

April 2026

MEDICAL DEVICE GUIDANCE

GN-02: Guidance on Licensing of Manufacturers,
Importers and Wholesalers of Medical Devices

Revision 8

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PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors.

REVISION HISTORY

<u>Guidance Version (Effective Date) [3 latest revisions]</u>	<u>Revision</u>
R6 ► GN-02: Revision 6 (28 November 2024)	R6
R7 ► GN-02: Revision 7 (21 October 2025)	R7
R8 ► GN-02: Revision 8 (01 April 2026)	R8

**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown.*

1. INTRODUCTION

1.1. Purpose

This document is meant to provide general guidance on the establishment licensing procedure for persons dealing with medical devices under the Health Products Act 2007 (*Act*). It also highlights the key regulatory responsibilities of persons dealing with medical devices in Singapore.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

1.2. Background

Any person who performs any of the following activity in Singapore: -

- manufacture of medical device(s);
- import of medical device(s);
- supply by wholesale medical device(s);

has to comply with the *Act*, Health Products (Medical Devices) Regulations 2010 (*Regulations*), and any other applicable regulatory requirements.

Licensing

- ensures that the HSA (henceforth termed “the Authority”) is aware of all manufacturers, importers, suppliers and distributors of medical devices in Singapore; and
- provides assurance to the Authority that licence holders have met the regulatory requirements and have documented procedures in place, where applicable, related to distribution records, complaint and product recall handling, field safety corrective actions (FSCA), mandatory adverse event reporting and for handling, storage, delivery, installation, and servicing, with respect to the medical devices they deal in.

1.3. Scope

This document applies to any person who performs any of the following actions in Singapore: -

- manufacture of medical device(s);
- import of medical device(s);
- supply by wholesale medical device(s).

1.4. Definitions

Definitions that do not indicate they are set out in the *Act* or *Regulations* are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

R7 ►

APPLICANT: for the purposes of this guidance document, an applicant is the person applying for a medical device licence ◀

EXPORT: with its grammatical variations and cognate expressions, means to take or cause to be taken out of Singapore by land, sea or air.

FIELD SAFETY CORRECTIVE ACTION (*as set out in the Regulations*):

any action taken to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, including

- the return of the medical device to its product owner;
- replacement or destruction of the medical device;
- any action regarding the use of the medical device that is taken in accordance with the advice of its product owner;
- the clinical management of any patient who has used the medical device;
- the modification of the medical device;
- the retrofitting of the medical device in accordance with any modification to it or any change to its design by its product owner;

- the making of any permanent or temporary change to the labelling or instructions for use of the medical device; or
- any upgrade to any software used with the medical device, including any such upgrade carried out by remote access.

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

LICENSEE (as set out in the Regulations): means a holder of any licence issued by the Authority under the *Act*.

MANUFACTURE (as set out in the Act): in relation to a health product, means to make, fabricate, produce or process the health product and includes: -

- any process carried out in the course of so making, fabricating, producing or processing the health product; and
- the packaging and labelling of the health product before it is supplied.

MEDICAL DEVICE: means a medical device as described in the First Schedule of the *Act*.

MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP): Medical Device Single Audit Program administered by The International Medical Device Regulators Forum (IMDRF).

ORIGINAL PACKAGING (as set out in the Regulations): in relation to a medical device, means the outer packaging for the medical device used when the medical device is supplied.

PREMISES: means any location that is used for activities dealing with medical devices, including storage, manufacture, etc.

PACKAGING: in relation to a medical device, means the container and other packaging material in which the medical device is supplied.

PRIMARY PACKAGING (as set out in the Regulations): in relation to a medical device, means packaging that maintains the sterility or integrity of the medical device.

PRODUCT OWNER (as set out in the Regulations): in relation to a health product, means a person who —

- 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
- 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.

REGISTRANT (as set out in the Act): in relation to a registered health product, means the person who applied for and obtained the registration of the health product under this Act.

NOTE: Registrant is not licensed under the Act. However, the registrant is required to register with HSA to facilitate product registration applications in MEDICS.

RETAIL: means selling or supplying it to a person who receives it for a purpose other than that of selling or supplying.

