ETHIOPIAN FOOD AND DRUG AUTHORITY

GUIDELINE FOR MEDICAL DEVICE POST-APPROVAL CHANGE NOTIFICATION

DOCUMENT No.:	**EFDA/GDL/098**	**VERSION No:**	**002**
DATE OFAPPROVAL:	**21.06.2026**	**DATE OF FIRST ISSUE:**	**2022**

Document History

Version No.	Reason for Amendment	Effective Date
001	It Is new guideline	2021
002	To align the requirements with the WHO GBT medical device assessment tool and to be align with EFDA Document control procedure	30.06.2026

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June, 2026
Addis Ababa, Ethiopia

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Abbreviations

EFDA	Ethiopian Food and Drug Authority
IFU	Instruction for use
IMDRF	International Medical Device Regulatory forum
PEBA	Polyethylene
PEEK	Polyethylene ethyl ketone
QMS	Quality Management System

1. Introduction

The Ethiopian Food and Drug Authority (EFDA) is the national regulatory body that is responsible to regulate medical products including medical devices. The authority has been striving to best regulate the medical device circulation in Ethiopia so as to increase access to safe, good quality and effective medical devices to the public. According to article 21 sub article (1) of the Food and Medicine Administration Proclamation No. 1112/2019, if any variation affecting the safety, quality and effectiveness of registered medical devices is introduced, the product may not be marketed unless the person who registers the product notifies such variation and get approved from the executive organ.

Medical devices undergo changes from time to time as part of their life-cycle. Any change to a registered medical device is linked to the principles of safety, quality and performance and the ability of the regulatory framework to manage the risk of the medical devices. Changes to a medical device must be approved prior to the modified device being supplied in Ethiopia, unless otherwise indicated. Before making any decision whether a changed medical device can continue to be placed in the market, the Authority should determine whether evidence of safety, quality and performance have been appropriately collected and reviewed based on the application submission made by the market authorization holder.

For any anticipated change to a medical device, a manufacturer must consider the impact of the change on the patient, practitioner and/or user of the medical device, and the impact of the change on the specifications of the medical device, and decide whether the change is expected to impact the safety, quality and performance of the medical device.

This guideline provides guidance on the categories of changes, the principles of change categorization; whether a Change Notification has to be submitted and what should be done by the market authorization holder in relation to each category of change to its registered medical device.

2. Scope and application

This guideline applies to all registered medical devices. It sets out points for consideration by the market authorization holder when a registered medical device is in the process of change or modification. The guideline also applies to all variations whether from the applicant's initiative or requested by the Authority. However, it does not apply to medical devices whose application is still under consideration by EFDA.

The guideline specifies the categories of changes in relation to registered medical devices and the requirements to be met to continue the placement of the medical devices in the Ethiopian market.

3. Terms and definitions

With due regard to the definition provided under the Food and Drug Administration Proclamation No. 1112/2019, for the purposes of this guideline the following terms and definitions apply.

Accessory means an article with an intended purpose as a medical device and that is intended specifically by its manufacturer to be used together with a medical device to enable that medical device to be used in accordance with its intended purpose as a medical device or augment or extend the capabilities of that medical device in fulfillment of its intended purpose.

Authority means Ethiopian Food and Drug Authority

Change means a post approval variation to any aspect of a medical device, including but not limited to a change to method and site of manufacture, specifications for the finished product, components or raw material, container and container labeling, and product information.

Cautions and precautions mean information which alerts the user to exercise special care necessary for the safe and effective use of the medical device. It may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the device of use or misuse and the care necessary to avoid such effects.

Contraindication means a general description of the disease or condition and the patient population for which the device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any reasonably foreseeable benefits.

Control mechanism means of verifying or checking that the specifications or outputs of the

device meet a standard or predetermined result. They are mechanisms put in place to maintain on-going control or regulate the output of a device.

Facility means a site that is substantially involved in the manufacture and/or design and manufacture of a medical device.

Indications for use means general description of the disease(s) or condition(s) the medical device will diagnose, treat, prevent or mitigate, including where applicable a description of the patient population for which the medical device is intended. The indications include all the labeled uses of the medical device, for example the condition(s) or disease(s) to be prevented, mitigated, treated or diagnosed, part of the body or type of tissue applied to or interacted with, frequency of use, physiological purpose and patient population.

Indirect contact means in relation to the nature of body contact of medical device, includes devices that contact the blood path at one point and serve as a conduit for entry into the vascular system. E.g. blood transfusion tubes, blood bags, etc.

