HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

May 2015

MEDICAL DEVICE GUIDANCE

GN-21: Guidance on Change Notification for Registered Medical Devices

Revision 3.2

HSA
Health Sciences Authority

PREFACE

R3.1 ►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. ◄ **R3.1**

Contents

1. INTRODUCTION

1.1. Purpose

Medical devices undergo changes as part of their product life cycle. This guidance document is intended to aid Registrants in determining whether a Change Notification has to be submitted for a medical device that is registered on the Singapore Medical Device Register (SMDR). Under the *Health Products (Medical Devices) Regulations 2010*, registrants are required to notify changes concerning registered medical devices to the Authority.

1.2. Background

Medical devices are classified into four risk classes (A to D) based on the classification rules set out in *GN-13: Guidance on the Risk Classification of General Medical Devices* and *GN-14: Guidance on the Risk Classification of In-Vitro Diagnostic Medical Devices*. Class A represents the lowest risk medical devices and Class D represents the highest risk medical devices.

These guidelines to Change Notification are based on the principles of safety, quality and efficacy of medical devices supplied in Singapore. Changes to a medical device can affect its safety, quality or efficacy. The Change Notification must be approved prior to the modified device being supplied in Singapore, unless otherwise indicated.

1.3. Scope

This guidance document applies to all medical devices registered on the SMDR. It sets out points for consideration by the Registrant when a registered medical device is in the process of modification. Owing to the various possible scenarios for changes made to a device, it is not the intention of this guidance document to describe every permutation and type of change that can occur. The Registrant and/or the Product Owner may contact the Medical Device Branch at hsa_md_info@hsa.gov.sg, for any clarifications regarding the classification of specific changes to a registered medical device.

This guidance document is also applicable to situations when a registered device undergoes any changes or proposed changes, including labelling changes, as a result of a reportable Adverse Event (AE) or an on-going Field Safety Corrective Action (FSCA).

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.

ACCESSORY: for the purposes of this guidance document, an accessory is an article with an intended purpose as a medical device and that is intended specifically by its Product Owner to:

- be used together with a medical device to enable that device to be used in accordance with its intended purpose as a medical device, or
- augment or extend the capabilities of that device in fulfilment of its intended purpose as a medical device

and therefore should be considered a medical device.

CONTROL MECHANISM: for the purpose of this guidance document, a means for verifying or checking that the specifications or outputs of the medical device meet a standard or predetermined result.

LABEL (*as set out in the Act*): in relation to a health product or an active ingredient, means any written, printed or graphic representation that appears on or is attached to the health product or active ingredient or any part of its packaging, and includes any informational sheet or leaflet that accompanies the health product or active ingredient when it is being supplied.

INTENDED PURPOSE: The use for which the medical device is intended according to the specifications of its Product Owner as stated on any or all of the following:

- the label of the medical device;
- the instructions for use of the medical device;
- the promotional materials in relation to the medical device.

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

OPERATING PRINCIPLE: for the purpose of this guidance document, the means by which a medical device produces or brings about a desired or appropriate effect.

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

(a) supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

(b) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

QUALITY MANAGEMENT SYSTEM: for the purpose of this guidance document, means certification to ISO 13485 or its equivalent.

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 the *Act*.

2. HOW TO USE THIS GUIDANCE

When several simultaneous changes are being implemented on a registered device, this guidance document should be used to assess each change separately. If a Change Notification is required, the Registrant shall describe how the modified device differs from the previously registered device (or device type) using Annex 1.

Registrants are reminded that the determination of documents required for Change Notification should be made through reference to all changes detailed in section 3 and **not solely** on one category of change.

Changes to accessories of registered medical devices will also come within the purview of this document.

This guidance document should be read together with other relevant guidance documents, including but not limited to:

- GN-12 Guidance on Grouping of Medical Devices for Product Registration
- GN-13 Guidance on the Risk Classification of General Medical Devices
- GN-14 Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices
- GN-15 Guidance on Medical Device Product Registration
- GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
- GN-18 Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostic (IVD) Medical Devices using the ASEAN CSDT

Not all changes to a registered medical device would fall under the scope of Change Notification. Qualification for Change Notification is dependent on the overall significance of the change, and its impact on safety, quality and/or efficacy of the medical device.

Some changes that will NOT qualify for Change Notification and require the submission of a NEW Pre-market Product Registration include:

- Change to the intended purpose of a registered medical device;
- Change to the risk classification of a registered medical device;
- Addition of variant(s) not considered a permissible variant as listed in GN-12 Guidance on Grouping of Medical Devices for Product Registration;
- Change to the medicinal substance in a device that incorporates a medicinal product in an ancillary role;
- An addition of medical devices with different device proprietary names into a single FAMILY listing even when they satisfy the FAMILY grouping requirements

The Registrant and/or the Product Owner should contact the Medical Device Branch, HSA, if there are any queries on whether a change in the registered device may require a new product registration.

3. CATEGORIES OF CHANGES

The following sections discuss the broad principles relating to particular types of changes and the relevant categories which these changes would be classified under. Changes to registered medical devices that require the submission of a Change Notification are classified into four categories namely:

a. **Technical Changes** for Class C and D medical devices affect the safety, quality or efficacy of these medical devices. These require HSA's approval prior to implementation of the change in Singapore.
b. **Review Changes** (closed list of changes) for Class A and B medical devices affect the safety, quality or efficacy of these medical devices. These require HSA's approval prior to implementation of the change in Singapore.
c. **Administrative Changes** include changes to the information submitted at the point of registration of the medical device and typically affect the SMDR listing information. These require HSA's approval prior to implementation of the change in Singapore.
d. **Notification Changes** may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.

