የኢትዮጵያ ምግብ እና መድኃኒት ባለስልጣን

Ethiopian Food and Drug Authority

መመሪያ ቁጥር 1010/2016

የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያ አምራቾች ቁጥጥር መመሪያ

Directive Number 1010/2024

Low-Risk Medical device Manufacturers Control Directive

ሀምሌ 2016

አዲስ አበባ፣ ኢትዮጵያ

July 2024

Addis Ababa, Ethiopia

በአገር ውስጥ የሚመረቱ የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያ ጥራት፣ ደህንነት እና ውጤታማነት ማረጋገጥ አስፈላጊ በመሆኑ፣ በምርቶቹ ደኅንነት፣ የጥራት እና የውጤታማነት መስፈርቶች መሠረት እንዲሠሩ የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያ አምራቾች በመቆጣጠር የሕዝብ ጤናን መጠበቅ አስፈላጊ በመሆኑ፣ የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያ ማምረቻ፣ ፣ባለሙያ፣ የማምረቻ ቦታ እና የማምረቻ ግብአቶች የሚመለከቱ መስፈርቶች መሟላታቸውን በማረጋገጥ ግልጽነትና ተጠያቂነት ያለው የብቃት ማረጋገጫ አሰጣጥ ስረአት መዘርጋት በማስፈለጉ፣ በዚህ መመሪያ የተደነገጉ የቁጥጥር መስፈርቶች ተላልፈው በሚገኙ የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያ አምራቾች ላይ ተገቢውን ህጋዊ እርምጃ መውሰድ አስፈላጊ በመሆኑ፣ “የኢትዮጵያ ምግብ እና መድኃኒት ቁጥጥር ባለሥልጣን በምግብና መድኃኒት አስተዳደር አዋጅ ቁጥር 1112/2011 አንቀጽ 71(2) መሰረት ይህን መመሪያ አዉጥቷል።”	**WHEREAS**, it is necessary to ensure quality, safety and effectiveness of locally manufactured low-risk medical device; **WHEREAS,** it is necessary to protect public health through regulation of low-risk medical device manufacturers to operate in accordance with safety, quality and effectiveness requirements of the products; **WHEREAS**, the need to ensure transparency and accountability for regulatory provisions regarding the layout, design, location, construction, and maintenance of the premise; installation of device and utilities, personnel of low-risk medical device manufacturer are important factor in the resulting safety, quality and effectiveness of products; **WHEREAS,** it is necessary to take appropriate legal action against manufacturers of low-risk medical device that violates regulatory requirements led down in this Directive; **NOW, THEREFORE**; the Ethiopian Food and Drug Authority issued this directive in accordance with Article 71 (2) of the Food and Medicine Adminis tration Proclamation No. 1112/2019
ክፍል አንድ **ጠቅላላ**	**PART ONE** **GENERAL**
1. አጭር ርዕስ ይህ መመሪያ “የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያ አምራቾች ቁጥጥር	**1. Short title** This directive may be cited as the "Low-Risk Medical Device Manufacturers control Directive

መመሪያ ቁጥር 1010/2016” ተብሎ ሊጠቀስ ይችላል፡፡	Number 1010/2024".
2. ትርጓሜ **የቃሉ አገባብ ሌላ ትርጉም የሚያሰጠው ካልሆነ በስተቀር በዚህ መመሪያ ዉስጥ፡-**	**2. Definition** Unless the context otherwise requires In this Directive
1) **“አዋጅ”** ማለት የምግብና መድኃኒት አስተዳደር አዋጅ ቁጥር 1112/2011 ነው፤	1) **"Proclamation"** means Food and Medicine Administration Proclamation No. 1112/2019;
2) **“የስጋት ደረጃው ዝቅተኛ የሆነ የህክምና መሳሪያ”** ማለት በዚህ መመሪያ እዝል 1 እና እዝል 2 ላይ በተቀመጡት የምደባ ደንቦች መሰረት እና ዝርዝራቸው እዝል 5 እና እዝል 6 ውስጥ የተጠቀሱት በክፍል 1 ወይም በክፍል ሀ ዉስጥ የተመደቡ የህክምና መሳሪያዎች ማለት ነው።	2) **“Low-risk medical device"** means those medical devices classified as class I or class A based on the classification rules attached as Annex I and Annex II of this directive and the list of which are provided in the Annex V and Annex VI respectively.
3) **“አምራች”** ማለት የስጋት ደረጃቸው ዝቅተኛ የሆኑ የሕክምና መሣሪያዎችን በማምረት ላይ የሚሳተፍ ማንኛውም ተቋም፣ መገልገያ ቦታ፣ ወይም ድርጅት ነው።	3). **“Manufacturer”** means any establishment, facility, firm or organization involved in the manufacturing of low risk medical devices
4) **“የቀዶ ጥገና መሳሪያ”** ማለት በተለያዩ የቀዶ ጥገና ሂደቶች ውስጥ ጥቅም ላይ እንዲውል የታሰበ ወይም እንደገና ጥቅም ላይ ሊውል የማይችል መሳሪያ ነው።	4**). “Surgical Instrument”** means either reusable or disposable device, intended to be used in various surgical procedures.
5) **“ለቀዶ ጥገና አገልግሎት የሚዉል የህክምና መሳሪያ”** ማለት በቀዶ ጥገና	5) **“Surgically invasive device”** means a device that penetrates inside the body

ወቅት የሰዉነት ቆዳን በማለፍ ወደ ሰዉነት ክፍል ዉስጥ የሚገባ የህክምና መሳሪያ ነዉ፡፡	through the surface of the body with the aid of or during a surgical operation.
6) **“ባለስልጣን”** ማለት የኢትዮጵያ የምግብና መድኃኒት ባለስልጣን ነው፤	6) "**Authority**" means the Ethiopian Food and Drug Authority
7) በአዋጁ ትርጉም የተሰጣቸውና በዚህ መመሪያ ውስጥ ጥቅም ላይ የዋሉ ቃላትና ሐረጋት በአዋጁ አንቀፅ 2 የተሰጣቸው ትርጉም ይኖራቸዋል፤	7) Definitions provided under Article 2 of the Proclamation shall also be applicable to this Directive.
8) ማንኛውም በወንድ ጾታ የተገለጸ አገላለጽ ሴትንም ይጨምራል፡	8) Any expression in the masculine gender shall also apply to the feminine gender.
3. የተፈፃሚነት ወሰን 1) ይህ መመሪያ የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያ አምራች ተቋማት ላይ ተፈፃሚ ይሆናል፡፡ 2) የዚህ አንቀጽ ንኡስ-አንቀጽ (1) ድንጋጌ ቢኖርም ይህ መመሪያ ከበሽታ አምጪ ተሕዋስያን ነጻ የሆኑ እና የስጋት ደረጃው ዝቅተኛ የሆነ የህክምና መሳሪያ ለመለካት የሚያገለግሉ ህክምና መሣሪያዎች አምራቾች ላይ ተፈጻሚ አይሆንም፡፡	**3. Scope of application** 1) This directive shall be applicable on manufacturers of low-risk medical devices. 2) Notwithstanding the provisions of sub article (1) of this article, this directive does not apply to manufacturers of medical devices used to measure pathogen-free and low-risk medical devices.

ክፍል ሁለት የብቃት ማረጋገጫ የምስክር ወረቀት	Part Two Certificate of competency
4. የብቃት ማረጋገጫ ምስክር ወረቀት አሰጣጥ	4. Issuance of Certificate of Competence
1) ማንኛውም ሰው የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያዎችን በማምረት ስራ ላይ ከመሰማራቱ አስቀድሞ ከባለስልጣኑ የብቃት ማረጋገጫ ምስክር ወረቀት ማግኘት አለበት፡፡	1) Any person shall obtain a certificate of competency from the Authority before starting manufacturing of low-risk medical device.
2) ማንኛውም ሰው የብቃት ማረጋገጫ ምስክር ወረቀት ለማግኘት ከዚህ በታች የተዘረዘሩትን ሁኔታዎች ማሟላት አለበት፡፡ ሀ. አስፈላጊውን የአገልግሎት ክፍያ መክፈል ለ. በባለስልጣኑ በተዘጋጀው ቅጽ መሰረት በኤሌክትሮኒክ የቁጥጥር መረጃ ስርዓት የሚከተሉትን ዋና ቅጂ ሰነዶች እና ማመልከቻውን መልቶ ማቅረብ፣ ሐ. የምርት እና የጥራት ማረጋገጫ ወይም የጥራት ቁጥጥር ክፍል ኃላፊ የትምህርት ማስረጃ መ. በምርት ክፍል ሀላፊ እና በድርጅቱ መካከል እንዲሁም በጥራት ማረጋገጫ ወይም የጥራት ቁጥጥር ሀላፊ እና በድርጅቱ መካከል ያለው የቅጥር ስምምነት ወይም ውል ሠ. የምርት እና የጥራት ማረጋገጫ ወይም የጥራት ቁጥጥር	2) Any person who requires a certificate of competency to manufacture any low-risk medical device shall fulfill the following requirements: a. Pay the appropriate service fee; b. Complete the online application and attach the following original documents through electronic regulatory information system. c. Certificates for the proof of educational level of the production and Quality assurance or quality control manager d. Employment agreement or contract between the production manager and the organization as well as the Quality assurance or quality control manager and the organization e. Work experience and resignation letter of the production manager and Quality assurance or Quality Control manager from the former employer.

ክፍል ኃላፊ ይሰራበት ከነበረ ድርጅት የተሰጠ እና የለቀቀ መሆኑን የሚገልፅ የስራ ልምድ ደብዳቤ ረ. ከዚህ በፊት የምርት ክፍል ክፍል ኃላፊነት እና በጥራት ማረጋገጫ ወይም የጥራት ቁጥጥር ሀላፊነት ኃላፊነት ይሰራ ከነበረ ይህን የሚያረጋግጥ ማስረጃ ከጤና ተቆጣጣሪ አካል የሚያቀርብ ሰ. በምርት ክፍል ሀላፊ እና በጥራት ማረጋገጫ ወይም የጥራት ቁጥጥር ሀላፊ የሙያ ፈቃድ ሰርተፊኬት ሸ. የምርት ክፍል ኃላፊ የፓስፖርት መጠን ያለው ጉርድ ፎቶ ቀ. በውልና ማስረጃ የተረጋገጠ የቤት ኪራይ ውል ወይም የቤት ካርታ ወይም የይዞታ ማረጋገጫ በ. በዚህ አንቀፅ ንዑስ አንቀፅ (ቀ) የተቀመጠው እንደተጠበቀ ሆኖ የመንግስት ቤቶች ሲሆን ከነዚህ ተቋማት በሚቀርብ ደብዳቤ የሚስተናገዱ ይሆናል፡፡ በተጨማሪም የእምነት ተቋማት እና እና ሌሎች ህጋዊ ሰውነት የተሰጣቸው አካላት ጋር የመፈጸም ውል ተቀባይነት ይኖረዋል፡፡ ተ. ኃላፊነቱ የግል ማህበር ሲሆን በውል እና ማስረጃ የተረጋገጠ የመመስረቻ ፅሑፍ እና መተዳደርያ ደንብ ወይም ከንግድ ቢሮ ወይም ከሚመለከተው የመንግስት አካል የተረጋገጠ የመመስረቻ ፅሑፍ እና መተዳደሪያ ደንብ ቸ. የግብር ከፋይ መለያ ቁጥር ኀ. ጅምር ህንፃ ከሆነ ህንፃው	f. Proof letter granted by health regulatory body for previously serving as a production manager and Quality assurance or Quality Control manager g. Valid Professional license of the production manager and Quality assurance or Quality Control manager h. Passport size photo of the production manager i. House rent contract or ownership certificate or leasehold title certificate authenticated by Document Authentication and Registration Agency. j. Without prejudice to this article sub-article (i) of this article, for government houses, supporting letter from this organization will be acceptable. Moreover, any agreement between Religious houses and other entities that have legal rights and grounds to rent houses are acceptable. k. If the applicant is Private Limited Company establishment document and administrative regulation attested by Document Authentication and Registration Agency l. Taxpayer identification numbers. m. For partially completed building, provide authorization for use of the building for service from responsible government body

