

Saudi Standards, Metrology and Quality Organization SASO

Technical Regulation for Leather Products

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Version (1)

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 6 (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: **“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 and businesses”**.

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.

The Board: SASO's Board of Directors.

SASO: Saudi Standards, Metrology and Quality Organization.

Regulatory Authorities: Governmental 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.

Market Surveillance Authorities: Governmental body/ bodies responsible for carrying out market surveillance operations.

Market Surveillance: Activities and measures carried out by the market surveillance authorities to verify that products meet the requirements stipulated in the relevant technical regulations, and to ensure that they do not pose a risk to health, safety, environment, or any other aspect related to the protection of the public interest.

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

Standard: A document specifying the characteristics of commodity, material, service, or anything that is subject to measurement. The standard also offers descriptions, characteristics, and level of quality, dimensions, measurements, safety and security requirements. It may include or pay attention to terms, codes, testing methods, sampling, packaging, and requirements of markings or labelling.

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:

- A product manufacturer, in case that he is resident in KSA, or the person identified as the manufacturer of the product, through linking the product to their name, or to a relevant commercial description, or any person who provides a product renewal.



- An agent, if the manufacturer is resident outside the KSA or an importer in the absence of an agent of the manufacturer.
- Any person in the supply chain, whose activities may affect the product properties.

Conformity Assessment Procedures: A document approved by the Board of Directors, which describes the procedures used directly, or indirectly for the conformity assessment.

Notified Bodies: Conformity Assessment Bodies, approved by SASO in accordance with the Regulation of Conformity Assessment Bodies Acceptance.

Certificate of Conformity: A certificate issued by SASO or an approved notified body, which ensures the conformity of a product, 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 with the requirements of the 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 product in accordance with the relevant legislation.

Saudi Quality Mark: A mark granted by SASO, which declares that the supplier has established an effective management system, which ensures that the products are produced in accordance with the applicable regulations, granting procedures, and relevant Saudi standards.

Placing on Market: Launching a product for the first time in the Saudi market for which the manufacturer/supplier is responsible.

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

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

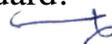
Recall: Any procedure that aims to recall products made available for the end-user.

Product: Leather products and articles thereof.

Tanning: The process of treating genuine leather fibers using chemicals, botanical or other substances.

Articles of Leather Products: Articles that contain natural leather or synthetic leather except footwear.

Label: Information shown on the product, as specified in the relevant standard.




1/2 Other terms and expressions mentioned in this Technical Regulation shall have the meanings specified in the applicable laws, regulations, and decrees in the KSA.

Article (2) Scope

This Technical Regulation shall apply to all leather products - whether natural leather or synthetic leather or a mixture of both - and to their articles, with the following exceptions:

- Footwear that are subject to the provisions of the Technical Regulation of Footwear and their Accessories and the relevant standards.
- Animal hides (pre-tanning), as they are considered raw materials intended for manufacturing and not a finished product intended for direct consumption.

Article (3) Objectives

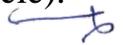
This Technical Regulation aims to lay out the essential requirements for leather products and their articles, included in the scope of this Technical Regulation, and to identify the conformity assessment procedures with which the suppliers shall comply, while placing or making these products available in the KSA markets, in order to ensure the conformity of these products to the basic requirements aiming at preservation of the environment, and the health and safety of the consumer.

Article (4) Obligations of Supplier

The supplier shall adhere to the following requirements:

4/1 General Requirements

- A) Compliance with the essential requirements to ensure the safety of leather products and their articles displayed in the KSA markets, and to provide the documentation proving the fulfilment of the requirements, upon request by the Regulatory Authorities.
- B) Leather products and their articles shall meet the technical requirements contained in this Technical Regulation and the relevant standards.
- C) Provide information related to potential health risks, in order to take preventive procedures against those risks.
- D) Compliance with the technical requirements of labelling.
- E) The required conformity assessment procedure.
- F) Availability of an effective environmental management system in the manufactory (A manufactory that has obtained an environmental certificate according to ISO 14001 is considered as met the requirements of this article).



