الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi FDA Products Classification Guidance

Version 8.0

Operations Sector

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Saudi FDA Products Classification Guidance

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Operations Sector Saudi Food &
Drug Authority
Kingdom of Saudi Arabia

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Saudi Food & Drug Authority Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health.

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed.

Document Control

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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 or more SFDA sectors. However, this guidance is not all-inclusive. Moreover, it does not provide any information about risk classes of medical devices.

1.2. Background

The SFDA consists mainly of four sectors: Food, Drug, Medical Devices and Operations. 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 drug, medical device or food. SFDA is also aware that other reasons behind this guidance 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 achieve greater consistency, transparency and quality of classification decisions related to these products.

1.3. Scope

This guidance document pertains to a product or category of products that are under the responsibility of each sector within SFDA regulation.

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 medical 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 as 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 the classification of certain products (please refer to chart 1 below for current classification decisions in SFDA), the SFDA will base its judgment on the current scientific evidence and the understanding of the product 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 public health.

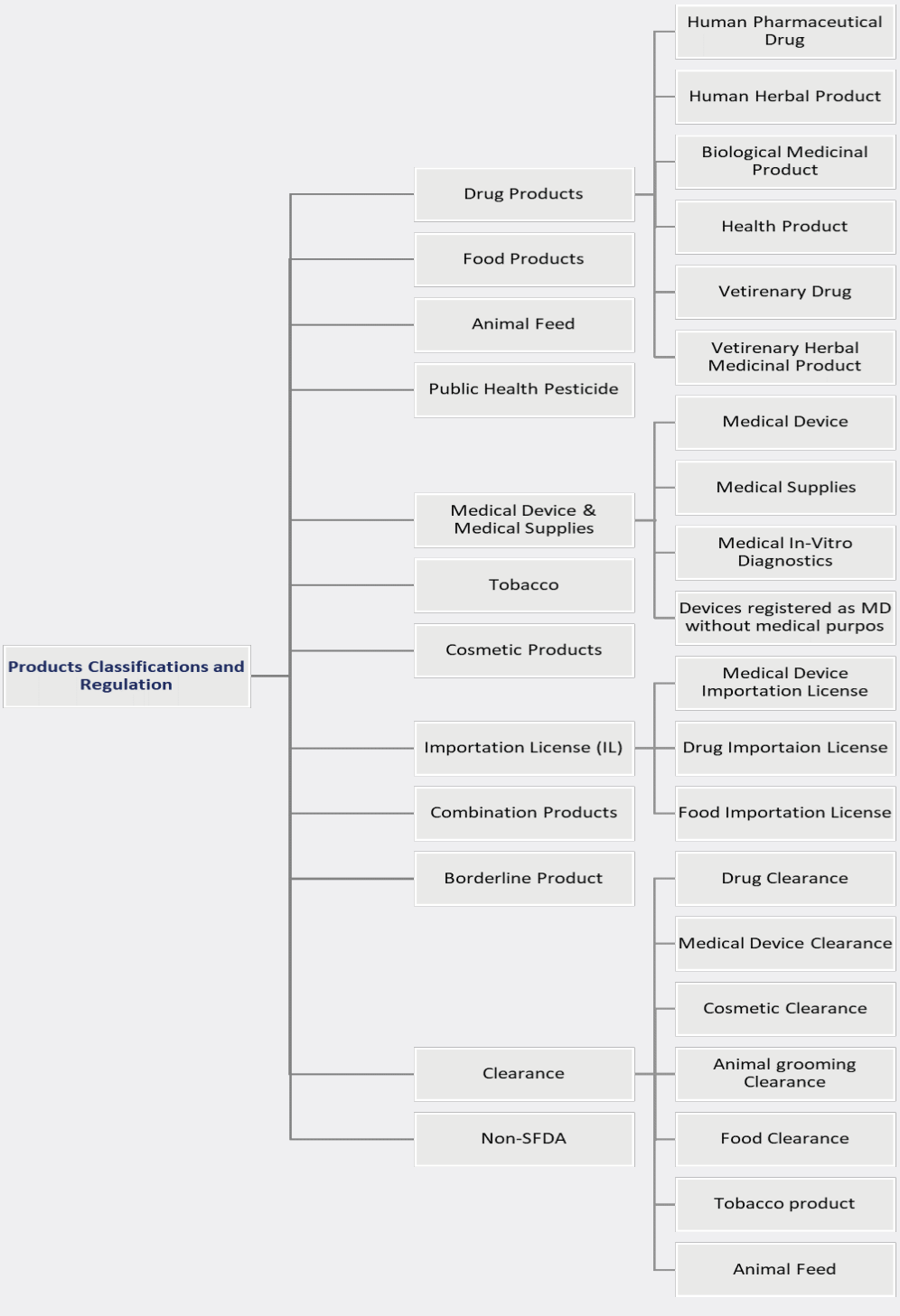
1.5. Disclaimer

This document is subject to change and updated annually; the most recent version of the classification product guidance is available on the Saudi Food & Drug Authority website. To ensure you are using the most recent revision, check the PCS electronic system at https://pcs.sfda.gov.sa/Default.En.aspx . The classification product guidance provides an overview and current understanding of the regulatory pathways supervised by SFDA. The information in this guidance is general, and some cases may require additional classification on a case-by-case basis.

1.6. Related Regulation

- This guideline should be read in conjunction with any relevant documents such as:
- Food Act & Regulation
- Implementing Regulation of the Law of Pharmaceutical and Herbal establishments and products
- Implementing Regulation of the Law of Medical Devices
- Veterinary Products Law In Arab Gulf Cooperation Council Countries
- Pesticides Law System and its Implementing Regulation in the Gulf Cooperation Council
- Feed Act & Regulation
- Implementing Regulation of Cosmetic Products Law
- Law of Combating Narcotic drugs and Psychotropic Substances approved by the Council of Ministers
- The Implementing regulations of the chemicals import Law
- Regulatory Framework for Drugs Approval
- MDS-REQ1 Requirements for Medical Devices Marketing Authorization
- Feed Product Registration Guide
- Requirements and Conditions of Tobacco Products Clearance
- SFDA Products Classification Guidance

Chart.1: Classification Decisions in SFDA



1.7. Definitions

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.

Biological medicinal products:
Medicinal products derived from a variety of natural sources or produced by biotechnology methods and other cutting-edge technologies. They include a wide range of products such as vaccines, blood and blood components, allergenics, advanced therapy medicinal products (ATMPs), recombinant proteins and biosimilars.

Combination Products:
A product consists of two or more of items subject to more than one different SFDA's regulation, and it may include:

- Integrated combination product:

A product consists of two or more regulated components that are combined/integrated as a single product.

- Non-integrated combination product:

A product consists of two or more separated items that are contained in the same package. (Co-packaged combination product).
Any regulated product packaged separately where the labeling information refers to be used with another specific regulated product where both are required to achieve the intended purpose of use. (Cross-labeled combination product).

Compound feed:
Mixture of at least two feed materials, whether or not containing feed additives, for oral animal feeding.

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.

Drug:
Any pharmaceutical product manufactured in a pharmaceutical dosage form and contain one or more of active substance used externally or internally in treatment of a disease in human, or prevent the disease.

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.
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.

Food:
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.

Food Supplement:
Food products used to supplement the normal diet, which contain ingredients weather alone or in combination, that have a nutritional or physiological effect. They have different forms of packaging. A food supplement consists of one or

mixture of the following components or others: vitamins, minerals, fatty acids, amino acids, enzymes, prebiotics and probiotics, collagen, dietary fibers, melatonin, propolis, pollen, herbs or food herbal extracts.

