

**MDA/GD/0020
October 2017
Second Edition**

MEDICAL DEVICE GUIDANCE DOCUMENT

CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE



Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents	Page
Preface.....	iii
1 Introduction.....	1
2 Scope and application	1
3 Terms and definitions	1
4 General principle	3
5 Categories of changes.....	3
6 Notification process	12
7 Requirements for change notification	12
Annex A Request for confirmation on change notification category for registered medical device.....	14
Annex B Change notification form	15
Annex C Summary table of changes.....	23
Annex D Medical device safety and performance declaration template.....	25
Annex E Application for change flowchart	26
Table 1 Change notification for category 2.....	5
Table 2 Change category for category 3.....	9
Table 3 Change notification fees.....	12

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.

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.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY

Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
Fax: (03) 8230 0200
Email: mdb@mdb.gov.my
Website: <http://www.mdb.gov.my>

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

Is 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 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.

3.9 operating principles

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

3.10 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.

3.11 registration holder

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

3.12 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 upon receipt of the acknowledgement from the Authority.

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 of a registered medical device;
- b) Change to the risk classification of a registered medical device;
- c) Change to software that affect safety and performance of the registered medical device;
- d) 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 First Edition October 2013;
- 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; and
- f) Addition of medical devices with device proprietary names different from the registered devices, into a device listing.
- g) 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 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**
Change in manufacturing facility, process and quality management system (QMS)	
<p>(a) All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes</p> <p><i>Example:</i></p> <p><i>Change of manufacturing site</i></p>	<p>i) Revised QMS certificate(s) (if applicable)</p> <p>ii) Medical Device labelling stating changes for each amended section (if applicable)</p> <p>iii) Declaration that there is no change to manufacturing and sterilisation process</p> <p>iv) Sterilisation validation report</p>
<p>(b) All changes to manufacturing processes (including changes made to outsourced processes) that result in a change in specifications of a registered medical device</p> <p><i>Example:</i></p> <p><i>Change in the equipment used for cutting the result in the change in length of sutures.</i></p> <p><i>Moulding or cutting manufacturing process</i></p>	<p>i) Revised QMS certificate(s) (if applicable)</p> <p>ii) Summary of new manufacturing process</p> <p>iii) Validation report covering new processes</p> <p>iv) Pre-clinical studies (if applicable)</p> <p>v) Software validation report (for software)</p> <p>vi) Clinical safety report (for operating principles and design characteristics change)(if applicable)</p> <p>vii) Risk analysis</p>
<p>(c) All changes to sterilisation processes (including changes made to outsourced processes)</p> <p><i>Example:</i></p> <p><i>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></p>	<p>i) Sterilisation technique (certificate)</p> <p>ii) Medical Device labelling stating changes for each amended section (if applicable)</p> <p>iii) Sterilisation validation report (including the sterilisation protocol, sterilisation standards applied, sterility assurance level, sterilisation revalidation report)</p> <p>iv) QMS certificate(s)</p>
Changes in design or specifications of a registered medical device	
<p>(a) All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device</p> <p><i>Example:</i></p> <p><i>Change from a quantitative assay to a qualitative assay</i></p> <p><i>Addition of a footswitch to an X-ray system that previously do not operate via a footswitch mechanism.</i></p>	<p>i) Revised QMS certificate(s) (if applicable)</p> <p>ii) Pre-clinical studies</p> <p>iii) Risk analysis</p> <p>iv) Clinical studies (if applicable)</p> <p>v) Medical Device labelling stating changes for each amended section (if applicable)</p> <p>vi) Software validation report (for software, if applicable)</p> <p>vii) Detailed summary of software changes (for software, if applicable)</p>
<p>(b) Unless the change only involves a design change that does not affect the safety or performance of the medical device (e.g. changes that improve the medical device</p>	<p>i) Revised QMS certificate(s) (if applicable)</p> <p>ii) Risk analysis</p> <p>iii) Usability testing report (if applicable)</p>

