MDA/GD/0020
April 2022
Fourth Edition
Due date public comment:
20 April 2022

MEDICAL DEVICE GUIDANCE DOCUMENT

CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737);

b) Medical Device Regulations 2012; and

c) Medical Device (Duties and Obligations of Establishments) Regulations 2019.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the incident of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE

1 Introduction

Changes in medical devices may take place from time to time as part of their life-cycle. Any change to a registered medical device is linked to the principles of safety and performance and the ability of the regulatory framework to manage the risk of the medical devices.

Before making any decision whether a changed medical device can continue to be placed in the market, the Authority will determine whether evidence of safety and performance have been appropriately collected and reviewed based on the notification made by the registration holder.

For any anticipated change to a medical device, a manufacturer must consider the impact of the change on the patient, practitioner and/or user of the medical device, and the impact of the change on the specifications of the medical device, and decide whether the change is expected to impact the safety and performance of the medical device.

This document provides guidance on the categories of changes, the principles of change categorisation, and what should be done by the registration holder in relation to each category of change to its registered medical device.

2 Scope and application

This guidance document specifies the categories of changes in relation to registered medical devices and the requirements to be met to continue the importation, exportation or placement of the medical devices in the market.

This document applies to all registered medical devices under the Act. It sets out points for consideration by the registration holder when a registered medical device is in the process of change or modification. Owing to the various possible scenarios for changes made to a medical device, it is not the intention of this document to describe every permutation and type of change that can occur.

This document is also applicable to situations when a registered medical device undergoes any changes or proposed changes as a result of a mandatory reportable incident or field corrective action under Section 40 or Section 41 of Act 737 respectively.

3 Terms and definitions

For the purpose of this document, the terms and definitions in ACT 737, the regulations under it and the following terms and definitions apply.

3.1 accessory

An article with an intended purpose as a medical device and that is intended specifically by its manufacturer to be used together with a medical device to enable that medical device to be used in accordance with its intended purpose as a medical device or augment or extend the capabilities of that medical device in fulfilment of its intended purpose.

3.2 Authority

The Medical Device Authority established under Medical Device Authority Act 2012 (Act 738).

3.3 cautions and precautions

Information which alerts the user to exercise special care necessary for the safe and effective use of the medical device.

It may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the device of use or misuse and the care necessary to avoid such effects.

3.4 contraindications

A general description of the disease or condition and the patient population for which the device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any reasonably foreseeable benefits.

3.5 control mechanism

A means of verifying or checking that the specifications or outputs of the device meet a standard or predetermined result. They are mechanisms put in place to maintain on-going control or regulate the output of a device.

3.6 facility

Means a site that is substantially involved in the manufacture and/or design and manufacture of a medical device.

3.7 indications for use

General description of the disease(s) or condition(s) the medical device will diagnose, treat, prevent or mitigate, including where applicable a description of the patient population for which the medical device is intended. The indications include all the labelled uses of the medical device, for example the condition(s) or disease(s) to be prevented, mitigated, treated or diagnosed, part of the body or type of tissue applied to or interacted with, frequency of use, physiological purpose and patient population.

3.8 indirect contact

In relation to the nature of body contact of medical device, includes devices that contact the blood path at one point and serve as a conduit for entry into the vascular system. e.g. blood transfusion tubes, blood bags, etc.

3.9 labelling

Written, printed or graphic matter presented by a manufacturer meant to provide information concerning a medical device to the users and others, which may be attached to the medical device itself, on its packaging or as a packaging insert or may be made available by other means, for example by electronic means, when appropriate for the purpose as an additional, or alternative way of transmitting certain information regarding the medical device.

3.10 multiple application

Combination of two or more Submission Identification (ID) of medical device per application of change notification.

Note: Limited to only 50 submission ID's in one application.

3.11 operating principles

The means by which a medical device produces or brings about an intended or appropriate effect.

3.12 recall

Means any action taken by the establishment of the device to remove the device and to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device:

a) may be hazardous to health;

b) may fail to conform to any claim made by the manufacturer/ Authorised Representative relating to its effectiveness, benefits, performance characteristics or safety; or

c) may not meet the requirements of the law.

3.13 registration holder

The manufacturer or the authorized representative who applied for and obtained the registration of the medical device under the Act.

3.14 single application

One Submission Identification (ID) of medical device per application of change notification.

3.15 warning

Describes serious adverse reactions and potential safety hazards that can occur in the proper use, or misuse, of a medical device, along with the consequent limitations in use and mitigating steps to take if they occur.