Herbal Product:
Any plant or herb manufactured in a pharmaceutical dosage form, and presented with a medical claim.

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.

Human cells, tissues, or cellular or tissue-bases products (HCT/Ps):
It means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, and cornea.

Immunological means
An action initiated by a substance or its metabolites on the human body and mediated or exerted (i.e. stimulation, modulation, blocking, replacement) by cells or molecules involved in the functioning of the immune system (e.g. lymphocytes, toll-like receptors, complement factors, cytokines, antibodies).

Medical device:
Any instrument, apparatus, implement machine, implant device, in vitro eagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination for diagnosis, prevention, monitoring, controlling, treatment or alleviation of disease or injuries or compensation for injuries. It is also used for investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life (Vital functions of a human being), control

Of not rof conception or assist for that, disinfection of medical devices and supplies and providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body. It 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.

Medical Device Accessories:
Any material or product made to be used with a medical device to enable it to achieve the purpose for which it was manufactured.

Medical Supplies:
Medical materials and products used in diagnosis, treatment, replacement, modification, disability cases or other medical uses for humans, including medical gases.

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. The fact that a product is itself metabolized does not imply that it achieves its principal intended action by metabolic means.

Pharmaceutical Dosage Form:
Physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient in individual doses.

Pharmacological means
An interaction at a molecular level between a substance or its metabolites and a constituent of the human body which results in initiation, enhancement,

reduction or blockade of physiological functions or pathological processes. Examples of constituents of the human body may include, among others: cells and their constituents (cell membranes, intracellular structures, RNA, DNA, proteins, e.g. membrane proteins, enzymes), components of extracellular matrix, components of blood and components of body fluids.

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

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).

Radiopharmaceutical Product:
A radioactive drug that can be administered safely to humans for diagnostic and therapeutic purposes.

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, as well as E-Liquids and Heated Tobacco Products which are used by Electronic Nicotine Delivery Systems (ENDS).

Veterinary Herbal Medicinal Products:
Any plant or herb manufactured in a pharmaceutical dosage form and presented for the purpose of preventing or treating a disease in an animal.

Veterinary Drug:
A substance or combination of substances used to treat or prevent animal disease, diagnose pathological conditions, reappearance, healing, or change the physiological function of an animal.

2. Product Classification System (PCS) Use Process

The ePCS provides services as major services:

2.1. Company sign up service

2.2. Product classification service (online submission of the product classification application and classification decision)

2.3. Appeal service

2.4. Innovative product classification service

Note 1:

- Performance target for sign up service is 1 working day
- Performance target for product classification service is 1 working day
- Performance target for appeal service is 3 working days

2.1 Company Sign Up Service (step by step procedure):

Applicant shall go to e-Product Classification System (PCS) website (https://pcs.sfda.gov.sa/Default.En.aspx)

Choose company login icon

Click registration icon and fill out the form with all required information:

- User name
- Password
- The name of the company in Arabic
- The name of the company in English

o The account manager name
o The legal capacity
o Copy of the authorization letter for the account manager certified from the chamber of commerce
o Email address Phone number
o Cell – phone number Commercial register number
o After complete all the information click register
https://www.sfda.gov.sa/sites/default/files/11-2023/SFDAVPC-E.pdf

2.2. Product Classification Service

The applicant shall fill up the application form in the PCS. Once completed, the system will generate a reference number for the applicant to facilitate communication with SFDA. The application will be assessed upon receiving, and the final decision will automatically be issued via email and can be viewed electronically via PCS.

2.2.1. Required documents for online classification application

- The purpose of using the product as provided by the manufacturer. User instructions as provided by the manufacturer.
- Product mechanism of action.
- Classification request letter indicating the name of the product and the name of the person responsible for the request with his contact information.
- Attach a product catalog with a clear image of the product. Attach the quality certificate from the manufacturer.

- Product registration certificate in the country of origin, if available.

Identification card and product (artwork).

- Attach a product declaration of conformity (D.O.C).
- A classification letter from the manufacturer of the product indicating the product classification.

2.2.2. Classification Service Fees

Submission fees (1000 SR) is mandatory in order to receive the classification decision. A SADAD number will be generated automatically by the ePCS after submitting the online application.

2.2.3. Application Status

Status	Meaning
Waiting Payment	Application is waiting for SADAD payment
Incomplete	Application is suspended; waiting for applicant feedback/response.
Under Process	Application is in under processing at SFDA and has no outstanding issue.
Classified	A final classification decision is assigned to the application
Expired	Application expired due to late payment or response

2.2.4. Classification Decision

The applicant will receive the final classification decision the email, and the decision can be viewed electronically through the PCS system.

The classification decision is considered valid for one year from the date of approval of the classification of the product. Obtaining the classification decision does not guarantee that a product will receive marketing authorization; however, it requires the applicant to commit to the regulatory path stated on the decision

2.3. Appeal Service:

The applicant has the right to appeal against the classification decision within 30 calendar days of receiving the final decision by submitting the regulatory or scientific justifications supporting the appeal.

https://www.sfda.gov.sa/sites/default/files/11-2023/SFDAVPC-E.pdf

2.4. Variation on Saudi FDA Products Classification Application

SFDA has developed this guideline to assist applicants on the details of the various categories of variations, which affect the classification request and to provide recommendations on the preparation of the variation application.
https://www.sfda.gov.sa/sites/default/files/11-2023/SFDAVPC-E.pdf

2.5. Innovative Product Classification Service:

The Saudi Food and Drug Authority (SFDA) launched the "Innovative Product Classification" service, which aimed to facilitate classification and registration processes and requirements by exempting independent researchers and inventors (those who do not have an established business entity) from the classification service fees and the commercial registry.However, applicant must fulfill some classification requirements such as product name, description, ingredients, intended use, mode of action, as well as the patent certificate. (Please refer to note box 2).

2.6. Regulation of raw materials

Raw materials and/or substances that are highly important in product's manufacturing, however, raw materials regulation in SFDA depends on several criteria such as the statutory definitions, the manufacture intended purpose, the current SFDA's regulations and standards. Therefore, SFDA has published a guidance to provide manufactures and stakeholders with information regarding the regulatory path of these materials.

Note 2:

PFor more information, please refer to:

Innovative Product Classification Service, on the following link:

- https://sfda.gov.sa/en/node/85972

Regulation of Raw Materials in SFDA, on the following link:

- https://www.sfda.gov.sa/en/node/88156

3. Food

A product would be considered as food if it falls within the above-mentioned definition. Moreover, food product must not contain any herb or ingredients with medicinal effect or medical claim, moreover, the product must not contain any unacceptable claim. Food products may including the following categories:

3.1. Meat and meat products.

3.2. Fish and Shell-Fish Products

3.3. Milk and dairy products

3.4. Processed fruits and vegetables products

3.5. Cereals, Pulses and Nuts and Their Products

3.6. Vegetable fats, Oils and Their Products

3.7. Water and Beverages, which do not contain ingredients with medicinal effect

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3.8. Honey and foods that contain bee products such as royal jelly, bee pollen and propolis

3.9. Energy drinks

3.10. Food additives that are intended for food industrial uses

3.11. Food sweeteners

3.12. Infant and baby foods such as cereal-based food, rusks, high protein food and others.

3.13. Foods for special medical purposes such as

o nutritionally complete formula, nutritionally incomplete formula, and Formulas for metabolic "genetic" disorders in patients over 12 months and

o Electrolyte products intended to be used for medical, rehydration (oral rehydration solution).