ለአገልግሎት እንደሚውል ከሚመለከተው አካል ፈቃድ ማቅረብ	
3) በኤሌክትሮኒክ የቁጥጥር መረጃ ስርዓት የቀረበውን ማመልከቻ ተገምግሞ ያልተሟላ ከሆነ አመልካቹ እንዲያስተካክል ሲመለስለት በድጋሚ አስተካክሎ ሊያቀርብ ይችላል፡፡	3) If the application submitted via electronic regulatory information system does not fulfill the requirements and retuned back for the applicant for correction, he/she can re-apply after correction.
4) የቀረበው ማመልከቻ ተሟልቶ ከቀረበ ድርጅቱ ከሁለት በማያንሱ የተቆጣጣሪ ቡድን በአካል በመገኘት እንዲታይ ይደረጋል፡፡	4) If the application submitted fulfils the requirements, the organization will be inspected on-site by a team having at least two appropriate inspectors.
5) በተቆጣጣሪዎች የተሞላዉ የኢንስፔክሽን ቅጽ ከተቀመጡት መመዘኛዎች አኳያ በባለሥልጣኑ ይገመገማል፡፡	5) The Authority will evaluate the dully filled inspection checklist by inspectors against the set requirements.
6) አመልካቹ መስፈርቶቹን ሳያሟላ ሲቀር ውሳኔው በጽሁፍ በቁጥጥር ቡድኑ ወይም እንደ አስፈላጊነቱ በስራ ክፍል ደረጃ እንዲያውቀው ይደረጋል፡፡	6)Where the requirements have not been met, the applicant shall be informed about the decision in writings by inspection team or inspection directorate as appropriate
7) በዚህ አንቀፅ ንዑስ አንቀፅ (4) የተቀመጠው እንደተጠበቀ ሆኖ አመልካቹ ማሟላት ያለበትን ሁኔታዎች በኤሌክትሮኒክ የቁጥጥር መረጃ ስርዓት እንዲያሟላ ተገልጸለት ድርጅቱ ተገቢዉን ክፍያ ከፍሎ በድጋሜ እስከ ሁለት ጊዜ ሊታይለት ይችላል፡፡	7) Notwithstanding sub-Article (4) of this Article, applicants who do not fulfill the requirements notified through electronic regulatory information system, two-round re-inspection may be carried out after the appropriate service fee payment.

8) በዚህ አንቀፅ ንዑስ አንቀፅ (7) የተቀመጠው እንደተጠበቀ ሆኖ በድጋሚ እስከ ሁለት ጊዜ ታይቶ የማይሟላ ድርጅት ያቀረበውን ማመልከቻ ውድቅ ይደረጋል፡፡ ነገር ግን እንደ አዲስ ሌላ ቤት ተከራይቶ ሊታይለት ይችላል፡፡	8) Notwithstanding sub-Article (7) of this Article, applicants who do not fulfill the requirements after the conduct of two round inspections, the submitted application shall be rejected. However, the application shall be processed if the applicant rents new houses and apply as new.
9) ቁጥጥር ባደረጉት ተቆጣጣሪዎች የተዘጋጀው የኢንስፔክሽን ሪፖርት በኤሌክትሮኒክ የቁጥጥር መረጃ ስርዓት ውስጥ ተያይዞ ፋይል መሆን አለበት፡፡	9) The inspection reports prepared by the inspectors shall be archived the in electronic regulatory information system.
10) አመልካቹ ማሟላት የሚገባዉን መስፈርት ማሟላቱ ከተረጋገጠ ባለሥልጣኑ በአምስት የስራ ቀናት ዉስጥ የብቃት ማረጋገጫ ምስክር ወረቀቱን ይሰጠዋል፡፡	10) Once requirements are met, the Authority shall issue certificate of competence within five working days.
11) በዚህ አንቀፅ ንዑስ አንቀፅ (10) የተቀመጠው እንደተጠበቀ ሆኖ አሳማኝ የሆነ ሁኔታ ሲያጋጥም አመልካቹን በማሳወቅ የብቃት ማረጋገጫውን በተቀመጠው የጊዜ ገደብ ላይሰጠው ይችላል፡፡	11)Without prejudice to sub-article (10) of this article, in the event of compelling circumstances, by notifying the applicant the certificate of competence may not be issued within the stipulated time.
12) የአመልካቹ የማመልከቻ ሰነድ የሚጠበቅበትን መስፈርት የማያሟላ ሆኖ ሲገኝ ማመልከቻዉ ለአመልካቹ እንዲስተካከል ተመላሽ ይሆንና አመልካቹ የሚጠበቅበትን ካሟላ በኋላ በስድስት ወር ጊዜ ወስጥ እንደገና ማመልከት ይችላል፡፡	12)If the submitted application does not fulfill the requirements and returned back to the applicant for correction, the applicant may resubmit the application after fulfilling the requirements within six months of the requested corrections.,
5. የብቃት ማረጋገጫ ምስክር ወረቀት ይዘት	**5. Content of the Certificate of Competence**

1) በዚህ መመሪያ መሰረት የሚሰጥ ማንኛውም የብቃት ማረጋገጫ ምስክር ወረቀት የሚከተሉትን መረጃዎች መያዝ ይኖርበታል፤ ሀ. የድርጅቱ ስምና አድራሻ፤ ለ. የድርጅቱ ባለቤት ስም፤ ሐ. የድርጅቱን ቴክኒካል ማኔጀር ስምና የሙያ ምዝገባ ፈቃድ ቁጥር፤ መ. የድርጅቱን ማከማቻ ክፍል ስራ አስኪያጅ ስምና የሙያ ምዝገባ ፈቃድ ቁጥር፤ ሠ. የድርጅቱ አይነት፤ ረ. በድርጅቱ የሚሰጥ አገልግሎት አይነት፤ ሰ. ድርጅቱ የሚያስመጣቸው፣ የሚልካቸው ወይም በጅምላ የሚያከፋፍላቸው የምርት ዓይነት፤ ሸ. የብቃት ማረጋገጫው የተሰጠበት ወይም አገልግሎቱ የሚያበቃበት ጊዜ፤ ቀ. የብቃት ማረጋገጫ የሰጠው ስልጣን ያለው ሰው ፊርማ እና የባለስልጣኑ ማህተም፤ በ. የብቃት ማረጋገጫው ቁጥር፤ ተ. የግብር ከፋይ መለያ ቁጥር፤ ቸ. በፈቃዱ ላይ የሚሰፍሩ ዝርዝር ሁኔታዎች ወይም ማሳሰቢያዎች፡፡	1) The content of the certificate of competence shall have the following information a. Name and complete address of the organization b. Full name of the Owner of the organization c. The organization's production manager name and professional license number d. The organization's quality assurance name and professional license number e. Type of organization f. types of low risk medical devicesto be manufactured g. Date of issue and expiry date of the certificate h. Signature of authorized person who issued the certificate of competence and stamp of the Authority i. Certificate number j. Taxpayer identification numbers k. Detail condition and notice on the license
6. የብቃት ማረጋገጫ ምስክር ወረቀት ስለማሳደስ	**6. Renewal of certificate of Competence**

1) ማንኛዉም ሰው የብቃት ማረጋገጫ ምስክር ወረቀቱን በየአመቱ ማሳደስ አለበት፡፡	1) Any manufacturer of low-risk medical device shall renew its certificate of competency annually.
2) በዚህ አንቀጽ ንኡስ-አንቀጽ (1) እንደተጠበቀ ሆኖ በተለያዩ ከአቅም በላይ በሆኑ ምክንያቶች መሆኑን አስፋላጊ ማስረጃዎች በሚቀርቡበት ወቅት ባለስልጣኑ የብቃት ማረጋገጫ ምስክር ወረቀቱን ሊያድስ ይችላል፡፡	2) Without prejudice to sub-article (1) of this article, if any force majours supported by objective evidences, the Certificate of competence may be renewed
3) የብቃት ማረጋገጫ ምስክር ወረቀት ለማሳደስ የተሰጠው የአገልግሎት ጊዜ ከማብቃቱ ሶስት ወር ሲቀረው ጀምሮ ማመልከት ይችላል፡፡	3) To renew certificate of competency, the applicant may apply for renewal three months before end of the validity date of the previous certificate.
4) በዚህ አንቀጽ ንኡስ-አንቀጽ (1) መሰረት የብቃት ማረጋገጫ ምስክር ወረቀት ሊታደስ የሚችለዉ ሀ. በዚህ መመሪያ ውስጥ የተቀመጡት መስፈርቶች መሟላታቸውን ሲረጋገጥ; ለ. ቀደም ሲል የተሰጠው የብቃት ማረጋገጫ ያልተቋረጠ, ያልተሰረዘ ወይም በራሱ በድርጅቱ ፈቃድ ያልተመለሰ መሆኑ ሲረጋገጥ; ሐ. አምራቹ የባለሥልጣኑን የቁጥጥር ርምጃዎች እንደ ምርት ከገበያ መሰብሰብ እና ጊዜያቸው ያለፈባቸውን ወይም የተበላሸ ምርቶችን አወጋገድን የሚያከብር መሆኑን ሲረጋገጥ፣ እና መ. የብቃት ማረጋገጫ እድሳት መስፈርቶችን ሲያሟላ	4) In accordance with Sub-article (1) of this article, the certificate of competency shall be renewed upon : a. Confirmation of the fulfillment of the requirements set in this directive; b. Confirmation that the previously issued certificate of competency is not suspended, revoked or not returned by the organization at its own discretion; c. Upon confirmation that the manufacturer has been compliance with the Authority`s regulatory measures such as product recall and disposal of expired or damaged products; and d. The applicant fulfill requirements to

5) የብቃት ማረጋገጫ ለማሳደስ አመልካቹ የሚከተሉትን መስፈርቶች ማሟላት አለበት፡- ሀ. ማመልከቻውን በባለስልጣኑ በተዘጋጀው ቅጽ መሰረት በኤሌክትሮኒክ የቁጥጥር መረጃ ስርዓት ላይ መሙላት ለ. ምንም ለውጥ የለም የሚለው መግለጫ ወይም ከቀደምት የብቃት ማረጋገጫ ምስክር ወረቀት መውጣት ሁኔታዎች የተደረጉ ማጠቃለያ ለውጦችን ወይም የቀረቡት ለውጦች ማጠቃለያ ተቀባይነት ያለው ሆኖ ተገኝቷል ሐ. አስፈላጊውን የአገልግሎት ክፍያ በመክፈል ላይ በቦታው ላይ ምርመራን ማክበር	renewal of certificate of competency 5) In order to renew the qualification certificate, the applicant must meet the following requirements:- a. Fill application online on the Complete the online application and attach the following original documents through electronic regulatory information system. b. Declaration of no change or submit summary changes made from previous conditions of Certificate of Competence issuance or the submitted summary of changes were found acceptable c. Up on payment of the required service fee compliance with onsite inspection
6) የዚህ አንቀፅ ንዑስ አንቀፅ 2 ቢኖርም የምስክር ወረቀቱ ከማለፉ በፊት ያላደሰ ወይም ለማደስ ያላመለከተ አመልካች የብቃት ማረጋገጫ ምስክር ወረቀት ጊዜው ከማለፉ በፊት ለምን እድሳት እንዳልተደረገ አሳማኝ ማስረጃ ካቀረበ በኋላ እድሳቱን ማመልከት ይችላል።	6) Notwithstanding sub-article 2 of this article, an applicant who has not renewed or applied for renewal before the certificate is expired may still apply for the renewal after providing a convincing justification for why the renewal application was not made before the Certificate of Competence is expired. .
7. የአድራሻ፣ የባለቤትነት፣ የባለሙያ፣ የምርት አይነት/የአገልግሎት ዘርፍ	**7. Change of address, ownership,**

ወይም ሌላ ለዉጥ	technical personnel, product type/service type or other change
1) ማንኛውም የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያዎች አምራች ባለስልጣኑን ሳይፈቅድ የብቃት ማረጋገጫ ካገኘበት አድራሻ መቀየር፣የባለቤትነት ለውጥ ማድረግ፣ የምርት ለውጥ ማድረግ፣ አዳዲስ ምርቶች ማምረት፣ ቴክኒክ ባለሙያ ለውጥ ማድረግ ወይም ሌላ መሰል ለወጥ ማድረግ የለበትም፡፡	1) Any low-risk medical device manufacturer shall not changes its authorized address, ownership, product change, product addition, technical professionals or others that might have impact on the medical devices safety, quality and performance; without getting prior authorization from the authority.
2) ማንኛውም የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያዎች አምራች ቀድሞ የተሰጠን የብቃት ማረጋገጫ ይዘትና እና ሁኔታዎች ላይ ማስተካከያ የሚያስከትል ማንኛውም አይነት ለውጥ ሲኖር፣ ማስካከያ የሚያስከትለው ይዘትና ሁኔታ በድጋሚ ለባለስልጣኑ ገቢ መደረግ አለበት፡፡	2) For any change that affects the terms and conditions of the pervious certificate of competency, the affected terms and conditions shall be notified to the authority.
3) ለውጥ ማድረግ የሚፈልግ ድርጅት ማመልከቻውን በኤሌክትሮኒክ የቁጥጥር መረጃ ስርዓት መሰረት ማድረግ አለበት፡፡	3)Any person who wants to make a change shall apply using electronic regulatory information system
8. የብቃት ማረጋገጫ ምስክር ወረቀት	**8. Display of certificate of competency**

የሚቀመጥበት ቦታ	
1) ማንኛውም ሰው የተሰጠውን የብቃት ማረጋገጫ ምስክር ወረቀት ዋናውን በማንኛውም ጊዜ በድርጅቱ ቴክኒክ ሃላፊ ክፍል ሆኖ በሚታይ ቦታ መስቀል አለበት፡፡	a. Any person shall display the original certificate of competence in the production manager office of the organization in a conspicuous place where it can be easily seen.
9. ስለ ምትክ የብቃት ማረጋገጫ ምስክር ወረቀት	**9. Replacement of certificate of competency**
1) ማንኛውም ሰው የተሰጠውን የብቃት ማረጋገጫ ሰረተፊኬት ፈቃድ አውጪው በሰጠው መረጃ ስህተት፣ የተበላሸ ወይም የጠፋበት ከሆነ ምትክ ሊያገኝ የሚችለው ቀጥሎ የተዘረዘሩትን መስፈርቶች ሲያሟላ ይሆናል፣ ሀ. የብቃት ምስክር ወረቀቱ የተበላሸበት ከሆነ፣ የተበላሸዉን የምስክር ወረቀት ሲመልስና አስፈላጊውን የአገልግሎት ክፍያ ሲከፍል፡፡ ለ. የብቃት ማረጋገጫ ምስክር ወረቀቱ የጠፋበት ወይም የተቃጠለበት ከሆነ የምስክር ወረቀቱ የጠፋበት ወይም የተቃጠለበት ስለመሆኑ የሚገልፅ ከፍትህ አካል ማረጋገጫ ሲያመጣና አስፈላጊውን የአገልግሎት ክፍያ ሲከፍል፡፡ ሐ. ፈቃድ አውጪው በሰጠው መረጃ ስህተት ከሆነ የምስክር ወረቀቱ ሲመልስና አስፈላጊውን የአገልግሎት ክፍያ ሲከፍል፡፡	1) Any low-risk medical device manufacturer whose a certificate of competency has a wrong information made by the authority or damaged or lost may request replacement certificate of competency by fulfilling the following information. a. If the certificate of competence is damaged, when the applicant returns it and pay the the required service fee b. If certificate of competence is lost or burnt, when the applicant has provided proof of evidence from justice organ and pay the required service fee c. If wrong information is made on the certificate of competence by the Authority, when the applicat returns it and pay the required service fee
10. የብቃት ማረጋገጫ ምስክር ወረቀት	**10. Return of Certificate of**

ስለ መመለስ	Competency
1) ማንኛውም ሰው የተሰጠው የብቃት ማረጋገጫ ምስክር ወረቀት በተለያየ ምክንያት ለመመለስ ሲፈልግ ስለ ድርጅቱ ሁኔታ እና በስሩ ስለሚገኙ ምርቶች የሚገልፅ የመግለጫ ደብዳቤ ፣ ቀድሞ የተሰጠውን የብቃት ማረጋገጫ ምስክር ወረቀት እና ማመልከቻ ደብዳቤ ማቅረብ አለበት፡፡	1)Where any person wants to return the certificate of competence granted by the Authority due to different reasons, it shall submit letter of declaration that describes status of organization and products available, previously issued certificate of competency and application letter.
2) በዚህ አንቀፅ ንዑስ አንቀፅ (1) የተቀመጠው እንደተጠበቀ ሆኖ ማንኛውም ሰው የብቃት ማረጋገጫ ምስክር ወረቀት መመለስ የሚችለው፡- ሀ. የአግልግሎት ጊዜ ያለፈበት ወይም የተበላሸ ምርት መወገዱ ሲረጋገጥ ለ. ከገበያ መሰብሰብ ያለበት ምርት ካለው መሰብሰቡ ሲረጋገጥ ሐ. ያልተሸጡ ወይም ጥቅም ላይ ያልዋሉ ምርቶች በህጉ መሰረት ለሌላ ተቋም ማስተላለፉ ሲረጋገጥ፤	2) Without prejudice to sub-article (1) of this article, any person shall return when:- a. Confirmed that products that are expired or damaged are disposed b. Confirmed that products decided to recal are recalled c. Confirmed that unsold or unused products have been transferred to another institution in accordance with the law.
3) ድርጅቱን ሳያሳውቅ የቴክኒክ ኃላፊው በስራ ሳይገኝ ቢቀር እና መተካት ሲፈልግ፤ ሀ. ድርጅቱ ባስልጣኑን ያሳውቃል፤ ለ. ባለስልጣኑ ተገቢውን የማረጋገጫ ስራ በማከናወን በ15 ቀን ውስጥ ምትክ የብቃት ማረጋገጫ ምስክር ወረቀት ለደረጅቱ ሊሰጥ ይችላል፤ ይህንንም ለሚመለከተው አካላትም ያሳውቃል፡፡	3)When the technical manager is absent from his/her work without announcing to the employer and the organization wants to replace; a) the organization shall notify the Authority b) After doing required verification, the Authority shall issue replacement certificate of competence to the organization within 15 days and by doing appropriate inspection and the same shall

4) የቴክኒክ ኃላፊው ሳያውቅ ድርጅቱ ለባለስልጣኑ ሳያሳውቅ ስራ ቢያቆም፤ ሀ. የቴክኒክ ኃላፊው ለባለስልጣኑ ያሳውቃል ለ. ባለስልጣኑ እንደ አስፋላጊነቱ የንግድና ኢንዱስትሪ፤ ገቢዎችና ግምሩክ መረጃዎች በማጣራት፤ ኢንስፔክሽን በመስራት እና ሌሎች የማረጋገጫ ስራዎች በማከናወን ይህንንም ለሚመለከተው አካላት ያሳውቃል።	notify to concerned bodies. 4)When the organization ceases its operation without knowledge of the technical manager and the Authority; a. The technical manager shall notify the Authority b. As appropriate, the Authority may verify information from Trade and Industry, Revenue and Custom, and conducting inspection activities and other necessary verification activities, the authority may revoke the certificate of competence; and the same shall iform to concerned bodies.
5) ድርጅቱ በስራ እያለ ለቴክኒክ ኃላፊው የመልቀቂያ ፈቃድ በተቀመጠው የጊዜ ገደብ ለመስጠት ፈቃደኛ ባይሆን ባለስልጣኑ አስፈላጊውን የማጣራት ስራ በመስራት የባለሙያውን ጥያቄ ሊቀበል ይችላል። ድርጅቱ የመተካት ስራ የማያከናውን ከሆነ አስተዳደራዊ ርምጃዎችን ይወስዳል። 6) ድርጅቱ፡- ሀ) አዲስ የብቃት ማረጋገጫ ለማግኘት ከዚህ ቀደም በተሰጠው ብቃት ማረጋገጫ ይዘት እና ሁኔታ ላይ የአገልግሎት አይነት፣ ቦታ፣ ባለሙያ ወይም የአግልግሎት ደረጃ ለውጥ ካደረገ፤	5) When the organization refused to give release letter to the technical manager while is in operation as per set timeline, the Authority may accept the request of the technical manager after through verification activities. If the organization doesn't replace ontime with a new technical manager, the Authority shall take appropriate administrative measures. 6). when the institution:- a) To get new certificate of competency when the institution change the service type, place, technical person or level of service to the terms and condition of existing certificate of competency issued. b) The certificate of competency suspended, revoked or fails to renew.

ለ) የብቃት ማረጋገጫ ምስክር ወረቀቱ ከታገደ ፣ ከተሰረዘ ስይም ሳይታደስ ከቀረ፣ ሐ) በሰሙ የብቃት ማረጋገጫ ምስክር ወረቀት ያወጣው ባለሙያ ከሞተ ወይም መ) የሚሰጠዉ አገልግሎት ለሕብረተሰቡ ጤና አደገኛ ነዉ ብሎ በባለሥልጣኑ ከታመነ ወይም ድንገተኛ የሕብረተሰብ የጤና ችግር ሊፈጠር ይችላል ተብሎ ከታመነ፣ የብቃት ማረጋገጫ ምስክር ወረቀቱን በሁለት ቀን ዉስጥ ለባለስልጣኑ መመለስ አለበት፡፡	c) The technical manager with whom the certificate of competency issued has been dead or d) The Authority believes that the service provided has imposed public health risk or may imposed sudden public health problems In such cases, the certificate of competency shall be returned to the Authority within two days
ክፍል ሶስት **ስለ የማምረቻ ቦታ ዲዛይንና አስፈላጊ ግብዓቶች**	**Part Three** **Premises and Equipment of the manufacturing site**
11. **ስለ ማምረቻ ቦታ**	**11. Locations of premises**
1) የማምረቻ ቦታው የሚገኝበት አካባቢ በምርቱ ወይም በቁሳቁሶች ላይ የሚያስከትለው አደጋ ወይም ብክለት አነስተኛ መሆን አለበት፡፡	1) Premises shall be situated in an environment that has minimum risk of causing any contamination of materials or products.
2) የማምረቻ ቦታው በህክምና መሳሪያ ጥራት ፣ደህንነት ወይም ውጤታማነት ላይ ቀጥተኛም ሆነ ቀጥተኛ ያልሆነ ተፅእኖ የሚያሳድሩ ክፍት የፍሳሽ ማስወገጃ፣ የቢራ ፋብሪካዎች ወይም እንደ ጭስ እና ብክለት ያሉ ጎጂ	2). The premises shall be located away from sites or activities that emit obnoxious materials like fumes and contaminants; open sewerage or other offensive trades having direct or indirect impact on the quality, safety or performance/effectiveness of the medical device.

ነገሮችን ከሚለቁ ተቋማት ወይም ተግባራት ርቀው የሚገኙ መሆን አለባቸው፡፡	
3) የማምረቻ ቦታው በሌሎች የንግድ ስራዎች ላይ ከሚሰሩ ወይም ከሌላ የንግድ ድርጅት ወይም የመኖሪያ ግቢ ጋር በቀጥታ ከሚገናኝ ከማንኛውም ህንፃ ጋር ቀጥተኛ አገናኝ እንዳይኖረው በሚያስችል መንገድ የተሰራ መሆን አለበት፡፡	3). Manufacturing of Medical devices shall be in a segregated standalone room(s) or shall not be performed with other activities belonging to other business or residency compound.
12. የማምረቻ ህንፃ ንድፍና ግንባታ ሁኔታ	**12. Design and construction of the manufacturing facility**
1) የማምረቻ ተቋሙ ንድፍ ከሚመረተው ምርት ጋር ተስማሚ የሆነና ከምርቱ ጋር ወጥነት ያለው እና የመሳሪያውን ጥራት ደህንነት እና አፈፃፀም ላይ ተጽእኖ ሊያሳድር ከሚችል ከማንኛውም የምርት አይነት ተለይቶ የተገነባ መሆን አለበት፡፡	1) The design of manufacturing facility shall be in such a way that is consistent with the product and built separately from any other type of production that may affect the quality, safety and performance of the device.
2) የህንፃው አቀማመጥ፣ ከፍታና ግንባታ እንዲሁም ሌሎች ተዛማጅ ነገሮች ምርቱ ለብክለት በማያጋልጥ መልኩ የተገነባ መሆን አለበት፡፡	2). The location and height of the facility shall be constructed in such a way that it minimizes contaminations and it is not exposed to any contamination.
3) የክፍሉ ስፋት ድርጅቱ እንደሚያመርተው ምርት ዓይነትና መጠን በቂ ሆኖ በሚመረተው ምርት ላይ የመበካከልና የመደባለቅ ሁኔታ የማያመጣ ሆኖ ስራውን በትክክል ሊያሰራ በሚያስችል	3). The size of the room shall accommodate all activities of the manufacturer depending on the type and the volume of devices manufactured by the organization and built in such a way that prevents mix-up and cross contaminations

መንገድ የተሰራ መሆን አለበት፡፡	
4) ህንፃው የተገነባበት ግብአት ከድንጋይ ወይም ከብሎኬት ወይም ከሸክላ እና ከሌሎች በምርቱ ጥራትና ደህንነት ላይ ተፅእኖ ከማያደርሱ ማቴርያሎች መሆን አለበት፡፡	4). The construction material shall be made of stone or block or bricks and metal sheets or other related materials that shall not affect the safety, quality and effectiveness of the medical device.
5) ድርጅቱ የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያዎች ለማምረት አገልግሎት የሚውሉ የሚከተሉት ክፍሎች አመክንዮአዊ ፍሰቶች በጠበቀ መልኩ ማምረቻ ሊኖሩት ይገባል፡፡ ሀ. ማከማቻ ክፍል (ጥሬ ዕቃዎች ፣ የተጠናቀቁ ምርቶች ፣ ናሙናዎች ፣ ማሸጊያ ወዘተ) ለ. የማምረቻ ክፍል፣ ሐ. የጥራት ቁጥጥር ላቦራቶሪ	5). The manufacturer shall have the following rooms with logical flow used for manufacturing of low-risk medical device: a. Store room(s) (raw materials, finished good, samples, packaging etc) b. Production area c. Quality Control Laboratory
6) የዚህ አንቀጽ ንዑስ አንቀጽ 5(ሐ) ቢኖርም አምራቹ የጥራት ቁጥጥር ሙከራዎችን ለሦስተኛ ወገን ቢያቀርብ ወይም የጥራት ቁጥጥር ክትትሎች በምርት ሂደቱ ውስጥ በሚካሄዱበት ጊዜ የጥራት ቁጥጥር ላቦራቶሪ አስፈላጊ ላይሆን ይችላል። በዚህ ሁኔታ በሶስተኛ ወገን የጥራት ቁጥጥር ላቦራቶሪ እና በአምራቹ መካከል ያለው ስምምነት	6) Notwithstanding sub-article 5(c) of this article, quality control laboratory may not be necessary if the manufacturer outsources the quality control tests to a third party or in cases where quality control checks are carried out throughout the production process. In such cases, the agreement between the third party quality control laboratory and the manufacturer should be provided as evidence and the inspection of

በማስረጃነት መቅረብ እና አስፈላጊ ሆኖ ሲገኝ የዚሁ ላብራቶሪ ምርመራ በባለስልጣኑ ይከናወናል።	the same laboratory shall be conducted by the Authority when needed.
7) የክፍሎቹ ግድግዳ ሊታጠብ በሚችልና የፕላስቲክ ቀለም የተቀባ ሆኖ ምንም ዓይነት የመሰነጣጠቅ ሁኔታ የሌለውና ቆሻሻ ሊይዝ የማይችል መሆን አለበት፡፡	7) The walls of the rooms shall be as appropriate, painted with washable paints and have no cracking conditions and which do not hold dusts.
8) እነደ ሚመረተው ምርት ባህሪይ አይነት የክፍሎቹ ወለል በቀላሉ ሊታጠብ የሚችል፣ በሴሚንቶ የተሰራ፣ ኮንክሪት፣ ኢፖክሲ፣ ሴራሚክ ወይም ከሌላ ተመሳሳይ ማቴሪያል የተሰራ ሆኖ ያልተሰነጣጠቀ ፣ ቆሻሻ የማይዝ፣ ውሀ የማያቁር እንዲሁም የውሃ ፍሳሽ ተዳፋት ወደ አንድ አቅጣጫ ሊፈስ በሚችል መልኩ የተሰራ መሆን አለበት፡፡	8)The floor of the rooms shall be, as appropriate, easy to wash, made of cement, concrete, epoxy, ceramic or other similar material depending on the characteristics of the medical device shall be unbroken, clean, water-resistant and having drainage slope designed to flow in one direction.
9) እንደሚመረተው ምርት ባህሪይ የክፍሎቹ ጣሪያ በክፍሎቹ ሙቀት ላይ ተፅእኖ ሊያሳድሩ ከማይችሉ ከሲሚንቶ ስላብ፣ አርቴፊሻል የድንጋይ ስላብ ወይም ቴናዞ የተሰራ መሆን አለበት ፡፡	9) The ceiling of the rooms, depending on the characteristics of the product, shall not affect the temperature of the rooms and may be made from cement slab, polyvinyl chloride, Gypsum board, aluminum panel or other suitable materials.
10) የህንፃዎቹ በርና መስኮት ምርቱን ሊበክሉ የሚችሉ ነብሳትና ቆርጣሚ	10) The doors and windows of the facility shall prevent the entry of insects and rodents that

እንስሳት የማያስገቡ መሆን አለባቸው።	can contaminate the product.
11) በክፍሎቹ ውስጥ በቂ ብርሃንና የአየር ዝውውር ሊኖረው ይገባል።	11) There shall be enough light and air circulation in the rooms.
12) እንደ አስፈላጊነቱ አማራጭ የሀይል ምንጭ ሊኖረው ይገባል።	12) Depending on the product type the manufacturer shall have adequate and alternative power source.
13) እንደ ሚመረተው ምርት ዓይነት 12) 12) ድርጅቱ አስፈላጊ የቆሻሻ ማስወገጃ ስርዓት ሊኖረው ይገባል።	13) Depending on the product type the manufacturer 12). The institution shall have a waste disposal system for the waste generated in the factory.
14). አምራች ድርጅቱ የስልክ፣ መብራትና የውሃ አገልግሎት ሊኖረው ይገባል።	14). The manufacturing facility shall have telephone, water and electricity.
13.ተጨማሪ ቦታ	**13. Ancillary Areas**
1) የማምረቻ ቦታው እንደ መፀዳጃ ቤት፣ የእጅ መታጠቢያ፣ የልብስ መቀየሪያና የአስተዳደር ቢሮ ሊኖሩት ይገባል።	1) The manufacturing site shall have service areas such as toilet, hand wash, changing room and administration office
2) እንዳስፈላጊነቱ የማረፊያ እና የመመገቢያ ክፍሎች ከሌሎች ክፍሎች የተለዩ መሆን አለባቸው።እነዚህ ቦታዎች ከማምረቻ እና ከማከማቻ ቦታዎች የተለዩ መሆን አለባቸው።	2). If applicable, rest and refreshment rooms shall be separate from other areas. These areas shall not lead directly to the manufacturing and storage areas.
3) መፀዳጃ ቤቶች ለወንዶች እና ለሴቶች የተለዩ በቀጥታ ከምርት ወይም ከማከማቻ ቦታዎች ጋር	3). Toilets, separate for males and females, shall not be directly connected with production or storage areas. There shall be written instructions for cleaning

መገናኘት የለባቸውም፡፡እንደነዚህ ያሉትን አከባቢዎች ለማፅዳትና ለማፀዳት የጽሑፍ መመሪያዎች መዘጋጀት ይኖርባቸዋል፡፡	and disinfection of such areas.
14. **አስፈላጊ ግብአት እና ቁሳቁሶች**	**14. Materials and Equipment**
1) የማምረቻ መሳሪያዎች አቀማመጥና ንድፍ ለስህተት የማያጋልጡ ሆኖ ለጽዳትና ጥገና ምቹ መሆን አለባቸው፡፡	1) Equipment shall be located, designed, constructed, adapted and maintained to suit the operations to be carried out.
2) የመሳሪያዎች አቀማመጥ እና ዲዛይን የስህተት አደጋን በመቀነስ ውጤታማ ጽዳት እና ጥገና ማድረግ አለባቸው.	2) The layout and design of equipment shall minimize the risk of errors and permit effective cleaning and maintenance.
3) እንደሚመረተው ምርት አይነት አምረች ድርጅቱ የውሃ ማጣሪያ ዘዴ ሊኖረው ይገባል፡፡	3). The manufacturer shall have a water treatment system depending on the product types it produces.
4) የዚህ አንቀፅ ንዑስ አንቀፅ 3 ቢኖርም የስጋት ደረጃው ዝቅተኛ የሆነ የህክምና መሳሪያ አምራች የሚፈለገውን ጥራት ያለው ውሀ ከማንኛውም የታወቁ ምንጮች ሊጠቀም ይችላል።	4). Notwithstanding sub-article 3 of this article, the manufacturer of low risk medical device may use the required quality of water generated from any other recognized sources.
5) በድርጅቱ እንደሚመረቱ ምርት ባህሪ የናሙና መውሰጃ፣ ማደባለቂያ፣ ምርት ማዘጋጃ፣ የውሃ ማጣሪያ፣ መለኪያዎች፣ የጥራት ሙከራ፣ የማምረቻ እና ሎሎች መሳሪያዎችና እና ማሽነሪዎች ሊኖሩት	5). According to the product type, the manufacturer shall have equipment for sampling, mixing, preparation, water treatment (if available), measurement, quality test, production and other related requirements.

ይገባል።	
6) ሁሉም ለመለኪያ የሚያገለግሉ ህክምና መሳሪያዎችና መለኪያዎች በየጊዜው ካሊበሬት ማድረግና የካሊበሬሽን ማስረጃዎች ሊኖሩት ይገባል።	6). All measuring devices used during manufacturing of the low risk medical devices shall be calibrated on a regularly scheduled basis and there shall be documentation and records showing proof of the calibration.
7) በምርቱ ማሸግያ ላይ የመለያ ቁጥር/ተከታታይ ቁጥር ፣ የተመረተበት ቀን፣ የመጠቀሚያ ጊዜ ለማተም የሚያስችል አሰራር ሊኖረው ይገባል።	7). The manufacturer shall have a system for printing serial number/batch number, production date and expiry date.
8) በድርጅቱ እንደሚመረቱ ምርት ባህሪ የህክምና መሳሪያ ፣ ጋዎን፣ ጓንት፣ ፕላስቲክ ልብስ፣ ቱታ፣ ቦቲ ጫማ፣ የፀጉር መሸፈኛ፣ የአፍ ማስክና የመሳሰሉት የሰራተኞች የደህንነት መጠበቂያ ቁሳቁስ ሊኖሩው ይገባል።	8). The organization shall have personal protective equipment like gloves, plastic clothing, coveralls, boots, hair net, face mask, face shield and other protective equipment depending on the type of medical devices manufactured within the facility.
9) በድርጅቱ እንደሚመረቱ ምርት ባህሪ የድንገተኛ እሳት አደጋ መከላከያና መቆጣጠሪያ መሳሪያ እና የመጀመሪያ ህክምና እርዳታ መስጫ መሳሪያ ሊኖረው ይገባል።	9). The organization shall have emergency fire prevention and control device and have first aid kit, and other important tools or materials depending on the type of medical devices manufactured within the facility.
ክፍል አራት **ስለ ባለሙያ**	**Part Four** **Professionals**
15. ጠቅላላ	**15. General**

1) የስጋት ደረጃቸው ዝቅተኛ የሆኑ የሕክምና መሣሪያዎችን አምራች ድርጅት የቴክኒክ/ የምርት ክፍል ሀላፊ እና የምርት ጥራት ቁጥጥር ኃላፊ የትምህርት ዝግጅት እና የስራ ልምድ በዚህ መመሪያ አባሪ 4 መሠረት መሆን አለበት፡፡	1) The qualification and experience of Technical⁄Production manager and the quality control manager of any low-risk medical device manufacturer shall be in accordance with Annex IV of this directive.
2) የዚህ አንቀጽ ንዑስ አንቀጽ 2 እንደተጠበቀ ሆኖ በአባሪ 4 የተዘረዘሩትን ሁለት ወይም ከዚያ በላይ የሕክምና መሣሪያዎችን በማምረት ላይ የተሰማራ አምራች፣ የቴክኒክ/ምርት እና የጥራት ቁጥጥር ሥራ አስኪያጅ ለሁሉም ምድቦች ተመሳሳይ መሆን አለበት፡፡	2) Notwithstanding sub-article 2 of this article, a manufacture engaged in the manufacturing of two or more medical devicescategories listed in Annex IV, the technical/production and quality control manager shall be common for all categories.
3) በአባሪ 4 ውስጥ የተካተተዉ የትምህርት መስኮች ማለትም "ተዛማጅ የትምህርት መስኮች" ተብለው የተጨመሩት አግባብነት ባላቸው አካላት (በሚመለከታቸው የሙያ ማህበራት እና የሙያ ፈቃድ ሰጪ አካላት) ተገምግመው ይረጋገጣሉ፡፡ አመልካቹ በባለሥልጣኑ የሚገመገሙ ማስረጃዎችን ማቅረብ አለበት።	3) The study areas that are added as “related fields” in the Annex IV will be assessed and validated by the appropriate bodies (Relevant Professional associations and professional license issuing bodies). The applicant shall submit such evidences that will be evaluated by the Authority.

4) የጥራት ቁጥጥር ሥራ አስኪያጅ ከምርት ማምረት ሂደት ገለልተኛ መሆን አለበት፡፡	4) The Quality control manager shall be independent of the production activity.
5) ቴክኒካል / የምርት ክፍል ሥራ አስኪያጅ እና የጥራት ቁጥጥር ሥራ አስኪያጅ ሀላፊነት በጽሁፍ መገለጽና ጥብቅ ክትትል መደረግ አለበት፡፡	5) Duties of technical/production and Quality control manager have been disclosed in written, and followed strictly.
6) እያንዳንዱ ቴክኒካል ሰው የተሰጠውን ኃላፊነት ለመወጣት በቂ ሥልጠና ሊሰጠው ይገባል.	6) Each technical person shall be properly trained to perform the assigned responsibilities.
7) የተቀጠሩ ሰራተኞች ብዛት በአምራቹ ለሚሰጠው የሥራ ጫና በቂ መሆን አለበት.	7). Number of personnel employed shall be adequate to the workload by the manufacturer.
16. የቴክኒክ/ የምርት ክፍል ኃላፊ ኃላፊነት	**16. Responsibilities of the Technical/ Production Manager**
ማንኛውም የቴክኒክ/የምርት ክፍል ሃላፊ፡- 1) የተሰጡትን ኃላፊነቶች በመወጣት የድርጅቱን ወጥ የሆኑ የአሰራር ስርዓቶች መተግበራቸውን ያረጋግጣል፤	The technical/production manager shall:- 1) Perform the assigned responsibilities and ensure the implementation of the organizational standard procedures.
2) በድርጅቱ ውስጥ የሚሰሩ የባለሙያዎችን ሚና እና ኃላፊነት ይለያል፤	2) Establish the roles and responsibilities of professionals working in the organization,

3) የሚያመረቱትን የህክምና መሳሪያ ጥራት ፣ደህንነት እና ውጤታማነት የሚያሳድጉ ስልጠናዎችን ለድርጅቱ ሰራተኞች ያመቻቻል እንዲሁም ይከታተላል፤	3) Follow and facilitate training for staffs which improve the quality, safety and effectiveness of medical device they manufacture;
4) የድርጅቱን ምርት፣ ቆጠራ እና የዝውውር ስርዓት የመቆጣጠር እና የምርቱን ጥራት ፣ደህንነት እና ውጤታማነት አደጋዎችን የመከታተል ኃላፊነት አለበት፤	4) Monitor the production, inventory and transfer system of the organizations and responsible for monitoring of quality, safety and effectiveness of the product.
5) ብሔራዊ ደረጃዎችን እና ህጎችን ተግባራዊ ያደርጋል፤	5) Ensure the implementation of national standards and laws;
6) የማከማቻ ክፍሉ ቁጥጥር በአግባቡ መከናወኑን ያረጋግጣል፤	6) Ensure that the control of the storage unit is carried out properly;
7) ድርጅቱ የሚያመርታቸው የህክምና መሳሪያዎች ጥራት፣ ደህንነት እና ውጤታማነት በተመለከተ ጉድለት ሲኖር ለባለስልጣኑ ያሳውቃል፡፡	7) Notify the defects about the quality, safety and effectiveness of medical devices they manufacture to the Authority.
8) ከድርጅቱ ከመልቀቁ ከአንድ ወር በፊት ለባለስልጣኑ የማሳወቅና በስሙ የወጣን ብቃት ማረጋገጫ የመመለስ ግዴታ አለበት፡፡	8) Notify the Authority one month prior to his departure if he leaves the organization and he is responsible for returning the license.
17.የጥራት ቁጥጥር ሥራ አስኪያጅ ኃላፊነት	**17. Responsibilities of Quality control manager**
የጥራት ቁጥጥር ሃላፊው፡- 1) ልዩ አያያዝ እና ማከማቻ የሚጠይቁ	The Quality control manager shall :- 1) Performs appropriate handling by

ምርቶችን በመለየት በተገቢው መንገድ እንዲያዙ ያደርጋል፤	identifying products that require special handling and storage.
2) ጥሬ ዕቃዎች ወደ ማምረቻ ቦታ ከመድረሳቸው በፊት የጥራት ማረጋገጫ ዕቅድ ያዘጋጃል፤	2) Prepare a quality assurance plan before raw materials are delivered to the production area.
3) ጥሬ ዕቃ እና የምርት ሂደቱ የተጠናቀቀ ምርት ማረጋገጫ ወጥ የሆነ የአሰራር ስርዓት በፅሁፍ ያዘጋጃል፤	3) Develop a written standard operating procedure for certifying raw materials and finished products.
4) ዋና ዋና ለሆኑ መሣሪያዎች የመለካት እና የመጠገን የአሰራር ስርዓት በጽሑፍ ያዘጋጃል፤	4) Develop a written procedure for calibration and maintenance of major device.
5) ለእያንዳንዱ ምርት የምድብ ማምረቻ መዝገቦችን ያዘጋጃል፤	5) Prepares batch manufacturing records for each product.
6) እንደአስፈላጊነቱ ለናሙና እና ለምርመራ የማምረቻ ቦታዎችን ያመቻቻል፡፡	6) Conducts sampling and investigation of products at the production areas as appropriate.
7) ሁሉንም ምርት የሚመለከቱ ቅሬታዎችን ይመረምራል እንዲሁም ቅሬታዎችን መዝግቦ ይይዛል፡፡	7) Investigates all product complaints and ensures the records are maintained
ክፍል አምስት **የአመራረት ስርአት እና ትግበራ**	**Part Five** **Production system and practices**
18. የመልካም አመራረት ስርዓት	**18. Good Manufacturing system**

1) አምራቹ አነስተኛ የስጋት ደረጃ ያላቸዉን የህክምና መሳሪያዎች ሲያመርት የህክምና መሳሪያ መልካም አመራረት ስርዓትን መከተል አለበት፡፡	1) Manufacturer shall follow Good Manufacturing Practices while manufacturing of its low-risk medical device(s).
2) የዚህ አንቀጽ ንዑስ አንቀጽ (1) እንደተጠበቀ ሆኖ የህክምና መሳሪያ አምራቹ በክፍል 8.3 የባለስልጣኑ የህክምና መሳሪያ መልካም አመራረት ስርዓት ጋይድላየን ላይ የተገለጹትን የንድፍና የዕድገት ደረጃ መስፈረቶችን ማሟላት አይጠበቅበትም፡፡	2). Notwithstanding sub-article (1) of this article, the manufacturer may skip the design and development requirements described in 'section 8.3' of the Authority's Medical devices Good Manufacturing Practice Guideline.
19.ሰነድ እና ሪከርድ	**19. Documents and records**
1) ማንኛውም የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያዎች አምራች ድርጅት ከምርት ማምረት ሂደቱ ጋር ተያያዥ የሆኑ የሚከተሉት ሰነዶች ሊኖረው ይገባል፡፡ ሀ) የምርቱን የአመራረት ሂደት ቅደም ተከተልና ፍሎው ቻርት የሚያሳይ ሰነድ፣	1) Any low-risk medical device manufacturer shall have the following documents related to production process. a). Document showing the order of production process and flow chart.
ለ) የጥሬ እቃ አቅራቢ ብቃት የሚገልፅ ሰነድ እና የጥሬ እቃ ጥራት ምርመራ ሰርተፌኬት፣	b). Certificate of analysis for raw materials and finished products, if applicable.
ሐ) የአምራች ድርጅቱ ፖሊሲ፣ማኑዋል፣ፕሮቶኮል፣ ባች ማኑፋክቸሪንግ ሪከርዲንግ ፣ዲዛይን ሪከርድ፣ማስተር ሪከርድ፣ለእያንዳንዱ የአሰራር ሂደቶች ወጥ የሆነ የስራ	c). Manufacturers policy, manual, protocol, device history record, batch manufacturing recorded, design recorded, master record, unified work guide for each process and similar technical documents if it is applicable.

መመሪያ እና መሰል የቴክኒክ ሰነዶች፣	
መ) ሁሉም የአመራረት ሂደቶች የሚያሳይ ወጥ የሆነ የአሰራር ሂደትን የሚያሳይ ሰነድ፣	d). All standard operating procedures related to manufacturing process and the product's quality control activities.
2) ሰነዶች በተገቢው እና በተፈቀደላቸው ሰዎች ይጸድቃለ፣ይፈረማለ እና ይጻፋሉ፣	2) Documents shall be approved, signed and dated by appropriate and authorized persons.
3) የሚመረቱትን ግብአቶች አስመልክቶ ሁሉም ጉልህ ተግባራት በሚከናወኑበት ወቀት ተመዘግብው ይቀመጣሉ፡፡	3) The records shall be made or completed at the time of each operation in such a way that all significant activities concerning the manufacture of devices are traceable.
4) መዝገቦች እና ተዛማጅ መደበኛ የአሰራር ሂደቶች ቢያንስ የተጠናቀቀው ምርት ማብቂያ ቀን ድረስ መቀመጥ አለባቸው፡፡	4) Records and associated Standard Operating Procedures shall be retained for at least the expiry date of the finished product.
20.ሀይጂን እና ሳኒቴሽን	**20. Hygiene and sanitation**
1) ማንኛውም የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያዎች አምራች ድርጅት የመልካም የንፅህና እና የሳኒቴሽን አጠባበቅ ስርአት መዘርጋት አለበት፡፡	1) Any low-risk medical device manufacturer shall establish a good hygiene and sanitation system.
2) በተቻለ መጠን ቀጥታ ግንኙነት የደህንነት አልባሳት ባልለበሱ ሰራተኞች እና ጥሬ እቃዎች፣መካከለኛ ወይም የተጠናቀቁ ምርቶች ፣ያልታሸጉ ምርቶች መካከል መራቅ አለበት፡፡	2). As far as possible, direct contact shall be avoided between the unprotected hands of personnel and raw materials, intermediate or finished, unpacked products.

3) ሁሉም ሰራተኞች ለስራቸው ተስማሚ የሆኑ ንፁህ የሰውነት መሸፈኛዎችን መልበስ አለባቸው፡፡	3) All personnel shall wear clean body coverings appropriate to their duties.
4) ወደ ማምረቻ ቦታው ከመግባቱ በፊት በቂ መገልገያ ያላቸው የወንድና የሴት የተለዩ የልብስ መለወጫ ክፍሎች መኖር አለባቸው፡፡	4) Before entry into the manufacturing area, there shall be change rooms separate for male and female with adequate facilities.
5) ማጨስ፣መብላት፣መጠጣት፣ማኘክ ወይም እጽዋት ማቆየት፣ምግብን፣መጠጥን እና የግል መድሃኒቶችን በምርት ክፍል ፣በቤተ ሙከራ ፣በማከማቻ እና በምርት ጥራት አለታዊ ተጽዕኖ ሊያሳድሩ በሚችሉባቸው አከባቢዎች መውሰድ አይፈቅድም፡፡	5) Smoking, eating, drinking, chewing or keeping plants, food, drink and personal medicinesshall not be permitted in production, laboratory, storage and other areas where they might adversely influence the product quality.
21. ማሸጊያና ገላጭ ጹሁፍ	**21. Labeling and packaging materials**
1) የገላጭ ጽሁፍ ህትመቱ በደማቅ ቀለሞች እና በሚነበብ መከናወን ይኖርበታል፡፡	1) The printing of labels shall be done in bright colors and in a legible manner.
2) ከተለያዩ ምርቶች ጋር የተያያዙ መለያዎችና የታተሙ የማሸጊያ ቁሳቁሶች፣ የምርት በራሪ ወረቀቶችን ጨምሮ ተለየተዉ በተናጠል መቀመጥ አለባቸዉ፡፡	2) Labels and printed packaging materials such as product leaflets shall be stored separately.
3) ከመለቀቁ በፊት ለኮንቴይነሮች፣ለካርቶን	3) Prior to release, all labels for containers,

፣ለሳጥኖች እና በራሪ ወረቀቶች እንዲሁም ሁሉም መለያዎች ጥራት ማረጋገጫ ክፍል ምርመራ ይደረግባቸዋል፡፡	cartons and boxes and all circulars, inserts and leaflets shall be examined by the Quality Control department.
4) ደረሰኝ፣የቁጥጥር ማመሳከሪያ ቁጥሮችን እና ተቀባይነት ማግኘቱን ወይም አለመቀበሉን የሚያመለክቱ ለእያንዳንዱ ጭነት የሁሉም መለያ እና የማሸጊያ እቃዎች ሰነድ መቀመጥ ይኖርባቸዋል፡፡	4) Records of receipt of all labeling and packaging materials shall be maintained for each shipment received indicating receipt, control reference numbers and whether accepted or rejected.
5) ጥቅም ላይ ያልዋሉ ኮድ ያላቸው እና የተጎዱ መለያዎች እና የማሸጊያ ቁሳቁሶች ተወግደው መረጃው ተመዝግቦ መያዝ ይኖርበታል፡፡	5) Unused coded and damaged labels and packaging materials shall be destroyed and recorded.
6) ለአደጋ ተጋላጭ የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያዎችን ማሸጊያቸው በሚታወቁ እና ጥራታቸው በተረጋገጠ በትክክል በሚሰሩ ቁሳቁሶች እንዲሁም መርዛማ ባልሆኑ፣ፈሳሽ ባልሆኑ፣ ሽታ በሌላቸው፣ባለተሰነጠቁ እና ጉዳት ባለደረሰባቸው መሳሪያዎች መሆን ይኖርባቸዋል፣ በተጨማሪ ማሸጊያው ለህክምና አገልግሎት እንዲዉል ታስቦ የተሰራ መሆን አለበት፡፡	6) The packaging of the low-risk medical device shall be made of known and traceable materials, non-toxic, non-leaching and odorless, free of holes, cracks, tears, and creases and localized thinning, Intended for use in medical applications.
7) የስጋት ደረጃቸው ዝቅተኛ የሆኑ የህክምና መሳሪያዎች ማሸጊያዎች	7) The packaging of the low-risk medical device shall allow sterilization, and provide

ለሰቴራይዜሽን ምቹ የሆኑ፣ ለምርቱ አካላዊ ጥበቃ ማድረግ የሚያስችሉ እና ጥቅም ላይ እስከሚውሉ ድረስ ከጀርም ነጻ ሆነው እንዲቆዩ ማድረግ ይኖርበቸዋል፡፡	physical protection.
22.የግላጭ ጽሁፍ መስፈርት	**22. Labeling requirements**
1) የምርቱ ግላጭ ጽሁፉ በአማርኛ እና በኢንግሊዘኛ ቋንቋ የተጻፈ መሆን አለበት፡፡	1) Labeling information shall be in Amharic and English language.
2) የምርቱ ግላጭ ጽሁፍ ቢያንስ የሚከተሉትን መረጃዎች መያዝ ይኖርበታል፡ ሀ. የአምራች ድርጅቱ ስም እና አድራሻ፣ ለ. የህክምና መሳርያው ፅንስ ስም፣ ሐ. ለወሳኝ ምርቶች የምርት የመቀበያ መስፈርቶች መ. የምርቱ መለያ ቁጥር፣ ሠ. እንደ አስፈላጊነቱ የባች ወይም ሎት ቁጥር ረ. ምርቱ የተመረተበት ቀን፣	2) Product labels shall have the following information, including but not limited to: a. Name and address of the manufacturer; b. Generic name of the product; c. Critical specifications of the finished product; d. Serial number, e. Lot number/Batch number, if applicable f. Production date, g. Expiry date or use-by date, as appropriate h. Use period, as appropriate; i. Storage condition and instruction, as needed; j. Single use or reuse, as appropriate k. Other relevant information

ሰ. አገልግሎቱ የሚያበቃበት ቀን ፣ ሸ. እንደ አስፈላጊነቱ፣ የምርት መጠቀሚያ ጊዜ ቀ. የምርቱ የአቀማጥ ሁኔታ፣ በ. ለነጠላ አገልገሎት ወይም በተደጋጋሚ መጠቀም እንደሚቻል መገለጽ ተ. ሌሎች አስፈላጊ መረጃዎች	
23.ማቀነባበር እና በድጋሚ መስራት	**23. Reprocessing and Reworking**
1) መልሶ መስራት አስፈላጊ ሆኖ ሲገኝ፣በጥራት ተቆጣጣሪ ክፍል የተጻፈ፣የጸደቀ እና የተሞከረ የአሰራር ሂደት መኖር አለበት፣	1) Where rework is necessary, written procedures shall be established, validated and approved by the Quality Control Department.
2) የህክምና መሳሪያው መለያ ቁጥር ዳግም ቢሰራ፣የአሰራር ሂደቱ መጽደቅ እና ተጽፎ መቀመጥ አለበት፣	2) If the product batch has to be reworked, the procedure shall be authorized and recorded.
3)ማቀነባበሩ እና የዳግም የመስራት ሂደቱ ያስፈለገበት ሁኔታ የተወሰዱ የማስተካከያ ተግባራት ዳግመኛ ችግሩ እንዳይከሰት ለቅድመ ጥንቃቄ በማህደር	3) An investigation shall be carried out into the causes necessitating re- processing and appropriate corrective measures shall be taken for prevention of recurrence.

ተይዘው መቀመጥ ይኖርባቸዋል፡፡	
24. ምርት ከገበያ መሰብሰብ	**24. Recall of Product**
1) አነስተኛ የስጋት ደረጃ ያላቸዉ የህክምና መሳሪያዎች የጥራት ጉድለት፣ የደህንነት ችግር እና የማይሰሩ መሆናቸዉ ሲረጋገጥ አምራቹ ከገበያ ለመሰበሰብ የሚያስችለዉ የአሰራር ስርዓት ሊኖረዉ ይገባል፡፡	1) The organization shall have the procedure for recall when the low risk medical devices have found poor quality, unsafe and non-functional after being placed on the market.
2) አምራቹ ከገበያ የተሰበሰቡ ምርቶችን ሪከርዶች የመያዝ እና ባለስልጣኑ በሚጠይቅበት ወቅት የማሳየት ግዴታ አለበት፡፡	2) The organization shall maintain the record of product recall and make available upon request by the Authority.
25. የምርት ደህንትየና ጥራት ቆይታ ጊዜ ጥናት	**25. product safety and Stability Study**
1) የመጠቀሚ ጊዜ ቆይታ ለሚያስፈልጋቸዉ አነስተኛ የስጋት ደረጃ ያላቸዉ የህክምና መሳሪያዎች አምራቹ የምርት የደህንትየና ጥራት ቆይታ ጊዜ ለማጥናት የሚያስችል የአሰራር ስርዓት ሊኖረዉ ይገባል፡፡	1) The organization shall have procedures for the conduct of product safety and stability studies for those low-risk medical devices that require shelf life and/or in-use stability determination.
2) የምርት የደህንትየና ጥራት ቆይታ ጊዜ ጥናት አቅድ እና ሪፖረት ባለስልጣኑ በሚጠይቅበት ወቅት መቅረብ አለበት፡፡	2) The plan and report of stability studies shall be available upon request by the Authority.
26. ድህረ ፍቃድ ቁጥጥር	**26. Post licensing control**
1) ማንኛውም የስጋት ደረጃቸው ዝቅተኛ የሆኑ ህክምና መሳሪያዎች አምራች	1) Any low-risk medical device manufacturer after obtaining certificate of competency

የብቃት ማረጋገጫውን ካገኘ በኋላ ስራውን መስራት ያለበት የባለስልጣኑ ባወጣቸው እና በሚያወጣቸው ደንብ እና ግዴታዎች መሰረት መሆን አለበት፡፡	shall work as per terms and conditions; and other applicable legal requirements of the Authority.
2)አስፈላጊ ሆኖ ሲገኝ ባለስልጣን መስሪያቤቱ ኢንስፔክተሮች ወደ ድርጅቱ በመላክ ድርጅቱ አስፈላጊ መስፈርቶች አሟልቶ እያመረተ መሆኑን ያረጋግጣል፡፡	2) When it is necessary, the Authority shall send inspectors to the manufacturers of low-risk medical device in order to ensure that all the requirements are met.
ክፍል ስድስት **አስተዳደራዊ እርምጃዎች**	**Part Six** **Administrative measures**
27. ጠቅላላ	**27. General**
1) ማንኛውም ሰው በዚህ መመሪያ የተደነገጉ ጉዳዮችን ተላልፎ ሲገኝ በአዋጅ ቁጥር 1112/2011 እና በአስተዳደራዊ እርምጃ አወሳሰድና ቅሬታ አቀራረብ መመሪያ መሰረት ተገቢው እርምጃ የሚወሰድበት ይሆናል::	1) The Authority shall take administrative measures on any person who violet the terms and conditions of this directive as per Proclamation no. 1112/2011 and Administrative Measures and Grievance Handling Directive.
2) የዚህ አንቀፅ ንዑስ አንቀፅ (1) ድንጋጌ ቢኖርም ማንኛውም ሰው ጥፋት ፈፅሞ ሲገኝ በሚከተሉት ድንጋጌዎች መሰረት እርምጃዎች ሊወሰድበት ይችላል፡፡	2)Without prejudice to sub-article (1) of this article, any person who found to be violation this directive, subject the following measures:
28. ማስጠንቀቂያ ስለ መስጠት	**28. Warning Letter**
1) ማንኛውም ድርጅት የፈፀመው ጥፋት የብቃት ማረጋገጫ ምስክር ወረቀት	1) If the violation committed by any institution is not lead to suspension or

የማያሳግድ ወይም የማያሰርዝ ከሆነ ባለስልጣኑ እንደአግባብነቱ የፅሁፍ ማስጠንቀቂያ ሊሰጠው ይችላል::	cancelation of the issued certificate of competencies, as appropriate, on this Directive, the Authority shall issue written warning letter.
2) ድርጅቱ በተሰጠው ማስጠንቀቂያ መሰረት አስፈላጊውን ማስተካከያ ካላደረገ ሌሎች አግባብነት ያላቸውን አስተዳደራዊ እርምጃዎችን ባለስልጣኑ ይወስዳል::	2) If institution is fail take the corrective action for violation indicated in the warning letter, the Authority shall take other appropriate administrative measures
29. የብቃት ማረጋገጫ ምስክር ወረቀት ስለ ማገድ	**29. Suspension of Certificate of Competence**
1) ማንኛውም ሰው ከዚህ በታች ከተዘረዘሩት ትፋቶች አንዱን ፈጽሞ ሲገኝ ባለስልጣኑ ከሁለት ወር እስከ ስድስት ወር ለሚደርስ ጊዜ የብቃት ማረጋገጫውን ያግዳል:: ሀ. የባለስልጣኑን ተቆጣጣሪ የቁጥጥር ተግባሩን እንዳያከናውን እንቅፋት የፈጠረ እንደሆነ፣ይህ ጥፋት ድርጅቱ በቁጥጥር ወቅት ወይም የቁጥጥር ባለሙያ ስምሪት ላይ እንዳለ በማወቅ ወይም ቁጥጥሩን መሰረት አድርጎ ህገወጥ ምርቶችን ካሸሸ፣ከደበቀ ወይም እንዳይገኙ ከደረገ ወይም ሌሎች መሰል ጥፋቶች ፈጽሞ ሲገኝ፣ ለ. ከባለሥልጣኑ ፈቃድ ሳይኖር ለግለሰብ ተጠቃሚ መሸጥ። ሐ. የአእምሮ ጤና ወይም የአካል ጉዳት ያለባቸው፣ የዕፅ ሱሰኛ፣ አደንዛዥ	1) The Authority shall suspend the certificate of competency for two to six months on any manufacturer of low risk medical device who found to be commit violation in one of the following reasons: a. The institution create obstacle for Authority inspectors during the conduct the inspection activities; this include not able to sign consent form, failure to notify the working hours of the institution, not cooperate with the Authority inspectors during inspection and others similar violations. b. Selling products to individual user without license from the Authority. c. Use of professionals which has mental health or physical disability, drug addicted, narcotic and psychotropic drug or other compound use which cause mental health. d. Allowing professional who does not have

እፅ እና ሳይኮትሮፒክ መድሀኒት ወይም ሌላ ውህድ የአእምሮ ጤናን የሚያስከትለ ባለሙያዎችን ማሰራት። መ. ሙያዊ ፈቃድ የሌለው ባለሙያ በተቋሙ ውስጥ እንዲሰራ መፍቀድ ሠ. ነፃ የሕክምና ናሙናዎችን መሸጥ ወይም ለሽያጭ ማቀረብ። ረ. አምራቹ ባች ቁጥር ማስቀመጥ ካልቻለ እና ምርቱ ለገበያ ከተከፋፈለ; ሰ. ከባለሥልጣኑ ፈቃድ ሳያገኙ የሕክምና መሣሪያዎችን እንደገና በማሸግ፣ በድጋሚ በመለጠፍ ወይም በመሸጥ ሌላ መለያ መረጃ በማያያዝ ከተሳተፉ። አምራቹ የመጀመሪያውን ማሸጊያው እንደገና ካስቀመጠ; ሸ. አምራቹ ከባለሥልጣኑ ፈቃድ ሳያገኝ የባለቤትነት ስም ወይም አድራሻ ቢቀይር ወይም ሙያዊ ለውጥ ካደረገ፣ ቀ. የህዝብ ጤናን የሚነኩ እና በባለስልጣኑ ከፍተኛ አመራሮች በሚያምኑት ሌሎች አስፈላጊ እና አሳማኝ ምክንያቶች መሰረት ጥሰት መፈፀም	professional license to practice in the institution e. Sale or made available to sale free medical samples. f. If the manufacturer fails to put batch number and distributed to the market; g. Participate in medical devices repacking, re-labeling or sale with affixing other labeling information without getting permission from the Authority. If the manufacturer relabeled the original packaging; h. If the manufacturer made ownership name or address change or professional change without getting permission from the authority, i. Engage in any act which constitutes a violation in accordance with other necessary and justifiable reasons which affect public health and believe by the top management of the Authority.
2) ድርጅቱ የንግድ ፈቃዱ በሚመለከተው የመንግስት አካል ከታገደ፣ የእገዳ ውሳኔው በሚመለከተው የመንግስት አካል እስኪነሳ ድረስ የብቃት ማረጋገጫው በባለስልጣኑ	2) The Authority shall suspend the certificate of competency on the basis of suspension business license of the institution by other concerned government body, until reversal of

ይታገዳል፡፡	such suspension is sought by the concerned government body.
3)ባለሥልጣኑ ድርጅቱ ስለተወሰደበት እርጃና እርምጃው ስለተወሰደበት ለድርጅቱ በፅሑፍ የማሳወቅ ግዴታ አለበት፡፡	3) The Authority shall notify the institution in written on action taken by the Authority and reasons thereof
30. የብቃት ማረጋገጫ ምስክር ወረቀት ስለመሰረዝ	**30. Revocation of certificate of competency**
1. ማንኛውም ድርጅት ከሚከተሉት ምክንያቶች በአንዱ ጥፋተኛ ሆኖ ከተገኘ ባለስልጣኑ የብቃት ማረጋገጫ ምስክር ወረቀቱን ሊሰርዝ ይችላል፤ ሀ. በአንቀስ 29 የተደነገገውን እገዳ የሚያስከትል ተመሳሳይ ተግባር ሁለት ጊዜ እና ከዛ በላይ ከፈጸመ፤ ለ. የብቃት ማረጋገጫው ታግዶ ሳለ ስራውን መስራት ከቀጠለ፤ ሐ. ብቃት ማረጋገጫውን በማጭበርበር ወይም ሃሰተኛ ሰነድ በማቅረብ ማግኘቱ ሲረጋገጥ፤ መ. የብቃት ማረጋገጫውን ለሶስተኛ ወገን አሳልፎ ከሰጠ፣ ሠ. የተበላሸ፣ የአገልግሎት ዘመን ያለፈበት፣ ከገበያ እንዲሰበሰብ ባበለስልጣኑ የታዘዘ የሕክምና መሣሪያ ለመሰብሰብ ፈቃደኛ ካልሆነ ወይም ገበያ ላይ እንዳይዉል የታገደ የህክምና መሣሪያ ከሸጠ ወይም ካከፋፈለ	1) The Authority shall revoke the certificate of competency on any manufacturer of low-risk medical device who found to be violation for one of the following reasons: a. Commit violations indicated in article 29 twice and more . b. Continue in doing its business while the certificate of competency is suspended. c. Obtained its certificate of competence through fraudulent acts or by submitting false documents. d. Found to transfer the certificate of competency issued to other third party. e. Fails to collect or discontinue selling or distributing medical devices having a quality defect, expired or recalled products. f. If the company manufactured product beyond the scope of the certificate of competence is issued for; g. If the manufacturer fails to renew the

ወይም ለሽያጭ ካቀረበ፣ ረ. አምራቹ ከብቃት የምስክር ወረቀት ወሰን በላይ ካመረተ ሰ. በየዓመቱ የብቃት ማረጋገጫ የምስክር ወረቀት ሳይታደስ ከቀረ; ሸ. ከህብረተሰብ ጤና ቁጥጥር አንጻር ባለስልጣኑ ህጋዊ፣ አስፈላጊ እና ምክንያታዊ ነው ብሎ ያመነባቸውንና የበላይ ሀላፊ ያጸደቃቸዉ ሌሎች መሰል ግድፈቶች መኖራቸው ሲረጋገጥ፡፡	certificate of competency annually; h. Engages in any act which constitutes a violation in accordance with other necessary and justifiable reasons which affect public health and believe by the top management of the Authority.
2) በዚህ አንቀፅ ንዑስ አንቀፅ (1) መሰረት የብቃት ማረጋገጫ ምስክር ወረቀቱን የተሰረዘበት ሰው በሌላ ባለሙያ እና ድርጅት የብቃት ማረጋገጫ በማውጣት በዘርፉ መሳተፍ አይችልም፡፡	2) Once the certificate of competency is revoked as per sub-article one of this article, the institution shall not participate in this business using certificate competency of other professional and institution.
3)ድርጅቱ በራሱ ፈቃድ ስራውን ካቋረጠ ባለስልጣኑ የብቃት ማረጋገጫ ምስክር ወረቀቱን ይሰርዛል፡፡	3) The authority shall revoke the certificate of competency when the institution stops to do business by its own reasons.
4)ድርጅቱ በሚመለከተው የመንግስት አካል የንግድ ፈቃዱ መሰረዙ ከተረጋገጠ ተቆጣጣሪዉ አካል በሚመለከተው የመንግስት አካል ስረዛው ተነስቶ በስራው እንዲቀጥል እስኪፈቀድለት ድረስ የብቃት ማረጋገጫ ምስክር ወረቀቱ ይሰረዛል፡፡	4) The Authority shall revoke the certificate of competency on the basis of cancelation business license of the institution by other concerned government body, until reversal of such cancelation is sought by the concerned government body.
5)ባለስልጣኑ ከላይ የተጠቀሱትን እርምጃዎች ሲወስድ ለድርጅቱ እና ለሚመለከታቸው አካላት በፅሁፍ የማሳወቅ ግዴታ አለበት::	5) The Authority shall have an obligation to notify the institution and other concerned bodies in written on the above administrative measures taken.

