Ethiopian Food and Drug Authority

Guideline for Marketing Authorization of

Low-risk Medical devices

First Edition

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ACRONYMS

EFDA	Ethiopian Food and Drugs Administration
EU	European Union
GMDN	Global Medical Device Nomenclature
IMDRF	International Medical Device Regulators Forum
NB	Notified Body
TGA	Therapeutic Goods Administration - Australia
USFDA	United States Food and Drug Administration

1 INTRODUCTION

The Food and Medicine Administration Proclamation No. 1112/2019 requires that all medical devices shall be thoroughly evaluated & registered before authorized to be marketed in Ethiopia. However, article 19(1) of the same proclamation decrees that "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 Non-IVD medical devices into four classes (Class I, lowest risk to Class IV, highest risk) and IVD medical devices into four classes (Class A, lowest risk to Class D, highest risk) with its separate guideline for classification of medical devices. As the Class I devices and class A IVD devices represent the lowest risk medical devices, 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 essential principles for safety and performance of general medical device and IVD medical devices shall be ensured prior to their placement on the Ethiopian market. In addition, some class I/A medical devices, such as those supplied in a sterile state and some measuring devices are not eligible for low risk approval pathway. Therefore, this guideline is intended to provide guidance for applicants and clarify the requirements for getting marketing authorization for medical devices those can be approved through low-risk approval procedure.

2 OBJECTIVE

The objective of this guideline is to provide guidance on requirements for marketing authorization of medical devices recognized by EFDA as low-risk products.

3 SCOPE

This guideline is applicable to all class A In vitro Diagnostic (IVD) Medical devices and class I medical devices other than IVD included in the low risk medical devices listed in this guideline. It is not applicable to all Sterile and most Measuring devices.

4 DEFINITIONS

- **Medical device Category**: means the broadest level of Medical devices categorization which divides the entire medical device product market into highest-level groups based on device

application, technology, or other common characteristics

- **Abbreviated assessment** means medical devices marketing authorization application assessment procedure that focuses on verifying completeness and authenticity of administrative documents with few or no technical requirements.
- **Applicant** means a manufacturer or authorized representative or local agent who may submit an application for premarket notification of medical device to the authority.
- **Authority** means the Ethiopian food and drug authority
- **License holder** means in relation to a registered medical device, means the person who applied for and obtained the registration of the medical device.
- **Low risk medical devices** means medical devices classified under class I Non-IVD and Class A IVD devices that full fill EFDA`s criteria for low risk.
- **Measuring devices** means devices whose intended purpose implies accuracy, claimed explicitly or implicitly, where a non-compliance with the implied accuracy could result in a significant adverse effect on the patient's health and safety.
- **Sterile** means, in respect of a medical device, a state free of viable micro- organisms.

5 CRITERIA FOR INCLUSION IN THE LOW-RISK MEDICAL DEVICES

Medical devices classified under I/A (refer to EFDA`s Guideline for classification of medical devices) are generally eligible for inclusion in the low-risk medical devices list unless they are sterile or have measuring functions. In addition, the following general principles are applied for inclusion:

a. The device must be in conformance with manufacturing and quality control standards
b. It must be perceived low risk to the patient or user
c. There must be other conformity assessments options applicable to the device
d. If the medical devices/accessories are in the same category attached under the annex 1 of this guideline, the devices can be applied as one application.

Note: *- If a manufacturer's devices are eligible for MA application through low risk devices application procedure but not included in the existing list, the applicants are advised to request for the products inclusion. However, the requests for inclusion will be considered during the normal revision period of the list. MA applications of such products should be processed through regular application route and follow normal review procedure.*

6 REQUIREMENTS

Generally, low risk medical devices marketing authorization applications do not require submission of full product dossier and will not undergo rigorous evaluation process. Hence, the administrative document and payment of service fee are the major requirements for this approval pathway. However, applicants looking for the MA should submit the administrative and when necessary, selected technical documents listed here under and must comply with all requirements of relevant national laws and internationally recognized standards and laws. Applicants are required to check the up-to-date list of low-risk medical devices to make sure that the application is eligible for submission via low-risk approval pathway.

***Note**: The list of low-risk medical devices in Annex I will be updated by the authority on regular basis (annually).*

6.1 Required documents

6.1.1 Application form

A dated and signed application form for submission of the dossier by mentioning the product included in the dossier from the applicants responsible for registration process. (Annex II)

6.1.2 List of devices

The applicant should submit the list of products subject to one application in a single listing table containing the individual device's details including Generic and Brand name, model (if applicable), intended use, short description, device's class, technical specifications and others. The format of listing the devices for submission is attached as Annex IV to this guideline.

6.1.3 Authorization letter and Agency agreement

The local agent/representative and the license holder shall have an agreement of registration or importation or distribution as per the requirements and template in General Medical device Marketing Authorization Guideline.

6.1.4 Marketing Authorization status in other countries

List of countries in which the medical device under registration is approved or cleared for market, under evaluation pending status, withdrawn (the reason thereof) should be summarized (in tabular form) and provided.

The countries in which the medical device under consideration has already been marketed should be listed and the approval paperwork for granted marketing authorization via notification or equivalent procedures should be provided as per the marketing history declaration template annexed to Medical device Market Authorization Guideline.

