New Guidance Notes on Changes for Listed Medical Devices

Briefing session

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Rundown

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- Introduction
- Fundamentals of New Guidance Notes
- Change Application Procedure
- Examples
- Change Application Form
- Q&A session

Reference material

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- The Draft for Guidance Notes on Changes for Listed Medical Devices is available on MDD website at:
- https://www.mdd.gov.hk/en/information-publication/traders/index.html

Traders

(Note: The Medical Device Control Office has been renamed as the Medical Device Division with effect from 1 October 2019. Please refer to Contact Us page for updates in contact information and contact our office for enquiry, if necessary.)

Briefing Seminar

- Briefing Seminar on the Listing Application of Medical Devices under Medical Device Administrative Control System (MDACS)

Reference Materials for Briefing Seminar

- Talk on Application for Listing Class II/III/IV General Medical Devices (Chinese)
- Talk on Application for Listing Class B/C/D In Vitro Diagnostic (IVD) Medical Devices (Chinese)
- Talk on Application for Listing Class II/III/IV General Medical Devices (English)
- Talk on Application for Listing Class B/C/D In Vitro Diagnostic (IVD) Medical Devices (English)
- Draft for Guidance Notes on Changes for Listed Medical Devices (Chinese) (For reference only. The document will be subject to revision.)
- Draft for Guidance Notes on Changes for Listed Medical Devices (English) (For reference only. The document will be subject to revision.)

1. Introduction

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- Changes may take place from time to time during the product life-cycle
- To safeguard public health, ensure the information of listed medical devices, should be up-to-date in the MDACS
- The Local Responsible Person (LRP) has to report timely of any change to the listed medical device

New Guidance Notes

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- According to clause 4.4.9 of GN-01 “Reporting changes”:
  - When there is any major change to the information related to the business of the LRP or the listed medical devices, the LRP shall inform the MDD as soon as possible and in no case later than 10 calendar days.

- The New Guidance Notes aims to assist and guide the LRP in:
  - categorising, managing and reporting changes of listed medical devices
  - differentiating changes to a listed medical device
  - reporting the changes to MDD accordingly

- For reference only, subject to revision

Table of Content of New Guidance Notes

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1. Introduction
2. Definitions and Abbreviations
3. General Principles
4. Determination of Major or Minor Changes
5. Reporting changes
6. Supply of Changed Medical Devices
7. Application Procedures
8. Enquiries
9. References
10. Appendix 1 Examples of Changes

2. Definitions and Abbreviations

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- 2.1 **Major Change**
  affect the safety, quality or performance (SQP) of a medical device.
  - (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 Other terms: refer to Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System)

3. General Principles

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- 3.1 When considering several simultaneous changes,
  - assess each change separately.
  - If any of the changes is considered as a Major Change,
  - collectively considered as a Major Change

- 3.2 Major Changes: shall be implemented upon approval of the Change Applications.

- 3.3 If the medical device undergoes any changes without notifying MDD or obtaining prior approval from MDD (as appropriate):
  - The listing of the medical device will become invalid immediately
  - no longer be regarded as listed under MDACS
  - 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