Types of change	Documents to be submitted**
ergonomics, aesthetic modification of the medical device)	
(c) All changes in specifications (including shelf life and stability) of a registered medical device	<ul style="list-style-type: none"> 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)
<p>(d) Is there a change to software that impacts the performance characteristics of the registered medical device such that the treatment or diagnosis of the patient is altered?</p> <p><i>Example:</i></p> <p><i>Upgrade of software version changes the performance characteristics like specificity or sensitivity of the diagnostic medical device.</i></p>	<ul style="list-style-type: none"> i) Revised QMS certificate(s) (if applicable) ii) Risk analysis iii) Software validation report iv) Detailed summary of software changes
Changes to materials in a general medical device	
<p>(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</p> <p><i>Example:</i></p> <p><i>Change in source of hyaluronic acid from Streptococcus zooepidemicus to Streptococcus equi</i></p>	<ul style="list-style-type: none"> i) Revised QMS certificate(s) (if applicable) ii) Pre-clinical studies iii) Clinical safety report (if applicable) iv) Biological safety data v) Information of sources/donors vi) Risk analysis
<p>(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</p> <p><i>Example:</i></p>	<ul style="list-style-type: none"> 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

Types of change	Documents to be submitted**
<i>Replacement of catheter surface coating from PEBA to PEEK</i>	
(c) All changes to materials that are used for shielding in medical devices emitting ionising radiation <i>Example:</i> <i>Change in shielding material of X-ray system from lead to tungsten</i>	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
(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
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
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 not arising due to safety or performance concerns <i>Example:</i> <i>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>	i) Revised QMS certificate(s) (if applicable) ii) Description of the warnings, precautions and/or contraindications iii) Reasons for the revision of approved indications iv) Medical Device labelling for new medical device(s) stating changes for each amended section
(b) Labelling changes that— i) 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) Preclinical 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

Types of change	Documents to be submitted**
Changes to registered medical devices registration information	
<p>(a) If within the medical device grouping, the change only—</p> <ul style="list-style-type: none"> i) involves the addition of new medical devices of the same design, within the existing range of sizes already registered; 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) 	<ul style="list-style-type: none"> 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) ix) Manufacturing information
<p>(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</p>	<ul style="list-style-type: none"> i) Declaration by registration holder to state— <ul style="list-style-type: none"> -the added models are class A sterile -the name of the medical device affected -the medical device identifier -no change in manufacturer for the class A sterile medical device -name and address for the manufacturing site(s) for class A sterile medical device ii) List of configurations of medical device iii) Declaration of conformity iv) Validation report and certificate
<p>(c) All changes to medical device registration that involve an increase or reduction in the number of medical devices in a set of a registered medical device</p>	<ul style="list-style-type: none"> 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) Device labelling stating changes for each amended section v) Description of the addition or reduction
<p>(d) All changes to the medical device name and/or medical device identifier</p>	<ul style="list-style-type: none"> 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) Device labelling stating changes for each amended section

Types of change	Documents to be submitted**
<p>**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</p> <p>**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.</p>	

Table 2: Change category for category 3

Types of change	Documents to be submitted**
Change in manufacturing facility, process and quality management system (QMS)	
(a) All changes to certificates for manufacturing and sterilisation facilities	Valid certificate and report
(b) Unless the change only— <ul style="list-style-type: none"> i) involves an update of certificate QMS validity date only OR; ii) involves a cancellation of QMS scope on the certificate for any of the multiple existing manufacturing facilities (that is not due to safety, and/or performance of the medical device), OR; iii) involves the change in conformity assessment body with no change in scope of the certification OR; iv) involves the expansion of scope of the QMS certification which does not affect the registered medical device 	Valid QMS certificate
Changes in design or specifications of a registered medical device	
(a) Unless the change only involves a change to software version number that does not affect safety or	<ul style="list-style-type: none"> i) Software validation report ii) Detailed summary of software changes

Types of change	Documents to be submitted**
<p>performance of the medical device, such as—</p> <ul style="list-style-type: none"> 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. 	
Changes to labelling of medical devices	
(a) Where the change only involves a reduction of indications for use not arising due to medical device safety or performance concerns	<ul style="list-style-type: none"> i) Description of the new indications for use ii) Reasons for the reduction of approved indications iii) Medical Device labelling for new medical device(s) stating changes for each amended section
(b) Labelling changes that only— i) involve the addition of Recognised Countries' approvals (e.g. CE marking)	<ul style="list-style-type: none"> i) Medical Device labelling stating changes for each amended section ii) Valid certificates from relevant bodies (where applicable)
(c) Other labelling changes involving information in the labelling that does not fall under above (a),(b), and (c)	<ul style="list-style-type: none"> 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)
Changes to registered medical devices registration information	
(a) If the change only involves an addition of Class A medical device accessories that complement the	<ul style="list-style-type: none"> i) Declaration by registration holder to state— <ul style="list-style-type: none"> - the added models are class A non-sterile - the name of the medical device affected - the medical device identifier

Types of change	Documents to be submitted**
registered medical device as a system	<ul style="list-style-type: none"> - no change in manufacturer for the class A non-sterile medical device - name and address for the manufacturing site(s) for class A non-sterile medical device ii) List of configurations of medical device iii) Declaration of conformity
b) All deletions of a medical device from medical device registration (for medical devices in grouping) <i>Example: The change only involves the reduction in the number of medical device in the grouping due to obsolescence and not due to safety or performance considerations</i>	<ul style="list-style-type: none"> 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) Device labelling stating changes for each amended section
c) All changes in the manufacturer information including changes in manufacturer's name and address (which is not the manufacturing site)	<ul style="list-style-type: none"> 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
d) A change in regulatory status on rejection or withdrawal in any recognised countries for any registered medical device	<ul style="list-style-type: none"> 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)
<p>**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</p> <p>**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.</p>	

5.6 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. Field corrective action report (FCA) according to MDA/GD/0013 shall be submitted together with application for changes to registered medical device.

6 Notification process

6.1 For Category 2 and 3 changes, each submission of notification for changes is allowed only for one medical device registration.

6.2 Submission of notification for changes shall be made using the form in Annex B.

6.3 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	
<i>Medical device that contains a medicinal product</i>	2500	

* The fees are exclusive of 6% GST

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) Change Notification Form (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)

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	:	<input type="checkbox"/> Category 1 <input type="checkbox"/> Category 2 <input type="checkbox"/> 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)

Change Notification Form

Please fill in medical device registration details:

Establishment License No. :
 Medical Device Registration Certificate No. :
 MEDCAST Registration Submission ID :
 Medical Device Name and include medical :
 device identifier

This checklist is provided to assist the registration holder in determining the required documents for each type of change to be made to any registered medical device.

All the required documents shall be submitted for the relevant sections of the CSDT to support the proposed change to the medical device. The documentation 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 other relevant documents issued by the Authority which may be required for the registered medical devices

Table 1. Change notification for category 2

Types of change	Documents to be submitted**	Provided	
		Yes	No (Please Justify)
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 <i>Example:</i> <i>Change of manufacturing site</i>	<ul style="list-style-type: none"> 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 		
(b) All changes to manufacturing processes (including changes made to outsourced processes) that result in a change in specifications of a registered medical device <i>Example:</i> <i>Change in the equipment used for cutting the result in the change in length of sutures.</i> <i>Moulding or cutting manufacturing process</i>	<ul style="list-style-type: none"> 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 		

Types of change	Documents to be submitted**	Provided	
<p>(c) All changes to sterilisation processes (including changes made to outsourced processes)</p> <p><i>Example:</i></p> <p><i>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></p>	<p>i) Sterilisation technique (certificate)</p> <p>ii) Medical Device labelling stating changes for each amended section (if applicable)</p> <p>iii) Sterilisation validation report (including the sterilisation protocol, sterilisation standards applied, sterility assurance level, sterilisation revalidation report)</p> <p>iv) QMS certificate(s)</p> <p>v) Post sterilisation functional test report</p>		
Changes in design or specifications of a registered medical device			
<p>(a) All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device</p> <p><i>Example:</i></p> <p><i>Change from a quantitative assay to a qualitative assay</i></p> <p><i>Addition of a footswitch to an X-ray system that previously do not operate via a footswitch mechanism.</i></p>	<p>i) Revised QMS certificate(s) (if applicable)</p> <p>ii) Pre-clinical studies</p> <p>iii) Risk analysis</p> <p>iv) Clinical studies (if applicable)</p> <p>v) Medical Device labelling stating changes for each amended section (if applicable)</p> <p>vi) Software validation report (for software, if applicable)</p> <p>vii) Detailed summary of software changes (for software, if applicable)</p>		
<p>(b) Unless the change only involves a design change that does not affect the safety or performance of the medical device (e.g. changes that improve the medical device ergonomics, aesthetic modification of the medical device)</p>	<p>i) Revised QMS certificate(s) (if applicable)</p> <p>ii) Risk analysis</p> <p>iii) Usability testing report (if applicable)</p>		
<p>(c) All changes in specifications (including shelf life and stability) of a registered medical device</p>	<p>i) Revised QMS certificate(s) (if applicable)</p> <p>ii) Pre-clinical studies (if applicable)</p> <p>iii) Clinical safety report (if applicable)</p> <p>iv) Risk analysis</p> <p>v) Medical Device labelling stating changes for each amended section (if applicable)</p> <p>vi) Software validation report (for software, if applicable)</p> <p>vii) Detailed summary of software changes (for software)</p>		

Types of change	Documents to be submitted**	Provided	
<p>(c) Is there a change to software that impacts the performance characteristics of the registered medical device such that the treatment or diagnosis of the patient is altered?</p> <p><i>Example:</i></p> <p><i>Upgrade of software version changes the performance characteristics like specificity or sensitivity of the diagnostic medical device.</i></p>	<ul style="list-style-type: none"> i) Revised QMS certificate(s) (if applicable) ii) Risk analysis iii) Software validation report iv) Detailed summary of software changes 		
Changes to materials in a general medical device			
<p>(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</p> <p><i>Example:</i></p> <p><i>Change in source of hyaluronic acid from Streptococcus zooepidemicus to Streptococcus equi</i></p>	<ul style="list-style-type: none"> i) Revised QMS certificate(s) (if applicable) ii) Pre-clinical studies iii) Clinical safety report (if applicable) iv) Biological safety data v) Information of sources/donors vi) Risk analysis 		
<p>(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</p> <p><i>Example:</i></p> <p><i>Replacement of catheter surface coating from PEBA to PEEK</i></p>	<ul style="list-style-type: none"> 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 		
<p>(c) All changes to materials that are used for shielding in medical devices emitting ionising radiation</p> <p><i>Example:</i></p> <p><i>Change in shielding material of X-ray system from lead to tungsten</i></p>	<ul style="list-style-type: none"> 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 		
<p>(d) All changes to the radiation source (e.g. radioisotopes)</p>	<ul style="list-style-type: none"> i) Revised QMS certificate(s) (if applicable) ii) Information on radiation source iii) Radiation safety test/test report 		

Types of change	Documents to be submitted**	Provided	
	iv) Risk analysis		
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		
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 not arising due to safety or performance concerns <i>Example:</i> <i>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>	i) Revised QMS certificate(s) (if applicable) ii) Description of the warnings, precautions and/or contraindications iii) Reasons for the revision of approved indications iv) Medical Device labelling for new medical device(s) stating changes for each amended section		
(b) Labelling changes that— i) 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) Preclinical 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		
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, within the existing range of sizes already registered; OR ii) involves addition of a new medical device with design change that	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)		

Types of change	Documents to be submitted**	Provided	
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)	viii) Software validation report (for software) ix) Manufacturing information		
(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 class A sterile -the name of the medical device affected -the medical device identifier -no change in manufacturer for the class A sterile medical device -name and address for the manufacturing site(s) for class A sterile medical device ii) List of configurations of medical device iii) Declaration of conformity iv) Validation report and certificate		
c) All changes to medical device registration that involve an increase or reduction in the number of medical devices in a set 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) Device labelling stating changes for each amended section v) Description of the addition or reduction		
d) All changes to the medical device name and/or medical device identifier	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) Device labelling stating changes for each amended section		
<p>**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</p> <p>**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.</p>			

