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منتجات النيكوتين الالكترونية (نظائر منتجات التبغ التقليدية)
Electronic Nicotine Products (Equivalents of Traditional Tobacco Products)

دولة الامارات العربية المتحدة
UNITED ARAB EMIRATES

منتجات النيكوتين الالكترونية (نظائر منتجات التبغ التقليدية)

المواصفات القياسية لدولة الإمارات العربية المتحدة

Standards of United Arab Emirates

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Foreword

The Emirates Authority for Standardization and Metrology (ESMA) is the body responsible for standardization activities in the State. Its tasks include preparing UAE technical regulations or standards through specialized technical committees.

The Authority, within the framework of the technical committees: National Technical Committee for the Food Products Standard Sector, has prepared the Standard titled "Electronic Nicotine Products (Equivalents of Traditional Tobacco Products)", after reviewing the Arab, foreign and international standards and related reference literature.

This standard has been approved as a UAE Technical Regulation by the Cabinet Resolution No. (5/2019) issued on …/…/1440 AH, corresponding to 06/01/2019 AD.

Electronic Nicotine Products (Equivalents of Traditional Tobacco Products)

1. Scope

This UAE Standard is concerned with the requirements of electronic nicotine products which are designed in the form of traditional tobacco products such as (cigarettes, cigar, pipe, cigarillo or hookah), which includes the following products:

- Electronic vape products which do not contain tobacco (and may or may not contain nicotine) and their refill packages, e.g. e-liquid containers.
- Heated tobacco products that contain tobacco (processed or unprocessed) which is heated by an electronic device (without combustion).

It also specifies the requirements for importing, manufacturing, packing, displaying and trading, and weights and descriptive data on their labels but does not include any products that are consumed through lighting and smoking with combustion or any products that contain nicotine such as nicotine patches and tobacco products which are consumed orally.

2. Supplementary References

2.1 GSO ISO 9001: Quality Management Systems – Requirements.

2.2 UAE.S/IEC 60335-1: Household and Electrical appliances – Safety – Part One: General Requirements.

2.3 UAE.S GSO ISO 8317: Child-Resistant Packaging – Requirements and Testing Procedures for Re-Closable Packages.

2.4 Cabinet Decree No. (10) of 2017 on the UAE System to Control the Percentages of Restricted Hazardous Substances in Electrical and Electronic Devices.

2.5 Resolution of the Board of Directors No. 26/2009 on the Emirates Conformity Assessment System (ECAS): List of Requirements and Conditions for Registration of Low Voltage Electrical Appliances.

2.6 IES 62133-1: Secondary cells and batteries containing alkaline electrolytes or other Non-acidic electrolytes - Safety requirements for enclosed, portable secondary cells and batteries made of them, for use in portable applications - Part 1: Nickel systems.

2.7 IEC 62133-2: Secondary cells and batteries containing alkalis or other non-acidic electrolytes - Safety requirements for enclosed secondary cell lithium cells, and batteries made of them, for use in portable applications - Part 2: Lithium systems.

2.8 GSO IEC 60086-4: Primary dry batteries - Part 4: Safety of lithium batteries.
2.9 GSO IEC 60335-2-29: Household electrical appliances and similar safety - Part 29 -2: Special requirements for battery chargers.
2.10 UAE.S 192: Additives permitted to be used in food.
2.11 GOS UAE.S 707: Flavorings permitted to be used in food products.
2.12 UAE.S 9: Labeling of Prepackaged Food Stuffs.
2.13 European Pharmacopoeia for Non-Sterile Inhalation Products.
2.14 European Pharmacopoeia – Study (Monograph) of Nicotine.
2.15 European Pharmacopoeia – Study (Monograph) of Purified Water.
2.16 European Pharmacopoeia – Study (Monograph) of Propylene Glycol.
2.17 European Pharmacopoeia – Study (Monograph) of Glycerol.
2.18 GSO IEC 61558-1: Safety of power transformers, power supplies, reactors and similar products - Part 1: General requirements and tests.

