



# Technical Regulations for Electronic Smoking Devices

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## Introduction

Pursuant to Saudi Arabia's accession to the World Trade Organization, according to Decree No. 244 from the Council of Ministers, dated 21.9.1426AH [October 24, 2005] regarding approval of the accession documents to the World Trade Organization and the requirement to align Saudi Arabia's relevant laws to the agreements with this organization, especially the agreement on Technical Barriers to Trade (TBT), which prohibits unnecessary technical requirements against the flow of goods between member states and non-discrimination between products of various origins through technical requirements and methods of compliance assessment. This is achieved by issuing technical regulations that include basic legal requirements and the unification of work procedures.

Based on Article 3.1 of the Regulation for the Saudi Standards, Metrology and Quality Organization (SASO), issued by Decree No. 216 from the Council of Ministers, dated 17.6.1431AH [May 31, 2010], which charges the organization to "issue Saudi standards, quality regulations and criteria, and compliance assessments that comply with WTO standards and criteria while also meeting Islamic sharia requirements and the interests of the Kingdom."

Based on Article 4.2 of the SASO Regulation, issued by Decree No. 216 from the Council of Ministers, dated 17.6.1431AH [May 31, 2010], which charges the organization to "issue regulations for compliance assessments for goods, products, and services according to accredited standards."

Based on Article 4.14 of the SASO Regulation, issued by Decree No. 216 from the Council of Ministers, dated 17.6.1431AH [May 31, 2010], which charges the organization to "review oversight rules and regulations related to the organization's fields of work, improve them, and propose modifications to the organization's work processes required to meet quality and safety requirements, and deliver these proposals to the relevant agencies to be studied and issued through legal channels."

Based on Article 6.1 of the SASO Regulation, issued by Decree No. 216 from the Council of Ministers, dated 17.6.1431AH [May 31, 2010], which charges the organization to "regard the organization as the authority within the Kingdom for all matters relating to standards and compliance assessment procedures, subject to the provisions of Article 4. The organization grants seals for quality, standards, and calibration. All public and private sector organizations must comply with Saudi standards in all purchases and operations.

AND WHEREAS the product standards in these regulations

are considered the basis for product compliance with safety requirements in the specific regulation.

The organization has prepared this technical regulation.

**NOTE:** This introduction and all Appendixes are considered an integral part of this regulation.

## Article 1

### Terms and Definitions

- 1.1. The terms and phrases below and other phrases contained in this regulation – when applying its provisions – have the meaning as provided for the term or as contained in current rules, regulations, and decrees of the organization, unless the context requires a different meaning.

**Kingdom:** Kingdom of Saudi Arabia

**Board:** SASO Board of Directors

**Organization:** Saudi Standards, Metrology and Quality Organization (SASO)

**Oversight Agency:** The government agency/agencies with an oversight mission according to their jurisdiction and responsibility to enforce or trace the enforcement of technical regulations, whether in customs ports, markets, or factories.

**Relevant Agency:** Agency legally responsible within the Kingdom to issue licenses and apply the provisions of this regulation on the trade of electronic smoking devices (e-cigarettes) and related equipment and materials.

**Technical Regulation:** A document approved by the board of directors that sets the specifications for products, related activities, and methods of production, to include current administrative provisions that must be adhered to. This may specifically include or examine terms, definitions, and packaging as well as requirements for the placement of symbols or trademarks the product, services, transactions, or methods of production.

**Standard:** Document that specifies the characteristics for a good, material, service, or any other matter that falls under the standard, to include its descriptions, specifications, level of quality, dimensions, standards, or safety and security requirements. It also includes terms, symbols, testing methods, sample extraction, packaging, data cards, and trademarks.

**Basic Requirements:** Mandatory product requirements that may affect safety, health, and the environment.

**Hazard(s):** Likely sources of harm.

**Risks:** Probability of the appearance of a hazard that may cause damage, related to the degree of intensity of damage. Normally calculated as the product of the likelihood of occurrence and the severity of damage.

**Supplier:** Means the following:



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- A manufacturer of electronic smoking devices if they reside in the Kingdom or any person who presents himself as a manufacturer of this equipment.
- An agent for the manufacturer in the Kingdom if the manufacturer resides outside of the Kingdom or the importer if there is no agent for the manufacturer in the Kingdom.
- Any person within the supply chain whose actions, may have an effect on the characteristics of the electronic smoking device.

