GN-10:2023(E)

Medical Device Administrative Control System (MDACS)

Guidance Notes on Changes for Listed Medical Devices

Guidance Notes: GN-10

中華人民共和國
香港特別行政區政府衞生署

Department of Health
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Revision History

Edition Number	Date of Revision	Summary of Revision	Reference Number
0	30 November 2023	First issue of GN-10 (Guidance Notes on Changes for Listed Medical Devices)	GN-10:2023(E)

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1. Introduction

1.1 Purpose

1.1.1 During the life-cycle of a medical device, changes may take place from time to time. To safeguard public health, the information in the Medical Device Administrative Control System (MDACS), including details of listed medical devices, should be up-to-date. The Local Responsible Person (LRP) has the responsibility to timely inform MDD of any change to the listed medical device. This document aims to assist the LRP in categorising, managing and reporting changes of listed medical devices. It is intended to guide the LRP to differentiate changes to a medical device listed under MDACS and report the changes to MDD accordingly.

1.2 Background

1.2.1 A listed medical device undergone changes shall remain in compliance with the Essential Principles of Safety and Performance of Medical Devices, and the management of changes under MDACS should allow timely availability of the changed medical device in the market.

1.3 Scope

1.3.1 This document applies to all medical devices listed under MDACS. It sets out points for consideration by LRP when a listed medical device is in the process of change. Owing to the various possible scenarios for changes made to a device, it is not the intention of this document to describe every permutation and type of change that can occur. The LRP may contact the Medical Devices Division (MDD), for further clarification regarding the specific changes to a listed medical device.

2. Definitions and Abbreviations

2.1 **Major Change** means a change that could be expected to affect the safety, quality or performance (SQP) of a medical device.

2.1.1 A Major Change typically may:

(a) result in risks to the patient not previously identified

(b) increase the probability of existing hazards occurring

(c) alter the presentation of existing or new risks to the user (may involve labelling changes or new indications for use)

2.2 **Minor Change** means a change that does not fall in the definition of Major Change.

2.3 Please refer to Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System) for other

definitions and abbreviations of the terms that appear in this document.

3. General Principles

3.1 To ensure continued compliance of the requirements on SQP of the listed medical device, a manufacturer must assess the effect of the change on the patient, practitioner and user of the medical device, and the impact of the change on the specifications of the device, and decide whether the change could reasonably be expected to impact the SQP of the device. When considering several simultaneous changes, this document can be used to assess each change separately. If any of the changes is considered as a Major Change, the said simultaneous changes shall be collectively considered as a Major Change.

3.2 Major Changes to the listed medical devices shall be implemented upon approval of the respective Change Applications.

3.3 The listing of a medical device will become invalid immediately if the said medical device undergoes any changes without notifying MDD within the specified timeframe or obtaining prior approval from MDD, as appropriate. If any Major Change has been implemented without prior approval by MDD, the concerned medical device will no longer be regarded as listed under MDACS, and the LRP shall cease to supply the medical device in a way that purports that the device is still listed under MDACS (e.g. displaying the HKMD number on the outer package or making such claims in the promotional materials).

3.4 More examples of changes are provided in Appendix 1.

4. Determination of Major or Minor Changes

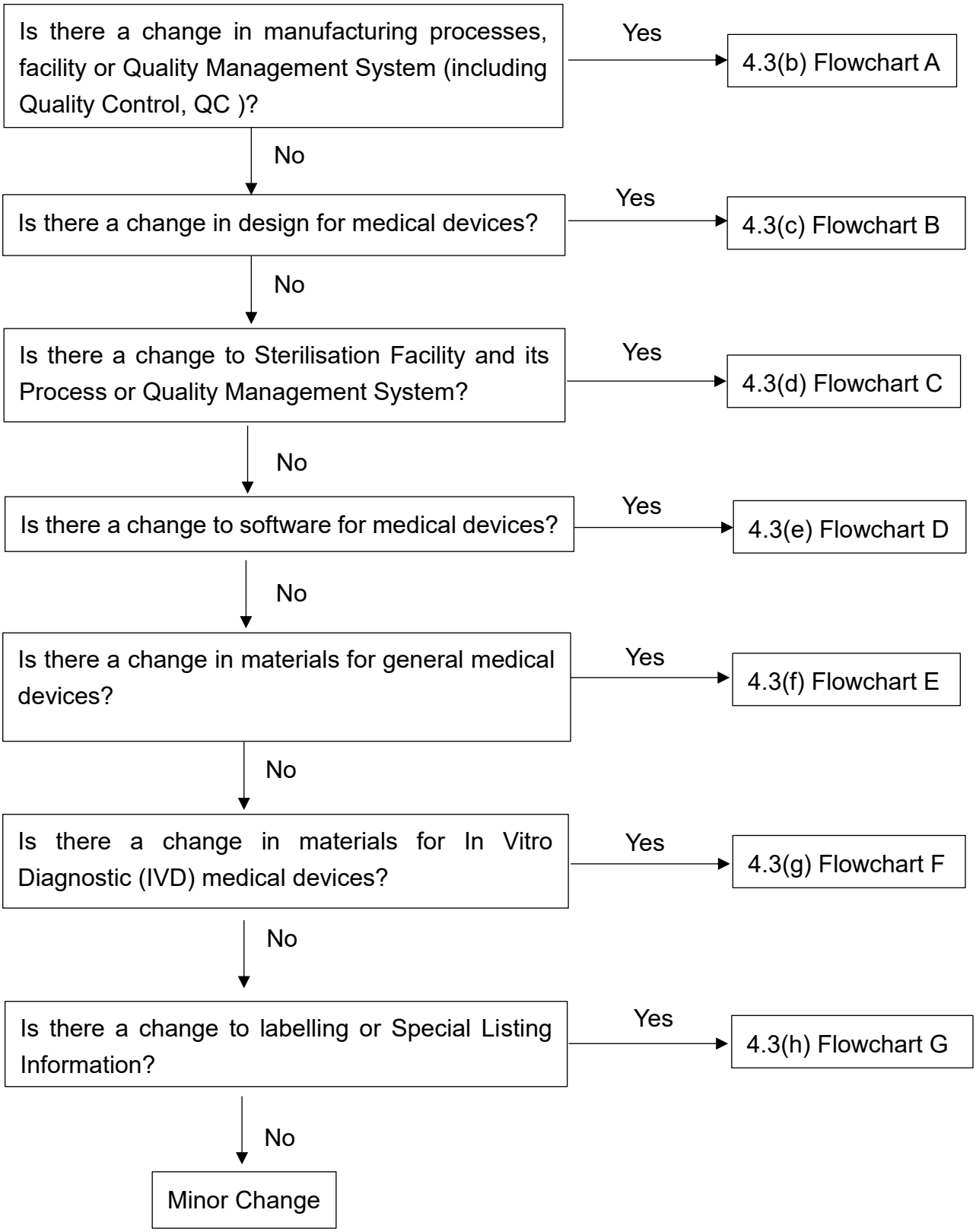
4.1 The following section presents flowcharts that serve as tools to assess whether a change is considered to be a Major Change.