3. Definitions

3.1 Tobacco
Leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco.
3.2 Nicotine
Nicotinic alkaloids.
3.3 Ingredient
Tobacco, any additive, as well as any other substance or element present in a finished tobacco product or related product, including paper, filter, ink, capsules and adhesives.
3.4 Flavouring
Additive to add smell and/or taste.
3.5 Characterizing Flavors
means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product.
3.6 Electronic Vape Products
Electronic devices and its accessories which operate through batteries, and can be used to heat the e-liquid to be vaporized, inhaled and exhaled by mouth as a smoke simulation, and they are free of tobacco.

A typical electronic cigarette consists of: the battery that is used to heat the solution tank containing the so-called "electronic liquid" that may be in a disposable cartridge or a tank that can be refilled from external cartridges.

3.7 Electronic Liquid

A liquid formula (or gel) in the Electronic Vape Products or in a replaceable cartridge (which may or may not contain nicotine) and some other additives such as distilled water, solvents, vegetable glycerin and propylene glycol.

3.8 External Cartridges (Single Container)

Any package used for refilling electronic nicotine products, whether in the form of rolls, tanks, small containers, capsules containing granules or other forms, and whether disposable or can be used for refilling each time.

3.9 Electrically Heated Tobacco Products

Battery-powered electronic devices used to heat tobacco (processed or unprocessed and formed in rolls, or powder or granules inside capsules) by thermal contact (without combustion or emission of smoke) and to orally inhale and exhale it to simulate smoking.

The typical full system of these electronic devices is usually composed of:

- The electric charger.
- Inhalation and/or heating device including an electronic battery that heats.
- The processed or unprocessed tobacco for use with the device either in the form of tobacco rolls (heated sticks) or tanks or small capsules containing granules or other forms.

3.10 Toxicity

The harmful effects that the product may have on the human organism, including the effects that occur over time, whether through consumption or repeated or continuous exposure to the effects of the product.

3.11 Package (pack)

The unit package of the product (with its accessories) sold to the consumer as a complete product unit, including the carton (the container of the unit package).

3.12 Label

Any label, tag, mark, picture, or any other descriptive data written, printed, stamped, affixed, engraved or embossed on the package in a non-removable manner.

3.13 Descriptive Data:
Any writing, pictures or graphics on the label related to the product's characteristics, properties, nature or consumption, or one of its ingredients or any other properties.

3.14 Main Display Area
The front and back panels of the package. If this is not easily identifiable, the largest area is considered the front panel and the second largest area is considered the back panel.

3.15 Health Warning
The warning about the harmful effects of the product on human health or other undesirable consequences of its consumption, including written warnings, attached health warnings, general warnings and information messages.

3.16 External Packaging
Any container in which the products or related products containing a unit package or a set of unit packages are placed. Transparent wrapping is not considered part of the outer packaging.

3.17 Production code (Batch Number)
A code for a quantity of the product that was produced under the same conditions during a specific period of time, usually for a specific product line and production unit.

4. Requirements

4.1 General requirements

4.1.1 The manufacturing facilities must meet the requirements of the Standard mentioned in Item (2.1).

4.1.2 The devices (Electronic and electrical) must meet the requirements of the Standard mentioned in Item (2.2) (or the equivalent) that is relevant to the safety of electrical equipment and devices, including the falling test, contact temperature and the electromagnetic compatibility (EMC) test.

4.1.3 The devices (Electronic and electrical) must meet the requirements of the Cabinet Decree mentioned in Item (2.4) on the UAE System to Control the Percentages of Restricted Hazardous Substances in Electrical and Electronic Devices.

4.1.4 The devices (Electronic and electrical) must meet the requirements of the Standard mentioned in Item (2.5) concerning electrical equipment designed for use within a specified voltage (low voltage or LVD).

4.1.5 Batteries, accumulators, secondary cells and chargers must meet the requirements of the applicable standards mentioned in Items (2.6), (2.7), (2.8) and (2.9).

