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MEDICAL DEVICE GUIDANCE DOCUMENT

CHANGE MANAGEMENT FOR REGISTERED MEDICAL DEVICES

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

CONTENTS

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 2012 (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 into ensuring the accuracy and completeness of this guidance document. In the event 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 MANAGEMENT FOR REGISTERED MEDICAL DEVICES

1. Introduction

During its lifecycle, a medical device may undergo various changes. Any modifications or changes made to a registered medical device must align with the essential principles of safety and/or performance, enabling a risk-based regulatory system to effectively control the associated market risks.

A manufacturer is obligated to assess the impact of any modification to a medical device on the patient, practitioner, and/or user. This assessment determines whether the change is anticipated to affect the device's safety, performance, or effectiveness, or the arrangements established to maintain quality system compliance with relevant standards (e.g., design verification, design validation, human factors, organizational structure, facility additions, deletions, or relocations), and/or applicable regulatory requirements. This is crucial for ensuring the continued safety, performance, and effectiveness of the medical device.

This document outlines general principles, categorization, reporting, and alternative pathways for managing changes. It employs a risk-based approach with illustrative examples.

2. Scope

This document applies to all registered medical devices under the Act 737 and outlines key considerations for manufacturers when a device undergoes any changes or modifications. It is also applicable when a registered medical device requires changes, or proposed changes, due to a mandatory reportable incident or field corrective action in accordance with Section 40 or Section 41 of Act 737.

Apart from Change Management submissions made in accordance with the applicable categories of change, the manufacturer may also update the information and supporting documents of a registered medical device prior to re-registration. Such updates shall be carried out through the Change Management module while the registration certificate remains valid.

In summary, the Change Management (CM) process applies to:

1. Any changes to a registered medical device; or
2. Updates arising from post-market issues, including reportable incidents and field corrective actions; or
3. Updates to information or documents required in preparation for re-registration.

3. Terms and Definitions

For the purposes of this document, the terms and definitions provided in Act 737, its subsidiary regulations, and the following definitions shall apply.

3.1 Editorial changes

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 do not alter the content and adding headers for ease of use.

3.2 Intended use

The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

[Source: Medical Device Regulations 2012]

3.3 In Vitro Diagnostic (IVD) Medical Devices

In vitro diagnostic tests are used for in vitro examination of specimens derived from the human body to provide information for screening, diagnosis, or treatment monitoring purposes.

Includes any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its manufacturer to be used in vitro for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information:

a) concerning a physiological or pathological state or a congenital abnormality
b) to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or
c) to monitor therapeutic measures; and includes a specimen receptacle.

[SOURCE: Guidance Document MDA/GD/0001 In-Vitro Diagnostic (IVD) Medical Device Classification System]

3.4 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.

3.5 Manufacturer

As defined in Section 2 of the Act 737.

3.6 MeDC@St

A web-based, centralized online application system administered by the MDA, used for submission and management of establishment licences, medical device registrations,

change management applications, and related regulatory filings.

3.7 Medical device

As defined in Section 2 of Act 737 and MDA/GD/0006: Guidance on the Definition of Medical Device.

3.8 Multiple application

A Change Management application involving two or more Medical Device Registration Certificate numbers. This applies when the same type of change affects multiple registered medical devices and can be consolidated into a single submission.

3.9 Non-significant change

A non-significant change is any change that has little or no potential to affect the safety and/or performance/effectiveness of the medical device.

[SOURCE: Guidance Document GHWP/WG2-WG1-WG3/F001:2024 Change management to registered Medical Devices]

3.10 Quality Control (QC)

It is part of quality management focused on fulfilling quality requirements.

[SOURCE: (ISO 9000 Quality management)]

3.11 Risk management

A systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk.

[SOURCE: ISO 14971:2019 Medical devices - Application of risk management to medical devices]

3.12 Single application

A Change Management application involving only one Medical Device Registration Certificate number.

3.13 Significant change

Any change that could reasonably be expected to affect the safety and/or performance/effectiveness of a medical device or its conformity with the essential principles.

[SOURCE: Guidance Document GHWP/WG2-WG1-WG3/F001:2024 Change management to registered Medical Devices]

3.14 Software as a medical device (SaMD)

Software as intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

NOTES:

a) SaMD is a medical device and includes in-vitro diagnostic (IVD) medical devices;
b) SaMD is capable of running on general purpose (non-medical purpose) computing platforms;
c) “without being part of” means software not necessary for a hardware medical device to achieve its intended medical purpose;
d) Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device;
e) SaMD may be used in combination (e.g., as a module) with other products including medical devices;
f) SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software;
g) Mobile apps that meet the definition above are considered SaMD.

[SOURCE: Guidance Document IMDRF, Software as a Medical Device (SaMD): Key Definitions]

4. General Principles

For any change made to a registered medical device, the manufacturer shall evaluate:

- the device concerned;
- the potential impact of the change on patients, practitioners, and/or users;
- the implications of the change on the intended use or indications for use, risk classification, and device specifications.

Following this evaluation, the manufacturer shall determine whether the change may reasonably be expected to influence the safety, performance, or effectiveness of the device, or its continued conformity with the Essential Principles and its overall risk–benefit profile throughout the device’s lifecycle.

5. Categorisation and Assessment of Changes

5.1 Categorisation of Changes

Changes to a registered medical device may be categorised as significant **or** non-significant, depending on the extent to which they impact the safety and/or performance of the device.

A significant change typically may:

i. introduce risks to the patient that were not previously identified;
ii. increase the probability of occurrence of existing hazards; or
iii. modify the presentation of existing or new risks to the user, including those arising from labelling changes or new indications for use.

Significant changes may include, but are not limited to, changes to:

i. the manufacturing process, facility, or equipment;
ii. the manufacturing quality control procedures, including methods, tests, reference standards, or procedures used to control the quality, purity, and sterility of the device or the materials used in its manufacture;
iii. the design of the device, including its performance characteristics, principles of operation, and specifications of materials, energy source, software, or accessories.

Note: Refer to Annex A for the complete list of significant changes.

A non-significant change is any change that has little or no potential to affect the safety and/or performance of the medical device.

5.2 UDI-DI Triggers

UDI-DI (Unique Device Identifier – Device Identifier) triggers are specific changes or events in a medical device's characteristics, labelling, or packaging that necessitate the assignment of a new UDI-DI. These triggers ensure that each distinct version or model of a device is uniquely identifiable, avoiding misidentification and maintaining traceability throughout the device's life cycle.

If the same Device Identifier (DI) continues to be used for newer versions of a medical device after changes have been made, it may lead to misidentification of the device and/or ambiguity in its traceability. A new UDI-DI should be assigned when changes are made to any of the following UDI-DI related device data elements:

- Brand name
- Device version or model
- Clinical size (including volume, length, gauge, diameter)
- Labelled as single-use
- Packaged as sterile
- Requirement for sterilisation before use
- Quantity of devices contained within a package
- Critical warnings or contraindications (e.g., contains latex or Bis(2-ethylhexyl) phthalate (DEHP))
- New or revised packaging configurations

Medical devices typically undergo changes throughout their product life cycle. When a change to a registered medical device results in the need for a new UDI-DI, the manufacturer shall determine whether a Change Management application or a new pre-market submission is required, in accordance with the applicable regulatory requirements.

5.3 Flowchart for Categorisation of Changes

The following section provides flowcharts to assist manufacturers in determining whether a change constitutes a significant change that must be reported to the MDA. Certain changes classified as non-significant may also require reporting, depending on their nature and impact.

The main flowchart in **Annex A** outlines the general categories of changes and offers practical guidance to support manufacturers in assessing whether a change may affect the safety and/or performance of a medical device.

Flowcharts A to G in **Annex B** present specific questions and decision pathways to further assist in determining whether a change should be categorised as significant or

non-significant. These flowcharts, together with their accompanying explanations, are intended to clarify the decision-making process for change categorisation.

The summary of the flowcharts is provided in Table 1.

Table 1. Summary of Flowchart Categorization based on Type of Changes

Flowchart	Changes
Main Flowchart	General Type of Changes to Medical Devices and In Vitro Diagnostic (IVD) Medical Devices
Flowchart A	Changes in Manufacturing Processes, Facility and/or Quality Management System (including QC) for Medical Devices and In Vitro Diagnostic (IVD) Medical Devices
Flowchart B	Changes in Design for Medical Devices and In Vitro Diagnostic (IVD) Medical Devices
Flowchart C	Changes to Sterilisation Facility and its Process
Flowchart D	Changes to Software for Medical Devices
Flowchart E1	Changes in Materials for General Medical Devices
Flowchart E2	Changes in Materials for In Vitro Diagnostic (IVD) Medical Devices
Flowchart F	Changes to Labelling of Medical Devices and In Vitro Diagnostic (IVD) Medical Devices
Flowchart G	Changes to Registered Medical Devices and In Vitro Diagnostic (IVD) Medical Devices registration information

5.4 Reporting of changes

A manufacturer is required to submit a Change Management application to the MDA for evaluation and approval once it has been determined that the proposed change to a medical device constitutes a significant change. For such changes, the affected medical device may only be placed on the market upon receipt of the MDA's approval.

Non-significant changes are generally not required to be reported to the MDA prior to implementation. However, the manufacturer shall maintain a documented assessment and supporting evidence within the Quality Management System (QMS) and/or technical documentation to demonstrate that the device remains safe and continues to perform as intended. Table 2 below provides a recommended approach for reporting various types of changes to assist manufacturers in determining the appropriate reporting pathway.

Table 2. Recommended Approach for Reporting Changes

Type of Changes	Submission Approaches
Significant Change	Changes that require evaluation and approval by the MDA prior to implementation and before the device is placed on the market.
Non-Significant Change – Notification Required	Changes that may be implemented immediately upon submission of complete documentation through MeDC@St.

Non-Significant Change – Notification Optional	Changes that do not require submission; however, the manufacturer may submit a notification voluntarily.
Non-Significant Change	Changes that do not require submission but must be fully documented within the manufacturer's QMS and/or technical documentation.

NOTE: QMS requirement: Manufacturer shall assess the changes, perform risk benefit of the product, document the changes and if applicable update the technical documentation.

All Change Management applications shall be submitted through MeDC@St. Manufacturers are required to provide complete supporting documentation as specified in Annex B.

Manufacturers are reminded that the determination of required documentation for a change management shall be based on all changes submitted, and not solely on an individual category of change.

5.5 Non-Significant Changes Not Subject to Change Management

The following types of changes are considered non-significant and are not subject to formal change management procedures:

- Changes to raw material suppliers (excluding medicinal substances and biological material suppliers) that do not affect the registered device specifications.
- Editorial changes that do not affect the device's intended use, safety, or performance.
- Rephrasing or rearrangement of information in the Instructions for Use (IFU) without altering the meaning.
- Labelling changes involving the addition and/or removal of languages not required by the MDA.
- Labelling changes involving the addition, removal, or modification of reference agency approvals (e.g., CE Marking) that do not affect the device's registration.
- Labelling changes involving the addition, removal, or modification of barcodes, provided they do not alter the device listing information.
- Labelling changes that involve only layout, colour, font size, or design adjustments, provided there is no change to the prominence or content of precautions, warnings, contraindications, and/or adverse events.
- Labelling changes that update distributor information, including EU Authorised Representatives (AR), provided these changes do not affect the registered medical device information.
- Updates to AR label information, such as changes to AR name, address, or ownership, are permitted only after approval in the Establishment License (EL) Module by the MDA. Rationale-related changes can only be implemented once approved in the EL Module.

