

HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

June 2018

MEDICAL DEVICE GUIDANCE

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

Revision 4



CONTENTS

1.	INTRODUCTION	4
1.1.	Purpose.....	4
1.2.	Background.....	4
1.3.	Scope.....	5
1.4.	Definitions	5
2.	LICENCES FOR DEALING IN MEDICAL DEVICES	10
3.	SECONDARY ASSEMBLY- LICENSING REQUIREMENTS	12
4.	APPLICATION PROCESS	12
5.	APPLICATION FOR NEW DEALER'S LICENCE	14
5.1.	Applicant Information	14
5.2.	Licence Information.....	14
5.3.	Company Information.....	15
5.4.	Class A Medical Devices.....	16
5.5.	Supporting Documents(s)	17
6.	CHANGES TO DEALER'S LICENCE INFORMATION.....	19
6.1.	Changes to Applicant Information Section	19
6.2.	Changes to Licence Information Section.....	19
6.3.	Changes in Company Information Section.....	22
6.4.	Changes to the Class A Medical Devices	22
7.	LICENCE RENEWAL	24
7.1.	Auto-renewal of Dealer's Licence	24
7.2.	Manual Submission of Licence Renewal Application	24
8.	LICENCE SUSPENSIONS AND REVOCATION.....	26
9.	INSPECTIONS	27
	ANNEX 1	28
	ANNEX 2 Types of Changes	29
	ANNEX 3.....	31
	ANNEX 4.....	32
	ANNEX 5.....	33
	ANNEX 6.....	34

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 (Publish Date) [3 latest revisions]</u>	<u>Revision</u>
R4 ► GN-02: Revision 4 (01 June 2018)	R4

**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 (*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.

APPLICANT: an applicant is the person applying for the 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*.

R4 ►

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.

R4 ►

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.

R4 ►

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

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*. ◀

R4 ►

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 Good Distribution Practice Standard for Medical Devices (GDPMDS) including the clauses related to secondary assembly or ISO 13485. ◀

4. APPLICATION PROCESS

All applications (new, amendment/submission of updates, renewal, withdrawal, cancellation) are to be submitted via the respective MEDICS e-services available online. It is not possible to submit an application if there is already a draft application saved. The applicant is advised to access the draft application which is saved under "My draft" in the Workbench@MEDICS and complete the submission.

R4 ►

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 are detailed in **Annex 4.** ◀

If the applicant anticipates difficulty in responding in full or within the specified timeframe, the applicant should contact the Authority to discuss the request for information/clarification.

R4 ▶

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

All dealer's licence applications are to be submitted via the online Medical Device Information and Communication System (MEDICS) e-service, **apply@medics**. The following are sections of the application form.

R4 ►

5.1. Applicant Information

The applicant is responsible to liaise with the Authority on all issues regarding the applications submitted, including input requests. It is the responsibility of the company to keep information, as well as contact information, of the applicant up-to-date in a timely manner.

5.2. Licence Information

Information on the Quality Management System (QMS) (e.g. ISO 13485 or Good Distribution Practice for Medical Devices (GDPMDS)) shall be provided in this section. The QMS should be established and maintained throughout the supply chain to ensure that the quality of medical devices is not adversely affected during their distribution and to ensure that appropriate records are kept.

For manufacturers, this is achieved through establishing and maintaining QMS such as those conforming to standards like ISO 13485. This ensures that medical devices manufactured or released for distribution are of appropriate quality.

Importers and wholesalers of medical devices of risk categories other than Class A medical devices are required to be certified to GDPMDS as a prerequisite for licence application. Certification to 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.

GDPMDS certification is not required for the following activities:

- Import for re-export only
- Import for non-clinical use only

In the case of the above-mentioned exceptions, a “Declaration of exemption from GDPMDS” (**Annex 1**) made on company letterhead should be submitted 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 certification, for the application of manufacturer, importer or wholesaler licence. Please refer to **Annex 5** for the declaration template. ◀

5.3. Company Information

This section shows the company’s business information registered under its CRIS account. Should there be a need to update the details, please use the MEDICS e-service for “*Change of business 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 business 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. Preferably, this contact person is also a CRIS administrator of the company. Preferably only one person is to be nominated as the contact person for all the dealer’s licences held by the company. 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.

R4 ►

5.4. Class A Medical Devices

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 declaration of the list of Class A medical devices that they deal in, via MEDICS. 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 Register” on the HSA website and will facilitate traceability of Class A medical devices manufactured or imported into Singapore. For more information and on examples of Class A medical devices, please refer to GN-22 Guidance for Dealers on Class A Medical Devices Exempted from Product Registration.