NOTE: Change Notification for all change(s) or proposed change(s) to registered medical devices which falls in the context, is in associated with, or is a consequence of, on-going Field Safety Corrective Actions (FSCAs) and/or open reportable Adverse Events (AEs) shall require prior approval from HSA prior to implementation of the proposed changes. This clause applies to all registered medical devices (Class A to D) regardless of the category of change selected (as per Section 3.1 or Section 3.2). Exception to this clause shall require the Registrant to possess a written advice from HSA that states otherwise.

3.1. Categories of Changes for Class C and D Medical Devices

Change Notification for Class C and D devices will fall into either one of the three following categories:

a. **Technical Changes**

b. **Administrative Changes**

c. **Notifications** *(closed list of changes)*

Table 1 presents guiding principles for the identification and classification of the category of Change Notification applicable for each proposed type of change to registered Class C and D medical devices. Table 1 shall be applied to determine the category of Change Notification applicable to these medical devices.

Only changes classified as 'Notifications' in Table 1 are a closed list and will not be subject to review unless the change falls in the context of, or is a consequence of a reportable AE or a FSCA. Changes classified as “Technical” and “Administrative” changes are not intended to be a closed list of changes.

Table 1 - Categories of Change Notification

Proposed type of change	**Change Notification Category**
1. Change in Manufacturing Facility, Process and Quality Management System (QMS)	
1 A All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes	Shall be classified as **Administrative Changes.** These changes require approval from HSA prior to implementation.
1 B All changes to manufacturing processes (including changes made to outsourced processes) that result in a change in specifications of a registered medical device	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.
1 C All changes to sterilisation processes (including changes made	Shall be classified as **Technical Changes.** These changes require

Proposed type of change	Change Notification Category
to outsourced processes)	approval from HSA prior to implementation.
1 D All changes to Quality Management System (QMS) certificates for manufacturing and sterilisation facilities	Shall be classified as **Administrative Changes.** These changes require approval from HSA prior to implementation.
Unless the change only - involves an update of certificate QMS validity date only **OR;** - involves a cancellation of QMS scope on the certificate for any of the multiple existing manufacturing facilities (that is not due to safety, quality and/or efficacy of the device), **OR;** - involves the change in certification body with no change in scope of the certification **OR;** - involves the expansion of scope of the QMS certification which does not affect the registered medical device	Shall be classified as **Notifications**. These changes may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.
2. Changes in Design or Specifications of a registered medical device	
2 A All changes to the control mechanisms, operating principles and/or design characteristics of a	Are classified as **Technical Changes** that require approval from HSA prior to implementation.

Proposed type of change	Change Notification Category
registered medical device	
Unless the change only - involves a design change that does not affect the safety, quality or efficacy of the medical device (e.g. changes that improve device ergonomics, aesthetic modification of the device)	Shall be classified as **Notifications**. These changes may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.
2 B All changes in specifications (including shelf life, stability and expiry date) of a registered medical device**.**	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.
Unless the change only - involves a change to software version number that **does not** affect safety, quality or efficacy of the medical device, such as: • Software changes solely to correct an inadvertent software error which does not add new functions, does not pose any safety risk and is intended to bring the system to specification; • Software changes which augment interfacing to other non-medical peripherals such as printers or VDUs and which has no diagnostic or therapeutic function; • Software changes which only	Shall be classified as **Notifications**. These changes may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.

Proposed type of change	Change Notification Category
modifies the appearance of the user interface with no risk to diagnostic or therapeutic function of the device.	
3. Changes to materials in a General Medical Device	
3 A All changes to biological materials that involve a change in type, source, processing and/or supplier of cells, tissues and/or derivatives of animal, human, microbial or recombinant origin without a change in the intended purpose of the biological material	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.
3 B All changes to materials or material formulation (of non-biological origin), including changes to device coating or surface modification techniques, that involve materials that make direct/indirect contact with body tissues and fluids, or are absorbed by the body	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.
3 C All changes to materials that are used for shielding in medical devices emitting ionising radiation	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.
3D All changes to the radiation source (e.g. radioisotopes)	Shall require the submission of a **New Premarket Application** to

Proposed type of change	Change Notification Category
	HSA.
3 E All changes to concentration or drug specifications (DS) of medicinal substances in medical devices that incorporate medicinal substances in an ancillary role	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.
3 F All changes to the type of medicinal substances in medical devices that incorporate medicinal substances in an ancillary role	Shall require the submission of a **New Premarket Application** to HSA.
4. Changes to materials in an *In-Vitro Diagnostic (IVD)* Medical Device	
4 A All changes to materials that affect performance specification of a registered IVD medical device including changes to biological materials that involve a change in type, source, processing and/or supplier of cells, tissues, and/or derivatives of animal, human, microbial or recombinant origin	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.
4 B All changes to the radiation source (e.g. radioisotopes in radioimmunoassay)	Shall require the submission of a **New Premarket Application** to HSA.
5. Changes to labelling of medical devices All changes in labelling, that are a consequence of a change that requires a technical change notification, shall be classified as **Technical Changes.**	
5 A	

Proposed type of change	Change Notification Category
All changes to the labelling of medical devices that involve addition and/or revision of the approved indications for use	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.
Unless the change only - involves a reduction of indications for use not arising due to device safety, quality or efficacy concerns	Shall be classified as **Administrative Changes.** These changes require approval from HSA prior to implementation.
5 B All changes to the labelling of medical devices that involve addition, removal and/or revision of warnings, precautions and/or contraindications	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.
Unless the change only - involves addition of contraindications, warnings and/or precautions not arising due to safety, quality or efficacy concerns.	Shall be classified as **Notifications**. These changes may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.
5 C **Labelling changes that** - modify the approved method of use **OR** - involve a change from 'professional use only' to 'home use'	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.
5D Labelling changes that involve	Shall be classified as **Notifications**.