4 General principle

The general principle for categorising any change to a registered medical device is linked to the principles of safety and performance and the ability of the regulatory framework to manage the risk of the medical devices. Before making any decision whether a changed medical device can continue to be placed in the market, the Authority will determine whether evidence of safety and performance have been appropriately collected and reviewed based on the notification made by the registration holder.

For any anticipated change to a medical device, a manufacturer must consider the impact of the change on the patient, practitioner and/or user of the medical device, and the impact of the

change on the specifications of the medical device, and decide whether the change is expected to impact the safety and performance of the medical device.

5 Categories of Changes

5.1 Change to a registered medical device may be categorized into the following 3 categories:

a) **Category 1 changes** of medical devices that affect their safety and performance and require new registration of the medical device;

b) **Category 2 changes** are changes that require evaluation and endorsement from the MDA prior to implementation of the change and before placing in the market; and

c) **Category 3 changes** may be implemented immediately.

5.2 For all categories of changes, prior to submission of change notification to the Authority the registration holder may submit a request for confirmation on change category using the template in Annex A. In cases where the category of change cannot be determined or has been deemed inaccurate by the Authority, the Authority shall determine the correct category of change and advise the registration holder to amend the category of change as deemed appropriate.

5.3 For categories 2 and 3, change notification as according to Annex E is required.

5.4 For category 1 changes, the following types of changes require the registration holders to apply for new registration according to Act 737 and Medical Device Regulations 2012 (MDR2012):

a) Change to the intended purpose and/or indication of use (e.g new and additional indication) of a registered medical device, unless it involves a reduction of indications for use not arising due to medical device safety or performance concerns;

~~b)~~ Change to the risk classification of a registered medical device;

c) Addition of variant(s) not considered a permissible variant according to the rules of grouping in Second Schedule of MDR2012 and MDA/GD/0005 Product Grouping;

d) Change to the type, concentration or drug specifications (DS) of medicinal substance in a medical device that incorporates a medicinal product as an ancillary role shall be refer to National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia; and

e) Addition of medical devices with device proprietary names different from the registered devices, into a device listing. Unless the devices with different proprietary names qualify to be listed together under one listing based on MDA guidance documents on grouping criteria for medical devices registration.

f) Changes due to wrong risk classification of a registered medical device.

5.5 The guiding principles for identification of category 2 of various types of change to registered medical devices are presented in Table 1.

Table 1: Change notification for category 2

Types of change	Documents to be submitted**
5.5.1 Change in manufacturing facility, process and quality management system (QMS)	
(a) All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes. *Example:* *Change of manufacturing site.*	i) Revised QMS certificate(s) (if applicable); ii) Medical Device labelling stating changes for each amended section (if applicable); iii) Declaration that there is no change to manufacturing and sterilisation process; iv) Sterilisation validation report. v) Declaration of conformity vi) Annexes
(b) All changes to manufacturing processes (including changes made to outsourced processes) that result in a change in specifications of a registered medical device. *Example:* *Change in the equipment used for cutting the result in the change in length of sutures.* *Moulding or cutting manufacturing process.*	i) Revised QMS certificate(s) (if applicable); ii) Summary of new manufacturing process; iii) Validation report covering new processes; iv) Pre-clinical studies (if applicable); v) Software validation report (for software); vi) Clinical safety report (for operating principles and design characteristics change) (if applicable); vii) Risk analysis. viii) Annexes
(c) All changes to sterilisation processes (including changes made to outsourced processes). *Example:* *Change in moist heat sterilisation parameters, or change in sterilisation method from ethylene oxide to gamma radiation, or change from batch release to parametric release.*	i) Sterilisation technique (certificate); ii) Medical Device labelling stating changes for each amended section (if applicable); iii) Sterilisation validation report (including the sterilisation protocol, sterilisation standards applied, sterility assurance level, sterilisation revalidation report); iv) QMS certificate(s); v) Annexes
5.5.2 Changes in design or specifications of a registered medical device	
(a) All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device. *Example:* *Change from a quantitative assay to a qualitative assay.* *Addition of a footswitch to an X-ray system that previously do not operate via a footswitch mechanism.*	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical studies; iii) Risk analysis; iv) Clinical studies (if applicable); v) Medical Device labelling stating changes for each amended section (if applicable); vi) Software validation report (for software, if applicable); vii) Detailed summary of software changes (for software, if applicable). viii) Annexes
(b) Changes that only involves a design change that does not affect the safety or performance of the medical device (e.g. changes that improve the	i) Revised QMS certificate(s) (if applicable); ii) Risk analysis; iii) Usability testing report (if applicable); iv) Annexes

