HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

**NOVEMBER 2011**

# MEDICAL DEVICE GUIDANCE

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

Revision 2

HSA
Health Sciences Authority

## 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. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

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

## CONTACT INFORMATION

For further information, please contact:

Medical Device Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667

Fax: (65) 6478 9028
Email: hsa_md_info@hsa.gov.sg
Website: www.hsa.gov.sg

# 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. It also highlights the key regulatory responsibilities of persons dealing with medical devices in Singapore.

## 1.2. Background

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);

has to comply with the Health Products Act 2007 (*Act*), Health Products (Medical Devices) Regulations 2010 (*Regulations*), any licensing conditions and any applicable legislative requirements.

Licensing

- ensures that 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 handling, field safety corrective actions (FSCA), mandatory problem 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.

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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 of a person associated with the use of a medical device. This may include:-

- the 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;

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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.*

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

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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

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PRODUCT OWNER: means a person who sells a medical device under his own name, or under any trade-mark, design, trade name or other name or mark owned or controlled by him, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, 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.

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

*NOTE Secondary Assembly is a manufacturing activity.*

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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; *

  * NOTE *As per the above, supply also comprises the exhibition of a device or use of a device for training/teaching purposes.*
- 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.

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WHOLESALE: 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 person is based on the activity performed by that person in relation to medical devices. There are three types of licences for dealing in medical devices:-

- Manufacturer's licence - any person who manufactures medical devices in Singapore;
- Importer's licence - any person who imports medical devices into Singapore;
- Wholesaler's licence - any person 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.*

## 3. THE APPLICATION PROCESS

All licence applications are to be submitted via the online Medical Device Information and Communication System (MEDICS).

### 3.1. Contact person for company

The contact person listed in the licence is the key contact person for the company. The contact person will be the person who will liaise with the Authority on all issues regarding applications submitted by the company, including input request on applications.

All communication with the company will be sent to the contact person. It is essential that the company keeps information on the contact person up-to-date in the system.

### 3.2. Application requirements

No supporting documents are required in the application for Registrant.

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

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| Manufacturer's Licence | Importer's Licence | Wholesaler's Licence |
|---|---|---|
| ISO 13485 certificate for finished medical device manufacturing | GDPMDS * OR ISO 13485 certificate with scope of storage and distribution included | GDPMDS * OR ISO 13485 certificate with scope of storage and distribution included |
| List of exempted Class A medical devices manufactured | List of exempted Class A medical devices imported | N.A. |

* GDPMDS certification can include the manufacturing activity of secondary assembly in its scope. Please refer to Annex 3 of the technical specification document *TS-01-R2, Good Distribution Practice for Medical Devices in Singapore – Requirements* for the type of activities that fall under the scope of secondary assembly.

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 abovementioned exceptions, a declaration should be submitted in place of the certificate. A template for the declaration is available here:
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html

The use of a conditional GDPMDS certificate as supporting documentation shall **only** be permitted for the application for a conditional Importer's licence with a validity period of 6 months. Please refer to *TS-01, Good Distribution Practice for Medical Devices – Requirements,* for information pertaining to conditional GDPMDS certification.

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The list of class A medical devices exempted from product registration is found in *GN-22, Guidance to the List of Medical Devices exempted from Product Registration.* The list of class A exempted medical devices manufactured or imported shall be up-to-date at the point of application and shall be updated on an annual basis or as the Authority requests. For companies that do not manufacture or import class A exempted medical devices, a letter of declaration made on company letterhead should be provided.

To minimise delay in the processing of the application, the forms must be completed in full and all required supporting documents are to be submitted.

One licence can apply to one or many premises provided the activities conducted at these premises are operated by the same legal entity and the premises are covered in the respective audits.

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*NOTE: The company address of the applicant in MEDICS shall be identical to the address stated in the Quality Management System (ISO 13485 or GDPMDS) certificate.*

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The applicant is required to make an attestation during submission of a dealer's license application in MEDICS. The attestation can be found in Annex 3.

If the information submitted during the application process is false or incomplete, the Authority may refuse to issue a licence.

## 4. CHANGES TO REGISTRANT ACCOUNT

An Amendment shall be required for the change in contact details of a Registrant. If the change results in a new legal entity, an Amendment shall not be submitted. Instead, applicants shall be required to apply for a new CRIS account and submit a new application for Registrant.

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## 5. CHANGES TO LICENCES

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 in accordance to each change. A summary of all changes described below is also provided in a tabular format in Annex 1.