Proposed type of change	Change Notification Category
clarification of existing instructions for use, not affecting safety, quality or efficacy of the medical device	These changes may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.
5 E **Labelling changes that only** - involve changes in layout, colour, font sizes and design, without change in prominence of precautions, warning and contraindications, **OR** - involve addition and/or removal of languages not required by the Authority, **OR** - involve the addition of reference agencies' approvals (e.g. CE marking)	Shall be classified as **Notifications**. These changes may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.
5 F Other labelling changes	Shall be classified as **Administrative Changes.** These changes require approval from HSA prior to implementation.
6. Changes to registered medical devices listing information	
6 A Addition of new medical devices to a device listing	Shall be classified as **Technical Changes.** These changes require approval from HSA prior to implementation.

Proposed type of change	Change Notification Category
Unless the change only - involves the addition of new devices of the same design, within the existing range of sizes already registered. **OR** involves addition of a new device with design change that does not affect the safety, quality or efficacy of the medical device (e.g. changes that improve device ergonomics, aesthetic modification of the device)	Shall be classified as **Administrative Changes.** These changes require approval from HSA prior to implementation.
Unless the change only - involves an addition of non-sterile Class A medical device accessories that complement the registered medical device as a system	Shall be classified as **Notifications**. These changes may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.
6 B All deletions of models from medical device listing	Shall be classified as **Administrative Changes.** These changes require approval from HSA prior to implementation.
Unless the change only - involves the reduction in the number of models listed due to obsolescence and not due to safety, quality or efficacy considerations	Shall be classified as **Notifications**. These changes may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.

Proposed type of change	Change Notification Category
6 C All changes to medical device listing that involve an increase or reduction in the number of devices in a pack of a registered device	Shall be classified as **Notifications**. These changes may be implemented immediately upon receipt of the acknowledgement email from HSA after submission via MEDICS.
6 D All changes to the Product Name **And/ OR** Product Identifier	Shall be classified as **Administrative Changes.** These changes require approval from HSA prior to implementation.
6 E All changes in the Product Owner including changes in Product Owner Name and Address	Shall be classified as **Administrative Changes.** These changes require approval from HSA prior to implementation.
6 F A change in regulatory status on rejection or withdrawal in any reference agencies for models registered on the SMDR.	Shall be classified as **Notifications**.

3.2. Categories of changes for Class A and B Medical Devices

The type of proposed changes to registered Class A and B devices shall fall into either one of these three following categories:

a. **Review Changes** *(closed list of changes)*
b. **Administrative Changes**
c. **Notifications**

Review Changes' are a closed list of changes to registered Class A and B medical devices that significantly affect the safety, quality or efficacy of

medical devices and hence require HSA's approval prior to implementation. The closed list of 'Review Changes' for registered Class A and B devices that significantly affect the safety, quality or efficacy of medical devices and hence require HSA's approval prior to implementation are:

(i) Change(s) to indications for use of the registered medical device (except reduction of indications for use not arising due to device safety, quality or efficacy concerns);

(ii) Addition of new model(s) (except Class A non-sterile accessories) to a registered medical device listing;

(iii) Change(s) to the sterilisation method and/or process (e.g. from Gamma Irradiation to Ethylene Oxide, etc.);

(iv) Addition, removal and/or revision of warnings, precautions and contraindications (except additions not due to safety, quality or efficacy issues);

(v) Modification of approved method of use, including change from "Professional use only" to "Home use".

Categorization of 'Administrative Changes' for registered Class A and B medical devices shall be in accordance to Table 1 in Section 3.1.

All other changes to Class A and B devices which do not fall into either the closed list of 'Review Changes' or 'Administrative Changes' (as per Table 1 in Section 3.1) shall be submitted as 'Notifications'.

Changes to registered Class A and B medical devices submitted under 'Notifications' will not be subject to review. These changes may be implemented immediately upon the successful receipt of the Change Notification application by HSA, unless the change is in the context of, or is a consequence of a reportable AE or an FSCA.

3.3. Addition and Changes to Non-sterile Class A Medical Devices in a Closed System

Non-sterile Class A medical devices that are specifically intended for use with a registrable medical device in a closed SYSTEM should be included in the product registration of that SYSTEM. Upon successful registration of the medical device SYSTEM, these non-sterile Class A devices would be listed on the SMDR.

For such non-sterile Class A devices that are listed together with other registrable medical devices as a closed SYSTEM on the SMDR, a change notification submission would be required only when there are changes to the listing information of these devices on the SMDR. There will be no processing fees for these change notifications.

An exception to this are Class A IVD analyzers intended for use with the respective registrable test kits to achieve a common intended purpose. These IVD analyzers are required for the test kits to perform and directly influence the quality, safety and performance of the IVD test. Therefore all changes to such analyzers would require a change notification submission via the appropriate route as applicable to the type of change.