o 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

3.14. Lozenges, which do not contain unacceptable claim or any ingredient with medicinal effect, and the concentration individual ingredients must not exceed the maximum value permitted as follows:

- Menthol must not exceed the maximum value permitted of lower than 5 mg as single serving size, and to a maximum daily serving of 50 mg
- Eucalyptus oil of lower than 0.5 mg as single serving size

3.15. Collagen products that may contain vitamins and minerals, and must not exceed the maximum daily serving of 10 g
3.16. Food products that contain Moringa leaves and must not exceed the maximum dose 8 g/day.
3.17. Novel foods, which do not contain ingredients with medicinal effect.
3.18. Foods for use in weight control diets as well as Formula foods for use in very low energy diets for weight reduction
3.19. Glucosamine food supplements that is in concentrations equal or lower than 1000 mg/day
3.20. Chondroitin sulfate food supplements that is in concentrations equal or lower than 900 mg/d
3.21. Para-aminobenzoic acid that is in concentrations lower than 1200 mg/d
3.22. Hyaluronic acid that is in concentrations lower than 150 mg/d
3.23. Coenzyme Q10 that is in concentrations lower than 200 mg/d
3.24. Spirulina Extract that is in concentrations lower than 2400 mg/d, and must adding a warning that the product is not suitable for people with Phenylketonuria
3.25. Shilajit (if meets the food definition as well as conditions stated above, this ingredient could be regarded as novel food and must comply with the SFDA.FD 5013.General Requirements for Novel Foods)
3.26. Melatonin that is in concentrations equal to or lower than 2 mg/d
3.27. Food supplements such as vitamins, minerals, fatty acids, amino acids, enzymes, prebiotics and probiotics, collagen, dietary fibers, melatonin, propolis, pollen, herbs or food herbal extracts. Please refer to Note 3 for details.
3.28. Purified water and vehicle syrup used for preparation or to be mixed with other product like medication or food supplements to assist special need with difficulty swallowing, Including pediatric, geriatric.

Note 3:

Updates on Food Supplements Regulation: Food supplements will be classified as Pharmaceutical Product if meets any of the following criteria:

Product	Classification
Contains medicinal herb(s) or herbs with medical intended purpose	**Herbal Product**
Concertation(s) is/are above the daily allowed limit stated in technical standards SFDA.FD 55	**Human Pharmaceutical Product**
Intended to treat, prevent and/or diagnose a human disease.	
Contains active medicinal/ pharmaceutical ingredient	
Not intended for ingestion such as topicals, inhalers, suppositories..etc	
Concertation(s) is/are within the daily allowed limit stated in technical standards SFDA.FD 55 and intended to treat, prevent and/or diagnose a human disease	**Health Product**
Products contain: fatty acids, amino acids, enzymes, prebiotics and probiotics, collagen, dietary fibers, and intended to treat, prevent and/or diagnose a human disease	

Please refer to Circular 1337 Updating classification criteria for food supplement

Food supplements must comply with technical standards SFDA.FD 55 Food Supplements

Note 4:

- Food products must comply with the SFDA & Gulf technical regulations and standards such as but not limited to:
- The food registration guideline https://www.sfda.gov.sa/sites/default/files/11-2023/SFDA-FRigster.pdf
- SFDA.FD 55 Food Supplements
- GSO 355 Infants and Young Children Food
- GSO 2106 Infants Formula And Formula For Special Medical Purposes Intended For Infants
- SFDA.FD 2333 Requirements For Health and Nutrition Claims
- SFDA.FD 654 General Requirements For Handling Of Foods For Special Medical Purposes
- GSO 2397 Foods For Special Dietary Uses – General Requirements For Athlete Food
- GSO 654 General Requirements for prepackaged foods for special dietary use
- GSO 2539 Vitamins And Minerals Permitted For Use In Foodstuff
- GSO 2522 Sports Drinks (Electrolyte Drinks)
- The SFDA General Rules for Products Claim
- SFDA.FD 5013 General Requirements for Novel Foods
- SFDA guidance to apply for the approval of novel food

General Classification Scheme of Food Products

4. Drug

4.1. Human Pharmaceutical Product

A product shall be considered as a drug if it meets the above-mentioned definition of pharmaceutical product. The following products are classified as drugs

4.1.1 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. (Please refer to SFDA.FD 55 Food Supplement)

4.1.2. Products contain any of the following substances:

- Salicylic acid in concentration more than %3 in rinse-off hair products, and more than %2 in other products.
- Hydroquinone, (except in artificial nail systems the concentration must be higher than %0.02).
- Tretinoin (Retinoic acid) and its salts.
- Benzoyl peroxide.

4.1.3. Eye preparations that achieves its primary intended purpose by pharmacological, immunological , and/or metabolic means

4.1.4. Ear preparations that achieves its primary intended purpose by pharmacological, immunological , and/or metabolic means

4.1.5. Peritoneal dialysis solutions

4.1.6. Solution for hemofiltration and haemodiafiltration

4.1.7. Saline and sterile water that are intended for intravenous injection

4.1.8. Parenteral nutrition solution

4.1.9. Injectable drug dosage form

4.1.10. Enema solutions products (rectal solution products)

4.1.11. Therapeutic Radiopharmaceuticals

4.1.12. Medical gases:

- Oxygen (Compressed and Liquid)
- Medical Air (Compressed)
- Synthetic air (Compressed)
- Carbon Dioxide (Compressed)

- Nitrous Oxide (Compressed)
- Nitrogen (Compressed).
- Mixture of Oxygen + Nitrous Oxide (Compressed)
- Mixture of Nitric Oxide + Nitrogen (Compressed)
- Mixture of Helium + Oxygen (Compressed)
- Mixture of Carbon Dioxide + Oxygen (Compressed)

4.1.13. Anti-lice medicinal products containing non-listed chemical ingredients such as malathion, permethrin, and pyrethrins

4.1.14. Oral products containing cannabidiol (CBD) oil.

4.1.15. Anti-flatulent products containing substances such as simethicone (Activated Dimethicone) for the symptomatic relief of bloating, colics or excess gas

4.1.16. Glucose Tolerance Beverage used for diagnosis of glucose intolerance

4.1.17. Products contains medicinal ingredients for treatment of gastroesophageal reflux disease (GERD), heartburn, acid regurgitation (antacids) or any other gastroesophageal symptoms.

4.1.18. Food supplements Not intended for ingestion such as topicals, inhalers, suppositories..etc.

4.1.19. Nicotine Pouch intended to be used for medical purpose/claim.

4.1.20. E-Liquids used by electronic delivery systems intended to be used for medical purpose and contains active ingredient such as herbs, vitamin and minerals are regulated as combination products lead by drug sector.(please refer to note 29)

Note 5:

Please refer to:

- Regulatory framework for drugs approval for various types of drug products and the procedure to submit and authorize the applications, on the following link:

https://www.sfda.gov.sa/sites/default/files/10-2021/RegulatoryFramework_1.pdf

- SFDA Circular 4998, for Nasal, Ear, Eye products, Hyaluronic and botulinum toxin injection products, on the following link:

https://www.sfda.gov.sa/sites/default/files/10-2020/Generalization-4998.pdf

- SFDA Circular 62057, regulation and classification of dialysis solutions on the following link:

https://www.sfda.gov.sa/sites/default/files/12-2021/oper2-62057.pdf (sfda.gov.sa)

- SFDA Circular 62058, regulation and classification of blood bags containing anticoagulants. on the following link:

sfda.gov.sa/sites/default/files/12-2021/oper1-62058.pdf

SFDA guidance to apply for the approval of novel food

4.2. Biological Medicinal Product

A product shall be classified as a biological medicinal product if it meets the above-mentioned definition of biological medicinal products and it include a wide range of products such as the followings:

Blood products and blood derivative products

- Vaccines
- Allergenics
- Analogous
- Toxins and Antitoxins
- Recombinant protein
- Biosimilars

Advanced Therapy Medicinal Products (ATMPs) including:

Gene therapy medicinal product

Cell based medicinal product (includes both somatic cell therapy medicinal products and tissue engineered products)

“Combined ATMP” products contain as an integral part of the product also a medical device.