Types of change	Documents to be submitted**
medical device ergonomics, aesthetic modification of the medical device).	
(c) All changes in specifications to shelf life and stability of a registered medical device. *Note: Other changes related to IVD performance testing and clinical evaluation*	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical studies (if applicable); iii) Clinical safety report (if applicable); iv) Risk analysis; v) Medical Device labelling stating changes for each amended section (if applicable); vi) Software validation report (for software, if applicable); vii) Detailed summary of software changes (for software, if applicable). viii) Annexes
(d) Change to software that affect safety and performance of the registered device such that the treatment or diagnosis of the patient is altered. *Example:* *Upgrade of software version changes the performance characteristics like specificity or sensitivity of the diagnostic medical device.*	i) Revised QMS certificate(s) (if applicable); ii) Risk analysis; iii) Software validation report; iv) Detailed summary of software changes; v) Annexes
5.5.3 Changes to materials in a general medical device	
(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. *Example:* *Change in source of hyaluronic acid from Streptococcus zooepidemicus to Streptococcus equi.*	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical studies, including biological safety data; iii) Clinical safety report (if applicable); iv) Information of sources/donors; v) Risk analysis; vi) Annexes
(b) All changes to materials or material formulation (of non-biological origin), including changes to medical 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. *Example:*	i) Revised QMS certificate(s) (if applicable); ii) List of materials making direct/ indirect contact with human body; iii) Pre-clinical studies; iv) Clinical safety report (if applicable); v) Risk analysis; vi) Annexes

Types of change	Documents to be submitted**
Replacement of catheter surface coating from PEBA to PEEK.	
(c) All changes to materials that are used for shielding in medical devices emitting ionising radiation. *Example:* *Change in shielding material of X-ray system from lead to tungsten.*	i) Revised QMS certificate(s) (if applicable); ii) Information on radiation source; iii) Information on materials for shielding of radiation; iv) Radiation safety test/test report; v) Risk analysis; vi) Annexes
(d) All changes to the radiation source (e.g. radioisotopes).	i) Revised QMS certificate(s) (if applicable); ii) Information on radiation source; iii) Radiation safety test/test report; iv) Risk analysis; v) Annexes
5.5.4 Changes to materials in an in-vitro diagnostic (IVD) medical device	
(a) All changes to the radiation source (e.g. radioisotopes in radioimmunoassay).	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical performance evaluation data; iii) Clinical performance evaluation data; iv) Information on source of material; v) Radiation safety test/test report; vi) Risk analysis; vii) Annexes
5.5.5 Changes to labelling of medical devices	
(a) All changes to the labelling of medical devices that involve addition, removal and/or revision of warnings, precautions and/or contraindications. *Example:* *Minor changes to clarify the existing wording of the warnings and precautions for a device may not trigger the need for approval. However, in the case where these changes add or remove a contraindication, or remove a warning or precaution, an endorsement by the MDA is required.*	i) Revised QMS certificate(s) (if applicable); ii) Description of the warnings, precautions and/or contraindications; iii) Reasons for the revision of approved changes; iv) Medical Device labelling stating changes for each amended section. v) Annexes
(b) Labelling changes that- g) Modify the approved method of use; OR ii) Involve a change from 'professional use only' to 'home use'.	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical Studies (if applicable); iii) Clinical safety report (if applicable); iv) Software validation report (for software); v) Risk analysis; vi) Medical device labelling stating changes for each amended section; vii) Annexes

5.5.6 Changes to registered medical devices registration information	
(a) If within the medical device grouping, the change only— i) involves the addition of new medical devices of the same design (e.g within the permissible variants that does not affect safety and performance of the device, e.g. sizes, volume, colours, shapes, length, diameter); Note: Case by case basis and subject to classification of medical device. Example: 1. Latex examination gloves with addition of different size. 2. Contact lens with addition of different colour. OR ii) involves addition of a new medical device with design change that does not affect the safety or performance of the medical device (e.g. changes that improve medical device ergonomics, aesthetic modification of the medical device).	i) Justification for addition of medical device(s) to be grouped within the registered medical device group; ii) List of configurations of medical devices; iii) Regulatory approval documents from the recognised countries (if applicable); iv) Medical Device information; v) Medical Device labelling stating changes for each amended section; vi) Declaration of conformity; vii) Pre-clinical studies (where applicable); viii) Software validation report (for software, if applicable); ix) Manufacturing information (if applicable); x) Annexes
(b) If the change only involves an addition of active, with measuring function or sterile Class A medical device accessories that complement the registered medical device as a system.	i) Declaration by registration holder to state - - the added models are active, with measuring function or sterile class A medical device accessories; - the name of the medical device affected; - the medical device identifier; - no change in manufacturer for the active, with measuring function or sterile class A medical device accessories; - name and address for the manufacturing site(s) for active, with measuring function or sterile class A medical device accessories; ii) List of configurations of medical device; iii) Declaration of conformity; iv) Validation report and certificate v) Medical Device labelling stating changes for each amended section. vi) Annexes