4.1.6 The product and/or cartridges must meet the requirements of child protection set forth in Item (2.3), so that they do not pose any potential health risks to children. It is necessary to ensure that these products are protected and resistant to harm caused by children, including the affixation of marks for protection from children and protection by appropriate mechanisms for opening and closing the packages.

4.1.7 The product and cartridges must remain conformant to the requirements of this Standard throughout the shelf life indicated on the package.

4.1.8 No modification or change in the ingredients or characteristics of the product and cartridges may be made unless the official approval from ESMA is obtained.

4.1.9 It is not allowed to import, manufacture or launch the product and cartridges in the market of the State unless the official approval from ESMA is obtained and the following documents are submitted:

4.1.9.1 Reports of the tests of safety of electronic components / falling test / leakage test / contact temperatures / electromagnetic efficiency, from scientific entities or laboratories accepted by ESMA.

4.1.9.2 A list of all ingredients and their quantities used in the product in descending order according to the weight of each ingredient, indicating the trade name, type and relevant quantities, accompanied by a statement specifying the reasons for including these ingredients in the products concerned, as well as level of emissions arising from the use and any other emissions.

4.1.9.3 The results of necessary toxicological studies for the product ingredients before and after use and its emissions, including when heated, issued by scientific entities or laboratories accepted by ESMA.

4.1.9.4 Data on nicotine doses and absorption when consumed in normal or reasonably expected conditions.

4.1.9.5 Acknowledgment that the manufacturer and importer assume full responsibility for the quality and safety of the product when placed in the market and used in normal or expected conditions.

4.1.9.6 Description for using the product ingredients and cartridges, including, where appropriate, the product opening and re-filling mechanism.

4.1.9.7 Description of the production process, including the sequence of production processes, and ensuring that the production process conforms to the requirements of this Standard.

4.1.9.8 Stability studies supporting the product's shelf life as indicated on the product label.

4.1.9.9 Laboratory reports from entities accepted from ESMA, including information on nicotine concentration in the product and cartridges, the quality and safety of the product, post-marketing and post-consumption analyses, and electrical safety and any other similar information upon request.

4.1.9.10 Risk assessment studies of the consumable part of the products.

4.1.10 Products and cartridges must meet the safety and quality requirements so that liquids do not break or leak during use and refilling.

4.1.11 The following materials must not be added in product, cartridges and e-liquids:

- Vitamins or other additives that give the impression that the product has a health benefit or reduces health risks.
- Caffeine, taurine or other additives and stimulants associated with stimulating performance and vitality.
- Colored additives with emission-coloring properties.
- Carcinogens or agents of genetic mutations or producing toxins before and after use of the products.
- Substances classified as legally-prohibited substances, such as narcotics, hallucinogens, tranquilizers, etc..
- Ethylene glycol and diethylene glycol, formaldehyde, acetaldehyde, acrolein, Crotone aldehyde, acetone, acetylpropionyl and diacetyl, pentane-3,2-dione and related ketones, and long chain preservatives of paraben.
- Acrylonitrile, benzene, 3,1-potadiene, isoprene, toluene.
- 4 amino-diphenyl, 1-amino-naphthalene, 2-amino-naphthalene.
- Ammonia.
- Cinnamic compounds.
- Respiratory allergens.

- Residues of heavy metals such as lead, cadmium, mercury, chromium, nickel, iron, arsenic and tin.
- Multipolar hydrocarbons, carbon monoxide, and nitrosamines of tobacco (e.g. NNK and NNN).
- Mineral oils, vegetable oils and fats such as (olive oil).

4.1.12 It is allowed to use the materials necessary for the manufacture of products and cartridges, such as sugar to replace the sugar lost during the treatment process, provided that these substances do not result in increase of addiction or toxicity.

4.1.13 Other product components such as filters, paper, parcels, capsules or any other related components shall not contain flavors that modify the smell or taste of the products or the emissions' intensity, nor shall they contain tobacco, tobacco extracts or nicotine.