Note 6:

Please refer to Guideline on Classification of Advanced Therapy of Medicinal Products

4.3. Veterinary Drugs

A product shall be classified as a veterinary product if it meets the above mentioned definition, and it may include

4.3.1. Veterinary Medicinal Product

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

4.3.2. Insecticides

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

o A substance, part of a substance or a combination of substances associated with a therapeutic (medicinal) property or pharmacological effect such as product that contain Nicarbazin to be used orally for reducing egg hatchability in pigeons.

4.3.3. 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.

4.3.4. Teat and Udder ProductsProducts applied internally to teats and udders for the prevention of mastitis.

4.3.5. In-Vivo Diagnostic Tools (Testing Kits)

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

4.4. Veterinary Herbal Medicinal Products

A product shall be classified as a veterinary herbal medicinal product if it meets the above mentioned definition that includes any the following criteria

- The presentation: by which the products is manufactured in a pharmaceutical dosage form for preventing or treating animal diseases.
- The function: by which the herbal substance(s) has pharmacological action on physiological function at the dose administered to the target animal. For example, a product containing pyrethrum, pyrethrins or alkaloids, such as digoxin from Digitalis sp., would be considered medicinal by function.
- The quantity: The amount of herbs consumed by the animal if exceeded the reasonable limit on how much the animal eats in its pasture environment.

However, it should be noted that preparations consisting of dried or crushed herb(s) which form a minor component of a product intended for oral administration to healthy animals, as part of the animal's diet, are not regarded as herbal veterinary medicines unless any of the above conditions applied

Note 7:
Products containing chemically defined isolated constituents or a mixture thereof are not herbal medicinal products
Please refer to Guideline on :
https://www.sfda.gov.sa/sites/default/files/08-2022/DataRequirementVeterinaryHerbalMedicinalProducts.pdf

4.5. Human Herbal and Health Products

4.5.1. Herbal Product

A product shall be classified as a medicinal herbal product if it meets the above mentioned definition of herbal product. The definition includes the following products:

- Traditional herbal products:

Traditional medicine (TM) refers to the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures.

- Non-Traditional herbal products (Stand-alone application):

Non-traditional herbal products must be supported by scientific evidence.

Note 8:

Please refer to the following:

Data Requirements for Herbal & Health Products Submission

List of herbs (medicinal plants) allowed

List of herbs (medicinal plants) prohibited

Raw medicinal plants and herbs are not considered herbal products. However, these products shall obtain a clearance permission. Please refer to Requirements for product clearance

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.

A product shall be classified as a health product subject for registration if it meets the above mentioned definition of health product and it may contain one or more of the following ingredients:

- Tar
- Medicated throat lozenges like resorcinol, cetylpyridinium and benzyl alcohol
- Nasal preparations that achieves its primary intended purpose by pharmacological, immunological , and/or metabolic means
- Alcohol hand sanitizers composed of these ingredients:
  - Ethanol %80-60
  - Isopropanol %70-60
- Antiseptic products including wipes, sponges, solutions..etc, intended for human containing any active ingredients of the following:
  - Benzalkonium
  - Benzethonium
  - Chlorhexidine
  - Chloroxylenol
  - Methylbenzethonium
  - Povidone-iodine

- Hydrogen peroxide (H2O2)
- Octenidine
- Throat lozenges which consist only of volatile oils, ascorbic acid (or its salts) and at least menthol with medical 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:
  - Menthol 20-5 mg
  - Eucalyptus oil 15-0.5 mg
  - Ascorbic acid 2000 mg

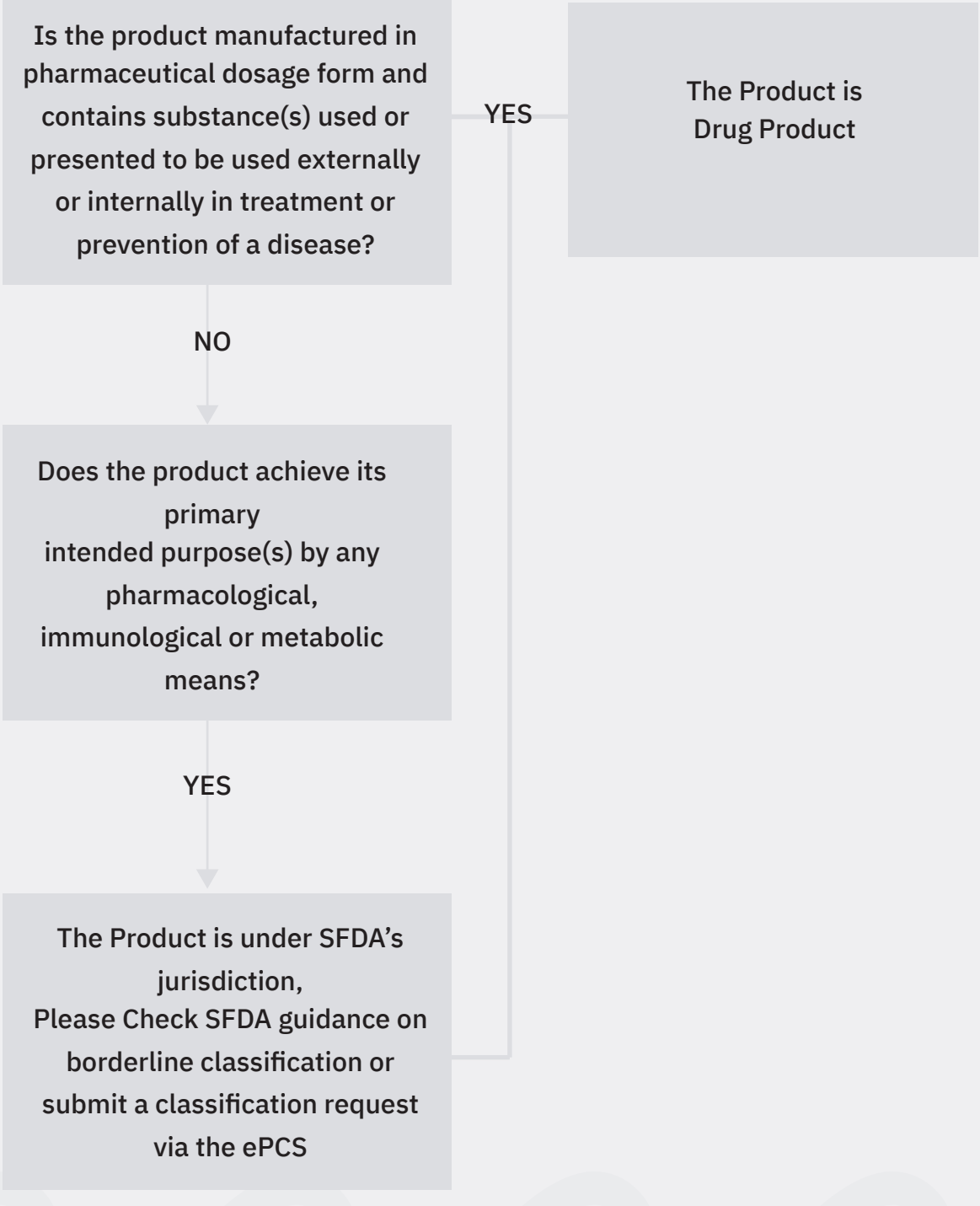
- Sulfur in concentration higher than 2 %.
- Topical products containing organic acids (Alpha-hydroxy acids (AHAs)) in total concentration of organic acids more than %10.
- Skin Care Products containing urea in a concentration greater than the recommended by the GSO standards for cosmetic products
- 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
- 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
- Insect repellents in direct contact with human skin
- 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 structure.
- Shilajet (if meet the health product definition i.e. presented in pharmaceutical dosage form, and medical claim, you may also refer to point 3.28)
- Products containing melatonin with medical claims or in concentrations more than 2 mg/day
- Products contain any of the following substances:

o Ichthammol and Coal tar

o Glucosamine in pharmaceutical dosage form and in concentrations higher than 1000 mg