For a low-risk medical device registered by other NRAs, the information submitted should be

true and should have confirmations for manufacturing process, specifications, packaging, manufacturing site and product information sameness with the product on the market in the authorizing country and the country of manufacturing.

6.1.5 Product information including Packaging & Labelling

Product information including the package insert, and labelling should be provided in accordance with the requirements of EFDA`s guideline for medical device labelling. All product information label statements are required to be in English or Amharic. The information provided should not vary significantly from the claims made for the same product in any other jurisdiction. Any information appearing in the product information [labels, patient information leaflet) should be based on scientific justification.

Primary packaging should be by unit of use and secondary packaging should provide protection of the packaged individual units in a box.

If labelling on the medical device itself, it should be in a format that will not be dislodged during cleaning, disinfecting or sterilization of the device.

The contents of the labels on the primary packaging of each unit or on the primary packaging of multiple devices should contain the following, where applicable:

a) Name and/or trademark of the manufacturer including the full physical address of the legal manufacturer. Name and address of Authorized Representative or Distributor maybe added but this additional label should not obscure any of the manufacturer's labels.
b) Country of origin
c) Type of product and main characteristics, i.e. details to identify the device and its use.
d) If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
e) Lot number prefixed by the word "LOT" (or equivalent harmonized symbol, if applicable)/batch code/model number or serial number.
f) For single use disposable devices, a date of when the device may be safely used with year and month should be clearly indicated
g) Information for particular storage conditions that apply (temperature, pressure, light, humidity, etc., as appropriate (or equivalent harmonized symbol.)
h) Information for handling, if applicable (or equivalent harmonized symbol).
i) Unique identification /device code, If applicable
j) Associated Bar code

k) For devices that have the CE marking approval, CE mark which should be on the item itself, or on the primary packaging as appropriate.

Brochures or manuals providing instructions for use and assembly must be provided in English, or Amharic languages, if applicable for the device under registration.

6.1.6 Certificates of Quality Management System

The application for registration or marketing authorization of low risk medical devices shall be supported by a valid, original and genuine Quality management system conformance certificate issued to the license holder/manufacturer by a competent and recognized conformity assessment body covering the concerned manufacturing sites and the product(s) under registration. Such certificate can be the 'latest version of ISO 13485 quality management system requirements- for regulatory purpose' or other relevant standard's conformance certificate applicable to the concerned device.

6.1.7 Free Sale Certificate or Certificate of Marketing Authorization

If the applicant submits a CE certificate, these certificates are not mandatory. Otherwise, the applicant should submit an original and valid free sale certificate or marketing authorization certificate issued by the responsible regulatory authority where the medical device is marketable, to attest that the device is marketable, without any restriction at their jurisdiction. This certificate shall indicate:-

a) the name and full address of the manufacturer,

b) the name(s) of the device(s) (with model if applicable)

c) whether the products are freely sold in the country of origin,

d) the reasons thereof clearly stated with appropriate Justification if the product is not freely sold.

e) If the manufacturer of the medical device has subsidiaries, the name and address of the subsidiaries with the name of the device they manufacture, and/or a separate free sale certificate should be submitted for each subsidiary.

6.1.8 Declarations of Conformity

The applicant should submit Declaration of Conformity (DOC) should be in accordance with requirements template annexed to medical devices market authorization guideline.

6.2 Payment of service fees

Each application should be accompanied by a relevant service fee for registration as per the

applicable service fee regulation in force at the time of application. For details, the applicants are advised to refer to the medical devices market authorization guideline to know the exact amount of payment needed for registration of medical devices.

7 POST APPROVAL CHANGES AND RE-REGISTRATION APPLICATIONS

7.1 Variation (Post-approval Change)

If there is any change after the product have been approved, the applicant should apply for variation to the authority as per the post approval change notification guideline. However, as all the requirements listed in the change notification guideline for the corresponding changes may not be required for low-risk devices, applicants are required to provide only the updated version of the corresponding certificate or document (which is/are required for the concerned device's first registration also) for the applicable type of change.

Example:- When the Manufacturing processes change, providing only Revised QMS certificate(s) may be enough instead of providing Summary of new manufacturing process, Validation report covering new processes, Pre-clinical studies, Software validation report, Clinical safety report and Risk analysis as in case of high risk devices.

Whenever a product has been withdrawn from the market for any reason (such as deficiencies in product quality defect or ADE reports) in other countries, the local agent or the manufacturer should notify EFDA as per the article 67(17) of proclamation No 1112/2019.

7.2 Re-Registration

As per the article 20(6) of the currently in-effect EFDA`s proclamation, every medical devices registered in accordance with the proclamation shall have its registration renewed every five years. Hence, marketing authorization holders should submit applications for re-registration of these low risk devices every five years by paying applicable renewal fees and submitting the following documents"-

a) Cover letter

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

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

d) Up to date and Appropriate Declaration of Conformity as per the Medical Device Registration Guidelines.

e) Letter of Confirmation of No Change after its recent approval by EFDA (if there has been no change).

f) Incident Reports and Recall information, Device Vigilance and Post-market Surveillance Reports (if any).

8 ANNEXES

8.1 Annex I: List of low risk medical devices

The following categories of Class I/A medical device and detail lists of medical devices stated in generic names have been drawn-up based on the Guidance on Risk Classification of General Medical Devices and Guidance on Risk Classification of IVD Medical Device and are recognized by EFDA as low risk medical devices for marketing authorization purposes.

8.1.1 I. List of Class A IVD Medical Devices

1. **Hematology, Pathology and microbiology Devices**
    1. Anaerobic Chamber.
    2. Animal and Human Sera.
    3. Automated Blood Cell Diluting Apparatus.
    4. Automated Medium Dispensing And Stacking Device.
    5. Automated Sedimentation Rate Device.
    6. Automated Slide Spinner.
    7. Automated Slide Stainer.
    8. Automated Tissue Processor.
    9. Balanced Salt Solutions or Formulations.
    10. Blood Cell Diluent.
    11. Blood Grouping View Box.
    12. Non-sterile Capillary Blood Collection Tube.
    13. Cell and Tissue Culture Supplies and Equipment.
    14. Chromosome Culture Kit.
    15. Coagulase Plasma.
    16. Cultured Animal and Human Cells.
    17. Device for Sealing Microsections.

18. Differential Culture Medium.
19. Dye and Chemical Solution Stains.
20. Enriched Culture Medium.
21. Manual Blood Cell Counting Device.
22. Manual Colony Counter.
23. Microbial Growth Monitor.
24. Microbiological Assay Culture Medium.
25. Microbiological Incubator.
26. Non-sterile Microbiological Specimen Collection and Transport Device.
27. Surgical Microscopes
28. Microtiter Diluting and Dispensing Device.
29. Multipurpose Culture Medium.
30. Osmotic Fragility Test.
31. Ouchterlony Agar Plate.
32. Radial Immunodiffusion Plate.
33. Red Cell Lysing Reagent.
34. Selective Culture Medium.
35. Staphylococcal Typing Bacteriophage.
36. Supplement for Culture Media.
37. Support Gel.
38. Synthetic Cell and Tissue Culture Media and Components.
39. Thromboplastin Generation Test.

2. Medical Laboratory general use devices :-

1. alcohol burner,
2. ASR stand
3. Auto samplers
4. Baths and Circulators
5. Beaker
6. Bellows
7. Biohazard hood
8. Biohazard Bags,
9. Bioreactors
10. Blenders
11. blood sedimentation pipettes,
12. Bunsen Burner
13. burettes,

14. Casework
15. Non-sterile clamps,
16. Cleanrooms
17. Cover Glass,
18. Crucibles
19. Cryo Vial,
20. Cryostats and Dewars
21. Desiccator Cabinets
22. Desiccators
23. Digesters
24. Dispensers
25. Medical laboratory Dissolution Systems
26. Medical laboratory Distillation Equipment
27. Dropper,
28. Dryers
29. ESR Stand,
30. ESR Tube
31. Evaporation Systems
32. Exhaust Fans and Blowers
33. Faucets
34. Filter Paper
35. Flasks,
36. Medical laboratory Fume Hoods
37. Funnel,
38. Glass jars,
39. Glass roods,
40. Glass Tube
41. Glove Boxes and Isolators
42. Homogenizers
43. Laboratory Incubators
44. Jugs,
45. Labeling tapes
46. Medical Laboratory Balances
47. Medical Laboratory Furniture, Storage,
48. Medical Laboratory Furniture, Casework,
49. Medical Laboratory Furniture, Carts
50. Medical Laboratory glass wares
51. Medical Laboratory supplies beakers,
52. Medical Laboratory heating plates
53. Medical Laboratory Ovens
54. Medical Laboratory Reactors
55. Medical Laboratory Stirrers
56. Medical Laboratory Valves
57. Medical Laboratory Shakers

58. Medical Laboratory Mixers
59. Lens Cleaning Tissue Paper
60. Measuring Cylinder,
61. Measuring jugs
62. Micropipettes,
63. Microscope Slide
64. Microscope lamp
65. Microscope lenses
66. Mills / Grinders
67. Non-sterile Neck Tube,
68. Petri Dish
69. Non-sterile Pipette Single/ Multi- Channel,
70. Non-sterile Pipettes
71. Non-sterile Plastic Tube
72. Polypropyl cylinders,
73. Positioning Equipment
74. Medical Reagent Bottle
75. Ring Pessary
76. Rotary microtome
77. Safety Box,
78. Safety cabinet
79. Sample Stool Container
80. Sample Urine Container
81. Sinks
82. Sonicators
83. Specimen receptacles; blood, tissues, urine, etc.(tubes)
84. Sprit Lamp,
85. Stirrer
86. Stool Container,
87. Stoppers,
88. Test tube racks
89. Test Tube Stand,
90. Non-sterile Test tubes,
91. Tourniquet,
92. Tubing, Fittings and Piping
93. Urine Cup,
94. Non-sterile Volumetric pipettes.
95. Non-sterile Vacutainer
96. Wash basins
97. Wash Bottle
98. Water Bath
99. Opalic ABO slide plate
100. Non-sterile Centrifuge Tube,
101. Non-sterile Pipettes

102.Bunsen Burner
103. Non-sterile Capillary Tube
104. Wax
105.Non-sterile Wooden Applicator

3. In Vitro Fertilization Media

a. IVF Media for Oocyte Handling:-
   1. Oocyte Obtaining
   2. Oocyte Processing
   3. Oocyte In Vitro Maturation
   4. Oocyte Polar Body Biopsy
   5. Oocyte Cryopreservation
   6. Oocyte Storage
   7. Oocyte Thawing
   8. Oocyte Transport

b. IVF Media for Sperm Handling
   1. Semen/Sperm Obtaining
   2. Semen/Sperm Processing
   3. Semen/Sperm Cryopreservation
   4. Sperm Storage
   5. Sperm Thawing
   6. Sperm Transport

c. IVF Media for Zygote Handling
   1. IVF with Insemination
   2. IVF with Intracytoplasmic Sperm Injection
   3. Zygotes Maintenance
   4. Zygote Intrafallopian Transfer (ZIFT)

d. IVF Media for In vitro Embryo Handling
   1. In Vitro Embryo Obtaining
   2. In Vitro Embryo Culture And Assessment
   3. In Vitro Embryo Biopsy
   4. Assisted Hatching
   5. In Vitro Embryo Cryopreservation
   6. In Vitro Embryo Storage
   7. In Vitro Embryo Thawing
   8. In Vitro Embryo Transport
   9. Embryo Transfer (Et)

8.1.2 II. List of Class I Non-IVD Medical Devices

4. Anesthesiology Devices

1. Airway exchange guide
2. Anesthesia Stool.

3. Anesthetic Cabinet, Table, or Tray.
4. Blow Bottle.
5. Breathing Tube Support.
6. Absorbent, carbon dioxide
7. Cardiopulmonary Emergency Cart.
8. Cast cutter
9. Cuff Spreader.
10. Ether Hook.
11. Gas Collection Vessel.
12. Gas Flow Transducer.
13. Gas Mask Head Strap.
14. Gas Pressure Calibrator.
15. Gas Volume Calibrator.
16. Heat and Moisture Condenser (Artificial Nose).
17. Inhaler spacer
18. Manual Algesimeter.
19. Medical Gas Yoke Assembly.
20. Medicinal Non-ventilatory Nebulizer (Atomizer).
21. Non-powered Oxygen Tent.
22. Nose Clip.
23. Patient Position Support.
24. Posture Chair for Cardiac or Pulmonary Treatment.
25. Pressure Tubing.
26. Rebreathing Bag
27. Reservoir Bag.
28. Stethoscope Head.
29. Switching Valve (Ploss).
30. Tee Drain (Water Trap).
31. Non-heated Humidifier
32. Tracheal Tube Stylet.

5. **Cardiovascular Devices**
    1. Blood pressure cuff

2. Defibrillation pads
3. Gel, ultrasound
4. Line Isolation Monitor
5. Paper Chart Recorder.
6. Portable Leakage Current Alarm.
7. Prosthetic Heart Valve Holder.
8. Prosthetic Heart Valve Sizer.
9. Spirometer (manual)

6. Sanitary devices

1. Adult dippers
2. Menstrual Pad
3. Baby dippers
4. Baby wipes

7. Dental Devices

1. Articulation Paper.
2. Dental Articulator.
3. Dental Protector.
4. Backing and Facing for an Artificial Tooth.
5. Base Plate Shellac.
6. Bite block
7. Cryogenic spray, dental.
8. Dental abrasives.
9. Dental absorbent.
10. Dental Amalgam Capsule.
11. Dental Amalgamator.
12. Dental broach.
13. Dental Bur.
14. Dental caries detector, electrical impedance.
15. Dental caries detector, optical induced fluorescence.
16. Dental Chair and Accessories.
17. Dental rubber dam.
18. Dental rubber dam clamp
19. Dental rubber dam frame
20. Dental rubber dam punch

21. Dental rubber dam clamp forceps
22. Dental dry field device.
23. Dental dry field kit.
24. Dental Extraction Kit.
25. Dental file rasp
26. Dental margin finishing file
27. Dental plastic filling material file
28. Dental Floss.
29. Non-sterile Dental forceps.
30. Dental implant debridement brush.
31. Dental implant extractor.
32. Dental prosthetic teeth bar.
33. Dental impression material syringe
34. Dental impression material mixer
35. Dental model duplicate agar impression material
36. Dental model duplicate elastomeric impression material.
37. Dental impression tray.
38. Dental mirror.
39. Dental Operating Light.
40. Dental Operative Unit and Accessories.
41. Dental placers.
42. Dental pulp testing electrode gel.
43. Dental root canal reamer
44. Dental ring.
45. Dental scaler, manual.
46. Dental scalers, pneumatic.
47. Dental scalers, rotary.
48. Dental scalers, ultrasonic.
49. Dental scaling system, pneumatic.
50. Dental scaling system, rotary.
51. Dental scaling system, ultrasonic.
52. Dental sectional matrix band.