### 5.1. Changes that Require Licence Amendment

For changes that may significantly affect the licensee's operations, the licensee shall inform the Authority at the point of change by means of an Amendment submission. The licensee should not effect, or operate according to, the change until and unless the Authority has given its approval for the change.

For all changes listed in this section 5.1, i.e. changes that require licence Amendments, an updated copy of the quality management systems (QMS) certificate (i.e. ISO 13485, GDPMDS) and a Summary Table of Amendments (Annex 2) shall be provided. If required, the Amendment shall be accompanied by additional particulars, information and documents as the Authority may request.

(A) Change in certification body

When a change in 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.

(B) Addition to scope of activities

When an addition is made to the scope of activities performed by the licensee, the quality management systems certification has to be updated to include the new activity in the certification scope. Approval from the Authority shall be obtained prior to the performance of these activities as part of the issued dealer's licences.

NOTE *The scope of activities certifiable under the GDPMDS are defined in Annex 1 of TS-01, Good Distribution Practice for Medical Devices – Requirements*

(C) Addition of cold-chain management under GDPMDS certification

Medical devices that are subjected to cold-chain management require special storage and handling conditions. As such, the inclusion of medical devices that require cold-chain management (e.g. in vitro diagnostic medical devices) to existing devices handled by a licensee is a significant change and the GDPMDS certificate has to be updated to include this scope of activity. Correspondingly, additions of medical device categories that require cold-chain management can be updated to the Authority in the same Amendment.

NOTE *If the GDPMDS certificate submitted to the Authority during dealer's licence application or a prior Amendment submission already includes cold-chain management, a licence Amendment would not be required.*

*NOTE Categories of medical devices are defined in Annex 2 of TS-01, Good Distribution Practice for Medical Devices - Requirements*

(D) Addition of sites/premises related to GDPMDS/ ISO 13485 activities

New sites/premises at which the scope of activities within the licensee's QMS certificate is conducted have to be verified for suitability to the activities performed. The updated QMS certificate identifying the new addresses/sites/premises shall be provided in evidence that the new addresses/sites/premises have been audited to QMS requirements for the relevant dealer's licence.

NOTE *For the removal of addresses/sites/premises related to GDPMDS activities, the licence holder may inform the Authority on the removal at the point of licence renewal. See section 5.2 with reference to this change.*

(E) Change of third party logistics/outsourced activities

Addition or removal of third party logistics/outsourced activities is a significant change that should be reflected on the licensee's updated QMS certification, and will require a licence Amendment submission.

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## 5.2. Changes to be Notified at Point of Licence Renewal

The changes listed below will not require the submission of an Amendment. The licensee shall notify the Authority of the changes at the point of licence renewal, as part of the renewal application.

(A) Change in company name

For a change in company name without a change in legal entity, licensees shall notify the Authority of the change at the point of licence renewal.

NOTE: *The company Unique Entity Number (UEN), as issued by ACRA, is used as the standard identification of a legal entity. In the event of a change in legal entity (i.e. change in UEN), a new licence application shall be submitted. A licence Amendment would not be applicable.*

(B) Removal of sites/premises related to GDPMDS/ ISO 13485 activities

The licensee may inform the Authority on the removal of former sites/premises where the licensee's scope of activities were performed at the point of licence renewal. A licence Amendment would not be necessary. (*However, addition of sites related to GDPMDS/ ISO 13485 activities shall require an Amendment submission. Please refer to section 5.1, part (C) for addition of sites related to GDPMDS/ ISO 13485 activities.)*

(C) Addition/Removal of new medical device category under GDPMDS certification (except for device categories that require addition of cold chain management to scope of activities)

Addition or removal of a new medical device category can be notified to the Authority during the licence renewal process. However, should the additional medical device category require cold-chain management, an Amendment shall be submitted to include the activity scope of cold-chain management. Approval from the Authority shall be required prior to commencing activities for devices that require cold-chain management.

NOTE *If the GDPMDS certificate submitted to the Authority during dealer's licence application or a prior Amendment submission already covers cold-chain management, a licence Amendment would not be necessary.*

NOTE: *Categories of medical devices are defined in Annex 2 of TS-01, Good Distribution Practice for Medical Devices - Requirements*

(D) Change to Exempted Class A Medical Devices list

Changes, comprising both additions and removals, to the Exempted Class A Medical Devices List submitted during licence application shall be updated during licence renewal. A licence Amendment will not be necessary.

### 5.3. Changes that Require New Licence Application

Licensees are reminded that not all proposed changes qualify as an '*Amendment*' or as a '*Notification at the point of licence renewal'*. The changes listed below will require the Registrant to submit a new License Application.