4. Determination of Major or Minor Changes

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

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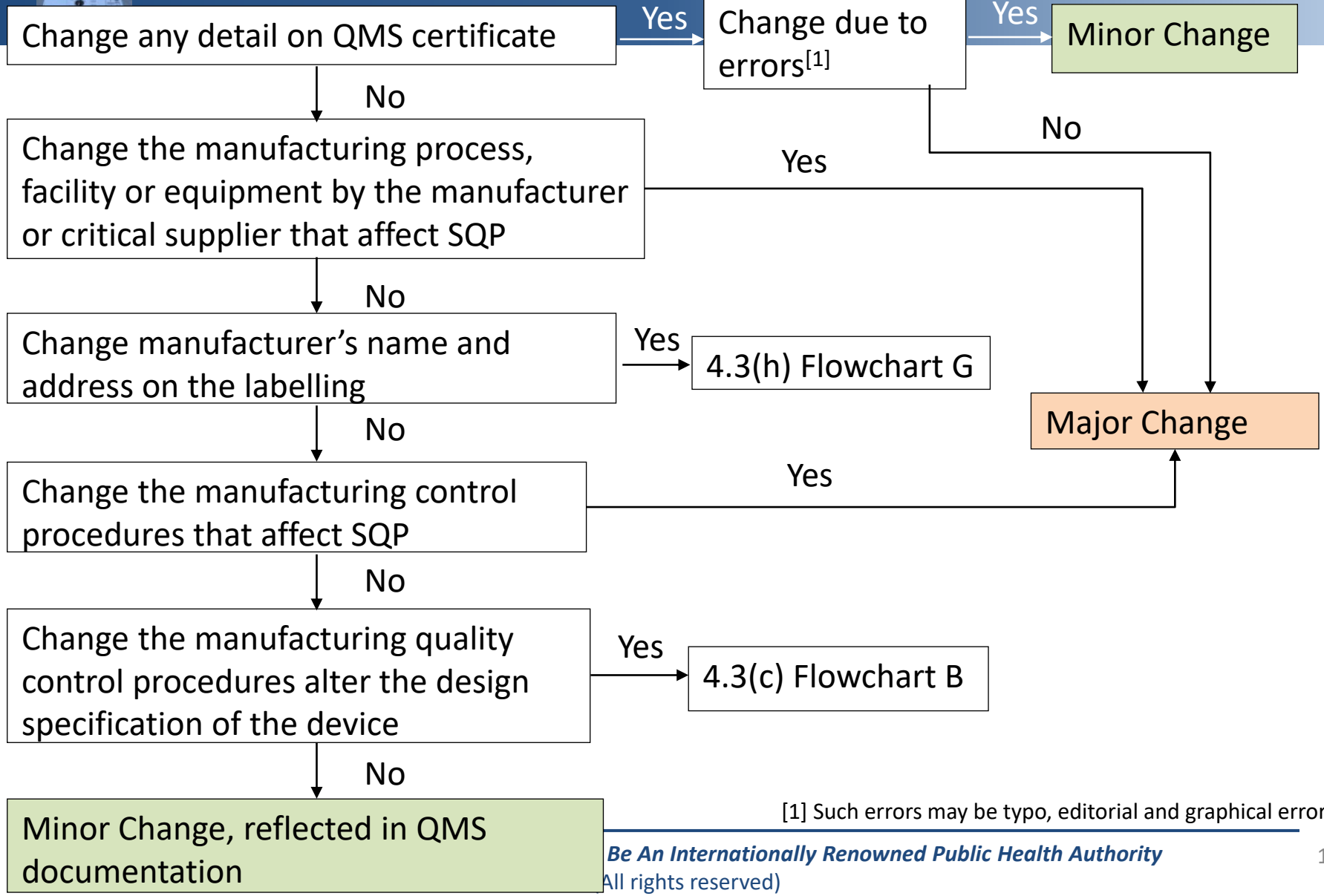

[1] Such errors may be typo, editorial and graphical errors.

4.3(c) Changes in Design – Flowchart B

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Change the control mechanisms or operating principles

Yes → Major Change

No ↓

Change the design characteristics or specification affecting the intended use

Yes → Major Change

No ↓

Pre-clinical or clinical data have identified new risks that adversely affects SQP

Yes → Major Change

No ↓

Results of a risk analysis undertaken during the design validation process raise new issues of SQP

