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 guiding principles for identification of category 2 of various types of change to registered medical devices are presented in Table 1.

Table 1: Change notification for Category 2

Types of change	Documents to be submitted**
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. Example: Change of manufacturing site's address.	i) Revised QMS certificate(s) (if applicable); ii) Medical device labelling stating changes for each amended section (if applicable); iii) Declaration that there is no change to manufacturing and sterilisation process; iv) Sterilisation validation report (if applicable); v) Declaration of conformity (if applicable); vi) Annexes
(b) All changes to manufacturing processes (including changes made to outsourced processes) that result in a change in specifications of a registered medical device. Examples: 1. Change in the equipment used for cutting the result in the change in length of sutures. 2. Moulding or cutting manufacturing process.	i) Revised QMS certificate(s) (if applicable); ii) Summary of new manufacturing process; iii) Validation report covering new processes; iv) Pre-clinical studies (if applicable); v) Software validation report (for software); vi) Clinical safety report (for operating principles and design characteristics change) (if applicable); vii) Risk analysis; viii) Annexes
(c) All changes to sterilisation processes (including changes made to outsourced processes). Example: Change in moist heat sterilisation parameters, or change in sterilisation method from ethylene oxide to gamma radiation, or change from batch release to parametric release.	i) Sterilisation technique (certificate); ii) Medical device labelling stating changes for each amended section (if applicable); iii) Sterilisation validation report (including the sterilisation protocol, sterilisation standards applied, sterility assurance level, sterilisation revalidation report); iv) QMS certificate(s); v) Annexes

5.5.2 Changes in design or specifications of a registered medical device	
(a) All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device. Examples: 1. Change from a quantitative assay to a qualitative assay. 2. Addition of a footswitch to an X-ray system that previously do not operate via a footswitch mechanism.	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical studies; iii) Risk analysis; iv) Clinical studies (if applicable); v) Medical device labelling stating changes for each amended section (if applicable); vi) Software validation report (for software, if applicable); vii) Detailed summary of software changes (for software, if applicable); viii) Annexes
(b) Changes that only involves a design change that does not affect the safety and/or performance of the medical device (e.g. changes that improve the medical device ergonomics, aesthetic modification of the medical device).	i) Revised QMS certificate(s) (if applicable); ii) Risk analysis; iii) Usability testing report (if applicable); iv) Annexes
(c) i) All changes in specifications to shelf life and stability of a registered medical device. ii) Any changes in analytical performance test for IVD medical devices.	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical studies (if applicable); iii) Clinical safety report (if applicable); iv) Risk analysis; v) Medical device labelling stating changes for each amended section (if applicable); vi) Software validation report (for software, if applicable); vii) Detailed summary of software changes (for software, if applicable); viii) Annexes
(d) Change to software that affect safety and performance of the registered device such that the treatment or diagnosis of the patient is altered. Example: Upgrade of software version changes the performance characteristics like specificity or sensitivity of the diagnostic medical device.	i) Revised QMS certificate(s) (if applicable); ii) Risk analysis; iii) Software validation report; iv) Detailed summary of software changes; v) Annexes

5.5.3 Changes to materials in a general medical device	
(a) All changes to biological materials that involve a change in type, source, processing and/or supplier of cells, tissues and/or derivatives of animal, human, microbial or recombinant origin without a change in the intended purpose of the biological material. Example: Change in source of hyaluronic acid from Streptococcus zooepidemicus to Streptococcus equi.	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical studies, including biological safety data; iii) Clinical safety report (if applicable); iv) Information of sources/donors; v) Risk analysis; vi) Annexes
(b) All changes to materials or material formulation (of non-biological origin), including changes to medical device coating or surface modification techniques, that involve materials that make direct/indirect contact with body tissues and fluids, or are absorbed by the body. Example: Replacement of catheter surface coating from PEBA to PEEK.	i) Revised QMS certificate(s) (if applicable); ii) List of materials making direct/ indirect contact with human body; iii) Pre-clinical studies; iv) Clinical safety report (if applicable); v) Risk analysis; vi) Annexes.
(c) All changes to materials that are used for shielding in medical devices emitting ionising radiation. Example: Change in shielding material of X-ray system from lead to tungsten.	i) Revised QMS certificate(s) (if applicable); ii) Information on radiation source; iii) Information on materials for shielding of radiation; iv) Radiation safety test/test report; v) Risk analysis; vi) Annexes
(d) All changes to the radiation source (e.g. radioisotopes).	i) Revised QMS certificate(s) (if applicable); ii) Information on radiation source; iii) Radiation safety test/test report; iv) Risk analysis; v) Annexes

5.5.4 Changes to materials in an in-vitro diagnostic (IVD) medical device	
(a) All changes to the radiation source (e.g. radioisotopes in radioimmunoassay).	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical performance evaluation data; iii) Clinical performance evaluation data; iv) Information on source of material; v) Radiation safety test/test report; vi) Risk analysis; vii) Annexes
5.5.5 Changes to labelling of medical devices	
(a) All changes to the labelling of medical devices that involve addition, removal and/or revision of warnings, precautions and/or contraindications and/or indications of use. Exception: Changes that are considered as editorial.	i) Revised QMS certificate(s) (if applicable); ii) Description of the warnings, precautions and/or contraindications; iii) Reasons for the revision of approved changes; iv) Medical device labelling stating changes for each amended section; v) Annexes
(b) Labelling changes that- i) modify the approved method of use; OR ii) involve a change from 'professional use only' to 'home use'. Note: Requires the usability test report.	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical Studies (if applicable); iii) Clinical safety report (if applicable); iv) Software validation report (for software); v) Risk analysis; vi) Usability test report (if applicable); vii) Medical device labelling stating changes for each amended section; viii) Annexes

5.5.6 Changes to registered medical devices registration information	
(a) If the change only— i) involve the addition of new medical devices of the same design (within the permissible variants that does not affect safety and performance of the device, e.g. sizes, volume, colours, shapes, length, diameter); Examples: 1. Latex examination gloves with addition of different size. 2. Contact lens with addition of different colour OR ii) involve addition of a new medical device with design change that does not affect the safety and/or performance of the medical device (e.g. changes that improve medical device ergonomics, aesthetic modification of the medical device).	i) Justification for addition of medical device(s) to be grouped within the registered medical device group; ii) Updated list of configurations of medical device indicating the name of medical devices affected; iii) Regulatory approval documents from the recognised countries (if applicable); iv) Medical device information; v) Medical device labelling stating changes for each amended section; vi) Declaration of conformity; vii) Pre-clinical studies (where applicable); viii) Software validation report (for software, if applicable); ix) Manufacturing information (if applicable); x) Annexes
(b) If the change only involves an addition of active, with measuring function or sterile Class A medical device accessories that complement the registered medical device as a system.	i) Declaration by registration holder to state - a. the added models are active, with measuring function or sterile class A medical device accessories; b. no change in manufacturer name and address for the manufacturing site(s) ii) Updated list of configurations of medical device indicating the name of medical devices affected; iii) Declaration of conformity; iv) Validation report and certificate (where applicable); v) Medical device labelling that indicate the addition of the medical device(s); vi) Annexes

(c) All changes to medical device registration that involve an increase or reduction in the medical devices in a set category of grouping of a registered medical device.	i) Declaration of conformity; 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; v) Description of the addition or reduction; vi) Annexes
(d) All changes to the medical device that: i) involve changes of medical device name and/or medical device identifier that does not involve any change to the intended use and technical specifications; OR ii) involve changes of medical device proprietary name due to company acquisition /merging.	i) Declaration of conformity; 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; v) 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.	