c) All changes to medical device registration that involve an increase or reduction in the number of medical devices in a set grouping of a registered medical device.	i) Declaration of conformity; ii) Declaration from manufacturer to state that there is no change to medical device in all aspects, including intended use, technical specifications; iii) List of configurations of medical devices; iv) Medical Device labelling stating changes for each amended section; v) Description of the addition or reduction. vi) Annexes
d) All changes to the medical device that: i. Involve changes of medical device name and/or medical device identifier and/or brief description of item(s) (in the list of the configurations); OR ii. Involve changes of medical device proprietary name due to company acquisition /merging. *Note: Change of brand without a valid reason is not allowed*	i) Declaration of conformity; ii) Declaration from manufacturer to state that there is no change to medical device in all aspects, including intended use, technical specifications; iii) List of configurations of medical device; iv) Medical Device labelling stating changes for each amended section. v) Annexes
**Section 6(4) of Act 737, the Authority may, in writing, at any time after the receipt of an application under subsection (1), request the applicant to give to the Authority within the period specified in the request additional information, particulars or document on the application or sample of the medical device; and **Section 6(5) of Act 737, if any additional information, particulars or document, or sample of the medical device required under subsection (4) is not given by the applicant within the period specified in the request or any extension of time granted by the Authority, the application shall be deemed to be withdrawn and shall not be further proceeded with, but without affecting the right of the applicant to make fresh application.	

5.6 The guiding principles for identification of category 3 of various types of change to registered medical devices are presented in Table 2.

Table 2: Change category for category 3

Types of change	Documents to be submitted**
5.6.1 Change in manufacturing facility, process and quality management system (QMS)	
(a) All changes to certificates for manufacturing and sterilisation facilities that i) involves an update of certificate QMS validity date only OR; ii) change in scope of the QMS certification which affect the registered medical device (that is not due to safety, and/or performance of the medical device) OR; iii) involves a cancellation of QMS scope on the certificate for any of the multiple existing manufacturing facilities that is related to the registered medical device (that is not due to safety, and/or performance of the medical device), OR; iv) involves the change in conformity assessment body with no change in scope of the certification OR; v) involves the expansion of scope of the QMS certification which does not affect the registered medical device.	i) Valid QMS certificate and report. ii) Annexes
5.6.2 Changes in design or specifications of a registered medical device	
(a) All changes only involve a change to software version number that does not affect safety or performance of the medical device, such as— i) 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	i) Software validation report. ii) Detailed summary of software changes. iii) Annexes

Types of change	Documents to be submitted**
bring the system to its original specification; ii) software changes which augment interfacing to other non-medical peripherals such as printers or VDUs and which has no diagnostic or therapeutic function; or iii) software changes which only modify the appearance of the user interface with no risk to diagnostic or therapeutic function of the medical device. Note: The change notification for this item may be consolidated for a maximum period of 6 months	
5.6.3 Changes to labelling of medical devices	
(a) Where the change only involves a reduction or rephrasing of indications for use not arising due to medical device safety or performance concerns.	i) Description of the new indications for use; ii) Reasons for the reduction of approved indications; iii) Medical Device labelling stating changes for each amended section; iv) Annexes
(b) Labelling changes that only— i) involve the addition of Recognised Countries' approvals (e.g. CE marking).	i) Medical Device labelling stating changes for each amended section; ii) Valid certificates from relevant bodies (where applicable); iii) Annexes
(c) Other labelling changes involving information in the labelling that does not fall under above (a) and (b). Rephrasing information/ Change in arrangement in IFU/ Change of colour/ or any administrative change (e.g. from Rd. to road), for example, do not required change notification. *Example:* *Minor changes to clarify the existing wording of the warnings, precautions, and/or how to use for a device in the IFU.*	i) Medical Device labelling stating changes for each amended section; ii) Details of changes and the reason for changes; iii) Documents supporting proposed changes detailed above (if applicable). iv) Annexes