Changes to the specifications of Class A IVD analysers which affect the performance specifications of the registered Class C and D test kits will require a **Technical Change** notification for the entire IVD SYSTEM.
Changes to the specifications of Class A IVD analyzers will require a **Review Change** notification if the change(s)

- affects the performance specifications of the registered Class A and B test kits; **and**
- falls within the closed list of changes categorized as Class A and B **Review Changes** in section 3.2.

For changes to the specifications of a Class A IVD analyzer that does not impact the performance specifications of the test kits, **Notification Change** notification will apply. **◄ R3.2**

For all other changes to the Class A IVD analysers, a change notification submission would be required only when there are changes to the listing information of these devices on the SMDR. There will be no processing fees for these change notifications.

3.4. Changes to Medical Devices due to an Adverse Event (AEs) and/or Field Safety Corrective Actions (FSCAs)

Changes to medical devices may arise from the occurrence of AEs or FSCAs. The proposed changes to the medical devices in these situations are intended to have an impact on the safety, quality and/or efficacy of the medical device. These changes to the medical devices require a Change Notification and may only be implemented after HSA's review and approval. Documents and information required for the review shall include details of the proposed correction and/or corrective action to the device, and where necessary, details shall adequately address situations, conditions and root cause analyses leading to the changes.

The determination of the category of change for Change Notification applications submitted in the context of, or as a consequence of or arising from open reportable AEs or on-going FSCAs shall be based on the type of change as per Section 3.1 (for registered Class C and D medical devices) and Section 3.2 (for registered Class A and B medical devices).

Changes submitted as context of, or as a consequence of or arising from open reportable AEs or on-going FSCAs would require prior approval from HSA before implementation. This clause applies to all registered medical devices (Class A to D) regardless of the category of change selected (as per Section 3.1 or Section 3.2). Exception to this clause shall require the Registrant to possess a written advice from HSA that states otherwise.

Turn-Around-Times (TATs) published in Section 5 of this guidance document will not be applicable to Change Notification applications submitted in the context of, or as a consequence of or arising from AEs or FSCAs.

In cases where the category of change cannot be determined or has been deemed inaccurate by HSA, HSA shall determine the correct category of change and advice the Registrant to amend the category of change as deemed appropriate. The fees chargeable for the change notification application will depend upon the category of change selected. Fees for the different categories are detailed in Section 6 of this guidance document.

4. APPLICATION PROCESS FOR CHANGE NOTIFICATION

Upon identifying all applicable categories of changes based on the requirements in Section 3 above, the changes may be grouped as per guidelines below, and submitted as a single Change Notification application for the medical device listing(s).

NOTE

1. *For changes within **one dossier** and involving listings of **a single risk class**:*
   Multiple changes (Notification, Administrative, Review and Technical changes) will be considered in one CHANGE NOTIFICATION application if they are submitted together. Fees and assessment done will follow the highest change category in that application.

2. *For changes in **two or more dossiers** involving listings of **a single risk class**:*
   a) *Applicants can submit one CHANGE NOTIFICATION application on MEDICS for (i) identical administrative changes to multiple SMDR listings or (ii) where the same new product is added to multiple SMDR listings, if the changes are submitted together. Non-identical changes in any one listing may result in the entire CHANGE NOTIFICATION application being rejected.*

   b) *Applicants can submit one CHANGE NOTIFICATION application for technical changes to the same medical device that is part of multiple device listings (as part of a FAMILY, SYSTEM, GROUP, TEST KIT). Product identifiers listed in each of the SMDR device listings selected must be the same.*
   Example:
   A change in design (Technical change) to a Calibrator (Product identifier: AB1234) that is listed as part of the following SYSTEMS that have been listed separately on SMDR:

SMDR device listing number	***Name of device listing***	***Models listed on SMDR***
DE12345	*APEX Troponin Test system*	*APEX Troponin test strip (AT987)* *APEX wash buffer (AT654)* ***APEX calibrator (AB12334)***
DE98765	*APEX CK-MB Test System*	*APEX CK-MB test strip (AC786)* *APEX wash buffer (AC423)* ***APEX calibrator (AB1234)***

   Change to the APEX calibrator (AB1234) in SMDR listings, DE12345 and DE98765, can be submitted in one CHANGE NOTIFICATION application.

   c) *Non-identical administrative changes and technical changes that do not fall under in the categories above: Applicant to submit separate CHANGE NOTIFICATION application for each change on MEDICS.*

3. ***Identical changes** involving **SMDR listings of different risk classes** may be submitted in one CHANGE NOTIFICATION application only for the following categories of change.*
   - *Change in product owner*
   - *Change in manufacture site*
   - *Addition of identical Class A non-sterile accessories*

4. ***Identical changes*** *arising from open Field Safety Corrective Actions (**FSCAs**) or reportable Adverse Events (**AEs**) involving **SMDR listings of different risk classes,** please seek advice from MDB on applicable requirements prior to the submission on application on MEDICS.*

Please note that it is not possible to submit a new change notification application if there is a pending change notification application for the same product. The Registrant has the option of either:

a. Withdrawing the pending change notification application and submitting a new change notification application, or
b. Submitting a new change notification application once the pending change notification application is completed.

Single applications submitted with changes belonging to multiple categories (Notification, Administrative, Technical and Review changes) shall be classified based on the most stringent category of change in that application, and evaluated accordingly. The fees and Turn-Around-Time (TAT) will follow the most stringent category applicable.

4.1. Requirements for Change Notification

Applicant is required to submit completed copies of the following:

a. Annex 1 to GN-21: Change Notification Checklist
b. Annex 2 to GN-21: Summary Table of Change Notification
c. Annex 3 to GN-21: Medical Device Safety and Performance Declaration AND
d. All supporting documents listed in Annex 1.