These changes must still be documented within the manufacturer's Quality Management System (QMS) to demonstrate that the device continues to comply with regulatory and safety requirements.

6. Bundling of Changes

Significant and non-significant changes that require notification submission in MeDC@St may be bundled for regulatory submission purposes, provided the changes meet the requirements outlined in this guidance.

Bundling allows multiple related changes to be submitted together in a single application or across multiple applications, depending on the nature and scope of the changes. There are two types of bundling changes:

6.1 Single or Multiple Type of Changes Under a Single Application

When changes involve one or multiple types of changes applied to a single registration certificate, such changes may be bundled and submitted under one Change Management application.

6.2 Single or Multiple Type of Change Changes Under Multiple Applications

Bundling of one or multiple types of changes across multiple applications is only permitted for the following type of changes:

- Change in Manufacturer Name and/or Address
- Change in Manufacturing Site Name and/or Address
- Change in Sterilisation Site Name and/or Address
- Change in Quality Management System (QMS) Information
- Change in Brand or Proprietary Name
- Change in Labelling Information

The changes are permitted for the same changes for multiple types of changes for multiple registration certificate numbers.

Such bundling is allowed only when the same changes are applied consistently across multiple registered certificate numbers.

6.3 Examples of Scenarios Involving Single or Multiple Types of Changes under Multiple Applications

(a) Single Type of Change Under Multiple Application

Where a single type of change applies to multiple certificates.

Example scenario:

- Change in Manufacturer Name

Certificate No.	Current Manufacturer	Proposed Manufacturer
GAXXXX001	ABC Medical Sdn. Bhd.	XYZ Medical Sdn. Bhd.
GAXXXX002	ABC Medical Sdn. Bhd.	XYZ Medical Sdn. Bhd.
GAXXXX003	DEF Medical Sdn. Bhd.	XYZ Medical Sdn. Bhd.

All certificates involve a change in manufacturer to Manufacturer XYZ

(b) Multiple Type of Changes Under Multiple Applications

Where more than one type of change (e.g. manufacturer name, brand, and/or site address) is applied consistently across multiple certificates.

Example Scenario:

Certificate No.	Current Manufacturer	Proposed Manufacturer	Current Brand	Proposed Brand
GAXXXX010	Manufacturer A	Manufacturer B	Brand A	Brand B
GAXXXX011	Manufacturer A	Manufacturer B	Brand A	Brand B
GAXXXX012	Manufacturer C	Manufacturer B	Brand C	Brand B

In this case:

- All certificates involve a change in manufacturer to Manufacturer B; and
- All certificates involve a change in brand to Brand B.

Even though the existing manufacturers or brands differ among certificates, the **proposed change outcome** is the same across all applications. Therefore, the changes may be bundled under a single Change Management submission.

7. Updates to Registered Device Information Prior to Re-Registration

Apart from Change Management submissions made in accordance with the applicable categories of change, manufacturers may also update the information and supporting documents of a registered medical device prior to re-registration. Such updates shall be carried out through the Change Management module while the registration certificate remains valid. This change is classified as a non-significant change and must be notified to the MDA.

Only medical devices with fully updated and current information may proceed with re-registration. Manufacturers are responsible for ensuring that all required information and documents are updated at any time within the five-year validity period of the certificate, and that these updates are completed before submission of the re-registration application. Re-registration cannot proceed if any required information or document has not been updated.

For the purpose of re-registration, the following information and documents shall be updated according to device class:

- Class A Medical Devices
    - Declaration of Conformity (DoC)
    - Quality Management System (QMS) information
    - Post-Market Surveillance (PMS) information

- Class B, C, and D Medical Devices
    - Declaration of Conformity (DoC)
    - Quality Management System (QMS) information
    - Post-Market Surveillance (PMS) information
    - Clinical Evaluation Report (CER) or Clinical Performance Report (CPR)
    - Risk Management Report
    - CAB Report and Certificate

Manufacturers must ensure that all updates are completed and approved, where required, prior to initiating the re-registration process.

However, the MDA reserves the right to request additional information or documents if deemed necessary to support the evaluation and approval of the re-registration application.

8. Predetermined Change Control Plan (PCCP) of SaMD

Any changes to an approved Predetermined Change Control Plan (PCCP) that was submitted during the initial premarket review (new medical device registration application) shall be managed through a formal change management application.

A PCCP outlines the pre-specified elements of Software as a Medical Device (SaMD) that may be modified post-market, along with the associated methodology, data requirements, and verification/validation processes that ensure ongoing compliance with safety and performance principles. Once the PCCP has been reviewed and approved as part of the premarket submission, it forms part of the regulatory decision for the device.

Therefore, any subsequent change to the approved PCCP within the allowable change boundaries must be submitted to the MDA through a change management application to ensure that the revised PCCP remains appropriate, scientifically justified, and consistent with the device's intended use and risk classification.

The change management process allows the MDA to assess whether:

- The proposed modification to the PCCP continues to support the safe and effective performance of the device;
- The change remains within the originally approved regulatory framework; and
- Any new information, risks, or methodologies introduced are adequately controlled and documented.

This approach maintains regulatory oversight while enabling innovation and continuous improvement under a controlled and transparent mechanism.

9. Replacement Reagent and Instrument Grouping Approaches

The Replacement Reagent and Instrument Grouping expedites the availability of low to medium-risk assays on instruments within the same family.

The Reagent Replacement Grouping is a risk-based approach that relies on the manufacturer's Quality Management System (QMS), including risk-based assessments, and criteria, testing, and internal documentation for each reagent application, to allow low or medium risk reagents to be added to a registered instrument.

Aligned with the principles outlined in the Instrument Grouping, a new instrument may be added to a registered instrument family.

9.1 General Eligibility Criteria

To qualify for this criteria:

- The IVD test kit/assay and instrument shall be registered with MDA; and
- The changes do not significantly affect the safety, performance, or intended use of the test system; and
- The manufacturer has an established Quality Management System (QMS) to support risk assessment, verification/validation, and documentation; and
- The change involves class A and B IVDs only; and
- Verification and validation confirm equivalent performance to the registered medical device.

9.2 Additional Criteria for Instrument Grouping (Addition of a New Instrument)

A new instrument may be added to an existing instrument grouping when it complies to the additional criteria below:

- It shares the same general architecture, design, detection method, and intended use as the approved master instrument.
- Differences such as throughput, user interface, or data storage do not affect assay performance.

- The new instrument's performance is verified and validated against acceptance criteria used for the master instrument.
- Comparative documentation (e.g., architecture, software, reaction conditions) demonstrates equivalence.

9.3 Additional Criteria for Replacement Reagent (Extension of a Registered Assay)

Registered assay/test kit may be applied to another registered instrument or instrument grouping when:

- The intended use and detection principle are the same.
- The assay's key components, formulation, and performance characteristics are the same.
- The instrument is already approved or part of an approved grouping.
- The new combination has been verified and validated by the manufacturer to confirm comparable analytical and clinical performance.

If the device meets all the eligibility criteria outlined under the Replacement Reagent and Instrument Family, the changes can be proceeded through the Change Management process in accordance with MDA's regulatory requirements, supported by comparative documentation, risk assessment, and performance validation data.

Note: This approach does not apply if:

- The assay or instrument is new and not previously approved.
- There is a change in measurement principle, detection method, or intended use.
- The device involves high-risk IVDs, blood banking, self-testing, or point-of-care use.
- There are significant reagent formulation changes or new sample types introduced.
- The instruments are classified as class A, whereas reagents and kits have different classification higher than Class A.

10. Change Management Fees

Submissions shall be accompanied by the applicable fee as specified in Table 3 below. Payment shall be made by the applicant after receiving approval or acknowledgement from the MDA.

Table 3. Change management fees

Medical Device Risk Class	Significant Change (RM)	Non-Significant Change (RM)
Class A	50	30
Class B	500	30
Class C	1000	30
Class D	1500	30
Medical device that contains a medicinal product	2500	30

Table 4 provides examples of how fees are calculated for single and multiple change notifications, including both significant and non-significant changes. Fees are based on the

type of change, device class, and the number of registration certificate numbers included in the application, with combined applications summing the fees for each change type.

Table 4. Example of Calculation Fees for Change Management of Single and Multiple Applications

No	Application	Calculation
1	Single application for one category (either significant or non-significant)	The applicant has submitted a single application for a significant change, Class B. Calculation fee = Fee for significant change, Class B = RM 500
2	Single application for significant and non-significant changes	The applicant has submitted a single application covering both a significant change, Class B and a non-significant change, Class B. Calculation fee = Fee for significant change, Class B + Fee for non-significant change, Class B = RM 500 + RM 30 = RM 530
3	Multiple applications for one category (either significant or non-significant)	The applicant has combined 3 registration certificate numbers under significant change, Class B. Calculation fee = Number of registration certificate numbers × Fee for significant change, Class B= 3 × RM 500 = RM 1,500
4	Multiple applications for both significant and non-significant changes	The applicant has combined 3 registration certificate numbers covering both significant change, Class B and non-significant change, Class B. Calculation fee = (Number of registration certificates × Fee for significant change, Class B) + (Number of registration certificates × Fee for non-significant change, Class B) = 3 × RM 500 + 3 × RM 30 = RM 1,590

11. Turn Around Time

The turn-around time (TAT) for the evaluation of each Change Management application is outlined as follows:

Table 5. Turn-Around Time for Change Management Applications

Application Type	Significant Change	Non-Significant Change
Single Application for Single Type of Change	30 working days	No TAT, as the change may be implemented immediately
Single Application for Multiple Type of Change	60 working days	
Multiple Application	60 working days	

The stated turn-around time applies upon submission of a complete application form together with all required supporting documents.