**Acceptance Agencies:** Compliance assessment agencies accepted by SASO, according to the regulation for acceptance of compliance assessment agencies.

**Certificate of Compliance:** A certificate issued by the organization or one of its acceptance agencies that confirms that the electronic smoking device or any batch thereof complies with the requirements of this technical regulation and related standards.

**Supplier's Declaration of Conformity:** A declaration by the supplier that its product complies with current legal requirements, without third-party interference in the design and production phases of the manufacturing or delivery process. The declaration may rely on reports based on testing the electronic smoking devices according to relevant specifications.

**Market Placement:** This is the initial placement of the electronic smoking devices on the market in the Kingdom and the party responsible is either the manufacturer or the importer.

**Market Exposure:** Provision of electronic smoking devices for distribution, consumption, or use in the kingdom as a commercial activity, whether for a material fee or without fee.

**Withdrawal:** A procedure to prevent the product from being offered on the market or in the supply chain.

**Recall:** A procedure to recover any product that may have been offered to the end-user.

**Product:** An electronic smoking device, also known as an electronic cigarette (e-cigarette) (which does or does not contain nicotine).

**Electronic Smoking Device:** A device known as an electronic cigarette. This is a device equipped to heat liquids electronically or to heat tobacco products that are used as an alternative to smoking tobacco products. It generates an aerosol that may or may not contain nicotine that is inhaled through the mouth.

- 1.2 Other words and phrases contained in this regulation have the meanings contained in current rules, regulations, and decrees of the organization.

### Article 2

#### Scope

This technical regulation sets the requirements for electronic smoking devices as defined in Article 1 that use heated tobacco

products or electronic liquids as an alternative to smoking combustible tobacco products.

This technical regulation sets the mandatory requirements for these devices during their provision to and offering in the Kingdom's markets.

Tobacco products, their derivatives, and alternatives are exempt from this regulation; the requirements published by the Saudi Food and Drug Authority apply in this case.

### Article 3

#### Objectives

This regulation sets the basic mandatory requirements for electronic smoking devices included within this regulation in order to ensure that these devices comply with Saudi law and relevant standards and meet safety provisions to protect the environment and the health and safety of the consumer.

### Article 4

#### Supplier Obligations

##### 4.1 General Requirements

- 4.1.1. The supplier must comply with technical requirements of this regulation or referenced technical regulations.
- 4.1.2. The supplier of electronic smoking devices must comply with requirements issued by the Saudi Food and Drug Authority regarding heated tobacco products, their derivatives, and alternatives, electronic liquids, and external refill packaging for the above.
- 4.1.3. The supplier must comply with the standards contained in Appendix 1-A of this technical regulation.
- 4.1.4. The supplier must comply with the requirements of the Anti-Smoking Law.
- 4.1.5. The supplier must not present the electronic smoking device as a healthy alternative to smoking.
- 4.1.6. The supplier must provide a manual that contains the following:
  - a. Components of the electronic smoking device.
  - b. Technical specifications of the device and its components.
  - c. Instructions on use and storage, to include a mechanism to open and refill the product, if available.
  - d. Assembly and use procedures.
  - e. Warnings on the possible risks from this device.

##### 4.2 Technical Specifications for the Electronic Smoking Device

The supplier of the electronic smoking device must meet technical specification and criteria for these products, according to the standards contained in Appendix 1.

##### 4.2.6 Metrological Requirements

The international system of units (SI units), or multiples or fractions thereof must be used during design,

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### Article 5

#### Electronic Smoking Device Labeling

- 5.1. All of the information provided in the technical data must be accurate and scientifically proven through testing.
- 5.2. The label must be understandable and written in Arabic and/or English.
- 5.3. The label must not make any claim contrary to Saudi laws and/or international health laws.
- 5.4. The label for the electronic smoking device must contain the following:
  - a. Trademark of the manufacturer and country of origin.
  - b. Parts comprising the electronic smoking device and their configuration.
  - c. Devices that contain electronic liquid must have warning labels regarding child safety and the probable risks to child safety from liquid containing nicotine if it leaks, according to the requirements of the Food and Drug Authority.
  - d. Technical specifications of the electronic smoking device.
- 5.5. Mandatory labels, including warning markings for heated tobacco products or electronic liquids, shall be included in accordance with the requirements of the Food and Drug Authority if the device includes heated tobacco or electronic liquid.
- 5.6. It must comply with the requirements of relevant agencies and rules for the regulation and handling of electronic smoking devices.
- 5.7. There must be sufficient markings to ensure the product can be sold (quick response code).