4/2 Requirements Related to Animal Hides

It is prohibited to trade and display leather of endangered animals, which are protected by international agreements.

The use of leather of forbidden animals is prohibited. In addition, the animal source of the hides shall be mentioned.

It is not permissible to treat rawhides or introduce products or materials in the manufacture of semi-finished or finished products, materials that are totally or partially made of leather or have a leathery appearance, or prepare them with products or materials that are harmful to human health or the environment. Parts that are likely to be in contact with human skin shall comply with the permissible limits for hazardous substances in accordance with the relevant standards contained in Annex (1).

4/3 Requirements of Harmful Substances

- A) The permissible values (pH) must be in accordance with the permissible limits in the relevant standards.
- B) Hazardous substances that may be harmful to human health, or pose a threat to the environment shall not be used when processing or preparing leather products except to the permissible limits, in accordance with the relevant standards, contained in Annex (1), and the most important of these harmful substances that must be adhered to regarding the permissible limits of the relevant standards are:
 - Chromium (VI).
 - Aromatic amine.
 - Formaldehyde
 - Chlorophenol
- C) The pigments or dyes used shall not contain cleavable arylamines, carcinogenic dyes, allergenic dyes, active-biomaterials treated dyes, or flame-retardant treated dyes.
- D) Avoid the use of low-biodegradable compounds such as Ethylenediaminetriacetate, which are commonly used after tanning.

4/4 Metrological Requirements

International system of units (SI Units), multiplies or parts thereof shall be used during design, manufacturing, or trading.

4/5 Packaging Requirements

- A) Leather products and articles thereof shall be packed in appropriate packaging.
- B) Ensure that the product is packaged according to its nature, and in accordance with the packaging requirements stipulated in the relevant standard.



- C) Ensure that the product packaging materials are free of lead, heavy metals, or any substance harmful to human health and safety, or to the environment.

Article (5) Labeling

1. Labelling shall meet the technical requirements contained in this Technical Regulation and the relevant standards, contained in Annex (1).
2. Products shall contain legible and non-erasable explanatory data. The manufacturer shall estimate the sizes of the text and the font that are compatible with the product.
3. Data shall be in Arabic or in both Arabic and English.
4. All the information contained in the labels shall be correct, proven and verifiable.
5. Images and phrases used on the product or the packaging shall not violate the public law, morals, and the Islamic values prevailing in KSA.
6. Labeling of the product, intended for placement and display in the market, shall meet the following conditions:
 - Name and type of the product.
 - Brand name and country of origin.
 - Components.
 - Leather type.
 - Number of pieces in the package.
 - Classification and date of manufacturing (for synthetic leather).
 - Classification and date of tanning (for tanned leather).

Article (6) Conformity Assessment Procedures

- 6/1 The supplier - responsible for market placement of leather products and their articles, subject to this Technical Regulation - shall obtain a certificate of conformity issued by a notified body approved by SASO, according to the following:
- Form (Type 3) regarding leather products and their articles for children under three years (36 months), as shown in Annex (2).
 - Form (Type 1a) regarding other products as shown in Annex (3).
- 6/2 The notified body shall carry out the conformity assessment procedures according to the specified form, in order to ensure fulfillment of the requirements of this Technical Regulation and the relevant Saudi standards set out in Annex (1).
- 6/3 The product shall be accompanied by a technical file, which includes the following:



- Supplier (manufacturer/importer) Declaration of Conformity, according to the form attached in Annex (4).
- Risk assessment document.
- Country of origin.
- Reports of the required tests specified in the Technical Regulation.
- A list of standards applied to the product contained in Annex (1).
- Product explanatory booklet in case the label cannot be affixed to the product.

6/4 Products that have obtained the Saudi Quality Mark or its equivalent shall be deemed as complying with the requirements stipulated in this Technical Regulation.