ANNEX A: Main Flowchart - General Type of Changes to Medical Devices and In Vitro Diagnostic (IVD) Medical Devices
(informative)

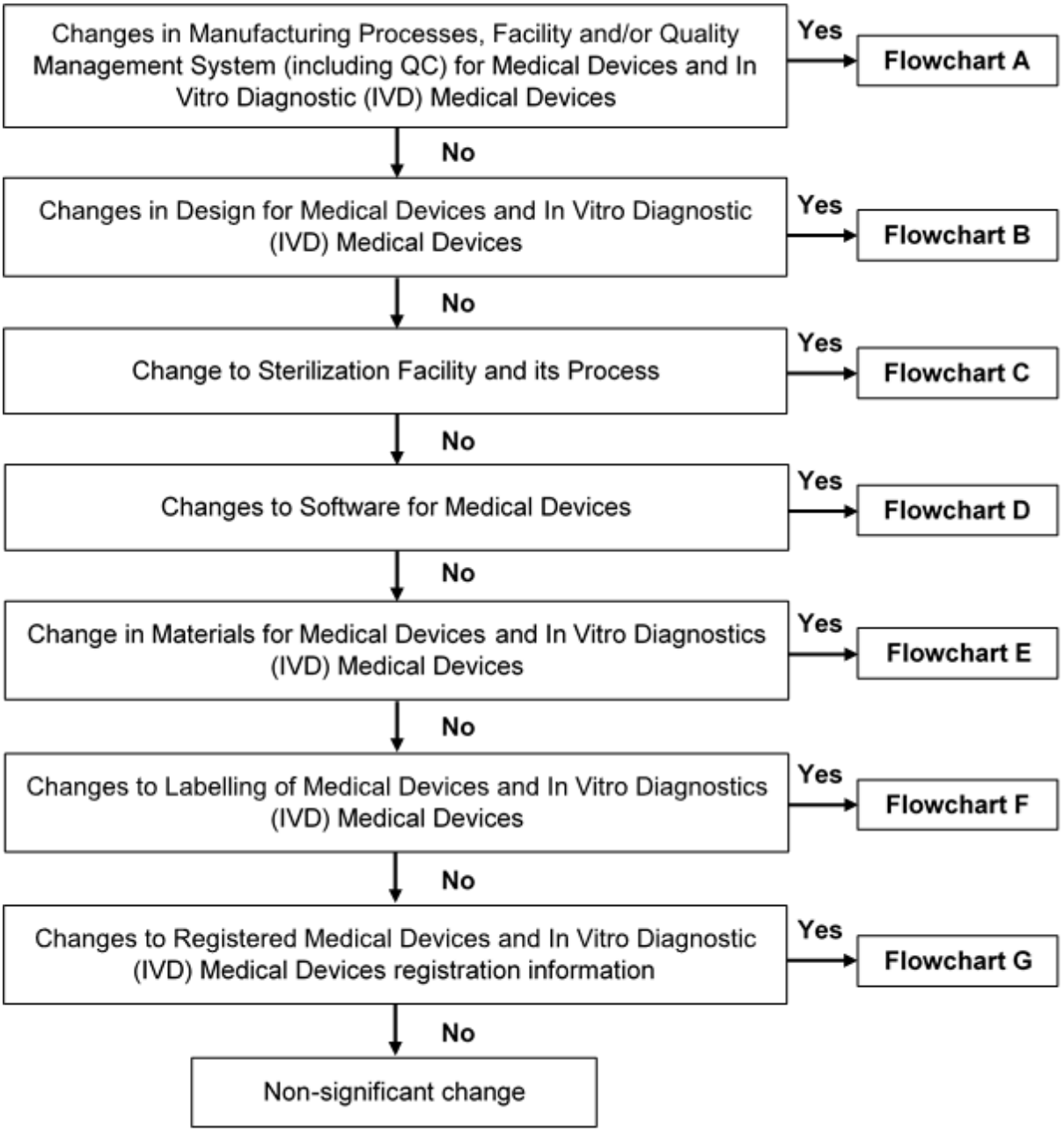

Figure A.1 Overview Flowchart of Types of Changes

ANNEX B: Flowchart A to G - Categorisation of Change Types and Supporting Documentation Requirements
(normative)

FLOWCHART A

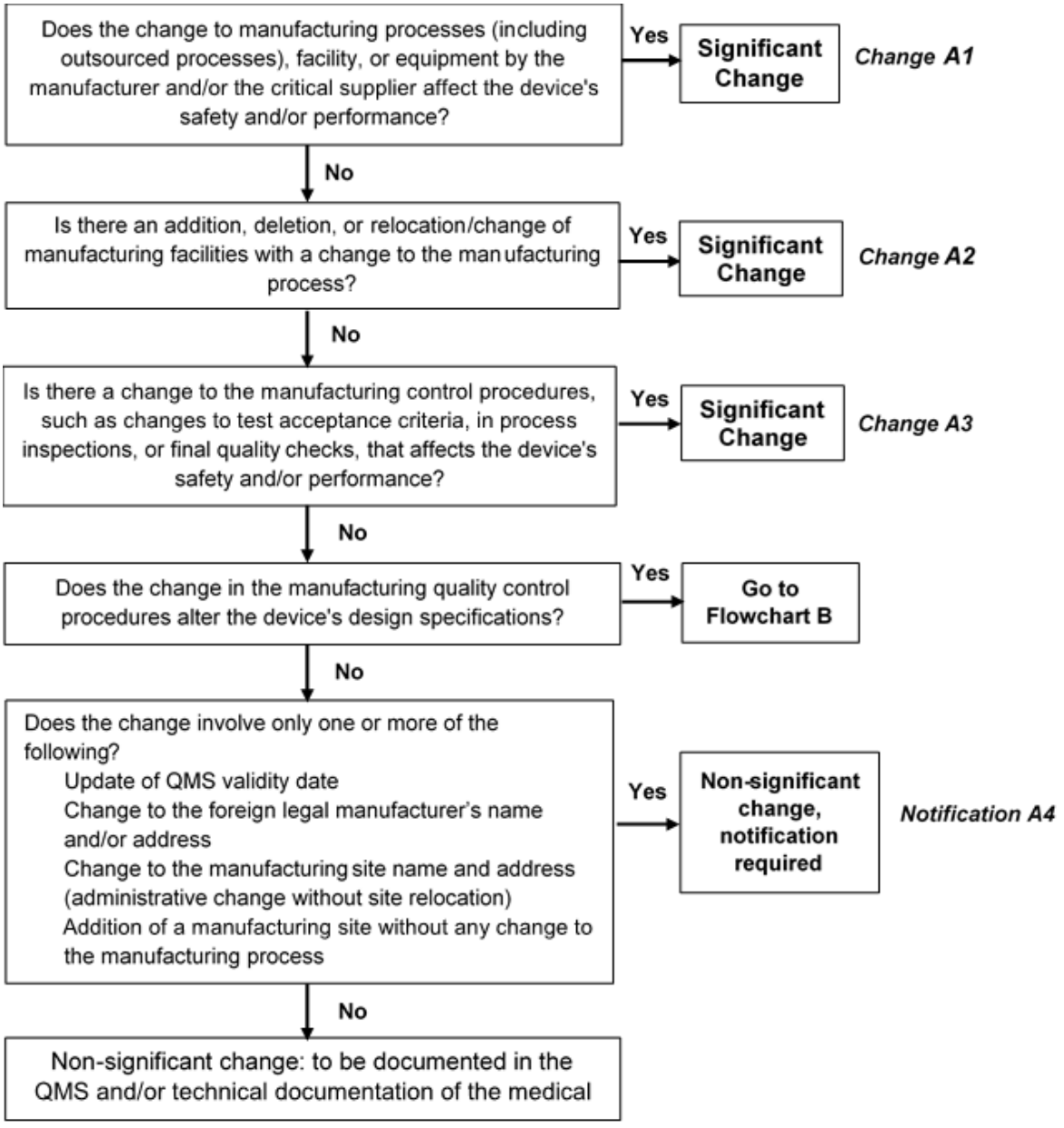

Figure B.1: Flowchart A - Changes in Manufacturing Processes, Facility and/or Quality Management System (including QC) for Medical Devices and In Vitro Diagnostic (IVD) Medical Devices

Table B.1: Flowchart A - Change Categories and Required Supporting Documentation

Flowchart Change No.	Description	Change Category	Supporting Documents
Change A1	Change in critical supplier with change in specification of registered medical device: *Examples include:* ● *Change of the supplier of the antibody with a different manufacturing process.* ● *Change of supplier of plastic raw material of catheter.*	**Significant**	● QMS certificate(s) ● Summary of new manufacturing process ● Validation report covering new processes ● Pre-clinical study reports ● Software validation report (for software-based devices) ● Clinical evaluation report ● Risk management report ● Change approval documents from recognised countries *(if applicable)*
Change A1	Change to manufacturing processes (including outsourced processes), facility or equipment by the manufacturer and/or the critical supplier that affects the device's safety and/or performance *Example of manufacturing process change (but not limited to):* ● *Change in the equipment used for cutting, resulting in the change in length of sutures.* ● *Moulding or cutting process modifications.* ● *Change from centrifugation to filtration process which*	**Significant**	● QMS certificate(s) ● Summary of new manufacturing process ● Validation report covering new processes ● Pre-clinical study reports ● Software validation report (for software-based devices) ● Clinical evaluation report ● Risk management report ● Change approval documents from recognised countries *(if applicable)*

Flowchart Change No.	Description	Change Category	Supporting Documents
	results in better molecule separation. ● *Change of implant manufacturing process from casting to 3D printing.* ● *Change from manual to automated operation, without altering the device specification.* ● *Changes to the packaging process, which is considered part of manufacturing.*		
Change A2	Change, addition, removal of manufacturing site with a change to manufacturing process	**Significant**	● Declaration of Conformity ● QMS certificate(s) ● Summary of new manufacturing process ● Risk management report ● Validation report covering new processes ● Change approval documents from recognised countries *(if applicable)*
Change A3	Changes to manufacturing control procedures *Examples include: modifications to test acceptance criteria, in-process inspections, or final quality checks, that may impact the safety and/or performance of the medical device.*	**Significant**	● Risk management report ● Summary of new manufacturing process *(if applicable)* ● Validation report covering new processes *(if applicable)* ● Pre-clinical study reports *(if applicable)* ● Software validation report *(for*

Flowchart Change No.	Description	Change Category	Supporting Documents
			software-based devices, if applicable) ● Clinical evaluation report *(if applicable)* ● Change approval documents from recognised countries *(if applicable)*
Notification A4	Change or addition of a manufacturing site without any change to the manufacturing process.	**Non-Significant, Notification Required**	● QMS Certificate(s) ● Declaration confirming no change to manufacturing process ● Labelling *(if applicable)* ● Declaration of Conformity
Notification A4	Changes in Manufacturing Site's Registered Name and Address (Administrative Office) *Examples include: A change in the manufacturing site address without a physical move, due to administrative updates to the address.*	**Non-Significant, Notification Required**	● QMS certificate(s) ● Declaration confirming no change to manufacturing process *(if applicable)* ● Declaration of Conformity
Notification A4	Changes to QMS Certificate *Examples include: Updates to the QMS validity date.*	**Non-Significant, Notification Required**	● QMS certificate(s) ● Declaration of Conformity ● Declaration confirming no change to manufacturing process *(if applicable)* ● Labelling *(if applicable)*
Flowchart A	Change to manufacturing processes (including outsourced processes), facility, or equipment by the manufacturer and/or supplier that does not affect the device's safety or performance.	**Non-Significant**	N/A