5.6.4 Changes to registered medical devices registration information	
(a) If the change only involves an addition of Class A medical device accessories that complement the registered medical device as a system.	i) Declaration by registration holder to state - - the added models are non-active, with non-measuring function or non-sterile class A medical device accessories; - the name of the medical device affected; - the medical device identifier; - no change in manufacturer for the non-active, with non-measuring function or non-sterile class A medical device accessories; - name and address for the manufacturing site(s) for non-active, with non-measuring function or non-sterile class A medical device accessories; ii) List of configurations of medical device; iii) Declaration of conformity; iv) Medical Device labelling stating changes for each amended section v) Annexes
b) All deletions of a medical device from medical device registration (for medical devices in grouping). *Example:* *The change only involves the reduction in the number of medical devices in the grouping due to obsolescence and not due to safety or performance considerations.*	i) Justification for deletion of medical device(s) to be grouped within the registered medical device; ii) Declaration from manufacturer to state that there is no change to medical device in all aspects, including intended use, technical specifications; iii) List of configurations of medical devices; iv) Medical Device labelling stating changes for each amended section. v) Declaration of conformity; vi) Annexes
c) All changes in the manufacturer information that only- i. involve changes in manufacturer's name and address; OR ii. involve changes in the manufacturing site's name only, with no change in the manufacturing site's address.	i) Declaration of conformity; ii) Declaration from manufacturer to state that they will undertake responsibility to provide post market support and assistance related to the medical devices already supplied under the former manufacturer's name (if applicable); iii) Medical Device labelling stating changes for each amended section. iv) Updated QMS certificate or pre-market approval certificate v) Annexes

d) A change in regulatory status on rejection or withdrawal in any recognised countries for any registered medical device.	i) Existing regulatory approval; ii) Documents from relevant regulatory authorities citing reason for the change in regulatory status; iii) Reason for company to withdraw from regulatory authorities (if applicable). iv) Annexes
**Section 6(4) of Act 737, the Authority may, in writing, at any time after the receipt of an application under subsection (1), request the applicant to give to the Authority within the period specified in the request additional information, particulars or document on the application or sample of the medical device; and **Section 6(5) of Act 737, if any additional information, particulars or document, or sample of the medical device required under subsection (4) is not given by the applicant within the period specified in the request or any extension of time granted by the Authority, the application shall be deemed to be withdrawn and shall not be further proceeded with, but without affecting the right of the applicant to make fresh application.	

5.7 Changes to medical devices due to a mandatory reportable incident and/or field corrective action

Changes to medical devices may arise from the occurrence of mandatory reportable incidents and/or field corrective actions under Section 40 or Section 41 of Act 737 respectively. The proposed changes to the medical device in these situations may have an impact on the safety and/or performance of the medical device.

The determination of the category of change for notifications in the context of, or as a consequence of or arising from mandatory reportable incidents and/or field corrective actions shall be based on Clause 5.

5.8 Changes to medical devices due to EU's recent regulatory framework transition to Medical Devices Regulation (MDR) and IVD Regulation (IVDR)

Table 3: Changes arising from the EU MDR/IVDR

No.	Type of change	Scope	Criteria	Examples	CN Submission
1	Changes to label and IFU with no new information related to safety and performance (GMD and IVD)	• Addition of symbols to harmonize information between label and IFU • Addition of warnings and precautions related to safe disposal of the device • Addition of Carcinogenic, Mutagenic, Toxic to Reproduction (CMR)/ Endocrine Disrupting (ED) safety information • Addition of symbols related to intended user • Addition of hyperlink to EUDAMED's Summary of Safety and Performance • Addition of statement to report serious safety incident to EU manufacturer and Member State competent authority • Change in design of existing symbol	• Changes due to EU MDR/IVDR updates • No change to material / material composition • No change to method of use / existing users • No addition of pack size • No change to sterile packaging • No new safety and performance data • No additional pre-clinical/clinical validation is required to support safety and effectiveness	•Date of manufacture • Symbols: Ø MD Ø Refer to IFU Ø Repackaging Ø Latex Ø DEHP Ø Single use device Ø Near patient testing Ø Self testing Ø Contains hazardous substances • EUH 208: May produce an allergic reaction •Warning related to disposing infectious or microbial waste •Addition of statement "Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established"	CN submission is not required
2	Changes to label and IFU related to material "-Free" claims (GMD)	Addition of symbols and information on label and IFU related to material "Free" claims	•Changes due to EU MDR updates •No change to material •No change to method of use •No additional pre-	• Addition of DEHP Free symbol •Addition of Latex Free symbol	Change Notification Category 3

			clinical/clinical validation is required to support safety and effectiveness		
3	Changes to IFU related to clarification of existing content and addition of safety information (GMD and IVD)	• Minor update of intended use with no change to approved scope • Addition of symbols and rephrase of existing information for clarity • Addition of adverse events and side effects	•Changes due to EU MDR/IVDR updates •No change to existing scope of approved intended use/indication •No change to method of use • No new safety and performance data •No change to device design, specifications or performance • No additional pre-clinical/clinical validation is required to support safety and effectiveness	• Rephrase intended use for clarity, based on existing clinical studies • Additional description of technology used in device • Addition of adverse reactions	Change Notification Category 3
4	Changes to IFU (IVD) related to clarification of performance data	Addition or clarification of performance data, based on previously submitted pre-clinical or clinical studies	•Changes due to EU IVDR updates • No change to method of use • No change to device design, specifications or performance • No additional pre-clinical/clinical validation is required to support safety and effectiveness	Addition of acceptance criteria value, based on previously submitted pre-clinical studies	Change Notification Category 3