Annex 1, Annex 2 and Annex 3 are found at the end of this guidance document.

Registrants are reminded that the determination of documents required for Change Notification should be made with reference to all submitted changes, and not solely on one category of change.

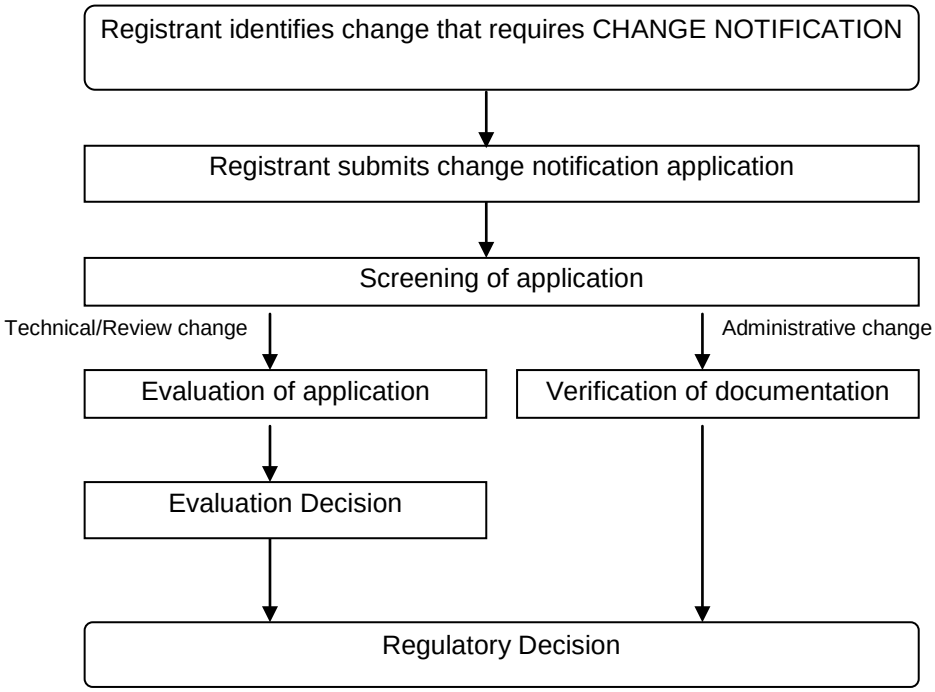

Figure 1: Process of Change Notification application for changes subjected to HSA's review

The application process for the assessment of Change Notification for registered Class A to D medical devices is summarized in Figure 1. This process applies for the following changes:

a. Technical changes for registered Class C and D medical devices
b. Review Changes for registered Class A and B medical devices
c. Administrative changes for all registered devices

The changes listed above will be subject to HSA's review and shall be implemented upon the regulatory approval by HSA. Upon verification of the documents submitted for Administrative Changes, the SMDR will be updated as necessary upon approval.

Change Notification applications that consist of 'Notifications' only will not be subjected to review and may be implemented upon successful receipt of the Change Notification application by HSA through MEDICS.

Upon the successful submission of the change notification application on MEDICS, no further amendment of the application will be allowed unless otherwise advised by HSA.

As application fees and Turn-Around-Times (TATs) for Change Notification applications are based on a per-application basis, HSA recommends the judicious grouping of different categories of changes that affect each device listing, before submission of each Change Notification. Refer to Section 5 and Section 6 of this guidance document for the TATs and the fees applicable for each Change Notification category.

An application for changes classified as 'Technical Change' or 'Review Change' will be evaluated. 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:

- The Change Notification is approvable – where Authority assessed that the changes made to the registered medical device meet prevailing requirements of safety, quality and efficacy for its intended purpose and may be registered for local supply; or
- The Change Notification is non-approvable – where the response provided by the applicant fails to address the deficiencies highlighted during the input request, or failure to adhere to specified time as stated in input request or provide information requested for within reasonable timeframe, or where changes made to the registered medical device does not meet prevailing requirements of safety, quality or efficacy for its intended purpose.

For a Change Notification that is approved or accepted as indicated in the previous sections by the Authority, the Registrant may proceed to implement the change(s) proposed in the Change Notification.

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

5. CHANGE NOTIFICATION TURN-AROUND-TIME (TAT)

Applicants should ensure that the dossiers are complete before submission. Incomplete submissions and untimely responses to queries will result in unnecessary delays to the review process and inevitably prolong the overall processing timeline.

The target turn-around-time (TAT) for change notification applications commences from the date of submission of the application and does not include ‘stop-clock time’ due to input requests for clarifications and additional information.

The TATs published in Tables 2 and 3 shall be applied based on the highest category of change selected for that application (e.g. if a Technical Change and an Administrative Change for a Class C medical device listing are submitted in one application, the TATs for a Technical Change for a Class C medical device shall apply). TATs shall apply to each application on a per-application basis.

In the event that the change notification submitted is in the context of, or as a consequence of or arising from an open reportable AE and/or an on-going FSCA, the application will be given priority review. The published TATs in Table 2 and Table 3 will not apply to such Change Notification applications.

Proposed changes submitted under the category of ‘Notifications’ can be implemented upon successful receipt of the Change Notification application by HSA unless the changes submitted in the application are due to an open reportable AE and/or an on-going FSCA. As such, no TAT applies for ‘Notification’ changes.