- Products containing Beta-Sitosterol for wound and burning healing
- Charcoal
- Vitamins and/or minerals with concentration within the daily allowed limit stated in technical standards SFDA.FD 55 and intended to treat, prevent and/or diagnose a human disease
- Products contain fatty acids, amino acids, enzymes, prebiotics and probiotics, collagen, dietary fibers, and intended to treat, prevent and/or diagnose a human disease.

General Classification Scheme of Food Products



5. Cosmetic Products

5.1. Classification Criteria of Cosmetic Products:

5.1.1. 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, SC...etc)
- Products that are taken through the anal or vagina (Enema, suppository, solution, tab, capsules... etc)

5.1.2. Ingredients

Cosmetic products should not contain any medicinal or therapeutic substances. Also, the cosmetic products shall comply with the cosmetic products safety requirements SFDA.CO/GSO 1943 and circulars issued by SFDA.

5.1.3. Product main function and claim

The product should be applied to the external parts of human body with a view 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 medicinal or therapeutic claims, and they should not have a significant physiological effect.

5.1.4. 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 9:

All cosmetic products must comply with the following:

- Any circulars issued by SFDA
- Any other technical requirements specified by the SFDA
- SFDA.CO/GSO 1943 Safety Requirements of Cosmetics and Personal Care Products
- GSO 2528 Cosmetic products- Technical regulation of cosmetic and personal care products claims
- SFDA Guidance for regulating Miswak
- Azelaic Acid restriction to cosmetic products. Circular 24367 SFDA guidance for regulating Musk and Ambergris Products
- Guide to cosmetic products restricted to professional use The link Tables mentioned in the GCC data Requirements for Human Drugs Submission (sfda.gov.sa)
- For Notifying Cosmetic Products The link: https://www.sfda.gov.sa/sites/default/files/05-2024/SFDA-Cosmatic3.pdf

General Classification Scheme of Cosmetic Products

Is the product presented to be used on external parts of the human body or with the mucous membranes of the oral cavity?

**e.g.: epidermis, hair, nails, lips and external genital organs, teeth, gums

YES

Is the product presented to be used for the following functions?

- cleaning,
- perfuming, or correcting body odors
- changing appearance,
- Protecting, or keeping the external parts of the body in good condition.

YES

Does the product comply with the SFDA & GSO standards and requirements?

YES → The product is cosmetic

NO → The cosmetic product is not allowed to be marketed

5.2. Products Category

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

5.2.1. Skin Products

a) Skin care Products

- Face care products other than facemask, Facemask, 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

b) Skin cleansing products

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

c) Body hair removal product

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

d) Body hair bleaching product

e) Correction of body odor and/or perspiration

Products with antiperspirant activity, Products without antiperspirant activity

f) Shaving and pre- / after- shaving products

g) 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 "carnival make-up", Other make-up products

h) Perfumes:

- Hydroalcoholic perfumes, Non hydroalcoholic perfumes

i) Sun and self-tanning products

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

j) Other skin products

5.2.2. Hair and Scalp Products

a) Hair and scalp care and cleansing products:

- Shampoo, Hair conditioner, Scalp and hair roots care products, Antidandruff products, Anti-hair loss products, other hair and scalp care and cleansing products.

b) Hair colouring products:

- Oxidative hair colour products, Non-oxidative hair colour products, Hair bleaching and dye remover products, other hair colouring products

c) Hair styling products:

- Products for temporary hair styling, Permanent wave products, Hair relaxer / straightener products, other hair styling products

d) Hair sun protection products, other hair and scalp products

5.2.3. Nail and cuticle products

a) Nail varnish and remover products:

- Nail varnish / Nail make-up, Nail varnish remover, Nail varnish thinner, Nail bleach, other nail varnish and remover products

b) Nail care products/ products with protection layer for nail

c) Nail glue remover products

d) Other nail and cuticle products:

- Cuticle softener, Nail sculpting products, other nail and cuticle products

5.3.4. Oral hygiene products

a) Tooth care products

- Toothpaste, Tooth cleansing powder / salt, other tooth care products,

b) Mouth wash / breathe spray

- Mouthwash, Breath spray, other mouthwash / breath spray products

c) Tooth whiteners

d) Other oral hygiene products

6. Animal general care products (grooming)

Animal general care products are products intended to be placed in contact with the external parts of the animal body with a view exclusively or mainly to a cosmetic effect such as cleaning, changing the appearance, or correcting body odors. Animal grooming products are subject to SFDA's regulation, and these products must obtain a clearance permission.

Example:

- Soaps, shampoos that are intended for animal bathing to clean, deodorize, or remove stains or dirt.
- Tooth care products intended to clean the animal teeth.
- Ear care products intended to clean the ears, remove earwax or dirt.

However, if such products contain a medicinal ingredient, intended for medical purposes such as diagnosis, treatment, prevention of a disease, or intended to affect an organic function of animals, then they will be regulated as veterinary drug.

7. Medical Device

A product shall be classified as medical device or a medical supply if it meets the above-mentioned definitions. The SFDA's interpretation of "similar or related article" under the definition of medical device should mean any article in any form. However, "similar or related articles" may be classified as devices as long as they intended for the purposes and meet the conditions stipulated in the medical device law.

Note 10:

- FPlease refer to MDS-REQ1 (Requirements for Medical Devices Marketing Authorization).

https://www.sfda.gov.sa/sites/default/files/12-2021/REQ1En_0.pdf

General Classification Scheme of Medical Device

Is the product presented to be used for humans ?

Yes

Is the product presented to be used for one or more of the following functions?
Diagnosis, prevention, monitoring, treatment or alleviation of disease or an injury or handicap
Investigation, replacement, modification, or support of the anatomy or of a physiological process
Supporting or sustaining life
Control or assisting 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

Yes

Does the product achieve its primary intended purpose(s) by non-pharmacological, non-immunological and non-metabolic means?

Yes

The product is a medical device

7.1. In-Vitro Diagnostic medical devices (IVDs):

Products would be considered as IVD if they meet the IVD definition and are intended by the manufacturer to provide information for medical or diagnostic purposes by in vitro examination of specimens derived from the human body.

Example:

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

7.2. 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
- General media such as saline for running instruments

Note 11:

When lancet and pen come in the same kit with blood glucose meter, then the whole kit is considered as medical IVD.

