
**Ethiopian Food and Drug Authority (EFDA)**

# Guidelines for Borderline Medical Devices

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**Addis Ababa**

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# Acronyms

| | |
|---|---|
| EFDA | Ethiopian Food and Drug Authority |
| HIV | Human immunodeficiency Virus |
| HCV | Hepatitis C Virus |
| IUD | Intra Uterine Device |
| IVD | In-vitro Diagnostic |
| NMR | Nuclear Magnetic Resonance |
| STD | Sexually Transmitted Diseases |
| SPF | Sun Protection Factor |
| SUSDP | Standard for the Uniform Scheduling of Drugs and Poisons |
| UV | Ultra-violent |

## 1. Introduction

Borderline products pose a challenge to regulators of medical devices and pharmaceutical products across the globe. Borderline cases are considered to be those cases where it is not clear from the outset whether a given product is a medical device, medicinal product or not. Regulatory solutions in the form of the 'rule of doubt' provide a guidance on the principles to identify specific class of the product is crucial. This particular guidance is therefore, developed with the intention of providing solutions to avoid such ambiguity of identifying a product's type.

Many manufacturers have difficulty in interpreting whether or not their product would be considered a medical device within the terms of the Food and Medicine Administration Proclamation No-1112/2019. This guidance document has been developed to aid with some of the more common areas of confusion. It is often assumed that because a product is considered a medical device in some countries, that it will also be a medical device in Ethiopia. This is not the case and manufacturers should always refer to the definitions of a medical device when making any borderline determinations. Any such decision will be based on the stated intended purpose of the product and its mode of action. Manufacturers should also consult the Authority's available published guidelines/directives/regulations in order to determine whether or not their product is considered a medical device in the country.

In general, medical devices must have a ′medical purpose′ which is determined by the definition of a medical device. They must also act primarily in a way that is not metabolic, immunological or pharmacological.

This guideline, therefore, provides principles that help to differentiate whether the product is medical device, accessory, medicinal product or not. It also provides some examples of products that fall under respective categories and additional non-exhaustive lists of products annexed to the document (Annex I). Hence, the borderline products that are not listed in this guideline will be reviewed in a case-by-case basis and hence, applicant need to consult the Authority in such cases.

## 2. Definition

**Authority** means the Food and Drug Authority of Ethiopia (EFDA).

**Borderline product** are those products where it is not clear from the outset whether a given product falls under the medical devices or the medicinal products or not.

**Drug-delivery product** means a product that is intended to administer a medicinal product.

**Medical devices** means any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article, including any in vitro diagnostic device, intended by the person under whose name it is or is to be supplied, to be used, alone or in combination, for human beings for the specific purpose of one or more of the following:

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

iii. investigation, replacement, modification, or support of the anatomy or of a physiological process;

iv. supporting or sustaining life;

v. control of conception;

vi. disinfection of medical devices;

vii. providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and that does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

**Medical device accessory** means an article intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

**Medicines** means any substance or mixture of substances used in the diagnosis, treatment, mitigation, or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof; used in restoring, correcting or beneficial modification of organic or mental functions in human; or articles other than food, intended to affect the structure or any function of the body of the human and it includes articles intended for use as a component of any of the above specified articles.

**Immunological** means an action in or on the body by stimulation and/or mobilisation of cells and/or products involved in a specific immune reaction.

**Pharmacological** means an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect.

**Metabolic** means an action which involves an alteration, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function. Note, the fact that a product is, or is not, itself metabolised does not imply that it achieves, or does not achieve, its principal intended action by metabolic means.

## 3. Objective

The objective of this document is to provide guidance and necessary principles of determining a product whether it falls under medical device or medicinal product or not. This will in turn determines under what category the product under question is regulated by the Authority.

## 4. Scope

This guidance document covers borderline products including medicinal products, accessories, the Medical devices and IVD devices.

## 5. Principles and Requirements for Distinguishing Borderline Medical Devices or Medicinal Products

The intended purpose of the product, taking into account the way the product is presented, and the method by which the principal intended action is achieved should be taken in to consideration to decide whether a product is to be regulated as a medical device or a medicinal product.

### 5.1. Medical Devices

The borderline product is categorized as a medical device if the following conditions are met:

a) If the principal intended action of the product is typically fulfilled by physical means (including mechanical action, physical barrier, replacement of, or support to, organs or body functions).

b) If the principal intended action of a product is deduced from the scientific data regarding its mechanism of action and the manufacturer's labelling and claims support the medical device.

c) If a product does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means.

d) If an integral part of the product contains both medical devices and medicinal products and the function of medicinal product is ancillary with respect to the principal intended action of a product.

**Note:** The medical device may be assisted in their function by pharmacological, immunological or metabolic means and the but as soon as these means are not ancillary with respect to the principal intended action of a product, the product no longer fulfils the definition of a medical device. The claims made for a product, in accordance with its method of action may, in this context, represent an important factor for its qualification as a medical device. These principles can be, for example, illustrated by bone cements. Plain bone cement without antibiotics is a medical device since it achieves its principal intended action (the fixation of prosthesis) by physical means. Bone cements containing antibiotics, where the principal intended action remains fixation of prosthesis, are also medical devices. In this case the action of the antibiotic, which is to reduce the possibility of infection being introduced during surgery, is clearly ancillary. If however the principal intended action is to deliver the antibiotic, the product no longer fulfils the definition of a medical device.

**Examples of medical devices**

The following examples should, in view of their principal intended action, generally be considered as medical devices subject to relevant criteria being met; the function of some of the devices indicated in these examples may be assisted by the presence of medicinal substances where such substances have an ancillary action to that of the device.

- Bone cements,
- Dental filling materials,
- Materials for sealing, approximation, or adhesion of tissues (e.g. cyanoacrylates, fibrin-based adhesives not of human origin)
- Resorbable materials used in osteo-synthesis (e.g. pins or bone screws manufactured using polylactic acid),
- Sutures, absorbable sutures,
- Soft and hard tissue scaffolds and fillers (e.g. calcium phosphate, bioglass),
- Bone void fillers intended for the repair of bone defects where the primary action of the device is a physical means or matrix, which provides a volume and a scaffold for osteo-conduction,
- Intrauterine devices, except products such as intrauterine contraceptives whose primary purpose is to release progestogens,
- Blood bags,
- Systems intended to preserve and treat blood,

  **Note:** Systems intended for the collection, storage and preservation of blood or blood components and as an ancillary function, the treatment of blood or blood components where this effect is achieved outside the human body, are classified as devices provided that any residual material is not intended to achieve its effect when the blood or cells are reintroduced into the body, e.g. systems incorporating chemicals activated by light to reduce the viral load where the quantity of chemical remaining has no intended effect when transfused.

- Gases and liquids for ocular endotamponades
- Cell separators, including those incorporating fixed antibodies for cell binding,

- Wound dressings, which may be in the form of liquids, gels and pastes, etc (e.g. hydrocolloid, hydrogel),
- Haemostatic products, for example patches, plugs and powders where the haemostatic effect results from the product's physical characteristics, or is due to the surface properties of the material. This includes products such as calcium alginate or oxidised cellulose where adhesion of platelets to the surface triggers platelet adhesion and aggregation
- Concentrates for haemodialysis,
- Pressure reducing valves and regulators,
- Irrigation solutions intended for mechanical rinsing (e.g. bladder irrigation solution, ocular irrigation solution). if it is normal saline it will be regulated as medicines.

**Note:** If the solution contains a medicinal substance such as chlorhexidine where the principal intended purpose is to provide a local antimicrobial effect, it will be a medicinal product. Solutions incorporating substances for other purposes, e.g. antimicrobial agent for the preservation of the solution remain a medical device.

- Devices such as catheters, guidewires and stents containing or incorporating radio isotopes where the radioactive isotope as such is not released into the body, used for example in cardiology for the prevention of restenosis.
- Other assistive technology products (eg. hearing aids)

## 5.2.Accessories of a medical devices

Accessory is an article intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

- Contact lens care products (disinfecting, cleaning, rinsing and hydrating solutions including those which aid the insertion and/or wearing of contact lenses without therapeutic claim),
- Disinfectants specifically intended for use with medical devices (e.g. endoscopes),

  **Note:** Multipurpose disinfectants or sterilisation agents are not covered by medical device.

- Lubricants specifically intended for use together with medical devices (e.g. for gloves, endoscopes, condoms),

- Skin barrier powders and pastes or other skin care products specifically intended for use together with ostomy bags,
- Gases used to drive cryoprobes and surgical tools.

## 5.3.Drug-delivery products regulated as medical devices

This category of product concerns a device that is intended to administer a medicinal product. In this case, that device is governed by Authority's relevant medical devices regulatory document(s).

**Examples of drug-delivery products regulated as medical devices**

- Drug delivery pump
- Implantable infusion pump
- Iontophoresis device
- Nebulizer
- Syringe, jet injector
- Spacer devices for use with metered dose inhalers
- Port systems

## 5.4.Medical devices incorporating, as an integral part, an ancillary medicinal substance

These medical devices:

a) incorporate, as an integral part, a medicinal substance with ancillary action are considered and regulated as medical devices. This case relates to a device that incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as per the definitions provided in the Proclamation 1112/2019. The substance incorporated in the device must meet the three following conditions:

   - The substance, if used separately, may be considered to be a medicinal product;
   - The substance is liable to act upon the human body;
   - The action of this substance is ancillary to that of the device.

b) incorporate a medicinal substance as an integral part, are considered as medical device, if and only if the device and the substance are physically or chemically combined at the time of administration (i.e. use, implantation, application etc) to the patient.

**Examples of medical devices incorporating, as an integral part, an ancillary medicinal substance**

- Catheters coated with heparin or an antibiotic agent,
- Bone cements containing antibiotic,
- Root canal fillers which incorporate medicinal substances with ancillary action,
- Soft tissue fillers incorporating local anaesthetics,
- Bone void filler intended for the repair of bone defects where the primary action of the device is a physical means or matrix, which provides a volume and a scaffold for osteo-conduction and where an additional medicinal substance is incorporated to assist and complement the action of the matrix by enhancing the growth of bone cells. In such cases, the ancillary nature would be determined by the performance of the matrix on its own and the extent of the enhancement of growth due to the presence of the substance. With reference to the overall purpose of the product, where the medicinal substance has such an effect that its ancillary nature cannot be clearly established, then the product should be considered in accordance with the concept of a drug delivery system,
- Condoms coated with spermicides,
- Electrodes with steroid-coated tip,
- Wound dressings, surgical or barrier drapes (including tulle dressings) with antimicrobial agent,
- Intrauterine contraceptives containing copper or silver.
- Ophthalmic irrigation solutions principally intended for irrigation which contain components which support the metabolism of the endothelial cells of the cornea
- Drug eluting coronary stents

It should be noted that the mere coating of a product with a chemical does not imply that the chemical is a medicinal substance. For example, hydroxyapatite, frequently used as coating for orthopaedic and dental implants, is not considered a medicinal substance. Other coatings which are in use and which are not medicinal substances are hydromers and phosphorylcholines.

## 5.5.Medical devices incorporating, as an integral part, an ancillary human blood derivative

The same rule applies when a medical device or an active implantable medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal

product constituent or a medicinal product derived from human blood or human plasma following the definitions provided in the Proclamation No. 1112/2019 and which is liable to act upon the human body with ancillary action to that of the device. Such a device should be assessed and authorised in accordance with relevant medical device regulatory document(s) approved and published by the Authority.

## 5.6.Medicinal products

The product considered as medicinal product includes:

a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

c) According to definition described above under “b”, substances used in or administered to human beings to make a medical diagnosis, even if they fulfil their function by physical or chemical means and not by pharmacological, immunological or metabolic means may be considered to be medicinal products.

In case of doubt, the Authority will review using the expert committee on case by case basis. The review process will be in accordance with Food and Medicines Administration Proclamation 1112/2019 and other published documents of the Authority and taking into consideration all the characteristics of the product including the principal mode of actions of that product.

**Examples of medicinal products:**

The following examples should generally be considered as medicinal products subject to relevant criteria being met:

- Spermicidal preparations,
- Gases intended to be used in anaesthesia and inhalation therapy, (e.g. oxygen, medical air supplied in containers) including their primary containers,
- Topical disinfectants (antiseptics) for use on patients,

- Haemostatic and sealant products interacting with the coagulation cascade through a pharmacological process i.e. where the primary mode of action is not mechanical(such as certain collagens which have a molecular structure capable of surface independent demonstrated interaction with platelet receptors and therefore achieve platelet adhesion through a pharmacological process).
- Water for injections, IV fluids and other fluids for drug injection and plasma volume expanders,
- In vivo diagnostic agents, e.g. x-ray contrast media, NMR enhancing agents, fluorescent ophthalmic strips for diagnostic purposes, carrier solutions to stabilize microbubbles for ultrasound imaging, radiopharmaceuticals for diagnostic use
- Gases for in-vivo diagnostic purposes, including lung function, tests, e.g. carbon dioxide for vascular diagnostic purposes,
- Fluoride dental preparations,

  **Note**: Dental preparations with a typical device mode of action, such as cements or varnishes incorporating fluoride, are medical devices, where the fluoride is of ancillary action to that of the device.
- Solutions administered in-vivo to the local circulation for the cooling of organs during surgery,

## 5.7.Drug-delivery products regulated as medicinal products

This category of product involves a device that is intended to administer a medicinal product in the case where the device and the medicinal product form a single integral product, which is intended exclusively for use in the given combination and which is not reusable. Such products are governed by relevant Authority's medicine regulatory document(s).

**Examples of drug-delivery products regulated as medicinal products**

The following examples of drug-delivery products are regulated as medicinal products:

- Prefilled syringes,
- Aerosols containing a medicinal product*
- Nebulizers pre-charged with a specific medicinal product*,

*Note: Empty aerosol and nebulizer supplied for use for patients will be considered as medical device where as those product supplied to the pharmaceutical manufacturing industry will be considered as raw materials.

- Patches for transdermal drug delivery,
- Implants containing medicinal products in a polymer matrix whose primary purpose is to release the medicinal product, for example plastic beads containing antibiotic for treating bone infections, or a matrix to release osteo-inductive proteins into the surrounding bone,
- Intrauterine contraceptives whose primary purpose is to release progestogens,
- Single-use disposable iontophoresis devices incorporating a medicinal product,
- Wound treatment products comprising a matrix whose primary purpose is the administration of medicinal products, for example wound dressings containing an antimicrobial agent where the primary action of the dressing is to administer the agent to the wound for the purpose of controlling infection,
- Temporary root canal fillers incorporating medicinal products, whose primary purpose is to deliver the medicinal product.

## 5.8. Other products

The devices that do not fulfil the definition of article 2(22) of Food and Medicine Administration Proclamation No. 1112/2019 are not considered as a medical device and hence, are not regulated by the Authority as a medical device.

Products that fulfil the definition of article 2(29) of the same proclamation are considered as a cosmetic and hence are regulated by the Authority as per the directives and other guidelines developed and approved for the product's regulation.

**The following are some of borderline products that are not regulated by the Authority:**

- Multipurpose disinfectants or sterilisation agents that do not have medical use.
- General purpose products (eg. printers to be used with medical devices)
- Devices used non-medical purpose (eg. breast pumps).
- Products for sports or leisure (eg. gym equipment with the function of measuring heart rate,
- Personal protective equipment (eg. masks used for protecting users from environmental pollutions)

- Software (eg. telecare alarm systems)

**The following examples of other products are regulated a cosmetic product:**

- non medicated skin cleansers and adhesives
- non medicated soaps
- Adhesive removers
- Sunscreens having SPF 4 or greater
- Sunscreens having SPF less than 4

## Reference:


1. *Guideline for Registration of Medical Devices, 3rd Edition, Ethiopian Food and Medicine Authority, Sept 2014, Addis Ababa, Ethiopia*
2. *Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative, Ref. MEDDEV 2.1/3 rev 3, Medical Devices: Guidance document, Cosmetics and medical devices, DG Enterprise and Industry, European Commission, Mar 2010.*
3. *Food and Medicines Administration Proclamation 1112/2019.*
4. *Chowdhuly N.(2012). Case study on Borderline Medical Products in Europe. Pharmaceuticals policy and Law, 14: 157-175.*
5. *Lyapina M, Yaneva -Deliverska M, Deliversky J, Kisselova A. (2015). Borderline and Classification in the Community Regulatory Framework for Medical device-Brief review on some Dentistry Products. Journal of IMAB - Annual Proceeding (Scientific Papers), 21(1): 709-712.*
6. *Device – medicine boundary products, Australian medical devices guidance, document number 35, Department of Health and Ageing, Therapeutic Goods Administration (TGA), Nov, 2005.*

## Annex I: Examples of Borderline Products and their Categories

| S. No. | Product Purpose | Category |
|---|---|---|
| **1** | **Absorbable, with shape, used in surgery:** | |
| | sutures | Medical Device |
| | Staples | Medical Device |
| | bone fixation devices | Medical Device |
| | Sponges | Medical Device |
| | tissue adhesives (may include fibrin based adhesives) | Medical Device |
| **2** | **Absorbable, without shape, used in surgery:** | |
| | visco-elastic fluids-Intra-Ocular | Medical Device |
| | visco-elastic fluids-Synovial (animal origin) | Medical Device |
| | haemostatic agents *(collagen)* | Medical Device |
| | haemostatic agents *(fibrin)* | Medicine |
| **3** | **Absorbable 'long-term'** | |
| | collagen injections | Medical Device |
| **4** | **Body 'cleaning' substances** | |
| | bulk laxatives | Medicine |
| | salt solution laxatives | Medicine |
| | enema solutions | Medicine |
| | medicated mouthwashes | Medicine |
| | Douches | Medical Device |
| | solutions for irrigation | Medical Device |
| | activated charcoal used internally | Medicine |
| **5** | **Body fluid replacements and nutrients:** | |
| | electrolyte solutions | Medicine |
| | plasma expanders | Medicine |
| | total parenteral nutrition solutions | Medicine |
| | blood substitutes | Medicine |
| | peritoneal dialysis solutions & substances prepacked for their preparation | Medicine |
| | haemodialysis solutions | Medical Device |
| | artificial tears for use with/without contact lenses | Medical Device |
| | artificial saliva | Medical Device |
| | soft contact lens lubricants | Medical Device |
| | hard contact lens lubricants | Medical Device |
| | contact lens solutions | Medical Device |
| | oxygen & other medical gases *(except cryogenic gases and gases for mechanical use)* | Medicine |
| | oxygen – chemical generators | Medicine |
| **6** | **Diagnostic imaging or similar agents *(in vivo)* for use in conjunction with:** | |
| | positron emission tomography | Medicine |
| | computerised axial tomography | Medicine |
| | nuclear magnetic resonance | Medicine |
| | Ultrasonography | Medicine |
| | X-Ray | Medicine |
| | gas mixtures for pulmonary function testing devices | Medicine |
| | radionucleotide scanning | Medicine |
| **7** | **Agents injected, ingested, or otherwise instilled into or applied to the body for use in device therapy:** | |
| | laser fluorescent dyes | Medicine |
| | laser/UV light activated agents | Medicine |
| | lithotripsy imaging agents | Medicine |
| | Pharmaceuticals | Medicine |

| | | |
|---|---|---|
| | Antiseptics | Medicine |
| | radioactive sources and implants | Medical Device |
| | electrode gels | Medical Device |
| | Lubricants | Medical Device |
| | lubricants with spermicide/viricide | Medical Device |
| | refrigerant sprays | Medical Device |
| | cryogenic and refrigerant gases | Medical Device |
| | gases for mechanical use only | Medical Device |
| **8** | **Diluents and preservatives for medicines:** | |
| | water for injections | Medicine |
| | saline for injections | Medicine |
| | blood anti-coagulants and preservatives (for subsequent *in vivo* use) | Medicine |
| **9** | **External use without added active substance:** | |
| | emollient & moisturising preparations, formulated & presented for therapeutic use | Medicine |
| | Uncompounded emollients, moisturisers presented for therapeutic use | Medical Device |
| | barrier protectants which claim prevention of transmission of infectious disease | Medical Device |
| | any of above three with non-therapeutic presentation | Not medicine/medical device |
| | non medicated skin cleansers and adhesives | Not medicine/medical device |
| | non medicated soaps | Not medicine/medical device |
| | adhesive removers | Not medicine/medical device |
| | skin adhesive and adhesive enhancers | Medical Device |
| **10** | **Other:** | |
| | gums *(as adhesives or lubricants)* | Medical Device |
| | polyhydroxy compounds | Medical Device |
| | cellulose derivatives | Medical Device |
| | petroleum jelly | Medical Device |
| | dusting powders, non therapeutic | Not medicine/medical device |
| | dusting powders, therapeutic uses | Medicine |
| | ostomy dressings | Medical Device |
| | Dextra nomer dressing | Medical Device |
| **11** | **Medicated devices - external or short-term internal use with an active additive:** | |
| | condom with spermicide | Medical Device |
| | condom with viricide | Medical Device |
| | catheter with heparin coating | Medical Device |
| | catheter with antibiotic coating | Medical Device |
| **12** | **Implantable non-absorbable with an active additive:** | |
| | bone cement with antibiotic | Medical Device |
| | active implantable medical device lead, steroid eluting | Medical Device |
| | intra ocular lens heparin coated | Medical Device |
| | devices albumin coated | Medical Device |
| | copper intra uterine contraceptive device | Medical Device |
| | dental cement with antibiotic/adrenalin | Medical Device |
| **13** | **Sunscreens having SPF 4 or greater** | Medicine |
| **14** | **Sunscreens having SPF less than 4** | Medicine |
| **15** | **Tissue replacements of biological origin** | |
| | 'manufactured' from human tissue | Therapeutic Device |
| | ‘manufactured’ from animal tissue | Medical Device |
| | direct transplants | Excluded |
| | blood & blood components | Medicine |
| | blood & blood components - other, and blood products | Medicine |

