**APPENDIX 4**

Request form for unregistered medical device for use on patients by QP and PHMC Facility (continued)

### 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 PHMC facility and I undertake to assume full responsibility for such use and shall adhere to the conditions of approval.

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 PHMC 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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Signature of Qualified Practitioner/ Head of Department</th>
</tr>
</thead>
</table>

**NOTE:**

- A copy of “SAR Device List” shall be provided to the QP/HOD signing off the forms.
- The signed document shall be **scanned** and submitted to HSA via MEDICS.
- The original signed hardcopy form **shall be maintained and kept on file** by the applicant. This information shall be submitted to the Authority upon request.
Letter of Authorisation Template

[To be printed on Company Letterhead of Product Owner]

Medical Devices Branch
Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for [name of Importer]

We, [name of Product Owner], as the Product Owner, hereby confirm that the medical devices listed below have been manufactured to the same safety, quality and performance specifications as the medical device listed under Singapore Medical Device Register (SMDR) listing number, [device listing number].

[List containing the following: (i) product names of medical devices for import, (ii) quantity for import, (iii) manufacturing site, (iv) ISO 13485:2003 certificate number, (v) SMDR listing number, (vi) invoice number (vii) invoice date]

We hereby acknowledge that we are aware of the import of the medical devices listed above into Singapore by [name of Importer] for the quantity specified. We shall keep [name of Importer] informed of any Field Safety Corrective Action (FSCA) that is applicable.

Yours Sincerely,

[Signature]
[Full Name and Title of Senior Company Official]
[Name and address of company]
CONTACT INFORMATION

Medical Devices Branch
Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg