G U I D E L I N E S

ON THE REQUIREMENTS

FOR THE REGISTRATION OF

MEDICAL DEVICES

P A R T II

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Introduction

This guide line is revised based on our day to day experience and findings. The difference between the previous guideline and this guideline is the introduction of device classification, re-registration requirement and individual device registration.

The method of classification for medical devices stated in this guideline depends on the intended use of the device, indications for use, duration of use, degree of invasiveness and local vs. systemic effect of the device. In addition, the classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned.

Class I includes devices with the lowest risk, class II medium risk and class III includes those with the greatest risk.

Because of the vast number and changing nature of variables involved it is difficult to set a simple classification rule. However, the general approach for device classification is as indicated in Annex III. It is the manufacturer who should assign the class of the device. In case where the manufacturer is unable to classify his device consultation with staff of DERD is important.

The class to which the device is assigned determines, among other things, the type of pre-marketing submission/application required for registration. Class I are subjected to general control indicated in section I requirement which is applicable to all class of devices. Class II devices in addition to the general requirement are subjected to special requirement as indicated in section II while class III are subjected to section III. Section IV states requirement for registration of some specific devices.

Separate application is required for each devices of class II and III while for class I it is possible to submit one application for the range of the devices the manufacturer intended to register with the Authority.

Before making an application for registration, the manufacturer is required to classify his device and compile the data and information needed based on the requirement for that class of device. Devices that are in the market before the issue of this guidance will be reclassified based on the nature of the devices and re-registration is required as indicated in section V.

Definition

Absorbable surgical ligatures and suture- Threads or strand of materials which are digested by body enzymes or hydrolyzed by tissue fluids. They include the following:

- cat gut (boilable, non-boilable)
- reconstituted collagen
- synthetic absorbable polymers
- kangaroo tendon
- ribbon gut and fascia lata

Diagnostics- are biochemicals which are used to test organ function, determine blood volume, and hemopoietic function or reveal anatomic evidence of disease or other conditions by outlining various body structures and cavities. It includes all biochemicals, such as reagents, antibiotic sensitivity discs and test kits for diagnosis of disease and other conditions (e.g. pregnancy)

Invitro diagnostics-refer to diagnostics which are used outside the body or which Do not achieve any of their principal intended purposes by chemical action in or on the body or by being metabolized.

Invivo diagnostics- refer to diagnostics which are administered or appleid to human beings and achieve their principal intended purposes by chemical action in or on the body or by being metabolized. Diagnostics which work by such chemical or metabolic action are regulated as "drugs" " Medical device" includes medical equipment and invitro diagnostics.

Medical Equipment- are health care instruments which do not achieve any of their principal intended purposes by chemical action in or on the body or by being metabolized. Instruments or articles which work by such chemical or metabolic action are regulated as drugs.

The term "Medical equipment" includes a great number of instruments and appliances such as thermometers, B.P apparatuses, syringes and needles, catheters, gloves, tubes of all kinds, cardiac devices, kidney dialysis machines, microscopes, x-ray machine and electronic devices to name a few.

Non absorbable sutures and ligature- strand of materials that are suitably resistant to the action of living mammalian tissue. They include the following:

- Silk
- Linen
- Polyamides (Nylon)
- Polyester
- Polyolefins
- stainless steel wire

Surgical dressings'' refer to a wide range of materials used for dressing of wounds. They are employed as coverings, adsorbents, protective or supports for injured or diseased parts and they include:

- Bandages
- Cotton wools
- Gauzes
- Plasters
- Lints
- Other wound dressing materials.

Suture - A thread or a strand of material used to approximate, sew or stitch together the edges of various tissues and hold them in a position until healing has taken place.

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Section I

General Requirement for Registration of All class Devices

1. **Application Form** as indicated in Annex I
2. **Consent form (Annex II)**
3. **Agency agreement**

3.1. An agency agreement should be made between the manufacturer and the agent responsible to act on behalf of the manufacturer in the country.
3.2. The agreement should specify that the representative is the sole agent in Ethiopia.
3.3. The agreement should be signed by both parties.
3.4. The agent representing the manufacturer should hold a license issued by the Ministry of Trade and certificate of competency issued by DACA.

4. **Certificate of compliance with manufacturing standards**

4.1. The applicant should submit:
4.1.1. A photocopy of valid manufacturing License(GMP certificate) issued by the National competent authority
4.1.2. A valid quality system certificate issued by a recognized certifying authority (e.g. ISO, DIN, TUV, BSI, etc.) , if available.
4.1.3. A confirmatory letter issued by the National competent Authority which indicates the names of the products and explains whether the products are freely sold in country of origin; If not, the reasons, thereof should be clearly stated
4.1.4. The documents indicated in 4.1.1. to 4.1.3 above should be authenticated by the Ethiopian Embassy in the country of origin.

5. **COMPANY PROFILE**

5.1. **Back ground information**

The manufacturer should submit background information about the company indicating the following major points.

5.1.1. Year of establishment,
5.1.2. Development since establishment,
5.1.3. Capital,
5.1.4. Organogram (organizational chart of the company)
5.1.5. Total working force,
5.1.6. Ownership,
5.1.7. Subsidiaries (if any)

5.2. **Production Unit**

The manufacturer should describe, in words or in schematic presentation, the production system and in process standard control mechanism.

5.3. **Quality Control Units**

The manufacturer should describe the quality control procedure on raw materials, and finished products

5.4. **Research and Development Unit (R and D), if there is any**

The manufacturer should give detailed information on at least the following major points.
5.4.1. The year R and D was initiated
5.4.2. Qualification of the personnel engaged in R and D
5.4.3. Major research areas and achievements attained.,
5.4.4. Affiliation with other institutions (if there is any)

6. Technical Information-

6.1. General product description design, drawing,
6.2. Methods of manufacture and diagrams of components and sub assemblies.
6.3. Description and explanation of the above mentioned drawings and diagrams.
6.4. Description of the methods used if the device require sterility.
6.5. If the device is to be connected to other device(s), proof must be provided that it conforms to the essential requirements when connected.
6.6. If the device require examination and analysis the manufacturer should submit appropriate method of examination with full details of the

procedures to be followed and descriptions of the required apparatus and specific testing conditions. Should the manufacturer use the methods of examination and specifications contained in well known pharmacopeias or compendiums, references can be made to these.

7. Stability Study report (where applicable)

The manufacturer should determine the shelf life of his products that bear expiration date on the basis of a stability study and submit the data thus generated.

The stability data must show:

7.1. The type of product
7.2. The batch number and size (minimum two)
7.3. Date of manufacture
7.4. Stability study design and method used for the determination of each parameter
7.5. Type and chemical nature of the packaging materials (test should be performed in the proposed market container-closure systems)
7.6. Methods of examination
7.7. Initial and all subsequent results of testing. The data must include the result of studies at suitable test intervals and must cover the whole shelf life of the product.
7.8. A summary consisting of proposed shelf-life and storage recommendations based on the data generated.

8. Labeling of packaging materials

8.1. Name of the product
8.2. Device category (See Annex IV)
8.3. Indication and direction for use
  8.3.1. Frequency of administration;
  8.3.2. Duration of application;
  8.3.3. Time of administration in relation to other factors;
  8.3.4. Route or method of application; and
  8.3.5. Any preparation necessary for use.
8.4. Storage condition
8.5. Manufactory and Expiration date(where applicable)

8.6. Name and address of the manufacturer

9. **Sample of Labeling materials and Actual products** (where applicable)
10. **<u>Product Registration and Marketing Experience of the Industry (Manufacturer)</u>**

The manufacturer should submit full information on its marketing experience and registration status of its products indicating:

10.1. List of countries to which it exports most of its products.

10.2. List of countries in which its products or the company itself is registered

10.3. List of countries where its product(s) has/have been withdrawn from the market. (if so, give reasons for withdrawal).

Section II

Requirement for Registration of Class II Devices

Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special
controls.

1. **Product Catalogue-**Supported both with pictorial representation and detailed product description (Definition, indication, direction for use, etc.)
2. **Report on pre-clinical studies**

Safety study

Class II devices to be implanted or administered in the body must be intensively and extensively evaluated for safety and the following data must be submitted.

a. A report on a toxicology should consist of a summary of:
   i. A description of the experiment system used;
   ii. A description of the species and strains of animals used;
   iii. The dose and site of implantation;
   iv. The critical parameters observed or measured before and after the commencement of the study
   V. The results of the study with an appropriate statistical analysis and conclusion.

b. **Types of toxicological studies to be performed**

i. Acute toxicity
ii. Sub chronic and chronic toxicity
iii. Teratology (for absorbable sutures and ligatures)
iv. Tumorigenicity
v. Irritation to the skin, eyes and mucosal surfaces
vi. Hemocompatibility
vii. Genotoxicity
viii. Effects on reproduction

Efficacy study

A report on the study of the efficacy of new class II devices must include:

a) a summary
b) a description of the experiment system used
c) a description of the species and strains of animals used
d) the dosage level and site of implantation
e) a description of the critical clinical parameters or characteristics studied;

NOTE: A study of the in vivo performance of absorbable ligatures/sutures should at least include:

- Examination of the tensile strength retention (expressed in percentage of the original mass); and
- Other characteristics such as non-capillarity, brittleness and other behaviors related to knot security and knot tying.

c. **Pharmacokinetics study**

Where required a pharmacokinetics study must show:

- The rate and extent of absorption of the device;
- The rate and extent of elimination of the metabolic products of the degradation of the device;

d. **Report on clinical studies**

The proof of safety and efficacy obtained using animals must be reproduced and demonstrated in clinical studies using human subject and/or target animals.

Section III

Requirement for Registration of Class III Devices

Class III is the most stringent regulatory category for devices. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls.

Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
Premarket approval and post marketing performance surveillance data is the required process of scientific review to ensure the safety and effectiveness of Class III devices. Premarketing safety and efficacy data requirement is as indicated in section II.

Additional requirement of class III devices are:

1. Safety and Effectiveness review data as indicated in section II
2. Performance review data-The review for performance of the new device compared with similar class and intended use device available in the market should be submitted
3. Commitment letter to evaluate and follow up the performance of the device and to submit the findings from such study within one year of marketing of the device.

Section IV

Requirement for Registration of Some Specific Devices

In addition to the general control requirements and specific class consideration, the following important points should be clearly indicated for each type of devices

I. **CLASS II SURGICAL LIGATURES, DRESSSINGS AND SUTURES**

1. **Certificate of Good Manufacturing Practice (GMP)**

The certificate should indicate

1.1 That the manufacturer has been approved and registered by the National competent authority as a manufacturer of surgical ligatures, dressings and sutures;

1.2 The type (s) of surgical ligature (s), dressing(s) and suture(s) approved for manufacture;

1.3 That the manufacturer complies with the requirements of a guide to Good manufacturing practice for surgical ligatures, dressings and sutures;

2. **Product Certificate**

The certificate should indicate;

1.2.1. The name(s) of basic raw material (s) from which the product is manufactured;

1.2.2. The name(s) of color additive(s), preservative(s) and coating or impregnating material(s) used;

3. **Technical Documentation**

Manufacturing and Packaging Procedures

3.1.1. List of the basic raw materials from which the ligature/dressings/suture is manufactured..

3.1.2. The name(s) of color additive(s), preservative(s), and coating or impregnating materials used.

3.1.3. Brief and general description of the manufacturing methods and packaging procedure.

3.1.4. Description on the precautions and in process controls that are made in connection with different stages of the manufacturing process, that are of importance in ensuring the quality of the finished product;

3.1.5. The label on the immediate package or the package insert must state:

a) The name and type of the suture/ligature("absorbable" and/or "non-absorbable")
b) The size number;
c) The length of the strand (s) in cm or m,
d) Whether the strand(s) are "plain", "hardened" or "chromicised";
e) The name(s) and percentage of any bactericide and medicament added
f) That the product is sterile, if the product is sterile;
g) Storage and handling conditions;
h) The expiration date, where it is relevant; and the batch number;
i) That the container should not be subjected to heat treatment;
j) That, for treated sutures, the suture is non capillary; and
k) Other indications by which the history of the suture may be traced.

II. IN-VITRO DIAGNOSTIC TEST KIT

1. Data on Performance of the Kit
    - **a.** Sensitivity of the test Kit
    - **b.** Specificity of the test Kit
    - **c.** Positive predictive value
    - **d.** Negative predictive Value

2. **Specimen collection and preparation for analysis, describing;**
   In addition to presentation of such data the labeling of IVD test kit should also bear the following information

- Special precautions/preparations;
- Additives necessary to maintain specimen integrity;
- Known interfering substances; and
- Recommended specimen storage, handling, and shipping instructions.

A step by step outline of recommended procedures from the reception of the specimen to the obtaining of results. In addition to the following, this should include a list of any points that might improve precision or accuracy:

- A list of materials provided and instruction for use, e.g., reagents, equipment, etc.;
- A list of necessary materials that are not provided (include details such as sizes, numbers, types, and quality);
- A description of the amounts of reagents necessary, and parameters such as time, temperature etc.;
- A statement related to final reaction stability and any time restrictions on accurate measurements;
- Details of calibration, identifying and listing and necessary preparation of the reference materials, samples, and blanks. Describe the calibration range including the highest and lowest values measured;
- Details of necessary quality control procedures and materials, e.g., positive and negative controls, acceptable performance limits.
- Explanation of the procedure for calculating the unknown, including the definition of each component of the formula, a sample calculation, and the number of significant figures appropriate for the answer;

- Limitations of the procedure, e.g., identify situations which will have an adverse impact on test results. If further testing either more specific or more sensitive, is indicated in all cases where certain results are obtained, the need for the additional test shall be stated;
- Expected values including how the range(s) was established and identify the populations on which it was established;
- Specific performance characteristics as appropriate including accuracy, specificity, precision, and sensitivity;

III.**X-RAY Equipment**

A) **The quality control manual for x-ray equipment should provide the following information:**

1. List of all x-ray and ancillary diagnostic imaging equipment systems
2. List of parameters to be monitored
3. The frequency of testing required for each parameter, i.e. daily, weekly, monthly, etc
4. The acceptable range within which the equipment must function
5. The tolerance level outside which the equipment should not continue in use

B) **The labeling or the catalogue and/or brochure of x-ray device should state**

1. Method of radiation protection
2. Imaging recording and processing
3. General Labeling
    a. Installation procedures and requirements;
    b. Principles of operation;
    c. Performance characteristics and specifications;
    d. Operating instructions;
    e. Calibration procedures, including equipment and/or materials;
    f. Operational precautions and limitations;
    g. Hazards; and
    h. Service and maintenance information

IV. **LATEX CONDOMS**

1. Quality standards and Specification

Condom is a class II device. Therefore, the application for registration where applicable should be as indicated in section II.

2. Labeling

The following labeling is specific to condom

a) The description of the condom whether it is colored, textured, flavored
b) The number of condom contained per box
c) The nominal width
d) A statement to store the condom in a cool dry place away from direct sun light
e) Whether the condom is lubricated or dry
f) When a medicinal ingredient is added, it shall be identified and its purpose indicated (eg. spermicide)
g) Instruction for use
    i. The need to handle the condom carefully, including removal from package so as to avoid damage to the condom by fingernails, jewelry, etc
    ii. How and when to put on the condom ;mention should be made that the condom should be placed on the erect penis before any contact occurs between the penis and the partner's body to assist in the prevention of sexually transmitted infections and pregnancy
    iii. The need to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis
    iv. The need, if an additional lubricant is desired, to use the correct type of lubricant which is recommended for use with condoms and the need to avoid the use of oil-based lubricants such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine etc
    v. The need to consult a doctor or pharmacist about the compatibility of topical medicines that may come in contact with the condom
h) Instruction how to dispose of the condom
i) A statement that the condom is for single use

V. **DIAGNOSTIC RADIOPHARMACEUTICALS**

1. **General Considerations**

Sufficient data from animal or human studies to allow a reasonable calculation of radiation absorbed dose to the whole body and to critical organs upon administration to a human subject must be submitted.

At a minimum, the following organs and tissues be included in dosimeter estimates:

(1) All target organs/tissues;
(2) Bone
(3) Bone marrow;
(4) Liver;
(5) Spleen;
(6) Adrenal glands;
(7) Kidney;
(8) Lung;
(9) Heart;
(10) Urinary bladder;
(11) Gall bladder;
(12) Thyroid;
(13) Brain;
(14) Gonads;
(15) Gastrointestinal tract; and
(16) Adjacent ogans of interest.

If the diagnostic radio pharmaceutical is for pediatric use, it may be appropriate to evaluate the radiation absorbed dose in all organs, rather than in selected organs. Moreover, it is recommend that organ dosimeter be estimated for the pediatric age groups (e.g., neonates, infants, children, adolescents) in which the diagnostic radio pharmaceutical is intended to be used.

It is recommend that the amount of radiation delivered by internal administration of diagnostic radio pharmaceuticals be calculated by internal radiation dosimeter. Methodology used to assess radiation safety be specified including reference to the body models that were used. The mathematical equations used to derive the radiation doses and the absorbed dose estimates be

provided along with a full description of assumptions that were made. Sample calculations and all pertinent assumptions be listed and submitted.

The safety hazards for patients and health care workers during and after administration of the radiolabeled product be identified, evaluated, and indicated appropriately.

2. **Calculation of Radiation Dose to the Target Organs or Tissues**

For radionuclides used as diagnostic agents (e.g., TC-99m, IN-111), the following items be determined based on the average patient:

a) The amount of radioactivity that accumulates in the target tissue(s) or organ(s)
b) The amount of radioactivity that accumulates in tissues adjacent to the target tissue(s) or organ(s)
c) The residence time of the diagnostic radiopharmaceutical in the target tissue(s) or organ(s) and in adjacent regions

3. **Maximum Absorbed Radiation Dose**

It is recommend that the amount of radioactive material administered to human subjects be the smallest radiation dose practical to perform the procedure without jeopardizing the benefits obtained.

Therefore, calculations anticipate possible changes in dosimeter that might occur in the presence of diseases in organs that are critical in metabolism or excretion of the diagnostic radio pharmaceutical. Possible changes in dosimeter resulting from patient-to-patient variations in antigen or receptor mass be considered in dosimetry calculations.

And also, the mathematical equations used to derive the estimates of the radiation dose and the absorbed dose be provided along with a full description of assumptions that were made. Sample calculations and all pertinent assumptions should be listed.

Calculations of dose estimates should be performed assuming freshly labeled material (to account for the maximum amount of radioactivity) as well as the

maximum shelf life of the diagnostic radio pharmaceutical (to allow for the upper limit of radioactive decay contaminants).

The units should be stated as Be expressed as gray (Gy) per megabecquerel (MBq) or per millicurie (mCi) of radionuclide

4. **None Clinical safety evaluation for Radiopharmaceuticals**

Because of the characteristics of diagnostic radiopharmaceuticals and the way they are used, the nonclinical safety evaluations of these drugs be made by considering the following modifications:

a) Long-term, repeat-dose toxicity studies in animals typically can be
b) Long-term rodent carcinogenicity studies usually can be omitted.
c) Reproductive toxicology studies can be waived when adequate scientific justification is provided.
d) Genotoxicity studies may be waived if adequate scientific justification is provided.

Special safety considerations for diagnostic radio pharmaceuticals include:

a) Verification of the mass dose of the radio labeled and unlabeled moiety;

b) Assessment of the mass, toxic potency, and receptor interactions for any unlabeled moiety;

c) Assessment of potential pharmacological or physiologic effects due to molecules that bind with receptors or enzymes;

d) Evaluation of all components in the final formulation for toxicity (e.g., excipients, reducing drugs, stabilizers, anti-oxidants, chelators, impurities, and residual solvents).

e) Analysis of particle size (for products containing particles) and an assessment of instability manifested by aggregation or precipitation.

Section V

Re-registration Requirements for medical Devices

Once a device is registered it is required to be re-registered. Re-registration is required after five years from the date of issue of the authorization. With applicable registration fee the following data should be submitted for re-registration;

1. Application form (As indicated in annex I)
2. Certificate of pharmaceutical products and/or Free Sale Certificate
3. Statements confirming that there is no change in general quality of the material
4. Sample of packaging materials and actual products (where applicable)
5. Performance evaluation data for the device after marketing of the product (for class II and III Devices)

Performance data and records done in institution or hospitals should provide:

a. The equipment name, Manufacturer, the model designation and serial number, the date and the county of manufacture
b. The equipment location (distribution)
c. A copy of the equipment acceptance test report
d. Quality control monitoring records (data, graphs, charts etc.)
e. The equipment service and repair record including service frequency and costs
f. Sensitivity and Specificity for invitro diagnostic test kits

Annex I

Application Form For Registration and Re-registration of Medical Devices

1. Name of the Devices _____

2. Generic Name (if applicable) _____

3. General use category (see Annex IV) _____

4. Device class (see Annex III) _____

5. Shelf life or use period _____

6. Name and address of Manufacturer _____
_____
_____

7. Name and address of Local agent _____
_____

8. Summary of use of the device _____
_____
_____

9. Documents attached _____
_____

For official use only

Application number _____
Date of Receipt _____
Approved subject to conditions (date) _____
Finally approved date _____
Registration date
_____
Registration number
_____

Name and signature of authority _____

Annex II

CONSENT FORM

We, ……assure you that the legalized documents, the company profile, and other documents that we have submitted are true and correct.

We agree to inform the Drug Administration and Control Authority, of Ethiopia, about any change or modification made on the information given in the documents submitted.

We also agree to allow officials from the Drug Administration and Control Authority ,of Ethiopia, to visit and have first-hand information about the industry at any time

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

Signed by: _____

Person authorized to

Sign on behalf of the manufacturer

_____

Date: _____

Annex III

General approach for Classification of Devices

The examples shown in the following table can be used as guidance. The classification may change depending on the site of use, the addition of a medicinal components, or the intended purpose specified by the manufacturer.

Ser. No	Intended use of device	Device classification	Example
1	Either do not touch patient or contact only intact skin	Class I	Examination glove, cotton wool, forceps
2	Non invasive device for channeling or storing and used for eventual administration	Class I	Spoon
3	Non invasive device for use with blood, other body fluids, organs, tissue	Class II	Scalpels, blood bags
4	May be connected to an active medical device	Class II	Blood pumps for heart-lung machine, infusion ports
5	Modify biological or chemical composition of blood, body liquids, other liquids intended for infusion	Class II	Diagnostic aid for oral administration, Cell separators
6	Non invasive device used for filtration, centrifugation, or exchange of gas or heat	Class II	Blood warmers, anesthetic breathing circuits
7	In contact with injured skin (mechanical barrier, absorb exudates)	Class I	Cotton wool, Gauze dressing
8	Intended for wounds which breach dermis and heal only by secondary intent	Class II	Orthopedic implants, Non-absorbable sutures
9	Invasive in body orifice or stomach (not surgically) for transient use (for short term in oral cavity, ear canal or nasal cavity)	Class I	Prostatic ballon dilatation, infusion cannulae, single use catheters
10	Invasive in body orifice or stomach for short and long term use (in oral cavity, ear canal or nasal cavity) or connected to an active medical device of class II or higher	Class II	Contraceptive diaphragm, suction catheters, tracheal tube, vaginal pessaries
11	Surgically invasive for transient use for diagnosis of defect in heart, central circulatory system	Class III	Neurological catheters, Heart valve
12	Surgically invasive and supply energy, have biological effect and mainly absorbed, re-useable	Class II	Vascular stents, Vascular prostheses, Haemodializers

	surgical instrument, device systems to administer medicine and potentially hazardous		
13	Surgically invasive and for short term use to monitor/correct defect of heart or central circulatory system by direct contact or for use in direct contact with central nervous system	Class III	Cortical electrodes, implant-able electrodes
14	Surgically invasive for short term use for the supply of energy, ionizing radiation	Class II	Surgical lesser, Surgical adhesive
15	Surgically invasive for short term use and has biological effect and mainly absorbed	Class III	Absorbable sutures
16	Surgically invasive and undergo chemical change in body-or administer medicine(not in teeth)	Class II	Non-absorbable sutures, contraceptive device
17	Surgically invasive for long term use and implantable devices to be placed in teeth	Class II	Dental drills, dental filling machine
18	Surgically invasive for long term use and implantable devices and has biological effect or mainly absorbed	Class III	Intrauterine device
19	Surgically invasive for long term use and implantable devices having direct contact with heart or central circulatory nervous system	Class III	Implantable pulse generators, Implantable electrodes
20	Surgically invasive for long term use and implantable devices which undergo chemical change in body-or administer medicine(not in teeth)	Class III	Implantable drug infusion device, penile implants
21	Active therapeutic devices intended to administer or exchange energy in potentially hazardous way, intended to control, monitor, influence directly a class II active therapeutic device	Class II	x-ray film
22	All active devices emitting ionizing radiation and related monitors in medical procedures	Class II	Diagnostic x-ray sources,
23	Active devices for diagnosis, may supply energy for imaging purpose, monitor vital physiological process	Class II	Gamma ray, radioactive therapy equipment, Magnetic resonance
24	Active devices to administer, remove medicines and other substances to/from the body in potentially hazardous	Class II	Lithotriptors, peripheral vascular grafts
25	All other active devices other than mentioned	Class I	Software for image processing,

	under item number 21-24		External electrodes, Stethoscope
26	Devices incorporating integral medicinal product able to act in ancillary way on human (animal) body	Class III	Heparin coated catheters
27	Devices used for contraception or prevention of sexually transmitted disease	Class II	Condoms
28	If the device under item number 27 is implantable or long-term invasive, contain drugs	Class III	Contraceptive diaphragm, Intrautherine device, condom with spermicides
29	Device specific for disinfecting cleaning, rinsing devices for contact lenses and other medical devices	Class II	Instrument grade disinfectant
30	Non active devices to record x-ray diagnostic images	Class II	
31	Devices utilizing animal tissues or derivatives (not devices in contact only with intact skin)	Class III	Absorbable sutures
32	Blood bags	Class II	
33	Clinical mercury thermometer	Class II	
34	Non implantable blood access device for insertion in to vein	Class II	
35	Devices for storage or transport of organs(corneas, sperm, embryos)	Class II	

Annex IV

Table for determination of possible device use category

The use category of the device can be determined but not limited to the following table;

Ser.No	Device use category
1	Anesthesiology
2	Cardiovascular
3	Clinical Chemistry
4	Dental
5	Ear, Nose, and Throat
6	Gastroenterology and Urology
7	General and Plastic Surgery
8	General Hospital and Personal Use
9	Hematology and Pathology
10	Immunology and Microbiology
11	Neurology
12	Obstetrical and Gynecological
13	Ophthalmic