Table 2 - Change Notification TAT for Class A (sterile) listings

Risk Classification	TAT for Change Notification (in working days)
Class A (sterile)	20

Table 3 - Change Notification TAT for Class B, C and D listings

Risk Classification	TAT for Change Notification (in working days)		
	Review Changes	**Administrative Changes**	**Technical Changes**
Class B	45	30	Not applicable
Class C	Not applicable	30	75
Class D*	Not applicable	30	90

**For TATs with regards to changes to Class D medical devices that incorporate a registrable medicinal product in an ancillary role, please contact HSA.*

6. CHANGE NOTIFICATION FEES

The fees applicable for the Change Notification applications are summarized in Table 4. Fees chargeable for applications that includes multiple changes will depend upon the highest category of change selected (e.g. if a Technical Change and an Administrative Change for a Class C medical device listing are submitted in one application, the fees for a Technical Change for a Class C medical device shall apply).

All fees are **non-refundable** once the application has been submitted via MEDICS. Withdrawal or rejection of the application will result in **forfeiture** of the fees charged.

Table 4 - Change Notification Fees

<table>
<tr><th>Risk Class</th><th>Notification Change</th><th>Administrative Change</th><th>Review Change</th><th>Technical Change</th></tr>
<tr><td>Class A (Sterile)</td><td rowspan="4">Not applicable</td><td>$25</td><td>$25</td><td rowspan="2">Not applicable</td></tr>
<tr><td>Class B</td><td>$500</td><td>$500</td></tr>
<tr><td>Class C</td><td>$500</td><td rowspan="2">Not applicable</td><td>$1700</td></tr>
<tr><td>Class D (including devices incorporating medicinal products in an ancillary role)</td><td>$500</td><td>$2800</td></tr>
</table>

ANNEX 1 to GN-21: Change Notification Checklist

This checklist is provided to assist the Registrant in determining the required documents for types of changes proposed. Submission of this checklist in MEDICS is mandatory.

NOTE:

All the required documents must be submitted for the relevant sections of the CSDT to support the proposed changes to the device. The documentary requirements in this checklist are meant to cover the broadest aspect for each category of change. If any required documents as defined in the respective category in this checklist are not available or applicable for the change proposed, please provide a clarification or justification as appropriate.

Please also refer to GN-15 for the relevant templates/documents which may be required for the registered devices.

Type of Change	**Documentary Requirements**	**Provided?**		
		Yes	**If no, please provide justification**	
All category of changes	Completed Annex 1 to GN-21: Change Notification Checklist			
	Completed Annex 2 to GN-21: Summary Table of Change Notification (As per Annex 2 to this guidance document)			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
	Completed Annex 3 to GN-21: Medical Device Safety and Performance Declaration (As per Annex 3 to this guidance document)[1]			
1 A All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes.	Quality Management System certificate(s)			
	Device labelling with changes redlined and annotated beside each amended section (if applicable)			
	Declaration letter from Product Owner on company letterhead stating that there is no change to existing manufacturing and sterilisation process			
	Sterilization validation report (if applicable)			