53. Dental shaded pontic kit.
54. Dental solution, scaling.
55. Dental wedge.
56. Dental X-Ray Exposure Alignment Device.
57. Dental X-Ray Film Holder.
58. Dental X-Ray Position Indicating Device.
59. Denture liner/dental cushion.
60. Disposable Fluoride Tray.
61. Electrode Gel for Pulp Testers.
62. Elevators, Dental.
63. Endodontic Paper Point.
64. Endodontic Silver Point.
65. Facebow
66. Fiber Optic Dental Light.
67. Fixture/appliance dental drill.
68. Gingiva bleaching protector.
69. Gingival Fluid Measurer.
70. Gingival retraction cord, non- medicated.
71. Gingival retraction kit.
72. Gingival retraction solution.
73. Gold or Stainless Steel Cusp.
74. Heat Source for Bleaching Teeth.
75. Impression Tube.
76. Intraoral Dental Wax.
77. Jaw Tracking Device.
78. Lead-Lined Position Indicator.
79. Manual Toothbrush.
80. Massaging Pick or Tip for Oral Hygiene.
81. Mouth guard, preformed.
82. Non-medicated dental surgical procedure kit
83. Oral Cavity Abrasive Polishing Agent.
84. Oral wound dressing.

85. OTC Denture Cushion or Pad.
86. Pantograph.
87. Toothbrush, powdered
88. Toothbrush, non-powdered
89. Preformed Impression Tray.
90. Preformed Tooth Positioner.
91. Prophylaxis Cup.
92. Resin Applicator.
93. Resin Impression Tray Material.
94. Rubber Dam and Accessories.
95. Saliva Absorber.
96. Silicate Protector.
97. Teething Ring.
98. Tooth preservation kit.
99. Warm-bonded endodontic obturation system.

8. Ear, Nose, And Throat Devices

1. Acoustic Chamber for Audiometric Testing.
2. Air Caloric Stimulator
3. Water Caloric Stimulator
4. Anti-stammering Device.
5. Audiometer Calibration Set.
6. Bone Particle Collector.
7. Ear irrigation Syringe
8. Ear, Nose, and Throat Drug Administration Device.
9. Ear, Nose, and Throat Examination unit
10. Ear, Nose, and Throat Treatment Unit.
11. Ear, Nose, and Throat Fiberoptic Light Source and Carrier.
12. Non-sterile Ear, Nose, and Throat Manual Surgical Instrument.
13. Earphone Cushion for Audiometric Testing.
14. Epistaxis Balloon.
15. External Nasal Splint.
16. Intranasal Splint.

17. Mirror; ENT,
18. Headband mirror,
19. ophthalmic mirror,
20. mouth mirror
21. General & plastic surgery mirror.
22. Nasal aspirator, manual.
23. Nasal Dilator.
24. Powered Nasal Irrigator.
25. ENT SET.
26. Short Increment Sensitivity Index (Sisi) Adapter.
27. Toynbee Diagnostic Tube.
28. Hearing aid accessories:- batteries,
29. Hearing aid accessories, Cleaning tools
30. Hearing aid accessories, Assistive listening devices
31. Hearing aid accessories, Hearing aid dryer/dehumidifier
32. Hearing aid accessories, Bluetooth streaming devices
33. Hearing aid accessories, Carrying case

9. Gastroenterology-Urology Devices

1. Compression dressing.
2. Non-sterile Enema Kit.
3. Gastroenterology-Urology Accessories to a Biopsy Instrument.
4. Gastroenterology-Urology Evacuator.
5. Hernia Support.
6. Interlocking Urethral Sound.
7. Ostomy Pouch and Accessories.
8. Protective Garment for Incontinence.
9. Rectal Dilator.
10. Revolving stool.
11. Ribdam.
12. Stomach PH Electrode.
13. Urethral Dilator.
14. Urine Collector (urine bags)
15. Urological Clamp.

16. Urological Table and Accessories.

10. General And Plastic Surgery Devices

1. Air-Handling Apparatus Accessory.
2. Non-sterile Amputation Set.
3. Bed sheets for hospital beds.
4. Dilation & Curettage Instrument Set.
5. Non-sterile Dissecting Set.
6. Drape Adhesive.
7. Dressing Instrument Set.
8. Elastic Adhesive Bandage.
9. External Aesthetic Restoration Prosthesis.
10. External Facial Fracture Fixation Appliance.
11. External Prosthesis Adhesive.
12. Eye Pad.
13. Manually operated Keratome
14. Non-sterile Crescent Knife.
15. Refractokeratometer
16. Head Light.
17. Hooks.
18. Hydrophilic Wound Dressing.
19. Inflatable Extremity Splint.
20. Non-sterile Mastectomy Instrument Set.
21. Non-sterile Micro Neuro Surgery Set.
22. Non-sterile Midwifery Instrument Set.
23. Non-sterile Minor Basic Surgery Set.
24. Non-sterile MVA Instrument Kit.
25. Needle-Type Epilator.
26. Non-inflatable Extremity Splint.
27. Nonpneumatic Tourniquet.
28. Nonpowered, Single Patient, Portable Suction Apparatus.
29. Non-resorbable Gauze/Sponge for External Use.
30. Occlusive Wound Dressing.

31. Operating Tables
32. Operating Chairs
33. Organ Bag.
34. Pliers.
35. Pneumatic Tourniquet.
36. Reusable surgical instrument for transient use supplied as non-sterile (not for use in respiratory, cardiac or neurological system).
37. Silicone Sheeting.
38. Skin Marker.
39. Speculum
40. Reusable suction unit bottle
41. Blood sampling suction unit
42. Suits for patients,
43. Surgical Camera
44. Surgical Microscope
45. Suture Retention Device.
46. Towels.
47. Tweezer-Type Epilator.

11. General Hospital And Personal Use Devices

1. Absorbent cotton roll.
2. Absorbent Cotton Wool.
3. Absorbent gauze roll.
4. Non-sterile Absorbent Tipped Applicator
5. Plaster of Paris Bandages.
6. Elastic Adhesive Bandages.
7. Cotton Crepe Bandages.
8. Soft Roll (Cast Padding).
9. Glutral Disinfectant Solution for disinfecting surgical instruments.
10. Povidone – Iodine Solution.
11. Urine Collection Bags.
12. Mucus Extractor.
13. Trolley Cover.

14. Caps.
15. Shoe Covers.
16. Leg Covers.
17. Mattress Cover.
18. Wood's Fluorescent Lamp.
19. General culture media (non-selective)
20. Powered Medical Examination Light.
21. Non-powered medical examination light
22. Administration sets for gravity infusion.
23. Apgar Timer.
24. Autoclave Indicator Tape.
25. Baby crib with matters mobile/fixed.
26. Battery-Powered Medical Examination Light.
27. Bed Board.
28. Bed pan.
29. Bed side lockers,
30. Body Waste Receptacle.
31. Bowls, lotion.
32. Burn Sheet.
33. Cast Cover.
34. Cerclage Wire.
35. Clinical Color Change Thermometer.
36. Cotton ball.
37. Cotton roll, general-purpose.
38. Thermometer Cover
39. Doctor chair.
40. Doctor's coat.
41. Dressing and sterilization drums.
42. Dressing jars with cover.
43. Elastic Bandage.
44. Enemacan (irrigator) set.
45. Examination bed.

46. Examination Gown.
47. Gloves, examination.
48. Hammer
49. Hand-Carried Stretcher.
50. Hospital beds, general-purpose, manually- operated .
51. Hospital beds, hydraulically-powered
52. Hospital beds, electrically-powered
53. Hospital Washing machine.
54. Ice Bag.
55. Ice-pack Freezers.
56. Immobilizer; wrist,
57. Immobilizer, ankle,
58. Immobilizer, elbow,
59. Immobilizer, arm,
60. Immobilizer, knee,
61. Immobilizer, shoulder,
62. Immobilizer, whole body.
63. Infusion set accessory, caps
64. Infusion set accessory, Connectors
65. Infusion set accessory, Adaptors
66. Infusion stopcock
67. Gravity pour infusion administration set without needle
68. Set for nutrition infusion
69. Infusion Stand.
70. Irrigating Syringe.
71. Lamb Feeding Nipple.
72. Lamps.
73. Lice Removal Kit.
74. Liquid Bandage.
75. Liquid Crystal Vein Locator.
76. Liquid Medication Dispenser.
77. Mattress Cover For Medical Purposes.

78. Medical Absorbent Fiber.
79. Skin approximate Tape
80. Surgical tape to temporarily hold organs
81. Adhesive Bandage.
82. Medical Chair
83. Medical Table.
84. Medical Disposable Bedding.
85. Non-sterile Medical Disposable Scissors.
86. Medical folding screens.
87. Medical Insole.
88. Medical Support Stocking, For General Purpose.
89. Neonatal Eye Pad.
90. Nipple Shield.
91. Non-Ac-Powered Patient Lift
92. Patient lifts and transfer aids
93. Patient transport chairs
94. Patient stretchers
95. Nonpowered Flotation Therapy Mattress.
96. Operation Light.
97. Operation Table.
98. Patient restraint.
99. Pediatric Position Holder.
100. Shoe cover, Personal protective devices for medical use
101. Eye google, Personal protective devices for medical use
102. Examination gown, Personal protective devices for medical use
103. face shield, Personal protective devices for medical use
104. resuscitation shield, Personal protective devices for medical use
105. manual pressure Infusor for I.V. Bag.
106. Protective Restraint.
107. Refrigerator Tag.
108. Ring Cutter.
109. Scalpel handles.

110. Sharp Container.
111. Skin Pressure Protectors.
112. POB Bandage.
113. Splint set.
114. Stand-On Patient Scale.
115. Sterilization drum stand.
116. General examination chair.
117. Surgical light mobile.
118. Temperature Regulated Water Mattress.
119. Therapeutic Medical Binder.
120. Therapeutic Scrotal Support.
121. Thermal papers.
122. Tongue Depressor.
123. Tourniquet strap.
124. Non-active automatic traction unit
125. Non-active automatic intermittent traction unit
126. Non-active simplified traction unit
127. Instrument Trolley,
128. Dressing Trolley,
129. Medicine Trolley,
130. Stretcher Trolley
131. Medicine envelope.
132. Patient Screen.
133. Stretcher Foldable.
134. Foot Step.
135. Kick Bucket.
136. Examination Couch.
137. Overbed Table.
138. ICU Bed.
139. Ultralow freezers.
140. Uterine Aspiration Set.
141. Vaccine refrigerators and ice-pack freezers.

142. Vaccine Transport Boxes.
143. Vein Stabilizer.
144. Washers for Body Waste Receptacles.
145. Patient weight scale, adult,
146. Patient weight scale, pediatric

12. Neurological Devices

1. Ataxiagraph.
2. Clip Forming/Cutting Instrument.
3. Clip Rack.
4. Clip Removal Instrument.
5. Cranial Drill Handpiece (Brace).
6. Cranioplasty Material Forming Instrument.
7. Electroencephalograph Electrode
8. Electroencephalograph Lead Tester.
9. Electroencephalograph Test Signal Generator.
10. Evoked Photon Image Capture Device.
11. Leukotome.
12. Microsurgical Instrument.
13. Neurosurgical Chair.
14. Neurosurgical Headrests.
15. Percussion hammer, palpatory.
16. Percussor.
17. Pinwheel.
18. Skull Plate Anvil.
19. Skull Punch.
20. Skull plate Screwdriver.
21. Tuning Fork.
22. Two-Point Discriminator.
23. Ultrasonic Scanner Calibration Test Block.

13. Obstetrical and Gynecological Devices

1. Amniotic Fluid Sampler (Amniocentesis Tray).

2. Assisted Reproductive Microscopes And Microscope Accessories.
3. Couch, Gynecology
4. Delivery beds
5. Fetal Stethoscope.
6. Heavy Duty Rubber gloves
7. Non-powered Breast Pump.
8. Unscented Menstrual Pad.
9. Vaginal speculum
10. Viscometer for Cervical Mucus.

14. Ophthalmic Devices

1. Adaptometer (Biophotometer).
2. Amsler Grid.
3. Anomaloscope.
4. Bagolini Lens.
5. Eye Drapes
6. Chart, eye;, colour discrimination
7. Closed-Circuit Television Reading System.
8. Color Vision Plate Illuminator.
9. Color Vision Tester.
10. Contact Lens Inserter/Remover.
11. Corneal Inlay Inserter Handle.
12. Corneal Radius Measuring Device.
13. Diagnostic Condensing Lens.
14. Diagnostic Hruby Fundus Lens.
15. Distometer.
16. Electronic Vision Aid.
17. Euthyscope.
18. Exophthalmometer.
19. Eye Charts
20. Flexible Diagnostic Fresnel Lens.
21. Fornixscope.
22. Fusion and Stereoscopic Target.

23. Gonioscopic Prism.
24. Haidinger Brush.
25. Haploscope.
26. Headband Mirror.
27. Image Intensification Vision Aid.
28. Intraocular Lens Guide.
29. Keratoscope.
30. Lens Measuring Instrument.
31. Low-Power Binocular Loupe.
32. Low-Vision Magnifier.
33. Low-Vision Telescope.
34. Maddox Lens.
35. Magnifying Spectacles.
36. Manual Refractor.
37. Maxwell Spot.
38. Nasolacrimal Compression Device.
39. Nearpoint Ruler.
40. Nystagmus Tape.
41. Operating Headlamp.
42. Ophthalmic Bar Prism.
43. Ophthalmic Bar Reader.
44. Ophthalmic Chair.
45. Ophthalmic Contact Lens Radius Measuring Device.
46. Ophthalmic Eye Shield.
47. Ophthalmic Fresnel Prism.
48. Ophthalmic Instrument Stand.
49. Ophthalmic Instrument Table.
50. Ophthalmic Knife Test Drum.
51. Ophthalmic Lens Gauge.
52. Ophthalmic Operating Spectacles (Loupes).
53. Ophthalmic Prism Reader.
54. Ophthalmic Projector.

55. Ophthalmic Refractometer.
56. Ophthalmic Rotary Prism.
57. Ophthalmic surgical instrument (non- sterile)
58. Ophthalmic Surgical Marker.
59. Ophthalmic Trial Lens Clip.
60. Ophthalmic Trial Lens Frame.
61. Ophthalmic Trial Lens Set.
62. Ophthalmoscope
63. Optical Vision Aid.
64. Optokinetic Drum.
65. Non-sterile Ophthalmic Blades / Knives
66. Perimeter.
67. Permanent Magnet.
68. Prescription Spectacle Lens.
69. Pupillograph.
70. Pupillometer.
71. Retinal camera
72. Retinoscope.
73. Schirmer Strip.
74. Simulatan (Including Crossed Cylinder).
75. Skiascopic Rack.
76. Spectacle Dissociation Test System.
77. Spectacle Frame.
78. Stereopsis Measuring Instrument.
79. Stereoscope.
80. Sunglasses (Nonprescription).
81. Tangent Screen (Campimeter).
82. Tonometer Sterilizer.
83. Transilluminator.
84. Visual Acuity Chart

15. Orthopedic Devices

1. Calipers for Clinical Use.

2. Cast Component.
3. Cast Removal Instrument.
4. Cement Dispenser.
5. Cement Mixer for Clinical Use.
6. Cement Monomer Vapor Evacuator.
7. Cement Ventilation Tube.
8. Corrective back brace
9. Depth Gauge for Clinical Use.
10. Goniometer.
11. Leather components of orthopaedic appliances
12. Manual Cast Application and Removal Instrument.
13. Noninvasive Traction Component.
14. Nonpowered Dynamometer.
15. Nonpowered Goniometer.
16. Nonpowered Orthopedic Traction Apparatus
17. Orthopedic Surgical Instruments
18. Protractor for Clinical Use.
19. Template for Clinical Use.