4.2 The main flowchart serves as a generalised discussion of the broad principles that can be used to determine if a change would affect the SQP of a medical device. It is by no means inclusive of all scenarios.

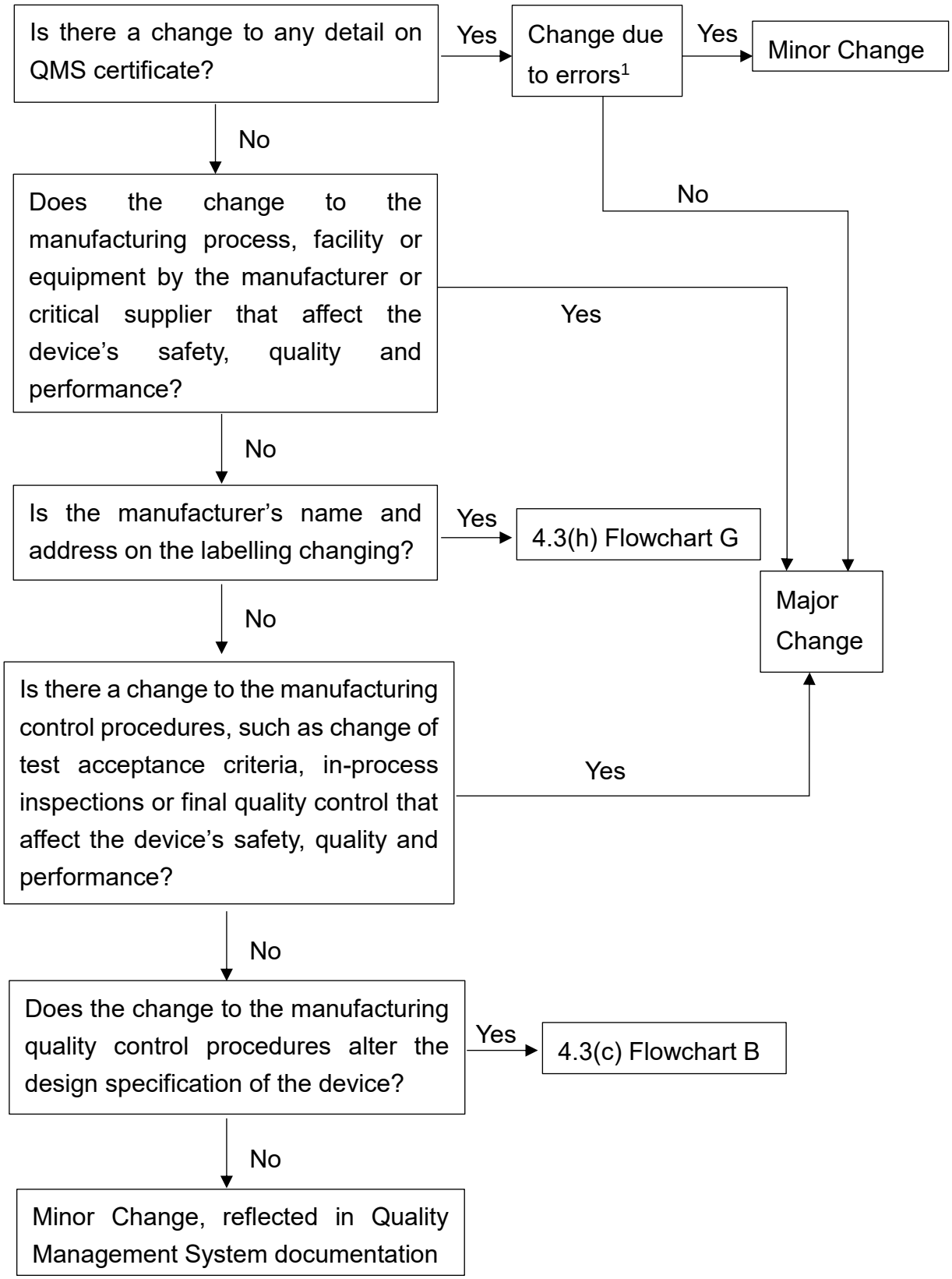
4.3 Flowcharts A to H provide specific questions and answers to assist in determining if a change is considered to be major or minor.

