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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); and
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 editorial changes

Editorial changes are simple clarifications that do not alter the substantive meaning of the information. Editorial changes may include punctuation changes, grammar corrections, typographical correction, reordering existing material, rephrasing sentences that does not alter the content and adding headers for ease of use.

3.7 facility

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

3.8 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.

3.9 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.

3.10 labelling

The label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

Notes:

1: Labelling can also be referred to as “information supplied by the manufacturer”.
2: Labelling can be in printed or electronic format and may either physically accompany the device or direct the user to where the labelling information can be accessed (such as through a website).

3.11 multiple applications

Combination 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.

3.12 operating principles

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

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 (Refer 5.3);

b) **Category 2** 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 upon submission of complete documents through MeDC@St.

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 category 1 changes, the following types of changes require the registration holders to apply for new registration.

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

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

c) Addition of devices not considered a permissible variant according to the rules of grouping in Second Schedule of MDR 2012 and MDA/GD/0005, Product Grouping;

d) Addition of variant(s) for Cluster (Class A and B) according to the rules of grouping in Second Schedule of MDR2012 and MDA/GD/0054 Product Grouping for In- Vitro Diagnostic (IVD) Medical Devices;

e) 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

f) 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.

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's address.	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 (if applicable); v) Declaration of conformity (if applicable); 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. Examples: 1. Change in the equipment used for cutting the result in the change in length of sutures. 2. 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. Examples: 1. Change from a quantitative assay to a qualitative assay. 2. 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 and/or performance of the medical device (e.g. changes that improve the medical device ergonomics, aesthetic modification of the medical device).	i) Revised QMS certificate(s) (if applicable); ii) Risk analysis; iii) Usability testing report (if applicable); iv) Annexes
(c) i) All changes in specifications to shelf life and stability of a registered medical device. ii) Any changes in analytical performance test for IVD medical devices.	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: Replacement of catheter surface coating from PEBA to PEEK.	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.
(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 and/or indications of use. Exception: Changes that are considered as editorial.	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- i) modify the approved method of use; OR ii) involve a change from 'professional use only' to 'home use'. Note: Requires the usability test report.	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) Usability test report (if applicable); vii) Medical device labelling stating changes for each amended section; viii) Annexes

5.5.6 Changes to registered medical devices registration information	
(a) If the change only— i) involve the addition of new medical devices of the same design (within the permissible variants that does not affect safety and performance of the device, e.g. sizes, volume, colours, shapes, length, diameter); Examples: 1. Latex examination gloves with addition of different size. 2. Contact lens with addition of different colour OR ii) involve addition of a new medical device with design change that does not affect the safety and/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) Updated list of configurations of medical device indicating the name of medical devices affected; 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 - a. the added models are active, with measuring function or sterile class A medical device accessories; b. no change in manufacturer name and address for the manufacturing site(s) ii) Updated list of configurations of medical device indicating the name of medical devices affected; iii) Declaration of conformity; iv) Validation report and certificate (where applicable); v) Medical device labelling that indicate the addition of the medical device(s); vi) Annexes

(c) All changes to medical device registration that involve an increase or reduction in the medical devices in a set category of 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) Updated list of configurations of medical device indicating the name of medical devices affected; 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 that does not involve any change to the intended use and technical specifications; OR ii) involve changes of medical device proprietary name due to company acquisition /merging.	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) Updated list of configurations of medical device indicating the name of medical devices affected; 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 notification 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 (for manufacturer); 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 and/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 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 submitted in batches of 6 monthly submissions from point of first implementation.	i) Software validation report; ii) Detailed summary of software changes; iii) Annexes
5.6.3 Changes to labelling of medical devices	
(a) Where the change only involves a reduction or rephrasing of indications for use not affecting the medical device safety and/or performance. Exception: Changes that are considered as editorial.	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). Exception: Changes that are considered as editorial.	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). The following changes do not require change notification: i) Rephrasing of information/change in arrange in IFU; ii) Labelling changes that involve the addition and/or removal of languages not required by the Authority; iii) Labelling changes that involves the update of distributor information, include EU authorised representative, and which does not affect the medical device registration information.	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 are non-active, with no measuring function or non-sterile and complement the registered medical device as a system.	i) Declaration by registration holder to state - a. the added models are non-active, with no measuring function or non-sterile class A medical device accessories; b. no change in manufacturer; ii) name and address for the manufacturing site(s); iii) Updated list of configurations of medical device indicating the name of medical devices affected; iv) Declaration of conformity; v) Medical device labelling that indicate the addition of the device(s); vii) Annexes
(b) All changes to the medical device that involve- i) 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 and/or performance considerations.	i) Justification for deletion of medical device(s); ii) Declaration from manufacturer to state that there is no change to medical device in all aspects, including intended use, technical specifications; iii) Updated list of configurations of medical device indicating the name of medical devices affected; iv) Medical device labelling stating changes for each amended section;

ii) changes of brief description of item(s) (in the list of the configurations) that does not involve any change to the intended use and technical specifications;	v) Declaration of conformity; vi) Annexes
(c) All changes in the manufacturer information that only- i) involve changes in manufacturer's registered name and address (administration office); 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 relevant official supporting document indicating the change; v) Annexes
(d) A change in regulatory status on rejection or withdrawal in any recognised countries for any registered medical device. Note: withdrawal due to commercial decision does not require change notification.	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 (refer Section 40 and Section 41 of Act 737). The proposed changes to the medical device in these situations may have an impact on the safety and/or performance of the medical device.

