



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

**Technical Regulation for Electronic Devices Used in Electronic
Smoking Systems**

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First Version

**Note:
Only the Arabic version of this Regulation is authentic in law and is
applicable where there are differences with this translation**

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Preamble

In line with the accession of the Kingdom of Saudi Arabia (KSA) to the World Trade Organization (WTO), as per the Decree No. 244 of the Council of Ministers, dated 21/09/1426 A.H., concerning the approval of documentation on the Kingdom's accession to the WTO, and the requirements by which the KSA shall adapt its relevant systems with the principles of WTO agreements, particularly, the Technical Barriers to Trade (TBT), which stipulates that no unnecessary technical requirements shall impede the flow of commodities among the member states, and that technical requirements and methods of conformity assessment shall not discriminate between products on the basis of origin, through the issuance of Technical Regulations that include the essential requirements and standardized business procedures.

In accordance with Article 3 (Clause-1), Statute of Saudi Standards, Metrology and Quality Organization, issued in accordance with the Council of Ministers Decree No. 216, dated 17/06/1431 A.H. (31/05/2010 A.D.), stipulating that: **“SASO shall issue Saudi standards, quality systems and guidelines and conformity assessment, compatible with international standards and guidelines, that meet the requirements of the World Trade Organization (WTO) Agreement, in addition to their compliance with Islamic Sharia and serving the interests of Saudi Arabia”**;

In accordance with Article 4 (Clause-2), Statute of Saudi Standards, Metrology and Quality Organization, issued in accordance with the Council of Ministers Decree No. 216, dated 17/06/1431 A.H. (31/05/2010 A.D.), stipulating that: **“SASO shall issue regulations for conformity assessment procedures of commodities, products, and services according to approved standards”**;

In accordance with Article 4 (Clause-14), Statute of Saudi Standards, Metrology and Quality Organization, issued in accordance with the Council of Ministers Decree No. 216, dated 17/06/1431 A.H. (31/05/2010 A.D.), stipulating that: **“SASO shall review the laws and control regulations related to SASO's work fields, and develop them, and propose amendments thereto in line with quality and safety requirements, and refer them to competent bodies in order to review and issue them, in accordance with applicable procedures”**;

In accordance with Article 6 (Clause-1), Statue of Saudi Standards, Metrology and Quality Organization, issued in accordance with the Council of Ministers Decree No. 216, dated 17/06/1431 A.H. (31/05/2010 A.D.), stipulating that: **“Subject to Article 4 of this Statute, SASO shall be the authority in charge of matters related to standards, conformity assessment procedures, granting the quality mark, metrology and calibration. All public and private sectors shall be adhered to the Saudi standards in all purchases”**.

Whereas the standards of the products included in a regulation shall be a basis for the conformity of such products with the essential safety requirements included in the specified regulation.

Therefore, SASO has developed this Technical Regulation.

Note: This preamble and all the annexes of this regulation shall form an integral part thereof.

Article (1): Terms and Definitions

1/1 When applying the articles of this regulation, terms and expressions hereunder – shall have the meanings indicated in front thereof, unless the context otherwise requires:

KSA: The Kingdom of Saudi Arabia.

SASO: Saudi Standards, Metrology and Quality Organization.

The Board: SASO's Board of Directors.

Regulatory Authorities: Government body/bodies with regulatory tasks in consonance according to their specializations, which are responsible for the implementation and enforcement of technical regulations, whether in customs, markets, or manufactories.

Competent Authority: The legally competent authority in the KSA designated to issue licenses and apply the provisions of this Technical Regulation related to trading of electronic smoking devices and their materials

Technical Regulation: A document approved by The Board that provides, the specifications of products, associated processes and production methods, including applicable administrative provisions; with which compliance is mandatory. It may include or pay attention to terms, definitions, packaging, and requirements of markings or labelling products, services, processes or production methods.

Standard: A document approved by the Board that provides, for the regular and recurring use, non-mandatory rules and instructions, and specifications of products or processes and production methods. It may include, or pay attention to terms, definitions, packaging, and requirements of markings or labelling products, services, processes or production methods.