7.3. Laboratory products for non-medical purposes:

a) The labeling of General Laboratory Use (GLU) products shall indicate that the device is For General laboratory Use and Not Specifically for medical use or for use in diagnostic procedures. Example

Example:

- Centrifuge Scales Balances
- Incubators that are not intended to cultivate microorganisms or for the purpose of diagnosis of disease
- Drying oven
- Autoclave for laboratory use
- Multipurpose tubes/ multipurpose containers Pipettes
- Mixers Shakers

b) Equipment or instrument 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) Products for non-medical purposes, even if these products are used for in-vitro examination of specimens derived from the human body, are not considered as medical-IVD's, thus are not regulated by the SFDA. However, these products must obtain a Medical Device Importation License (MDIL) "If only imported / claimed to be used in the Medical field institutions".

Example:

- Paternity tests
- Tests for detecting drugs of abuse/alcohol/ c purposes
- Products in a kit with reagents, solutions, or buffer..etc.

d) All kits such as reagents, controls, calibrators, indicators ...etc, which are used for non-clinical / non-medical purposes are not considered IVD medical devices. However, these kits shall obtain a Medical Device Importation License (MDIL) as non-medical IVD, "If only imported / claimed to be used in the Medical field institutions".

Examples

- Reagents used for food and water testing
- Limulus Amebocyte Lysate (LAL) tests for the detection of endotoxins in injectable pharmaceuticals, biological products and medical devices
- Distillation machines used in the medical field / applications only International quality and efficiency samples for clinical/medical labs

Note 12:
Standard materials that contain narcotics or psychotropic substances are considered as the substance they contain. (Please refer to the general rules on the attached tables of narcotics and psychotropic substances control)

7.4. 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.

Examples:

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

Note 13:
Chemicals which fall into the above category shall obtain a Medical Device Importation License. However, if the definition of a medical device or medical supplies applies, the product must comply with the relevant Medical Device Law. Please refer to MDS-REQ1 Requirements for Medical Devices Marketing Authorization

7.5. 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 Law

Example:
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.

7.6. Topical Products:

7.6.1. 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, regardless of any ancillary actions that exerted by any ingredient that constitute the product, it is considered a Medical Device.

Examples:

- 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 microenvironment of a wound such as honey wound dressing gel
- Wound dressing with antimicrobial substance such as silver to protect the dressing and reduce odor (please refer to points 13)
- Absorbable hemostatic dressings
- Silicone sheets or gel intended for medical purpose such as scars, burning or wound treatment
- Topical patches, creams, ointments and gels that externally applied for the purpose of temporary relieve of pain and irritations (please refer to point 4.5.2.13)

7.6.2. Products for skin peeling:

Products that act physically for the treatment of acne and does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means are considered Medical Devices. However, there are some products that could act by chemical peeling using chemical substances such as trichloroacetic acid. In this case, the decision will be taken considering the primary mode of action, the depth of peeling, the concentration and the PH of the solution. (For more information, refer to SFDA Guidance for Borderline Products Classification).

7.7. Medical Radioactive Materials:

Material emitting ionized radiations, whether alone or within other medical devices or supplies, used for diagnosis and treatment.

Note 14:

In-vivo dosimeter to record dose received by a patient during a radiotherapy procedure is a medical device.

7.8. Medical Imaging Materials:

Anything used to improve contrast that can be obtained using medical imaging techniques. These materials are not radioactive and must obtain a medical importation license.

Examples:

- Iopamidol contrast media
- Barium sulfate enema kit used as a contrast in medical imaging

Note 15:

Please refer to MDS-REQ4 (Requirements for the Import and Clearance of Imaging Materials and Particle Accelerators Used in Radioisotopes Formation for Medical Applications)

7.9. General hygiene products:

General hygiene products are not considered medical devices, as the medical device and medical supplies 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
- Feminine hygiene products (sanitary pads)
- General hand cleansing wipes
- General use disinfectants / cleaners for environment, rooms, surfaces
- Dental disclosing solution/tablets
- Insect repellent (please refer to point 4.5.2.12)
- Water or fiber dental floss

However, similar products may be regulated as medical devices, if there is a specific medical purpose and meet the medical device definition.

Examples of medical device:

- Sanitary pads claiming medical purpose by non-pharmacological, non-metabolic, non-immunological means
- Adult nappies
- 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
- Anti-lice products containing natural source oils or ingredients

7.10. 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

Examples of non-medical devices:

- Portable ramps
- grab rails at doorways or stairs,

7.11. Medical personal protective equipment:

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 law

Examples of non-medical device:

- Non-medical protective gloves Dust Mask
- Gum shields for boxers
- Mouth guards for non-medical purposes
- Air Purifying Dust/Particulate Respirators

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

Examples for medical devices:

- Surgical and medical examination gloves
- Medical masks.

- Surgical apron.
- Sharps containers.
- Surgical apparel which includes surgical caps, hoods, masks, gowns, drapes, operating room shoes and shoe covers, and isolation masks and gowns.

7.12. General health products:

Products for sport or leisure purposes, which are used to maintain a healthy status, are not considered medical devices unless there is intended medical purpose like treatment or diagnosis of pain or injury or monitoring of disease.

Examples of non-medical devices:

- Fitness equipment in general.
- Manual massager with no medical.
- purposes Watches/activity trackers with/without a heart rate monitor.
- Body Composition analyzer.

Examples of medical devices:

- Heat/cold pads for pain relief.
- Bandages.
- Electrical nerve stimulator for pain relief.
- Heating and chilling units for packs
- Device for rehabilitation
- Cryotherapy devices with medical intended use

Note 16:

- Blood pressure monitors are considered to be medical devices regardless of where they are used.
- Smartwatch is considered as a medical device when it has diagnosing features.
- Please refer to MDS-REQ5 (Requirements on Importation and Shipments Clearance of Medical Devices and Supplies)

7.13. Educational and Research Use Only (RUO) products/devices:

These products/devices must have no intended medical purposes and must be labeled “For research Use Only”. All RUO products/devices shall obtain a Medical Device Importation License (MDIL) “ If only imported / claimed to be used in the Medical field institutions”. It may include:

7.13.1. Medical devices for research/educational use:Medical Products/devices which fall into this category shall obtain a Medical Device Importation License

which are based on a purchasing order and a attestation letter from the end user.

7.13.2. Kits for research/educational use:

Kits which fall into this category shall obtain a Medical Device Importation License.

7.13.3. 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 shall 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 17:

- Chemicals labeled research institutions are not regulated by SFDA; “If these research / educational center not related to the Medical field institutions” these chemicals must obtain an importation license from Ministry of Education

7.13.4. Demo Medical Devices

If a device is intended for presentation or demonstration proposes, it shall be labeled “for presentation or demonstration purposes only”. Medical Device Importation License is required for this type of devices. Please refer to MDS-REQ5 (Requirements on Importation and Shipments Clearance of Medical Devices and Supplies).

7.14. 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. A disinfectant is not considered an accessory to the medical device because it is explicitly stated in the definition of medical device 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 of medical devices:

- for Detergents for sterilization of medical devices.
- Disinfectants for dental water line and the fluid pathways of haemodialysis machine.
- Denture disinfecting products.
- Autoclave machine.

Note 18:

- A pre-sterilization device to clean instruments before being sterilized is considered a medical device. For example, Ultrasonic cleaning unit.
- Accessories of medical device disinfectants falls under the scope of Medical Device Law.

Examples of sterilization accessories:

- Sterilization packaging.
- Physical/chemical/enzymatic Sterilization process indicator. Instrument tray
- Sterilization process indicators that contain living microorganism, achieve its intended purpose through biological effect do not fall under the Medical Device definition, and therefore are not considered as Medical Device.
- 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.

7.15. 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.