Yes → Major Change

No ↓

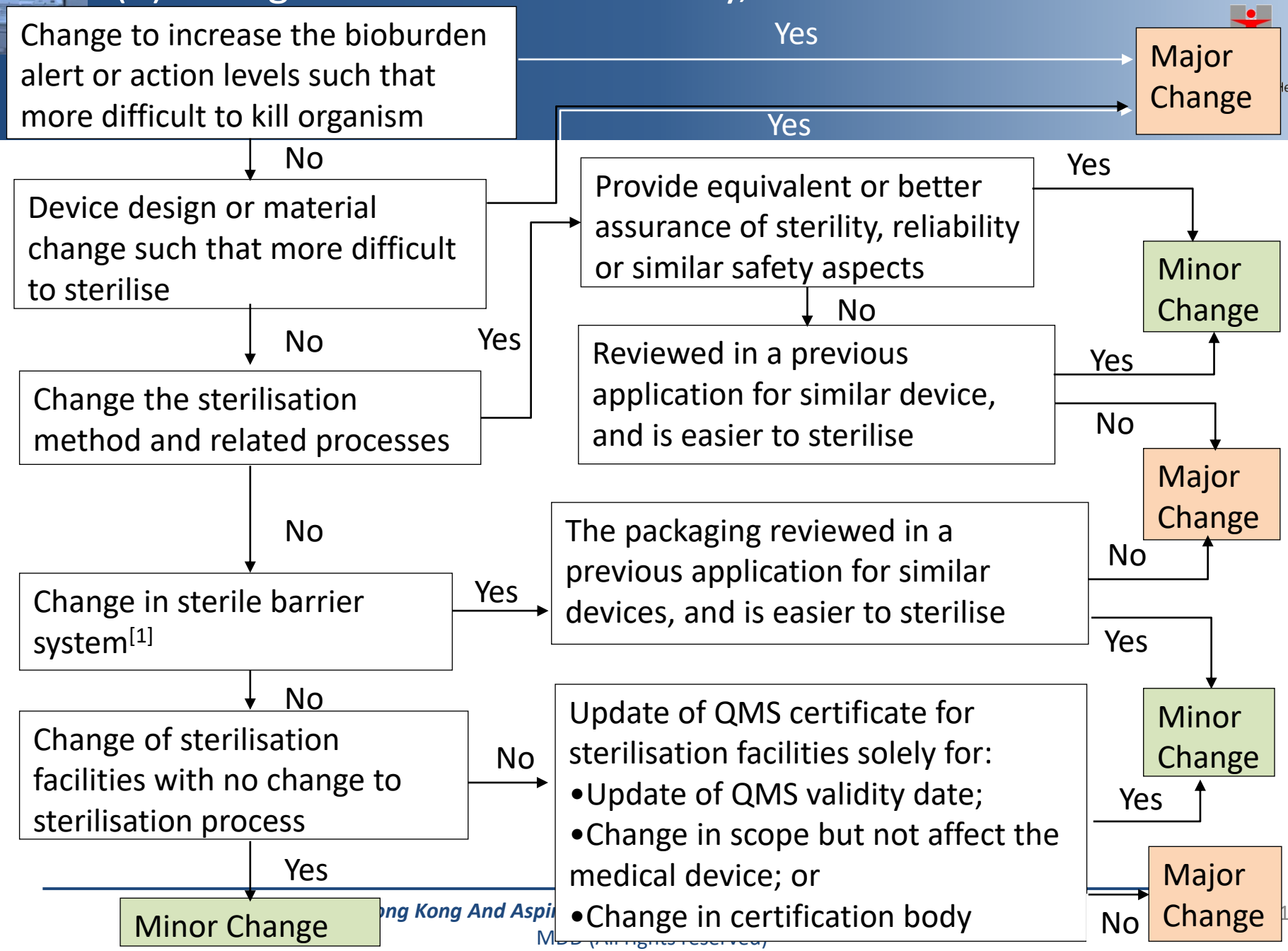
Change to the design, manufacturing or components that change its intended performance

Yes → Major Change

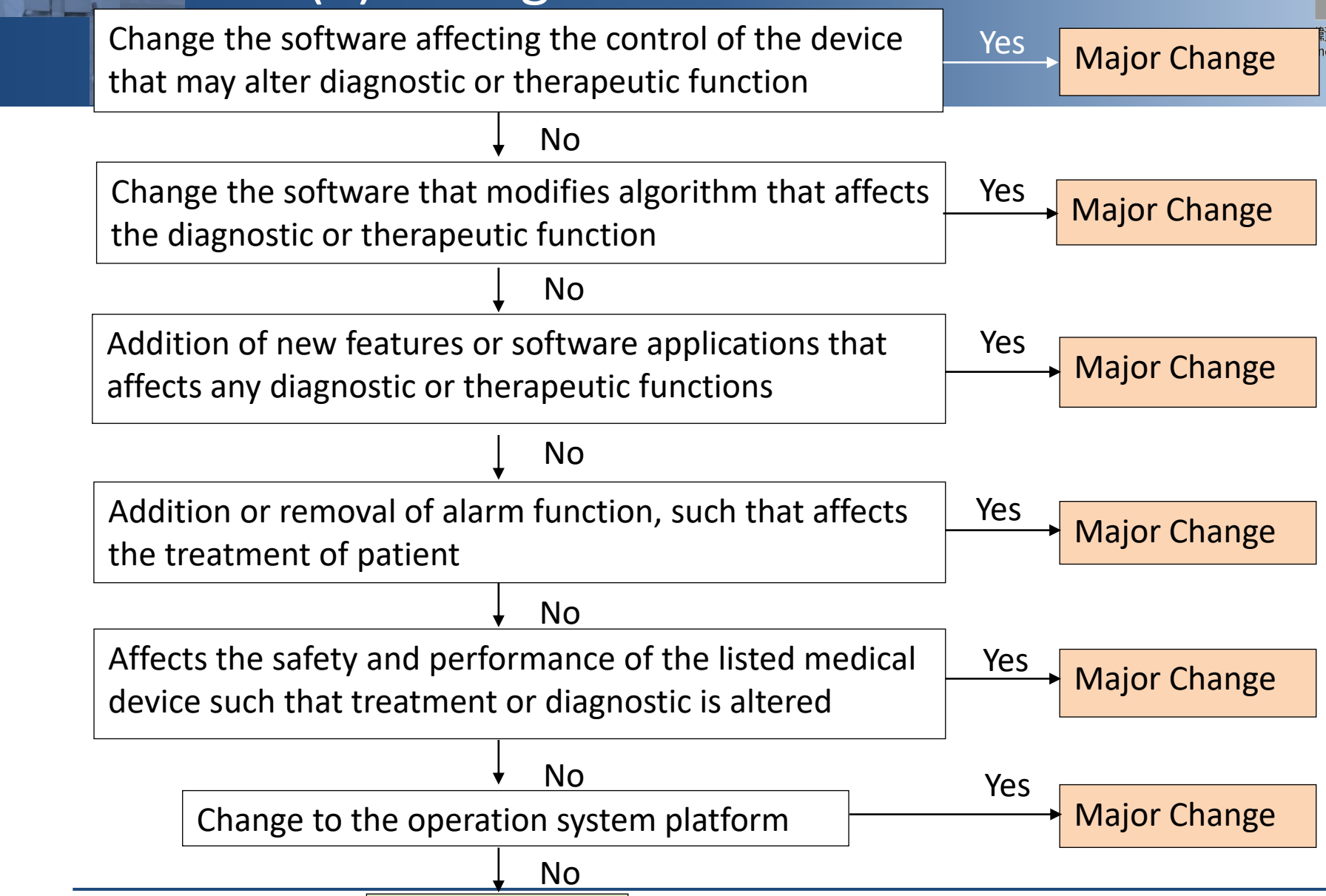
No ↓

Minor Change

4.3(d) Changes to Sterilisation Facility, Process or QMS – Flowchart C



4.3(e) Changes to Software - Flowchart D



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

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Change in radiation source or types of medicinal substances in an ancillary role

Yes → Major Change

No

Change in biological materials

Yes → Major Change

No

Change in material or formulation (of non-biological origin) including changes to device coating or surface modification techniques

Yes → Major Change

No

Change in materials for shielding in medical devices emitting ionising radiation

Yes → Major Change

No

Change to concentration or drug specification of medicinal substances in medical devices

Yes → Major Change

No

Change in material, which results in design or specifications change of a medical device

Yes → 4.3(c) Flowchart B

No

Minor Change

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

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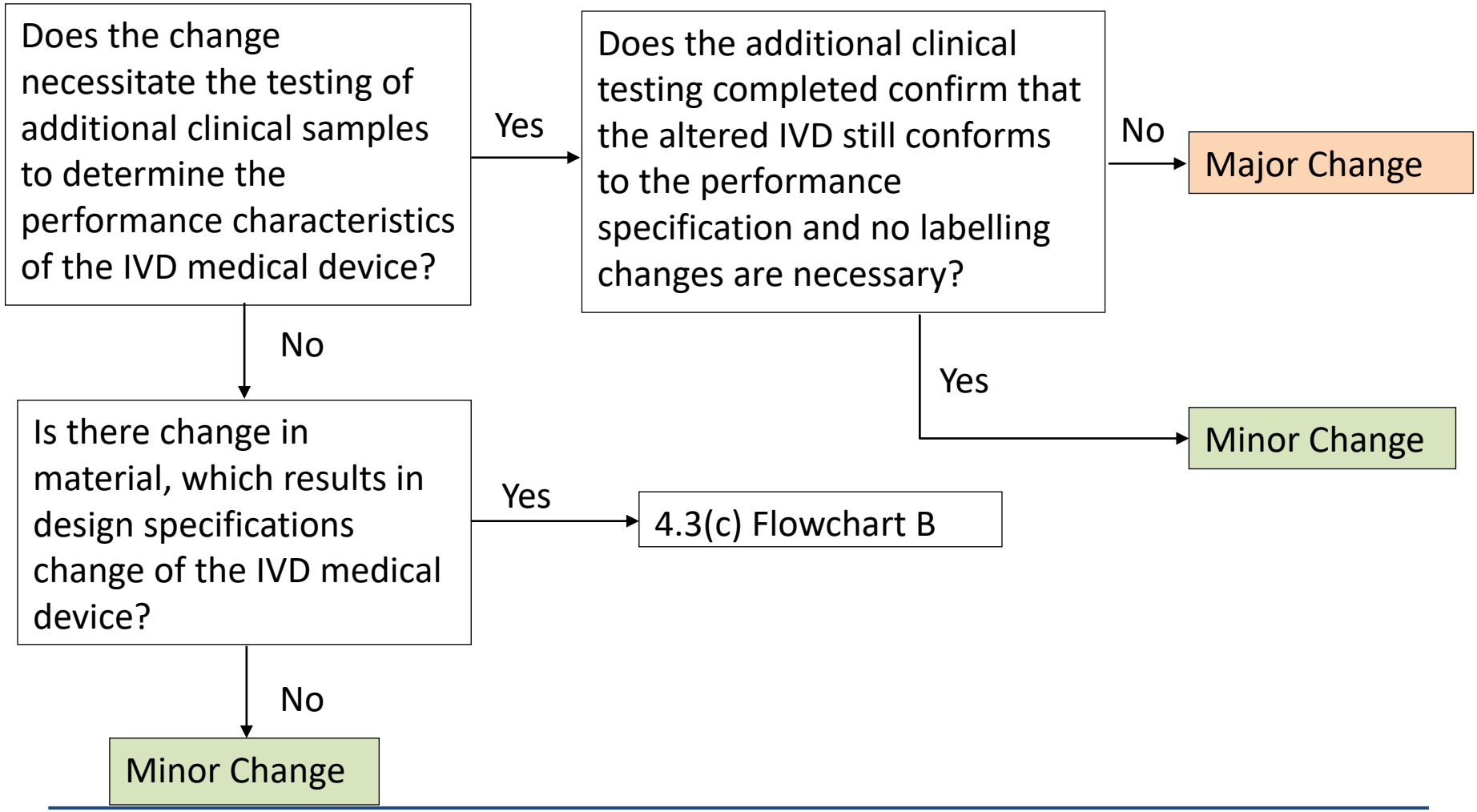

4.3(h) Changes to Labelling and Special Listing Information – Flowchart G

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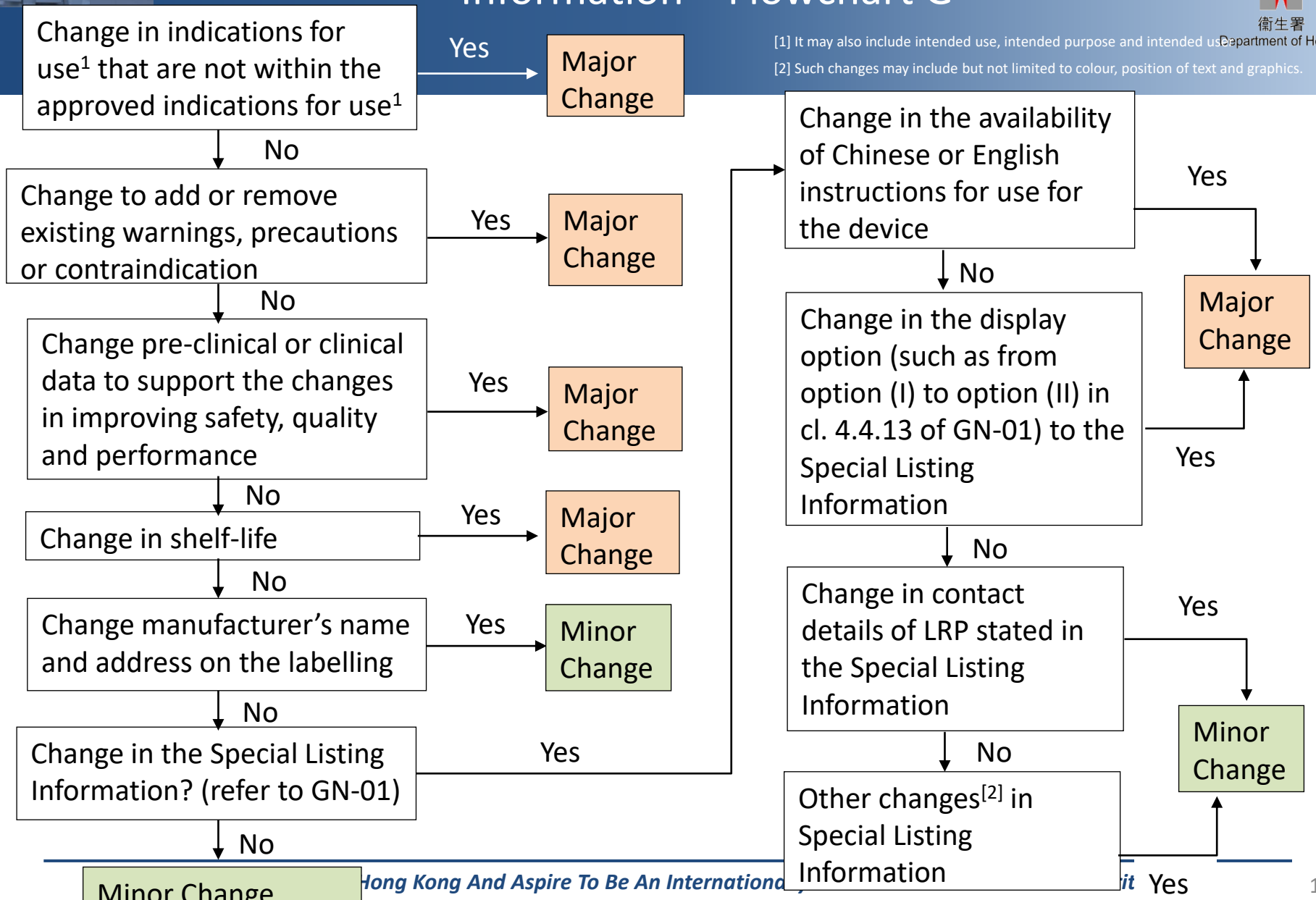
[1] It may also include intended use, intended purpose and intended user.