(A) Type of dealer's licence

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

(B) Change in legal entity

If a change results in a new legal entity, an Amendment shall not be submitted. Instead, applicants shall be required to submit a new Dealer's Licence Application.

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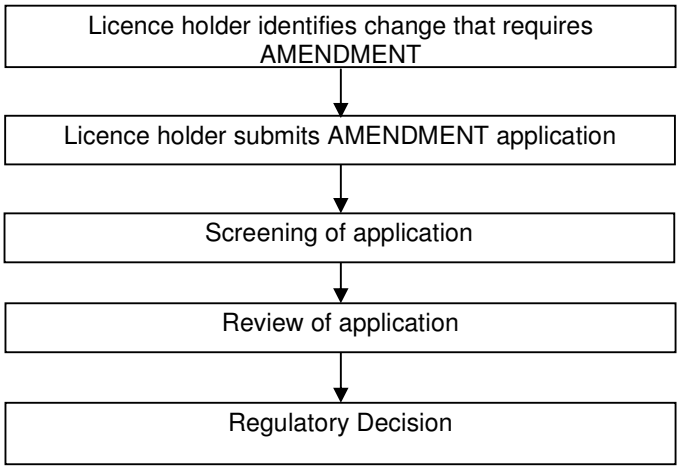
## 5.4. Application Process for Amendment




The process above is applicable solely to changes in a licence holder's activities that require an Amendment submission to the Authority.

### 5.4.1. Submission of Amendment Application

All applications are to be submitted via the online Medical Device Information and Communication System (MEDICS).

Currently, it is not possible to submit a new Amendment application if there is a previously submitted Amendment application pending for the same licence. The Registrant shall be required to withdraw the pending Amendment application and submit a new Amendment application containing the cumulative changes from both the previous and new applications.

Applicant shall submit the following data through MEDICS:

- Summary table of Amendments (Annex 2), AND
- Updated or new QMS certificate

NOTE *For a manufacturer's licence, a change in the QMS (ISO 13485) certificate shall also require a Change Notification submission to registered products manufactured under the same QMS certificate. The Registrant shall submit a Change Notification for the registered devices in accordance to GN-21, Guidance on Change Notification.*

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### 5.4.2. Screening of Amendment Application

The application is screened before it can be accepted for review to ensure that there are no major deficiencies that would hinder the review. If any major deficiencies are identified during the screening, an input request will be made to the Registrant. The licensee will be required to submit all of the requested information and material identifier in the input request within **14 calendar days** from the date of request. Any deficiencies indicated must be addressed before the application can be accepted for review.

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

If the licensee fails to provide all requested information within the stipulated timeline, or the submitted information is incomplete, deficient or contains unsolicited information, the application will be rejected.

If the licensee wishes to submit the application at a future time, it will be processed as a new application.

### 5.4.3. Acceptance and Review of Amendment Application

The application will be routed for review based on the type of changes proposed by the licensee. Review will begin upon acceptance of the Amendment application

### 5.4.4. Regulatory Decision

For an Amendment that is approved by the Authority, the licensee may proceed to implement the change(s) proposed in the Amendment.

Licensees are required to ensure full compliance with the conditions of the licence.

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### 5.5. Changes That May be Effected upon Acceptance of Amendment Application

Amendments are considered significant changes and require approval from the Authority before the changes can be effected by the licensee.

For changes that can be notified at the point of licence renewal in Section 5.2, the licensee may proceed to effect the changes. Such changes shall be notified to the Authority at the point of licence renewal.

NOTE *For changes that require an Amendment, certain changes will have to be effected prior to the issuance of the updated QMS certificate, particularly for the purpose of allowing the Certification Body to perform a full audit to the change (e.g. a change in manufacturing site that requires issuance of a new ISO 13485 certificate). In such cases, licensees will still be required to submit an Amendment and obtain a conditional approval from the Authority prior to implementation of the change, and inform the Authority the date by which the updated certificate will be available for submission. Approval will be given on condition that the updated QMS certificate or any additional supporting documents, as requested by the Authority, is submitted by a stipulated deadline. Failure to subsequently submit the required documents will invalidate the existing licences held.*

In the event that the Amendment application for a change is rejected, all unapproved changes made to the activities of the licensee shall not be effected.

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## 6. LICENCE RENEWAL

All dealer's licences are valid for 12 months from the date of approval. Licensees are required to submit a licence renewal application to the Authority for each of the licences held, to ensure their licences remain valid for the duration of the licensee's activities.