Essential Requirements: The special requirements of the products; that may affect the safety, health, and the environment; that must be adhered to.

Hazard(s): A potential source of harm.



Risk (s): A potential risk causing damage; associated with the severity of damage.

Supplier:

- Manufacturer of electronic smoking devices, in case that he is resident in KSA, or the person identified as the manufacturer of the product.
- An agent, when the manufacturer is resident outside the Kingdom or an importer in the absence of an agent of the manufacturer.
- Any person in the supply chain, whose activities may affect the electronic smoking devices characteristics.

Notified (Approved) Bodies: Conformity Assessment Bodies “Third Party”, approved by SASO in accordance with the regulation of approving Conformity Assessment Bodies.

Certificate of Conformity: A certificate issued by SASO or a notified body, which ensures the conformity of the electronic smoking devices, or any batch thereof, with the requirements of relevant standards.

Supplier Declaration of Conformity: A declaration by the supplier by which it declares that a product conforms to the requirements herein and applicable legislations, without the mandatory intervention of a third party neither in the design stage, nor in the production stage of the manufacturing process. A declaration may depend on testing the electronic smoking devices in accordance with the relevant legislation.

Placing on Market: Launching the electronic smoking devices for the first time in the Saudi market for which the manufacturer/supplier is responsible.

Making Available on the Market: Any supply of the electronic smoking devices for distribution, consumption or use in the KSA, in the course of a commercial activity, in return for payment or free of charge.

Withdrawal: Any procedure that aims to prevent a product from being placed in the market or in a supply chain.

Recall: Any procedure that aims to recall products made available for the end-user.

Product: Electronic smoking devices commonly known as electronic cigarettes (that may or may not contain nicotine).

Electronic Devices used in Electronic Smoking Systems: Devices commonly known as electronic cigarettes are devices designed to heat electronic liquids or tobacco products as an alternative to smoking aerosol products, which may contain or not contain nicotine, inhaled through the mouth.

1/2 The terms and expressions specified herein shall have the meanings specified in the applicable laws, regulations, and decrees of SASO.

Article (2) Scope

This technical regulation sets out the requirements for electronic smoking devices defined in Article (1), which use heated tobacco products or electronic liquid as an alternative to smoking combustible tobacco products.

This technical regulation specifies the requirements that must be adhered to in such devices during their supply or display in the KSA markets.

Tobacco products, derivatives and alternatives are excluded from this regulation, and shall adhere to the requirements of the Saudi Food and Drug Authority (SFDA).

Article (3) Objectives

This technical regulation aims to lay out the essential requirements that shall be met by the electronic smoking devices covered by the scope of this regulation, in order to ensure their conformity to the requirements of the applicable laws in the KSA and the relevant standards, and to ensure that safety conditions are met, and to preserve the environment and the health and safety of the consumer.

Article (4) Obligations of Supplier

4/1 General Requirements

- 4/1/1 Supplier shall comply with the technical requirements of this regulation and the referenced technical regulations.
- 4/1/2 Supplier of electronic smoking devices shall comply with the requirements issued by the General Authority for Food and Drug Administration (SFDA) relating to heated tobacco products, its derivatives, alternative substances, electronic liquids and their external supply packages.
- 4/1/3 The requirements of the standards set out in Annex (1-a) of this technical regulation shall be adhered to.
- 4/1/4 Supplier shall comply with the requirements of the anti-smoking system.
- 4/1/5 Supplier shall not offer e-smoking devices as a healthy alternative to smoking.
- 4/1/6 The supplier shall provide a manual that includes the following:
 - A) Components of electronic smoking devices.
 - B) The technical characteristics of the devices and their components.
 - C) Usage and storage instructions, including the mechanism of opening and refilling the product if applicable.
 -  D) Assembly and use processes.

E) Warning concerning the potential risks in such devices.

4/2 Technical Requirements for Electronic Smoking Devices

The supplier of electronic smoking devices shall meet the technical specifications and criteria of these products in accordance with the requirements of the relevant standards contained in Annex (1).

4/3 Metrological Requirements

International System of Units (SI Units), its multiplies, or its parts shall be applied during designing, manufacturing or distribution.

Article (5) Labelling for Electronic Smoking Devices:

- 5/1 All information used in the technical labels shall be correct, and scientifically proven.
- 5/2 The data/labels shall be understandable and written in Arabic and/or English.
- 5/3 The data/labels shall not contain any advertisement or publicity contradictory to the regulations of KSA and/or WHO.
- 5/4 The labels for electronic smoking devices shall include the following data:
 - A) Factory trademark and country of origin.
 - B) The constituent parts of the electronic smoking devices and their counts.
 - C) Devices containing an electronic liquid shall have warnings related to child safety, potential risks to children safety from the liquids containing nicotine, in case of leakage, as per the requirements of Saudi Food and Drugs Authority.
 - D) Technical characteristics of electronic smoking devices (Vaping Devices).
- 5/5 Mandatory labels data, including warning signs for heated tobacco products or electronic liquids, shall be added, as stipulated by the SFDA requirements in case the devices contain heated tobacco or electronic liquids.
- 5/6 The requirements of the competent authorities and laws relating to the regulation and trading of electronic smoking devices shall be adhered to.
- 5/7 Adequate markings shall be placed to allow traceability (QR code).

Article (6) Conformity Assessment Procedures

6/1 Electronic Smoking Devices

- 6/1/1 The supplier - responsible for displaying and/or placing electronic smoking devices in KSA markets shall obtain a correspondent national certificate as per the regulation of issuing corresponding national Certificates of Conformity in

accordance with the program of conformity assessments tests and the certification of electrotechnical components and devices (IECEE).

6/1/2 Notified Bodies shall implement the inspection procedures in accordance with the specified model, in order to ensure fulfillment of the requirements of this Technical Regulation and relevant standard, as follows:

- A) A technical file shall be attached with electronic smoking devices that includes the following:
- 1) Legal licenses for electronic smoking devices issued by the competent authorities.
 - 2) Supplier (manufacturer/importer) Declaration of Conformity in accordance with the model attached in Annex (2) of this technical regulation.
 - 3) Risk Assessment Document.
 - 4) The supplier shall cooperate with the Regulatory Authorities, by providing the technical file documents and Certificates of Conformity, and any other documents proving the conformity of the electronic smoking devices with the requirements of this regulation, upon request.
 - 5) A product bearing the Saudi Quality Mark, or its equivalent, shall be deemed to be complying with the requirements stipulated in this regulation.

6/2 Liquid packaging and/or tobacco packaging

6/2/1 Supplier of electronic smoking devices - pre-packaged or supplied with packaging for alternative tobacco materials - shall comply with SFDA requirements for heated or liquid tobacco substances and their derivatives and alternatives.

6/2/2 Packaging shall meet the SFDA requirements and conditions in relation to the relevant ingredients and explanatory data/labels.

Article (7): Responsibilities of Regulatory Authorities

Regulatory Authorities, as a part of their competences, shall carry out the following:

7/1 Verify fulfillment of electronic devices of smoking to the requirements of the specified conformity assessment procedures, and the technical documents accompanied with the consignment.

7/2 Regulatory Authorities are entitled to randomly take samples of electronic smoking devices, and send such samples to the competent laboratories to ascertain the extent of the conformity of such sample with the requirements set out in this Technical Regulation.

- 7/3 Regulatory Authorities have the right to charge the suppliers (manufacturers/importers) with the costs of tests and associated fees.
- 7/4 In case of a non-conformity of the product, Regulatory Authorities shall take the necessary legal actions, to prevent the supply of such products, to withdraw from warehouses, or destruction of the products.