Flowchart Change No.	Description	Change Category	Supporting Documents
	Example include: Change in a non-critical supplier with no change in finished product performance specifications		
Flowchart A	A supplier's manufacturing process, facility, or equipment changes, provided device specifications have not changed and incoming inspections to evaluate the material/equipment remain the same.	**Non-Significant**	N/A
Flowchart A	Changes to QMS Certificate *Examples include:* ● *Change in conformity assessment body with no change in scope of certification* ● *Cancellation of QMS scope that does not impact device safety or performance* ● *Correction of typos, zip code, or other administrative errors on the certificate*	**Non-Significant**	N/A
Flowchart A	Changes to manufacturing QC process *Examples include:* ● *Addition of new QC specifications or tests* ● *Change of measuring or monitoring equipment without altering test parameters*	**Non-Significant**	N/A

Flowchart Change No.	Description	Change Category	Supporting Documents
	● *Modification or addition of test acceptance criteria/methods that provide equivalent or better assurance of reliability.*		

FLOWCHART B

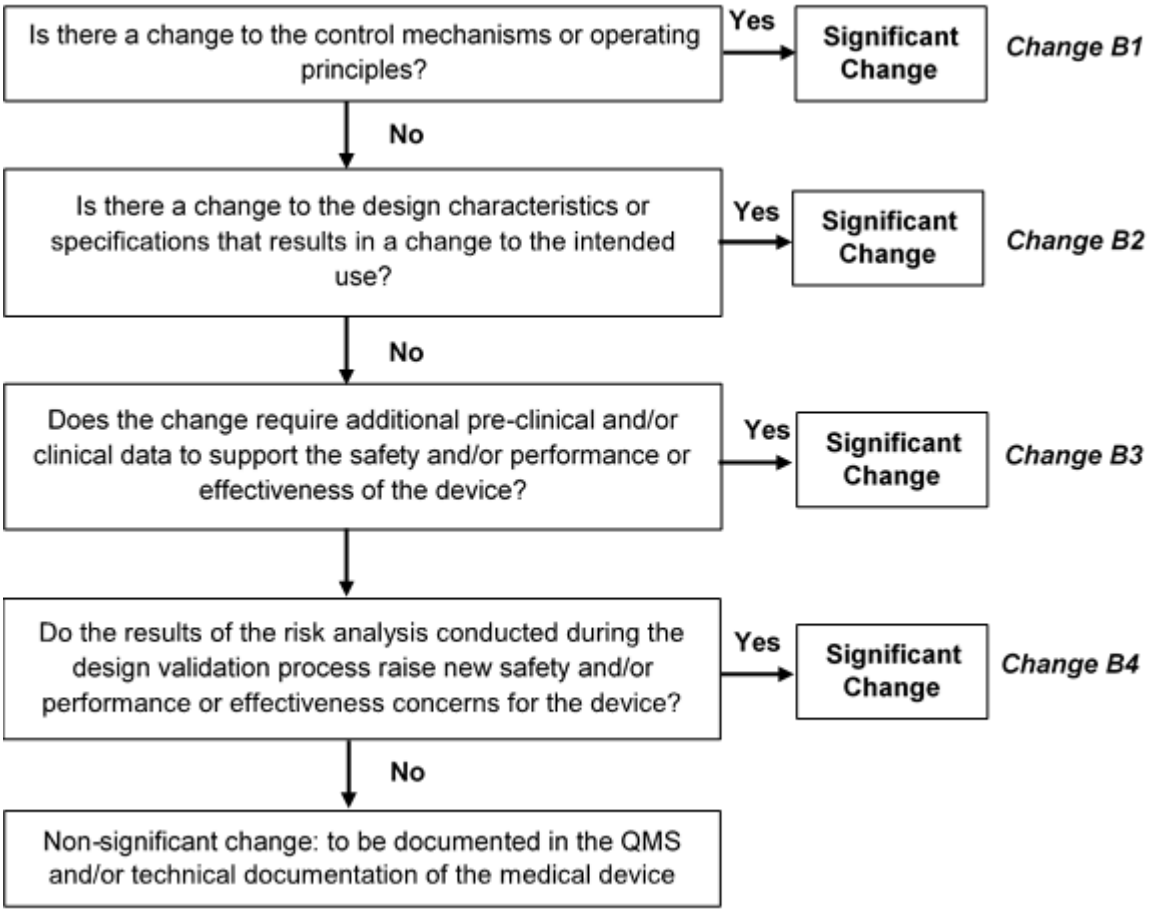

Figure B.2: Flowchart B - Changes in Design for Medical Devices and In Vitro Diagnostic (IVD) Medical Devices

Table B.2: Flowchart B - Change Categories and Required Supporting Documentation

Flowchart Change No.	Description	Change Category	Supporting Documents
Change B1	Changes to control mechanisms or operating principles of a medical device *Examples include:* • *Change in the source of energy used by the device.* • *Change from a quantitative assay to a qualitative assay.* • *Addition of a footswitch to an X-ray system that previously did not operate via a footswitch.* • *Change of an RIA test to an ELISA test.*	**Significant**	• Pre-clinical study reports • Risk management report • Clinical evaluation report *(if applicable)* • Software validation report *(for software devices, if applicable)* • Detailed summary of software changes *(for software devices, if applicable)* • Labelling *(if applicable)* • Change approval documents from recognised countries *(if applicable)*
Change B2	Change in design characteristics/specifications allowing additional or broader intended use *Examples include:* • *Introduction of a smaller-sized hip prosthesis or fracture fixation screw that differs significantly from predicate designs.* • *Addition of urine as a specimen type in the intended use for a creatinine test.* • *Adjustment of ventilator flow rate to allow use in paediatric patients in addition to adults.*	**Significant**	• Pre-clinical study reports • Risk management report • Clinical evaluation reports • Software validation report *(for software devices, if applicable)* • Labelling • Change approval documents from recognised countries *(if applicable)*

Flowchart Change No.	Description	Change Category	Supporting Documents
	• *Addition of a transducer in an ultrasound system, expanding intended use for trans-cardiac applications.*		
Change B3	Change in Design Characteristics/Specifications Requiring Additional Pre-Clinical and/or Clinical Data, identified new risks that adversely affect the safety and/or performance of the device. *Examples include: Addition of new connectivity features (e.g., Bluetooth, Wi-Fi) to devices.*	**Significant**	• Pre-clinical study reports • Clinical evaluation report • Risk management report • Software validation report *(for software devices, if applicable)* • Detailed summary of software changes *(for software devices, if applicable)* • Labelling • Change approval documents from recognised countries *(if applicable)*
Change B4	Results of risk analysis conducted during the design validation process identifies new safety and/or performance issues Examples include: • *Change from an internal direct current (DC) power source to an external alternating current (AC) source, or vice versa.* • *During clinical validation, durability issues are found with ceramic dental caps,*	**Significant**	• Pre-clinical study reports • Clinical evaluation report • Risk management report • Labelling • Change approval documents from recognised countries *(if applicable)*

Flowchart Change No.	Description	Change Category	Supporting Documents
	requiring consideration of alternative materials. • *Change to the cable design and grip of a steerable ablation catheter, resulting in improved deliverability and procedural times.*		
Flowchart B	Changes to the design, manufacturing, or components that modify intended performance without introducing new risks affecting safety or performance**.** *Examples include: Change of on/off button design or shape to improve ergonomics; additional pre-clinical evaluation is conducted, but no new risks are identified.*	**Non-Significant**	N/A
Flowchart B	Other changes to design and specifications that do not affect device safety or performance *Examples include, but are not limited to:* • *Change of colour of the cap of a reagent.* • *Changes to smartphones, computers, or tablets used with the device (design or operating platform/firmware) without affecting the medical software.* • *Changes to storage media (CD, USB, Web, etc.) for standalone*	**Non-Significant**	N/A

Flowchart Change No.	Description	Change Category	Supporting Documents
	software without altering the medical software. ● *Change in the shape or location of handles, buttons, or other components without affecting mechanical or electrical safety.* ● *Change of design specification tolerances within validated ranges without creating new features.* ● *Addition of a touchscreen button replacing a physical button.* ● *Change of on/off button design or shape for improved ergonomics, with additional pre-clinical evaluation conducted and no new risk identified.* ● *Change of connector design due to ISO updates.* ● *Design changes solely to improve ergonomics or aesthetics, such as:* ○ *Change of device surface colour with no patient contact.* ○ *Modification of device surface lift (appearance only).* ○ *Minor change to on/off button colour for aesthetic improvement.* ○ *Change to the design of a handle to improve user experience (e.g., easier or more comfortable to hold).*		

FLOWCHART C

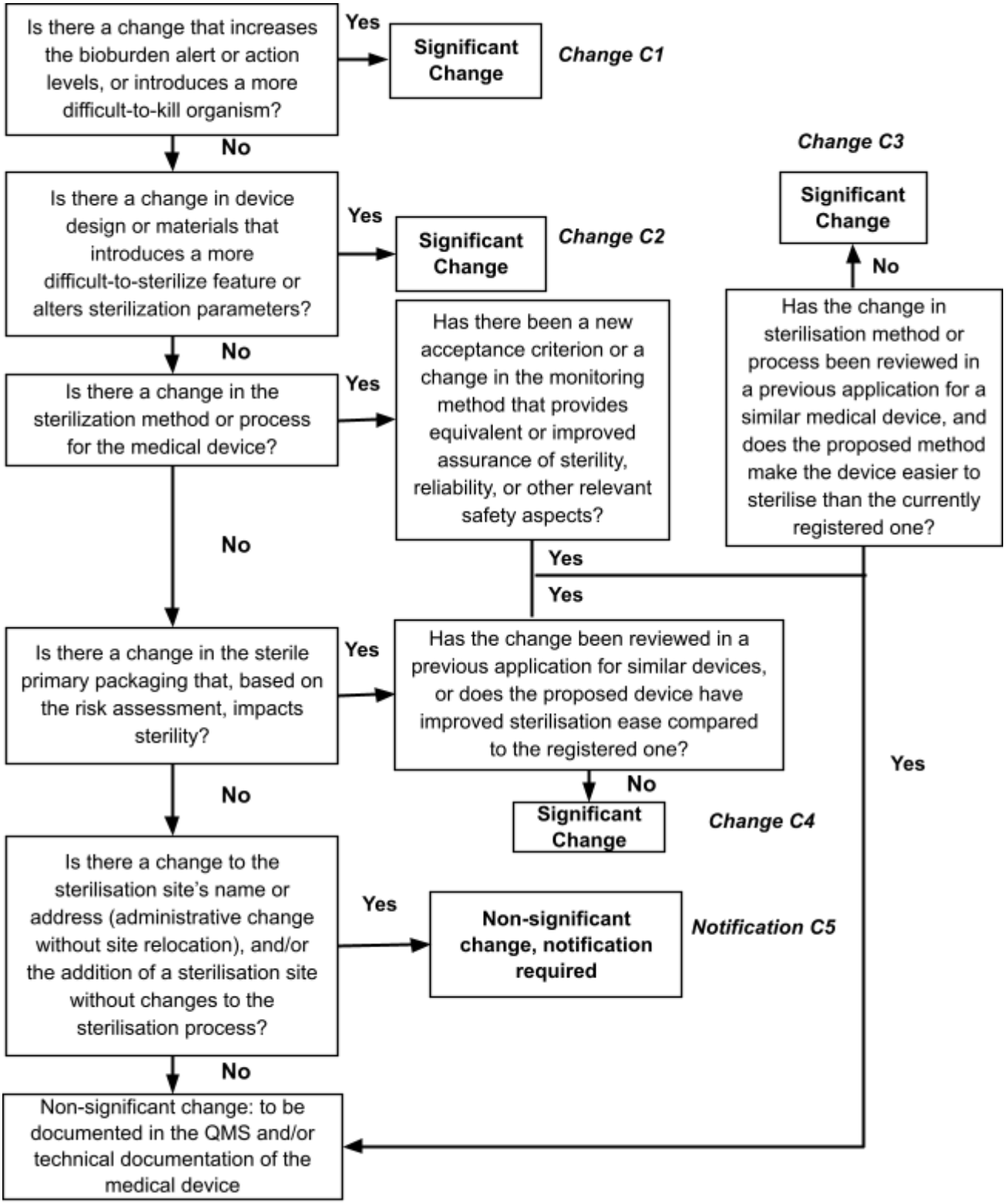

Figure B.3: Flowchart C- Change to Sterilisation Facility and its Process and/or Quality Management System