Flowchart:		Decision on categorisation of changes
4.3(a)	Main Flowchart	General Changes made to Medical Devices
4.3(b)	Flowchart A	Changes in Manufacturing Processes, Facility or Quality Management System (including Quality Control, QC)
4.3(c)	Flowchart B	Changes in Design for Medical Devices
4.3(d)	Flowchart C	Changes to Sterilisation Facility and its Process or Quality Management System
4.3(e)	Flowchart D	Changes to Software for Medical Devices
4.3(f)	Flowchart E	Changes in Materials for General Medical Devices
4.3(g)	Flowchart F	Changes in Materials for In Vitro Diagnostic (IVD) Medical Devices
4.3(h)	Flowchart G	Changes to Labelling or Special Listing Information

4.3(a) General Changes made to Medical Devices - Main Flowchart

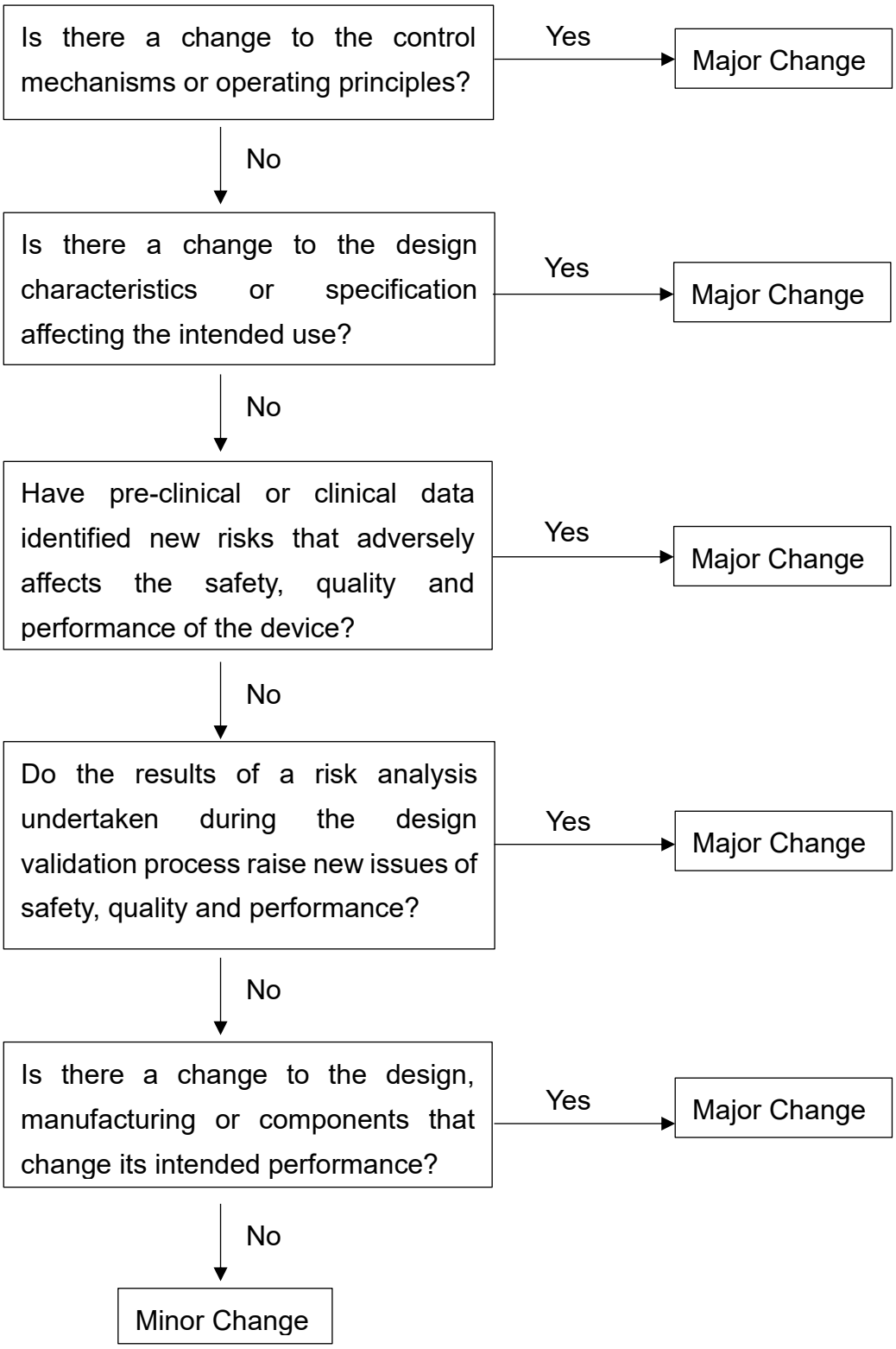


4.3(b) Changes in Manufacturing Processes, Facility or Quality Management System (including QC) – Flowchart A