Article (8) Violations and Penalties

- 8/1 It is prohibited to manufacture, import, launch, or even advertise the products non-conforming with the requirements of the articles stipulated in this Technical Regulation.
- 8/2 Failure to meet the requirements of this Regulation shall be a sufficient reason for Regulatory Authorities, executive authorities, and conformity assessment bodies to consider the electronic smoking devices as non-conforming, which may pose a risk to the health and safety of consumers and to the environment, including:
- A) Non-compliance to WHO requirements regarding data and advertising of smoking.
 - B) Failure to issue or improper issuance of the Certificate of Conformity or the Supplier Declaration of Conformity.
 - C) Lack, unavailability, or incompleteness of the technical documentation upon request.
 - D) Lack or incomplete technical data or instructions provided in the relevant standards.
- 8/3 In case of a violation of the provisions hereof, Competent Authorities shall take all necessary actions to eliminate such violations, and their effects from the market. To this end, the Competent Authorities may:
- A) Mandate the violating party – that is responsible for placing and offering of the product – to withdraw the product from the warehouses or markets in order to remedy such violations, if possible, or re-export them, within the period specified by the authorities
 - B) Withdraw or restrain the products, or take any other necessary action to recall such products, as the case may be. The violating party shall bear all associated expenses.
- 8/4 In case of non-conformity of the products, SASO shall take the necessary actions concerning products non-conforming with the requirements of this Regulation, including the cancellation of the relevant Certificate of conformity, while taking the necessary measures with the Notified body, which issued the

certificate in accordance with regulation of conformity assessment bodies acceptance.

- 8/5 Without prejudice to any more severe punishment provided by the applicable regulations, a party that violates the provisions of this regulation shall be punished by the penalties provided in the applicable laws and regulations.

Article (9) General Provisions

- 9/1 Supplier shall bear full legal responsibility for the implementation of the requirements of this Technical Regulation, and shall be subject to the penalties stipulated in the Anti-Commercial Fraud laws and/or any other related laws, in case any violation of the articles thereof is proven.
- 9/2 This Technical Regulation shall not impede the supplier to comply with all other systems/regulations applicable in the KSA; pertaining to trading, transporting, or storing of electronic smoking devices, in addition to the rules/regulations related to the environment, security, and safety.
- 9/3 Suppliers of electronic smoking devices shall provide the inspectors of the executive authorities, Regulatory Authorities, and conformity assessment bodies with all necessary information and facilities, when required, to carry out their assigned tasks.
- 9/4 SASO, in coordination with the relevant authorities, shall prepare the models of conformity and all the necessary procedures for the implementation of the provisions of this regulation.
- 9/5 If new originated cases that cannot be treated under the provisions of this Technical Regulation, or a dispute arises as a result of the application of those provisions, such matter shall be referred to the competent committee in SASO, in order to issue a proper resolution regarding the case or dispute, while taking the public interest into consideration.
- 9/6 The supplier of electronic smoking devices may submit a new request after elimination of the reasons of rejection for the conformity assessment procedures request, and after the necessary corrections have been made. The supplier shall be responsible for any additional expenses determined by SASO.
- 9/7 SASO shall examine the complaints received regarding the products having a Certificate of Conformity, and verify the validity of such complaints, and take the necessary legal actions in case of any violations.
- 9/8 SASO have the right to cancel the Certificate of Conformity, if the supplier violates the provisions herein, and shall take the legal actions to ensure the preservation of the rights of SASO.

9/9 SASO shall, exclusively, have the right to interpret the articles herein. All beneficiaries of the application of this Technical Regulation shall adhere to the interpretations issued by SASO.

Article (10) Transitional Provisions

- 10/1 The supplier shall adhere to the provisions of this Technical Regulation within a period of six months as of the date of publication in the Official Gazette.
- 10/2 Products, not complying with the provisions specified in this Technical Regulation shall not be traded after one year from the date of publication in the Official Gazette.
- 10/3 This Technical Regulation, once adopted, shall supersede all the preceding regulations related to the scope of this regulation.

Article (11) Publication

 This Technical Regulation shall be published in the Official Gazette.