Table B.3: Flowchart C - Change Categories and Required Supporting Documentation

Flowchart Change No.	Description	Change Category	Supporting Documents
Change C1	Changes that increase the bioburden alert or action levels**,** or introduce organisms that are more difficult to eliminate**.** *Examples include: Addition of pre-sterilisation transport steps.*	**Significant**	• Sterilization validation report • Risk management report • Change approval documents from recognised countries *(if applicable)*
Change C2	Changes to device design or materials that introduce features that are more difficult to sterilize. *Examples include:* • *Change to packaging where a single-pouched sterile device is placed into a double pouch.* • *Changes in packaging characteristics, configuration, or density that could affect sterilant absorption/penetration, residue levels (where applicable), or overall sterilization effectiveness, in addition to the safety of the sterile device.*	**Significant**	• Sterilization validation report • Risk management report • Packaging validation report *(if applicable)* • Change approval documents from recognised countries *(if applicable)*
Change C3	Changes in the sterilisation method or process for a medical device that do not provide equivalent or better assurance of sterility and have not been reviewed in	**Significant**	• Sterilization validation report • Risk management report • QMS certificate(s) *(if applicable)* • Labelling *(if applicable)* • Change approval documents from

Flowchart Change No.	Description	Change Category	Supporting Documents
	previous applications for similar devices. *Examples include:* ● *Change in sterilisation method from ethylene oxide to gamma radiation.* ● *Changes in the density or configuration of the sterilization load.* ● *Changes to quality control verification and validation processes, such as introducing parametric release.* ● *Change in moist heat sterilisation parameters.* ● *Transition from standard steam sterilisation to pre-vacuum steam cycles to improve steam penetration and eliminate air pockets.* ● *Adjustment of gamma radiation sterilisation dose (e.g., from 25 kGy to 30 kGy), with additional validation.* ● *Enhanced dose mapping to ensure uniform radiation distribution, providing equivalent or improved sterility.* ● *Change in sterilisation load size (e.g., from 8 pallets to 10 pallets) with no change in sterilisation parameters, accompanied by additional validation.* ● *Change in sterilisation process and/or*		recognised countries *(if applicable)*

Flowchart Change No.	Description	Change Category	Supporting Documents
	addition/change of sterilisation site.		
Change C4	Changes in the sterile primary packaging where the risk assessment concludes a potential impact on sterility, and the change has not been reviewed in previous applications for similar devices. *Examples include:* ● *Removal of tray from sterile packaging, or change from foil laminate to Tyvek pouch.* ● *Original heat-sealing package barrier found to have a risk of leakage, requiring a change to the sterile packaging barrier.* ● *Change in primary packaging material that may impact sterility, with additional validation conducted; material has not been previously reviewed.*	**Significant**	● Design verification and validation documents ● Risk management report ● Clinical evidence *(if applicable)* ● Labelling *(if applicable)* ● Change approval documents from recognised countries *(if applicable)*
Notification C5	Changes to the sterilisation site's name or address (administrative changes without physical relocation), or the addition of a sterilisation site without any change to the sterilisation process. *Examples include:*	**Non-Significant, Notification Required**	● QMS certificate(s) ● Declaration confirming no change to sterilisation process

Flowchart Change No.	Description	Change Category	Supporting Documents
	• *Transfer of sterilisation activities from Location A to Location B with no change to sterilisation process.* • *Qualification of an additional sterilisation site for a medical device, where the sterilisation process and parameters are exact duplicates of existing sites.*		
Flowchart C	Changes to sterilisation processes that do not introduce new risks to device safety or efficacy. *Examples include:* • *Change from Biological Indicator/Batch Release to Parametric Release, with risk assessment confirming no additional risks to product safety or efficacy.* • *Change from a pre-blended sterilant (EtO and CHCs) to EtO post-blended with nitrogen, with the ultimate EtO concentration remaining the same in both cycles.* • *Change from using air (80% nitrogen, 20% oxygen) to pure nitrogen in the aeration process to avoid explosive gas mixtures.* • *Change in sterilisation load (e.g., from 8 pallets to 10 pallets) in the*	**Non-Significant**	N/A

Flowchart Change No.	Description	Change Category	Supporting Documents
	same chamber, with no change in sterilisation parameters and within validated range. • *Change in aeration time post-sterilisation to reduce EtO content, aligning with other products, with no impact on safety or performance.*		

FLOWCHART D

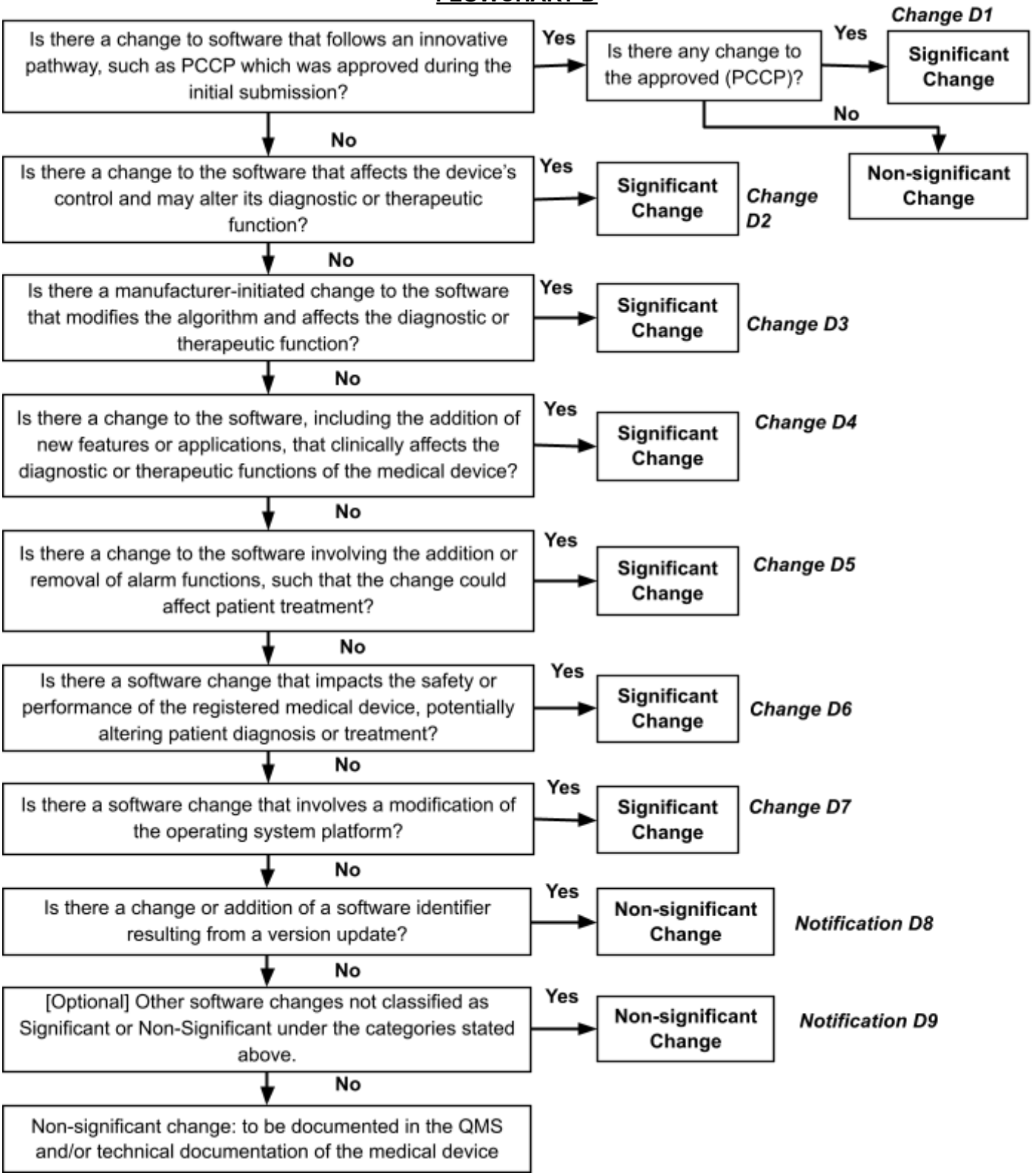

Figure B.4: Flowchart D - Changes to Software for Medical Devices

Table B.4: Flowchart D - Change Categories and Required Supporting Documentation

Flowchart Change No.	Description	Change Category	Supporting Documents
Change D1	All changes to a PCCP that was previously approved during initial registration, including but not limited to: ● *Description of change* ● *Change plan/protocol* ● *Impact assessment*	**Significant**	● Supporting documentation for the new PCCP including description of change, protocol and impact assessment ● Change approval documents from recognised countries *(if applicable)*
Change D2	Changes to software that affect the control of the device and may alter its diagnostic or therapeutic function *Examples include:* ● *Software changes affecting critical steps for laser delivery in eye treatment.* ● *Software changes in insulin pumps that enable insulin dosage to be controlled based on readings from compatible continuous blood glucose monitors.*	**Significant**	● Software validation report ● Risk management report ● Labelling ● Change approval documents from recognised countries *(if applicable)*
Change D2	Changes in software that add new device indications which may alter the diagnostic or therapeutic function. *Example include: The intended purpose of the device remains unchanged, but the user group is expanded to include paediatric patients.*	**Significant**	● Software validation report ● Risk management report ● Labelling ● Clinical evaluation report ● Change approval documents from recognised countries *(if applicable)*
Change D3	Changes to software initiated by the manufacturer that modify the algorithm and impact the	**Significant**	● Software validation report