REFURBISHING: means restoring used medical devices to a condition of safety and effectiveness comparable to when new and without significantly changing the equipment's performance, safety specification and/or intended use as in its original medical device.

This restoration includes actions such as repair, rework, software/hardware updates, and the replacement of worn parts with original parts.

It may involve any or all of the following actions:

- (a) stripping the medical device into component parts or sub-assemblies;
- (b) checking parts of the medical device for suitability for reuse;
- (c) replacing component parts or sub-assemblies of the medical device that are not suitable for reuse;
- (d) assembling reclaimed or replacement component parts of the medical device or another medical device;
- (e) testing the reassembled medical device against the specifications of the original medical device or, if the product owner of the original medical device has revised those specifications, the revised specifications;
- (f) identifying the reassembled medical device as a refurbished medical device.

SECONDARY ASSEMBLY (*as set out in the Regulations*): means the process of repackaging a medical device from its original packaging into secondary packaging, without any breach of the primary packaging, before the medical device is supplied.

NOTE: Secondary Assembly is a manufacturing activity.

SECONDARY PACKAGING (*as set out in the Regulations*): in relation to a medical device, means the outer packaging for the medical device used in substitution for the original packaging.

NOTE: Secondary packaging is typically placed on the outer side of the primary packaging containing the medical device. This does not include shipping cartons that are meant for transport or shipping of the medical devices.

SUPPLY (*as set out in the Act*): in relation to a health product, means to transfer possession of the medical device by any means whether or not for reward, and includes the following:

- to sell the health product, whether by retail, wholesale or auction;
- to expose or display the health product as an invitation to treat;

- to transfer possession of the health product by exchange, gift, lease, loan, hire or hire-purchase;
- to supply the health product in connection with a contract for the provision of any goods or the performance of any service, or any advertising, sponsorship or promotional activity
- to supply the health product by way of administration to or application in any person in the course of any diagnosis, treatment or test;
- to offer, agree or attempt to supply the ways described above, or to cause or permit the health product to be supplied; and
- to keep or possess the health product for the purpose of supplying it in any of the ways described above.

WHOLESALE (*as set out in the Act*): in relation to a medical device, means any one or more of the following: -

- supplying the medical device to a person who obtains the medical device for the purposes of supplying it again to some other person;
 - supplying the medical device to a person as a commercial sample in the normal course of a lawful trade;
 - supplying the medical device to a Government department or statutory body which requires the medical device for the purposes of the public service or use in connection with the exercise of any statutory power;
 - supplying the medical device to a person or an institution concerned with scientific education or research which requires the medical device for the purpose of education or research;
 - supplying the medical device to a person who requires the health product for the purpose of enabling him to comply with any requirements made by, or in pursuance of, any written law with respect to the medical treatment of persons employed by that person in any business or trade carried out by that person;
 - supplying the medical device to a person who requires to use the medical device, other than by way of administration to one or more persons, for the purpose of his business or trade;
- supplying the medical device by export to a party outside Singapore.

2. LICENCES FOR DEALING IN MEDICAL DEVICES

Licensing of dealers is based on the activity performed by that company in relation to medical devices. There are three types of **dealer's licences** for dealing in medical devices: -

- Manufacturer's licence - any company who manufactures medical devices in Singapore;
- Importer's licence - any company who imports medical devices into Singapore;
- Wholesaler's licence - any company who supplies medical devices by wholesale (which includes export) in Singapore.

NOTE:

- *A licensed local manufacturer does not require a wholesaler's licence to supply by wholesale medical devices manufactured by the licensed manufacturer.*
- *A licensed local manufacturer does not require an importer's licence to import medical devices, for use in manufacturing another medical device by the licensed manufacturer.*

The following types of medical device manufacturing activities do not require a manufacturer's licence.