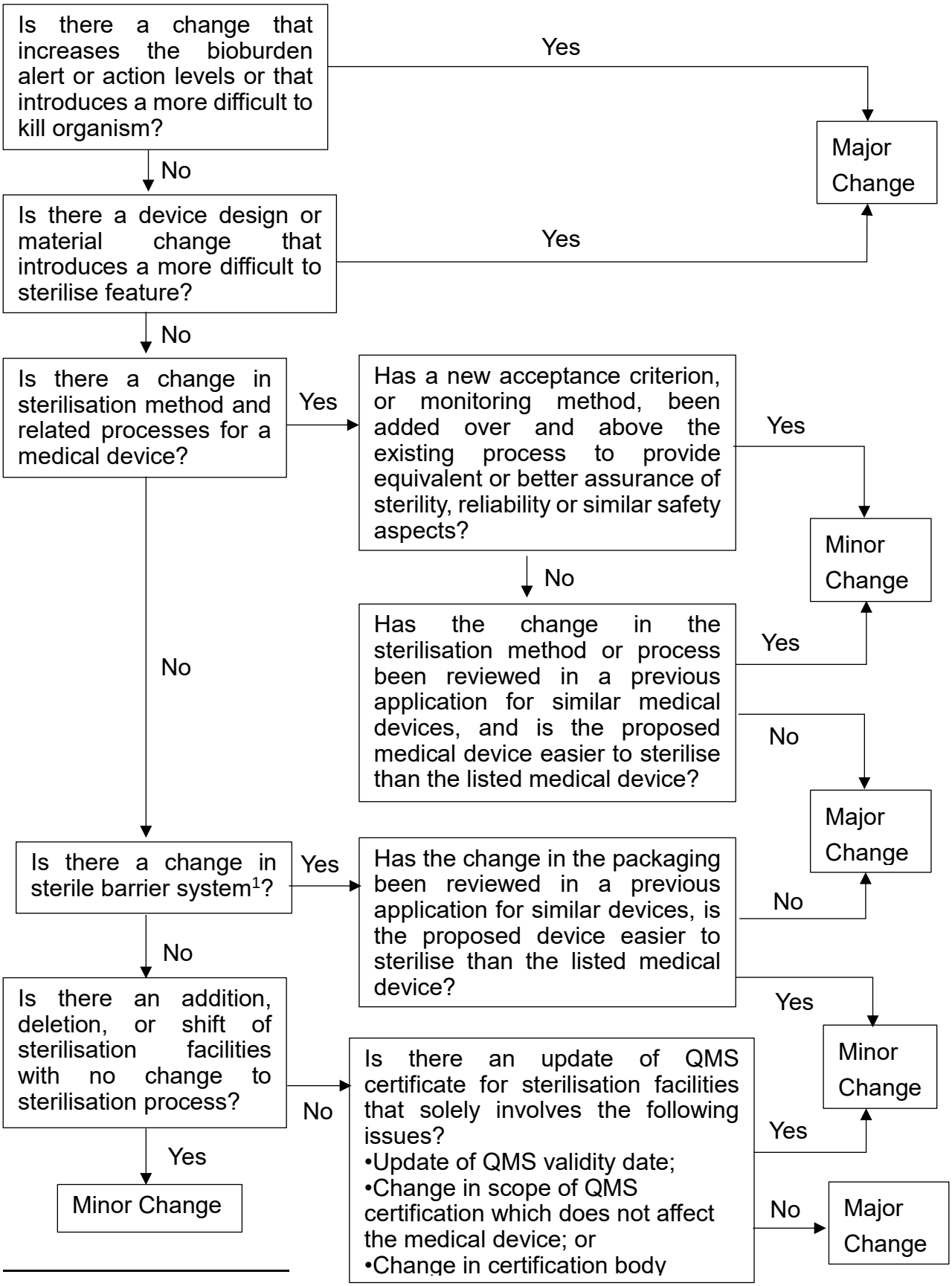


[1] Such errors may include but not limited to typo, editorial and graphical errors.