4.1.14 The packages or their outer packaging shall not contain printed vouchers, discount offers or a reference to free distribution, two-for-one offers or any other similar offers that may suggest economic advantages to consumers and thus induce them to purchase the products.

4.2 **Requirements for the Electronic Liquid:**

4.2.1 The electronic liquid shall be manufactured according to the requirements of the Standard mentioned in Item (2.1).

4.2.2 The components of electronic liquid such as nicotine and solvents shall be of high purity and in line with pharmaceutical grade specification and must meet the requirements of the European Pharmacopoeia mentioned in Items (2.13 – 2.17).

4.2.3 The microbiological limits of the nicotine used in electronic liquid shall not exceed what is specified in the European Pharmacopoeia for Non-Sterile Inhalation Products mentioned in Item (2. 13).

4.2.4 The content of nicotine in the electronic liquid shall be less than or equal to 20 milligrams per milliliter.

4.2.5 The capacity of the integrated electronic liquid tank shall not exceed 10 ml.

4.2.6 The capacity of the electronic liquid's refill packages shall not exceed 50 ml per package.

4.2.7 The electronic liquid packages shall not be easily breakable, damageable or destroyable.

4.2.8 Electronic liquid packages shall function in such a manner as to ensure that the electronic liquid does not leak to the mouth during inhalation.

4.2.9 The ingredients used in electronic liquids shall not pose a health hazard (except for nicotine and other types of tobacco extracts if used), whether in product use conditions or as-is, at the concentration used and under the conditions of use for which they are intended.

4.2.10 Materials prohibited under Item (4.1.11) shall not be added to the electronic liquid.

4.2.11 It is allowed to add the following moisturizing substances: glycerol (of food grade and non-petroleum products), 1-2 propylene glycol, 1-3 butylene glycol, triethylene glycol (with a minimum purity of 99.5%) and they shall be suitable for human consumption and in line with pharmaceutical grade specification in conformity with the requirements of the European Pharmacopoeia.

4.2.12 The additives used in the product shall be of the food grade and authorized in accordance with the Standard mentioned in Item 2.10.

4.2.13 The substances with the flavored characteristics shall be permitted in accordance with the standard mentioned in Item 2.11.

4.2.14 If hypersensitivity constituents are used, this should be indicated on the label of the product in accordance with the Standard mentioned in item 2.12.

5. Descriptive Data:

5.1 General requirements:

5.1.1 It is prohibited to use any names, symbols, marks, images or phrases that violate public order.

5.1.2 The product and its accessories shall not be described or presented with labels, descriptive data, names, shapes or symbols that may lead to an erroneous, misleading or promotional impression, inside or outside the package, about their characteristics, or that may mislead consumers, and in a false or deceptive manner, or that may lead to erroneous impression about their characteristics in any way, suggest that they are less harmful than any other type of products, or indicate a reduced risk of smoking-related diseases, including, but not limited to: Low or no tar and/or nicotine; light, very light, mild, moderate, natural, organic; no additives; no (or very little) flavors; or claims about economic advantages compared to traditional cigarettes, or suggestion of

therapeutic benefits in terms of weight loss, sex appeal, social status, social life, or qualities such as femininity, masculinity or elegance, or improved biological performance, or the size and appearance of the products in terms of their resemblance to food or cosmetics.

5.1.3 The information shall be clear and easily legible and the colors used for writing shall be distinctly different from the background colors and not close thereto or overlapping therewith.

5.1.4 The descriptive data (In Arabic or English for Items 5.2.1 to 5.2.7) shall be placed directly on the package, and may be placed on a non-removable sticker.

5.1.5 No words, names, images, marks, symbols or data may be written on the outer cellophane wrapper.

5.1.6 The health warning on the package directly and any outer cover of the package, and shall be fully visible in front of the consumer on the main display interface, indelible and irremovable, this includes that it must not be partially or totally hidden or permanently covered by tax stamps, price marks, security features and wrappers, etc.

5.2 The following descriptive data shall be written on the label of the unit package of the product and the label of the cartridges:

5.2.1 Product name and trade name.

5.2.2 Number of units per package.

5.2.3 Validity or packing dates for month and year (according to validity studies).

5.2.4 Production code (batch number)

5.2.5 Product ingredients (the name or type of flavor used shall be placed near the product name).

5.2.6 Country of origin, manufacture or packaging

5.2.7 The phrase (**For sale in the United Arab Emirates)**.

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5.2.8 For products which contain nicotine, the following health warning should be written in both Arabic and English on packages (literally):

(يحتوي على النيكوتين الذي يسبب شدة الإدمان وزيادة ضربات القلب ورفع ضغط الدم، وضار صحياً للمرأة الحامل والمرضع والأشخاص الذين يعانون من الأمراض الرئوية المزمنة مثل الربو والإنسداد الرئوي).

(Contains nicotine which causes severe addiction, increased heart rate and high blood pressure. Nicotine is harmful to the health of pregnant and nursing women, and people suffering

from chronic pulmonary diseases such as asthma and pulmonary embolism.)

5.2.9 The health warning shall be in conformity with the following requirements:

5.2.9.1 The producing companies may increase or decrease and fix a health warning (Provided in clause 5.2.8) to suit the different sizes of product packaging, provided it covers more than 50% (excluding the frame) of the main display area (in English on the lower front) and (in Arabic on the lower back) on the outside of the package.

5.2.9.2 The health warning and its location, form and measurements shall be in accordance with the appendix 1 attached to this Standard, and it may not be changed, modified or rephrased in any way.

5.2.10 Add the following sentence in both Arabic and English on packages, in addition to (**18+**) symbol which should not be less than 1 cm x 1 cm:

(يحظر بيع واستهلاك هذا المنتج من قبل الأشخاص دون سن الثامنة عشر، ولا ينصح باستخدامه لغير المدخنين).

(**It is prohibited to sell and consume this product by individuals under the age of 18, and it is not recommended for non-smokers**)

5.2.11 For products which contains electronic liquid the following sentence shall be added on packages in both Arabic and English:

(قد يشكل هذا المنتج خطراً على الصحة عند استنشاقه أو بلعه أو تماسه مع الجلد).

(**This product may pose a health hazard when inhaled, swallowed or gets in contact with the skin**)

5.2.12 The health warning requirements shall be applied in accordance with appendix 1 and shall be changed in accordance with the requirements of the public interest.

5.3 Each package (full system) of the product shall contain a printed leaflet containing the following data printed in Arabic or English:

5.3.1 Instructions for using and storing the product, including indicating that the product is not recommended for use by young people and non-smokers.

5.3.2 Circumstances where the product must not be used and warnings mentioned in Section 5.2 and any special warnings for certain groups of consumers.

5.3.3 Instructions for product use and storage.
5.3.4 Addiction and toxicity.
5.3.5 Potential adverse effects.

الملحق –1: نموذج التحذير الصحي

تحذير صحي : يحتوي على النيكوتين الذي يسبب شدة الإدمان وزيادة ضربات القلب ورفع ضغط الدم، وضار صحياً للمرأة الحامل والمرضع والأشخاص الذين يعانون من الأمراض الرئوية المزمنة مثل الربو والإنسداد الرئوي.

Health warning: Contains nicotine which causes severe addiction, increased heart rate and high blood pressure. Nicotine is harmful to the health of pregnant and nursing women, and people suffering from chronic pulmonary diseases such as asthma and pulmonary embolism.

يحظر بيع وإستهلاك هذا المنتج من قبل الأشخاص دون سن الثامنة عشر، ولا ينصح بإستخدامه لغير المدخنين.

It is prohibited to sell and consume this product by individuals under the age of 18, and it is not recommended for non-smokers.

قد يشكل هذا المنتج خطراً على الصحة عند استنشاقه أو بلعه أو تماسه مع الجلد.

This product may pose a health hazard when inhaled, swallowed, or gets in contact with the skin.