(A) Manufacture by way of fitting or adjusting the medical device to meet the requirements of the end user

Certain medical devices require fitting and adjustments at the start of, or during the use of the device. Examples

- Fitting of hearing aids using fitting software
- Taking dental impression for making dentures or crowns from resins
- Adjustment of spectacles by hand/ using special tools for better fit
- Adaptation and fitting of the orthopaedic implants to the patient's anatomy

(B) Manufacture to enable the continued use of the medical device by the end user

Medical devices are subjected to wear and tear with use. The processing of a medical device to enable continued use for the original purpose it was provided to the end user, will not require a manufacturing licence*. Example of such activities include but not limited to:

- Fix and refit broken frame or refitting lenses or replacing screws
- Fix and refit of prosthetics

NOTE The refurbishing of medical devices and reprocessing of single use devices are considered manufacturing activities. Any facility involved in these activities will require a manufacturing licence and be subjected to the duties and obligations of a manufacturer of a medical device under the Act and Regulations.

Any person or healthcare institution carrying out activities in paragraphs (A) and (B) above are still subjected to the duties and obligations of a manufacturer of a medical device under the *Act and Regulations*.

3. SECONDARY ASSEMBLY- LICENSING REQUIREMENTS

Secondary Assembly is a manufacturing activity. A manufacturer licence is not required if the company —

- (i) holds an importer's licence or a wholesaler's licence, and
- (ii) is able to comply with the requirements of the SS 620: Singapore Standard for Good Distribution Practice for Medical Devices – Requirements (GDPMDS) including the clauses related to secondary assembly or ISO 13485.

4. APPLICATION PROCESS

R7▶ All licence-related applications, including new applications, amendments, renewals, withdrawals and cancellations, must be submitted via the Singapore Health Product Access and Regulatory E-System (SHARE) online platform. ◀

Each application is screened before it can be accepted for review and an input request will be made to the applicant for clarification or request for additional supporting documents or information. The applicant will be required to submit all of the requested documents or information in the input request within the specified timeframe. The target turnaround times (TAT) and fees for the processing of dealer's licence applications and amendments can be found on [HSA website](#). R7▶ -- ◀

If the applicant fails to provide the essential information within the stipulated timeframe, or the submitted information is false, incomplete or deficient, the Authority may reject the application or the applicant would be required to withdraw the application. If the applicant wishes to re-submit the application at a future time, it will be processed as a new application.

Due to business reasons, the applicant may also withdraw an application while in progress or cancel an existing licence if the company does not require the licence anymore.

5. APPLICATION FOR NEW DEALER'S LICENCE

5.1. Applicant Information

R7▶ The applicant is responsible for all transactions with the Authority regarding submitted applications, including responding to input requests for additional information. It is the company's responsibility to ensure that contact details are kept accurate and updated in a timely manner. ◀

5.2. Licence Information

R7▶ Details on the Quality Management System (QMS) (e.g. ISO 13485, or GDPMDS) shall be provided in this section. The QMS must be established and maintained across the supply chain to ensure that the quality of medical devices is not compromised during their distribution, and to ensure that appropriate records are maintained.

For manufacturers, this requirement is fulfilled by implementing and maintaining a QMS that conforms to standards such as ISO 13485. This ensures that medical devices manufactured or released for distribution meet the required quality standards.

Importers and wholesalers dealing with medical devices of risk categories other than Class A are required to be certified to SS 620 (GDPMDS) as a mandatory pre-requisite for licence application. Alternatively, certification to ISO 13485 (with relevant scope covering distribution activities, etc) may also be accepted.

Certification to ISO 13485 and SS 620 (GDPMDS) is performed by third party certification bodies that are accredited by the Singapore Accreditation Council (SAC). The list of accredited third-party certification bodies can be found on the SAC website at www.sac-accreditation.gov.sg. ◀

R7▶ Importers and wholesalers dealing with medical devices that are solely for export or re-export purposes are required to submit a declaration (Annex 1) in place of the GDPMDS certificate. ◀

Companies dealing with only Class A medical devices may submit a declaration of conformity (DoC) to a QMS, in-lieu of ISO 13485 or GDPMDS, for the application of manufacturer, importer or wholesaler licence. Please refer to **Annex 5** for the declaration template.

5.3. Company Information

The company's Unique Entity Number (UEN), as issued by the "Accounting and Corporate Regulatory Authority" (ACRA), is used as the standard identification of a legal entity. The applicant has to ensure that the company address in the dealer's licence application is the same as that registered under ACRA.

The contact person for the company is the person who will be contacted if the applicant is non-contactable. In addition to the applicant, the contact person will also be informed of important announcements from the Authority. It is the responsibility of the company to keep the information on the contact person up-to-date.

