HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

MARCH 2009

MEDICAL DEVICE GUIDANCE

GN-15: Guidance on Medical Device Product Registration

Revision 3

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.

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1. INTRODUCTION

1.1. Purpose

This document is meant to provide general guidance on registration of medical devices under the Health Products Act 2007 (*Act*).

1.2. Background

The *Act* and Health Products (Medical Devices) Regulations (*Regulations)* requires all medical devices to be registered with the HSA prior to placing them on the Singapore market.

All medical devices shall meet the requirements of the *Act* and *Regulations*, its conditions of registration and any other applicable legislative requirements.

Registration of medical devices is:-

- to ensure that the Authority is aware of the medical devices that are used or that are available in the Singapore market;
- to assess that the medical devices meet appropriate levels of safety, quality and performance (for medium and high-risk medical devices); and
- to provide a means for the Authority to enforce requirements or take necessary actions to protect public health.

1.3. Scope

This document applies to all medical devices.

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: for the purposes of this guidance document, an applicant is the person applying for a medical device registration.

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

GLOBAL HARMONIZATION TASK FORCE (GHTF): A voluntary group of representatives from national medical device regulatory authorities and the regulated industry. The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness /performance and quality of medical devices, promoting technological innovation and facilitating international trade. The primary way in which this purpose is accomplished is via the publication and dissemination of harmonised documents on basic regulatory practices. These documents, which are developed by five different GHTF Study Groups, provide a model for the regulation of medical devices that can then be adopted/implemented by national regulatory authorities.

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: for the purposes of this guidance document, means any location that is used for activities dealing with medical devices, including storage, manufacture, etc.

PRODUCT OWNER: for the purposes of this guidance document, means a person who sells a medical device under his own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for one or more of the following activities:- designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on his behalf.

REGISTRANT: in relation to a registered health product, means the person who applied for and obtained the registration of the health product under the *Act*.

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

RETAIL: for the purposes of this guidance document, means selling or supplying it to a person who receives it for a purpose other than that of selling or supplying.

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

- supplying the health product to a person who obtains the health product for the purposes of supplying it again to some other person;
- supplying the health product to a person as a commercial sample in the normal course of a lawful trade;
- supplying the health product to a Government department or statutory body which requires the health product for the purposes of the public service or use in connection with the exercise of any statutory power;
- supplying the health product to a person or an institution concerned with

scientific education or research which requires the health product for the purpose of education or research;

- supplying the health product 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 health product to a person who requires to use the health product, other than by way of administration to one or more persons, for the purpose of his business or trade;
- supplying the health product by export to a party outside Singapore.

2. RISK CLASSIFICATION FOR MEDICAL DEVICES

The risk presented by a particular medical device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use. Other considerations include its intended user(s), its mode of operation and the technology used. The factors influencing device classification include the duration of medical device contact with the body, the degree of invasiveness, whether the medical device delivers medicinal products or energy to the patient, whether they are intended to have a biological affect on the patient and local versus systemic effects, etc. General medical devices are classified into four risk classes as show below:

Table 1: Classification system for General Medical Devices

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Surgical retractors / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	Moderate-high Risk	Lung ventilator / bone fixation plate
D	High Risk	Heart valves / implantable defibrillator

For medical devices used for a *in vitro* diagnostic purpose, commonly known as *in vitro* diagnostic (IVD) medical devices, the following factors are to be considered during risk classification: intended purpose of the medical device, technical/scientific/medical expertise of the intended user (lay person or professional), importance of the information to the diagnosis (sole determinant or one of several), and impact of the results to the individual and/or to public health.

Table 2: Classification system for *In Vitro* Diagnostic Medical Devices

CLASS	RISK LEVEL	DEVICE EXAMPLES
A (IVD)	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyser, prepared selective culture media
B (IVD)	Moderate Individual	Vitamin B12, Pregnancy self testing,

	Risk and/or Low Public Health Risk	Anti-Nuclear Antibody, Urine test strips
C (IVD)	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self testing, HLA typing, PSA screening, Rubella
D (IVD)	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

The classification rules to be used for determining risk classification of medical devices for the purpose of product registration in Singapore can be found in the *Regulations*.

3. REGULATORY CONTROL ON MEDICAL DEVICES

Imposition of regulatory controls takes into account the risk associated with a medical device. Hence, not all **medical devices** shall be subjected to product registration.

IMPORTANT:

Meeting the requirements of the *Health Products Act 2007* and *Health Products (Medical Devices) Regulation* does not exempt the dealers or medical devices from regulatory controls under Acts and Regulations in force that are applicable.

3.1. Medical device meant for export only

For medical devices imported solely for re-export or manufactured solely for export, the Authority shall be notified of their importation and exportation.

3.2. List of exempted medical devices

Certain medical devices, due to the low risk associated with their use, are exempted from product registration. The complete list of these medical devices and their intended purposes can be found in the *Regulations*.

The medical devices are solely exempted for a specific intended purpose, as

listed in the *Regulations*. The specific intended purpose also restricts any claims in advertising and promotional activities to those that are listed in the *Regulations* for the specific medical device.

If the proposed intended purpose of a medical device is different from that listed in the *Regulations*, then that medical device shall require product registration.

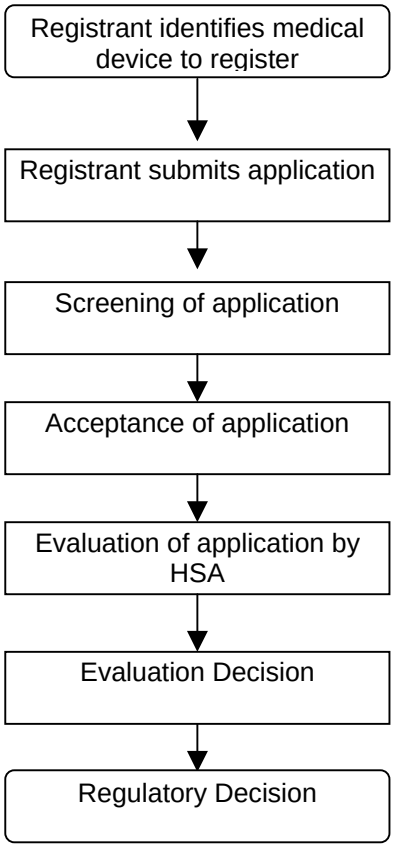
Exemption from product registration does not exempt the dealers (companies that manufacture, import or supply by wholesale) of these medical devices from their legal duties and obligations under the *Act* and *Regulations*. Hence, they are required to keep distribution records, complaint records, report adverse events and notify the Authority of Field Safety Corrective Actions (FSCA), etc.

3.3. All other medical devices

All other medical devices shall require registration or approval from the Authority before they can be imported or supplied in Singapore.

4. THE APPLICATION PROCESS FOR CLASS B, C AND D MEDICAL DEVICES

The process described below is applicable solely to class B, C and D medical devices.



First and foremost, always identify whether the device product is a medical device, that is, whether the device product meets the definition of a medical device. See Annex 1 for determination of medical devices. Registrants should seek clarification from the Authority when in doubt.

4.1. Pre-Submission Consultation

Once the device product has been established as a medical device and the submission dossier for product registration has been prepared based on the ASEAN Common Submission Dossier Template (CSDT) format (see Section 7 for more information on the format), a pre-submission consultation may be arranged with the Authority where necessary. A pre-submission consultation

may be necessary if there are specific issues or when there is uncertainty as to whether the application dossier will meet the prevailing submission requirements. Advice given by the Authority will be based on knowledge current at the time of the meeting. However, such advice is non-binding and shall not have direct bearing on the eventual outcome of the application concerned. The pre-submission consultation will be limited to one per company. Please submit a request for a pre-submission consultation using the request form available at www.hsa.gov.sg.

4.2. Submission of Application

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

The Registrant shall be required to make the following attestation during submission of a product registration application:

On behalf of the Product Owner and the Registrant,

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 objective evidence to establish that the above medical device meets safety, quality and performance requirements.*
c. *I hereby attest that there are no misleading claims made relating to the quality, safety and performance of the above medical device*
d. *I am informed and I understand that it is a serious offence under Section 30(10) of the Health Products Act 2007 to make any statement or furnish any document that I know to be false or do not believe to be true, in support of this application for registration.*

4.3. Screening of Application

The application will be screened before the application can be accepted for evaluation to ensure that there are no major deficiencies that would hinder the evaluation. If any major deficiencies are identified during the screening, an

input request will be made to the Registrant. The Registrant will be required to submit all of the requested information and material identified in the input request within **30 calendar days** from the date of request. Any deficiencies indicated must be addressed before the application can be accepted for evaluation.

If the Registrant anticipates difficulty in responding in full or within the specified timeframe, they should contact the Authority to discuss the request for information as soon as possible after receipt of the input request for information/clarification.

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

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

The following applications will be rejected at the screening stage:

- applications for device products that are not medical devices;
- applications not submitted in the prevailing required format;
- low risk (Class A) medical device applications submitted via the medium (Class B and C) and high risk (Class D) product registration route, or vice versa.

4.4. Acceptance of Application

Upon acceptance of an application, the Registrant will be billed for the evaluation fee.

4.5. Evaluation of Application

Evaluation will only begin after receipt of payment of the evaluation fee.

Evaluation by the Authority is based on the information submitted by the Registrant. Additional supporting data submitted after acceptance of the application will not be considered, unless the Authority requests for such data.

The Authority may engage external evaluators or experts in the evaluation process, where necessary. All external evaluators or experts are bound by agreement to protect the information made available to them. The identity of the external evaluators or experts shall be kept confidential.

During the course of the evaluation, the Authority may request for additional information or seek clarification on the information provided. Once an input request is submitted, a stop clock is started. The stop clock will end only when the Authority receives complete and satisfactory response(s) from the Registrant.

The Registrant will be required to submit all of the requested information and materials identified in the input request within **30 calendar days** from the date of request. **No reminder will be sent for the input request.**

If the Registrant anticipates difficulty in responding in full or within the specified timeframe, they should contact the Authority to discuss the request for information as soon as possible after receipt of the input request for information or clarification.

If the requested information cannot be provided in a reasonable timeframe, the Registrant will be requested to withdraw the application.

If the stop clock time exceeds the timeframe agreed to between the Authority and the Registrant, the application will be rejected. Once an application is rejected, a new application for the same medical device has to be submitted if the Registrant wishes to register the medical device. The new application should include documents to address all concerns raised in the input request.

4.6. Evaluation Decision

An evaluation decision is made based on the outcome of the Authority's evaluation of the submitted information. The decision can be one of the following:

- Registrable – where the Authority assessed that the medical device meets prevailing requirements of safety, quality and performance for its intended purpose and may be registered for local commerce; or
- Rejection – where the response provided by the applicant fails to address the deficiencies highlighted during the input request, or failure to adhere to agreed timeframe for input request, or where the medical device does not meet prevailing requirements of safety, quality and performance for its intended purpose.

4.7. Regulatory Decision

For medical devices that receive a "Registrable" evaluation decision, the Registrant may submit an application to list the medical device on the Singapore Medical Device Register (SMDR).

The Registrant is required to make the following attestation during submission of an application to list the medical device on the SMDR:

On behalf of the Product Owner and the Registrant,

a. *I hereby attest that the information provided on this application is accurate, correct and complete.*
b. *I hereby attest that I have objective evidence to establish that the above medical device meets safety, quality and performance requirements.*
c. *I hereby attest that there are no misleading claims made relating to the quality, safety and performance of the above medical device.*
d. *I am informed and I understand that it is a serious offence under Section 30(10) of the Health Products Act 2007 to make any statement or furnish any document that I know to be false or do not believe to be true, in support of this application for registration.*

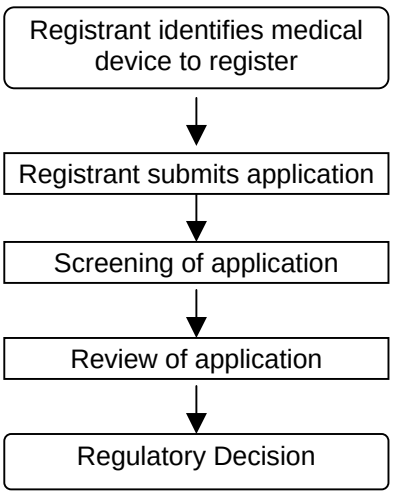
Registrants are required to ensure full compliance with the conditions of registration.

Conditions of registration may include post-approval studies. These are usually required for medical devices where not all the long-term questions about its safety and effectiveness have been answered and these can only be answered by a large clinical study. The Registrant is required to continue to study its safety and effectiveness and submit the results within the stipulated timeframe to the Authority.

The product registration on MEDICS is an electronic registration. **No hardcopy or paper certificate** will be issued upon registration of the medical device. If the Registrant wishes to have a hardcopy of the registration, the Registrant may request for a hardcopy certificate upon payment of a fee.

5. THE APPLICATION PROCESS FOR CLASS A MEDICAL DEVICES

The process described below is applicable solely to class A medical devices that are not exempted from medical device product registration.



5.1. Submission Requirements for Class A Medical Devices

Submission in CSDT format is not required for Class A medical devices. The following are the data requirements for Class A medical devices:

- copies (in English and in original colour) of:
  - the labels on the medical device and its packaging are to be provided for the primary and secondary levels of packaging. Labels must be provided for all the components of a medical device system, members of a medical device family and accessories submitted for registration. Alternatively, a representative label may be submitted for variants, provided the variable fields on the artwork are annotated, and the range of values for the variable fields are indicated;
  - the instructions for use (where applicable);
  - the patient information leaflet (where applicable); and
  - the promotional material (including brochures and catalogues).
- for sterile medical devices: the sterilisation validation report.
- for medical device with measuring function: certification on medical device metrology or equivalent.
- for active medical devices: certification to electrical safety standards, e.g. IEC 60601

The name, address and contact information (telephone, fax and email) for all authorised importers of the medical device shall also be provided.

For Class A *In Vitro* Diagnostic (IVD) medical devices containing materials of animal, human, microbial and/or recombinant origin, the following information must be submitted in addition to the information above:

- a list of all materials of animal, human, microbial and/or recombinant origin used in the IVD medical device and in the manufacturing process of the IVD medical device. This includes, but not limited to animal or human cells, tissues and/or derivatives, and cells, tissues and/or derivatives of microbial or recombinant origin; and
- identity of immediate sources of the above.

5.2. Review of Application

For class A medical devices, the risk associated with the use of the medical

device has been determined to be low. The Authority **does not** conduct a pre-market evaluation of the safety, quality and performance for such medical devices.

The Authority's role in the review of the application is to determine that:

- the class A medical device is correctly classified, i.e. it is not a class B, C or D medical device;
- the intended purpose/ indications for use for the class A medical device is appropriate for the design of the medical device, i.e. no exaggerated claims are made.

In the event that the medical device is incorrectly classified or the product claims are questionable, the Authority may request for the **full technical documentation** of the medical device.

5.3. Regulatory Decision

Class A medical devices shall be listed on the SMDR after the Authority has verified their risk classification and medical device claims.

All product registration will be issued an electronic registration in MEDICS. **No hardcopy or paper certificate** will be issued upon registration of the medical device. If the Registrant wishes to have a hardcopy of the registration, the Registrant may request for a hardcopy certificate upon payment of a fee.

6. EVALUATION ROUTES

For class B, C and D medical devices, there are two evaluation routes: abridged evaluation and full evaluation.

6.1. Abridged evaluation route

The abridged evaluation route applies to medical devices that have been evaluated and approved in **at least one** of the GHTF founding members (Australia, Canada, European Union, Japan and United States of America). The type of approvals from each country/region that qualify for abridged evaluation are:

Table 3: Type of Approvals that Qualify for Abridged Evaluation

Country/Region	Approval Type
Australia	Therapeutic Goods Administration (TGA) licence
Canada	Health Canada Licence
European Union (EU)	For general medical devices: • Annex II Section 3 or Annex V of MDD (for Class IIA) • Annex II Section 3 or Annex III coupled with Annex V of MDD (for Class IIB) • Annex II Section 3 and 4 of MDD (for Class III) • Annex II Section 3 and 4 of AIMDD (for active implantable medical devices) For IVD medical devices: • Annex IV (including Section 4 and 6) of IVDD (for List A IVD) • Annex IV (excluding Section 4 and 6) or Annex V coupled with Annex VII of IVDD (for List B and self-testing IVD)
Japan	Ministry of Health, Labour and Welfare (MHLW) Licence
United States of America (USA)	• US FDA 510(K) clearance letter [510(K) exempted products do not qualify for abridged evaluation

	route.]; or • US FDA PMA approval letter

For the abridged route, all aspects of the medical device's quality including packaging, labelling (including instruction of use), and intended purpose/indications for use, intended for supply in Singapore shall be the same as that approved by the agency that has approved the medical device.

The abridged evaluation route allows the Registrant to submit summary data sets in certain sections of the submission document. The Authority reserves the right to request for detailed test results or data, if deemed necessary.

An approval by a reference regulatory agency does not bind the Authority, and the Authority is not obligated to register a medical device in Singapore based on a prior approval from a reference agency.

6.2. Full evaluation route

All other medium and high-risk medical devices shall be subjected to the full evaluation route.

7. APPLICATION REQUIREMENTS

Regulatory controls should be proportional to the level of risk associated with a medical device. The level of regulatory control increases with increasing degree of risk, taking account of the benefits offered by use of the medical device.

7.1. Data requirements for Medical Devices

Documents in support of applications submitted to the Authority should be organised according to the ASEAN Common Submission Dossier Template (CSDT) format. Annexes 2 and 3 summarise the CSDT submission requirements for abridged and full dossiers. Annexes 2 and 3 are for

reference only and Registrants are to refer to the Guidance on Preparation of a Product Registration Submission for General Medical Devices Using the ASEAN CSDT and the Guidance on Preparation of a Product Registration Submission for *In Vitro* Diagnostic Medical Devices using the ASEAN CSDT for details. In order to facilitate the screening and evaluation process, Registrants are advised to adhere to the prevailing required format. As stated above, applications not presented in the correct format shall be rejected.

In instances where there is a need to further assess the quality, safety and performance of a medical device, the Authority may request additional information or impose conditions not otherwise described in available guidance documents and guidelines.

In addition to a dossier prepared in the CSDT format, the following documents/information shall also be submitted in the application:

- name, address and contact information (telephone, fax and email) for all authorised importers and wholesalers of the medical device
- a Declaration of Conformity for the medical device (please refer to the Guidance on Declaration of Conformity for details and format); and
- a Letter of Authorisation for the Registrant by the product owner (please refer to Annex 4).

IMPORTANT:

For a period of six months after the start of Phase 2 of the medical device regulation implementation, the Voluntary Product Registration (VPR) format will still be accepted in addition to the CSDT format. This exception is meant for registrants who have already prepared applications in the VPR format prior to the start of Phase 2.

7.2. Data Requirements for Combination Products

A combination product is defined as a product that combines a medicinal product and a medical device such that the distinctive nature of the medicinal

product component and device component is integrated in a singular product. 'Integrated' means a single component product (such as coated or incorporated within) rather than a pack containing the two components (i.e. a medicinal product and a device).

Examples of products meeting the definition of combination products are:

- syringes supplied pre-filled with a medicinal product,
- drug eluting stents,
- heparin coated catheters.

Examples of products not meeting the definition of combination products are:

- procedure packs containing empty syringes and vials of medicinal product,
- medicinal product and medical device separately packaged but meant to be used together to achieve an intended purpose.

The Guidance on Product Registration of Combination Products will be published in the near future.

7.3. Language requirements

All documents to be submitted in support of product registration must be in **English**. The following rules apply for the acceptance of translations:

- the translation shall be prepared by a court certified translator (sworn translator);
- the translation must be on official letterhead and bear the stamp or signature of the translator or translation service;
- the translation shall bear a signed and dated statement by the translator that it is an accurate translation of the original document;
- the translation requires notarisation by a notary public to establish the authenticity of the signature on the document, before the document is authenticated.

In the event the translation was prepared in-house or by any person with a

vested interest in the outcome of the application made, the translation shall be proof-read by an independent and court certified translator. An official letter declaring that the English translation was proof-read and conforms to the source language document must be provided.

7.4. Grouping of medical devices

Each application shall contain only one of the following:

- a SINGLE medical device;
- one medical device FAMILY;
- one medical device SYSTEM;
- one medical device TEST KIT;
- one medical device GROUP.

Please refer to the Guidance on Grouping of Medical Devices for Product Registration.

8. CHANGE NOTIFICATION

The Registrant is required to notify the Authority whenever there is a change to any information declared by him to the Authority at the point of application. For significant changes, the Registrant shall not allow the changed medical devices into the Singapore market unless the Authority has given its approval for the change.

The Guidance on Change Notification will be published in the near future.

9. AMENDMENTS OF REGISTRATION

If there are any errors in the information listed in SMDR for the medical device, the Registrant shall submit a written request to the Authority to make the necessary amendments.

10. SUSPENSION AND REVOCATION OF REGISTERED MEDICAL DEVICE

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

- the approval of the medical device registration has been obtained through fraud or misrepresentation;
- the medical device registration has contravened or is contravening any provision of the *Act* and *Regulations*, any conditions attached to the medical device registration or any other prescribed requirement;
- the medical device registration no longer satisfies any of the prescribed requirements based on which the product registration was issued; or
- it is in the public interest to do so.

The compliance history of the medical device and the risk to the health and safety of patients, users or other persons of allowing the medical device registration to remain valid shall also be considered.

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

As soon as a registered product is suspended or revoked, the Registrant and all dealers are required to immediately suspend all activities related to the importation or supply of the affected medical devices until such time as the registered product is reinstated.

Suspended product registration may be reinstated if the situation that gave rise to the suspension is corrected or the reason for the suspension was unfounded.

Revoked product registration shall not be reinstated. The Registrant may

submit an application for a new product registration if the situation that gave rise to the revocation is corrected.

11. FEES

Please refer to the fee schedule for details on the fees.

The application fee is payable at the time of submission in MEDICS. Evaluation fees are payable upon acceptance of the application for evaluation.

The screening fees are **non-refundable** once the application has been successfully submitted via MEDICS. Registrant is advised to ensure that the product application is compiled according to the prevailing required format. Failure to arrange the submission documents accordingly will lead to rejection of the application.

The evaluation fees are **non-refundable** once the application is accepted for evaluation, regardless of the final decision by the Authority. Withdrawal of the application after the application is accepted will result in **forfeiture** of the evaluation fees. Rejection of the application by the Authority will also result in the **forfeiture** of the evaluation fees.

ANNEX 1

DETERMINATION OF MEDICAL DEVICES PRODUCTS

Medical devices are intended for use for a medical purpose. The product owner assigns a medical purpose to the medical device. The product owner determines through the label, the instructions for use and the promotional materials related to a given medical device its specific medical purpose.

As the legislation essentially aims to protect patients and users, the medical purpose relates to finished products regardless of whether they are intended for use alone or in combination. This means that the legislation becomes valid for products having reached the stage of manufacture where they are ready for supply to the final user.

Registrants should seek clarification from the Authority when in doubt.

A. Concept of Finished device

"Finished device" does not only refer to a medical device that is in a state ready for use. Prior to use by the final user, further preparatory processing, preparation, configuration, installation, assembling, adaptation or fitting to the needs of the user or patient may be required. Examples of activities carried out by the final user includes:

- sterilisation of medical devices supplied non-sterile;
- assembling of systems;
- configuration of electronic equipment;
- preparation of a dental filling;
- adaptation of prosthesis to the needs of the patient.

The above activities are normally not considered manufacturing activities if they are carried out by the final user as part of the use or preparation for use.

B. Raw materials and intermediate products

Raw materials or intermediate products are normally not medical devices. Such raw materials may need to have properties or characteristics that are determinant for the safety and quality of finished devices. It is therefore the responsibility of the physical manufacturer of finished medical devices to select and control by adequate means his raw materials or intermediate products.

C. Spare parts of medical devices

Spare parts supplied for replacement of existing components of a medical device are not medical devices. If spare parts, however, change significantly the characteristics or performances of a medical device, such spare parts are to be considered as medical devices in their own right.

D. Devices for toiletry or cosmetic purpose

The following products intended to have a toiletry or cosmetic purpose are not medical devices, even though they may be used for prevention of a disease.

- tooth brushes
- dental sticks
- dental floss

E. Products that are not medical devices

The following products are not used medically in preventing, diagnosing, curing or alleviating diseases, ailments, defects or injuries. There is currently either no objective evidence or insufficient objective evidence to support claims that these products can be used for a medical purpose. Hence these products shall not be considered medical devices. The list below is not an exhaustive list of such products.

- slimming devices (such as slimming belts);
- massagers;

- magnetic therapy devices;
- aromatherapy/audio therapy devices;
- beds, chairs, pillows and bedding;
- spa baths and saunas;

Generally, these products are consumer-oriented and rely on the body's normal response to an external physical change. Products intended for these purposes can only make claims about general well-being and must not make specific therapeutic claims by way of reference to particular diseases or medical conditions. There shall be no claims to suggest, directly or indirectly, that the improvement in general well-being will lead to therapeutic effects. Severe penalties apply for false or misleading claims.

Registrants should seek clarification from the Authority when in doubt.

F. Aids for handicapped persons

Equipment intended for alleviation of or compensation for a handicap must display a direct link between the corrective function and the person concerned. Therefore, the following equipment are not considered to be medical devices:

- acoustic signals at traffic lights,
- special water taps, toilet equipment for handicapped.

G. Multipurpose products

Products with multiple purposes that may be used occasionally in a medical environment are normally not medical devices, unless a specific medical intended purpose is assigned to them. Examples include multipurpose PC, printer, scanner, screen, etc.

ANNEX 2

CSDT requirements for General Medical Devices

<table>
<tr><th rowspan="2">CSDT Section No.</th><th rowspan="2">CSDT Section Heading</th><th colspan="3">Abridged dossiers</th><th colspan="2">Full dossiers</th></tr>
<tr><th>Class B</th><th>Class C</th><th>Class D</th><th>Class B</th><th>Class C & D</th></tr>
<tr><td>3.0</td><td>Executive Summary</td><td colspan="5" rowspan="3">Required[1]</td></tr>
<tr><td>4.1.1</td><td>Essential Principles and Evidence of Conformity</td></tr>
<tr><td>4.2</td><td>Device Description</td></tr>
<tr><td>4.3</td><td colspan="6">Summary of Design Verification and Validation Documents</td></tr>
<tr><td></td><td>• Sterilisation validation</td><td colspan="3" rowspan="4">Summary[2]</td><td colspan="2" rowspan="4">Detailed Information[3]</td></tr>
<tr><td></td><td>• Shelf life data</td></tr>
<tr><td></td><td>• Projected useful life</td></tr>
<tr><td></td><td>• Metrological requirements</td></tr>
<tr><td rowspan="3">4.3.1</td><td colspan="6">Pre-clinical Studies</td></tr>
<tr><td>• All pre-clinical studies as appropriate for the device, e.g. physical test data, biocompatibility studies, animal studies and software verification and validation studies</td><td colspan="3">Summary</td><td colspan="2" rowspan="2">Detailed Information</td></tr>
<tr><td>• Biological safety (for devices containing biological materials)</td><td colspan="3">Detailed information</td></tr>
<tr><td rowspan="3">4.3.2</td><td colspan="6">Clinical Evidence</td></tr>
<tr><td>• Clinical evaluation report</td><td>May be required for certain medical devices</td><td colspan="2">Required</td><td rowspan="2">May be required for certain medical devices</td><td rowspan="2">Required</td></tr>
<tr><td>• Copies of studies referenced in report</td><td>Not required</td><td colspan="2">Not required</td></tr>
<tr><td>4.4</td><td>Device Labelling</td><td colspan="5">Required</td></tr>
</table>

4.5	Risk Analysis	May be required for certain medical devices	Required
4.6	Manufacturer Information	Required	

[1] Required: Indicates that the section is to be provided as described in the Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT.

[2] Summary: Indicates that a summary of the studies undertaken is to be provided. The summary should include a brief description of the study objectives, test methods, results and conclusions.

[3] Detailed information: Indicates that full study reports containing complete descriptions of the objectives, protocols, methods of data analysis, results and conclusions are to be provided.

ANNEX 3

CSDT requirements for *In Vitro* Diagnostic Medical Devices

<table>
<tr><th rowspan="2">CSDT Section No.</th><th rowspan="2">CSDT Section Heading</th><th colspan="3">Abridged dossiers</th><th colspan="2">Full dossiers</th></tr>
<tr><th>Class B (IVD)</th><th>Class C (IVD)</th><th>Class D (IVD)</th><th>Class B (IVD)</th><th>Class C & D (IVD)</th></tr>
<tr><td>3.0</td><td>Executive Summary</td><td colspan="5" rowspan="3">Required[1]</td></tr>
<tr><td>4.1.1</td><td>Essential Principles and Evidence of Conformity</td></tr>
<tr><td>4.2</td><td>Medical Device Description</td></tr>
<tr><td rowspan="2">4.3.1</td><td colspan="7">Summary of Design Verification and Validation Documents: Preclinical Studies</td></tr>
<tr><td>• Analytical Sensitivity
• Analytical Specificity
• Precision (Repeatability/ Reproducibility)
• Linearity/Assay's Measuring (Reportable Range)
• Traceability, & Expected Values (Controls, Calibrators, Methods)
• Cut-off Value
• Trueness
• Stability of reagent
• Stability of specimen type
• Devices containing Instrument and Articles, if any (ie. Accuracy, Precision/Reproducibility , Linearity, Carryover, Interfering Substances, Shelf-life)
• Sterilisation validation, for any sterile product
• Software verification and validation, if any</td><td colspan="3">Summary[2]</td><td colspan="2">Detailed Information[3]</td></tr>
</table>

	• Devices containing Biological Material, if any	Detailed Information	Detailed Information	
4.3.2	Summary of Design Verification and Validation Documents: Clinical Evidence			
	• Clinical (Diagnostic) Sensitivity • Clinical (Diagnostic) Specificity • Comparison Studies Using Clinical Specimens • Clinical Studies/ Performance evaluation studies involving human specimens • Reference Interval (Expected Values) • Performance evaluation studies under simulated conditions for the normal conditions of use, including for self-testing and near patient conducted by lay person and trained personnel • Batch Release	Summary	Detailed Information	
	• Use of Existing Bibliography	Not required	May be required for certain medical devices	Required
4.4	Device Labelling	Required		
4.5	Risk Analysis	May be required for certain medical devices	Required	
4.6	Manufacturer Information	Required		

[1] Required: Indicates that the section is to be provided as described in the Guidance on Preparation of a Product Registration Submission for *In Vitro* Diagnostic Medical Devices using the ASEAN CSDT.

[2] Summary: Indicates that a summary of the studies undertaken is to be provided. The summary should include a brief description of the study objectives, test methods, results and conclusions.

[3] Detailed information: Indicates that full study reports containing complete descriptions of the objectives, protocols, methods of data analysis, results and conclusions is to be provided.

ANNEX 4

Letter of Authorisation Template

[To be printed on Company Letterhead of Product Owner]

Medical Device Branch
Therapeutic Products Division
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for *[name of Registrant]*

We, *[name of Product Owner]*, as the Product Owner, hereby authorise *[name of Registrant],* as the Registrant to prepare and submit applications for the evaluation and registration of medical devices to the Health Sciences Authority on our behalf.

This authorisation shall apply to the following medical devices:

[List containing product names of medical devices]

We also authorise *[name of Registrant]* to make declarations and to submit documents on our behalf, regarding the above medical devices, in support of this application. These declarations and submissions are made pursuant to the requirements of the Health Products Act 2007, the Health Products (Medical Devices) Regulations and any other applicable laws that may also be in force.

Yours Sincerely,

[Signature]

[Full Name and Title of Senior Company Official]

[Company stamp]

ANNEX 5

Product Evaluation Target Turn Around Time (TAT)

- All turn around time 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.
- TAT will be extended if the evaluation involves an external expert. This usually applies to products that incorporate novel technologies or materials, etc.
- TAT for evaluation will only start after receipt of the evaluation fee and its installment payments, if applicable.

<table>
<tr><th>Risk Classification</th><th>Screening</th><th>Abridged Evaluation</th><th>Full Evaluation</th><th>Registration</th></tr>
<tr><td>Class B</td><td rowspan="4">20 working days</td><td>60 working days</td><td>120 working days</td><td rowspan="4">20 working days</td></tr>
<tr><td>Class C</td><td>120 working days</td><td>180 working days</td></tr>
<tr><td>Class D</td><td>180 working days</td><td>270 working days</td></tr>
<tr><td>Incorporating a medicinal product</td><td colspan="2">Case by Case (about 270 working days)

(Device will be jointly evaluated by MDB and PBB. Actual TAT will depend on type and nature of product. For example, new medicinal chemical entity will require longer evaluation time than a well characterised chemical entity.)</td></tr>
</table>

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Officers:

Mr Cai Yiting
Regulatory Specialist

Mr Sanjay S Kumar
Regulatory Specialist

Medical Device Branch
Therapeutic Products Division
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HSA
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