4.3(c) Changes in Design for Medical Devices – Flowchart B

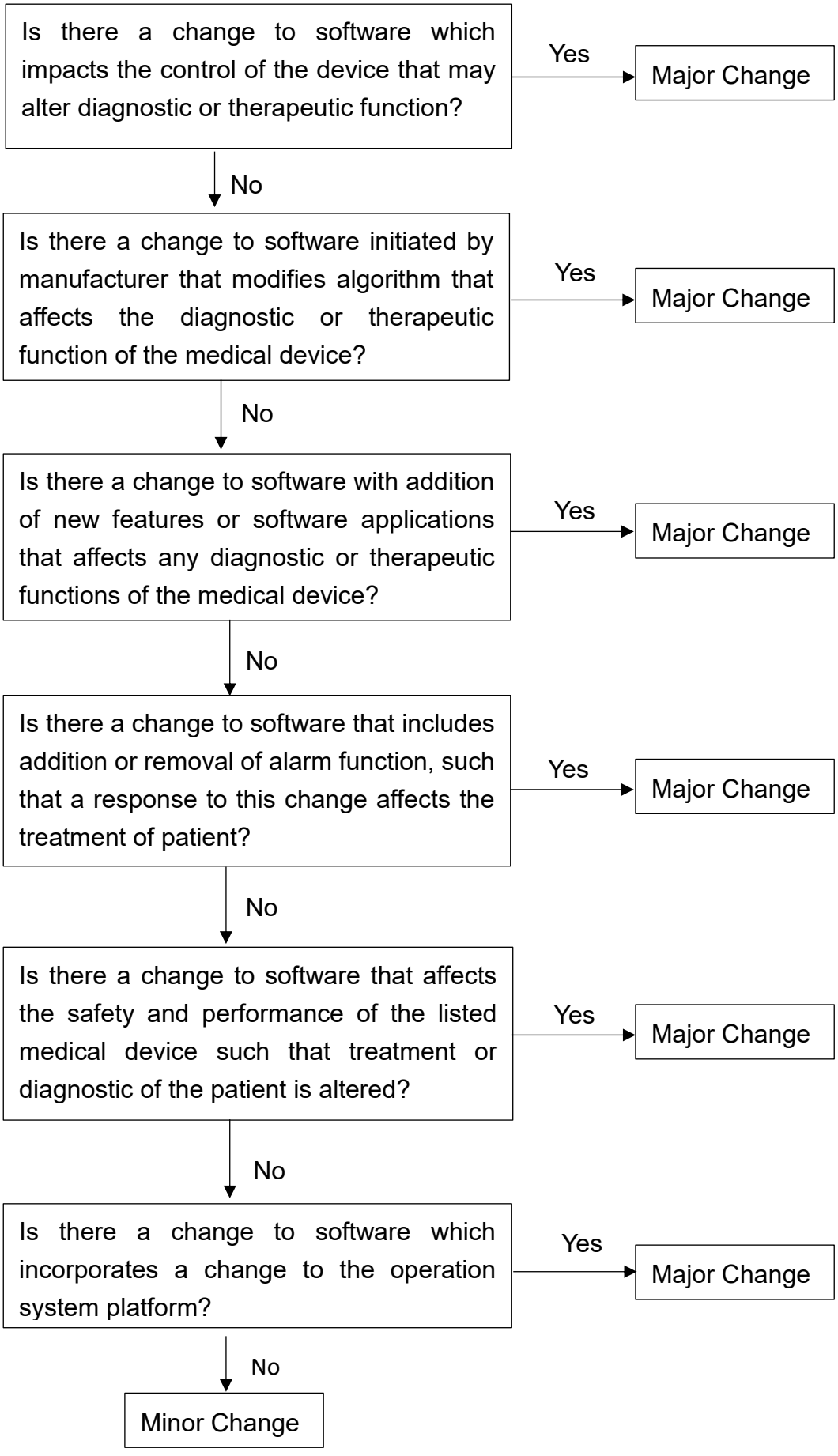


4.3(d) Changes to Sterilisation Facility and its Process or Quality Management System – Flowchart C

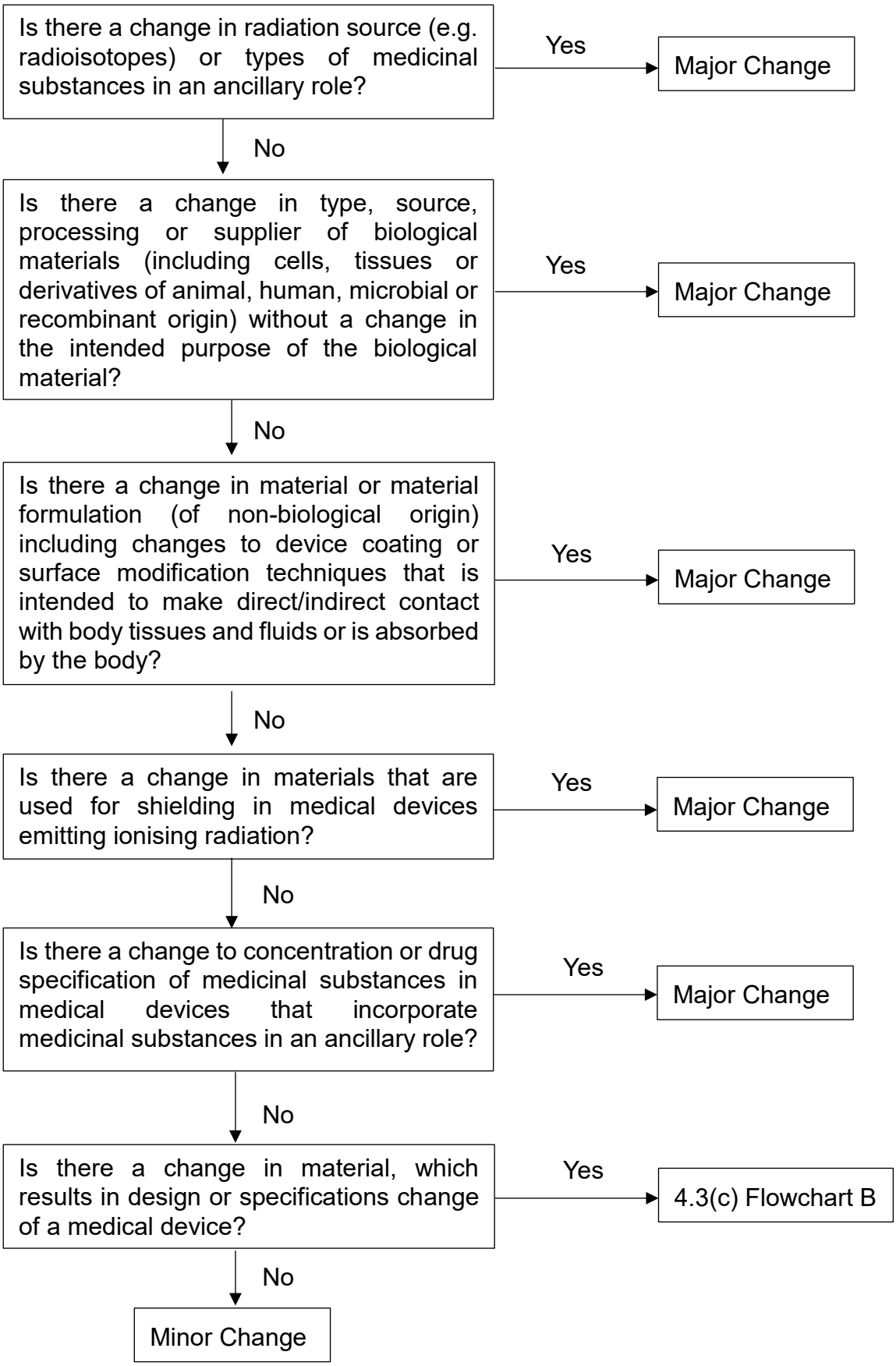


[1] Sterile barrier system means minimum package that prevents ingress of microorganisms and allow aseptic presentation of the product at the point of use.