5.4. Class A Medical Devices

R7▶ Since Class A medical devices do not require product registration, prior to import and supply in Singapore, device dealers (manufacturer and/or importer) will be required to submit a notification via Product Notification in SHARE. This information will be input and managed by the licensee and they are to ensure that this information is updated and accurate. This list would be published on the “Class A Medical Device Database” on the HSA website and will facilitate traceability of Class A medical devices manufactured or imported into Singapore. For changes to the list of Class A medical devices, device dealers (manufacturer and/or importer) shall submit an “Amendment” under “Product Notification” in SHARE, prior to import and supply of the devices. For more information and on examples of Class A medical devices, please refer to GN-22 Guidance for Dealers on Class A Medical Devices ◀

5.5. Supporting Documents(s)

The supporting documents required to obtain a licence are as follows:

R7▶

	Manufacturer's Licence	Importer's Licence	Wholesaler's Licence
Type of QMS certification	ISO 13485 ¹ or MDSAP ¹ or Declaration of conformity to a QMS (Annex 5) ²	ISO 13485 ¹ or MDSAP ¹ or SS 620 (GDPMDS) ³ or Declaration for dealing with medical devices that are solely for export or re-export purposes (Annex 1) or Declaration of conformity to a QMS (Annex 5) ²	ISO 13485 ¹ or MDSAP ¹ or SS 620 (GDPMDS) ³ or Declaration for dealing with medical devices that are solely for export or re-export purposes (Annex 1) or Declaration of conformity to a QMS (Annex 5) ²

¹ The scope of ISO 13485 or MDSAP certificate must include distribution of the categories of medical devices and the activities performed at the facility, where applicable. R8▶ The QMS certificate, together with the audit report, should be submitted.

² Declaration of conformity (**Annex 5**) is applicable for licensee companies who manufacture, import or wholesale Class A medical devices only.

³ SS 620 (GDPMDS) certification can include secondary assembly in its scope. Please refer to Annex D of GN-33 Guidance on the Application of Singapore Standard Good Distribution Practice for Medical Devices, for the type of activities

that fall under the scope of secondary assembly. The QMS certificate, together with audit report, should be submitted. ◀

To avoid delays in the processing, the application form must be completed in full and accompanied by all required supporting documents. Applications containing false, incomplete, or deficient information may be rejected by the Authority, or the applicant may be required to withdraw the application. ◀

6. CHANGES TO DEALER'S LICENCE INFORMATION

Every licensee is required to notify the Authority whenever there is a change to any particulars formerly declared by him to the Authority at the point of the licence application. Failure to notify the Authority would invalidate the existing licences held.

R7▶ For changes to dealer's licence information, licensee is to submit an "Amendment" in SHARE. Updated QMS certificate or QMS declaration (Annex 1 or Annex 5) shall be provided in the amendment application. A summary of the changes is available in **Annex 2**. ◀

R7▶ -- ◀

7. LICENCE RENEWAL

R7▶ All dealer's licences are valid for 12 months from the date of approval. Licences **not renewed on time will expire** and become invalid.

7.1. Auto-renewal of Dealer's Licence

All licensees on GIRO will be included into the **auto-renewal scheme**. Auto-renewal of licences means that the licences will automatically be renewed (after successful GIRO fee payment) without having the licensees to manually submit renewal applications through SHARE. Notification emails will be sent to the

company 60, 45 and 30 calendar days before the licence expiry date. If the licensee does not wish to have its licence automatically renewed, the licensee will have to submit a cancellation with an effective date more than 30 calendar days before the licence expiry date. There will be no refund of any fees paid.

7.2. Manual Submission of Licence Renewal Application

The manual submission scheme will apply to licensees which are **not** on GIRO. These licensees must submit renewal applications before their licences expire through SHARE. This will ensure their licences remain valid throughout the duration of their activities. Licensees can submit their renewal application after receiving the notification emails that will be sent to the company 60, 45 and 30 calendar days before the licence expiry date.

For these licensees who are not on the auto-renewal scheme, they are required to submit a licence renewal application to the Authority for each of the licences held prior to the licence expiry date, to ensure their licences remain valid for the duration of the licensee's activities.

