Ethiopian Food and Drug Authority

General Guidelines for Marketing Authorization of Medical Devices

Fourth Edition

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ACRONYMS

BSE	Bovine Spongiform Encephalopathy
CE	Conformité Européen
DoC	Declaration of Conformity
EFDA	Ethiopian Food and Drug Authority
EMA	European Medicine Agency
EPSP	Essential Principles of Safety and Performance
eRIS	Electronic Regulatory Information System
GHTF	Global Harmonization Task Force
GMP	Good Manufacturing Practice
IMRF	International Medical Device Regulation Forum
ISO	International Organization for Standardization
IVD	In-Vitro Diagnostic
OEM	Original Equipment Manufacturer
QA	Quality Assurance
QMS	Quality management system
SRA	Stringent Regulatory Authority
STED	Summary of Technical Documentation
TSE	Transmissible Spongiform Encephalopathy
WHO	World health Organization
WHOPARs	World health Organization Public Assessment Reports

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- Solomon Shiferaw (Senior Pharmacist), Technical Advisor at EFDA.
- Keneni Benti (MSc in Biomedical Engineering), Medical Device Registration Dossier Assessor at EFDA.
- Bikila Bayisa (Senior Pharmacist), Technical Advisor at EFDA.
- Daniel Takele (BSc in Biomedical Engineering), Medical Device Registration Dossier Assessor at EFDA.

1 INTRODUCTION

The Ethiopian Food and Drug Authority (EFDA) is mandated to safeguard the health and safety of patients and users, by assessing the quality, safety and effectiveness of the medical devices prior to registration and marketing authorization. Article 20(1) of the Food and Medicines Proclamation No. 1112/2019 decrees that any medical devices manufactured, imported, exported, stored, distributed, transported, sold, hold, used, or transferred to any other person in the country shall be registered and granted marketing authorization. Hence, dealers of medical devices should ensure that internationally accepted standards and procedures are followed during the design, manufacture, and marketing of their products.

This Guideline is developed to replace the former *Guidelines for Registration of Medical devices, third edition, 2014* and therefore renamed as the *General Guidelines for Marketing Authorization of Medical devices, fourth edition, 2021*. It is prepared to provide general guidance and summary of requirements for submission of marketing authorization applications for different types of medical devices. It highlights general information and provides overall technical guidance as well as principles regarding concepts of medical device classification, general criteria for medical device grouping, issues related to borderline medical devices, and other common principles. The detail guidance regarding principles for medical devices classification, bundling, borderline products and registration requirements for IVD and non-IVD medical devices are addressed in other subsequent guidelines. This guideline also provides brief information regarding abbreviated review procedure for products approved by stringent regulatory authorities, IVD medical devices registration through WHO collaborative procedures, low risk products expedited assessment, and fast track designation of priority medical devices listed in the '*Fast-track Medical devices Marketing Authorization guideline'* developed as part of implementation of different strategies devised by the authority to speed up the marketing authorization process and improve the quality of dossier assessment. Hence, applicants are advised to refer to relevant specific marketing authorization application submission guidelines applicable to the product concerned; understand the appropriate route of application and apply through the right application pathway via the Authority's online registration platform (Electronic Regulatory Information System).

The guideline is developed based on the Authority's day-to-day experience as well as recommendations on the regulation of medical devices by different relevant international organizations, such as the European Commission, International Medical Device Regulation Forum (IMDRF) and Competent National Regulatory Authorities.

2 DEFINITION

For the purposes of this Guideline, the following have the meanings hereby assigned to them. They may have different meanings in other contexts.

Medical device:- Refers to any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Medical device grouping: Means a systematic bundling or grouping of medical devices based on different criteria for the purpose of making a single registration application for similar products.

Generic Name: Means the generic device group that is the most specific level at which products are aggregated based on common technology or intended use. This is a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

Trade Name: Means a proprietary or brand name given by a company for marketing its product.

Subsidiary manufacturer:- Means a manufacturer of medical devices whose voting stock is more than 50% controlled by another company, usually referred to as the parent company or holding company; it is a manufacturer that is partly or completely owned by another company that holds a controlling interest in the subsidiary company.

Virtual manufacturer: Means a manufacturer that fully sources its own named product from another company (sometimes known as the 'original equipment manufacturer'), which has designed and manufactured an identical EFDA approved product and take legal responsibilities by placing its own name and address on the product.

Applicant: - Means a person, manufacturer, or company who may submit an application for registration of a medical device to the Authority.

Authority: - Means "The Food and Drug Authority (FDA) of Ethiopia"

Authorized local agent (representative):- Any company or legal person established within a country or jurisdiction who has received a mandate from the manufacturer to act on its behalf for specified tasks with regard to the manufacturer's obligations under the legislation of medical devices and other regulatory guidance's issued by the Authority.

Marketing Authorization: - Means issuance of certificate for the marketability of a medical device after full or abbreviated assessment of the provided supporting documents and other evidences by the Authority. Registration or Market Authorization can be interchangeably used to describe the same concept.

Conformity assessment:- The systematic examination of evidence generated, and procedures undertaken by a manufacturer to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the essential principles of safety and performance of medical devices

Clinical evaluation: - The review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation

Clinical investigation: - Any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device

Instrument: - Equipment or apparatus intended by the manufacturer to be used as an IVD medical device

Intended use/purpose: - The objective intent of the manufacturer regarding the use of a device, process, or service as reflected in the specifications, instructions, and information provided by the manufacturer of the medical device.

Invasive device: - A device that, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

In Vitro Diagnostics Medical devices: - Means reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.

Non-In Vitro Diagnostic Medical devices: - Means all Medical devices other than In vitro diagnostic medical devices.

Labelling:- Any legend, word, or mark attached to, included in, belonging to, or accompanying any medical device, including:(1) the immediate container label; (2) the carton, wrapper, or similar item; and (3) information materials about the medical device such as an instructional brochure or package insert.

Manufacturer:- A company that carries out at least one step of the manufacture of a medical device, which includes the responsible person and/or company that designs and/or manufactures a medical device with the intention of making the medical device available for use, under his/her/its name, whether or not such medical device is designed and/or manufactured by that person or on behalf of that person by another person(s).

Manufacture (manufacturing):- All operations of generating a medical device, including purchase of materials and components, production, quality control, packing, labeling, release, storage, and shipment

Personalized medical devices: - Medical devices that are intended for a particular individual, which could be either a custom-made, patient-matched, or adaptable medical device.

Performance evaluation: - Review of the performance of a medical device based upon data already available, scientific literature, and, where appropriate, laboratory, animal, or clinical investigations.

Quality system: - A system that consists of the organizational structure, responsibilities, procedures, processes, and resources for implementing a quality management system

Quality management system: - A management system designed to direct and control an organization with regard to quality, from establishing a quality policy and quality objectives to implementing and maintaining a quality system.

Reagent: - Chemical, biological, or immunological components, solutions, or preparations intended by the manufacturer to be used as an IVD medical device.

Technical Documentation: - Recognized evidence of a quality management system that demonstrates compliance of a given device to the essential principles of safety and performance of medical devices

Verification:- Confirmation, by examination and provision of objective evidence, that specified requirements have been fulfilled

3 SCOPE OF THE GUIDELINE

This guideline is applicable for marketing authorization of all IVD and Non-IVD medical devices that are intended for sale and use in Ethiopia.

4 OBJECTIVES

The objective of this guideline is to provide high-level guidance on all matters related to marketing authorization application submission and their respective decision-making processes. It is intended to be used inline with other specific guidelines developed for a particular route of application or groups of products. It is not intended to provide detailed instruction on how to submit application, requirements, or how to conduct dossier scientific review.

This document is envisioned as having many building blocks in it and is sufficiently expandable to accommodate additional and ancillary documents.

5 GENERAL GUIDANCE AND PRINCIPLES

The content of this guideline should be read in conjunction with relevant information described in other latest versions of national laws, EFDA's regulation, directives, guidelines and other reference documents. The safety, quality and performance of the product to be registered should not be inferior to the available options.

Applicants should submit complete applications in line with the requirements of this guideline as well as other relevant guidelines to facilitate the assessment process. However, alternate approaches to the principles and practices described in this guideline may be acceptable provided that they are supported by adequate scientific justification. It is important to note that the Authority may request additional information or material, or define conditions not specifically described in this guidance, in order to adequately assess the safety, performance, and quality of a medical device prior to and after approval.

This section of the guideline highlights different general concepts and guiding principles applicable to all types of marketing authorization applications and suggests relevant reference supplementary documents. These relevant documents include guidance/guidelines for classification, bundling and requirements for MA of different categories of medical devices.

5.1. Principles of Medical Devices Classification

The approach of risk-based classification of medical devices and subsequently applying different conformity assessment techniques to each class is a globally accepted practice. The global adoption of a rules-based classification procedure would offer significant benefits to manufacturers, users, patients, and regulatory authorities and support global convergence of regulatory systems.

Article 19(1) of Food and Medicine Administration Proclamation (number 1112/2019) states that the rigor of regulatory assessment of medicines and medical devices shall be commensurate with the product type, nature and potential risk to human health. Furthermore, it is not economically feasible or justifiable in practice to subject all medical devices to the most rigorous conformity assessment procedures available. Therefore, the Authority has developed a graduated system of control which permits levels of controls that corresponds to the level of potential hazard inherent in the type of device concerned.

These levels of control depend on the appropriate medical device classification that is linked with device safety and performance. The purpose of the risk classification is to make sure that

the assessments for registration and regulatory requirements applied to a medical device is proportional to its risks. Both the Non In vitro diagnostic and In vitro diagnostic medical devices are classified into four classes based on the risks that the devices pose to individuals as well as public health. Accordingly, based on different criteria, Non In vitro diagnostic medical devices are classified into Class I, II, III, and IV; Class I being the devices with lowest risk and Class IV being the devices with highest risk. Similarly In vitro diagnostic medical devices are classified into Class A, B, C, and D; Class A being the devices with lowest risk and Class D being the devices with highest risk. These separate designation of Roman numbers for Non In vitro diagnostic medical devices classification and Latin Letters for In vitro diagnostic medical devices classification is to help the applicants and the Authority's staff to easily identify and distinguish between the two categories. Any other alternative classification rules selected by the device manufacturer may be acceptable, with appropriate justification. However, if a medical device classified as lower risk class by the applicant is found to be in higher risk as per the authority`s classification, the later shall be applied.

The determination of classification for both Non-IVD and IVD medical devices should be based on a set of rules derived from those features that create risk. Hence, the intention of medical devices classification is to stipulate a series of principles and rules that allow a medical device to be assigned to one of four classes based on its intended use, and thereby:

- Assist a manufacturer to allocate its medical device to an appropriate class using a set of classification rules; and
- Allow EFDA to pronounce upon matters of interpretation for a particular medical device, when required to do so.

5.1.1. Classification of medical devices other than IVD

The classification of medical devices other than IVD is based on the hazard presented by the particular medical device substantially on its intended use and the technology it utilizes.

a) Consequently, the classification rules for medical devices other than IVD takes the following factors into account. ,whether the device is life supporting or sustaining;
b) Whether it is invasive and if so, to what extent and for how long;
c) Whether it incorporates medicinal products, or human/animal tissues/cells;
d) If it is an active medical device;
e) If it delivers medicinal products, energy or radiation;
f) Whether it could modify blood or other body fluids; and

g) Whether it is used in combination with another medical device

Accordingly Medical devices other than IVD are classified as indicated in table 1 below in a manner that sufficiently accommodates all medical devices and allows an efficient and defined conformity assessment system.

Table 1:- The general approaches for medical device classification other than IVD medical devices

Class	**Risk Level**	**Device examples**
I	Low Risk	Surgical retractors / tongue depressors
II	Low–Moderate Risk	Hypodermic needles / suction equipment
III	Moderate–High Risk	Lung ventilator / bone fixation plate
IV	High Risk	Heart valves / implantable defibrillator

For further details regarding the factors taken in to account for classification rules, and classes of medical devices other than IVD please refer to *the guideline for classification of medical devices other than IVD Medical devices*.

5.1.2. Classification of IVD Medical Devices

The classification of an IVD Medical Device is based on the following criteria:

a) Intended use and indications for use as specified by the manufacturer (including but not limited to specific disorder, populations, condition, or risk factor for which the test is intended);
b) Technical/scientific/medical expertise of the intended user (lay person or healthcare professional);
c) Importance of the information to the diagnosis (sole determinant or one of several factors), taking into consideration the natural history of the disease or disorder, including presenting signs and symptoms which may guide a physician; and,
d) Impact of the result (true or false) to the individual and/or to public health.

Based on these criteria, IVD medical devices are classified in to four as indicated in table 2.

Table 2:- The general approaches for IVD medical device classification

Class	Risk Level	Examples
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyzer, prepared selective culture media
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12, Pregnancy self-testing, Anti-Nuclear Antibody, Urine test strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self-testing, HLA typing, PSA screening, Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

For further details regarding the factors taken in to account for classification rules, and classes of IVD medical devices please refer to the guideline for classification of IVD Medical devices.

5.2. Medical Devices Grouping for Marketing authorization application

The principles of medical devices grouping is concerned with determining whether certain medical devices can be included together and submitted in one product marketing authorization application. Grouping of medical devices for product registration facilitates the inclusion of multiple devices in one application. Under article 20(1) of the Food and Medicine Administration Proclamation No. 1112/2019, all medical devices to be supplied and marketed in the country are required to be registered with EFDA prior to supply unless it is exempted from the registration requirement by the Authority's directives.

Medical devices range from simple devices (e.g. syringe) to highly complex devices (e.g. implantable pacemakers) including devices that comprise of myriad components (e.g. patient monitoring systems). These various components or modules can be sold individually, in different combinations as required by the end user, as a convenient all-in-one kit, or as an individually customized pack. Individual medical devices are also typically available in various

configurations including length, diameter, etc. There are also certain device specific attributes, such as those specific to in vitro diagnostic devices and hearing aids, which should be considered when categorizing devices for the purpose of grouping.

To provide a better application submission principles for the diverse categories of medical devices that can be bundled and submitted together, grouping criteria that applies to all medical devices and also device specific grouping principles have been developed and are presented in two separate guidelines as *Guidelines for General Grouping of Medical devices* and *Guidelines for Device Specific Grouping*.. The guideline provides guidance on how a collection of medical devices can be grouped and submitted in one registration application as one or more of the following:

- Single
- Family
- Set
- System
- IVD Cluster
- IVD Test kit

  Hence, applicants should determine the appropriate grouping of medical devices and submit product marketing authorization applications

5.3. Issues related to Borderline Medical devices

Borderline cases are considered to be those cases where it is not clear from the outset whether a given product is a medical device, an in vitro diagnostic medical device, or not. Borderline cases are those cases where the product falls within the definition of a medical device but is excluded from the Authority's relevant documents by their scope. Where a given product does not fall within the definition of medical device or is excluded by the scope of the Authority's relevant documents, and/or national legislation, the later shall be applicable.

The principal intended action of a medical device may be deduced from the scientific data regarding its mechanism of action and the manufacturer's labeling and claims. As mentioned in the detention section, a medical device does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means. In general, the functions of medical devices are achieved by physical means (including mechanical action, physical barrier, or replacement of or support

to organs or body functions). The function of some devices may be assisted by the presence of medicinal substances, where such substances have an ancillary action to that of the device.

The applicants are advised to read the specific guideline developed by the Authority to provide detail guidance on borderline medical devices for the purpose of identifying whether their products can be registered as medical device or not.

6 ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES & IVDS

Regulatory controls are intended to safeguard the health and safety of patients, users and others by ensuring that manufacturers of medical devices follow specified procedures during design, manufacture and marketing.

The manufacturer of a medical device is expected to design and manufacture a product that is safe and effective throughout its life-cycle. Essential Principles of Safety and Performance for medical devices describe fundamental design and manufacturing requirements that, when met, provide assurance that a medical device is safe and performs as intended, by the manufacturer. Essential principles of safety and performance provide broad, high-level, criteria for design, production, and postproduction throughout the life-cycle of all medical devices, ensuring their safety and performance. Premarket dossier evaluation is one of the approaches employed by the authority for applying controls relative to a device's safety and performance to ensure compliance with the Essential Principles of Safety and Performance and to ensure that the product maintains applicable standards throughout its lifecycle.

It is the responsibility of the manufacturer to demonstrate that its product is safe and perform as its intended use based on essential safety and performance criteria for medical device. The purpose of essential principles of safety and performance of medical device is to describe generic safety and performance criteria of medical device collectively referred to as 'essential principles' that may be used to assess the safety and performance of a particular medical device. A manufacturer should be able to demonstrate that its medical device is safe by reviewing these essential principles, selecting those that are relevant to the manufacturer's particular device, and by ensuring through its design and manufacturing controls that the device meets the requirements.

Medical devices and IVD medical devices shall achieve the performance intended by their manufacturer and should be designed and manufactured in such a way that, during intended conditions of use, they are suitable for their intended purpose. They should be safe and perform

as intended, should have risks that are acceptable when weighed against the benefits to the patient, and should not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons.

The checklists for the Essential requirements for the safety and performance of medical devices and IVD medical devices that should be filled and provided with the registration dossier of the respective application type are included as annex in the respective Guidelines of Registration Requirements for both categories of the devices (Non-IVD and IVD). These checklists are constructed based on the following broad concepts: -

a) General requirements of EPSP.
b) Clinical Evaluation
c) Chemical, Physical, and Biological Properties
d) Sterilization and Microbial Contamination
e) Considerations of Environment and Conditions of Use
f) Protection against Electrical, Mechanical, and Thermal Risks
g) Active Medical Devices and IVD Medical Devices and Medical Devices Connected to Them
h) Medical Devices and IVD Medical Devices that Incorporate Software or are Software as a Medical Device
i) Medical Devices and IVD Medical Devices with a Diagnostic or Measuring Function
j) Labeling
k) Protection against Radiation
l) Protection against the Risks posed by Medical Devices and IVD Medical Devices intended by the Manufacturer for use by Lay Users
m) Medical Devices and IVD Medical Devices Incorporating Materials of Biological Origin

7 MEDICAL DEVICE CONFORMITY ASSESSMENT

The Authority is responsible to ensure a high level of protection of public health and safety. Public trust and confidence in medical devices, and in the administrative systems by which they are regulated, are based on the safety and performance of such products throughout their life cycle.

Conformity assessments, conducted before and after a medical device is placed on the market, and post-market surveillance of devices in actual use are complementary elements of the medical device global regulatory system. Medical device conformity assessments are intended to provide the objective evidence of safety, performance, and benefits and risks to maintain public confidence in the product.

Conformity assessment is primarily the responsibility of the medical device manufacturer. However, it is done in the context of the established regulatory requirements and both the process and conclusions are subject to further review by the Authority. In general, the degree of involvement of the Authority in such reviews is proportional to the risks associated with a particular category of devices. The conformity assessment elements reflect the need to make conformity assessment more rigorous as the risk class of a medical device increases.

The necessary conformity assessment elements are:

a) a quality management system (QMS)
b) a system for post-market surveillance
c) technical documentation
d) a declaration of conformity
e) the registration of manufacturers and their medical devices by the authority

7.1. Quality management system (QMS)

The manufacturer should implement, document and maintain a QMS that ensures the medical devices it designs, manufactures and supplies to the market are safe, perform as intended and comply with the relevant provisions of the EFDA's regulatory requirements. The scope and complexity of the QMS should be in agreement with the range of the different medical devices that are under QMS control, the processes employed, the size and structure of the organization, and the specific applicable national / regional regulatory requirements in the country of origin.

Processes required by the QMS but carried out on the manufacturer's behalf by third parties should remain the responsibility of the manufacturer and should be subject to control under the

manufacturer's QMS. As part of EFDA's conformity assessment process, the Authority assesses the adequacy of this control.

The depth of EFDA's Conformity assessment of the manufacturer's QMS depends on the class of the medical device. Manufacturers of Class I devices and Class A IVD devices shall implement and maintain the basic elements of a QMS but have the option to exclude design and development controls. The QMS for manufacturers of Class I & II devices and Class A & B IVD devices are normally not subjected to premarket on-site audit by EFDA. The exception is where assurance of sterility or of a measuring function is required, in which situation the associated procedures may be subject to the Authority's premarket audit. The Authority can conduct an on-site audit of the manufacturing facilities of these Class I & II devices and Class A & B IVD devices if deemed necessary.

Manufacturers of Class III & IV devices and Class C & D IVD devices should implement and maintain an effective QMS that includes design and development controls, and should comply with the Authority's current Good Manufacturing Practices of Medical devices.

For Class III & IV devices and Class C & D IVD devices, EFDA shall have confidence that the manufacturer has an appropriate and effective QMS in place, suitable for the range of different medical devices that are under QMS control. To ensure this, the Authority will review any relevant existing certification and/or regulatory audit reports, and will undertake periodic on-site audits of the manufacturer's facility to ensure that the manufacturer's manufacturing practices comply with the Authority's current Good Manufacturing Practices (cGMP). If the audit findings confirms that the manufacturer`s QMS meets the requirements of the Authority's Medical devices cGMP, the Authority may issue a certificate with the list of medical devices covered by the QMS and indicating its validity period. For more details, the manufacturers can refer the authority`s *Guideline for Medical Devices Good Manufacturing Practices.*

7.2. System for Post-market Surveillance

Prior to placing the product on the market, the manufacturer should establish, as part of its QMS, a process to assess the continued conformity of the device to the Essential Principles of Safety and Performance through the post-marketing phase. This process should include complaint handling, post-market vigilance reporting, and any subsequent corrective & preventive actions. For each device, manufacturers should plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. The post-market

surveillance system should be suited for actively and systematically gathering, recording and analyzing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and for drawing the necessary conclusions and for determining, implementing and monitoring any preventive and corrective actions. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer should implement the appropriate measures and inform EFDA. It is also mandatory to immediately report to the Authority when a serious incident is identified or a field safety corrective action is implemented.

The post-market surveillance system should be based on a post-market surveillance plan, and this post- market surveillance plan should be part of the technical documentation to be submitted to the Authority during registration application.

Manufacturers should prepare a post-market surveillance report summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. The report should be updated when necessary and made available to EFDA upon request. Manufacturers of class III & IV devices and class C & D IVD devices should submit the Post-market surveillance report as well as Device Vigilance report to the Authority every time the device's market authorization is renewed. Manufacturers of other classes of Non-IVD or IVD medical devices should also periodically perform post-market surveillance and submit the reports to the Authority when requested. Manufacturers of all classes of Non-IVD and IVD medical devices shall immediately report to EFDA any adverse effects which led to or may lead to serious health threat.

7.3. Technical Documentation

Manufacturers of all classes of device are expected to demonstrate conformity of the device to the Essential Principles of Safety and Performance of Medical Devices through the preparation and holding of technical documentation that shows how each medical device was developed, designed and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity. This technical documentation should be updated as necessary to reflect the status, specification and configuration of the device.

As part of its task to demonstrate conformity of a device to EFDA's medical device regulatory requirements, the manufacturer should submit technical documentation to provide evidence that the medical device is in conformity with the essential principles of safety and performance, labelling, risk analysis and other national regulatory requirements(eg. For radiation emitting devices). The technical documentation should reflect the status of the medical device at a particular moment in time (e.g. at the moment of premarket submission or when requested by the Authority for post-marketing purposes) and it should be prepared in a manner that meets regulatory requirements. In general, the extent of evidence included in the technical documentation is expected to increase with the class of the medical device, its complexity, and the extent to which it incorporates new technology.

The Technical documentation submitted to the Authority, should incorporate an attestation that the contents is truthful and accurate, and should indicate the name, position and signature of the responsible person who has been authorized to submit it on the manufacturer's behalf.

The Authority determines the adequacy of the documented evidence in support of the manufacturer's attestation of conformity in contrast with the essential principles of safety and performance, and its other regulatory requirements, through a review of the documents.

EFDA's requirement for technical documentation follows the IMDRF's Submission Table of Contents for Marketing Authorization of Medical devices and IVD Medical devices. The Authority has developed two registration requirements guidelines for these groups of devices (IVD and Non-IVD) and is implementing these requirements.

7.4. Declaration of Conformity

The manufacturer shall attest that its medical device complies fully with all regulatory requirements and draws up a written "Declaration of Conformity". The declaration of conformity shall state that the requirements specified in this guideline and all relevant documents have been fulfilled in relation to the device that is covered. The manufacturer shall continuously update the declaration of conformity.

Where, concerning aspects are not covered by this guideline, devices are subject to other EFDA's relevant documents that requires a declaration of conformity by the manufacturer for the demonstration of fulfilment of the requirements.

7.5. Registration of Manufacturers and/or License holders, Local representatives and their medical devices

As required in article 23 sub-article (1) of Food and Medicine Administration Proclamation No. 1112/2019, no medical device institution may engage in medical device trade unless it is registered and licensed as appropriate by the executive organ or regional health regulator. The same proclamation urges the devices marketed in the country to be registered before they are marketed in the country.

Registration of manufacturers and their medical devices by the Authority is the most critical and basic level of regulatory control of devices in the market. However, EFDA does not have the mandate or intention to register and license overseas medical devices manufacturers. The collection and retention of information on manufacturers, authorized representatives, importers and distributors, wholesalers and the medical devices supplied to the market by those parties are fundamental elements of EFDA's regulatory control.

Prior to placing a medical device on the market, the manufacturer, distributor, importer, wholesaler and authorized representative should provide EFDA with adequate information with respect to facility licensing and medical device registration requirements.

Detail guidance document for EFDA's regulatory requirements of licensing or registering medical device manufacturers, distributors, importers, authorized representatives, and wholesalers can be found from the Authority's official website for approved documents publication (www.fmhaca.gov.et).

The following three tables (*Table 3 to Table 5*) summarize the EFDA's overall conformity assessment elements of Medical devices and IVD Medical devices in which the conformity to each element is dependent on the device's class.

Table 3: Class I devices and Class A IVD Medical Devices

	Conformity Assessment Elements	**Manufacturer Responsibilities**	**Conformity assessment requirement**
Conformity assessment of the Quality	Quality Management System	Establish and maintain a full QMS or a QMS without design and development controls	ISO 13485 Conformance certificate is reviewed. Premarket Regulatory audit normally not required unless deemed necessary by the Authority to investigate specific safety or regulatory concerns.

Management System	Post-market Surveillance	a) Establish and maintain PMS system b) Record and evaluate reports of adverse events. c) document, maintain and implement: i. complaint handling; ii. distribution records; iii. mandatory problem/adverse event reporting; iv. field corrective action; and v. recall.	Device PMS and Vigilance Plan and the plans' implementation report may be requested and reviewed by the Authority. Premarket regulatory audit normally not required. Regulatory audits may be conducted on establishment as deemed necessary by the Authority to investigate specific safety or regulatory concerns.
Conformity assessment of device safety & performance	Technical Documentation	Prepare technical documentations in the format of EFDA's Registration requirements and have available for review upon request. Technical documentation will not be required if the device is in the list of low risk devices to be registered by notification.	Premarket submission not required. May be requested by the Authority for the purpose of investigating specific safety or regulatory concerns.
	Declaration of Conformity	Prepare, sign, and maintain.	Manufacturer to submit to Authority during registration process and to keep in file and present upon request by the Authority.
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.

Table 4: Class II devices and Class B IVD Medical Devices

	Conformity Assessment Element	**Manufacturer Responsibility**	**Conformity assessment requirement**
Conformity assessment of the QMS	Quality Management System	Establish and maintain a full QMS	ISO 13485 Conformance certificate is reviewed. Premarket Regulatory audit normally not required unless deemed necessary by the Authority to investigate specific safety or regulatory concerns.
	Post-market Surveillance	a) Establish and maintain PMS system b) Record and evaluate reports of adverse events. c) document, maintain and implement: i. complaint handling; ii. distribution records; iii. mandatory problem/adverse event reporting;	Device PMS and Vigilance Plan and the plans' implementation report may be requested and reviewed by the Authority. Premarket regulatory audit normally not required. Regulatory audits may be conducted on establishment as deemed necessary by the Authority to investigate specific safety or regulatory concerns.

		iv. field corrective action; and v. recall.	
Conformity assessment of device safety & performance	Technical Documentation	Prepare technical documentations in the format of EFDA's Registration requirements and submit for premarket review.	The Authority reviews the Premarket submission of technical documentations.
	Declaration of Conformity	Prepare, sign, and maintain.	Manufacturer to submit to Authority during registration process and to keep in file and present upon request by the Authority.
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.