6 Notification process

6.1 For applications involving a single submission ID, the establishment can apply for the **TYPES OF CHANGES** as below:

i. Category 2

as stipulated in Table 1: Change notification for Category 2

Or;

ii. Category 3

as stipulated in Table 2: Change notification for Category 3

Or;

iii. Combination of Category 2 and Category 3

as stipulated in Table 1: Change notification for Category 2, and Table 2: Change notification for Category 3

6.2. For an application involving multiple submission ID, the establishment can apply for the **TYPES OF CHANGES** as below:

i. Category 2

5.5.1 (a)- All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes as stipulated in Table 1: Change notification for Category 2

Or;

ii. Category 3

5.6.1 (a)- All changes to certificates for manufacturing and sterilisation facilities; and/or

5.6.4 (c)- All changes in the manufacturer information including changes in manufacturer's name and address (which is not the manufacturing site) as stipulated in Table 2: Change notification for Category 3

Or;

iii. Combination of Category 2 and Category 3

as per type of changes in i and ii above.

6.3 The details explanation on this can be referred to the Guidelines on "How to Submit Change Notification for Medical Device."

6.4 All submission of notification of changes shall be accompanied with a fee as per the table below. Payment shall be made by the applicant prior to endorsement/acknowledgement by MDA.

Table 3: Change notification fees

Medical Device Risk Class	Category 2 (RM)	Category 3 (RM)
Class A	50	30
Class B	500	
Class C	1000	
Class D	1500	
Medical device that contains a medicinal product	2500	

7 Requirements for Change Notification

Refer Annex E for change notification process flow.

a) Registration holder is required to submit completed copies of the following documentation:

   i) Request for confirmation on change notification category for registered medical device (Annex A), if necessary. Refer 5.2.

   ii) Template for Proposed Timeline for Depletion of Stock Supply (Annex B).

   iii) Summary Table of Change Notification (Annex C).

   iv) Medical Device Safety and Performance Declaration (Annex D).

   v) All supporting documents listed in Annex A, Annex B, Annex C and Annex D.

   vi) Updated Common Submission Dossier Template (CSDT).

b) Registration holders 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.

c) Upon the successful submission of the change notification, further amendment of the application will be allowed only ONCE (within the same change category).

8 Turn Around Time

The turn-around time per application is as follows:

Table 4: Turn Around Time for Change Notification Application

Category of Change	Timeline
Category 2	30 days
Category 3	15 days
Combination Category 2 and Category 3	45 days
Multiple Application	45 days

Upon submission of complete application form and supporting documents.

9 Grace Period of Supply

9.1 Establishment may concurrently supply both the current stock (the registered medical device) and the changed medical device.

9.2 If the changes of the registered medical device are due to reportable incident or Field Corrective Action (FCA), establishments shall implement the changes (upon approval of CN) before placing them in the market.

9.3 Establishment required to notify the Authority of the proposed timeline by fill up the Annex B for phasing out of current stocks from the market during submission of the CN. The concurrent supply of both current registered and changed medical devices may be allowed by the Authority for stipulated timeline upon review and evaluation of the information provided.

9.4 Establishment shall ensure that appropriate mechanisms are established to identify and differentiate the changed medical device from the registered medical device and maintain relevant records to ensure traceability of both versions of medical devices. All records shall be made available to the Authority upon request.

ANNEX A:
(normative)

Request for confirmation on change notification category for registered medical device

[To be printed on Company Letterhead of the registration holder]

[Your reference number]

Chief Executive
Medical Device Authority

Company address *[Date]*

Dear Sir/Madam,

Request for confirmation on change notification category for registered medical device

The registration holder of the medical device(s) stated below, hereby request for confirmation on change notification category for registered medical device(s) as per description stated below:

Establishment Licence No.	:
Medical Device Registration Certificate No.	:
MEDCAST Registration Submission ID	:
Medical Device Name and include medical device identifier	:
Proposed Change Category	: ☐ Category 1 ☐ Category 2 ☐ Category 3

Description of change	:
Relevant Document (attached)	:

I am aware that a false declaration is an offence under Section 76 of Act 737 and may result in the cancellation of registration of the above medical devices under Section 5 of Act 737.