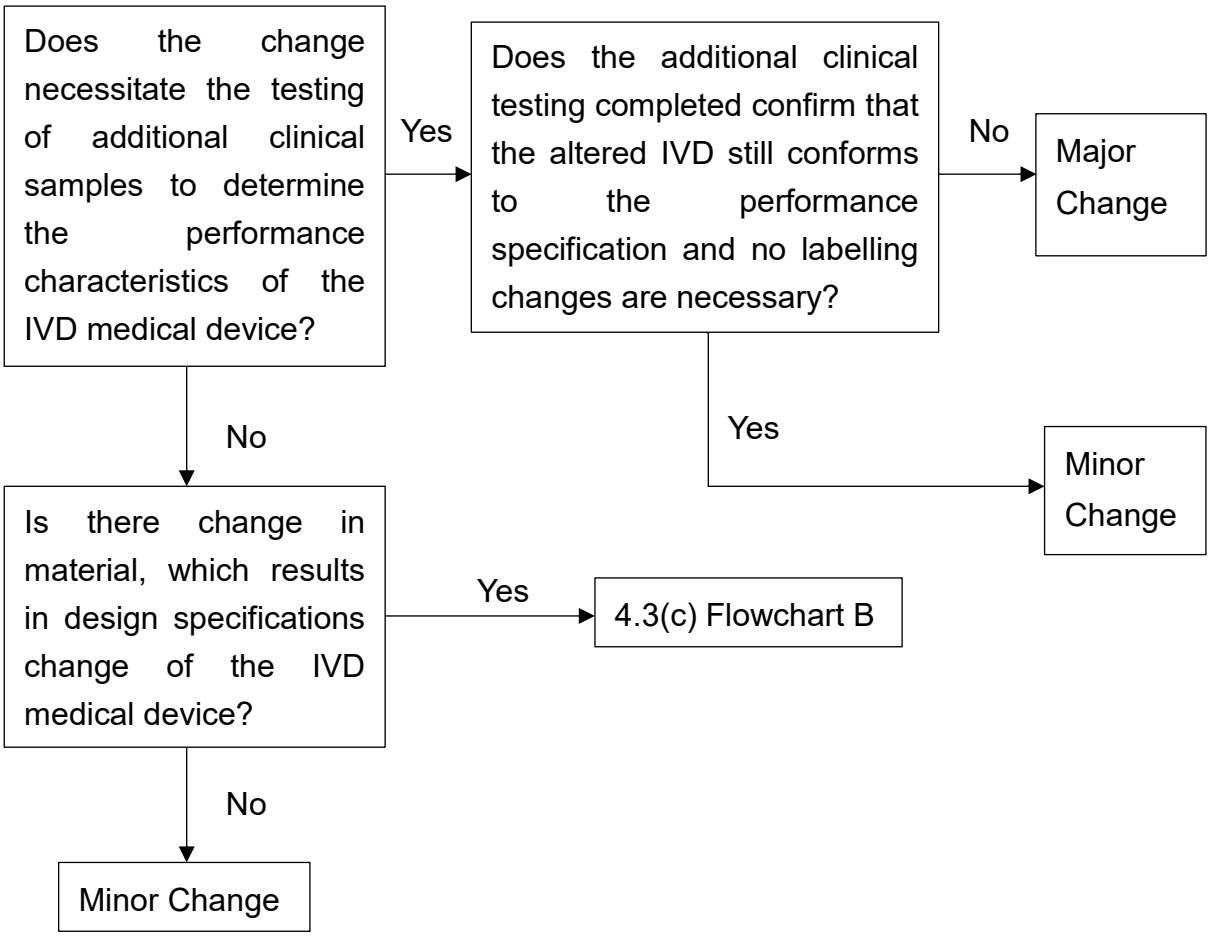
4.3(e) Changes to Software for Medical Devices - Flowchart D