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



5. Reporting Changes

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

- All certifications / licences relating to the listed device shall remain valid and be made available to MDD upon request.

- 5.2 Minor Changes
  LRP shall notify MDD within 24 weeks from the time the LRP is aware of the change.

6. Supply of Changed Medical Devices

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- 6.1 Concurrently supply the original version and changed version of the listed medical device:
  - include a proposed schedule in the Change Application
  - Upon approval, the concerned medical device shall be supplied in the changed versions.
  - The original version could only be supplied concurrently, if they are still in compliance with the Essential Principles
  - 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 for the consumers and users to differentiate and identify the changed device from the original version.
  - in particular self-use medical devices,
  - and maintain relevant supply records to ensure traceability

7. Application Procedures

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- 7.1 Change Application form from MDD website

- 7.2 Submission of Change Applications
  - 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.

- 7.3 Acknowledgement upon receipt of a Change Application
  - Within 2 weeks after the submission of the Change Application

- 7.4 Circumstances requiring new listing
  - the discretion of the MDD to require the LRP to submit a new application
  - such as the change of manufacturer's name

7. Application Procedures

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- 7.5 Multiple submissions for changes or subsequent changes
  - will not be accepted by MDD when a previously submitted Change Application is still under evaluation
  - Or, 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
  - either be approved or rejected
  - 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
  - the LRP shall return the original copy of the existing Listing Certificate to MDD for replacement.

Examples of Changes

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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
Changes to sterilisation facility and its process or QMS	Change of sterilization method (e.g. from gamma irradiation to ethylene oxide)	Major
	Change to the packaging where a single pouched sterile device is put into a new double pouch.	Major
Change in design for medical devices	Change from a quantitative assay to a qualitative assay	Major
	Addition of a footswitch to an X-ray system that previously do not operate with a footswitch mechanism	Major

Examples of Changes

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Category	Change	Type
Change in design for medical devices	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
Changes to software	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
	Bug fixing to correct the display error on the data table from the software analysis result.	Minor
	Change in software to strengthen the cybersecurity	Minor

Examples of Changes

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Category	Change	Type
Change in materials	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
	Change of formulation of a reagent that increase the performance (e.g. sensitivity)	Major
	Change of sources or types of materials (e.g. conjugate, antibodies, antigens)	Major
	Change in the preservatives or the formulations of existing materials that does not affect the performance characteristics or lead to labelling changes	Minor

Examples of Changes

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Category	Change	Type
Changes to Labelling and Special Listing Information	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 to AMDNS code	Minor

The New Guidance Notes

Summary

Summary

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	Major Changes	Minor Changes
Meaning	Affect the safety, quality or performance (SQP) of a medical device.	Do not fall in the definition of Major Change
How to determine	Use the flowchart in section 4 or refer to the Example of Changes in Appendix 1. Or otherwise, the LRP may contact MDD for further assistance.	
How to implement	Need approval before implementation. Application for changes is required to get the approval from MDD.	No need approval before implementation. But notification of changes to MDD is required.
How to report or notify	By submitting a Change Application Form	By submitting a Change Application Form
When to report or notify	At least 12 weeks before any planned implementation	notify MDD within 24 weeks from the time the LRP is aware of the change.

Summary

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	Concurrent supply (section 6.1)
Possible?	Yes
How	Fill in the "proposed schedule" in the Change Application Form
Requirement	1. Original version is still in compliance with the Essential Principles of Safety and Performance of Medical Devices as stipulated in MDACS. 2. Ensure that appropriate mechanisms to differentiate and identify the changed version and original version. 3. Ensure traceability of both versions.
Transition to changed version	Normally completed in 24 weeks, or any time upon MDD's instruction

Summary

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- 3.3 If the medical device undergoes any changes without notifying MDD or obtaining prior approval from MDD (as appropriate):
  - The listing of the medical device will become invalid immediately
  - no longer be regarded as listed under MDACS
  - 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

New Change Application Form

(For reference only)

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Current Change Form

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Medical Device Division

Change Form for Listed Medical Devices

To: **Medical Device Division (Fax No: 3157 1286)** **MDD Reference: AN**

(Attn: **Secretary to MDLAB)**

Listing No: **HKMD No.**

LRP Name:

☐ **Application for Change(s) to the existing Listing**

We, _____ [Name of the LRP], confirm that there is/are change(s) to the listed medical device details since the latest approval. Attached please find the completed change form together with valid supporting document(s) for your consideration.