I hereby submit a processing fee of RM150.

Yours Faithfully,

[Signature]
[Responsible person of Authority establishment]
[Company stamp]

Note:
1. This request may be submitted by hand or mail to the above address.
2. Processing fee shall be paid through bank draft. CASH WILL NOT BE accepted. We will not be responsible for the cash sent or brought to MDA.
3. Kindly inform that payment can be combined for a maximum of 5 submissions only.
4. Payment to be made upon receive of payment advice from the Authority. The bank draft must be made payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN". Information on your reference number and Phone No. of the applicant must be written at the back of the bank draft but not in the table section.
5. Complete submission for request for confirmation on change notification category will be processed within 14 working days.

ANNEX B
(Normative)

Template for Proposed Timeline for Depletion of Stock Supply

This template is provided to assist the registration holder to determine the timeline to deplete the current stocks of registered medical devices while concurrently supply both the registered and changed medical devices. The template shall be submitted during change notification application and subject to the Authority's approval.

Please fill in medical device registration details:

Medical Device Registration Certificate No. :
MEDCAST Registration Submission ID :
Medical Device Name :

List of Configurations:

No	Name of Medical Device	Device Identifier Number	Quantity of Current Stock	Location of Current Stock	Proposed Timeline for Phase Out Current Stock (State duration (in month) and specific date)

ANNEX C
(informative)

Summary Table of Changes

This annex provides guidelines on completing the Summary Table of Change Notification. Annex

(a) This summary table is to be completed and submitted for all change applications.

(b) List the proposed changes, according to the "category of change", 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.

(c) 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 **MeDC@St medical device registration number.**

- With reference to the 'type of changes' categories in Table 1, highlight the type of change proposed.
- Specify the MeDC@St medical device registration number for the registered medical device(s) included in this change (if the proposed change is identical and applicable to identical medical devices across multiple device registrations on the MeDC@St; list the applicable medical device registrations). Confirm these medical 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 medical device and change (update) of labelling often occur together.*

ii) **Present:** Please state clearly the current scope and aspects of the medical 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 recognised countries:** Please state the reference agency status (approved/authorised for marketing) for these proposed changes.

(a) Type of changes	(b) Present	(c) Proposed	(d) Reason for change	(e) Status of proposed change in recognised countries
Type of change: *e.g. Change in material: Delivery tube material changed from polyvinyl chloride(PVC) to silicone* **Category of change:**	*Delivery tube material: polyvinylchloride (PVC)* **Registration no:** **List of medical device** i) ii) iii)	*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 change: *e.g. Change in manufacturing facility* **Category of change:**	*Name and address of current manufacturing facility A* **Registration no:** **List of medical device** i) ii) iii)	*Name and address of new manufacturing facility B*	*Reason for 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 D
(normative)

Medical Device Safety and Performance Declaration Template

[To be printed on Company Letterhead of the registration holder]
Chief Executive
Medical Device Authority
Ministry of Health,
Putrajaya Malaysia

[Date]

Dear Sir/Madam,

Declaration of Medical Device Safety and Performance on Change Notification

I, on behalf of *[company name],* the manufacturer of the medical device(s) stated below, hereby declare that the medical device(s) in this change notification,

☐ is/are not a subject of a mandatory reportable incident and/or an ongoing field corrective action

☐ is/are not a subject of a mandatory reportable incident and/or has been reported to the MDA or regulatory agency (incident occurs outside Malaysia).

☐ conform(s) to the Essential Principles for Safety and Performance as per the statutory requirements of the Medical Device Act 2012 (Act 737) and the Medical Device Regulations 2012.

This declaration shall apply to the following medical device(s):
[List containing medical devices names and registration submission ID]

I am aware that a false declaration is an offence under Section 76 of Act 737 and may result in the cancellation of registration of the above medical devices under Section 5 of Act 737.