### Article 6

#### Procedures to Assess Compliance

##### 6.1. Electronic Smoking Devices

- 6.1.1. The supplier – the official responsible for offering and/or placing the electronic smoking device in the Kingdom's markets must obtain a national certificate of compliance and control according to the System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE).
- 6.1.2. The oversight agency must conduct inspections following forms specified by SASO to ensure compliance with this regulation and related standards, as follows:
  - a. A technical folder containing the following must accompany the electronic smoking devices:
    1. Regulatory licenses for the electronic smoking device from relevant agencies.
    2. A declaration of conformity from the supplier (manufacturer/importer) according to the form in Appendix 2 of this technical regulation.
    3. Risk assessment document.

agencies by providing technical folder documents, compliance certificates, and any other documentation to verify the electronic smoking device's compliance with this regulation when required.

5. Products that have obtained the Saudi seal of quality or its equivalent, are considered to be in compliance with applicable requirements.

##### 6.2. Packaging for liquid materials and/or tobacco

- 6.2.1. The supplier of electronic smoking devices, whether pre-loaded or provided with packaged refills of tobacco-alternative materials, must comply with the Food and Drug Authority regulations for heated tobacco products or liquids and their derivatives and alternatives.
- 6.2.2. The shipping packaging must comply with requirements of the Food and Drug Authority regarding related to components and associated labeling.

### Article 7

#### Responsibilities of the Oversight Agencies

The oversight agencies must perform the following within the scope of their jurisdiction and authority:

- 7.1. Ensure that the electronic smoking device comply with the specified procedures and the technical documents attached to the shipment.
- 7.2. The oversight agency may take random samples of the electronic smoking devices and send them to specialized laboratories to verify the level of compliance with this regulation.
- 7.3. The oversight agency may charge the supplier (manufacturer and exporters) for the cost of testing and related costs.
- 7.4. If the product is found to be non-compliant, the oversight agency will take legal action against the supplier to prevent distribution of the particular product, or to remove it from warehouses or destroy it.

### Article 8

#### Violations and Penalties

- 8.1. The handling and importation of electronic smoking devices that do not comply with this regulation is prohibited.
- 8.2. The failure of devices to comply with this regulation is sufficient cause for oversight and executive agencies and compliance agencies to rule that the device is noncompliant due to the threat it poses to the health and safety of consumers and the environment in the following cases:
  - a. It does not comply with the requirements of the World Health Organization regarding smoking-related labels and warnings.
  - b. No certificate of compliance and/or declaration of



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conformity has been issued or one has been issued incorrectly.

- c. Did not produce or complete technical documents when requested.
- d. Did not produce or complete technical data or instructions as specified by relevant standards.

8.3. When a violation of this regulation has been confirmed, the agencies relevant to the case, must take all actions necessary to remove the violation and its effects, such as the following:

- a. Charge the violating party to remove the products to correct the problem if possible, or re-export them, within a timeline set by the enforcement authorities.
- b. Remove or seize the products in violation or take other action to recall them, as the case may be, while holding the violating party liable for all related costs.

8.4. When a product violation is confirmed, SASO will take the necessary action against the violating products, to include revocation of the relevant certificate of compliance, and take appropriate measures with the acceptance agency that issued the certificate, according to the regulation on acceptance for compliance agencies.

8.5. Without prejudice to any harsher penalty required by current law, any person who violates this regulation will be punished as required by current law.

### Article 9

#### General Provisions

- 9.1. The supplier – the party responsible for placing the product in the Kingdom’s markets – bears full legal responsibility for compliance with this regulation. The supplier is subject to the penalties contained in the Anti-Commercial Fraud Law and any other relevant law if it is proven that they violated any article of this regulation.
- 9.2. This regulation does not exempt the supplier from compliance with all other current law within the Kingdom relating to handling, transporting, and storing electronic smoking devices, to include laws and regulations regarding the environment, security, and safety.
- 9.3. Suppliers of electronic smoking devices must provide inspectors from oversight agencies, enforcement agencies, and compliance agencies all access and information they request for the execution of their assigned duties.

9.4. SASO, in coordination with related agencies, will prepare compliance forms and all procedures for the enforcement of this regulation.