31. እገዳና ስረዛ ስለማንሳት	31. Reversing of suspension and revocation
ማንኛውም የብቃት ማረጋገጫ ምስክር ወረቀት የታገደበት ወይም የተሰረዘበት ድርጅት የተጣለበት እገዳ ወይም ስረዛ ሊነሳለት የሚችለው በዚህ መመሪያ አንቀፅ 32 መሰረት ቅሬታ አቅርቦ ቅሬታው ተቀባይነት አግኝቶ ሲወሰን ይሆናል፡፡	The suspension and revocation of certificate of competency imposed on institution shall be removed after review and accepting the compliant submitted as per the article 32 of this directive.
32. ስለቅሬታ አቀራረብ	32. Complaint Handling
ማንኛዉም ሰዉ ስለብቃት ማረጋገጫ ምስክር ወረቀት አሰጣጥ፣ እድሳት፣ እገዳና ስረዛ ወይም ሌሎች ባለሥልጣኑ የሚወስዳቸዉ እርምጃዎችን በተመለከተ ቅር ከተሰኘ አቤቱታውን እርምጃው ከተወሰደበት ቀን ጀምሮ በአንድ ወር ጊዜ ዉስጥ ባለስልጣኑ ላቋቋመዉ ቅሬታ ሰሚ አካል ማቅረብ ይችላል፡፡	1) Any person who has compliant related to issuance, renewal suspension or revocation of certificate of competency or other administrative measures taken by the Authority shall appeal to compliant handling body of the Authority within one month.
ክፍል ስምንት ልዩ ልዩ ድንጋጌዎች	Part Seven Miscellaneous provisions
33. መረጃን ይፋ ስለ ማድረግ	33. Disclosure of Information
1) ባለሥልጣኑ በማንኛውም ድርጅት የአሰራር ግድፈቶች፣ የተረጋገጡ ተጨባጭ ጥቆማዎች ወይም ሌሎች የህብረተሰቡን ጤና አደጋ ውስጥ የሚጥሉ ጥፋቶችን ካገኘ መረጃን ለሕብረተሰቡ በማንኛውም የመገናኛ ዘዴ ይፋ ሊያደርግ ይችላል፡፡	1) The Authority may notify the public when there is misconduct by the institutions, confirmed complaints or on issues that put the public at risk using any of public communication methods.
2) ባለሥልጣኑ የብቃት ማረጋገጫ ምስክር ወረቀቱ የታገደበት፣የተሰረዘበትን ወይም	2) As applicable, the Authority may notify the public on institutions that are pending or cancel or not renewed their certificate of competencies.

ሳያሳድስ የቀረ ድርጅትን በተመለከተ አስፈላጊ ሆኖ ሲገኝ መረጃዎች ለህብረተሰቡ እንዲደርሱ ሊያደርግ ይችላል፡፡	
3) ማንኛዉም ሰዉ በባለሥልጣኑ ምስጢር ተብለው ከተያዙ መረጃዎች በስተቀር ስለ ማኛውም መድሀኒትና መሳርዎች የሚፈልገውን መረጃ ማግኘት ይችላል፡፡	3) Any person shall get any information except information that is considered confidential by the Authority.
34. የአገልግሎት ክፍያ	**34. Service Fee**
ማንኛዉም የመድኃኒት ወይም የህክምና መገልገያ ወይም መሳሪያ ድርጅት የብቃት ማረጋገጫ ምስክር ወረቀት ለማዉጣት፣ ለማሳደስ፣ ምትክ ለማግኘት እና ለቅድመ ፈቃድ እንስፔክሽን አግባብ ያለውን የአገልግሎት ክፍያዎች ለባለስልጣኑ መፈጸም ይኖርበታል፡፡	1) Any low risk medical device manufacturer who seek a new or renewed or replacement of certificate of competency and pre-licensing inspection shall pay appropriate service fee to the Authority.
35. የመሸጋገሪያ ድንጋጌ	**35. Transitory Provision**
የዚህ መመሪያ አንቀጽ 36 ቢኖርም አዲስ አመልካቾች እና መመሪያው ከመውጣቱ በፊት ሲሠሩ የነበሩ አምራቾች ይህ መመሪያ ከወጣበት ቀን ጀምሮ በ1 አመት ውስጥ የዚህን መመሪያ መስፈርት ማሟላት አለባቸው።	Notwithstanding article 36 of this directive, new applicant and those manufacturers who have been operating before the issuance of this Directive, need to fulfill the requirement of this Directive in 1 year from the effective date of this directive.
38. **መመሪያው የሚጸናበት ጊዜ** ይህ መመሪያ በፍትሕ ሚኒስቴር ተመዝግቦ ከባለስልጣኑ ይፋዊ ድረ ገፅ ከተጫነበት ጊዜ ጀምሮ ተፈጻሚ ይሆናል፡፡	38. **Effective date** 1) This directive shall come in to effect as of the date of its registration with ministry of justice and its uploading on

	official website of the authority.
ሄራን ገርባ **የኢትዮጵያ ምግብ እና መድኃኒት ባለሥልጣን** **ዋና ዳይሬክተር**	**Heran Gerba** **Ethiopian Food and Drug Authority** **Director General**

Annex I: General Approach for Classification of Medical Devices Other than IVD

Application of the classification rules shall be governed by the intended purpose of the devices, the part of the body affected by the use of the device, the duration of contact with the patient, the degree of invasiveness, and its direct or indirect risks on the individual as well as public health.

Low risk medical devices for the purpose of this directive are Non-IVD medical devices classified as class I and IVD medical devices classified as class A. This particular Annex is only for Non-IVD medical devices classification rules. The manufacturer shall take into consideration all classification and implementation rules in order to establish the proper classification for the device. Where a manufacturer states multiple intended purposes for a device, and as a result the device falls into more than one class, it shall be classified in the higher class. If several classification rules in the Authority's medical device classification guideline apply to the same device, the rule resulting in the higher classification shall apply and therefore such device shall not be within the scope of this directive. The list of Low risk Non-IVD medical devices is provided in Annex V. Please note that the list is not exhaustive.

1.	All non-invasive devices are in Class I unless one or more of the rules in the Medical device classification guideline applies	Body fluid collection devices intended to be used in such a way that a return flow is unlikely (e.g., to collect body wastes such as urine collection bottles, ostomy pouches, incontinence pads or collectors used with wound drainage devices). They may be connected to the patient by means of catheters and tubing Devices used to immobilize body parts and/or to apply force or compression on them (e.g., non-sterile dressings used to aid the healing of a sprain, plaster of Paris, cervical collars, gravity traction devices, compression hosiery) Devices intended in general for external patient support (e.g., hospital beds, patient hoists, walking aids, wheelchairs, stretchers, dental patient chairs) - Corrective glasses and frames -Stethoscopes for diagnosis. Eye occlusion plasters Incision drapes Conductive gels Non-invasive electrodes (electrodes for EEG or ECG) Image intensifying screens Permanent magnets for removal of ocular debris
2.	-All non-invasive devices are class I if they are:-	- Devices that provide a simple channeling function, with gravity providing the force to transport the liquid, e.g., administration sets for infusion - Devices intended to be used for a temporary containment or storage function, e.g., cups and spoons specifically intended for administering medicines Syringes without needles
3.	All non-invasive devices which come into contact with injured skin: are in Class I if they are intended to be used as a mechanical barrier, for	- Wound dressings, such as: absorbent pads, island dressings, cotton wool, wound strips, adhesive bandages (sticking plasters, band aid) and gauze dressings which act as a barrier, maintain wound position or absorb exudates from the wound

	compression or for absorption of exudates.	
4.	All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I:	
	-are in Class I if they are intended for transient use,	• Handheld mirrors used in dentistry to aid in dental diagnosis and surgery • Dental impression materials • Tubes used for pumping the stomach • Impression trays • Enema devices • Examination gloves • Urinary catheters intended for transient use • Prostatic balloon dilation catheters
	if they are used for short term and only used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity.	• Dressings for nose bleeds • Materials for manufacturing dentures
5.	All surgically invasive devices intended for transient use (only reusable surgical instruments), in which case they are in Class I.	• Scalpels and scalpel handles • Reamers • Drill bits • Saws, that are not intended for connection to an active device • Retractors forceps, excavators and chisels • Sternum retractors for transient use
6.	All other active devices are in Class I.	• Active diagnostic devices intended to illuminate the patient's body in the visible spectrum such as examination lights or to optically view the body such as surgical microscopes • Devices intended in general for external patient support (e.g. hospital beds, patient hoists, wheelchairs, dental patient chairs) • Active diagnostic devices intended for thermography

		• Dental curing lights

Annex II: Classification Approaches for IVD Medical Devices

It must be emphasized that even if a particular device type is given as an example, this does not mean that such devices are in all cases in the class indicated by the example. The following table contains only class A devices and it is important to refer to the IVD Medical device Classification Guideline for all classes of In Vitro Diagnostic Medical devices. The list of Low risk IVD devices is provided in Annex VI. Please note that the list is not exhaustive.

Rule	Explanation	Example
	The following IVD medical devices are classified as Class A**:**	-Selective/differential microbiological media (excluding the dehydrated powders which are considered not to be a finished IVD medical device), identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup. -Diagnostic staining reagent and etc
	-Reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination.	
	-Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures.	
	-Specimen receptacles	-Specimen Collection receptacles.

ETHIOPIAN FOOD AND DRUG AUTHORITY

Annex III: Certificate of competence for Low-risk medical device Manufacturer

Ref. No. **Issued Date:**

Expiry Date:

Name :

Product Type :

Owner's Full Name :

Production Manager's Full Name :

Quality Assurance Full Name :

Address of the Manufacturer Site -

Region: Addis Ababa

Kebele: House No: new Tel:

This Certificate of Manufacturer competency is issued in fulfillment of the requirements set by the Authority.

Signature of an Authorized Officer

Warning:

1. The certificate of competence shall be renewed every year, otherwise it will be considered as it is cancelled.
2. The certificate of competence can be suspended or revoked if the organization is found not working in compliance with the laws and standards of the Authority
3. Any change such as location, building, product type or technical persons in the organization without the prior approval of the authority is prohibited.

Annex IV: Low risk medical device manufacturers professional requirements

S.No.	Medical device group	Technical/production manager	quality control manager	Minimum required years of experience
1	Dental devices	BSc and above in Biomedical engineering, any dentistry areas, and related fields in medical device areas.	BSc and above in Biomedical engineering, any dentistry areas, and related fields in medical device areas.	0 year for both
2	Medical Hospital furniture	BSc and above in Biomedical engineering, Mechanical engineering, manufacturing technology and other related engineering	BSc and above in Biomedical engineering, Mechanical engineering, manufacturing technology and other related engineering	0 year for both
3	Ophthalmic and optical device	BSc and above in Biomedical engineering, related professionals in the areas of ophthalmology	BSc and above in Biomedical engineering, related professionals in the areas of ophthalmology	0 year for both
4	Surgical instruments	BSc and above in Biomedical Engineering or professionals in related areas	BSc and above in Biomedical Engineering or professionals in related areas	0 year for both
5	Personal protective device and dressings other than glove	BSc and above in Textile engineering or Biomedical engineering or professionals in related areas	BSc and above in Textile engineering or Biomedical engineering or professionals in related areas	0 year for both
6	In vitro diagnostic devices	BSC and above in Biomedical	BSC in Medical laboratory	0 year for both

		Engineering or Pharmacy or Medical laboratory technology, or professionals in related areas	technology, Chemistry, chemical engineering or professionals in related areas	
7	Laboratory device	BSc and above in Biomedical engineering, material science, or professionals in related areas	BSc and above in Biomedical engineering, material science, or professionals in related areas	0 year for both
8	Examination gloves	BSC and above in Biomedical engineering or Pharmacy or Chemical Engineering, chemistry, professionals in related areas	BSC and above in Biomedical engineering or Pharmacy or Chemical Engineering or chemistry or professionals in related areas	0 year for both
9	Anaesthetic and respiratory devices	BSc -and above in Biomedical engineering, related areas of Anesthesiology	BSc -and above in Biomedical engineering, related areas of Anesthesiology	0 year for both
10	Assistive products for persons with disability	BSc and above in Biomedical engineering, and professionals in other related areas	BSc and above in Biomedical engineering, and professionals in other related areas	0 year for both
11	Sanitary devices	BSc and above in Biomedical engineering, textile engineering and professionals in other related areas	BSc and above in Biomedical engineering, chemistry, textile engineering, and professionals in other related areas	0 year for both
12	Other low risk medical devices	To be decided on case by case basis		

Annex V. List of Class A IVD Medical Devices and their associated accessories

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)

Annex VI. 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