Table 5: Class III & IV Devices and Class C & D IVD Medical devices.

	Conformity Assessment Element	**Manufacturer Responsibility**	**Conformity assessment requirement**
Conformity assessment of the QMS	Quality Management System	Establish and maintain a full QMS	ISO 13485 Conformance certificate is reviewed. Premarket Regulatory audit is also required.
	Post-market Surveillance	a) Establish and maintain PMS system b) Record and evaluate reports of adverse events. c) document, maintain and implement: i. complaint handling; ii. distribution records; iii. mandatory problem/adverse event reporting; iv. field corrective action; and v. recall.	Ensure an appropriate post-market surveillance system is established, maintained and implemented by the manufacturer. Device PMS and Vigilance Plan and the plans' implementation report is reviewed by the Authority. Regulatory audits may be conducted as deemed necessary by the Authority to investigate specific safety or regulatory concerns.
Conformity assessment of device safety & performance	Technical Documentation	Prepare technical documentations in the format of EFDA's Registration requirements and submit for premarket review.	The Authority reviews the Premarket submission of technical documentations.
	Declaration of Conformity	Prepare, sign, and maintain.	Manufacturer to submit to Authority during registration process and to keep in file and present upon request by the Authority.
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.

***Note**: Although the conformity assessment requirement for Class III & IV Devices and Class C & D IVD Medical devices are the same, it needs to be understood that the technical documentation for a Class IV devices and Class D IVD devices are expected to be more elaborative as compared to the Class III devices and Class C IVD devices. The main difference for a Class IV devices and Class D IVD devices documentation would be in the level of details in the clinical/performance data and details of the manufacturer's QC release program.*

8 APPLICATIONS FOR MEDICAL DEVICES MANUFACTURED BY SUBSIDIARY MANUFACTURERS AND VIRTUAL MANUFACTURERS

8.1. Medical devices manufactured by Subsidiary Manufacturers

If the manufacturer of a medical device has one or more subsidiaries, the applicant is responsible for submitting the technical documents of each specific product under registration from each of the subsidiaries and/or from the site where the file is kept.

If the medical device use accessory and/or consumable (such as reagents, controls, etc.) which is manufactured by a company's subsidiary, the free sale certificate shall indicate the same and/or a separate free sale certificate shall be part of the document. The relevant technical documents shall be submitted to support the safety and performance of the accessory and/or consumable.

When a multinational medical device industry manufactures an identical products by two or more than two of its subsidiary manufacturers, the evidence of each manufacturing site's conformance to the relevant quality management system (such as ISO 13485 or EFDA's medical device GMP requirements) shall be submitted during registration. All the sites shall be stated in all the submitted administrative and supporting technical documents and they are subject to Good Manufacturing Practices Compliance Audit by the Authority.

If different activities of design, development, manufacturing or release are carried out wholly or partly by different subsidiary manufacturers of the same legal manufacturer, there shall be clear information in the submission of the application to inform EFDA the scopes of each manufacturer's activities in the realization of the subject product.

After the application is evaluated and the Marketing Authorization is issued, the legal manufacturer or any of the subsidiary manufacturers or the legal manufacturer's distribution

representative(s) identified during the application can place the registered device on Ethiopian market.

The relationship between the legal manufacturer, subsidiary manufacturer and their agreement linkage with the local agent is shown in the flowchart annexed to this guideline (Annex VIII).

8.2. Medical devices manufactured by Virtual Manufacturers

A virtual manufacturer is an organisation that fully sources its own named product from another company (known as the 'original equipment manufacturer'), which has designed and manufactured a medical device that is identical with EFDA approved product. By placing their own name and address on the product, the virtual manufacturer shall take on the legal responsibilities for the medical device and is therefore regarded as the manufacturer in accordance with this guidelines.

In practice, there is no difference in the regulatory requirements applying to an actual product's manufacturer and a virtual manufacturer.

The details of how such manufacturers should comply with EFDA's registration requirements are provided in *Annex I* of this guideline. It gives clear understanding regarding the following concepts and requirements:-

a) Responsibilities of a virtual manufacturer;

b) Technical documentation needed from a Virtual Manufacturer;

c) The Contractual agreement between the OEM and the Virtual manufacturer;

d) If a Virtual manufacturer wants to change from being the legal manufacturer to the distributor.

9 MARKETING AUTHORIZATION APPLICATION SUBMISSION PATHWAYS AND REQUIREMENTS

9.1. General Principles

The authority has devised various risk proportionate based application submission pathways with different rigor levels of assessments. The applicants should refer to the relevant guidelines so as to submit complete application via the right pathways and to understand the documentation to be submitted for each type of application path ways. It has established this

systematic strategy to expedite the Marketing Authorization process of medical devices in order to ensure ease of access for the patients and users without compromising the safety, quality and effectiveness.

9.1.1 Product Dossier Clarity and Completeness

Applicants shall submit all necessary sections of a product dossier, identified in this guideline and relevant supplementary guidelines to the application type and the device concerned. Not providing the required information may result in rejection of the dossier, significant delays in the assessment process, or cancellation of the registration request.

Manufacturers should make every effort to ensure that their product dossier is clear and well-organized. Poorly prepared dossiers are an obstacle to efficient market authorization assessment and may be rejected without full review.

Applicants should not duplicate files, even if it is possible to include the same evidence under multiple subheadings. The evidence should be provided under one appropriate subheading and then make specific references (including both section and page numbers) to that material in any subsequent sections that appear relevant. Such references should be specific: references to specific sections or pages of a document should be provided when possible.

9.1.2 Applicability of Supporting Evidence to the Product under review

The manufacturer shall carry out relevant investigations to support the intended use, such as analytical and/or clinical effectiveness as well as all applicable safety and performance parameters. Studies in support of the intended use should consider the intended user and the intended setting of use.

The manufacturer shall provide the appropriate technical specifications and the minimum safety and performance requirements that shall be met by a product to ensure that it is safe and performs optimally.

9.2. General common requirements for different types of applications

The summary of relevant requirements for applying a medical device with its applicable route of application is provided in the following subsections. The details of all requirements and the descriptions of each requirement is provided in separate guidelines which need to be read in conjunction with this guideline to understand the appropriate application pathway, submission processes as well as detail requirements for obtaining marketing authorization certificate for a

medical device. This subsection only highlights some requirements which are common to all types of applications and sites the corresponding formats (annexes).

9.2.1 Application Form

Applicants should fill out and submit all the information in the application form for Marketing Authorization of Medical Devices as per the attached *Annex II* of this guideline. The date of application should correspond to the date of submission of the registration dossier to the Authority.

9.2.2 Application letter

The license holder/marketing authorization holder should provide an original application letter (with the company's original stamp and an authorized person's signature from the company) describing that the applicant (local agent) mentioned on the letter is the one authorized to submit the application for registration of the medical device described on the letter. The content and format should be as per the template annexed to this guideline (*Annex III*).

A license holder or manufacturer should not authorize more than one registrants or local agents for the registration of the same product at the same time.

9.2.3 Agency agreement

Before registering a medical device to be used in Ethiopia, an overseas manufacturer should sign an agreement with a local agent who will act on behalf of it. The agreement should be as per the following conditions:-

a) An agency agreement should be made between the product license holder and/or manufacturer of the medical device for registration and the agent responsible for the registration and/or import, distribution, and sale of the product in Ethiopia. Where the manufacturer manufactures a product at two or more places, the agreement and responsibility of each party made between the manufacturers should be submitted. In such a case, the agency agreement between the local agent and the manufacturer should be the site where the file is kept and the applicant for registration.
b) The agreement should be signed by both parties and such is what is to be presented. The seal/stamp of both parties should also be affixed to the document for agency agreement.
c) Even though there is no limit for the number of local agents to register or import a license holder's medical devices, it is still mandatory to specify in the agreement the position of the agent/representative in that agreement (eg. first, second or third

agent…). The appointed agent(s) is/are responsible for correspondence and complete compliance with regulatory requirements pertaining to the product‘s distribution life cycle in the country.

d) The agreement should state that if any fraud or unsuspected and unacceptable adverse event occurs to the consumer under normal utilization, both parties will be responsible for collecting the product from the market and are responsible for substantiating any event.
e) The agreement should specify that the manufacturer or license holder and local representative shall collect and submit to the Authority device safety and performance evidence within one year of its marketing in Ethiopia for all class III and higher devices as well as class C and higher IVD devices.
f) The agreement should specify that both parties are responsible for device vigilance and post-marketing reporting of the device.
g) For the purpose of administration, the agreement should remain valid at least for the period of one year from the date of submission to the Authority, unless it is found to be satisfactory for the termination of the agreement.
h) The agent representing the manufacturer for importation should hold a license issued by the ministry of trade and certificate of competence issued by the Authority at the time of importation of the product.

The template of agency agreement and authorization letter are annexed to this guideline (*Annex IV*).

Note:

Where an entity other than the actual manufacturer of the product wants to register and market the product in the country, the following requirements should be fulfilled.

A valid, original, signed and dated agreement made among the three parties (the actual manufacturer, supplier and local agent or registrant).

A valid, original, signed and dated agreement between the actual manufacturer and the supplier as well as another agreement between the supplier and local agent or registrant.

The supplier should submit a valid and original license issued by a responsible local government body indicating that the entity is engaged in the relevant activities.

9.2.4 Service Fee for Registration of Medical device

Application for registration of medical device should be accompanied with the receipt of service fees as per the Rate of Service Fees issued by Council of Minister Regulation No. 370/2015 for each category of application as indicated in the following table.

Table 6: - Rate of Service Fees for Medical device Registration

S.No	Service(s)	Fee	When to pay
1	New Application Screening	350 birr	Before submitting the dossier or in parallel with the application submission
2	New Application Evaluation	1300 birr	Before submitting the dossier or in parallel with the application submission
3	Laboratory Test	200 US dollars	Before submitting the dossier or in parallel with the application submission
4	Renewal Application Evaluation	870 birr	Before submitting the dossier or in parallel with the application submission
5	Major Variation Application Evaluation	870 birr	Before submitting the dossier or in parallel with the application submission
6	Minor Variation Application Evaluation	650 birr	Before submitting the dossier or in parallel with the application submission
7	Agency Agreement	50 US dollars	Before submitting the dossier or in parallel with the application submission

Forms for Agency agreement, Screening & Evaluation as well as Laboratory test service payment are annexed to this guideline (*Annex V*) and applicants are required to fill these forms and bring to the authorized person in the Authority for the form's approval for the payment.

9.2.5 Declaration of conformity

By drawing up the declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Guideline and other relevant documents of the Authority applicable to the device.

At a minimum, the declaration should contain the following information:

- An attestation that each device that is subject to the declaration complies with the applicable Essential Principles for Safety and Performance and the applicable requirements of Labelling and Instructions for Use for Medical Devices,
- Information sufficient to identify the device/s to which the Declaration of Conformity applies,
- The Universal Medical Device Nomenclature (UMDN) code for the device,
- The classification of the device/s in accordance with the guidance found in the Principles of Medical Devices Classification,
- The date on which the Declaration of Conformity is issued,
- The name and address of the device manufacturer, and
- The name, position, and signature of the responsible person who has been authorized to complete the Declaration of Conformity upon the manufacturer's behalf.

The Authority will review and confirm the adequacy of the Declaration of Conformity and, examine the supporting documents or other evidences. The template for declaration of conformity is attached to this guideline (*Annex VI*).

9.2.6 Global Market History

The medical device(s) subject to the registration application should be supported by the marketing history globally covering the up to date indication of the markets (all countries or jurisdictions) where the device is approved for marketing, including any marketing under compassionate use regulations.

As an evidence, the list shall be supported by copies of Marketing Authorization, free sale certificates or any other supporting certificates issued by the National Regulatory Authorities of the listed Countries.

The template for declaration of Global market History is attached to this guideline (Annex VII).

9.3. Applications for registration of Medical device for full assessment

All medical products regulated by EFDA including medical devices follow various regulatory processes from their premarket assessment to post-market control in order to protect the public health by ensuring the safety, performance and quality of the products. One of the EFDA's premarket assessments is the evaluation of registration dossiers of the medical devices.

Two separate guidelines are developed and being implemented to provide uniform format for applicants for use when filing Non-IVD medical device and IVD medical device documents submission to EFDA for market authorization. These guidelines are intended to provide a comprehensive and well-organized structure for premarket medical device application submissions that assists the manufacturers to submit complete & consistent registration dossier so as to facilitate the marketing authorization process of their products.

It remains the applicant's responsibility to ensure all regulatory requirements are met, and that clear and transparent evidence of conformity to these requirements are provided. Therefore, the applicant should submit the complete registration dossiers of the medical devices, as per the applicable registration requirements set in *Guideline for Registration requirements of Medical devices other than In Vitro Diagnostic Devices* and *Guideline for Registration requirements of In Vitro Diagnostic Medical Devices,* for registration of all medical devices that are not exempted from registration (refer to *Guideline for Importation of Medical devices Exempted from Registration*), or not listed in the authority`s low risk medical device (refer to *Guideline for Registration of Low risk Medical devices*).

9.4. Registration of Medical devices approved by a Stringent Regulatory Authority or prequalified by WHO/UNFPA

This path way is applicable for medical devices that are arleady approved by competnt mediical devices regulatory authorites recognized as SRA by EFDA and products already prquialified by international agencies (WHO, and/or UNFPA).

Stringent Regulatory Authority (SRA) is a stringent government body or other entity that exercises a full legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical devices marketed within its jurisdiction fully comply with legal requirements.

An applicant claiming to have a registration certificate or Marketing Authorization certificate issued by a Stringent Regulatory Authority should submit all applicable administrative and technical documents required in the relevant EFDA's registration requirements guidelines as per the registration process explained in this guidelines. The same procedure is applicable for products that are evaluated and prequalified by internationally recognized organizations (such as WHO, , UNFPA, etc.) in an attempt of prequalifying for procurement. As the later medical devices may not have Registration certificate or Market Authorization certificate, the claim of the prequalification shall be supported by the confirmation letter for the product's acceptance

for the prequalification or evidence for presence of the subject product in the prequalified products list or the submission of evaluation report(s) made by the prequalifying organization for the subject medical device.

At present, EFDA accepts the registration submissions as an SRA or prequalified products application if they're supported by one or more of the following document(s).

1. A Marketing Authorization certificate or registration certificate or free sale certificate issued by one of the following competent national regulatory authority:
    - US Food and Drug Administration
    - Ministry of Health, Labour and Welfare, Japan
    - Trapeutic Goods Administration, Australia
    - Health Science Authority, Singapore
    - Competent Authorities from one of the 27 Member States of the European Union who are responsible in Europe for the oversight of Directive 93/42/EEC, Directive 98/79/EC, MDR 745/2017, IVDR 746/2017.
    - Medicine and Healthcare Products Regulatory Agency, UK
    - Health Canada, Canada
    - Ministry of Food and Drug Safety, South Korea
2. Evidence for WHO prequalification
3. Evidence for UNFPA prequalification

The list of Authorities that are recognized by the EFDA as Stringent Regulatory Authorities will be updated as deemed necessary.

The aim of SRA/prequalified products route of application and assessment is to increase efficiencies and avoid duplication of effort and to reduce the time wasted to evaluate the products compliance with the EFDA's requirements by focussing on aspects where EFDA's evaluation brings added value. EFDA will review the filled information in eRIS and supportive documentation and then determine the product`s eligiblity for SRA route of application. If the

applicant intentionall submits misleading information (submiting a Non-SRA application as SRA), that particular application will be rejected either during screening or evaluation stage.

The applicants should submit all documentation required for registration of medical devices through full assessment path way, but it takes shorter processing time as it will focus on verifiying genuinness of submitted information. A product's approval by a Stringent Regulatory Authority/ prequalification provides a level of assurance relating to the quality, safety and performance in countries where the product is approved, but it may not always provide the same assurance level when the product is used in Ethiopia. Hence, whenever deemed necessary, the Authority may conduct a full assessment of the application and further informations may be requested.

9.5. Registration of Low-risk medical devices

As it is stated under article 19(1) of Ethiopian Food and Medicine Administration Proclamation No: 1112/2019, the rigor of regulatory assessment of medicines and medical devices shall be commensurate with the products type, nature and potential risk to human health. Accordingly, EFDA has classified medical devices into four risk classes (Class I to IV for Non-IVD devices and Class A to D for IVD devices) using its guideline for classification of medical devices. Class I devices and Class A IVD devices represent the lowest risk medical devices and therefore the evaluation to ensure their safety, quality and performance/effectiveness requires minimum exertion for effective utilization of limited resource and to ease the accessibility of the products for consumers. This class of medical devices fall in the jurisdiction that permits abbreviated assessment or approval by notification procedure as they are generally considered as low risk products. Although Class I/A medical devices have been exempted from the thorough evaluation & registration requirements, their conformance with the applicable essential principles for safety and performance for general medical device and IVD Medical Devices shall be ensured prior to their placement on the Ethiopian market. To achieve this, EFDA has developed separate guideline with minimized requirements of issuing marketing authorization certificate for the low risk medical devices. If a manufacturer's device falls into a generic category of the listed low risk medical devices in the *Guideline for Registration of Low Risk medical device,* a premarket registration application is as per the requirements set in this guideline and EFDA's approval of the subject device's compliance to the requirements is mandatory.

9.6. Registration of Accessories and Spare parts

In order to set regulatory requirements for manufacturers and importers of Medical device accessories and spare parts, EFDA has developed a separate guideline which describes the detail requirements that are applicable to the types of accessories and spare parts concerned. In the guideline, accessories and spare parts are divided into three categories based on the level of their impact on the parent device's safety and performance as well as whether the accessory or spare part needs EFDA's clearance for use. Accordingly, they are divided into the followings:

Accessories and Spare parts:-

a) With significant impact on the safety and performance of the parent device(s),

b) With little or no impact on the safety and performance of the parent device(s), and

c) General purpose (off-the-shelf) Accessories and Spare parts which do not need EFDA's clearance for use.

To have detail understanding of how to categorize and meet the EFDA's regulatory requirements of medical devices accessories and spare parts, manufacturers, importers and registrants of medical devices accessories and spare parts are recommended to refer to the *Guideline for Marketing Authorization and Import permit of Medical Device Accessories and Spare parts.*

10 EXEMPTION OF MEDICAL DEVICES FROM REGISTRATION

The regulation scope of the Authority includes all medical products which fulfil the definition of medical devices irrespective of their risk class. However, in order to avoid unnecessary detailed evaluation of low risk devices which do not need much attention impose any risk to the paitent or users, time and resourceas well as those devices which have been approved by Stringent Regulatory Authorities, EFDA has established a systematic strategy to expedite the Marketing Authorization process of such devices. For these devices, the Authority performs an abbreviated means of assessment and requires a minimized submission of low risk devices for their marketing approval. In addition, EFDA does not require registration of medical devices intended to be used in different circumstances:

a) Custom made & personal use devices

b) Devices for national health emergency

c) Investigational devices

d) Devices for Research , demonstration, training, education and other non clinical uses

In its effort of promoting the access of essential medical devices in the country's market, the Authority has developed and is implementing a separate guidelines to manage and give important permission for the device's importation without compromising their safety, quality and performance. These medical devices which are exempted from registration shall not be imported and placed on the market withouth EFDA's prior approval. Therefore, Applicants who are interested in importing these devices are adviced to refer to the guideline (*Guideline for Importation of Medical devices through special acess).*

11 APPLICATION REVIEW AND MARKETING AUTHORIZATION

Applicants need to get username and password from the concerned authorized person of the Registration department of the Authority for submitting application online through the Authority's regulated products registration platform (www.eris.efda.gov.et). All the required documents shall be attached at its respective attachment spaces in PDF format. All applications pass through two stages of the review process. The first stage is screening (validation of application), which occurs before the scientific review with the aim of ensuring completeness & eligibility of the application for the apporoval pathway in order to facilitate the subsequent scientific review. The second stage is evaluation which includes the detail assessment of the submitted administrative and technical documents against the applicable EFDA's regulatory requirements & procedures.

EFDA conducts risk-based assessment of medical device applications to evaluate whether they meet scientific and evidentiary standards for safety, performance and quality. This risk-based assessment forms the scientific foundation for regulatory decisions.

11.1 Screening

Screening involves an examination of the application to ensure that it is well-organized and that all the required forms and relevant documents have been submitted. Identifying missing information in the application prior to scientific review enables EFDA to avoid spending time and review resources on an application that would not allow critical analysis, signal identification or regulatory decision-making.

11.2 Assessment

The way an assessment is conducted will depend on the type of application (New SRA, New Non-SRA, Re-registration, Post approval change notification or Low risk devices application). EFDA uses a multidisciplinary team providing a broader expertise and the applications are assigned to a single assessor except New Non-SRA applications which are assigned to two assessors (to assess sequentially one after the other). At the end, a final review is conducted by a team leader to ensure that scientific and evidentiary standards for safety, performance and quality are adequately met.

The EFDA's medical device dossier assessment is evidence-based, taking into account national laws and regulations, regional and international guidelines, and, where applicable, standards. The reviewer determines the information necessary to approve the product application and considers whether further information can be obtained in post-approval studies without compromising safety.

The model adopted for review may allow for questions to be asked during the review to supplement or clarify information supplied, until the reviewer is satisfied that enough information has been provided to allow a conclusion to be reached. The assessment model used by EFDA is that the review is completed on the basis of the information submitted, and a list of questions is then sent to the applicant setting a specified time-limit for response, and a number of further rounds of assessment of the responses takes place before a decision is made.

If the provided information and the submitted documents are found to be complete and satisfactory for registering the medical device under evaluation, the market authorization certificate is issued.

11.3 Issuance of Marketing Authorization Certificate

A medical device shall only be placed on the market in Ethiopia when a marketing authorization certificate has been issued by the Ethiopian Food and Drug Authority unless the device is exempted from registration.

A marketing authorization lays down the terms under which the marketing of a medical devices is authorized in Ethiopia. A marketing authorization is composed of: (i) a decision granting the marketing authorization issued by the athority; and (ii) a technical dossier with the data submitted by the applicant in accordance with the relevant authority's regulatory requirements.

In order to obtain a marketing authorization, an application shall be submitted to the authority by the applicant/marketing authorization holder based on the registration requirements applicable to the subject device. Following satisfactory assessment report, a dated and signed marketing authorization certificate is granted by the authority to the License holder through its local agent/representative. The local agent or the representative who submitted the application and facilitated the certification process on behalf of the License holder shall immediately deliver the certificate to the License holder.

12 POST APPROVAL

12.1 The Validity of the Marketing Authorization Certificate and Renewal application requirements

The Marketing authorizations granted by the authority have a duration of five years validity period allowing marketing of the products within this time frame. The cerificates shall be renewed every five years. The option of applying for re-registration is opened when three months is left for the MA certificate's expiration. Applicants are recommended to apply for renewal at least two months before the expiry of the certificate as re-registration application assessment may take time.

With the applicable re-registration fee, the following data shall be submitted for re-registration of the device:

a) Cover letter or Application letter (As per *Annex III*)

b) Valid and genuine Quality Management System Conformance Certificate from accredited and recognized Conformity Assessment Body.

c) Valid, original and genuine Free sale Certificate or Marketing Authorization Certificate from relevant and Competent National Regulatory Authority.

d) Valid, original and genuine Manufacturing License

e) Declaration of Conformity (As per *Annex VI*).

f) Valid, original and genuine Good Manufacturing Practice Certificate (if applicable)

g) Letter of Confirmation of No Change OR Summary of Changes after its recent approval by EFDA.

h) Device Vigilance and Post-market Surveillance Reports (for devices that are sterile, have measuring functions and all class III/C and above).

If the applicant wants to re-register a medical device whose MA certificate is expired before submitting renewal application, the applicant shall request new applications and therefore the registration requirement and the assessment time shall also be the same with new medical device registration procedure.

12.2 Request for Corrections of Issued Marketing Authorization Certificate

Applicants can request a review of a decision or can appeal their complaints after market authorization certificate is granted in accordnace with the complaint handling procedure set by the Authority If an applicant wishes to request for the correction of a Market authorization certificate, the request shall be made within a month from the date of issuance of the certificate. No certificate shall be corrected if the request for correction is made later than one month after the certificate is issued.

12.3 Post-approval Change Notification

Changes in medical devices may take place from time to time as part of their life-cycle. Any change to a registered medical device is linked to the principles of safety and performance and the ability of the regulatory framework to manage the risk of the medical devices.

Article 21(1) of Food and Medicines Administration Proclamation (No. 1112/2019) indicated that if variation affecting the registered medical device's safety, quality or effectiveness is introduced, the product may not be marketed unless the person who registers the product notifies such variation and get approval from the Authority.

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 and performance have been appropriately collected and reviewed based on the notification made by the applicant.

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 and performance of the medical device.

The Authority has separate guideline - "*Guideline for Post-approval Change Notification of Medical Devices*" to facilitate the application for changes to the registered medical devices. This, the aforementioned guideline provides guidance on the categories of changes, the principles of change categorization, and what should be done by the applicant in relation to each category of change to its registered medical device. Hence, applicants are advised to consult this guideline before summation of the application for variations to the registered medical devices.

12.4 Voluntary Withdrawal of Marketing Authorization Certificate

When an approved medical device previously placed on the market is no longer actually present on the market or the manufacturer stops manufacturing the product, the marketing authorization certificate for that medical device will cease to be valid. A marketing authorization holder must notify EFDA of any action taken to suspend the marketing or to withdraw a medical device from the market, to request the withdrawal or to not request the renewal of a marketing authorisation together with the reasons for such action. The marketing authorization holder must in particular declare if the action concerns the quality of the medical device or the protection of public health.

13 REFERENCES

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14. ANNEXES

14.1. Annex I: Requirements for Virtual Manufacturers

A. Responsibilities of a Virtual Manufacturer

Where conformance to a Quality management system is required, the virtual manufacturer shall have a quality management system that will be audited by its notified body or EFDA. In addition, virtual manufacturers shall hold the full technical documentation which shall be reviewed by the Authority.

The Virtual Manufacturers:-

a) have to fulfil their obligations themselves regardless of any partial or total outsourcing of the production via subcontractors or suppliers;

b) should integrate the quality system of critical subcontractors and of crucial suppliers with their quality system;

c) need to control the quality of services provided and of components supplied and the quality of production thereof regardless of the length of the contractual chain between the manufacturer and the subcontractor or supplier".

The virtual manufacturer shall sign a Declaration of Conformity that the devices concerned meet the relevant EFDA's registration requirements. All virtual manufacturers, including those manufacturing Class I/A medical devices, are required to comply with EFDA's registration requiements.

B. Technical documentation needed from a Virtual Manufacturer

All manufacturers shall hold full technical documentation in order to demonstrate that the medical device that they place on Ethiopian market, under their own name, meets the regulatory requirements. The technical documentation shall be fully integrated into the manufacturer's quality management system where applicable and shall contain data relevant to the manufacturer (e.g. labels, instructions for use, risk assessment etc.). Where the virtual manufacturer does not hold the rights related to product design, EFDA may accept a technical file from the virtual manufacturer that has redacted proprietary information as long as the redacted information is not essential for the purposes of the Authority's assessing whether the medical device complies with the regulatory requirements. Redactions shall be as limited as

possible. In cases where the virtual manufacturer holds redacted technical documentation, they must have contractual arrangements to ensure full disclosure of all applicable information by the original equipment manufacturer (OEM) directly to EFDA and the virtual manufacturer's notified body.

The following may constitute proprietary information:

a) unique material formulae or ingredients which are specific to the medical device and not in general use which are of high commercial and intellectual benefit to the OEM.

b) unique manufacturing processes which have been designed by the OEM and give them a competitive advantage in the market place.

c) technical drawings and technologies (applicable where a patent is also being applied for) but not yet granted.

d) software algorithms.