To ensure timely licence renewal application approvals by the licence expiry date, licensees are required to submit their renewal applications via SHARE at least 14 calendar days prior to the expiry date of their dealer's licences. ◀

8. LICENCE SUSPENSIONS AND REVOCATION

A licence may be suspended or revoked if there are reasonable grounds to believe that: -

- the issue of the licence has been obtained by fraud or misrepresentation;
- the licensee has contravened or is contravening any provision of *the Act and Regulations* relating to medical devices, any condition attached to the licence or any other prescribed requirement;
- the licensee no longer satisfies any of the prescribed requirements based on which the licence was issued; or
- it is in the public interest to do so.

The compliance history of the licensee and the risk to the health and safety of patients, users or other persons of allowing the licence to remain valid will also be considered.

When a decision to suspend or revoke a licence has been taken, the licensee is given written notice of the intention and the reason(s). The licensee is also given an opportunity to be heard prior to the suspension or revocation.

As soon as a licence is suspended or revoked, the licensee is required to immediately cease all activities related to the manufacturing, importation or wholesale supply of medical devices.

A suspended licence may be reinstated if the situation that gave rise to the suspension is corrected. A revoked licence will not be reinstated. If the situation that gave rise to the revocation is corrected, a new licence application can be submitted.

9. INSPECTIONS

The Authority may conduct inspections or assessments of licensees to determine their compliance with the *Act* and *Regulations*, and any applicable licence conditions. Licensees are required to ensure full compliance with the conditions of the licence.

ANNEX 1

R7▶

[To be printed on company letterhead]

Declaration for dealing with medical devices that are solely for export or re-export purposes

I hereby attest that [*Company name*] is only dealing with medical devices that are solely for export or re-export purposes and that the medical device will not be supplied in Singapore. This attestation is for the purpose of my **importer / wholesaler's** licence application(s) (*delete accordingly). ◀

I am informed and I understand that the above licence(s) may be suspended or revoked if there are reasonable grounds to believe that:

- the company is in breach of the above attestation;
- the issuance of the licence has been obtained by fraud or misrepresentation by my company;
- the licensee has contravened or is contravening any provision of the *Act* and *Regulations* relating to medical devices, any condition attached to the licence or any other prescribed requirement;
- the licensee no longer satisfies any of the prescribed requirements based on which the licence was issued; or
- it is in the public interest to do so.

I am informed and understand that:

- the company shall adhere to storage conditions of the medical device as stipulated by the product owner
- the company shall adhere to transportation conditions of the medical device as stipulated by the product owner
- the company has to maintain records of import and supply
- the company has to maintain records of complaints
- the company has to report defects and adverse effects to HSA
- the company has to notify HSA concerning product recalls; and
- there is prohibition against false or misleading advertisement of the medical device which the company markets.

I am informed and I understand that it is a contravention of Section 24(6) of the Health Products Act to make any statement or furnish any document which I know to be false or misleading.

Signature and Date

Name & Designation

Name and Address of Company

ANNEX 2

Types of Changes

R7► Changes that require Amendment submission

Type of change	Supporting documents required	Remarks
Operating sites address(es)/premises of third party logistics service providers/outsourced activities related to GDPMDS or ISO 13485 or MDSAP activities (Addition/Removal)	<ul style="list-style-type: none"> Updated QMS certificate with address(es) of new certified sites/premises and/or third party logistics/outsourced activity locations R8► and audit report 	To update information under site details and/or outsource provider section.
Device type (i.e. General Medical Devices and/or In-vitro Diagnostic Devices (IVD))	<ul style="list-style-type: none"> Updated QMS certificate and audit report 	If IVD is selected as a device type, scope shall include IVD devices.
Risk classification	<ul style="list-style-type: none"> Updated QMS certificate and audit report 	Licensees are responsible to ensure the accuracy of the risk classification of devices imported, wholesaled or manufactured as indicated under the respective dealer's licences.
Quality Systems	<ul style="list-style-type: none"> R8► New ISO 13485, MDSAP or GDPMDS certificate and audit report; or QMS declaration 	For conversion to other QMS certification type, a new QMS certificate from the certification body or declaration letter from licensee is required to be submitted as a supporting document.
Certification body	<ul style="list-style-type: none"> R8► New QMS certificate from new certification body and audit report 	
QMS Certificate validity date	<ul style="list-style-type: none"> R8► New QMS certificate with new validity date and audit report 	Update validity date in SHARE
Scope of operations	<ul style="list-style-type: none"> R8► Updated QMS certificate with new scope of activities and audit report 	<p>For GDPMDS</p> <p>NOTE: The scope of activities certifiable under the GDPMDS is defined in Annex A of GN-33 Guidance on the Application of Singapore Standard Good Distribution Practice for Medical Devices</p> <p>The categories of medical devices for inclusion in GDPMDS scope of certification are defined in Annex B of GN-33 Guidance</p>