Labeling means written, printed or graphic matter presented by a manufacturer meant to provide information concerning a medical device to the users and others, which may be attached to the medical device itself, on its packaging or as a packaging insert or may be made available by other means, for example by electronic means, when appropriate for the purpose as an additional, or alternative way of transmitting certain information regarding the medical device.

Operating principles means **t**he means by which a medical device produces or brings about an intended or appropriate effect.

Recall means any action taken by the establishment of the device to remove the device and to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device: -

a) May be hazardous to health;
b) May fail to conform to any claim made by the manufacturer/Authorized Representative relating to its effectiveness, benefits, performance characteristics or safety; or
c) May not meet the requirement of the law.

Market Authorization Holder means the manufacturer or the authorized representative who applied for and obtained the registration of the medical device under the Proclamation No. 1112/2019.

Proclamation means Ethiopian Food and Medicine Administration Proclamation No. 1112/2019

4. General principles

The general principle for categorizing any change to a registered medical device is linked to the principles of safety, quality and performance; and the ability of the regulatory framework to manage the risk of the medical devices. Before making any decision whether a changed medical device can continue to be placed in the market, the Authority will determine whether evidence of safety, quality and performance have been appropriately collected and reviewed based on the notification made by the market authorization holder.

For any anticipated change to a medical device, a manufacturer must consider the impact of the change on the patient, practitioner and/or user of the medical device, and the impact of the change on the specifications of the medical device, and decide whether the change is expected to impact the safety, quality and performance of the medical device. When simultaneous changes are being implemented on a registered device, this guideline should be used to assess each change separately.

5. Categories of changes

Changes to a registered medical device are categorized into the following three (3) categories:

a) **Category 1 changes** of medical devices are considered as ***critical changes*** that affect their safety, quality and performance and require new registration of the medical device;

b) **Category 2 changes** are considered as ***major changes*** that require evaluation and endorsement from EFDA prior to implementation of the change and before placing in Ethiopian market; and

c) **Category 3 changes** are considered as ***minor changes*** that may be implemented immediately.

All applicants are required to submit their application as per the categories of changes indicated in the below table. In cases where the category of change is inappropriate during application submission, the Authority shall advice the market authorization holder to amend the category of change as deemed appropriate.

The following types of changes are some of the category 1 changes which require the market authorization holders to **apply for new pre-market product registration** according to medical device registration guideline and other medical device related national laws.

a) Change to the intended purpose and/or indication of use of a registered medical device,

unless it involves a reduction of indications for use not arising due to medical device safety or performance concerns;

b) Change to the risk classification of a registered medical device;

c) Change to software that affects safety, quality and performance of the registered medical device;

d) Addition of variant(s) not considered a permissible variant according to the rules of Authority's and IMDRF Product Grouping;

e) Change to the type, concentration or drug specifications (DS) of medicinal substance in a medical device that incorporates a medicinal product as an ancillary role shall be refer to medicine registration guideline; and

f) Addition of medical devices with device proprietary names different from the registered devices, into a device listing. Unless the devices with different proprietary names qualify to be listed together less than one listing based on Medical device grouping criteria for medical devices registration.

g) Addition of model(s) that do not fulfill the grouping criteria, including permissible variants, as listed in the Grouping of Medical Devices for Product Registration.

6. Change Type Assessment and Required Documents

A, 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**
6.1.1 Change in manufacturing facility, process and quality management system (QMS)	
a) All changes to manufacturing and/or sterilization facilities with no changes to the manufacturing and/or sterilization processes. *Example: Change of manufacturing site.*	i) Revised QMS certificate(s) ii) Medical Device labeling stating changes for each amended section; iii) Declaration that there is no change to manufacturing and sterilization process; iv) Sterilization validation report.

b) All changes to manufacturing processes (including changes made to outsourced processes) that result in a change in specifications of a registered medical device. *Example: Change in the equipment used for cutting the result in the change in length of sutures. Molding or cutting manufacturing process.*	i) Revised QMS certificate(s); 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.
c) All changes to sterilization processes (including changes made to outsourced processes). *Example: Change in moist heat sterilization parameters, or change in sterilization method from ethylene oxide to gamma radiation, or change from batch release to parametric release* .	i) Sterilization technique (certificate); ii) Medical Device labeling stating changes for each amended section (if applicable); iii) Sterilization validation report (including the sterilization protocol, sterilization standards applied, sterility assurance level, sterilization revalidation report); iv) QMS certificate(s).

