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.
3. If content input could not be fully displayed in the field of "Description of change", please describe the change(s) in separate attachment.

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

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)	☐	☐	

Item	Description	Major Change	Minor Change	Description of change
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	☐	☐	
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	☐	☐	
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	☐	☐	
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	☐	☐	

Item	Description	Major Change	Minor Change	Description of change
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	☐	☐	
7.	Other changes that are not specified in above sections	☐	☐	
(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	☐		

(C)	Changes to Marketing approvals and/or essential principles	Applicable
9.1	Addition of marketing approval(s) / Removal or change of current marketing approval(s)	☐
9.2	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	☐

10	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] Justification if prolonged transition period is required:	
(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	
(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)