[1] Except changes implemented as a result of reportable AE/ FSCA

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
	For changes in manufacturing/ sterilization site of medical devices containing medicinal products in an ancillary role, please contact the Medical Device Branch, Health Sciences Authority for further advice.			
1 B All changes to manufacturing processes (including changes made to outsourced processes) that result in a change in specifications of a registered medical device	Quality Management System certificate(s)			
	Device labelling with changes redlined and annotated beside each amended section (if applicable)			
	Summary of new manufacturing process			
	Validation studies covering new processes			
	Pre-clinical studies			
	Software validation report (For software only)			
	Clinical studies (For operating principles and design characteristics change) (if applicable)			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
	Risk analysis			
	For changes in manufacturing/ sterilization site of medical devices containing medicinal products in an ancillary role, please contact the Medical Device Branch, Health Sciences Authority for further advice.			
1 C All changes to sterilisation processes (including changes made to outsourced processes)	Sterilisation technique			
	Device labelling with changes redlined and annotated beside each amended section (if applicable)			
	Sterilization validation report (including the Sterilisation Protocol, Sterilisation Standards applied. Sterility Assurance Level, Sterilisation Revalidation report)			
	Quality Management System certificate(s)			
	Post Sterilisation functional test report			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
1 D All changes to Quality Management System (QMS) certificate(s) for manufacturing and sterilisation facilities	Updated Quality Management System Certificate(s)			
	Device labelling with changes redlined and annotated beside each amended section (if applicable)			
	Reason for cancellation of QMS certificate (if applicable)			
2 A All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device	Pre-clinical studies			
	Risk analysis			
	Clinical studies (if applicable)			
	Device labelling with changes redlined and annotated beside each amended section			
	Software validation report (For software only)			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
	Detailed summary of software changes (For software only)			
2 B All changes in specifications of a registered medical device	Pre-clinical studies			
	Clinical studies (if applicable)			
	Risk analysis			
	Device labelling with changes redlined and annotated beside each amended section			
	Software validation report (For software only)			
	Detailed summary of software changes (For software only)			
3 A All changes to biological materials that involve a change in type, source, processing and/or supplier	Pre-clinical studies			
	Clinical studies (if applicable)			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
of cells, tissues, and/or derivatives of animal, human, microbial or recombinant origin without a change in the intended purpose of the biological material	Biological safety data			
	Information of sources/donors			
3 B All changes to materials or material formulation (of non-biological origin) including changes to device coating or surface modification techniques, that make direct/indirect contact with body tissues and fluids, or is absorbed by the body	List of materials making direct/ indirect contact with human body			
	Pre-clinical studies			
3 C All changes to materials that are used for shielding in medical devices emitting ionising radiation	Information on radiation source			
	Information on materials for shielding of radiation			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
3 E All changes to concentration or drug specifications (DS) of medicinal substances in medical devices that incorporate medicinal substances in an ancillary role	Contact the Medical Device Branch, Health Sciences Authority for further advice			
4 A All changes to materials that affect performance specification of a registered IVD medical device, including changes to biological materials that involve a change in type, source, processing and/or supplier of cells, tissues, and/or derivatives of animal, human, microbial or recombinant origin Biological materials (including supplier of materials)	Pre-clinical performance evaluation data			
	Clinical performance evaluation data			
	Information on source of material			
5 A All changes to the labelling of medical devices that involve addition and/or revision of the approved	Regulatory approval documents from the reference agencies for the change			
	Device Information			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
indications for use	Device labelling for new product(s) with changes redlined and annotated beside each amended section			
	Declaration of conformity document			
	Pre-clinical studies			
	Clinical studies			
	Risk analysis			
	Software validation report (For software only)			
Changes that involve a reduction of indications for use not due to device safety, quality or efficacy considerations	Reasons for the reduction of approved indications			
	Device labelling for new product(s) with changes redlined and annotated beside each amended section			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
5 B All changes to the labelling of medical devices that involve addition, removal and/or revision of warnings, precautions and/or contraindications **OR** involves addition of contraindications, warnings and/or precautions not due to safety, quality or efficacy issues.	Reasons for addition or removal of contraindications, warnings and precautions			
	Device labelling with changes redlined and annotated beside each amended section			
	Pre-clinical studies			
	Clinical studies			
	Risk Analysis			
5 C **Labelling changes that only** - instructs the user to use the device in a different manner from that originally approved **OR** - involve a change from 'professional use only' to 'home use'	Preclinical Studies			
	Device labelling with changes redlined and annotated beside each amended section			
	Clinical Studies			
	Software validation report (For software only)			
	Risk analysis			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
5 D Labelling changes that involve clarification of existing instructions for use, not affecting safety, quality or efficacy of the medical device	Device labelling with changes redlined and annotated beside each amended section			
5 E **Labelling changes that only** - involve changes in layout, colour, font sizes and design, without change in prominence of precautions, warning and contraindications **OR** - involve addition and/or removal of languages not required by the Authority **OR** - involve the addition of reference agencies' approvals (e.g. CE marking)	Device labelling with changes redlined and annotated beside each amended section			
5 F Other labelling changes	Device labelling with changes redlined and annotated beside each amended section			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
	Details of changes and the reason for changes			
	Documents supporting proposed changes detailed above (if applicable)			
6 A Addition of new medical devices to a device listing	Justification for addition of product(s) to be grouped within the registered product based on GN-12: Guidance on Grouping of Medical Device for Product Registration			
	Annex 2 for GN-17 and GN-18: List of Configurations of Medical Devices to be Registered			
	Regulatory approval documents from the reference agencies			
	Device Information			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
	Device labelling with changes redlined and annotated beside each amended section			
	Declaration of conformity document			
	Letter of Authorisation (GN-15)			
	Pre-clinical studies			
	Clinical studies (if applicable)			
	Risk analysis			
	Software validation report (For software only)			
	Manufacturing information			
Unless the change involves the addition of new devices of the same design, within the existing range of sizes already registered.	Justification for addition of product(s) to be grouped within the registered product based on GN-12: Guidance on Grouping of Medical Device for Product Registration			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
OR involves a design change that does not affect the safety, quality or efficacy of the medical device (e.g. changes that improve device ergonomics, aesthetic modification of the device	Annex 2 for GN-17 and GN-18: List of Configurations of Medical Devices to be Registered			
	Regulatory approval documents from the reference agencies			
	Device Information			
	Device labelling with changes redlined and annotated beside each amended section			
	Declaration of conformity document			
	Letter of Authorisation (GN-15)			
	Pre-clinical studies (where applicable)			
	Software validation report (For software only, where applicable)			
	Manufacturing information			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
	The quality management system certificate			
Unless the change Involves addition of Class A non-sterile medical device accessories that complement the registered medical device as a SYSTEM/ GROUP	Declaration on Registrant's letterhead to state (1) The added models are class A non-sterile (2) The name of the device affected (3) The device identifier (4) The name of Product owner for class A non-sterile device (5) Name and address for the manufacturing site(s) for class A non-sterile device			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
	Letter of acknowledgement from the product owner of the Class A non-sterile device, that they have no objection that their said Class A non-sterile product is to be listed on SMDR as a part of the registered SYSTEM /GROUP. *(applicable only where, the product owner of the Class A non-sterile device differs from that of the SYSTEM/GROUP)* The quality management system certificate			
	The quality management system certificate			
	Annex 2 for GN-17 and GN-18: List of Configurations			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
6 B / 6 C All deletions of models from device listing **OR** Changes which increase or reduce the number of devices in a pack of a registered device **OR** reduction in the number of models listed due to obsolescence and not due to safety, quality or efficacy considerations	Justification for addition or deletion of product(s) to be grouped within the registered product Propose: Justification for deletion of product(s) or justification for addition of product(s) to be grouped with the registered product based on GN-12: Guidance on Grouping of Medical Device for Product Registration.			
	Annex 2 for GN-17 and GN-18: List of Configurations of Configurations			
	Device labelling for new product(s) (if applicable)			
6 D All changes to Product Name only (including identifier)	Declaration of Conformity document			
	Declaration letter from Product Owner on company letterhead to state that there is no change to device in all aspects, including intended use, technical specifications.			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
	Annex 2 for GN-17 and GN-18: List of Configurations of Configurations			
	Device labelling with changes redlined and annotated beside each amended section			
	Letter of Authorisation (GN-15)			
6 E (i) All changes to Product Owner	Declaration of Conformity document			
	Declaration letter, from Product Owner on company letterhead, to state that they will undertake responsibility to provide post market support and assistance related to the medical devices <*state device name*> already supplied under the former product owner's name (if applicable)			
	Device labelling with changes redlined and annotated beside each amended section			
	Letter of Authorisation (GN-15)			