| | | |
|---|---|---|
| | blood substitutes and expanders | Medicine |
| **16** | **Pre-filled or pre-loaded devices intended to deliver a medicine:** | |
| | syringe *(other than prefilled with sterile water for catheter inflation)* | Medicine |
| | transdermal patch | Medicine |
| | hormone eluting IUD | Medicine |
| | blood bags *(which contain & deliver an anticoagulant/preservative)* | Medical Device |
| | blood bags without anticoagulant/preservative | Medical Device |
| | preservative solutions for use in blood bags | Medical Device |
| | IV nutrition etc. bags *(filled)* | Medicine |
| | parenteral nutrition bags *(filled)* | Medicine |
| | peritoneal dialysis bags *(filled)* | Medicine |
| | IV nutritional etc. bags *(unfilled)* | Medical Device |
| | parenteral nutrition bags *(unfilled* | Medical Device |
| | peritoneal dialysis bags *(unfilled)* | Medical Device |
| | oxygen & medical gas containers *(filled)* or delivery units | Medicine |
| | oxygen & medical gas containers *(empty)* | Medical Device |
| | internal sponge, membrane or similar for delivery of spermicide or STD virucide | Medicine |
| | styptics *(pencils, wool etc.)* | Medicine |
| | corn, callus removal pads with medication | Medicine |
| | analgesic plasters | Medicine |
| | medicated paste bandages | Medicine |
| | gingival retraction cords coated with adrenalin | Medicine |
| | gingival retraction cords coated with astringent | Medical Device |
| **17** | **System or procedure packs, or kits *(comprise a medicine(s) and/or device(s) and include procedural trays, first aid kits etc)*:** | |
| | kits, procedural tray, procedural packs, first aid kits, if it contains: medicine(s) only | Medicine |
| | kits, procedural tray, procedural packs, first aid kits, if it contains: device(s) only | Medical Device |
| | kits, procedural tray, procedural packs, first aid kits, if it contains: both device(s) & medicine(s) | Medical Device |
| **18** | **Dual treatment goods:** | |
| | Lithotripter | Medical Device |
| | dissolution agent used with lithotripter | Medicine |
| **19** | **Diagnostic goods for *in vitro* use:** | |
| | that incorporate material of human origin | Therapeutic Device |
| | for self diagnosis *(home use)* | Therapeutic Device |
| | for diagnosis of HIV or HCV infection | Therapeutic Device |
| | professional/laboratory use without products of human origin | Therapeutic Device |
| | *In vitro* test kits other than above | Therapeutic Device |
| **20** | **Extra-corporeal therapies:** | |
| | immunoadsorption columns-charcoal activated | Medical Device |
| | Immunoadsorption columns- monoclonal antibodies | Medical Device |
| | haemo-perfusion columns | Medical Device |
| **21** | **Tissue storage and transport solutions:** | |
| | *In vitro* fertilisation media | Medical Device |
| | other storage & transport solutions containing ingredients of animal origin | Medical Device |
| | other storage & transport solutions containing ingredients of non-animal origin | Medical Device |

| | | |
|---|---|---|
| **22** | **Apheresis Solutions** | Medical Device |
| **23** | **Diagnostic goods for *in vivo* use:** | |
| | Allergen skin tests - scratch test | Medicine |
| | Allergen skin tests-patch | Medicine |
| **24** | **Antiseptics, disinfectants, cleaners, soaking solutions:** | |
| | antiseptics and skin disinfectants | Medicine |
| | antiseptic 'wipe' | Medicine |
| | paper tissue with – antiseptic | Medicine |
| | paper tissue with- viricide | Medicine |
| | alcohol swab (with antiseptic claim) | Medicine |
| | alcohol swab (with no claims other than cleaning the skin) | Medical Device |
| | fabric dressing with antiseptic | Medicine/Medical Device *(dependent on manufacturer's intended purpose)* |
| | toothpaste *(SUSDP scheduled or with therapeutic claims beyond permitted oral hygiene claims)* | Medicine |
| | toothpaste other | Not medicine/medical device |
| | tooth whitener | Not medicine/medical device |
| | contact lens cleaning solutions | Medical Device |
| | sterilants (except sterilant gases) for use on medical devices | Medical Device |
| **25** | **Antiseptics, disinfectants, cleaners, soaking solutions:** | |
| | instrument grade disinfectants | Medical Device |
| | hospital grade disinfectants with specific claims | Medical Device |
| | | |