Table 2: Change category for category 3

Types of change	Documents to be submitted**	Provided	
Change in manufacturing facility, process and quality management system (QMS)			
(a) All changes to certificates for manufacturing and sterilisation facilities	Valid certificate and report		
(b) Unless the change only— i) involves an update of certificate QMS validity date only OR; ii) involves a cancellation of QMS scope on the certificate for any of the multiple existing manufacturing facilities (that is not due to safety, and/or performance of the medical device), OR; iii) involves the change in conformity assessment body with no change in scope of the certification OR; iv) involves the expansion of scope of the QMS certification which does not affect the registered medical device	Valid QMS certificate		
Changes in design or specifications of a registered medical device			
(a) Unless the change only involves 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 bring the system to its original specification; ii) software changes which augment interfacing to other non-	i) Software validation report ii) Detailed summary of software changes		

Types of change	Documents to be submitted**	Provided	
<p>medical peripherals such as printers or VDUs and which has no diagnostic or therapeutic function; or</p> <p>iii) software changes which only modify the appearance of the user interface with no risk to diagnostic or therapeutic function of the medical device.</p>			
Changes to labelling of medical devices			
(a) Where the change only involves a reduction of indications for use not arising due to medical device safety or performance concerns	<p>i) Description of the new indications for use</p> <p>ii) Reasons for the reduction of approved indications</p> <p>iii) Medical Device labelling for new medical device(s) stating changes for each amended section</p>		
(b) Labelling changes that only— ii) involve the addition of Recognised Countries' approvals (e.g. CE marking)	<p>i) Medical Device labelling stating changes for each amended section</p> <p>ii) Valid certificates from relevant bodies (where applicable)</p>		
(c) Other labelling changes involving information in the labelling that does not fall under (a) and (b) above	<p>i) Medical Device labelling stating changes for each amended section</p> <p>ii) Details of changes and the reason for changes</p> <p>iii) Documents supporting proposed changes detailed above (if applicable)</p>		
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	<p>i) Declaration by registration holder to state—</p> <ul style="list-style-type: none"> - the added models are class A non-sterile - the name of the medical device affected - the medical device identifier - no change in manufacturer for the class A non-sterile medical device - name and address for the manufacturing site(s) for class A non-sterile medical device <p>ii) List of configurations of medical device</p> <p>iii) Declaration of conformity</p>		

Types of change	Documents to be submitted**	Provided	
b) All deletions of a medical device from medical device registration (for medical devices in grouping) <i>Example: The change only involves the reduction in the number of medical device in the grouping due to obsolescence and not due to safety or performance considerations</i>	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) Device labelling stating changes for each amended section		
c) All changes in the manufacturer information including changes in manufacturer's name and address (which is not the manufacturing site)	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		
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)		
<p>**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</p> <p>**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.</p>			

ANNEX C
(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 **MEDCAST medical device registration number**.
 - With reference to the ‘type of changes’ categories in Table 1, highlight the type of change proposed.
 - Specify the MEDCAST 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 MEDCAST ; 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
<p>Type of change:</p> <p><i>e.g. Change in material: Delivery tube material changed from polyvinyl chloride(PVC) to silicone</i></p> <p>Category of change:</p>	<p><i>Delivery tube material: polyvinylchloride (PVC)</i></p> <p>Registration no:</p> <p>List of medical device</p> <p>i)</p> <p>ii)</p> <p>iii)</p>	<p><i>Delivery tube material: silicone</i></p>	<p><i>Improve patient safety by changing to DEHP-free tubing material</i></p>	<p><i>Australia TGA – pending</i></p> <p><i>EU Notified Body – approved/authorised for marketing</i></p> <p><i>Health Canada – not supplied</i></p> <p><i>US FDA – not supplied</i></p> <p><i>Japan MHLW – not supplied</i></p>
<p>Type of change:</p> <p><i>e.g. Change in manufacturing facility</i></p> <p>Category of change:</p>	<p><i>Name and address of current manufacturing facility A</i></p> <p>Registration no:</p> <p>List of medical device</p> <p>i)</p> <p>ii)</p> <p>iii)</p>	<p><i>Name and address of new manufacturing facility B</i></p>	<p><i>Reason for to move manufacturing activities from facility A to facility B</i></p>	<p><i>Australia TGA – pending</i></p> <p><i>EU Notified Body – approved/authorised for marketing</i></p> <p><i>Health Canada – not supplied</i></p> <p><i>US FDA – not supplied</i></p> <p><i>Japan MHLW – not supplied</i></p>

