QUESTION	ANSWER
Introduction	
What is a Change Notification?	Change Notification application is meant to notify the Authority if there are any changes or proposed changes to any particulars provided in relation to the registration of medical device, and/or if there are any changes or proposed changes that may affect the safety, quality or efficacy of a registered medical device.
How to apply for Change Notification?	The application should be submitted online via Medcast 2.0+ system. The applicant should determine the correct Category for each change before submit the application online.
Category	
How may I know the correct Category for my change(s)?	Change to a registered medical device may be categorized into Category 1, Category 2 and Category 3. Please refer to section 5.3, Table 1 and Table 2 in the MDA/GD/0020
What If I still unable to determine the correct category?	You may submit a request for confirmation on change notification category for registered medical device. Please refer Annex A in the MDA/GD/0020. This request need to be submitted by hardcopy to the Authority address together with the payment. Processing fee shall be paid through bank draft.
What happened if my change(s) is categorized as Category 1?	Category 1 changes of medical devices that affect their safety and performance. The change(s) do not qualify for a Change Notification. Please register the medical device with New Registration instead
What happened if my change(s) is categorized as Category 2?	Category 2 are changes that require evaluation and endorsement from the MDA prior to implementation of the change and before placing in the market. The change(s) can be notified and submitted through Medcast 2.0+
What happened if my change(s) is categorized as Category 3?	Category 3 changes may be implemented immediately upon submission of complete documents. The change(s) can be notified and submitted through Medcast 2.0+
What happened if my change(s) are categorized as Category 2 and Category 3?	The implementation of changes are according to the category of cahnges. The change(s) can be notified and submitted through Medcast 2.0+
Can I combine the change(s) under Category 2 and Category 3 under one application?	Yes, you may combine any changes under Category 2 and Category 3 under one application. There is no limitation for the changes to be selected for one medical device

Can I combine change(s) for more than one medical device to be submitted as one application?	Yes, you may combine change(s) for two up to 50 medical devices in on application.However the change(s) of each medical device must be similar change(s) and the change(s) only subject to the certain change(s) allowed as below; Category 2 5.5.1 Change in Manufacturing Facility, Process and Quality Management System (QMS) (a) All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes. Category 3 5.6.1 Change in Manufacturing Facility, Process and Quality Management System (QMS) (a) All changes to certificates for manufacturing and sterilisation facilities that i) involves an update of certificate QMS (for manufacturer); OR; ii) change in scope of the QMS certification which affect the registered medical device (that is not due to safety, and/or performance of the medical device) OR; iii) involves a cancellation of QMS scope on the certificate for any of the multiple existing manufacturing facilities that is related to the registered medical device (that is not due to safety, and/or performance of the medical device), OR; iv) involves the change in conformity assessment body with no change in scope of the certification, OR; v) involves the expansion of scope of the QMS certification which does not affect the registered medical device. Category 3 5.6.4 Changes to Registered Medical Devices Registration Information (c)All changes in the manufacturer information that only- Involve changes in manufacturer's name and address, OR (ii) Involve changes in the manufacturing site's name only. With no changes in the manufacturing site's address
Changes arising from the EU MDR/IVDR	

My regsitered medical device(s) has been impacted due to EU's recent regulatory framework transition to Medical Devices Regulation (MDR) and IVD Regulation (IVDR). Do I need to notify the changes arised from that transition to the Authority?	European Union (EU) is one of MDA reference regulatory agencies commonly referenced in abridged evaluation route for medical device registration. With that trasition, the related changes will impact existing registered medical devices, especially IFU and labels. Please refer to Table 3 in the MDA/GD/0020. For changes that do not fall within the covered scope and criteria in the Table 3, approach as prescibed in Table 1 and Table 2 in the MDA/GD/0020.
Turn-around time	
What is turn-around time for an application?	Please refer to Table 5 in the MDA/GD/0020.
Can I submit new application of change notification if there is a pending change notification application in the system?	The Medcast 2.0+ system will not allow for another submission of a new change notification application for the same medical device, when there is a pending change notification application. The pending application needs to be completed before submitting a new change notification application.
If the registered medical device has achieved the re-registration timeline and some changes need to be implemented to the medical device, should the medical device proceed with Change Nitification application first or Re-registration application?	As the re-registration application is available to be applied prior one year to the expiry date, the applicant is advise to proceed with Change Notification application fist in order to notify the change to the Authority before submit for re-registration. However, for the medical device that has past the expiry date are not applicable to apply for Change Notification application, since the medical device registration is expired. For this situation, the applicant is advise to proceed for Re-registration application with
Fee / Payment	
What is the fee apply for this type of application?	All submission of notification of changes shall be accompanied with a fee as per the Table 3 in the MDA/GD/0020.
What is the payment method allow for the type of application?	FPX and Bank Draft