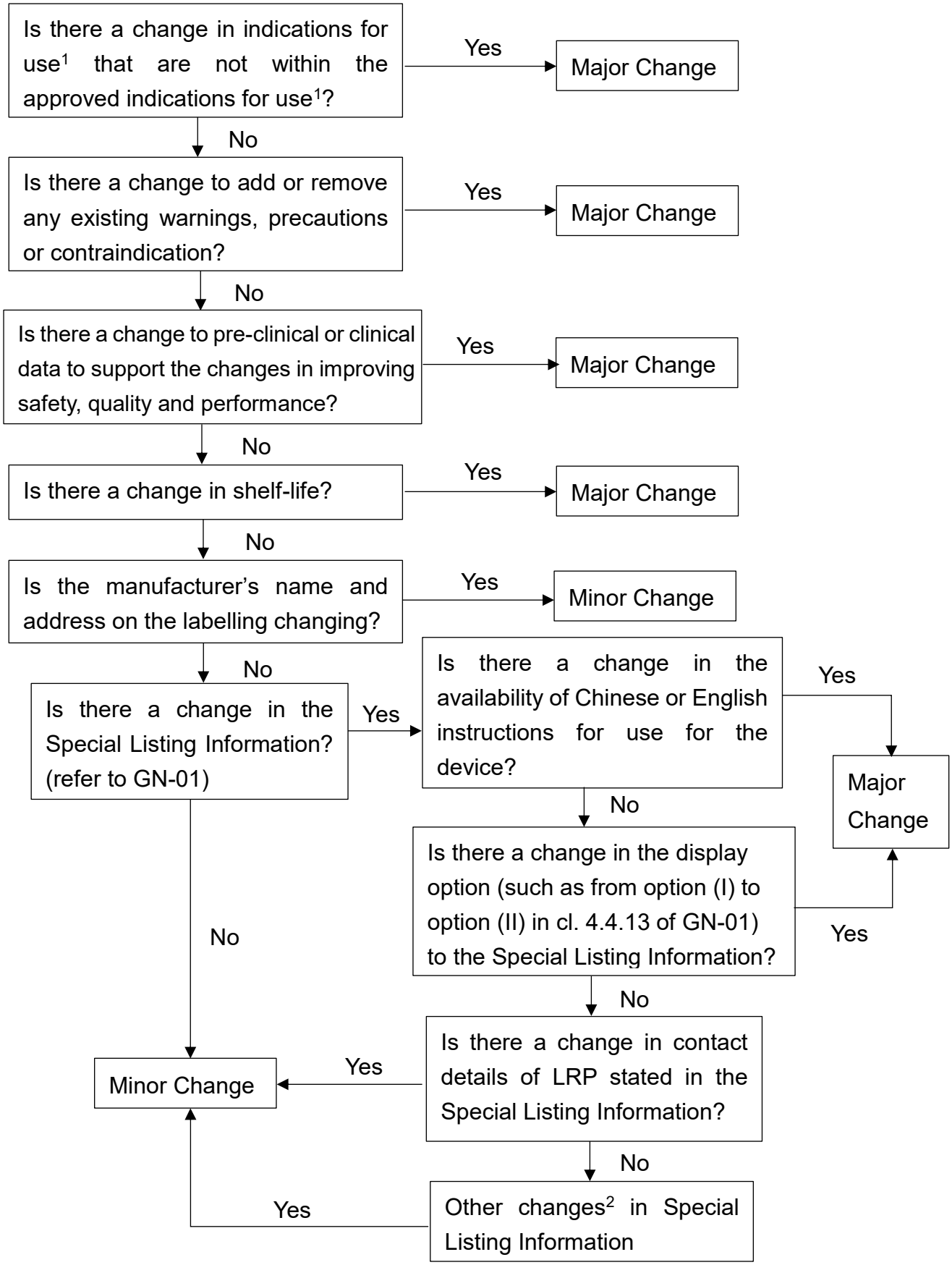
4.3(f) Changes in Materials for General Medical Devices – Flowchart E



4.3(g) Changes in Materials for In Vitro Diagnostic (IVD) Medical Devices – Flowchart F



4.3(h) Changes to Labelling and Special Listing Information – Flowchart G



[1] It may also include intended use, intended purpose and intended user

[2] Such changes may include but not limited to colour, position of text and graphics.

5. Reporting Changes

5.1 Major Changes

5.1.1 The LRP shall report any Major Change of a listed medical device by submitting a Change Application to MDD as soon as possible, and should be at least 12 weeks prior to any planned implementation.

5.1.2 MDD may require the LRP to submit, when necessary, any information and documents as the basis for supporting the change. All certifications/licences relating to the listed device shall remain valid and be made available to MDD upon request.

5.2 Minor Changes

5.2.1 For Minor Changes, the LRP shall notify MDD within 24 weeks from the time the LRP is aware of the change.

6. Supply of Changed Medical Devices

6.1 LRP intends to concurrently supply the original version and changed version of the listed medical device shall include in the Change Application a proposed schedule of such arrangement. Upon approval of the Change Application, the concerned medical device shall be supplied in the changed versions. The original version could only be supplied in the market concurrently, if they are still in compliance with the Essential Principles of Safety and Performance of Medical Devices as stipulated in MDACS. Unless otherwise specified by MDD, transition to the changed version shall be completed in 24 weeks, or any time upon MDD's instruction.

6.2 The LRP shall ensure that appropriate mechanisms are in place for the consumers and users to differentiate and identify the changed device, in particular self-use medical devices, from the original version based on device or manufacturing attributes (e.g. batch / lot / serial number, expiry date), and maintain relevant supply records to ensure traceability of both versions. All supply records shall be made available to MDD upon request.

7. Application Procedures

7.1 Change Application form

7.1.1 An application for change to the listed medical device shall be made on the Change Application form. The Change Application form and other guidance notes related to MDACS can be obtained from MDD website at https://www.mdd.gov.hk.

7.2 Submission of Change Applications

7.2.1 The Change Application can be submitted by email, by hand, or by mail. For electronic submission, the Change Application can be sent to the email address mdd_app@dh.gov.hk. For applications with great file size, submission with a portable storage device (PSD) is also acceptable. The Change Application form and all documents submitted will not be returned.

7.3 Acknowledgement upon receipt of a Change Application

7.3.1 Upon receiving a Change Application, MDD will acknowledge its receipt. In the event that the acknowledgement is not received within a period of 2 weeks after the submission of the Change Application, the LRP may contact MDD to enquire whether the submission has reached MDD.

7.4 Circumstances requiring new listing

7.4.1 It is the discretion of the MDD to require the LRP to submit a new application for the device based on the information submitted. For certain changes, such as the change of manufacturer's name, the LRP may be required to submit a new listing application instead of a Change Application. In general, the change of principle of operation of the medical device will require a new listing application. Please refer to MDD website at https://www.mdd.gov.hk for the latest version of guidance notes on listing of medical devices.

7.5 Multiple submissions for changes or subsequent changes

7.5.1 In general, multiple submissions of Change Applications of the same device will not be accepted by MDD when a previously submitted Change Application is still under evaluation.