The declaration of list of Class A medical devices can be performed via MEDICS e-service *Amendment for Dealer’s license/Submission of update of Class A Medical Device Exemption List*.

For licensee companies that do not manufacture or import Class A medical devices, a “Declaration letter of non-dealing in Class A medical devices” (**Annex 6**) made on company letterhead should be submitted as a supporting document during new licence application or during amendment to change QMS type. ◀

5.5. Supporting Documents(s)

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

R4 ►

	Manufacturer's Licence	Importer's Licence	Wholesaler's Licence
Type of QMS certification	ISO 13485 ¹ or Declaration of conformity to a QMS (Annex 5) ²	ISO 13485 ¹ or GDPMDS ³ or Declaration of exemption from GDPMDS (Annex 1) or Declaration of conformity to a QMS (Annex 5) ²	ISO 13485 ¹ or GDPMDS ³ or Declaration of exemption from GDPMDS (Annex 1) or Declaration of conformity to a QMS (Annex 5) ²
Other document where applicable	Declaration letter of non-dealing in Class A medical devices (Annex 6)	Declaration letter of non-dealing in Class A medical devices (Annex 6)	Nil

¹ The scope of ISO 13485 certificate must include import, storage and/or distribution of the categories of medical devices and the activities performed at the facility, where applicable.

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

³ GDPMDS certification can include secondary assembly in its scope. Please refer to Annex 3 of the technical specification document TS-01 (Good Distribution Practice for Medical Devices – Requirements) or Annex E 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.

To minimise delay in the processing of the application, the application form must be completed in full and all required supporting documents are to be submitted. If the information submitted during the application process is false, incomplete or deficient, the Authority may reject the application or the applicant would be required to withdraw the licence 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.

The following sections list the types of changes and the relevant routes of notification to be taken by the licensee accordingly. A summary is available in **Annex 2**.

6.1. Changes to Applicant Information Section

R4 ►

The applicant is responsible to liaise with the Authority on all issues regarding the applications submitted, including input requests. It is the responsibility of the company to keep information, as well as contact information, of the applicant up-to-date in a timely manner. Applicant information of multiple medical device licences may be updated collectively using the *Global Update of Applicant Details* function under `others@medics`. ◀

6.2. Changes to Licence Information Section

The type of dealer's licence held cannot be changed. A new dealer's licence application shall be submitted.

For changes to device Risk Classification, QMS Certification Type, Certification Body, QMS Certificate Expiry Date, Scope of Operations, Cold-Chain Management, Operating Site Address(es) and premises of third party logistics/outsourced activities, the licensee shall inform the Authority on the change(s) by means of a licence amendment application.

NOTE: For a manufacturer's licence, a change in the QMS (ISO 13485) 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.

R4 ►

An updated copy of the QMS certificate or QMS declaration and a Summary Table of Amendments (**Annex 3**) shall be provided. If required, the amendment shall be accompanied by additional particulars, information and documents as the Authority may request.

(A) Change of risk classification of medical devices

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. Updates to the risk classification may be done via licence amendment application at no charge.

(B) Change of QMS (Quality Management System) certification type

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. ◀

(C) Change of certification body

When a change of certification body occurs, the existing QMS certificate issued by the former certification body would no longer be valid. A licence amendment is necessary to verify that licensees remain certified to the relevant QMS requirements for the particular dealer's licence held. A new QMS certificate issued by the new certification body should be submitted in the licence amendment application.

(D) Change of certificate expiry date

QMS certificates that have expired are no longer valid and cannot be used to support the dealer's licences. Licensees who do not update the MEDICS system with a renewed certificate risk having their licences suspended. Updates

to the QMS certificate expiry date may be done via licence amendment application at no charge. A new valid QMS certificate should be submitted with the licence amendment application.

(E) Change of scope of operations

Any change of the scope of activities within the licensee's QMS certificate has to be verified for consonance with the activities authorised in the licence. When there is a change in the scope of operations/activities performed by the licensee, the QMS certificate and the "Scope of operation" under licence information section shall be updated with the new scope. An updated QMS certificate should be submitted with the licence amendment application.

R4 ►

NOTE: The scope of activities certifiable under the GDPMDS is defined in Annex 1, of TS-01, Good Distribution Practice for Medical Devices – Requirements and Annex A of GN-33 Guidance on the Application of Singapore Standard Good Distribution Practice for Medical Devices

The categories of medical devices for inclusion in GDPMDS scope of certification are defined in Annex 2 of TS-01, Good Distribution Practice for Medical Devices – Requirements and Annex B of GN-33 Guidance on the Application of Singapore Standard Good Distribution Practice for Medical Devices. ◀

(F) Change of cold-chain management

Medical devices that are subjected to cold-chain management require special storage and handling conditions. As such, for the inclusion of medical devices that require cold-chain management (e.g. *in-vitro* diagnostic medical devices) to existing devices handled by a licensee, the QMS certificate (ISO 13485 or GDPMDS) of the licensee has to be updated to include this activity. A licence amendment application is required to include/remove this activity and update the information on "Scope of operations". An updated QMS certificate should be submitted with the licence amendment application.