Full redaction of all formulas, ingredients, algorithms or manufacturing processes shall not be accepted. Where redactions are made, the justification for these redactions by the OEM shall be documented and the top-level information provided shall be sufficient to understand the medical device and any associated risks.

Any technical documentation provided to EFDA shall include a statement drawn up by the virtual manufacturer indicating they fully understand all the documentation provided and that they accept full legal responsibility.

C. The Contractual agreement between the OEM and the Virtual manufacturer

Virtual manufacturers shall ensure an appropriate contract is in place with the OEM. As a minimum, the contractual agreement shall contain the following:

a) A direct link between the medical devices being placed on the market by the manufacturer that holds the rights to the product design and the virtual manufacturer they are supplying who does not hold the design rights.

b) Arrangements for post-market surveillance and vigilance activities (i.e. details of who is responsible for what in relation to these requirements, including reporting of adverse incidents). All virtual manufacturers shall ensure that incidents or

potential incidents are reported and also brought to the attention of the manufacturer that holds the rights to the product design. Similarly, the OEM shall be responsible for notifying the virtual manufacturer to enable them to take appropriate action with regard to their own products.

c) Provisions for post-production follow-up, including ensuring that post-market clinical follow-up provisions are in place.

d) Arrangements for details of any changes to the medical devices to be notified to both parties, with documented approval granted by the OEM where the virtual manufacturer wish to make changes.

e) Provisions for unannounced audits – i.e. EFDA shall have access to any critical suppliers (including the manufacturer who holds the rights to the design).

f) The contract should include the fact that the virtual manufacturer may not enter into another contract with another virtual manufacturer for the same device, i.e. a virtual manufacturer shall not be the OEM for another virtual manufacturer for the same medical device.

g) Provision for the OEM to provide fully un-redacted information upon request of EFDA.

h) Provision for the OEM, where relevant, to maintain and provide to EFDA the certification covering the products concerned.

i) Provision for the OEM, where relevant, to maintain and provide to the virtual manufacturer evidence of their product's registration with a competent authority.

D. If a Virtual manufacturer wants to change from being the legal manufacturer to the distributor

A virtual manufacturer shall be considered as a distributor and not the manufacturer in the following situations where they:

a) provide a translation of the information supplied by the manufacturer for the purpose of making the product available in Ethiopian market (without affecting the integrity and detail of the information provided by the manufacturer). The

manufacturer shall have a process to verify that all translations are fit for purpose prior to authorization

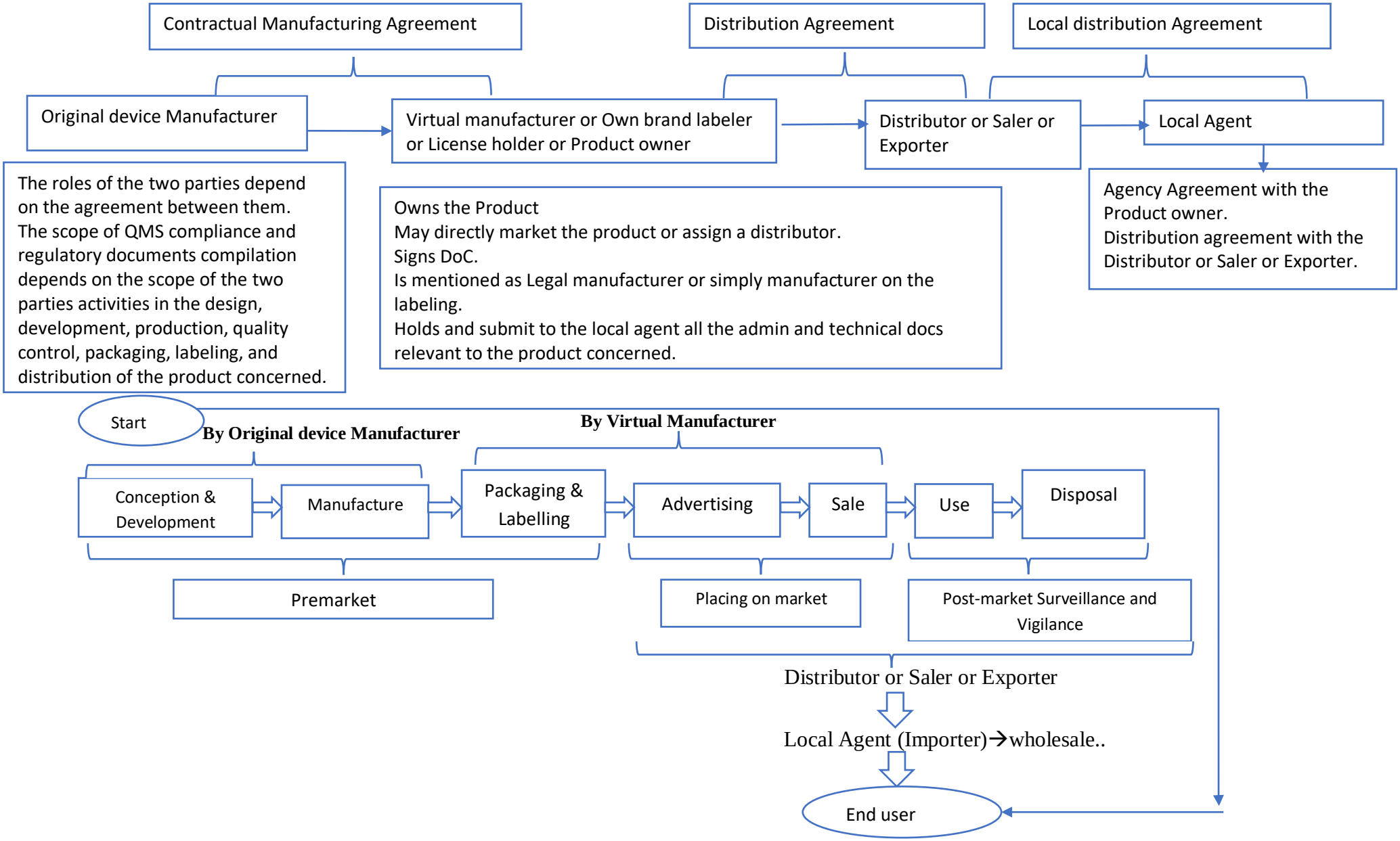
b) change the size and/or presentation of the outer packaging of a device that has already been placed on the market without affecting the integrity of the device itself.

c) affix their brand name or trademark on the labelling with the agreement of the manufacturer and the manufacturer is identified on the labelling and packaging.

d) stipulate clearly who the device is 'distributed by' and 'manufactured by' on the packaging and labelling.

e) do not change the intended purpose of the device or modify the device or its packaging in such a way that its compliance with the legislation is affected.

In order to be considered as the distributor, there shall to be signed agreement with the manufacturer. The manufacturer's name shall be visible as the legal manufacturer on the packaging and labelling. These details shall be easy to read. There is the option for the distributor to be identified on the packaging and labelling with the term 'distributed by'.


Contractual Manufacturing Agreement
Distribution Agreement
Local distribution Agreement
Original device Manufacturer
Virtual manufacturer or Own brand labeler or License holder or Product owner
Distributor or Saler or Exporter
Local Agent
The roles of the two parties depend on the agreement between them.
The scope of QMS compliance and regulatory documents compilation depends on the scope of the two parties activities in the design, development, production, quality control, packaging, labeling, and distribution of the product concerned.
Owns the Product
May directly market the product or assign a distributor.
Signs DoC.
Is mentioned as Legal manufacturer or simply manufacturer on the labeling.
Holds and submit to the local agent all the admin and technical docs relevant to the product concerned.
Agency Agreement with the Product owner.
Distribution agreement with the Distributor or Saler or Exporter.
Start
By Original device Manufacturer
By Virtual Manufacturer
Conception & Development
Manufacture
Packaging & Labelling
Advertising
Sale
Use
Disposal
Premarket
Placing on market
Post-market Surveillance and Vigilance
Distributor or Saler or Exporter
Local Agent (Importer)→wholesale..
End user

Annex II: Application Form for Registration of Medical Devices

The applicant for registration of a medical device is required to provide the completed Application form below by summarizing the registration dossiers. Information that is not provided in the dossier should not appear in the formats in the application form. Annexes and addendum in the registration dossier should always be cross-referenced in the application form.

Application Form for Registration of a Medical Device Food and Drug Authority of Ethiopia			
S. No.	**Title**	**To be completed by the applicant**	**Remarks**
1	**Applicant**		
	Name		
	1.2. Physical address including street number, telephone, e-mail, etc.		
	1.3. Contact person in the company		
2	**Type of Application** New Re-Registration Variation		
3	**Representative in Ethiopia**		
	3.1 Name		
	3.2. Physical address including street number, telephone, e-mail, etc.		
	3.3. Contact person in the company		
4	**Manufacturer of the Product**		
	4.1 Name		
	4.2. Physical address including street number, telephone, e-mail, etc.		
	4.3. Contact person in the company		
5	**Application group:**		
6	**Details of the Product**		
	6.1. Device Common or Generic Name		
	6.2. Brand Name		
	6.3. Model(s)		
	6.4. Device's intended use		
	6.5. Device's short description		
	6.6. Device's class		
	6.7. Its classification rule number		
	6.8. Device's list of configurations (its accessories and parts that are intended to be used together)		
7	**Device Safety and Performance Conformity Assessment**		
	7.1. Declaration of conformity		
	7.2. Standards to which the device complies		
	7.3. Summary Technical Documentation		
8	**Essential Principle Checklist** (for Device		

	Safety and Conformity Assessment)			
9	**Regulatory Situation in Other Countries**			
10	**List of Documents Attached with This Application**			
	Chapter one	**1.**		
		2.		
		3……		
	Chapter two	**1.**		
		2.		
		3……		
	Chapter three	**1.**		
		2.		
		3……		
	Chapter four	**1.**		
		2.		
		3……		
	Chapter Five	**1.**		
		2.		
		3……		
	Chapter Six	**1.**		
		2.		
		3……		
11	**Declaration by Applicant**			
	I, the undersigned, certify that all the information in the accompanying documentation concerning an application for registration of the medical device listed below is correct and true, and reflects the total information available. Name of the Device (trade name, common name): _____ Device Type (*IVD or Non-IVD*): _____ Duly authorized to represent (applicant company name) _____ I further confirm that the information referred to in my application file is available for verification. I also agree that I am obliged to comply with the requirements of the Authority related to the Medical Device Registration at any time in future. **Name**: _____ **Signature**: _____ **Position in company**: _____ **Date**: _____			

Annex III:- Application letter template (*by the Manufacturer or License Holder*)

[Logo of the License holder/Manufacturer]

Date: [DD/MM/YYYY]

Application Letter

We ---------- a license holder/Manufacturer of its legal entity, registered and works under the laws of Country ---------- having registered organizational Actual address at plot No.: ---------- street/road/: ----------City: ----------Tel:+ ---------- e-mail: ---------- Fax :+ ---------- P.O.Box: ----------

Here by authorized ---------- agent in Ethiopia addressed at or having its legal entity, registered and works under laws of Ethiopia, Sub-city: ----------Woreda: --------- e-mail address: ----------Tel: + ---------- Mobile: + ----------P.O.Box:---------- Street/Road/: ----------

-to represent our company and submit the required documents to the Authority for the registration of the following medical device(s):-

Device Name: _____ Brand Name: _____

Model(s): _____ Registration type [New, Renewal, Variation…]: _____

(*Please use separate page (s) and attach to this letter if the devices the agent is authorized to register are more than one devices*).

We, [the license holder/manufacturer], do here by assure that the legalized documents, the company profile and other documents that we have submitted are true and correct. We agree to inform the Ethiopian Food and Drug Authority about any change or modification made on the information given in the documents submitted.

We also agree to allow officials from the Authority to visit and have first-hand information about the industry at any time.

We recognize and accept the right of the Authority to suspend or to revoke the registration certificate that is already issued to us if any fraud or anything contradictory to our registration documents is discovered.

The appointed agent is responsible for correspondence and complete compliance with regulatory requirements pertaining to the product's life cycle in the country.

[License holder/Manufacturer Seal/Stamp] Signature: _____ Date: _____

Annex IV: Agency Agreement form

[Logo of the license holder/Manufacturer]

Date: [DD/MM/YYYY]

Agency/Distribution/ Agreement

We ---------- a license holder/Manufacturer of its legal entity, registered and works under the laws of Country ---------- having registered organizational Actual address at plot No.: ---------- street/road/: ----------City: ----------Tel:+ ---------- e-mail: ---------- Fax :+ ---------- P.O.Box: ----------

Here by authorized ---------- agent in Ethiopia addressed at or having its legal entity, registered and works under laws of Ethiopia, Sub-city: ----------Woreda: --------- e-mail address: ----------Tel: + ---------- Mobile: + ----------P.O.Box:---------- Street/Road/:---------- as [first/second/third] agent of our products in the territory of The Federal Democratic Republic of Ethiopia.

This Agency Agreement is made as of [DD/MM/YYYY], between the license holder/Manufacturer and the agent.

As its [first/second/third…] agent in Ethiopia, the distributor accepts the appointment.

Accordingly, the distributor/agent is authorized to submit [License holder/Manufacturer] applications for registration of distribution agreement with Food and Drug Authority of Ethiopia (EFDA) as well as to promote, import, distribute and sale License holder/Manufacturer products in Ethiopia.

We, the [License holder/Manufacturer] and the [Agent] have the following shared duties and responsibilities: -

1. If any fraud or unsuspected and unacceptable adverse events occur to the consumer under normal utilization, the License holder/Manufacturer/ and the Agent will be responsible for collecting the product from the market and are responsible for substantiating any event.
2. The local agent/Distributor shall notify any governmental authority or regulatory body in the territory about any reportable event and/or field safety corrective actions in compliance with its vigilance requirements set forth under the laws and regulations of the territory. Accordingly, distributor shall notify the license holder/Manufacturer without delay about any potential reportable events and/or field safety corrective actions affecting products.

3. The License holder/Manufacturer/ and the Agent are responsible for the Medical Device vigilance and post marketing reporting of the product safety, quality and performance follow up.
4. The appointed agent(s) is responsible for correspondence and complete compliance with regulatory requirements pertaining to the product distribution life cycle in the country.
5. This agency agreement shall come into force as of its date of signature and remain valid until [DD/MM/YYYY] unless terminated by either party with a written notice at any time. (written notice -----days prior to termination).

[License holder/Manufacturer Seal/Stamp] [**Agent Seal/Stamp]**

Signature: ---------- Signature: ----------

Date: ---------- Date: ----------

TO WHOM IT MAY CONCERN

1. Proof of payment for agency agreement fee ($50USD) as fixed by the Ministry of Council of Ethiopia which shall be deposited to Ethiopian Food and Drug Administration Control Authority (EFDA) account number at Commercial Bank of Ethiopia (CBE).
2. The original agency agreement shall be sent to the respective authority (EFDA) archive office through unopened and properly packed DHL.
3. The agency agreement shall be sent to Medicine Registration and Licensing Directorate both in softcopy of scanned pdf and hardcopy after signed by both parties, with fee paid receipt and, signed fee order in CD or flash. The CD and the flash shall be returned to the applicant after the softcopy of scanned pdf of the document is uploaded on the system (eRIS).
4. Valid Certificate of Competency (COC) shall be submitted in softcopy of scanned pdf.
5. We shall not consider any agreement sent to authority in any form other than the above mentioned and more than five (5) pages with unnecessary information from the regulatory perspectives (please refer proclamation 1112/2019).
6. The suppliers'/license holder/manufacturer and the authorized agent can have an agreement with an additional article between each other as per their negotiations and their country`s legal frame/regulation/ in separate document/paper which shall be separate from agreement sent to authority(EFDA).
7. The agreement shall be made only between suppliers'/license holder/manufacturer and the authorized local agent. There shall not be any an intermediate actors or export as the license holder rather than a facilitator for collection, packing and shipping of the product on behalf of main manufacturer (the export shall act only as facilitator or for administrative purpose.) otherwise, the responsibility of the three parties/thrice parties/ (license holder/manufacturer, exporter and local agent) shall be clearly addressed in the agreement and signed by each parties.

Annex V:- Payment Request format for Agency agreement, Screening, Evaluation and laboratory test service fees

A. Agency Agreement payment request form

Ethiopian Food and Drug Authority

AGENCY AGREEMENT FEE

Name of the license holder	Country	Type of Product	Name of Local Agent	Name of Exporter if Any	Type of Agent	Amount in USD	Receipt No
						50 USD	

Approved by: _____

Date: _____

Signature:_____

B. Screening, Evaluation, and lab test Payment request form

Ethiopian Food and Drug Authority

Payment for Dossier Screening, Evaluation and laboratory test Services

SN	Brand Name	Generic Name	Application number	Manufacturer name	Country	Agent	Application type	Screening fee (Birr)	Evaluation fee (Birr)	Laboratory fee (USD)	CPO Number
1											
total											

For official use only

Medicine Registration and Licensing Directorate;

Customer Service Team

Approved by:_____

Signature:_____

Date: _____

Finance and Procurement directorate

Receipt Number_____

Received by_____

Signature: _____

Date:_____

Annex VI: - Declaration of Conformity - Template

[To be printed on Company Letterhead of Product Owner]

Name and Address of Product Owner:

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations.

Manufacturing Site:

< Physical manufacturing site(s) including sterilization site(s) >

Medical Device(s):

< e.g. product name and model number>

Risk Classification: e.g. Class I, rule

< Risk Classification of medical device(s) according to the classification rule, and the rule(s) used to determine the classification>

Quality Management System Certificate:

< Certification Body and Certificate Number, issue date, expiry date>

Standards Applied:

- *<eg. ISO 13485>, US FDA Quality System Regulations, Japan MHLW Ordinance 169>*

This declaration of conformity is valid from *<Day Month Year>*

Authorised Signatory:

_____ _____

Name, Position Date

Annex VII: Global Marketing History Declaration - Template

[To be printed on Company Letterhead of the product owner]

We [the licence holder/manufacturer, and its complete address] hereby declare that the product(s) subject to this application is/are being marketed without restriction in the countries listed in the following table.

Name of the medical device: _____

Brand or Trade Name of the device: _____

S.No.	**Name of the Countries**	**Year of start of marketability**	**Registration status [registered or not] (provide the registration number if registered)**	**Specify how the device got approval to be marketed if not registered**
1				
2				
3				
…				

[*Please use separate page(s) and attach to this declaration letter if the listed countries are more than five*].

I, the undersigned, am aware that making a declaration, which I know to be false, is an offence and violation of the Proclamation no. 1112/2019 and may result in the cancellation of registration of the above medical device.

[Full Name and Title of Senior Company Official]: _____

Position: _____

Signature: _____

Date: _____

*[License holder/manufacturer Seal]:*_____

Annex VIII:- Legal (owner) and Subsidiary Manufacturers Relationship Flowchart