		on the Application of Singapore Standard Good Distribution Practice for Medical Devices.
Cold-chain management for GDPMDS certification (Addition/Removal)	<ul style="list-style-type: none"> • R8 ► Updated QMS certificate with new scope of activities and audit report 	Select/deselect the “cold-chain management” checkbox. Update the scope of activities, including statement on storage condition.
Secondary assembly for GDPMDS certification (Addition/Removal)	<ul style="list-style-type: none"> • R8 ► Updated QMS certificate with new scope of activities and audit report 	Select/deselect the “secondary assembly” checkbox. If “secondary assembly” is selected in SHARE, scope shall include this activity.

For a manufacturer’s licence, a change in the QMS (ISO 13485 or MDSAP) certificate may also require a Change Notification submission to registered products manufactured under the same QMS certificate in the facility. The Registrant shall submit a Change Notification for the registered devices in accordance to GN-21 Guidance on Change Notification for Registered Medical Devices.

Changes that require New Dealer Licence Application

Type of change	Supporting documents required
Type of dealer’s licence (e.g change from an importer to a wholesaler licence)	R8 ► QMS certificate and audit report or QMS declaration (For Class A only)
Change to Unique Entity Number (UEN) of company	R8 ► QMS certificate and audit report or QMS declaration (For Class A only)



ANNEX 5

[To be printed on company letterhead]

Declaration of Conformity to a Quality Management System (QMS)

Dear Sir/Madam

I hereby attest that *[Company name]* **manufactures, imports and/or wholesales*** only medical devices classified as Class A under the Health Products (Medical Devices) Regulations 2010.

The **manufacture, import and/or wholesale*** of the Class A medical devices is carried out by *[Company Name]* at the following location(s):

No.	Activity	Address of company
1	Manufacture/ Import/ Wholesale	

[Company name] has established a QMS in accordance with the requirements of *[ISO 13485 / GDPMDS*]* for the **manufacture, import and/or wholesale*** of Class A medical devices at the above stated locations. *[Company name]* will continuously monitor, control and maintain the QMS processes to ensure conformity to *[ISO 13485 / GDPMDS*]* throughout the life cycle of the Class A medical devices.

This declaration is for the purpose of my application(s) for **manufacturer's, importer's and/or wholesaler's* licence(s)**. I am informed and I understand that the licence(s) may be suspended or revoked if there are reasonable grounds to believe that:

- the company is in breach of the above attestation;
- the issuance of the licence has been obtained by fraud or misrepresentation by my company;
- the licensee has contravened or is contravening any provision of the Act and Regulations relating to medical devices, any condition attached to the licence or any other prescribed requirement;
- the licensee no longer satisfies any of the prescribed requirements based on which the licence was issued; or
- it is in the public interest to do so.

I am informed and understand that:

- the company shall adhere to storage conditions of the medical device as stipulated by the product owner
- the company shall adhere to transportation conditions of the medical device as stipulated by the product owner
- the company has to maintain records of import and supply
- the company has to maintain records of complaints
- the company has to report defects and adverse effects to HSA
- the company has to notify HSA concerning product recalls; and
- there is prohibition against false or misleading advertisement of the medical device which the company markets.

I am informed and I understand that it is a contravention of Section 24(6) of the Health Products Act to make any statement or furnish any document which I know to be false or misleading.

**Delete as appropriate*

Signature and Date

Name & Designation

Name and Address of Company

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg

