Saudi FDA Products Classification Guidance

دليل تصنيف المنتجات في الهيئة العامة للغذاء والدواء

Version 3.0

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Saudi FDA Products Classification

Guidance

Version 3.0

Saudi Food & Drug Authority

Kingdom of Saudi Arabia

Please review and send your comments and suggestions to pcs@sfda.gov.sa

Please visit SFDA’s website at www.sfda.gov.sa for the latest update
SFDA

Vision and Mission

رؤية والرسالة

Vision

To be the leading regional regulatory authority for food, drugs and medical devices with professional and excellent services that contributes to the protection and advancement of the health in Saudi Arabia.

الرؤية

Mission

To ensure the safety of food; the safety, quality and efficacy of drugs; and the safety and effectiveness of medical devices, by developing and enforcing an appropriate regulatory system.

الرسالة

حماية المجتمع من خلال تشريعات ومنظومة رقابية فعالة لضمان سلامة الغذاء والدواء والأجهزة الطبية ومنتجات التجميل والمبيدات والأعلاف
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1. Introduction

1.1 Objectives
This guidance presents the Saudi Food and Drug Authority’s (SFDA)’s current view on specific products or a category of products and whether it should be under the responsibility of Saudi Food and Drug Authority and particularly where the regulation may be on the borderline between two SFDA sectors. However, this guidance is not all-inclusive and there some products are still not included. Moreover, it does not provide any information about risk classes of medical devices.

1.2 Background
The SFDA consists mainly of three sectors: Food, Drug and Medical Devices, and Products. Each sector is responsible for distinctive products with different regulatory requirements. Therefore, the SFDA have been receiving a huge number of requests from the industry since its establishment. Most are relating to whether a product should be classified as a drug, or a device or food. SFDA is also aware that other reasons behind this Guide include further identification of the subsequent scheme/path within each sector. Therefore, this guidance document has been issued to help SFDA stakeholders as well as SFDA staffs to classify products easily with a view to achieving greater consistency, transparency and quality of classification decisions relating to these products.

1.3 Scope
This guidance document pertains to a product or category of products that is under the responsibility of each sector within SFDA regulation it also covers some other products, which are not regulated by the SFDA.

1.4 General Principles
SFDA will determine the classification of a product mainly on statutory definitions. Other definitions included in the associated regulated guidelines will also be considered. For example, a product may be classified as a device if it “does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means. If the product acts by such means, it will be classified as a drug. On the other hand, if the
product contains a substance that has an ancillary action by assisting the product in achieving its primary intended actions, the product may be classified as device. However, this is not always the case. Some products come at the borderline between two definitions (food/drug) or (drug/medical device). These products will be classified on a case-by-case basis.

In achieving the final decision about classification of certain products, the SFDA will base its judgment on the current scientific understanding of the product and its characteristics. Moreover, the SFDA believes that global regulatory convergence is critical in achieving cooperation among regulatory bodies. Therefore, the authority will make its best endeavor in aligning its regulations with the common international practice and limit local requirements to where genuinely required or scientifically justified to protect the public health.
1.5 Definitions

**Combination Products:** It includes:

A) A product comprised of two or more regulated components, i.e., drug/device, biological/device, or drug/device/biological, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

B) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products

**Cosmetic:** Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.
**Dietary Supplement:** Is a product (other than tobacco) that bears or contains a concentrated sources of nutrients or other substances with a nutritional or physiological effect intended to supplement the diet by increasing the total dietary intake and is not in a pharmaceutical dosage form.

**Dosage form:** The finished formulation of pharmaceutical product, e.g. tablet, capsule, suspension, solution for injection, suppository.

**Drug:** A) An article intended for use in the diagnosis, cure mitigation, treatment, or prevention of disease and which is intended to affect the structure or function of the human or animal body, or;

B) a substance or a combination of substances which may be used in or administered to human or animal 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.

**Animal Feed:** Any substances, single mixed processed or semi-processed, intended to feed animals, and used as a raw material or as an ingredient in the preparation of manufacturing or processing of feed originating from plant, approved animal source, or aquatic source.

**Feed material:** Any products of vegetable or animal origin, whose principal purpose is to meet animals’ nutritional needs, in their natural state, fresh or preserved. Compound feed: Mixture of at least two feed materials, whether or not containing feed additives, for oral animal feeding.

**Premix:** are mixtures of vitamins, mineral salts, amino acids, enzymes or others, as defined by the bylaws, intended to be added to feeds or water, often used as a carrier substance, used in feed manufacturing to enhance sufficiency.

Feed Additives: components added to animal feed, which may or may not contain nutritional value, are intentionally added to the feed for technical, sensory, nutritional purposes and/or favorably improve animal production and performance or to satisfy the nutritional needs of animals.