6.1.2 Changes in design or specifications of a registered medical device

Types of change	Documents to be submitted**
a) All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device. *Example: Change from a quantitative assay to a qualitative assay. 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 labeling 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).

b) Changes that only involves a design change that does not affect the safety or performance of the medical device (e.g. changes that improve the medical device ergonomics, aesthetic modification of the medical	i) Revised QMS certificate(s) (if applicable); ii) Risk analysis; iii) Usability testing report (if applicable).
c) All change in specifications (including shelf life and stability) of a registered medical device.	i) Revised QMS certificate(s) (if applicable); ii) Pre-clinical studies (if applicable); iii) Clinical safety report (if applicable); iv) Risk analysis; v) Stability study (if applicable); vi) Medical Device labeling stating changes for each amended section (if applicable); vii) Software validation report (for software, if applicable); viii) Detailed summary of software changes (for software, if applicable).
d) Change to software that affects safety, quality 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 diagnostic medical devices*	i) Revised QMS certificate(s) (if applicable); ii) Risk analysis; iii) Software validation report; iv) Detailed summary of software changes.
6.1.3 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: changes in source of hyaluronic acid from streptococcus zooepidemicus to*	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;

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.
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.
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.
6.1.4 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.

6.1.5 Changes to labeling of medical devices	
a) All changes to the labeling of medical devices that involve addition, removal and/or revision of warnings, precautions and/or contraindications. *Example: Minor changes to clarify the existing wording of the warnings and precautions for a device may not trigger the need for approval. However, in the case where these changes add or remove a contraindication, or remove a warning or precaution, an endorsement by the authority is required.*	i) Revised QMS certificate(s) (if applicable); ii) Description of the warnings, precautions and/or contraindications; iii) Reasons for the revision of approved indications; iv) Medical Device labeling for new medical device(s) stating changes for each amended section.
b) Labeling changes that modify the approved method of use; OR involve a change from 'Professional use only' to 'home use'.	i) Revised QMS certificate(s) (if applicable); ii) Preclinical Studies (if applicable); iii) Clinical safety report (if applicable); iv) Software validation report (for software); v) Risk analysis; vi) Medical Device labeling stating changes for each amended section.
6.1.6 Changes to registered medical devices registration information	

a) If within the medical device grouping, the change only— i) involves the addition of new medical devices of the same design, within the existing range of sizes already registered; OR ii) Involves addition of a new medical device with design change that does not affect the safety 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) List of configurations of medical devices; iii) Regulatory approval documents from the recognized countries (if applicable); iv) Medical Device information; v) Medical Device labeling 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).
b) If the change only involves an addition of active, with measuring function or sterile Class I/A medical device accessories that complements the registered medical device as a system.	i) Declaration by market authorization holder to state - the added models are class I/A sterile; - the name of the medical device affected; - the medical device identifier; - no change in manufacturer for the class I/A sterile medical device; - name and address for the manufacturing site(s) for class I/A sterile medical device; ii) List of configurations of medical device; iii) Declaration of conformity; iv) Validation report and certificate.

c) All changes to medical device registration that involves an increase or reduction in the number of medical devices in a set 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) List of configurations of medical devices; iv) Device labeling stating changes for each amended section; v) Description of the addition or reduction.
d) All changes to the medical device name and/or medical device identifier.	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) List of configurations of medical device; iv) Device labeling stating changes for each amended section.

B, 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**
6.2.1 Change in manufacturing facility, process and quality management system (QMS)	

a) All changes to certificates for manufacturing and sterilization facilities that - i) involves an update of certificate QMS validity date only 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	i) Valid QMS certificate and report.
6.2.2 Changes in design or specifications of a registered medical device	
Types of change	**Documents to be submitted****

b) Change in software version that does not affect safety 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.	i) Software validation report. ii) Detailed summary of software changes.
6.2.3 Changes to labeling of medical devices	
a) Where the change only involves a reduction of indications for use not arising due to medical device safety or performance concerns.	i) Description of the new indications for use; ii) Reasons for the reduction of approved indications; iii) Medical Device labeling for new medical device(s) stating changes for each amended section.
b) Labeling changes that only involve the addition of Recognized Countries' approvals (e.g. CE marking).	i) Medical Device labeling stating changes for each amended section; ii) Valid certificates from relevant bodies (where applicable).
c) Other labeling changes involving information in the labeling that does not fall under above (a) and (b).	i) Medical Device labeling stating changes for each amended section; ii) Details of changes and the reason for changes;
Types of change	**Documents to be submitted****

Rephrasing information/Change in arrangement in instruction for use (IFU)/Change of color/font size/location of information/correction of spelling mistake or any administrative change (e.g. from Rd. to road), for example, do not required Change Notification. Example: Minor changes to clarify the existing wording of the warnings, precautions, and/or how to use for a device in the IFU.	iii) Documents supporting proposed changes detailed above (if applicable).
6.2.4 Changes to registered medical devices registration information	
a) If the change only involves an addition of Class I/A medical device accessories that complement the registered medical device as a system or family.	i) Declaration by marketing authorization holder to state - - the added models are class I/A non-sterile; - the name of the medical device affected; - the medical device identifier; - no change in manufacturer for the class I/A non-sterile medical device; - name and address for the manufacturing site(s) for class I/A non-sterile medical device; ii) List of configurations of medical device; iii) Declaration of conformity.
b) 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 device in the grouping due to obsolescence and not due to safety or performance considerations.*	i) Justification for deletion of medical device(s) to be grouped within the registered medical device; ii) Declaration from manufacturer to state that there is no change to medical device in all aspects, including intended use, technical specifications; iii) List of configurations of medical devices; iv) Device labeling stating changes for each amended section.

Types of change	Documents to be submitted**
c)	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 labeling stating changes for each amended section.

7. Application Process for Change Notification

For all the change categories, the application is made through the Authority's electronic based regulated products registration platform (eRIS) by filling all necessary information and attaching the relevant genuine documents as per the requirements set in this guideline.

Upon identifying all applicable categories of changes based on the requirements in the tables, the changes may be grouped (if applicable), and submitted as a single Change Notification application for the medical device listing(s).

Note:

1. For changes within one dossier and involving listings of a single risk class:

Multiple changes (Notification, Administrative, Review and Technical changes) will be considered in one Change Notification application if they are submitted together. Fees and assessment will follow the highest change category in that application.

2. For changes in two or more dossiers involving listings of a single risk class:
    a. Applicants can submit one Change Notification application on eRIS for:
        - Identical administrative and notification changes to multiple eRIS listings (recently valid Marketing Authorization certificates).

Non-identical changes in any one listing (MA certificate) may result in the entire Change Notification application being rejected.

    b. Applicants can submit one Change Notification application for technical changes to the same medical device that is part of multiple device listings (as part of a FAMILY, SYSTEM, GROUP, TEST KIT). Product identifiers listed in each of the eRIS device listings selected must be the same.

3. Identical changes involving eRIS listings of different risk classes may be submitted in one Change Notification application only for the following categories of change.

- Change in product owner.
- Change in manufacture and/or sterilization site.
- Change only involves an update of QMS certificate validity date.
- Addition of identical Class A or Class I accessories.

Please note that it is not possible to submit a new Change Notification application if there is any kind of pending application (eg. Change Notification or Renewal Application) for the same product or marketing authorization certificate. The registrant has the option of either:

- Withdrawing the pending application and submitting a new Change Notification application, or
- Submitting a new Change Notification application once the pending application is completed.

8. Change which do not require submission of Change Notification

The following specified change(s) would not require the submission of Change Notification to the authority:

- Labeling changes that only involve changes in layout, colour, font sizes and design, without change in prominence of precautions, warnings and contraindications.
- Labeling changes that involve the addition and/or removal of languages not required by the Authority.
- Labeling changes that involve the addition/removal of reference agency approvals (e.g. CE Marking).
- Labeling changes that involves the update of distributor information which does not affect the device listing information.
- Labeling changes that involves the addition/change or removal of barcodes, and which does not change the device listing information.
- Labeling changes that involve the addition of a Unique Device Identifier (UDI), and which does not change the device listing information.
- Labeling changes that involve the change in date format of an existing labeling date field (e.g. from MMYY to DDMMYY).
- Change in regulatory status on rejection or withdrawal in any reference agencies

- Change involves only a design change that does not affect performance characteristics and/or specifications of the medical device (e.g. changes that improve ergonomics, aesthetic modifications)
- Raw material supplier changes (except medicinal substances and biological material suppliers) that do not change the registered medical device specifications.
- Change in scope of the quality management system (QMS) certification which does not affect the registered medical device.
- Change in certification body with no change in scope of QMS certificate.