7.5.2 Should two Change Applications be unavoidable, the LRP shall withdraw the Change Application under evaluation and submit a new Change Application including all changes and supporting documents.

7.6 Application results

7.6.1 A Change Application to a listed medical device may either be approved or rejected. The LRP will be informed of the results. In case a Change Application is rejected, the LRP shall not proceed with the change, otherwise the listing status of the device will become invalid immediately.

7.7 Replacement of Listing Certificate

7.7.1 If the issuance of an updated Listing Certificate is necessary, the LRP shall return the original copy of the existing Listing Certificate to MDD for replacement.

8. Enquiries

Enquiries concerning this document and MDACS should be directed to:

Medical Device Division,
Department of Health,
Telephone number: 3107 8484
Facsimile number: 3157 1286
Email address: mdd@dh.gov.hk
Website: www.mdd.gov.hk

9. References

9.1 Global Harmonization Working Party. Categorisation of Changes to a Registered Medical Device. GHWP/WG2-WG1-WG3/F001:2023. http://www.ahwp.info/index.php/. accessed on 21 July 2023.

9.2 International Organization for Standardization. Medical devices — Quality management systems — Requirements for regulatory purposes. ISO 13485.

9.3 Department of Health. Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System. Guidance Notes GN-00.

9.4 Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01.

9.5 Department of Health. Guidance Notes for Listing Class II/III/IV General Medical Devices. Guidance Notes GN-02.

9.6 Department of Health. Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Devices. Guidance Notes GN-06.

9.7 Department of Health. Essential Principles of Safety and Performance of Medical Devices. Technical Reference TR-004.

10. Appendix 1 Examples of Changes

Category	Change	Type
Changes in manufacturing process, facility or Quality Management System (QMS)	Changes to QMS Certificate, such as: Change/Addition/Removal of manufacturing facility	Major
	Change of device manufacturing process from casting to 3D printing	Major
	Change of scope of QMS certificate	Major
	A change in supplier that extrudes the polymer tubing with no change in finished product performance specifications.	Minor
Changes to sterilisation facility and its process or QMS	Change of sterilization method (e.g. from gamma irradiation to ethylene oxide)	Major
	Change in moist heat sterilisation parameters	Major
	Change to the packaging where a single pouched sterile device is put into a new double pouch.	Major
	Change of contract sterilizers (with no change to cycle parameters), the method of validating the process remains the same.	Minor
Change in design for medical devices	Change from a quantitative assay to a qualitative assay	Major
	Change in the design characteristics that allows for additional or broader intended use	Major
	Addition of a footswitch to an X-ray system that previously do not operate with a footswitch mechanism	Major
	A device is modified to use an internal battery instead of an external AC power source.	Major
	The addition of a new component, a combined filter and disposable cartridge for convenience.	Major
	Addition of two new stent lengths which are outside of the range of previously listed stent lengths.	Major
	Addition of two new stent lengths which are within the range of the previously listed stent lengths.	Minor
	Reduction in size of the wire diameter to reduce the overall pacing lead diameter, facilitating smaller introduction into the vessel.	Major

Category	Change	Type
	Modification of a detachable handle that allows the user to torque the lead body in order to provide a more ergonomic feel.	Major
	A change to the throughput or test volume of a clinical chemical analyser.	Major
Changes to software	Insulin Pump – Software changes that allow for wireless communication with compatible blood glucose monitors.	Major
	Upgrade of software version changes the performance characteristics like specificity or sensitivity of the In-vitro diagnostic medical device	Major
	The addition of new features or software applications.	Major
	Addition to software of an early warning alarm of an electrocardiogram to signal a potential cardiac event such as atrial fibrillation.	Major
	Change in software of electrocardiogram that provides or adds a visual on-screen alarm to an existing audible alarm.	Minor
	Bug fixing to correct the display error on the data table from the software analysis result.	Minor
	Change in software to alter colours and location of menu on graphic user interface of medical devices that does not affect safety and performance of the device but results in version change	Minor
	Change in software to strengthen the cybersecurity	Minor
Change in materials for General Medical Devices	Change in the drug of a drug eluting stent	Major
	Change in the concentration of the drug in a drug eluting stent	Major
	Change of material to a cardiovascular catheter that comes in contact with body tissue	Major
	Introduction of a colourant change into the flush port is an access port for flush syringes for IV line clearance or volume block and is not intended to be used for fluid administration or withdrawal from a patient.	Minor
Changes in materials for IVD Medical Devices	Change of formulation of a reagent that increase the performance (e.g. sensitivity)	Major

Category	Change	Type
	Change of sources or types of materials (e.g. conjugate, antibodies, antigens)	Major
	A change to the sample preparation, such as the inclusion of a stabilizer for an IVDD that is intended to simplify preparation requirements or increase sample stability.	Major
	Change in the preservatives or the formulations of existing materials that does not affect the performance characteristics or lead to labelling changes	Minor
Changes to Labelling and Special Listing Information	Change of IFU that involves a change from 'professional use only' to 'home use'.	Major
	All changes to the labelling that involve addition, removal or revision of warnings, precautions, contraindications and potential adverse events	Major
	Change of product shelf life (from 2 years to 3 years)	Major
	Addition/Revision of approved indications / intended use on IFU	Major
	Reduction of indications / intended use not arising due to medical device safety or performance concerns	Minor
	Addition of languages, other than Chinese or English required in other regulatory jurisdictions	Minor
	The Special Listing information of the device is now displayed on the outer package of each unit, where it was previously displayed on the delivery note.	Major
	Change in telephone number or address of LRP in the Special Listing information	Minor
	Change to the label due to typo error	Minor
	Change to AMDNS code	Minor