16. Physical Medical Devices

1. Arm Sling Pouch
2. Patient Handling Patient Specific Sling - Lift, patient transfer, sling/harness/strap
3. Sling bandage
4. Walkers
5. Crutches
6. Cervical Collar
7. Leg Support
8. Walking Stick
9. Philadelphia Collar
10. Chest Support
11. Skin Traction Kit
12. Surgical Splint

13. Crepe Bandage
14. Elastic Bandage
15. POP Bandage
16. Gauze sponge
17. X-ray detectable gauze
18. Non-woven gauze
19. Cane, and Walker Tips and Pads.
20. Chilling Unit.
21. Cold Pack.
22. Congenital Hip Dislocation Abduction Splint.
23. Daily Activity Assist Device.
24. Daily Activity Assist Device.
25. Denis Brown Splint.
26. Exercise Component.
27. External Limb Orthotic Component.
28. External Limb Prosthetic Component.
29. Flotation Cushion.
30. Force-Measuring Platform.
31. Hot or Cold Disposable Pack.
32. Intermittent Pressure Measurement System.
33. Orthosis; Limb, shoulder, elbow, wrist, hand, hip, knee, ankle, foot, finger, footwear insert, spine
34. Manual Patient Rotation Bed.
35. Mechanical Chair.
36. Mechanical Table.
37. Mechanical Walker.
38. Moist Heat Pack.
39. Non powered Lower Extremity Pressure Wrap.
40. Nonpowered Sitz Bath.
41. Plinth.
42. Powered Exercise Equipment.
43. Powered Finger Exerciser.

44. Powered Heating Unit.
45. Powered Table.
46. Pressure relieving mattress/ pads
47. Pressure-Applying Device.
48. Ptosis Crutch.
49. Prosthetic and Orthotic Accessory. Orthotic footwear
50. Self-exam pad, breast
51. Therapeutic Massager.
52. Therapeutic Vibrator.
53. Traction Accessory.
54. Truncal Orthosis.
55. Walking aids; crutch, frame, table, and stick Crutch.
56. Wheel chairs
57. Wheelchair, attendant/occupant driven,
58. Wheelchair, attendant/occupant driven,
59. Wheelchair, attendant/occupant driven, rear wheels, non-collapsible, etc.
60. Wheelchair Accessory.
61. Wheelchair Component.
62. Wheelchair Platform Scale.
63. Wheelchairs (manual)
64. Wheelchair (powered)

17. **Radiology Devices**

1. Diagnostic X-Ray Tube Mount.
2. Light Beam Patient Position Indicator.
3. Operating room surgical light
4. Light; headlamp, headlight, headband
5. Manual Radionuclide Applicator System.
6. Medical display screen; LCD monitor
7. Medical Image Communications Device.
8. Medical Image Storage Device.

9. Nuclear Anthropomorphic Phantom.
10. Nuclear Flood Source Phantom.
11. Nuclear Scanning Bed.
12. Nuclear Sealed Calibration Source.
13. Nuclear Uptake Probe.
14. Personnel Protective Shield.
15. Radiation shield; apron, bib, blanket, eye, thyroid
16. Radiographic Anthropomorphic Phantom.
17. Radiographic Film Illuminator.
18. Radiographic Film Marking System.
19. Radiographic Grid.
20. Radiographic Head Holder.
21. Radiographic Intensifying Screen.
22. Radiologic Patient Cradle.
23. Radionuclide Test Pattern Phantom.
24. Software, image viewing and recording only
25. Wall-Mounted Radiographic Cassette Holder,
26. X-ray viewer box

8.2 Annex II: Application Form for Registration of Low Risk Medical Devices

The applicant for registration of low risk medical device is required to provide the completed templates 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 Low risk medical Device **Medicine Registration and Licensing Directorate** **Food and Drug Authority of Ethiopia**			
S. No.	**Title**	**To be completed by the applicant**	**Page number and/or Annex**
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	**Devices category:**		
6	**Devices list:**		
7	**Device Safety and Performance Conformity Assessment**		
8	**List of Documents Attached with This Application** (Indicate page number, location in the dossier, and annexes, as applicable)		
9	**Declaration by Applicant**		

	I, the undersigned, certify that all the information in the accompanying documentation concerning an application for registration of the medical device category mentioned below is correct and true, and reflects the total information available. Device Category: _____ 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: _____

8.3 Annex III: Medical device Categories

1. Hematology, Pathology and microbiology Devices
2. Medical Laboratory general use devices :-
3. In Vitro Fertilization Media
4. Anesthesiology Devices
5. Cardiovascular Devices
6. Sanitary devices
7. Dental Devices
8. Ear, Nose, And Throat Devices
9. Gastroenterology-Urology Devices
10. General And Plastic Surgery Devices
11. General Hospital And Personal Use Devices
12. Neurological Devices
13. Obstetrical and Gynecological Devices
14. Ophthalmic Devices
15. Orthopedic Devices
16. Physical Medical Devices
17. Radiology Devices

8.4 Annex IV: Format for listing of low risk medical devices for premarket notification application

Products	**Product's details**
Product 1	
Name of the Product 1 (common name, brand name, trade name)	
Model/Serial No.	
Device intended use	
Device description	
Device classification	
Reason for classification (classification rule number)	
Shelf life (if applicable)	
Product 1 Specifications	**Values**
a) Specification 1	
b) Specification 2	
c) Specification 3	
d) Specification …….n	
Product 2	
…….	……
Product ……..n	

Please use this listing format for all devices subject to the same application and submit with a single listing table.