(G) Change of operating site address(es) certified to GDPMDS/ISO 13485 (including those of the third party logistic service providers/outsourced activities)

The updated QMS certificate identifying the new site address(es) shall be provided as objective evidence that the new site address(es) have been audited to QMS requirements for the relevant dealer's licence. Changes to site address(es) may be done via licence amendment application at no charge.

Addition or removal of site address(es) of third party logistics service providers/outsourced activities should also be reflected on the licensee's updated QMS certificate, and will require a licence amendment application. The locations of the third party logistics company and/or where the outsourced activities are conducted should be indicated under the "Site Address(es)" section of the application form.

6.3. Changes in Company Information Section

Licensees shall notify the Authority of changes in company information (company name, business address, contact information and contact person information) through the e-service "Change of business information" under MEDICS. The new company information will be updated for all dealer's licences held by the company.

In the event of a change in legal entity (i.e. change in UEN), a new CRIS account shall be created. All dealer's licences related to the former (invalid) UEN will similarly be invalidated, and new licence applications should be made under the new CRIS account with the valid UEN.

R4 ►

6.4. Changes to the Class A Medical Devices

Changes to the list of Class A medical devices submitted by device dealers (importers and/or manufacturers) during licence application shall be updated prior to import and supply of the devices. Licence holders may submit their

updates through the “*Amendment for dealer’s licence/Submission of update of Class A Medical Device Exemption List*” e-service in MEDICS.

The importer or manufacturer is not required to submit updates if the company is not dealing in Class A devices and has previously submitted a declaration to the Authority that the company does not deal with any Class A medical devices. In the event that the importer or manufacturer decides to deal with such medical devices, the submission of updates on the list of Class A medical devices will be required. ◀

7. LICENCE RENEWAL

All dealer's licences are valid for 12 months from the date of approval. Licences not renewed on time will expire and become invalid. During renewal of licences, the system does not allow any change of information to be made. Please refer to Section 6 on the various routes to make changes to the licence information.

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 the MEDICS e-service. Under this scheme, licences will be automatically renewed, unless the licensee has opted out of the auto-renewal scheme. Notification emails will be sent to the applicant 60 days and 45 days before the licence expiry date with instructions on how the licensee can opt out of the auto-renewal scheme if the licensee does not wish to have its licence automatically renewed. If the licensee wishes to opt out of this auto-renewal scheme, the licensee will have to do so at least 30 days before the licence expiry date.

7.2. Manual Submission of Licence Renewal Application

R4 ►

The manual submission scheme will apply to licensees which are **not** on GIRO. Licensees which are currently not on GIRO are encouraged to join this payment mode for ease of licence renewal. These licensees will need to submit renewal applications for their licences through the MEDICS e-service upon notification via email. ◀

An email notification for licence renewal will be sent from the Authority to the licensee 60 calendar days before the expiry date of the dealer's licence and a reminder will be sent 45 calendar days before the 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. All pending amendment submissions made for the licence to be renewed have to be approved before a licence renewal submission can proceed.

To ensure timely licence renewal application approvals by the licence expiry date, licensees are required to submit their renewal applications via MEDICS at least 10 working days prior to the expiry date of their dealer's licences. It is not possible to submit a new renewal application if there is a draft renewal application pending for the same licence. Applicant is advised to access the draft application which is saved under "My draft" in the Workbench and complete the submission.

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

[To be printed on company letterhead]

Declaration for Exemption from GDPMDS Certification

I hereby attest that *[Company name]* qualifies to be exempted from GDPMDS certification for the purpose of my application(s) for * **importer's / wholesaler's** licence(s) (*delete accordingly).

The activities for exemption are:

Activity 1: Dealing with medical devices that are solely for export or re-export. The medical device will not be supplied in Singapore; or

Activity 2: Dealing with medical devices for non-clinical use. The medical device will not be used on any patient.