Article (7) Responsibilities of Regulatory Authorities

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

- 7/1 Verify that the products fulfill the specified conformity assessment procedures and the technical documents attached to the consignments.
- 7/2 Randomly sample the products and refer such samples to the competent laboratories to ascertain the extent of conformity with the requirements contained in this Technical Regulation.
- 7/3 Regulatory Authorities have the right to charge the suppliers (manufacturers and importers) with the costs of testing and the associated fees.
- 7/4 In case of a non-conformity of the product, Regulatory Authorities shall withdraw the concerned products from warehouses, and take the necessary legal actions.

Article (8) Responsibilities of Market Surveillance Authorities

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

- 8/1 Enforce the market surveillance procedures to the products in markets and the products stored in the warehouses of traders and manufacturers, in order to verify the safety of the products and the extent of fulfillment of the requirements stipulated in this Technical Regulation and in the relevant standards.
- 8/2 Take samples of the product, whether from the market or warehouses of suppliers (manufacturers and importers), in order to conduct the necessary tests and to verify the conformity of such products with the requirements set out in this Technical Regulation.



- 8/3 In case of non-conformity of the product – displayed or stored – with the requirements of this Technical Regulation, Market Surveillance Authorities shall take all administrative actions including withdrawal and recall of such products. Procedures and penalties – stipulated in Article (9) – shall be applied after taking the necessary actions.

Article (9) Violations and Penalties

- 9/1 It is prohibited to manufacture, import, launch, or even advertise the products non-conforming to the provisions of this Technical Regulation.
- 9/2 Failure to meet the requirements of this Technical Regulation shall be a sufficient reason for Market Surveillance Authorities and Regulatory Authorities to consider the product as non-conforming, which may pose a risk to the health and safety of the consumer and to the environment, including, but not limited to:
- A) Non-fixation or improper fixation of conformity labels, Saudi Quality Mark, or its equivalent.
 - B) Failure to issue or improper issuance of the Certificate of Conformity or the Supplier Declaration of Conformity.
 - C) Unavailability or incompleteness of the technical documentation.
 - D) Unavailability or incompleteness of product data/labels or the usage guidelines.
- 9/3 In case of a violation of the provisions of this Technical Regulation, Market Surveillance Authorities – depending on the situation - shall take all necessary actions to eliminate such violations, and their effects from the market. To this end, Market Surveillance Authorities may:
- A) Mandate the violating party – responsible for placing and displaying the product – to withdraw the product from the warehouses or markets in order to remedy such violations, if possible. The product may be exported or destroyed (according to the nature of the product) within the period specified by the Market Surveillance Authorities.
 - B) Withdraw, restrain or destroy the products, or take any other necessary action to recall such products from the markets. Market surveillance Authorities – as the case may be - may announce the withdrawal of the product from the markets, and the violating party shall bear all associated expenses.
- 9/4 In case of non-conformity of the products, SASO shall take the necessary actions concerning products non-conforming with the requirements of this Technical 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 the Regulation of Conformity Assessment Bodies Acceptance



- 9/5 Without prejudice to any other law, a party that violates any of the provisions hereof shall be subject to the penalties stipulated in applicable Anti-Commercial Fraud Law or any other superseding law.

Article (10) General Provisions

- 10/1 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 of this Technical Regulation is proven.
- 10/2 This Technical Regulation shall not impede the supplier to comply with all other systems/regulations applicable in the Kingdom of Saudi Arabia; pertaining to trading, transporting, or storing the product, in addition to the rules/regulations related to the environment, security, and safety.
- 10/3 All suppliers of the products subject to the provisions of this Technical Regulation shall provide the inspectors of the Regulatory and Market Surveillance Authorities with all necessary information and facilities, when required, to carry out their assigned tasks.
- 10/4 Where new originated cases that cannot be treated under the provisions of this Technical Regulation, or where 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.
- 10/5 The supplier may submit a new request after elimination of the reasons of rejection, and after the necessary corrections have been made. The supplier shall be responsible for any additional expenses determined by SASO.
- 10/6 SASO shall examine the complaints received regarding the products having a Certificate of Conformity or a Quality Mark, if any, and verify the validity of such complaints, and take the necessary legal actions in case of any violations.
- 10/7 SASO has the right to annul the Certificate of Conformity or the Quality Mark license, if any, if the supplier violates the provisions herein, and shall take the legal actions to ensure the preservation of the rights of SASO.
- 10/8 If any modifications were made to the product during the validity period of the Certificate of Conformity or the Quality Mark license, if any, (except for figure modifications), the certificate or the license for this product shall be annulled, and a new request shall be submitted
- 10/9 SASO exclusively have the right to interpret the articles of this Technical Regulation. All beneficiaries of the application of this Technical Regulation shall adhere to the interpretations issued by SASO.