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

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)]

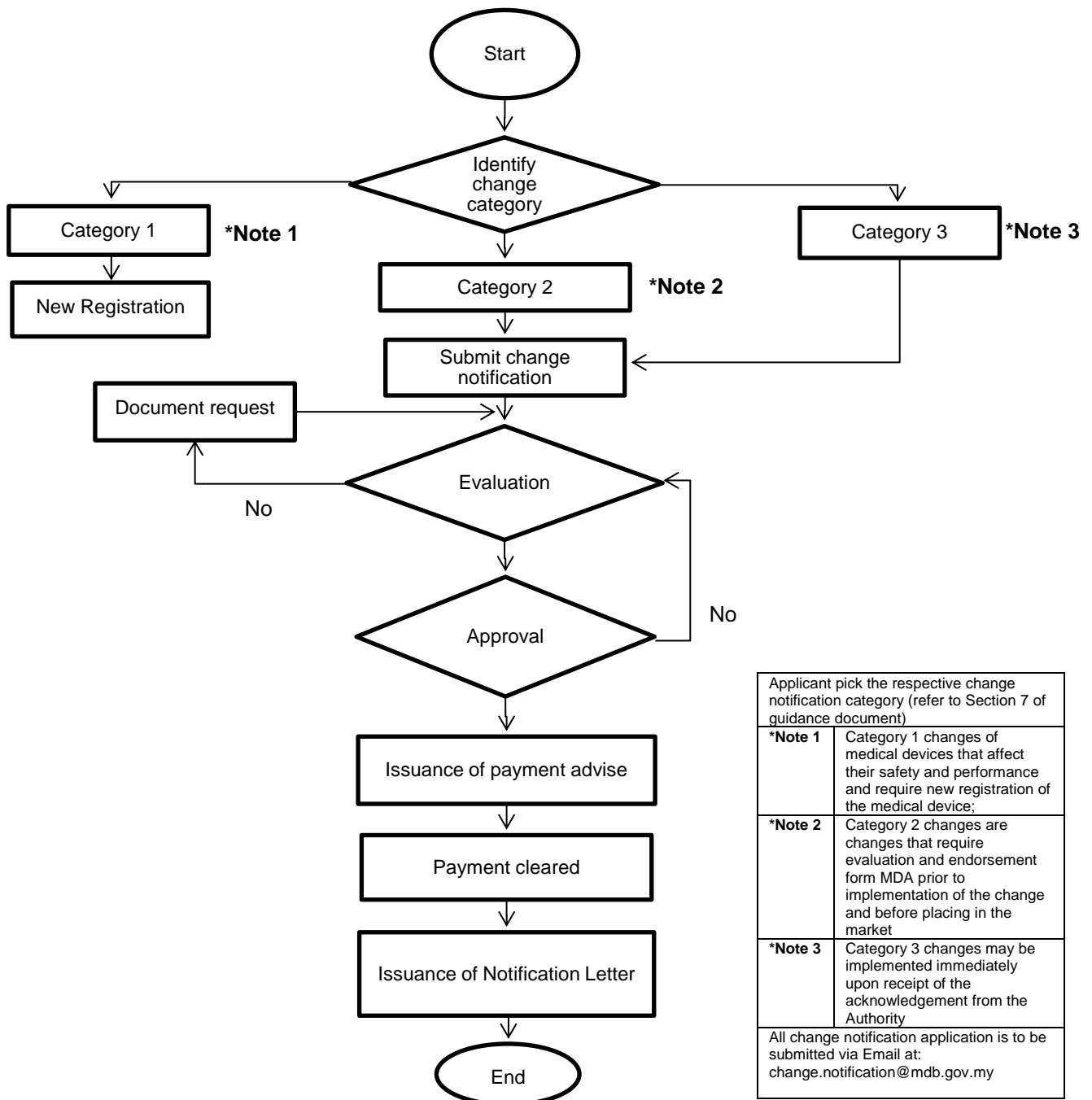
[Company stamp]

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.

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.



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.mdb.gov.my>