☐ **Application for Withdrawal of the Listing (Delisting)**

We, _____ [Name of the LRP], confirm to remove the captioned listing from the List of Medical Devices under the Medical Device Administrative Control System. We will continue with all the post market surveillance and vigilance activities stipulated in the *Code of Practice COP-01: Code of Practice for Local Responsible Persons* and *Guidance Notes GN-03: Adverse Incident Reporting by Local Responsible Persons* for products supplied to users. Moreover, we confirm that the assigned HKMD No. will no longer be used in any advertisement, promotional materials and/or other labeling of the device(s) from the date of delisting.

Please complete the following checklist and return it to Medical Device Division with valid supporting document(s)

Current Change Form

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Item	Description	Check the *box, if there is any change/update*	Details *(Use separate sheet if necessary)*
1	**Particulars of Local Responsible Person (LRP)**		
	(a) Business Registration Certificate of LRP *(Please provide a copy of valid Business Registration Certificate of LRP.)*	☐	
	(b) LRP's name (in English / Chinese*)	☐	
	(c) LRP's address in Hong Kong (in English / Chinese*)	☐	
	(d) Contact details (e.g. Contact Person and Post, E-mail, Telephone, Fax, contact telephone for public enquiries, mobile telephone for urgent use (24 hours), etc.)	☐	
2	**Particulars of Manufacturer**		
	(a) Manufacturer's address (in English / Chinese*)	☐	
	(b) Quality Management System Certificate (i.e. ISO13485 certificate)	☐	
3	**Particulars of the Device**		
	(a) Model name(s) / product code(s) of device(s) *(Please indicate Addition/Deletion/Amendment* of device(s) in the existing Certificate of Listing, if any)**	☐	
	(b) Intended use / Indications for use	☐	

Current Change Form

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	(c) Contraindications	☐	
	(d) Device labeling (including instructions for use, device package labels and Special Listing Information) *(Please provide details on changes(s) to content of the instructions for use)*	☐	
	(e) Manufacturing site(s)	☐	

	(f) Device design and performance specifications	☐	
	(g) Sterilization method	☐	
	(h) Shelf life	☐	
	(i) Risk analysis and/or clinical/performance evaluation*	☐	
	(j) AMDNS code and term (as device description) *(Please provide AMDNS code and term if they have not been covered in the existing Certificate of Listing.)*	☐	

Current Change Form

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4	**Marketing Approvals and Essential Principles**		
	(a) TGA ARTG Certificate	☐	
	(b) EC Certificate(s) and EC Declaration of Conformity (EC DoC)	☐	
	(c) Health Canada Licence	☐	
	(d) Japan (Ministry of Health, Labour and Welfare) Certificate	☐	
	(e) U.S. FDA 510(k) Letter / Pre-Market Approval (PMA) Letter / Certificate to Foreign Government (CFG)*	☐	
	(f) MDACS Conformity Assessment Certificate issued by the Conformity Assessment Bodies recognized by MDD	☐	
	(g) Essential Principles Conformity Checklist (Form MD-CCL in most recent version) or Essential Requirements Checklist in accordance with relevant EU directives or regulations supplemented with Essential Principles Declaration of Conformity (EP DoC)	☐	
5	**Others (please specify) (e.g. LRP designation letter):**	☐	

Signature:

(Name)

(Position)

(Date)

(Company chop)

New Change Application Form (Draft only)

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Medical Device Division

Change Application Form for Listed Medical Devices

To: **Medical Device Division**
(Attn: Secretary to MDLAB)

MDD Reference: AN_____
(for official use only)

Listing No: **HKMD No.** _____

LRP Name: _____

☐ Application for Change(s) to the existing Listing [Please complete Part A-D]

☐ Application for Withdrawal of the Listing (Delisting) [Please complete Part E]

Points to note:

1. For the change in contact details of LRP (e.g. Contact Person and Post, E-mail, Telephone, Fax, Contact Telephone for public enquiries, Mobile Telephone for urgent use (24 hours), etc.), please send email to mdd_app@dh.gov.hk to process separately. Submission of this form is not required for such changes.
2. Update of validity date of a certificate is not regarded as a change.