Yours Faithfully,

[Signature]
[Full Name and Title (Top Management Official)]
[Company stamp]

ANNEX E:
(informative)

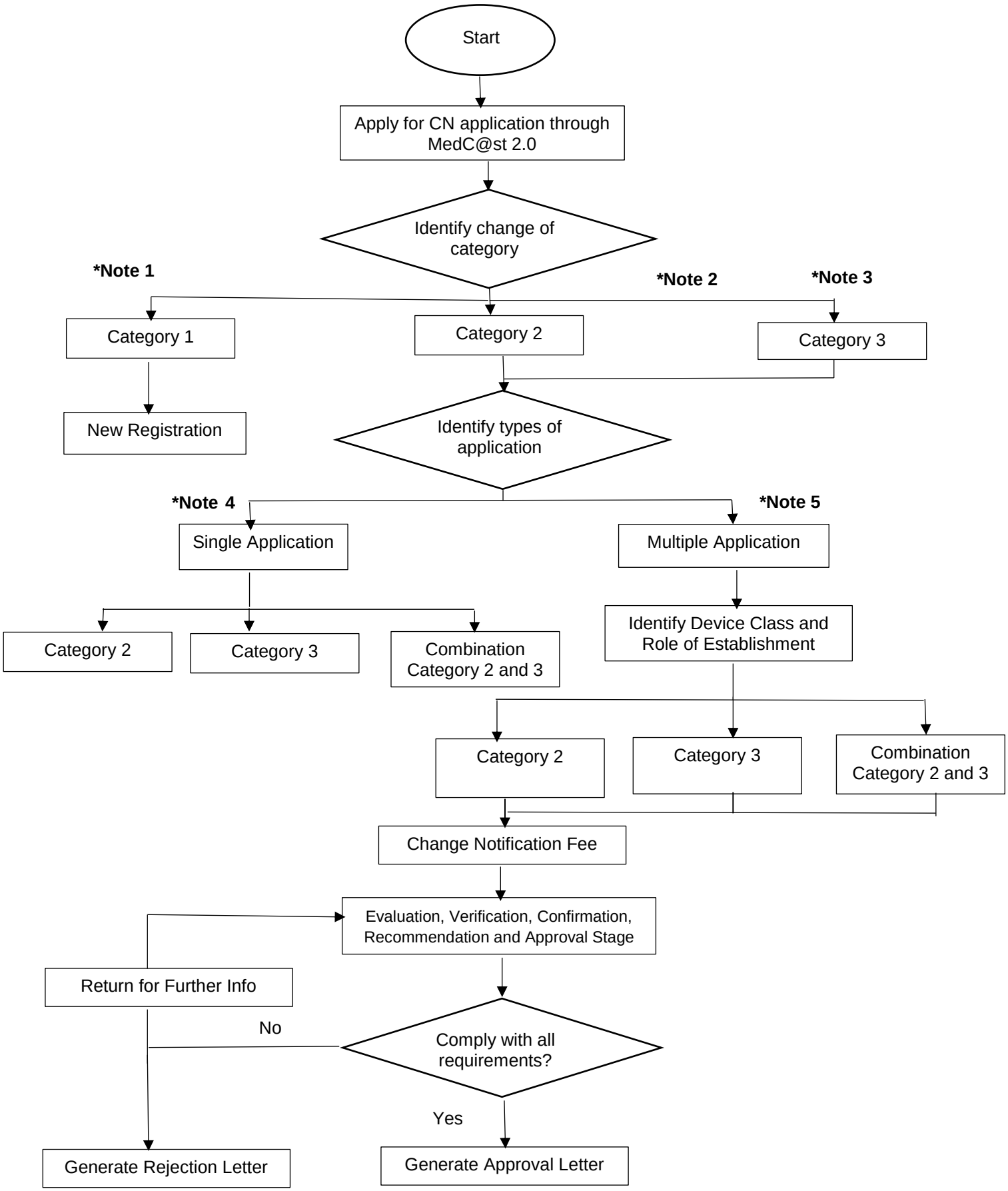
Application for Change Flowchart

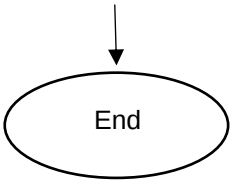
The flowchart below describes the process for change notification. Applicants shall ensure that the change notification required documents are complete before submission. Incomplete submissions and untimely responses to queries will result in unnecessary delays to the review process and inevitably prolong the overall processing timeline.

If the application is a wrong category submission, the applicant needs to re-apply the change notification.

Any additional information, particulars, document on application shall be submitted by the applicant within thirty (30) days from the date of request by the Authority or the application may be dropped.

Flowchart for Change Notification Application





Applicant pick the respective change notification category (refer to Section 7 of guidance document)	
*Note 1	Category 1 changes of medical devices that affect their safety and performance and require new registration of the medical device;
*Note 2	Category 2 changes are changes that require evaluation and endorsement form MDA prior to implementation of the change and before placing in the market
*Note 3	Category 3 changes may be implemented immediately.
*Note 4	Refer 6.1
*Note 5	Refer 6.2
All change notification application is to be submitted through MeDC@st 2.0+	
The details explanation on this can be referred to the Guidelines on “How to submit Change Notification for Medical Device”.	

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Websie: https://portal.mda.gov.my/