Example of non-medical devices:

- Medical gas pipeline system (excluding system with pressure gauges and regulators).
- Medication refrigerators.
- Bedside cabinets.
- Overbed 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.
- Hospital linen hampers.
- Mortuary fridge

Example of medical devices:

- Examination/treatment chair
- Surgical lights as these devices are used to effectively illuminate the field or the patient
- Patient’s bed
- Devices intended for temporary storage and transport of organs for transplantation (i.e. containers, bags and similar products)
- Devices intended for long-term storage of biological substances and tissues such as corneas, sperm, human embryos, etc. (i.e. containers, bags and similar products)
- Fridges specifically intended for storing blood, tissues etc.
- Devices intended to be used for a temporary containment or storage function, e.g. cups and spoons specifically intended for administering medicines

7.16. Dental devices:

Dental devices, which used for treatment of patient, are considered Medical Devices.

Examples:

- Dental impression materials and (mixer/syringe /trays).
- Dental restorative materials (composites /glass ionomer ...).
- Restorations and base metal alloys.
- Implant system.
- Amalgamator.
- Articulator and facebow.
- Dental units.
- Scaler.
- Pulp tester.
- Rubber dam and accessories.
- Orthodontic appliance and accessories.
- Dentistry products with aluminum chloride used in hemostasis.
- A %5 sodium fluoride desensitizing agent, which is administered by a dental professional.
- Dental operating light.
- Tooth whiteners products containing more than %6 Hydrogen Peroxide or other compounds or mixtures that release hydrogen peroxide in equivalent concentration, (For example, %18 carbamide peroxide is approximately equivalent to %6 hydrogen peroxide).
- Dental compressor.

Example of non-medical devices:

- Dental casting furnace
- Dental laboratory drilling system hand piece/motor
- Dental laboratory burs

7.17. Devices registered as Medical Devices without an intended medical purpose:

There are some devices which fall under the scope of the Medical Device Law. These devices are covered below and shall also be classified using the risk classification rules for medical devices.

- Contact lenses or other items intended to be introduced into or onto the eye. For Example: Non-prescription colored contact lenses
- Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
- For Example: Solid body contour modifying implant (e.g. Clavicle or collarbone piercing)
- Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.

Note 19:

- Dermal fillers containing hyaluronic acid are considered as medical devices

- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

For Example: Body sculpting equipment

- High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra- violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.

For Example: Intense pulsed light (IPL) machines for body hair removal

Note 20:
Please refer to:
MDS-REQ 3 (Requirements for safe use of medical devices inside healthcare facilities)
MDS-G007 (Guidance for the operation and use of radiation emitting medical devices)

Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.
For Example: Transcranial (no surgically invasive) stimulation

7.18. Ophthalmic products:

Eye drops:

o Eye drops intended for the alleviation dryness or discomfort caused by environmental factors in non-pharmacological, non-immunological and/or non-metabolic means are considered medical devices

o Balanced Salt Solution (BSS)

BSS intended for eye irrigation during surgical procedure is considered a medical device.

Contact lenses and their care products:
Non-corrective lenses coloured or not are considered medical devices.
Examples:
UV blocking contact lenses to alleviate photophobia

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

Note 21:
Contact lenses for cosmetic purposes which have no medical claims must comply with the Medical Device Law. See point 7.17
Products specifically intended to be used for disinfecting, cleaning, rinsing or, hydrating contact lenses are medical devices.

7.19. Nasal and ear saline preparations:

Nasal and ear saline preparations are considered medical devices

7.20. Lubricants, moisturizers and Gels

7.20.1. Sexual Lubricant:

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

7.20.2. Coupling gel:

o 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 product is considered a medical device

7.20.3. Body orifice gel:

o 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.

Example:

- Products containing lactic acid for changing vaginal PH
-

7.21. Non-systemic contraceptive and STI barrier prophylactics

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

Example of drug products:

- Intrauterine device with progestin.

7.22. Devices for blood and organ products

- Blood bags (including those containing or coated with an anticoagulant) are considered medical devices.
- Kidney donor-organ preservation/transport perfusion set is considered a medical device.
- Hemodialysis Solutions (please refer to points 4.1.5 and 4.1.6).
- Organ preservation solutions.

Note 22:

Minimally manipulated biological products intended for human applications, must obtain a Medical Device Importation License.

- **Examples of these products:**
  - Bone ligaments Tendons, fascia Cartilage.
  - Ocular tissues (corneas and sclera).
  - Skin.
  - Vascular grafts (veins and arteries except preserved umbilical cord veins).
  - Pericardium, amniotic membrane (when used alone without added cells for ocular repair).
  - Heart valve allografts.
- **Note the following are not considered minimally manipulated biological products:**
  - Vascularized organs (liver, kidney, lung, heart....etc.)
  - Major manipulation (e.g. advanced therapeutic drug, gene therapy, tissues engineering therapy)
  - Biologic products imported for research purposes
- **Note that medical devices manufactured utilizing tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are required to obtain Medical Device Marketing Authorization.**
  - Please refer to the Requirements for Importation of Minimally Manipulated Biological Products Intended for Human Application
  - Please refer to the Requirements for Importation of Minimally Manipulated Biological Products Intended for Human Application

7.23. Cupping Devices:

Devices used to perform cupping include suction cups and suction pump are considered medical devices.

Examples:

- Suction cup.
- Suction pump.
- Twist rotary.
- Rubber bulb suction.

> **Note 23:**
>
> Please refer to SFDA.MD 2017/0001 (Safe Use and Handling of Cupping Devices and their Applications)

7.24. 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 as primary intended action. In this case, such products are considered drug products.

7.25. Raw materials and components:

Raw materials, component parts or semi-finished products that requires further manufacturing process are not considered medical devices. However, these products shall obtain a Medical Device Importation License

7.26. Custom-made medical device (CMDs):

- A medical device that meets, at a minimum, the following requirements:
- Intended for a particular individual (patient or Healthcare Professional);
- Manufactured as a result of a written request from an authorized Healthcare Professional who, at their responsibility, gives specific design characteristics;
- Aims to address the anatomical, physiological features or pathological condition of the individual for whom it is manufactured.

Examples:

- A dental crown manufactured according to a written prescription provided by a dentist containing specific design characteristics for a particular patient's individual condition.
- An orthosis made in accordance with a written prescription containing specific design characteristic to aid a person with neuromuscular or musculoskeletal impairment of the lower extremity, such as a Knee Ankle Foot Orthosis (KAFO).
- Hand prosthesis intended to replace a lost body part and/or function made in accordance with a written prescription, where the practitioner provides patient specific design characteristics necessary for the manufacturing of the device.

Examples of Devices which are not considered CMDs may include:

- Devices that are mass-produced which need to be adapted to meet the specific requirements of any professional user,
- Devices that are mass-produced by means of industrial manufacturing processes, potentially made in accordance with the written prescriptions of an authorized person.

8. Tobacco

It includes the following product types: Cigarettes

- Cigars and Tuscan cigars Sijaritus
- Almeassel tobacco
- Hand-rolling tobacco and A mixture of tobacco pipe
- E-Liquids and Heated Tobacco Products which are used by Electronic Nicotine Delivery Systems (ENDS)
- Non-nicotine e-liquids which are used by electronic smoking device, and does not contain any medical ingredients or medical claims
- Non-smoked tobacco such as (Timpak, shamma, swika etc.) is prohibited.