**Foodstuff:** Any substance whether processed, semi-processed or unprocessed, which is intended for direct human consumption or to be used in manufacturing, preparing or treating a foodstuff. It does not include perfumes, tobacco and any other substances used only as drugs.
**Herbal Product:** Any finished labeled medicinal products that contain as active ingredients aerial or underground parts of plants or other plant materials or the combination of them, whether in crude state or plant preparation that is used to treat or prevent diseases or ailments or to promote health and healing. Plant materials include juices, gums, fatty oils and any other substance of this nature.

**Health Product:** Finished labeled products in pharmaceutical dosage forms, which are usually low risk ingredients that are intended to restore, correct, modify physiological functions by exerting pharmacological, immunological or metabolic actions.

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

**Medical device:** means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
   - Diagnosis, prevention, monitoring, treatment or alleviation of disease,
   - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
   - Investigation, replacement, modification, or support of the anatomy or of a physiological process,
   - Supporting or sustaining life,
   - Control of conception,
   - Disinfection of medical devices,
   - Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

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

**Metabolic means:** Is 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.
Pharmacological means: In the context of the MDD and AIMD, is understood as 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.

Public Health Pesticides: Any chemical substances, inorganic, organic or natural product or biological product containing elements of microorganisms used in the control of pests (including attractive and repellents substances).

Tobacco: A Product obtained from a blend of *Nicotiana Tabacum* and / or *Nicotiana Rustica* species which has been flue – cured, air cured, fire cured or sweltered.

Tobacco Products: Any products consisting wholly or partially of tobacco leaves as raw material which has been manufactured for the purpose of direct or non-direct smoking or absorption such as Cigarettes, Almeassel tobacco, Meassel Fruit flavored, cigar.
2 Food

The product considered as a food when it falls under the following categories:

2.1. Meat and meat products.
2.2. Fish and Shell-Fish Products
2.3. Milk and dairy products.
2.4. Processed fruits and vegetables products.
2.5. Cereals, Pulses and Nuts and Their Products.
2.6. Vegetable fats, Oils and Their Products
2.7. Water and Beverages, which do not contain ingredients with medicinal effect.
2.8. Honey and foods that contain bee products such as royal jelly, bee pollen and propolis.
2.9. Energy drinks
2.10. Food additives that are intended for food industrial uses.
2.11. Food sweeteners.
2.12. Infant and baby foods.
2.13. Foods for special medical purposes
2.14. Proteins, Carbohydrates and Amino acids products that are used as food supplement, with exception of amino acids and protein products in pharmaceutical form.
2.15. Vitamins and minerals supplements with exception of supplements marketed in pharmaceutical forms.
2.16. Lozenges, which do not contain unacceptable claim or any ingredient with medicinal effect, and the concentration of Menthol, is less than 5 mg.
2.17. Collagen products that may contain vitamins and minerals with exception of products marketed in pharmaceutical forms.
2.18. Food products that contain Moringa leaves with exception of products marketed in pharmaceutical forms.
2.19. Novel foods, which do not contain ingredients with medicinal effect.
2.20. Prebiotic and Probiotic that are intended for food industrial use.
2.21. Food products which contain fish oil
2.22. Fibers products with exception of products marketed in pharmaceutical forms.
2.23 Sports food such as sports drinks, products in powder forms that are intended for sports people and persons who exercise to achieve specific nutritional or functional support, with exception of supplements marketed in pharmaceutical dosage forms.

2.24 Weight management products with exception of products marketed in pharmaceutical forms.

3. DRUG

3.1 Human Drug

A product would be considered as a drug if it falls within the above-mentioned definition. The definition is including the following products:

1. One or more vitamins and/or minerals with concentrations above the upper concentration limit of vitamins and minerals. The upper and lower concentrations limits will be calculated according to the product total daily dose. (Appendix 1)

2. Products contain any of the following substances:
   - Salicylic acid in concentration more than 2%* (please see cosmetic classification section for cosmetics containing this ingredient).
   - Hydroquinone.
   - Ichthammol and coal tar
   - Tretinoin (Retinoic acid) and its salts.
   - Glucosamine.

3. Medicated eye drops

4. Peritoneal dialysis solutions

5. Solution for hemofiltration and haemodiafiltration

6. Saline and sterile water that are intended for intravenous

7. Parenteral nutrition solution

8. Injectable medicines dosage form

9. Peritoneal dialysis solution

10. Blood derivative products

11. Enema solutions products (rectal solution products)

12. Therapeutic Radiopharmaceuticals

14. Vaccines

15. biotechnology medicines

16. Immunoglobulins.

17. Anti-louse products containing non-listed chemical ingredients such as malathion, permethrin, and pyrethrins

**Note:**
Products used for cosmetic purposes and contain one of the above ingredients within the concentrations recommended by the GSO standards for cosmetic products will be classified as cosmetic.

### 3.2 Veterinary Drugs

#### 3.2.1 Veterinary Medicinal Product

When a substance, part of a substance or a combination of substances associated with a therapeutic (medicinal) property or pharmacological effect.

#### 3.2.2 Insecticides

Veterinary products, which contain substances that kill insects or external parasites, such as pyrethrins, pyrethroids or organophosphate compounds.

#### 3.2.3 Shampoos

A shampoo for animals will be considered medicinal if it contains an insecticide or an ingredient, which has a pharmacological effect or is presented as an insecticidal shampoo.

#### 3.2.4 Teat and Udder Products

Products applied internally to teats and udders for the prevention of mastitis.
3.2.5 Herbal Products

Herbal products require a market authorization if they are medicinal by presentation or function. For example, a product containing pyrethrum, pyrethrins or alkaloids, such as digoxin from Digitalis sp., would be considered medicinal by function.

3.2.6 Diagnostic Tools (Testing Kits)

Any substance or combination of substances administered to animals with a view to making a medical diagnosis.

4. Herbal and Health products

Note:
For further details, please refer to the Requirements for Herbal & Health Products Submission

4.1 Herbal product

A product would be considered as a medicinal herbal product when it falls within the following definition: Finished, labeled products in pharmaceutical dosage forms that contain one or more of the following: powdered plant materials, extracts, purified extracts, or partially purified active substances isolated from plant materials.
- The number of herbs in the oral dosage form products should not exceed five herbs.
- Homoeopathic preparations are not allowed to be marketed in Saudi Arabia due to the lack of supporting evidence of its safety and efficacy

4.2 Health product:

1. A product would be considered as a health product subject for registration when it falls within the following definition: Finished, labeled product in pharmaceutical dosage form which may contain one or more of the following ingredients:
2. Amino acid
3. Charcoal.
4. Tar.
5. One or more vitamins and/or minerals with concentrations equal or below the upper concentration limit provided that none of these vitamins and/or minerals are below the lower concentration limit. The upper and lower concentrations limits will be calculated according to the product total daily dose. (Appendix 1)

6. Anti-lice products containing natural source oils or ingredients.

7. Medicated throat lozenges like resorcinol, Cetylpyridinium and Benzyl Alcohol.

8. Antiseptic products intended for human use and containing any ingredients of the following:
   - Benzalkonium
   - Benzethonium
   - Chlorhexidine
   - Chloroxylenol
   - Methylbenzethonium
   - Povidone-iodine
   - Hydrogen peroxide (H2O2)

9. Alcohol hand sanitizers composed of these ingredients:
   - Ethanol 60-80%
   - Isopropanol 60-70%

10. A lipid, including an essential fatty acid or phospholipids e.g. omega 3.

11. Throat lozenges which consist only of volatile oils, ascorbic acid (or its salts) and at least menthol with no unacceptable claim and at concentration of 5 mg or more. The concentration of the individual ingredients (menthol, eucalyptus oil and Ascorbic acid) must not exceed the maximum value as follows:
   a. Menthol 5-20 mg
   b. Eucalyptus oil 0.5-15 mg
   c. Ascorbic acid 100 mg

12. Natural enzyme products.

13. Oral, Nasal or ear Saline solution products e.g. ear drops, nasal spray, nebulizers.

14. Sulfur in concentration higher than 2%

15. Electrolyte products other than those used as fluid replacement for athletes.

16. Topical patches, creams, ointments and gels containing counter irritant ingredient as an externally applied substance that causes irritation or mild inflammation of the skin for the temporary relieve of pain in muscles or joints by reducing inflammation in deeper adjacent structures (these products should comply with the Canadian Counterirritant monograph.)
17 Microorganism whole or extracted, except a vaccine and antibiotics, eg probiotics.

18 Insect repellents in direct contact with human skin

19 Topical products containing organic acids (Alpha-hydroxy acids (AHAs)) in total concentration of organic acids more than 10% .

20 Skin Care Products containing urea in a concentration greater than the concentration recommended by the GSO standards for cosmetic products.

21 Toothpaste products contain one of the following ingredients:
   o Triclosan
   o Chlorhexidine
   o Cetylpyridinium
   o Cetrimide

22 Aromatic and medicinal herbal oils that contain one or more of oils that are extracted from medicinal plants that have non nutritional claims and used internally

23 Products containing medicinal herbs that are not in its natural form and have gone through any manufacturing process such as grinding, extraction, packaging or any other manufacturing process.

5. Cosmetic Products

The following list is a main category of cosmetic products with examples (but non-exclusive):

5.1 Skin Products

5.1.1 Skin care Products

   Face care products other than face mask, Face mask, Eye contour products, Lip care products, Hand care products, Foot care products, Body care products, External intimate care products, Chemical exfoliation products, Mechanical exfoliation products, Skin lightening products,

5.1.2 Skin cleansing products

   Soap products, Bath / shower products, Make-up remover products, External Intimate hygiene products, other skin cleansing products

5.1.3 Body hair removal product

   Chemical depilatories, Physical epilation products, other body hair removal products

5.1.4 Bleach for body hair products
5.1.5 Correction of body odour and/or perspiration
Products with antiperspirant activity, Products without antiperspirant activity

5.1.6 Shaving and pre- / after- shaving products

5.1.7 Make-up products
Foundation, Concealer, Other face make-up products, Mascara, Eye shadow, Eye pencil, Eyeliner, Other eye make-up products, Lip stick, Lipstick sealer, Other lip make-up products, Body or face paint, including "carneval make-up", Other make-up products

5.1.8 Perfumes:
Hydroalcoholic perfumes, Non hydroalcoholic perfumes

5.1.9 Sun and self-tanning products
Before and after sun products, Sun protection products, Self-tanning products, other sun and self-tanning products

5.1.10 Other skin products:
A. Hair and Scalp Products
   1. Hair and scalp care and cleansing products:
      Shampoo, Hair conditioner, Scalp and hair roots care products,
      Antidandruff products, Antihairloss products, Other hair and scalp care and cleansing products
   2. Hair colouring products:
      Oxidative hair colour products, Non-oxidative hair colour products,
      Hair bleaching and dye remover products, other hair colouring products.
   3. Hair styling products:
      Products for temporary hair styling, Permanent wave products, Hair relaxer / straightener products, other hair styling products
   4. Other hair and scalp products.
   5. Hair sun protection products, other hair and scalp products.

B. Nail and cuticle products
   1. Nail varnish and remover products:
Nail varnish / Nail make-up, Nail varnish remover, Nail varnish thinner, Nail bleach, other nail varnish and remover products

2. Nail care / nail hardener products:
Nail care products, Nail hardener, other nail care / nail hardener products


4. Other nail and cuticle products:
Cuticle remover / softener, Nail sculpting products, other nail and cuticle products

C. Oral hygiene products

1. Tooth care products
Toothpaste, Tooth cleansing powder / salt, other tooth care products

2. Mouth wash / breathe spray:
Mouthwash, Breath spray, other mouthwash / breath spray products

3. Tooth whiteners

4. Other oral hygiene products

5.2 Classification criteria of Cosmetic products:
5. 2.1 Site of application and dosage form
The products should be intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity. Products that are intended for (internal use) cannot be considered to be cosmetic products, e.g.:

- Products that are taken orally (syrup, solution, drink, capsules, tablet...etc).
- Products that are taken through the eyes or nose or ear (drops, sprayer...etc).
- Products intended for injection (IV, IM, IS...etc).
- Products that are taken through the anal or vagina (Enema, suppositiry, solution, tab, capsules... etc).
5.2.2 Ingredients
Cosmetic products should not contain any medical or therapeutic substances. Also, the cosmetic products must comply with the COSMETIC PRODUCTS SAFETY REQUIREMENTS GSO 1943 and circulars issued by SFDA.

5.2.3 Product main function and claim
The product should be applied to the external parts of human body with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.

Cosmetic products should not contain medical or therapeutic claims, and they should not have a significant physiological effect.

5.2.4 Product presentation
The product should not be presented as treating or preventing disease in human beings. The following features of the product should be taken into account:

- Product claims and the context in which the claims are made
- Labeling and packaging/packaging inserts (including graphics)
- Promotional literature, including testimonials and literature issued by third parties on behalf of the supplier.
- Advertisements
- The product form and the way it is to be used e.g. capsule, tablet, injection etc.

Particular target of the marketing information e.g. specific population groups with, or particularly vulnerable to, specific diseases of adverse conditions.

**Note:**

All cosmetic products must comply with the following:

- Safety Requirements of Cosmetics and Personal Care Products GSO1943, in addition to the specific product standard (if any), which can be obtained through the GSO website: www.GSO.org.sa
- Circulars issued by SFDA
- Any other technical requirements specified by the SFDA
6. Medical Device
The medical device definition states that Medical device “means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article . . .”. The SFDA’s interpretation is that “similar or related article” under this definition should mean any article in any form. However, “similar or related articles” may be classified as devices as long as they also meet the conditions stipulated in point A and B of the medical device definition.

6.1 In-Vitro Diagnostic medical devices (IVDs):
“Means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes”

Examples:

- ABO Blood grouping
- Blood glucose meters and strips.
- Blood collection tubes, urine sample containers are considered as IVDs.
- General-purpose laboratory equipment labeled or promoted for a specific medical use.
- Densitometry analyser IVD.
- Self-pregnancy test.
- The calibrators and control materials used to verify the performance of the analyzers.
- Swabs.

Note 1:
If the specimen is not derived from the human body or if the procedure takes place in or on the human body (in vivo), the devices are considered Medical Devices.

Example:
- A pulse oximeter.
  Body composition analyzer.

Note 2:
A Helicobacter pylori breath test kit containing labelled urea is a combination products containing two parts:

- Urea is considered a medicinal substance.
- A sample container is considered an IVD.
6.2 Laboratory products for non-medical purposes:

a. Products for General Laboratory Use (GLU) are not considered in vitro diagnostic medical devices unless such products are intended for clinical diagnostic purposes. The labeling must indicate that the device is For General laboratory Use and Not for use in diagnostic procedures.

Example:

- Centrifuge
- Scales
- balances
- Incubators
- Drying oven.
- Autoclave for laboratory use.
- Multipurpose tubes.
- Pipettes.
- Mixers.
- Shakers.
- Products to transfer sample which does not come into direct contact with the human body such as plastic pipettes to transfer blood drop from finger to rapid test.

Note:

GLU should not be used for medical purposes. For example, GLU incubators is not intended to cultivate microorganisms and for the purpose of diagnosis of disease

b. Devices for detection, reading of non-clinical samples, e.g. pathological agents in the environment, are not IVDs neither general laboratory use. Therefore, they are not regulated by the SFDA.
c. Devices for detection of agents of biological or chemical warfare in the environment are not IVD because they do not have a medical purpose.

d. Devices for non-medical purposes, even if these devices are used for in-vitro examination of specimens derived from the human body, for example paternity tests or tests for detecting drugs of abuse/alcohol, are not IVD’s. therefore, they are not regulated by the SFDA

e. All kits such as reagents, standards, calibrators indicators …etc, which are used for non-clinical / non-medical purposes are not considered IVD medical devices. However, these kits must obtain a Medical Device Importation License (MDIL) as non-medical IVD

**Examples:**
- Reagents used for food and water testing.
- Limulus Amebocyte Lysate (LAL) tests for the detection of for endotoxins in injectable pharmaceuticals, biological products and medical devices.

**6.3 Accessories of IVD medical devices:**
The accessories are treated like IVDs in terms of the applicable regulations. They are intended specifically by their manufacturer to:
- Be used together with an IVD medical device to enable that device to be used in accordance with its intended use as an IVD medical device.
- Or to augment or extend the capabilities of that device in fulfilment of its intended use as an IVD medical device.

**Examples:**
- A cleaning solution specifically intended by its manufacturer to be used with a defined automated IVD instrument.
- Bar code scanners.
- General media such as saline for running instruments.
6.4 Chemicals used with/as medical devices:

Some chemical substances and mixtures which are used in its final form in some medical
device application require Medical Device Importation License.

Example:

- Chemical substances and mixtures used in fabrication of prosthesis.
- Calibration gases and chemicals for medical devices.
- Chemical substances and mixtures used to sterilize medical devices.

Note:

Chemicals which fall into the above category must obtain a Medical Device Importation License. However, if the definition of a medical device or an accessory applies, the product must comply with the relevant Medical Device Interim regulations.

6.5 In Vitro Fertilization (IVF) and Assisted Reproduction Technologies (ART) products:

Because IVF procedure and product is intended to modify and support a physiological
process, they are considered medical devices under the Medical Device Interim Regulation.
Examples of products, which could be qualified as medical devices:

- IVF workstations.
- Pipettes or syringes
- Washing, separating, sperm immobilizing, cryoprotecting solutions.
- Devices manufactured utilizing animal tissues or derivatives rendered non-viable
- Devices incorporating, as an integral part, a human blood derivative or a medicinal product is liable to act on the human body with action ancillary to that of the devices.
- Media intended for use in the IVF process to support the growth storage of the embryo.
6.6 Topical Products:

6.6.1 Wound Management products:

If a wound management product acts physically and does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, it is considered a Medical Device.

**Examples of medical devices:**

- Non-medicated dressing used as a physical barrier, for compression or for absorption of exudates such as Hydrogel dressings and Alginate dressing.
- Devices principally intended to manage the micro-environment of a wound such as honey wound dressing gel.
- Wound dressing with antimicrobial substance such as silver to protect the dressing and reduce odour.
- Absorbable hemostatic dressings.
- Silicone sheets or gel for scars.

6.7 Radiation Emitting Device/products:

Any device or component of device or accessory to a device, which produces and emits radiation for the purpose of diagnosis, treatment or alleviation of disease, an injury is considered a medical device.

**Examples:**

- Imaging Products (X-ray, CT, MRI, US, Nuclear imaging products).
- Diagnostic Radioactive materials.
- Digital imaging/x-ray film cassette.

**Note:**

In-vivo dosimeter to record dose received by a patient during a radiotherapy procedure is a medical device.
6.8 General hygiene products:

General hygiene products are not considered medical devices, as the medical definition does not apply. Moreover, some of these products may achieve its intended purpose through chemical action on the human body.

**Examples of non-medical devices:**

- Baby nappies.
- Teats (regulated by food sector)
- Feminine hygiene products (sanitary pads)
- General hand cleansing wipes.
- General use disinfectants / cleaners for environment, rooms, surfaces.
- Dental disclosing solution/tablets.
- Insect repellent.

However, similar products may be regulated as medical devices, if there is a specific medical purpose.

**Examples of medical device:**

- Sanitary pads claiming pain relief by physical means.
- Nibble shields to protect or relieve sore, damaged or cracked nipples or to be which is used to cover and protect the nipple of a nursing mother.
- Electrical and manual Breast pumps
- Surgical Razors and clippers
- Reusable/ single use Patient Bedding set.
- General disinfectants claiming prevention of disease.
- Sitz bath.

6.9 Assistive/supportive products:

Assistive and products/devices are regulated as medical devices if they are intended for alleviation of or compensation for an injury or handicap or support of the anatomy of human beings.

**Examples of medical device:**

- Wheelchairs.
- Patient’s beds.
- Hearing aids
- Walking crutches.
- Patient hoists.
- Commode chairs.
- Abdominal/breast/perineal binders.
- Orthoses.

However, products for daily use by everyone are not be considered as medical device

**Examples of non-medical devices:**
- Portable ramps

**6.10 Devices/products for Personal protection:**
If the product is used in a medical field such as operating room with a view to protect the health and safety of the patient, it is considered a medical device. Where a product is intended to protect the user then it falls outside the scope of medical device interim regulation.

**Examples non-medical device:**
- Medical laboratory protective gloves
- Dust Mask.
- Gum shields for boxers.
- Air Purifying Dust/Particulate Respirators.

These types of products should not contain any claims related to prevention of disease. However, if such claims are present or implied, the product is considered to be medical device.

**Examples for medical devices:**
- Surgical and examination gloves
- Surgical and examination Face masks.
- Surgical apron.
- Sharps containers.
- Surgical apparel which includes examples includes surgical caps, hoods, masks, gowns, drapes, operating room shoes and shoe covers, and isolation masks and gowns.

6.11 General health products:
Products for sport or leisure purposes which are used to maintain a healthy status are not considered to be medical devices unless there is intended medical purpose like treatment or diagnosis of pain or injury.

Examples for sport products that are not considered medical devices:
- Fitness equipment in general.
- Manual massager with no medical purposes.
- Watches/activity trackers with/without a heart rate monitor.

Examples of medical devices:
- Heat/cold pads for pain relief.
- Bandages.
- Electrical nerve stimulator for pain relief.
- Body Composition analyzer.
- Heating and chilling units for packs.
- Devices for rehabilitation.

Note:
Blood pressure monitors are considered to be medical devices regardless of where they are used.

6.12 Educational and Research Use Only (RUO) products/devices:
6.12.1 Medical devices for research/educational use:
Medical Products/devices which fall into this category must obtain a Medical Device Importation License which are based on a purchasing order and a attestation letter from the end user.

6.12.2 Kits for research/educational use:
Kits which fall into this category must obtain a Medical Device Importation License.
6.12.3 Devices labeled as for Research Use Only “RUO”:
RUO devices must have no intended medical purposes and be labeled “For research Use Only” to avoid their potential misuse by institutions or laboratories. Such devices are not considered Medical Devices. However, they must obtain a Medical Device Importation License. This type of product may target the local market and a purchasing order and an attestation letter from a buyer is not required.

Examples:
- RUO products used for Basic Research in research centers.
- RUO products used in Pharmaceutical Research.

Note:
All RUO products/devices must obtain a Medical Device Importation License (MDIL).

6.12.4 Educational Devices:
Devices for educational and training purposes are not regulated as medical devices:

Examples:
- Mock-ups.
- Patient simulators.

6.12.5 Demo Medical Devices:
If a device is intended for presentation or demonstration proposes, it must be labeled “for presentation or demonstration purposes only”. Medical Device Importation License is required for this type of devices.

6.13 Sterilization and disinfection:
Classification of disinfectants is based on the intended purpose of the product. Any article intended to be used for disinfection of medical devices is considered to be a medical device. Therefore, manufacturers should avoid using “disinfection of medical devices” on the labeling of its products if they are not intended for this purpose.
A disinfectant is not considered an accessory to the medical device because it is explicitly stated in the definition and, therefore, is a standalone medical device. However, a disinfectant that is specifically intended for the disinfection of a specific medical device is considered an accessory to this device.

**Example medical devices:**

- Ethylene oxide sterilizer
- Detergents for sterilization of medical devices.
- Disinfectants for dental water line and the fluid pathways of haemodialysis machine
- Denture disinfecting products.
- Medical Washers

**Note1:**

A pre-sterilization device to clean instruments before being sterilized is considered a medical device. For example, Ultrasonic cleaning unit.

**Note2:**

Accessories of medical device disinfectants falls under the scope of Medical Device interim regulations

**Examples of sterilization accessories:**

- Sterilization packaging.
- Physical/chemical/enzymatic Sterilization process indicator.
- Instrument tray

However, general disinfectants intended for general use for rooms, hard surfaces are not considered medical devices.Claims corresponding to these devices should be clearly distinguished from those for a medical device status.

**6.14 Healthcare facility products and adaptations:**

Not all devices/equipment, which are used in the health care facility, are medical devices. As these devices do not meet the medical device definition.

**Examples of non-medical devices:**
- Medical gas pipeline system.
- Medication refrigerators.
- Bedside cabinets.
- Overbred tables.
- Trolleys for general use (Crash/Emergency trolley is a medical device).
- Mayo Stand.
- Air purifiers / Air decontamination units / Mobile air decontamination units.
- Gallipots.
- Drug storage cabinet.
- Dressing trolleys.
- Hospital linen hampers
- Mortuary fridge

However, some devices are considered medical

**Example of medical devices:**
- Examination/treatment chair.
- Surgical lights as these devices are used to effectively illuminate the field or the patient.
- Patient’s beds.
- Refrigerators

**6.15 Dental devices:**

Dental Products, which are used on the patient, are highly likely to be considered Medical Devices.

**Examples:**
- Dental impression materials and trays.
- Dental impression material mixer/syringe.
- Restorations and base metal alloys.
- Implant analog system.
- Amalgamator.
- Articulator.
• Hand held mirror.
• Polishing and cleaning agent which are use professionally.
• Etching gel.
• Dentistry products with aluminum chloride used in hemostasis.
• A 5% sodium fluoride desensitizing agent which is administered by a dental professional.
• Saliva absorber.
• Tooth whiteners products containing more than 6% Hydrogen Peroxide.

**Example of non-medical products:**

• Dental casting furnace.
• Dental laboratory drilling system handpiece/motor.
• Dental laboratory burs.

**6.16 Cosmetic devices:**

There are some cosmetic devices which fall under the scope of the Medical Device Interim Regulation (MDIR). Article 3.C of MDIR states that “contact lenses and laser surgical equipment for cosmetic purposes and their accessories” are regulated by the SFDA.

However, some cosmetic devices fall under the definition of a medical device. These devices may replace, modify or support the anatomy or a physiological process in or on the human body. For examples:

• Laser/Intense Pulse Light (IPL) Hair removal devices.
• Artificial light tanning devices.
• Disincrusting device for cleaning with an intensity not exceeding 4 mA.
• Tanning solariums with ultraviolet UV lamps or combined or separate (UV) and infrared (IR) applications
• Defocused aesthetic lasers for epilation.
• Electrical epilators using needles, tweezers or equivalent accessories or light pulses for photo-epilation.
• Ultrasound stimulators and micro-current stimulators.
- Partial or total heat treatment appliances using resistive or capacitive radiofrequency.
- Pulsed electrostimulator.
- Skin tightening by laser or photon light.
- LED Light therapy and rejuvenation for skin.
- Microdermabrasion Machine.

6.17 Ophthalmic products:

6.17.1 Sunglasses and spectacle frames:
Spectacle lenses which are used to attenuate rays of light by absorption, reflection, or polarization to protect the eyes from light are considered medical devices.

6.17.2 Eye drops:
Eye drops intended for the alleviation dryness or discomfort caused by environmental factors are considered medicinal products and regulated by the Drug Sector.

6.17.3 Balanced Salt Solution (BSS)
BSS intended for eye irrigation during surgical procedure is considered a medical device. see 5.2.1.

6.17.4 Contact lenses and their care products:
Non-corrective lenses, coloured or not are considered to be medical devices on the basis that they prevent, treat or alleviate disease.

Examples:
- UV blocking contact lenses to alleviate photophobia.
- Contact lenses for therapeutic use as a bandage.

Note:
- Contact lenses for cosmetic purposes which have no medical claims must comply with the Medical Device Interim regulation. See 5.16
- Products specifically intended to be used for disinfecting, cleaning, rinsing or, hydrating contact lenses are medical devices.
6.18 Lubricants, moisturizers and Gels

6.18.1 Sexual Lubricant:
A non-medicated substance intended to be applied to the penis and vagina for lubrication during sexual intercourse. It is considered a medical device.

6.18.2 Coupling gel:
A medium designed to be applied between an analytical device (e.g., ultrasound transducer) and the patient, allowing signals to pass through the skin during an examination. This type of products is considered a medical device.

6.18.3 Body orifice gel:
A substance intended to facilitate entry of a device into a body orifice in the body whether it is a natural opening or any permanent artificial opening. It is considered a Medical Device.

6.19 Contraception devices:
A contraceptive product which acts as by physical means and is intended to control birth is considered a medical device.

**Examples:**
- Condoms with/without spermicide.
- Condom with desensitizing agent such as benzocaine.
- Contraceptive diaphragms
- Intrauterine device IUD /with Copper

However, if a product has pharmacological, metabolic or immunological actions. Then, the product is considered medicinal product.

**Example of medicinal products:**
- Intrauterine device with progestin.

6.20 Devices for blood and organ products
- Blood bags (including those containing or coated with an anticoagulant) are considered to be medical device.
• Kidney donor-organ preservation/transport perfusion set is considered a medical device.
• Hemodialysis Solutions

6.21 Cupping Devices:
Devices used to perform cupping include suction cups and suction pump are considered to be medical device.

Examples of Cupping Devices:
• Suction cup
• Suction pump
• Twist rotary
• Rubber bulb suction

Note:
• Please refer to SFDA.MD 0001/2017 (Safe Use and Handling of Cupping Devices and their Applications)

6.22 Irrigation solutions:
Irrigation solutions intended for mechanical rinsing are considered to be medical devices unless such solutions contain ingredients that have an antimicrobial action on the body such as chlorhexidine and iodine. In this case, such products are regulated by the drug sector.

6.23 Raw materials and components:
Raw materials, component parts or semi-finished products that requires further manufacturing process are not normally considered medical devices.

6.24 Spare parts
Medical device spare parts which are supplied for the replacement of existing components of a medical device that has already obtained a medical device marketing authorization or listed in the medical device national registry are not considered medical devices as long as they do not significantly impact the performance and safety of a medical device.
7 Tobacco:

It includes the following product types:

1. Cigarettes.
2. Cigars and Tuscan cigars.
3. Almeassel tobacco.
4. Hand-rolling tobacco and A mixture of tobacco pipe.

Non-smoked tobacco such as (Timpak, shamma, swika etc.) is prohibited, as well as all types of electronic nicotine delivery systems (ENDS) including electronic cigarettes.

Note:

Please refer to the GCC Standardisation Organisation (GSO) for more information.

8 Animal Feed and Public Health Pesticides:

8.1 Animal Feed includes the following types:

1. Feed materials
2. Feed additives
3. Premixture
4. Compound feed

Note:

Please refer to the SFDA Guideline for registration of Feed.

8.2 Public Health Pesticides

Note:

Please refer to the SFDA List of Public Health Pesticides.

9 Borderline Products:

Products which are difficult to determine whether they are considered as drugs, medical device, herbal or health products are called borderline products.
There are different categories of borderline products, and it may fall generally into the following:

- Food products, especially dietary supplement.
- Cosmetic product
- Health products
- Herbal products
- Drug
- Medical device

The following criteria may be taken into consideration during classification decision-making process:

- Product ingredients and format,
- The claim about the product,
- Public perception and history of use
- Products representation to the consumers.
- Past decisions in SFDA
- Classification schemes of other regulatory authorities

## 10 Combination product:

In order to decide whether a product is regulated as a medical device or a medicinal product, the following points should be considered:

- The intended purpose of the product taking into account the way the product is presented
- The method by which the intended purpose is achieved.

Products that achieve their intended purpose by pharmacological, immunological or metabolic action in/on the body; shall be regulated by drug Sector

Products that do not achieve their principal intended action in or on the body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means, shall be regulated by medical device sector.

### Examples of combination products:

Pre-filled syringes, transdermal patches, wound dressing with antimicrobial agent, surgical scrub brush with antimicrobial agent.. etc.
9 Policy for Classification:
Once the request for such a product has been submitted to the Products Classification Department (PCD), the leading sector for the premarket review will be determined by the PCD based on the product’s primary mode of action. The leading sector should collaborate with the related sectors to identify the requirements to approve such products. The leading sector and the related sector should cooperate in the reviewing process to ensure the quality, safety and efficacy of the product.
Appendix: 1

Table for The Upper and lower Concentrations Limits of Vitamins and Minerals

<table>
<thead>
<tr>
<th>Life Stage Group</th>
<th>Vitamin A (μg RAE/day)</th>
<th>Vitamin C (mg/day)</th>
<th>Vitamin D (μg/day)</th>
<th>Vitamin E (mg/day)</th>
<th>Vitamin K₁ and K₂ (μg/day)</th>
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<td>0.2 25</td>
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<td>Adults ≥ 19 y</td>
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<tr>
<th>Life Stage Group</th>
<th>Thiamine (mg/day)</th>
<th>Riboflavin (mg/day)</th>
<th>Niacin Or Niacinamide (mg/day)</th>
<th>Vitamin B₆ (mg/day)</th>
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Appendix 2

Comments on Products Classification Guidance

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الرجاء تعبئة هذا النموذج وارساله عن طريق البريد الإلكتروني: pcs@sfda.gov.sa