Flowchart Change No.	Description	Change Category	Supporting Documents
	diagnostic or therapeutic function of the device. *Examples include:* • *X-ray lung nodule assessment software updates that improve detection rates for small nodules.* • *Software changes modifying QC interpretation or cut-off calculations of an IVD device.* • *Algorithm changes to an X-ray system with enhanced sensitivity to improve lesion detection.*		• Risk management report • Clinical evaluation report • Labelling • Change approval documents from recognised countries *(if applicable)*
Change D4	Changes to software that introduce new features or applications impacting the diagnostic or therapeutic functions of a medical device. *Examples include:* • *Insulin pump software updated to allow wireless communication with compatible blood glucose monitors.* • *Software change enabling a blood oxygen monitor to also report blood CO_2 concentrations*.	**Significant**	• Software validation report • Risk management report • Clinical evaluation Report • Labelling • Change approval documents from recognised countries *(if applicable)*
Change D4	A software change that alters the way data is read or interpreted by the user**,** such that the patient's diagnosis or treatment may differ compared to the previous software version.	**Significant**	• Software validation report • Risk management report *(if applicable)* • Change approval documents from recognised countries *(if applicable)*
Change D5	Changes to software that add or remove alarm functions**,** where	**Significant**	• Software validation report

Flowchart Change No.	Description	Change Category	Supporting Documents
	the user's response to these alarms may affect patient treatment. *Examples include:* • *Addition of an early-warning alarm in an electrocardiogram system to signal a potential cardiac event such as atrial fibrillation.* • *Modification of software to add or remove alarms used to monitor diagnostic procedures on an infectious disease analyzer.*		• Clinical evaluation report • Risk management report • Labelling • Change approval documents from recognised countries *(if applicable)*
Change D6	Software changes that affect the safety, performance, or effectiveness of a registered medical device and may alter patient diagnosis or treatment. *Examples include:* • *A software update to a blood oxygen monitor enabling more accurate reporting of blood CO_2 concentrations (e.g., improved accuracy up to 0.5% deviation).* • *A software upgrade that changes the performance characteristics, such as specificity or sensitivity of an in vitro diagnostic medical device.*	**Significant**	• Software validation report • Clinical evaluation report • Pre-clinical study reports • Risk management report • Labelling • Change approval documents from recognised countries *(if applicable)*
Change D6	Software changes that affect the operating performance, processing time, or processing conditions of IVD analyzers. *Examples include:*	**Significant**	• Software validation report • Risk management report • Labelling • Change approval documents from

Flowchart Change No.	Description	Change Category	Supporting Documents
	• *Software updates that enhance the sensitivity of the detector or sensor.* • *Software changes that support increased throughput of the IVD analyzer.*		recognised countries *(if applicable)*
Change D7	Software changes that involve a change to the operating system platform or OS version**,** where such changes may affect device functionality or compatibility. *Examples include:* • *Software change combined with an operating system change from Linux to Windows or another platform.* • *Addition or modification of OS version(s) that are not backward compatible, such as a transition from Windows to iOS.*	**Significant**	• Software validation report • Risk management report • Labelling • Change approval documents from recognised countries *(if applicable)*
Notification D8	Changes involving software version updates that require a new identifier, without impacting device safety or performance. *Example include: SW 1.1 → SW 1.1.1 / SW 1.2*	**Non-Significant, Notification Required**	• List of configurations • Labelling
Notification D9	Other software changes that do not fall under the Significant or Non-Significant notifications described above**,** but for which the establishment intends to update the information in MeDC@St**.** This submission is optional**.**	**Non-Significant, Notification Optional**	• Any supporting document related to the non-significant software change that the establishment intends to update in MeDC@St.
Flowchart D	Changes to software where an innovative pathway**,** such as PCCP has been used and	**Non-Significant**	N/A

Flowchart Change No.	Description	Change Category	Supporting Documents
	approved during initial registration**.**		
Flowchart D	Software changes that require re-validation of assay or test kit specifications but do not affect the safety or performance of the device. *Examples include:* ● *Software adjustments to calibration of an IVD analyzer.* ● *Software updates to support a new cartridge design.*	**Non-Significant**	N/A
Flowchart D	Other changes related to software that do not impact the safety and/or performance of the medical device, including but not limited to: *Examples include:* ● *Simple bug fixes to correct display errors in software analysis results.* ● *Software changes introducing non-therapeutic/non-diagnosti c features, e.g., printing, faxing, improved image clarity, or reporting format.* ● *Disabling software functions that do not interact with other functions.* ● *Addition, change, or deletion of OS version(s) within the same platform (e.g., adding Windows X for a product originally using Windows 7).* ● *Changes to alter colors or locations of menus on the GUI without affecting safety or performance.* ● *Addition of languages for users without altering intended*	**Non-Significant**	N/A

Flowchart Change No.	Description	Change Category	Supporting Documents
	use, principle of operation, or performance. ● *Changes in software distribution or storage methods (USB, CD, DVD, downloads, etc.).* ● *Cybersecurity improvements, e.g., adding encryption to configuration files, adding passcodes for remote access, adding timeouts, or adjusting restricted user access.* ● *Software changes to prevent invalid characters in barcode inputs.* ● *Software updates restoring DICOM conformance to fetch prior studies automatically via PACS.* ● *Correcting bottle size parameters in cleaning solutions to prevent fluid detection errors.* ● *IVD analyzer software modifications to ensure new reagent data does not merge with existing tables.* ● *Code modifications to correct wording or minor logic errors without altering core detection/measurement algorithms.* ● *Adjustments to Machine Learning datasets without changing labeled product design specifications.* ● *Software changes that correct inadvertent logic errors without safety risk.* ● *Modifications to user interface appearance with negligible impact on diagnosis or therapy* ● *Updates to software information symbols and*		

Flowchart Change No.	Description	Change Category	Supporting Documents
	details without affecting safety or performance. ● *Allowing new connections to barcode readers, handheld devices, or other devices.*		

FLOWCHART E1

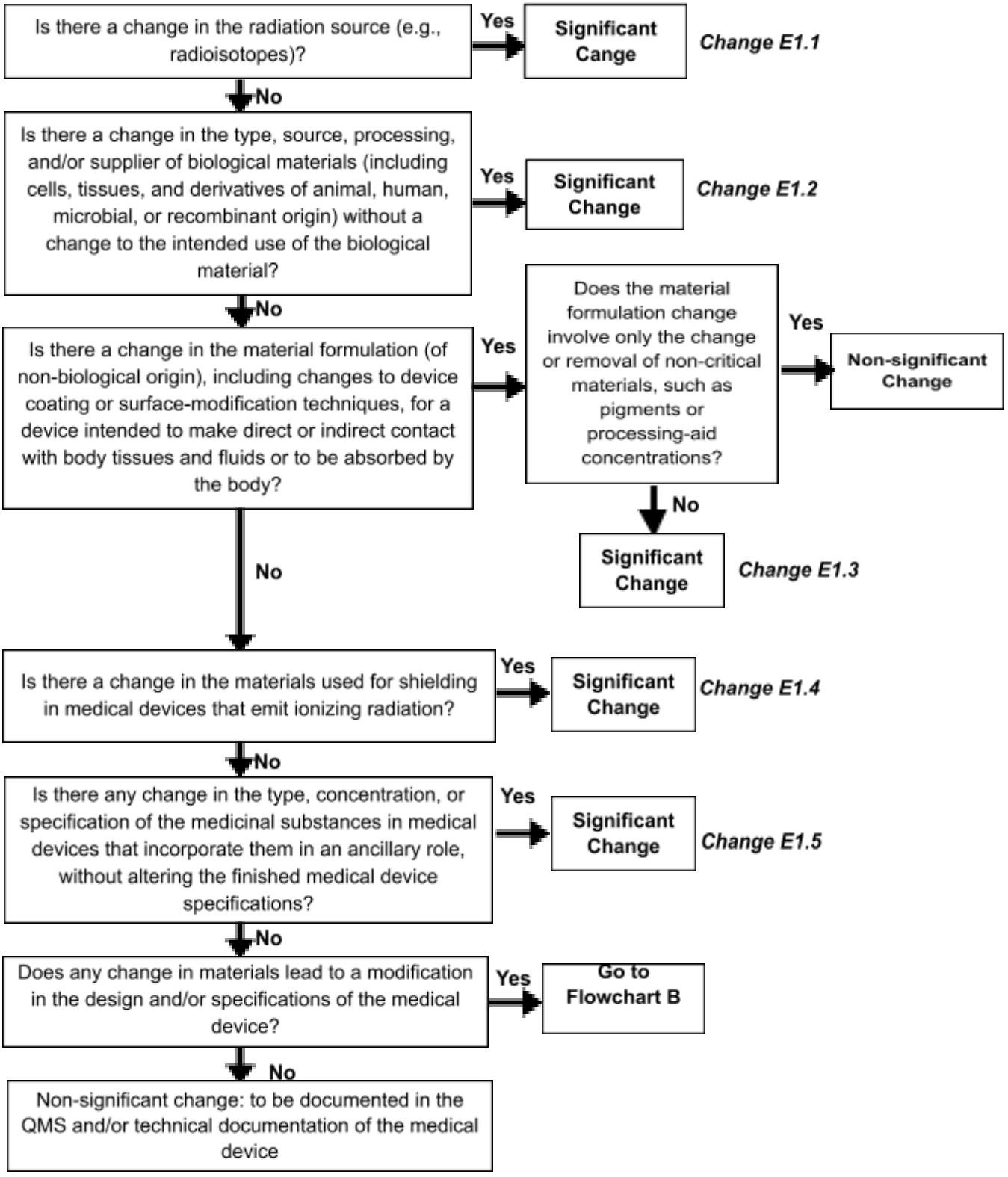

Figure B.5: Flowchart E1- Changes in Materials for General Medical Devices

Table B.5: Flowchart E1 Change Categories and Required Supporting Documentation

Flowchart Change No.	Description	Change Category	Supporting Documents
Change E1.1	Changes to the radiation source used in a medical device. *Example: radioisotopes*	**Significant**	● Information on radiation source ● Radiation safety test ● Pre-clinical study reports *(if applicable)* ● Clinical evaluation report *(if applicable)* ● Risk management report ● Change approval documents from recognised countries *(if applicable)*
Change E1.2	Changes to the type, source, processing, or supplier of biological materials (including cells, tissues, or derivatives of animal, human, microbial, or recombinant origin) without changing the intended use of the biological material. *Examples include:* ● *Change in source of hyaluronic acid from Streptococcus zooepidemicus to Streptococcus equi.* ● *Conversion from a polymer-sheathed hypotube to a bare, uncoated stainless steel hypotube.* *Note: Changes involving the supplier of unprocessed biological material/tissue do not require submission.*	**Significant**	● Pre-clinical study reports ● Clinical evaluation report ● Risk management report ● Change approval documents from recognised countries *(if applicable)*
Change E1.3	Changes to material or material formulation of non-biological origin, including changes to device coating or	**Significant**	● Pre-clinical study reports ● Clinical evaluation report