9.5. If any situation arises not addressed by this regulation, or there arises any discrepancy in its enforcement, the matter will be referred to a committee within SASO for an appropriate decision on the matter or discrepancy.

9.6. The supplier of the electronic smoking device may submit another application after removing the cause for the rejection of the previous application and after making corrections to the cause that led to the rejection. It must pay any additional fees specified by SASO.

9.7. SASO will evaluate complaints it receives regarding products that have been granted a certificate of compliance to verify the validity of these complaints. It will take legal action if any violations are found.

9.8. SASO may revoke a certificate of compliance if the supplier violates any articles of this regulation and will take legal actions to protect the agency’s rights.

9.9. SASO has sole authority to interpret the articles of this regulation. All parties who benefit from the application of this regulation must comply with any interpretations issued by the organization.

### Article 10

#### Transitional Provisions

- 10.1. Suppliers must comply with this technical regulation within six months from the date of publication in the Official Gazette.
- 10.2. Dealing in products that do not comply with this technical regulation are prohibited one year after the date of publication in the Official Gazette.
- 10.3. This regulation, after approval, annuls any previous regulation within the scope of this technical regulation.

### Article 11

#### Publication

This regulation will be published in the Official Gazette.



## Appendix 1

## List of Standards for Electronic Smoking Devices

#	Name of Standard		Standard No.
1	Vapour products -- Routine analytical vaping machine -- Definitions and standard conditions	Vapour products -- Routine analytical vaping machine -- Definitions and standard conditions	ISO 20768
2	Routine analytical cigarette-smoking machine — Definitions and standard conditions	Routine analytical cigarette-smoking machine — Definitions and standard conditions	ISO 3308
3	Household and similar electrical appliances. Safety - Part 1: General requirements.	Household and similar electrical appliances. Safety - Part 1: General requirements.	IEC 60335-1
4	Information Technology Equipment - Safety - Part 1: General requirements	Information Technology Equipment -Safety - Part 1: General requirements	IEC 60950-1
5	Degrees of Protection Provided by Enclosures (IP Code)	Degrees of Protection Provided by Enclosures (IP Code)	IEC 60529
6	Safety of power transformers, power supply units and similar - Part 1: General requirements and tests	Safety of power transformers, power supply units and similar - Part 1: General requirements and tests	IEC 61558-1
7	Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells and for batteries made from them, for use in portable applications	Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells and for batteries made from them, for use in portable applications	IEC 62133
8	Determination of certain substances in electrotechnical products - Part 1: Introduction and overview	Determination of certain substances in electrotechnical products - Part 1: Introduction and overview	IEC 62321-1
9	Audio/video, information and communication technology equipment - Part 1: Safety requirements	Audio/video, information and communication technology equipment - Part 1: Safety requirements	IEC 62368-1
10	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.	IEC 63000
11	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity - Product family standard	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity - Product family standard	CISPR 14-2
12	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission.	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission.	CISPR 14-1
13	Primary dry battery - Part 4: Safety of lithium batteries.	Primary dry battery - Part 4: Safety of lithium batteries.	GSO IEC 60086-4

Note: The list of standards in this Appendix is subject to review. Suppliers are responsible for checking the SASO website to ensure they are using the most recent standards and versions mentioned in the lists.



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### B. List of Products and Customs Classification

Serial No.	Category	Product	Customs Article
1	Electronic Smoking Devices	Devices and tools for electronic smoking (such as cigarettes, water pipes (shisha), pipes, and the like.)	8543
		Electronic smoking device – e-cigarette (device to vaporize tobacco alternative materials)	
		Electronic Smoking Devices (electronic shisha)	
		Other types of electronic smoking devices	

Note: the products and customs classifications on the saber website (<https://saber.sa/>) are the most current and approved.

## Appendix 2

### Supplier Declaration of Conformity

This form must be completed on company letterhead.

**1. Data on the Supplier**

- Name: .....
- Address: .....
- Point of Contact: .....
- Email: .....
- Telephone No.: .....
- Fax: .....

**2. Product Details:**

- Product Trademark: .....
- Model: .....

- Description of Product: .....
- Category (according to standards): .....
- Reference standards / technical specifications: .....

**We declare that the product mentioned in this declaration complies with Saudi Technical Regulation No. ( ) and the associated Saudi standards.**

Company Official: .....

Name of Company: .....

Signature: ..... Date: / /