I further declare that the activity of *[Company name]* is * **Activity 1 and/or Activity 2** (*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

Company Stamp

ANNEX 2 Types of Changes

R4 ►

Type of change	E-service	Supporting documents required	Remarks
1. APPLICANT INFO			
Change in applicant information	Global Update of Applicant Details	Nil	
2. LICENCE INFO			
Type of dealer's licence	New application	All supporting documents required for a new licence application	
Risk classification	Amendment	Nil	Select the correct checkbox.
Certification – Quality Systems	Amendment	<ul style="list-style-type: none"> • New ISO 13485 certificate or GDPMDS certificate • Summary table of amendments (Annex 3) 	Select the checkbox for either ISO 13485, or GDPMDS.
Certification body	Amendment	<ul style="list-style-type: none"> • New QMS certificate from new certification body • Summary table of amendments (Annex 3) 	Select or key in the correct certification body.
QMS Certificate expiry date	Amendment	<ul style="list-style-type: none"> • New QMS certificate with new expiry date • Summary table of amendments (Annex 3) 	Update expiry date.
Scope of operations	Amendment	<ul style="list-style-type: none"> • Updated QMS certificate with new scope of activities • Summary table of amendments (Annex 3) 	Update the scope of activities, including statement on storage condition. Select/deselect the “cold-chain management” checkbox, where applicable.
Cold-chain management for GDPMDS certification (Addition/Removal)	Amendment	<ul style="list-style-type: none"> • Updated QMS certificate with new scope of activities 	Select/deselect the “cold-chain management” checkbox. Update the scope of activities, including statement

		<ul style="list-style-type: none"> • Summary table of amendments (Annex 3) 	on storage condition.
Operating sites address(es)/premises of third party logistics service providers/outsourced activities related to GDPMDS or ISO 13485 activities (Addition/Removal)	Amendment	<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 • Summary table of amendments (Annex 3) 	To update information, click on the hyperlink Add/Edit info under “Site Address(es)”.
3. COMPANY INFO			
Change in company information (name, business address, contact person details)	Change of business information	<ul style="list-style-type: none"> • All supporting documents required during new CRIS application 	A change in legal entity would require the submission of new dealer’s licence applications.
Change in legal entity, UEN	New application	All supporting documents required for a new licence application	A change in legal entity would require a new CRIS account and submission of new dealer’s licence applications.
4. CLASS A MEDICAL DEVICES			
Change to non-dealing with Class A medical devices	Submission of update of Class A Medical Device Exemption List.	<ul style="list-style-type: none"> • Declaration of non-dealing in class A medical devices (Annex 6) 	Medical devices on the list which are no longer imported or manufactured cannot be removed. For such items, the status should be changed from “active” to “inactive”.
Update of Class A medical devices	Submission of update of Class A Medical Device Exemption List.	<ul style="list-style-type: none"> • Class A exemption list 	<p>Applicant has to download the latest spreadsheet from MEDICs, insert the new items, save and upload the new file.</p> <p>Medical devices on the list which are no longer imported or manufactured cannot be changed or removed. For such items, the status should be changed from “active” to “inactive”.</p>

ANNEX 3**Summary Table of Amendments**

Type of change (according to Annex 2 in GN- 02)	Previously approved	Proposed	Reason for change	Supporting documents submitted
e.g. Sites/premises related to ISO 13485 activities (Addition)	Name and address of current warehouse site A	Name and address of new warehouse site B	Reason for warehouse site shift to new location	ISO 13485 certificate XYZ

ANNEX 4**R4 ►****New Licence and Licence Amendment Application Target Turn Around Time (TAT) and fees**

All turn-around times are estimated & based on complete submissions with all the necessary information/ documents. TAT does not include 'stop clock time' due to input requests for clarifications or additional information to be provided by the applicant.

Application type	Target TAT (excluding stop-clock time incurred by the applicant)	Fees
New medical device dealer's licences (including manufacturer's, importer's and wholesaler's licences)	10 working days	\$1000 per licence
Amendment of dealer licence	10 working days	\$150 per application
Submission of Class A medical device exemption list	Not applicable	Not applicable



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

Company Stamp

ANNEX 6

[To be printed on company letterhead]

Declaration of Non-Dealing of Class A Medical Devices

Dear Sir/Madam

I hereby attest that *[Company name]* does not **manufacture/import*** medical devices classified as Class A under the Health Products (Medical Devices) Regulations 2010.

R4 ►

This declaration is made in response to the following licence condition in the **manufacturer's licence/importer's licence***.

Licence condition:

The holder of this licence shall submit details and declare all Class A Medical Devices in the Class A Exemption List prior to import/supply in Singapore, in accordance with the format specified by the Authority, as applicable. ◀

This declaration is for the purpose of my application(s) for **manufacturer's and/or importer'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 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

Company Stamp

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

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

Email: hsa_md_info@hsa.gov.sg