Note 24:

Tobacco products must comply with the SFDA and Gulf technical regulations and standards such as but not limited to:

SFDA FD 5005: E-Liquids and Heated Tobacco in Electronic Systems for Smoking

- GSO 597: Cigarettes
- GSO 2047: Tuscan cigars and cigarettes
- GSO 2051: Tobacco and its products- Sijaritus
- GSO 1415: Almeassel tobacco
- GSO 1749: Fruit flavored Almeassel tobacco
- GSO 2050: A mixture for tobacco pipe

9. Animal Feed and Public Health Pesticides

9.2. Animal Feed includes the following types:

9.2.1. Feed materials

Is a product of vegetable or animal origin, the main purpose of which is to meet the nutritional needs of animals and which is used for oral feeding, in their natural state, fresh or preserved. Such as:

- Grain products.
- Grain by-products.
- Green feed.
- Animal protein products.
- Plant protein products.

9.2.2. Feed additives

Are substances, micro-organisms or preparations that are intentionally added to feed for technological purposes, to improve its taste, to increase its nutritional value, or to improve the animal's performance, whether these ingredients contain nutritional value or not. Products listed in the below table are just an example:

Zootechnical feed additives	Nutritional feed additives	Sensory feed additives	Technological feed additives
Digestibility enhancer	Vitamins	Colorant	Acidity regulators
Gut flora	Minerals	Flavors	Silage additive
Substance for environment	Amino acids		Antioxidant
Enzyme	Urea's		Gelling agent

9.2.3. Premix:

Are mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, and is intended for incorporation in compound feeding stuffs, feed materials or water and not meant for direct feeding to animals.

9.2.4. Compound feed:

A mixture of at least two feed materials, whether or not containing feed additives and offered directly for feeding animals.

9.3. Public Health Pesticides

Note 25:

Please refer to the SFDA List of Public Health Pesticides. Feed-Through pesticides: Pesticides that are incorporated into animal feed, move through its digestive tract unchanged, and deposited in the animal's manure.

10. Products for Clearance

Some products do not need a marketing authorization/ registration application. However, a clearance approval must be obtained in order to permit the entry of the product into Saudi Arabia. Products in this category may include but are not limited to the followings:

- Unregistered Drug or Products
- Unregistered Veterinary Products
- Samples
- Raw Medical Plants
- Animal grooming

- Proficiency Test samples for food products
- Medical Devices
- Food

Note 26:

Please refer to:

- Clearance Conditions and Requirements
- MDS-REQ 5 Clearance Requirements of Medical Devices
- Clearance Requirements of Cosmetics and their raw materials
- Clearance Requirements of Animal Feed
- Clearance Requirements of Tobacco
- Food Clearance Conditions and Requirements

11. Products Not Under SFDA's Jurisdiction (NSFDA)

As the main purpose of SFDA is to ensure the safety, quality and efficacy of products under Drug, Food, Cosmetic, and Medical Device regulation, therefore, products failed to satisfy all sets of SFDA's regulations or are excluded from their provisions will be classified outside the SFDA' s responsibility.

The following products are the most common examples:

Product for Human:

- Personal protective non-medical masks and gloves such as

o Community masks made of cloth, other textiles, or other materials such as paper

o Gloves intended for use in food industry

o Household cleaning gloves

- Air and furniture freshener
- Platelet Rich Plasma preparations manufactured in hospitals
- Sunglasses and spectacle frames
- Surface and environmental disinfectants without medical claims such as copper film for disinfectant, ultraviolet sterilization for general purpose, swimming pool disinfectant..etc.

Devices for human:

- Teats (Except for Single Use Teats used in hospital environment on neonate to administer medications and special nutrition are regulated as Medical Devices.)
- Hair wigs and eyelashes with no medical claim
- Electrical devices with no medical claim
- Synthetic nails with no medical claim
- Patient ID bracelet/band
- Biological Sterilization process indicator
- Sterilization equipment for devices in manufacturing process
- Non-medical cotton swab such as cotton sticks for ear cleaning or applying cosmetics
- Educational devices: Devices for educational and training purposes are not regulated as medical devices such as mock-ups and patient simulators
- Non-medical razor and shaving machine
- Toothbrush for non medical purposes either manual or electrical
- Water or fiber dental floss

Product for animals:

- Bees Feed
- Bees drug products
- Agricultural pesticides
- Standard materials, reagents that contains pesticide ingredients.

Devices for animals:

- Veterinary In-Vitro Diagnostic kit (veterinary IVD)
- Litter box deodorizers for pets
- Veterinary Medical device

Note 27:

- For walk-through disinfectant gates regulation, please refer to the following guidance WALK-THROUGH DISINFECTION GATE

12. 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
- Cosmetic product
- Health and Herbal products
- Drug products
- Medical device

Note 28:

- Please refer to SFDA Guidance for Borderline Products Classification

13. Combination product

In order to decide whether a product is regulated as a medical device or a drug 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
- Wound dressing with antimicrobial agent

- Surgical scrub brush with antimicrobial agent
- A Helicobacter pylori breath test kit containing labelled urea
  - Urea is considered a medicinal substance
  - A sample container is considered an IVD
- First aid kit

Note 29:

Please refer to SFDA Guidance for Combination Products Classification
For first aid kits, please refer to the Guidance on Criteria of Medical Devices Bundling/Grouping within one MDMA Application
Combination Products Classification decisions came into effect since December 2021.
Please refer to point Human Pharmaceutical Product the E-Liquids used by electronic delivery systems.

Still need a classification of your product?

If you still need a classification decision about your product which is not covered in this guidance, please submit a product classification request via the e-PCS (please refer to point 2 of this document; the e-Product Classification System (PCS) Use Process).

Note 30:

Classification Updates:

- The medical gases regulation under SFDA.
- Revise the radioactive materials regulation
- Revise rule 21.
- Revise the regulation of Oral products containing cannabidiol (CBD) oil.
- Relaunch the PCS system under "غد"

Appendix 1

What is New in The Guidance for Products classification (Version 8.0)?

The following table shows statements that added, deleted or replaced to the past version 7.0, NOV 20, 2023:

Section	Current Amendment
Introduction Classification Disclaimer	This document is subject to change and updated annually; the most recent version of the classification product guidance is available on the Saudi Food & Drug Authority website. To ensure you are using the most recent revision, check the PCS electronic system at https://pcs.sfda.gov.sa/Default.En.aspx . The classification product guidance provides an overview and current understanding of the regulatory pathways supervised by SFDA. The information in this guidance is general, and some cases may require additional classification on a case-by-case basis
Definitions	Medical Device Accessories: Any material or product made to be used with a medical device to enable it to achieve the purpose for which it was manufactured
Product Classification System (PCS)	Variation on Saudi FDA Products Classification Application SFDA has developed this guideline to assist applicants on the details of the various categories of variations, which affect the classification request and to provide recommendations on the preparation of the variation application.
Food	Purified water and vehicle syrup used for preparation or to be mixed with other product like medication or food supplements to assist special need with difficulty swallowing, Including pediatric, geriatric.
Human Pharmaceutical Product	• Benzoyl peroxide. • Nicotine Pouch intended to be used for medical purpose/claim. • E-Liquids used by electronic delivery systems intended to be used for medical purpose and contains active ingredient such as herbs, vitamin and minerals are regulated as combination products lead by drug sector.(please refer to note 29)
Veterinary Drugs	A substance, part of a substance or a combination of substances associated with a therapeutic (medicinal) property or pharmacological effect such as product that contain Nicarbazin to be used orally for reducing egg hatchability in pigeons
Cosmetic Products Note 9:	Guide to cosmetic products restricted to professional use Guide to Regulations and Requirements For Notifying Cosmetic Products
Assistive/supportive products:	Examples of non-medical devices: • grab rails at doorways or stairs,

Appendix 2

Comments on Products Classification Guidance

Please submit comments to the following E-mail: Classificationfeedb@sfda.gov.sa			
SN	**Item No.**	**Item text**	**Proposed Amendment**
1			
2			
3			
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