Flowchart Change No.	Description	Change Category	Supporting Documents
	surface modification techniques, for medical devices that are intended to make direct or indirect contact with body tissues and fluids or are absorbed by the body. *Example include:* *Change of material for a cardiovascular catheter in contact with body tissue (e.g., change to/from polyether block amide (PEBA), polyamide, or polyether ether ketone (PEEK)).*		● Risk management report ● Labelling ● Change approval documents from recognised countries *(if applicable)*
Change E1.4	Changes to materials used for shielding in medical devices that emit ionising radiation. *Examples include: Change in shielding material of an X-ray system from lead to tungsten.*	**Significant**	● Information on materials used for radiation shielding ● Radiation safety test ● Risk management report ● Labelling ● Change approval documents from recognised countries *(if applicable)*
Change E1.5	Changes to the type, concentration, or specification of medicinal substances in medical devices that incorporate medicinal substances in an ancillary role, without altering the finished device specifications. *Examples include:* ● *Change in the concentration of the drug in a drug-eluting stent.* ● *Change in the concentration of antibiotics or substitution with a different antibiotic in a*	**Significant**	● Evidence demonstrating no change to finished device specifications ● Risk management report ● Clinical evaluation report ● NPRA variation approval letter

Flowchart Change No.	Description	Change Category	Supporting Documents
	catheter coated with antibiotic.		
Flowchart E	Changes in material formulation that involve only the change or removal of non-critical materials, such as pigments or processing aids, without affecting finished product specifications or device performance. *Examples include:* ● *Change in supplier or vendor of a material, provided it meets the manufacturer's previously reviewed specification.* ● *Introduction of a colorant change into the flush port of a PICC (Peripherally Inserted Central Catheter); the flush port is not intended for fluid administration or withdrawal.* ● *Change in coating material formulation of a balloon catheter (e.g., increase of surfactant from 1% to 2%) with no change to finished product specifications and no direct patient contact.* ● *Change of material formulation to aid manufacturing process, not retained in the final product, with no change to finished product specifications or patient contact.* ● *Removal of pigment with no impact on material*	**Non-Significant**	N/A

Flowchart Change No.	Description	Change Category	Supporting Documents
	formulation or finished product specifications.		

FLOWCHART E2

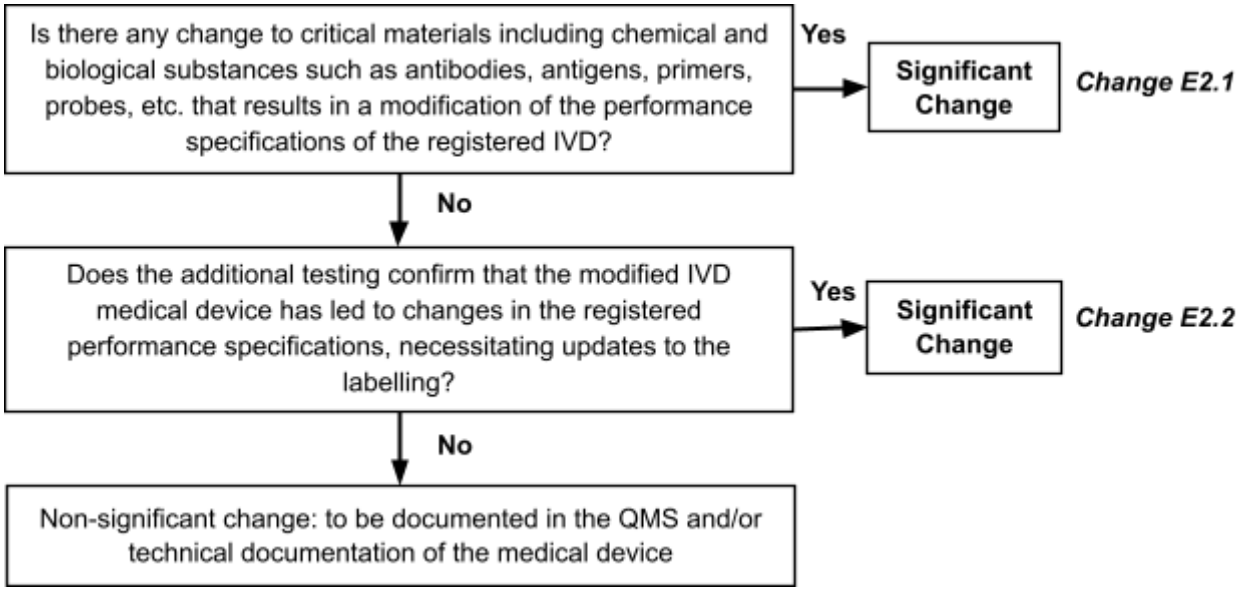

Figure B.6: Flowchart E2- Changes in Materials for In Vitro Diagnostic (IVD) Medical Devices

Table B.6: Flowchart E2 - Change Categories and Required Supporting Documentation

Flowchart Change No.	Description	Change Category	Supporting Documents
Change E2.1	Changes in material that result in alteration of performance specifications of the device or IVD test kit. *Examples include:* • *Formulation changes of reagents (e.g., buffer concentration adjustments, addition of preservatives).* • *Changes in synthesis or purification methods of biological components.*	**Significant**	• Pre-clinical study report • Clinical performance report • Risk management report • Labelling • Change approval documents from recognised countries *(if applicable)*

Flowchart Change No.	Description	Change Category	Supporting Documents
	• *Conversion from liquid to solid reagent or vice versa; change from RIA to non-RIA methods.* • *Material changes to meet regulatory requirements, e.g., removal of OPE/NPE components from IVD reagents to comply with REACH requirement in the EU, with no change in performance specification.* • *Conversion of primary antibodies in IVD reagents from hybridoma to recombinant products with performance specification changes.*		
Change E2.1	Changes to the materials of an IVD that result in a change to the operating principle of the product. *Examples include: Change from Immunofluorescence to ELISA.*	**Significant**	• Pre-clinical study report • Clinical performance report • Risk management report • Labelling • Change approval documents from recognised countries *(if applicable)*
Change E2.2	Changes that require additional testing to confirm that the altered IVD medical device results in changes to registered performance specifications, which may necessitate labelling updates. *Examples include:* • *Change of sources or types of materials (e.g., conjugates,*	**Significant**	• Pre-clinical study report • Clinical performance report • Risk management report • Labelling • Change approval documents from recognised countries *(if applicable)*

Flowchart Change No.	Description	Change Category	Supporting Documents
	antibodies, antigens, primers, or substrates). • *Change to sample preparation, such as the inclusion of a stabilizer to simplify preparation or increase sample stability.*		
Flowchart E2	Changes in supplier or source of materials where the material continues to meet the manufacturer's previously reviewed specifications and does not affect the device's performance specifications. *Examples include:* • *Change in supplier or vendor of a material with no change in material specification.* • *Change of material source, e.g., magnesium stearate in an IVD reagent from animal to vegetable origin, with no change in performance specification.*	**Non-significant**	N/A

FLOWCHART F

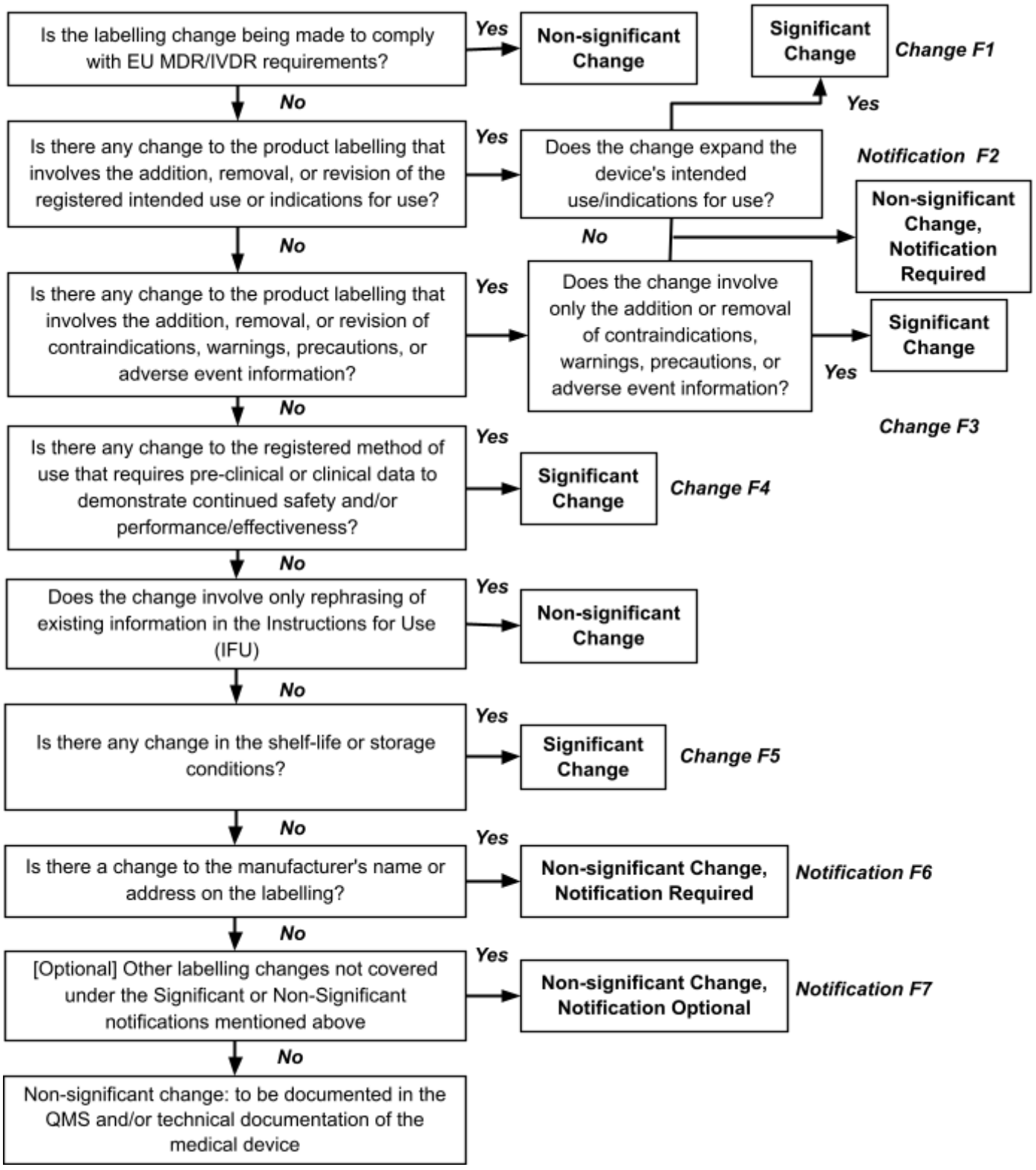

Figure B.7: Flowchart F- Changes to Labelling of Medical Devices and In Vitro Diagnostic (IVD) Medical Devices

