Category 3 changes may be implemented immediately upon submission of complete documents through MeDC@St.

The guiding principles for identification of category 3 of various types of change to registered medical devices are presented in Table 2.

Table 2: Change notification for Category 3

Types of change	**Documents to be submitted****
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.	i) Valid QMS certificate and report; ii) Annexes

5.6.2 Changes in design or specifications of a registered medical device	
(a) All changes only involve a change to software version number that does not affect safety and/or performance of the medical device, such as— i) software changes solely to correct an inadvertent software error which does not add new functions, does not pose any safety risk and is intended to bring the system to its original specification; ii) software changes which augment interfacing to other non-medical peripherals such as printers or VDUs and which has no diagnostic or therapeutic function; or iii) software changes which only modify the appearance of the user interface with no risk to diagnostic or therapeutic function of the medical device. Note: The change notification for this item may be submitted in batches of 6 monthly submissions from point of first implementation.	i) Software validation report; ii) Detailed summary of software changes; iii) Annexes
5.6.3 Changes to labelling of medical devices	
(a) Where the change only involves a reduction or rephrasing of indications for use not affecting the medical device safety and/or performance. Exception: Changes that are considered as editorial.	i) Description of the new indications for use; ii) Reasons for the reduction of approved indications; iii) Medical device labelling stating changes for each amended section; iv) Annexes
(b) Labelling changes that only— i) involve the addition of Recognised Countries' approvals (e.g. CE marking). Exception: Changes that are considered as editorial.	i) Medical device labelling stating changes for each amended section; ii) Valid certificates from relevant bodies (where applicable); iii) Annexes

(c) Other labelling changes involving information in the labelling that does not fall under above (a) and (b). The following changes do not require change notification: i) Rephrasing of information/change in arrange in IFU; ii) Labelling changes that involve the addition and/or removal of languages not required by the Authority; iii) Labelling changes that involves the update of distributor information, include EU authorised representative, and which does not affect the medical device registration information.	i) Medical device labelling stating changes for each amended section; ii) Details of changes and the reason for changes; iii) Documents supporting proposed changes detailed above (if applicable); iv) Annexes
5.6.4 Changes to registered medical devices registration information	
(a) If the change only involves an addition of Class A medical device accessories that are non-active, with no measuring function or non-sterile and complement the registered medical device as a system.	i) Declaration by registration holder to state - a. the added models are non-active, with no measuring function or non-sterile class A medical device accessories; b. no change in manufacturer; ii) name and address for the manufacturing site(s); iii) Updated list of configurations of medical device indicating the name of medical devices affected; iv) Declaration of conformity; v) Medical device labelling that indicate the addition of the device(s); vii) Annexes
(b) All changes to the medical device that involve- i) All deletions of a medical device from medical device registration (for medical devices in grouping). Example: The change only involves the reduction in the number of medical devices in the grouping due to obsolescence and not due to safety and/or performance considerations.	i) Justification for deletion of medical device(s); ii) Declaration from manufacturer to state that there is no change to medical device in all aspects, including intended use, technical specifications; iii) Updated list of configurations of medical device indicating the name of medical devices affected; iv) Medical device labelling stating changes for each amended section;

ii) changes of brief description of item(s) (in the list of the configurations) that does not involve any change to the intended use and technical specifications;	v) Declaration of conformity; vi) Annexes
(c) All changes in the manufacturer information that only- i) involve changes in manufacturer's registered name and address (administration office); OR ii) involve changes in the manufacturing site's name only, with no change in the manufacturing site's address.	i) Declaration of conformity; ii) Declaration from manufacturer to state that they will undertake responsibility to provide post market support and assistance related to the medical devices already supplied under the former manufacturer's name (if applicable); iii) Medical device labelling stating changes for each amended section; iv) Updated QMS certificate or relevant official supporting document indicating the change; v) Annexes
(d) A change in regulatory status on rejection or withdrawal in any recognised countries for any registered medical device. Note: withdrawal due to commercial decision does not require change notification.	i) Existing regulatory approval; ii) Documents from relevant regulatory authorities citing reason for the change in regulatory status; iii) Reason for company to withdraw from regulatory authorities (if applicable); iv) Annexes
**Section 6(4) of Act 737, the Authority may, in writing, at any time after the receipt of an application under subsection (1), request the applicant to give to the Authority within the period specified in the request additional information, particulars or document on the application or sample of the medical device; and **Section 6(5) of Act 737, if any additional information, particulars or document, or sample of the medical device required under subsection (4) is not given by the applicant within the period specified in the request or any extension of time granted by the Authority, the application shall be deemed to be withdrawn and shall not be further proceeded with, but without affecting the right of the applicant to make fresh application.	