Please complete the following checklist and return it to Medical Device Division with valid supporting document(s) in Part D:

New Change Application Form (Draft only)

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Item	Description	Major Change	Minor Change	Description of change
(A)	**Changes related to Medical Devices**			
1	Change in manufacturing processes, facility or Quality Management System (including Quality Control, QC) [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(b) – Flowchart A]			
1.1	Change of manufacturer's address	☐		_____
1.2	Addition/Removal/Change of manufacturing site	☐		_____
1.3	Other changes in manufacturing processes, facility or Quality Management System (including Quality Control)	☐	☐	Please specify: _____
2	Changes in Design for Medical Devices [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(c) – Flowchart B]			
2.1	Change to the control mechanisms or operating principles	☐		_____
2.2	Addition/Removal/Change of models or product codes	☐	☐	_____
2.3	Change to the design, or addition/removal/modification of a component	☐	☐	_____
2.4	Change in Magnetic Resonance (MR) safety or compatibility	☐		_____
2.5	Other changes in design	☐	☐	Please specify: _____

New Change Application Form (Draft only)

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Item	Description	Major Change	Minor Change	Description of change
3	Changes to Sterilisation Facility and its Process or Quality Management System [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(d) – Flowchart C]			
3.1	Change in sterilisation method and related processes	☐	☐	_____
3.2	Change in sterilisation facilities	☐	☐	_____
3.3	Other changes to Sterilisation Facility and its Process or Quality Management System	☐	☐	Please specify: _____
4	Changes to Software for Medical Devices [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(e) – Flowchart D]			
4.1	Addition of new features or software applications	☐	☐	_____
4.2	Enhancement of current features		☐	_____
4.3	Other changes to software	☐	☐	Please specify: _____
5	Changes in Materials [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(f) – Flowchart E and clause 4.3(g) – Flowchart F]			
5.1	Changes in materials	☐	☐	Please specify: _____

New Change Application Form (Draft only)

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6	Changes to Labelling and Special Listing Information [Please refer to Guidance Notes on Changes for Listed Medical Device, clause 4.3(h) – Flowchart G]			
6.1	Change in indications / intended use	☐	☐	_____
6.2	Change in any warnings, precautions, contraindication and potential adverse events	☐	☐	_____
6.3	Change in shelf-life or storage conditions	☐		_____
6.4	Change in the Special Listing Information (refer to GN-01)	☐	☐	_____
6.5	Addition/Removal of symbols	☐	☐	_____
6.6	Change in artwork/formatting of label, such as change of date format, addition of 2D barcodes		☐	_____
6.7	Other changes in labelling	☐	☐	Please specify: _____
7.	Other changes that are not specified in above sections	☐	☐	Please specify: _____
(B)	**Changes related to Local Responsible Person (LRP)**			
8	Change of Particulars of LRP [Please also complete part 6.4, if applicable]			
8.1	Change of name of LRP (Not transfer of LRP)	☐		_____
8.2	Change of LRP's Address in Hong Kong	☐		_____

New Change Application Form (Draft only)

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(C)	**Changes to Marketing approvals and/or essential principles** Please specify: _____	☐
9	Proposed schedule for concurrent supply upon approval of Change Application (if applicable):	☐
	Transition to the changed version be completed in (e.g. 5 weeks) _____ weeks [Please refer to clause 6.1 of Guidance Notes on Changes for Listed Medical Device, transition to the changed version shall be completed in 24 weeks]	
(D)	Submission of supporting documents regarding the changes in Parts A-C (if applicable) ☐ ISO 13485 certificate ☐ Business Registration Certificate ☐ LRP Designation letter ☐ Instructions for Use (IFU) ☐ Device Label ☐ Special Listing Information ☐ Risk analysis/ management ☐ Clinical evaluation ☐ Others, e.g. test/study report ☐ Marketing approval(s) ☐ Essential Principles Conformity Checklist MD-CCL ☐ Essential Requirements Checklist / General Safety and Performance Requirements Checklist in accordance with relevant EU directives or regulations and Essential Principles Declaration of Conformity	

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(E)	**Apply for delisting**	
	We, _____ [Name of the LRP], wish to remove the captioned listing from the List of Medical Devices under the Medical Device Administrative Control System. We will continue with all the post market surveillance and vigilance activities stipulated in the Code of Practice COP-01: Code of Practice for Local Responsible Persons and Guidance Notes GN-03: Adverse Event Reporting by Local Responsible Persons for products supplied to users. Moreover, we confirm that the assigned HKMD No. will no longer be used in any advertisement, promotional materials and/or other labelling of the device(s) from the date of delisting. Reason for delisting: _____	☐

Signature _____ Name _____ Position _____ Date _____	(Company chop)

Thank you

Q&A Session

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