Table B.7: Flowchart F - Change Categories and Required Supporting Documentation

Flowchart Change No.	Description	Change Category	Supporting Documents
Change F1	Changes that involve the addition or expansion of explanations or information on the intended use and/or indications for use, without altering the approved scope of the medical device. *Examples include: Modification of indications for use to exclude femoral implementation, where the exclusion is reflected as a contraindication to ensure safety and effectiveness.*	**Significant**	• Description of the intended use and/or indication for use • Labelling • Clinical evaluation report • Change approval documents from recognised countries *(if applicable)*
Notification F2	Changes that involve a reduction of intended use or indications for use**,** not arising due to safety or performance concerns of the medical device.	**Non-Significant, Notification Required**	• Description of the intended use and/or indication for use • Labelling
Change F3	Changes to labelling that involve the addition of warnings, precautions, or contraindications, not prompted by safety or performance concerns of the medical device. *Examples include: Addition of a contraindication, such as "not for paediatric use."*	**Significant**	• Description of the warnings, precautions, and/or contraindications • Labelling • Risk management report • Change approval documents from recognised countries *(if applicable)*
Change F3	Changes to labelling that involve the removal of warnings, precautions, or contraindications, not	**Significant**	• Description of the warnings, precautions, and/or contraindications

Flowchart Change No.	Description	Change Category	Supporting Documents
	prompted by safety or performance concerns of the medical device. *Examples include: Deletion of a contraindication, such as "not for paediatric use."*		• Labelling • Risk management report • Change approval documents from recognised countries *(if applicable)*
Change F4	Changes to the registered method of use that require pre-clinical or clinical data to demonstrate continued safety, performance, and/or effectiveness of the medical device.	**Significant**	• Pre-clinical study report • Clinical evaluation report • Software validation report *(for software-based devices, if applicable)* • Risk management report • Labelling • Change approval documents from recognised countries *(if applicable)*
Change F4	Change in the intended user population from "professional use only" to "home use", which may impact safety, performance, usability, or effectiveness of the device.	**Significant**	• Pre-clinical study report • Clinical evaluation report • Software validation report *(for software-based devices, if applicable)* • Risk management report • Labelling • Change approval documents from recognised countries *(if applicable)*
Change F5	Changes to the shelf-life or storage conditions of a medical device	**Significant**	• Shelf life validation/accelerated/ real-time stability study report

Flowchart Change No.	Description	Change Category	Supporting Documents
			• Risk management report • Labelling • Change approval documents from recognised countries *(if applicable)*
Notification F6	Changes to the manufacturer's name or address on the device labelling that do not affect device safety or performance.	**Non-Significant, Notification Required**	• Labelling
Notification F7	Other label/labelling changes that do not fall under previously defined significant or non-significant categories, and which the establishment intends to update in MeDC@St voluntarily.	**Non-Significant, Notification Optional**	• Any supporting document related to the non-significant change that the establishment intends to update in MeDC@St.
Flowchart F	Changes to device labelling or Instruction for Use (IFU) that do not affect device safety, performance, or regulatory information, including but not limited to: • *Minor wording clarifications in warnings and precautions* • *Correction of typographical errors or grammar* • *Rephrasing or reordering of existing IFU content without changing meaning (e.g., "Avoid exposure to temperature and humidity extremes" → "Keep away from sunlight")* • *Changes to make instructions easier, safer, or more effective to follow*	**Non-Significant**	N/A

Flowchart Change No.	Description	Change Category	Supporting Documents
	• *Addition of languages required by other regulatory jurisdictions* • *Updates to distributor information, including EU authorised representatives, without affecting device registration information* • *Updates to AR label information (e.g., change of AR name or address)* • *Addition/removal of reference agency approvals (e.g., CE Marking)* • *Addition/change/removal of barcodes without affecting device listing information* • *Changes to layout, colour, font sizes, or design without altering prominence of precautions, warnings, contraindications, or adverse events* • *Addition of symbols to product label to align with IFU* *Note: Labelling changes that are not included under the labelling requirements in the Medical Devices Regulations 2012 and ISO 20417:2021 – Medical devices: Information to be supplied by the manufacturer.*		

FLOWCHART G

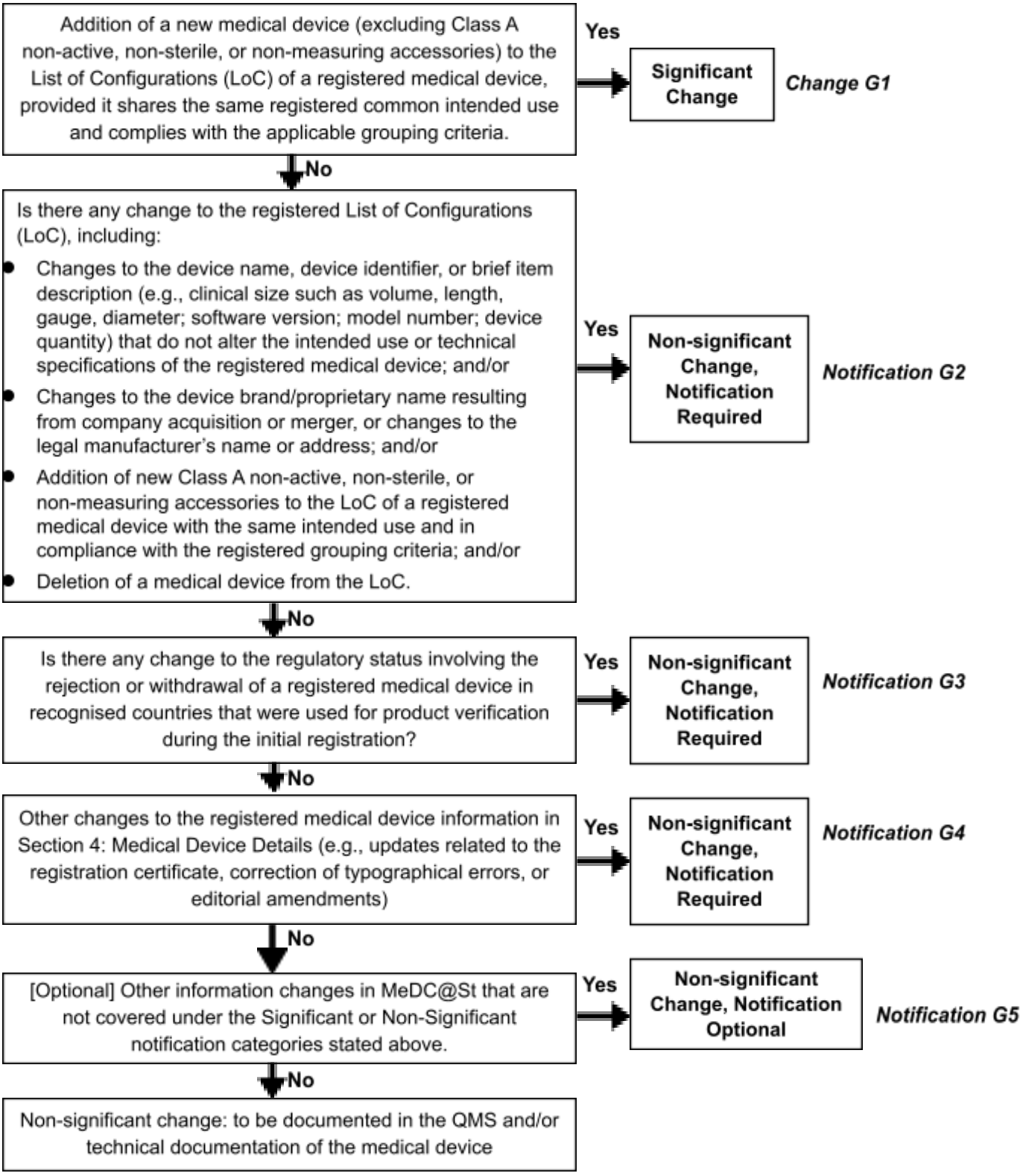

Figure B.8: Flowchart G - Changes to Registered Medical Devices and In Vitro Diagnostic (IVD) Medical Devices registration information

Table B.8: Flowchart G - Change Categories and Required Supporting Documentation

Flowchart Change No.	Description	Change Category	Supporting Documents
Change G1	Addition of a new medical device (except Class A non-active, non-sterile, or non-measuring accessories) to the List of Configurations of a registered medical device with the same registered common intended use**,** provided the manufacturer claims that the change does not affect the safety or performance of the device. *Note: The addition of a new medical device may result in a change of the registered grouping type.*	**Significant**	• Updated list of configurations of the medical device, indicating the name of the affected devices • Manufacturer declaration • Regulatory approval documents from recognised countries • Medical device information including brochure/catalogue • Labelling • Declaration of Conformity • Pre-clinical study reports • Clinical evaluation report • Software validation report *(for software, if applicable)* • Manufacturing process information *(if applicable)*
Change G1	Addition of active, measuring, or sterile Class A medical device accessories that complement the registered medical device as a system. *Note: The addition of a new medical device may result in a change of the registered grouping type.*	**Significant**	• Updated list of configurations of the medical device, indicating the name of the affected devices • Regulatory approval documents from recognised countries *(if applicable)* • Medical device information including brochure/catalogue • Labelling • Declaration of Conformity

Flowchart Change No.	Description	Change Category	Supporting Documents
			• Pre-clinical study reports • Software validation report *(for software, if applicable)* • Manufacturing process information *(if applicable)*
Notification G2	Addition of Class A medical device accessories that are non-active, have no measuring function, and are non-sterile, complementing the registered medical device as a system. *Note: The addition of a new medical device may result in a change of the registered grouping type.*	**Non-Significant, Notification Required**	• Updated list of configurations of the medical device, indicating the name of the affected devices • Regulatory approval documents from recognised countries *(if applicable)* • Medical device information including brochure/catalogue • Labelling • Declaration of Conformity
Notification G3	Change in the regulatory status of the medical device in recognised countries that were used for product verification during initial registration.	**Non-Significant, notification required**	• Declaration of Conformity • Labelling *(if applicable)* • Reason for status change
Notification G4	Deletion of medical device(s) from a list of configuration in registration certificate *Note:* *The medical device is allowed for deletion from the LoC if:* • *The medical device has not been placed on the market, is not in commercial distribution, and there are no*	**Non-Significant, Notification Required**	• Updated list of configurations of the medical device, indicating the name of the affected devices • Manufacturer declaration and justification for deletion • Declaration of Conformity • Labelling *(if applicable)*

Flowchart Change No.	Description	Change Category	Supporting Documents
	post-market surveillance (PMS) issues. ● *The deletion of medical devices may result in a change of the registered grouping type.*		
Notification G4	Changes to the list of configurations of a registered medical device that involve updates to (such as typo or editorial corrections): ● Brief description of item(s) ● Model or Version Number ● Identifier	**Non-Significant, Notification Required**	● Updated list of configurations of the medical device, indicating the name of the affected devices ● Declaration of Conformity ● Labelling *(if applicable)*
Notification G5	Other changes to information in MeDC@St that do not fall under the Significant or Non-Significant notifications described above.	**Non-Significant, Notification Optional**	● Any supporting document related to the non-significant change that the establishment intends to update in MeDC@St.

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

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