For any changes, the establishments shall submit a change notification based on Clause 5 for the purpose of FCA submission. Refer to MDA/GD/0013*, Field Corrective Action (FCA)* for further information.

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	Change Notification Submission
1	Changes to label and IFU with no new information related to safety and/or 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/description 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 • Addition of disposal information such as environmental and bio-waste information.	• 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"	Change Notification 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-clinical/clinical validation is required to support safety and effectiveness	• Addition of DEHP Free symbol •Addition of Latex Free symbol	Change Notification Category 3 5.6.3 (c)
3	Changes to IFU related to clarification of existing content and addition of safety information (GMD and IVD)	• Minor update of intended use and/or indication with no change to approved scope • Addition/change of symbols and rephrase of existing information for clarity • Addition/change of adverse events and side effects • Addition of UDI • Addition of hazard symbols and information in label • Addition of MRI safety statement • Updating/revisions of warnings and precautions • Addition of symbols/description related to patient target group	•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 5.6.3 (c)
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	Addition of acceptance criteria value, based on previously submitted pre-clinical studies	Change Notification Category 3 5.6.3 (c)

			• No additional pre-clinical/clinical validation is required to support safety and effectiveness		

6 Notification process

6.1 All change notification application is to be submitted through MeDC@st 2.0+.

6.2 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	

Table 4: Example of calculation fees for Change Notification of single and multiple applications.

No	Application	Calculation
1	Single application for one category (either Category 2 or Category 3)	Example: The applicant has submitted single application under Category 2, Class B. $Calculation\ fee = fee\ for\ Category\ 2\ and\ Class\ B$ $= RM\ 500$
2	Single application for Category 2 and Category 3	Example: The applicant has submitted single application under Category 2, Class B and Category 3, Class B $Calculation\ fee = fee\ for\ Category\ 2, Class\ B$ $+ fee\ for\ Category\ 3, Class\ B$ $= RM\ 500 + RM\ 30 = RM\ 530$
3	Multiple application for one category (either Category 2 or Category 3)	Example: The applicant has combined 3 submission ID under Category 2, Class B. $Calculation\ fee$ $= number\ of\ submission\ ID\ x\ fee\ for\ Category\ 2$ $= 3\ x\ RM\ 500$ $= RM\ 1500$
4	Multiple application for Category 2 and Category 3	Example: The applicant has combined 3 submission ID under Category 2, Class B and Category 3, Class B

		$Calculation\ fee =$ $(number\ of\ submission\ ID\ x\ fee\ for\ Category\ 2) +$ $(number\ of\ submission\ ID\ x\ fee\ \ for\ Category\ 3)$ $= (3\ x\ RM\ 500) + (3\ x\ RM\ 30)$ $= RM\ 1500 + RM\ 90 = RM1590$

7 Requirements for Change Notification

7.1 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) Summary Table of Change Notification (Annex B).

iii) Medical Device Safety and Performance Declaration (Annex C).

iv) All supporting documents listed in Annex B and Annex C.

7.2 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.

7.3 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 5: Turn Around Time for Change Notification Application

Application	Category of Change	Timeline
Single Submission ID	Category 2 or Category 3	30 working days
Single Submission ID	Combination Category 2 and Category 3	60 working days
Multiple Submission ID	Category 2, Category 3, or Combination Category 2 and Category 3	60 working days

Upon submission of complete application form and supporting documents.

ANNEX A
(normative)

Request for confirmation on change notification category for registered medical device

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

[Your reference number]

Chief Executive
Medical Device Authority
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya Selangor,
Malaysia

Establishment 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 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]

NOTES:
1. This request may be submitted by hand or mail to the above address together with the payment.
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. The bank draft shall be made payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN". Information on reference number and telephone number of the applicant shall 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 30 working days.

ANNEX B
(informative)

Summary Table of Changes

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

(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 and identifier** 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 and identifier** 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 C
(normative)

Medical Device Safety and Performance Declaration Template

[To be printed on Manufacturer's Letterhead of the registration holder]
Chief Executive
Medical Device Authority
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC,
63000 Cyberjaya Selangor,
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,

☐ 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.

☐ conform(s) to the Post Market requirements as per The Medical Devices (Duties and Obligations of Establishments) Regulations 2019.

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]

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
Website: http://www.mda.gov.my