Type of Change	Documentary Requirements	Provided?		
		Yes	If no, please provide justification	
6 E (ii) A change in Product Owner Address	Device labelling with changes redlined and annotated beside each amended section			
	Letter of Authorisation (GN-15)			
6 F A change in regulatory status on rejection or withdrawal (in any reference agencies) for models included in the SMDR Listing.	Declaration of Conformity document			
	Existing regulatory approval certificate(s)			
	Documents from relevant regulatory authorities citing reason for the change in regulatory status			
	Reason for company to withdraw from regulatory authorities			

ANNEX 2 to GN-21: Summary Table of Change Notification

Guidelines on completing the Summary Table of Change Notification

This summary table is to be completed and submitted for all Change Notification applications (Technical Changes, Review Changes, Administrative Changes, and Notifications).

List the proposed changes, according to the "Category of change" categories in GN-21, to the registered medical device(s) in the summary table below. All applicable types of changes are to be included; any change not specified in this table will not be included for the change notification application.

Information to be included in the table is explained below:

(i) **Type of changes:** Please state clearly the **type of change**, **category of change** and **SMDR device listing number.**

- With reference to the 'type of changes' categories in GN-21, highlight the type of change proposed.
- Specify the SMDR device listing number for the registered medical device(s) included in this change (if the proposed change is identical and applicable to identical devices across multiple device listings on the SMDR; list the applicable device listings). Confirm these device(s) subjected to the change.

NOTE *All applicable types of changes are to be included. If the types of change proposed affects/results in another type of change, all types of changes shall be included. For example, change in material of device and change (update) of labelling often occur together.*

(ii) **Present:** Please state clearly the current scope and aspects of the device to be changed.

(iii) **Proposed:** Please state clearly the proposed scope and aspects of change.

(iv) **Reason for change:** Please state clearly the rationale for the proposed scope and aspects of change.

(v) **Status of proposed change in reference agencies:** Please state the reference agency status (approved/authorised for marketing) for these proposed changes.

(vi) Indicate in the check box if the medical device(s) in this Change Notification application is a subject of an on-going field safety corrective action.

Please select the correct box.

R3.2 ►

The change(s) in this Change Notification application is/are related to field safety corrective action and/or reportable adverse events.

☐ Yes ☐ No

Type of Changes	Present	Proposed	Reason for change	Status of proposed change in reference agencies
Type of change: *e.g. Change in material: Delivery tube material changed from polyvinyl chloride (PVC) to silicone* **Category:** (same tubing is in all the SMDR Device listing below) **SMDR Device listing no(s):** (i) DE 001111, (ii) DE 002222, (iii) DE 003333, *(iv)* DE 004444.	*Delivery tube material: polyvinyl chloride (PVC)*	*Delivery tube material silicone*	*Improve patient safety by changing to DEHP-free tubing material*	*Australia TGA – pending* *EU Notified Body – approved/authorised for marketing* *Health Canada – not supplied* *US FDA – not supplied* *Japan MHLW – not supplied*

Type of Changes	Present	Proposed	Reason for change	Status of proposed change in reference agencies
Type of change: *e.g. Change in Manufacturing Facility* **Category:** **SMDR Device listing no(s):** DE 005555	*Name and address of current manufacturing facility A*	*Name and address of new manufacturing facility B*	*Reason for product owner's decision to move manufacturing activities from facility A to facility B*	*Australia TGA – pending* *EU Notified Body – approved/authorised for marketing* *Health Canada – not supplied* *US FDA – not supplied* *Japan MHLW – not supplied*

ANNEX 3 to GN21: Medical Device Safety and Performance Declaration Template

Safety and Performance Declaration Template

[To be printed on Company Letterhead of Registrant]

Medical Device Branch
Pre-Marketing Division
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

I, *[name of Company]*, the Registrant of the medical device(s) stated below, hereby declare that the medical device(s) in this Change Notification application,

☐ The change(s) to the medical device in this Change Notification application is/are not due to reportable adverse events and/or field safety corrective action ◄ **R3.2**

☐ Medical device(s) in this Change Notification application conform(s) to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations

☐ The added model(s) is/are not a subject of an open reportable adverse event and/or an on-going field safety corrective action (If applicable) ◄ **R3.2**

This declaration shall apply to the following medical device(s):

[List containing product names of medical devices]

I, the Registrant, am aware that a false declaration is an offence under the Health Products Act (Cap. 122D) and may result in the cancellation of registration of the above medical devices under Section 37(1) of the Act.

Yours Sincerely,

[Signature]

[Full Name and Title of Senior Company Official]

[Company stamp]

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Device Branch
Pre-marketing Division
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg
Tel: 6866 3560
Fax: 6478 9028
Email: hsa_md_info@hsa.gov.sg

HSA
Health Sciences Authority