Annex No. (1)

A) List of standards for electronic smoking devices

No.	Title in Arabic	Title in English	Standard
1	منتجات البخار – آلة التبخير التحليلية الروتينية – التعاريف والشروط القياسية	Vapour products – Routine analytical vaping machine – Definitions and standard conditions	ISO 20768
2	آلة تدخين السجائر التحليلية الروتينية – التعاريف والشروط القياسية	Routine analytical vaping machine – Definitions and standard conditions	ISO 3308
3	الأجهزة الكهربائية المنزلية وما يشابهها – السلامة – الجزء الأول: المتطلبات العامة	Household and similar electrical appliances. Safety – part 1: General requirements.	IEC 60335-1
4	أمان معدات تكنولوجيا المعلومات – الجزء الأول: متطلبات عامة.	Information Technology Equipment - Safety - Part 1: General requirements.	IEC 60950-1
5	درجات الحماية التي توفرها المرفقات (كود IP)	Degrees of Protection Provided by Enclosures (IP Code)	IEC 60529
6	سلامة محولات الطاقة وإمدادات الطاقة والمفاعلات والمنتجات المماثلة – الجزء 1 متطلبات عامة واختبارات.	Safety of power transformers, power supply units and similar - Part 1: General requirements.	IEC 61558-1
7	متطلبات السلامة للخلايا الثانوية المحمولة مختومة، وبطاريات مصنوعة منها، لاستخدامها في التطبيقات المحمولة.	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	تحديد بعض المواد في المنتجات الكهروتقنية – الجزء 1: مقدمة ونظرة عامة.	Determination of certain substances in electro- technical products - Part 1: Introduction and overview	IEC 62321-1
9	معدات تكنولوجيا المعلومات والاتصالات، الصوتية والمرئية – الجزء 1: متطلبات السلامة.	Audio/video, information and communication technology equipment - Part 1: Safety requirements.	IEC 62368-1

10	الوثائق الفنية لتقييم المنتجات الكهربائية والإلكترونية وفقاً لتقييد المواد الخطرة.	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.	IEC 63000
11	التوافق الكهرومغناطيسي – متطلبات الأجهزة المنزلية والأدوات الكهربائية وأجهزة مماثلة – الجزء 2: الحصانة – معيار منتجات العائلة.	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity - Product family standard.	CISPR 14-2
12	التوافق الكهرومغناطيسي – متطلبات الأجهزة المنزلية والأدوات الكهربائية وأجهزة مماثلة – الجزء 1 الانبعاثات.	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission.	CISPR 14-1
13	البطارية الابتدائية الجافة – الجزء 4: سلامة بطاريات الليثيوم	Primary dry battery - Part 4: Safety of lithium batteries.	GSO IEC 60086-4

Note: The list of mentioned standards in this appendix shall be deemed subject to review. suppliers shall be liable to ensure that they use the updated standards.

B) List of HS codes for relevant products categories

Serial	Category	Products	Custom Item
1	Vaping Devices	Vaping Devices and Instruments (like cigarettes, hookah and pipes and a like)	8543
		Vaping Devices (vaping machines of alternatives for tobacco)	
		Vaping devices (electronic hookah)	
		Other Vaping Devices	

Note: Products and HS codes in the electronic platform of Saber shall be deemed the updated and verified version.

Annex. No (2)**Supplier Declaration of Conformity Form**

This form shall be filled in on the company's official papers.

1) The Supplier Data

- Name: _____
- Address: _____

- Contact person:
- E-mail: _____
- Phone number: _____
- Fax: _____

2) Product details:

- Trade mark of the product: _____
- Model: _____
- Product description: _____
- Type (according to standards): _____
- Reference standards/The technical standard: _____

We, hereby, acknowledge that the product abovementioned in this declaration is in conformance with the Saudi technical regulation (_____), and the Saudi standards\----- attached thereto.

Person in Charge: _____

Name of the Company: _____

 Signature: _____ Date: ___ / ___ / ___