To ensure that renewal application approvals are obtained by the dealer's licence expiry date, licensees are required to submit their renewal applications

via MEDICS no later than **40 calendar days** prior to the expiry date of their dealer's licence. An email notification reminder for licence renewal will be sent from the Authority to the licensee 60 calendar days before to the expiry date of the dealer's licence.

All pending Amendment submissions made for the licence to be renewed have to be approved before a licence renewal submission can proceed.

NOTE *If a change to a dealer's licence that requires an Amendment coincides with the time of licence renewal, the change is permitted to be submitted as part of the renewal application. However, the changes shall not be effected until approval of the licence renewal application has been given by the Authority.*

The supporting documents required for dealer's licence renewal are as follows:

| Manufacturer's Licence | Importer's Licence | Wholesaler's Licence |
|---|---|---|
| ISO 13485 certificate for finished medical device manufacturing | GDPMDS<br>OR<br>ISO 13485 certificate with scope of storage and distribution included | GDPMDS<br>OR<br>ISO 13485 certificate with scope of storage and distribution included |
| List of exempted Class A medical devices manufactured | List of exempted Class A medical devices imported | N.A. |
| Summary Table of Notifications at Point of Licence Renewal (Annex 2) | | |

If the licensee fails to provide all requested information within the stipulated timeline, or the submitted information is incomplete, deficient or contains unsolicited information, the application will be rejected.

Failure of the licensee to meet the deadline for licence renewal will lead to a suspension, and thereafter revocation, of their expired dealer's licence(s).
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## 7. 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;

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- the licensee fails to submit the renewal application or pay to the Authority within the prescribed time, the renewal fee as may be prescribed for the renewal of the dealer's licence;

  NOTE *Suspended licences will require 14 calendar days to be activated. This may affect the licensee's import consignments.*

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- 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 suspend all activities related to the manufacturing, importation or 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.

## 8. KEY REGULATORY RESPONSIBILITIES OF LICENCE HOLDERS AND REGISTRANTS

Under the *Act* and *Regulations*, a licensee has other responsibilities. The sections of the guidance document that follow describe the key obligations. It is imperative that a licensee has access to and is familiar with the current version of the *Act* and *Regulations* in order to meet the regulatory requirements.

### 8.1. Labelling

Section 18(1) of the *Act* states that no person shall supply a medical device unless the presentation of the device complies with prescribed requirements. The requirements are set out in the *Regulations*. All medical devices, including those not subjected to product registration, must comply with the labelling requirements.

### 8.2. Device Advertising

Part V of the *Act* outlines the requirements, controls and prohibition with regards to the advertising of medical devices. A person publishing advertisement that contravenes the *Act* and *Regulations*, such as a false or misleading advertisement, may be ordered to publish a corrective advertisement as specified by the Authority.

### 8.3. Furnishing of information

The *Act* requires the licensee and registrant of medical devices to furnish information or documentation regarding the medical devices within the specified period when requested by the Authority.

### 8.4. Verification of quality, safety and efficacy of health product

The *Act* requires the licensee and registrant to take measures to verify quality,

safety, or efficacy of medical devices. Measures may include product evaluation and testing.

### 8.5. Maintenance of Records

#### 8.5.1. Distribution Records

The *Act* requires that licensees and registrant each maintain records of distribution for each device sold. The distribution records should contain sufficient information to permit a complete and rapid withdrawal of the device from the market. The minimum retention period for distribution records should be the projected useful life of the product or two years after the product is shipped, whichever is longer. The distribution record maintained should also contain a record of the information of the implant when supplied by a healthcare facility.

#### 8.5.2. Complaint Handling

The *Regulations* requires licensees and registrants to maintain records of reported problems regarding medical devices they have to deal with. These records must include all actions taken in response to these problems.

### 8.6. Reporting of adverse events

The *Act* requires licensees and registrants of medical devices to report incidents involving devices. The *Regulations* specifies the timeline for reporting of events.

### 8.7. Field Safety Corrective Action

Licensees and registrants of a device are required to notify the Authority upon undertaking or intending to activate a FSCA, of the reason(s) for doing so. As soon as possible after completion of a FSCA, the licensees and registrants are to report to the Authority, the results of the FSCA and the action taken to prevent a recurrence of the problem.

## 9. QUALITY MANAGEMENT SYSTEMS AND GOOD DISTRIBUTION PRACTICE

Manufacturers of medical devices operate at a high level of quality assurance. This is achieved through establishing and maintaining quality management systems such as those conforming to standards like ISO 13485 R2 ► or Good Distribution Practice for Medical Devices (GDPMDS) (Secondary Assembly).◄ R2 This ensures that medical devices released for distribution are of appropriate quality.

This quality management system 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.

Importers and wholesalers of medical devices should ensure that the medical devices that they handle are stored at the correct conditions, including during transportation, and that contamination is avoided.

This can be achieved by implementation of Good Distribution Practice for Medical Devices (GDPMDS). Certification to GDPMDS is a mandatory requirement that importers and wholesalers must meet.

Certification to GDPMDS is to be performed by recognised certification bodies that are accredited by the Singapore Accreditation Council.

## 10. INSPECTIONS AND AUDIT

The Authority may conduct inspections of licensee to determine their compliance with the *Act* and *Regulations*.

## ANNEX 1 ◄ R2

## Summary of Licence Changes

| Type of change | Submit Amendment | Notify at point of licence renewal | Supporting documents required | Remarks |
|---|---|---|---|---|
| **Registrant account** | | | | |
| Registrant contact details, applicant info | Yes | N/A | No supporting documents required | A change in legal entity would require an application submission for a new Registrant account. |
| **Dealer's licence** | | | | |
| Change in current certification body | Yes | N/A | New QMS certificate from new certification body<br><br>Summary Table of Amendments | - |
| Change in company name | No | Yes | All supporting documents required during licence renewal | A change in legal entity would require the submission of new dealer's licence applications. Changes that accompany a change in legal entity cannot be submitted as an Amendment or Notification during licence renewal. |
| Sites/premises related to GDPMDS/ ISO 13485 activities (Addition) | Yes | N/A | Updated QMS certificate with new sites/premises listed<br><br>Summary Table of Amendments | - |

| | | | | |
|---|---|---|---|---|
| Sites/premises related to GDPMDS/ ISO 13485 activities (Removal) | No | Yes | All supporting documents required during licence renewal | |
| Scope of activities (Addition) | Yes | N/A | Updated QMS certificate with new scope of activities<br><br>Summary Table of Amendments | - |
| Scope of activities (Removal) | No | Yes | All supporting documents required during licence renewal | - |
| Categories of medical devices (Addition/Removal) that do NOT require addition of cold-chain management to GDPMDS certification | No | Yes | | |
| Categories of medical devices (Addition) That require addition of cold-chain management to GDPMDS certification | Yes | N/A | Updated QMS certificate with new categories and cold-chain management included in scope<br><br>Summary Table of Amendments | - |
| Change of third party logistics/outsourced activities (Addition/Removal) | Yes | N/A | Updated QMS certificate with address(es) of third party logistics/outsourced activity | - |

| | | | | |
|---|---|---|---|---|
| | | | locations included<br><br>Summary Table of Amendments | |
| Exempted Class A medical device list (Addition/Removal) | No | Yes | All supporting documents required during licence renewal | - |
| Type of dealer's licence | No | No | - | New dealer's licence application to be submitted |
| Changes to registered products | No | No | - | Change Notification to be submitted for the registered products affected by change in manufacturer's licence, in accordance to GN-21. |

## ANNEX 2 ◄ R2

### Summary Table of Amendments / Notifications at Point of Licence Renewal

| Type of change (according to Annex 1 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 3 ◄ R2

Attestation

The applicant is required to make the following attestation during submission of a dealer's license application in MEDICS:

*On behalf of the Manufacturer/ Importer/ Wholesaler,*

a. *I hereby attest that the information provided on this application and in any attached documentation is accurate, correct and complete.*

b. *I hereby attest that I have direct knowledge of the established procedures and systems in place in respect to distribution records, complaint handling, adverse event reporting and field safety corrective actions, including product recalls.*

c. *I hereby attest that the company has established procedure and system in place, where applicable, for handling, manufacturing, storage, delivery, installation, corrective action and servicing in respect to medical devices handled by the company, and*

d. *I am informed and I understand that it is a serious offence under Section 24(6) of the Health Products Act 2007 to make any statement or furnish any document which I know to be false or does not believe to be true in support of this application.*

If the information submitted during the application process is false or incomplete, the Authority may refuse to issue a licence.

## ANNEX 4 ◄ R2

License and Amendment Application Target Turn Around Time (TAT)

- 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.
- Screening and review will only start after receipt of the license fee.

| Application type | Screening | Review |
|---|---|---|
| New License Application | 7 working days | 7 working days |
| License Amendment Application | 7 working days | 7 working days |

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

**Contact Information:**

Medical Device Branch
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg
**T**: 6866 3560
**F**: 6478 9028

HSA
Health Sciences Authority