Article (11) Transitional Provisions

- 11/1 The supplier shall take corrective actions in accordance with the provisions of this Technical Regulation within a period of no more 180 days as of the date of publication in the Official Gazette.
- 11/2 Subject to the provisions of item (1) of this Article, products not complying with the provisions specified in this Regulation may be traded for a period of no more than 365 days as of the date of publication in the Official Gazette.
- 11/3 This Technical Regulation - once adopted – shall supersede all preceding regulations related to the scope of this Technical Regulation.

Article (12) Publication

This Technical Regulation shall be published in the Official Gazette.



Annex (1)

A) List of Leather Products and Articles thereof and Related Standards

No.	Title of Standard in Arabic	Title of Standard in English	Standards No.
1	الجلود – الاختبارات الكيميائية – تعيين بعض ملونات الأزو المستخدمة في صباغة الجلود – الجزء الأول: تعيين بعض الامينات العطرية المستخرجة من ملونات الأزو.	Leather - Chemical tests - Determination of some azo colorants used in dyeing leather - Part 1: Determination of some aromatic amines extracted from azo colorants.	SASO-ISO-17234-1
2	الجلود -التقدير الكيميائي للمحتوى المعدني - الجزء الأول: استخراج المعادن.	Leather - Chemical Determination of Mineral Content - Part 1: Mineral Extraction.	SASO-ISO-17072-1
3	الجلود -التقدير الكيميائي للمحتوى المعدني – الجزء الثاني: مجموع المحتوى المعدني.	Leather - Chemical Determination of Mineral Content - Part Two: Total Mineral Content.	SASO-ISO-17072-2
4	الجلود – الإختبارات الكيميائية – تحديد محتوى خماسي كلوروفينول.	Leather - chemical tests - determination of pentachlorophenol content.	SASO-ISO-17070
5	الجلود – التقدير الكيميائي لمحتوى الكروم السداسي في الجلود – الجزء الأول: الطريقة اللونية	Leather - Chemical Determination of Hexagonal Chromium Content in Leather - Part 1: Colorimetric method	SASO-ISO-17075-1
6	الجلود – التقدير الكيميائي لمحتوى الكروم السداسي في الجلود – الجزء الأول: طريقة الكروماتوغرافي.	Leather - Chemical Determination of Hexagonal Chromium Content in Leather - Part 1: Chromatographic method.	SASO-ISO-17075-2
7	الجلود – التحديد الكيميائي لمحتوى الفورمالدهايد – الجزء الأول: طريقة استخدام السائل الكروماتوغرافي عالي الأداء.	Leather - Chemical Determination of Formaldehyde Content - Part 1: Method for using high performance chromatography liquid.	SASO-ISO-17226-1
8	الجلود – التحديد الكيميائي لمحتوى الفورمالدهايد – الجزء الثاني: طريقة استخدام التحليل بالمقياس اللوني.	Leather - Chemical Determination of Formaldehyde Content - Part Two: Method for using chromatography.	SASO-ISO-17226-2
9	الجلود -دباغة جلد الأغنام الأزرق المائي – المواصفات.	Leather - Tanning of aqua sheepskins - Specifications.	SASO-ISO-5431
10	الجلود -دباغة جلد الضأن الأزرق المائي – المواصفات.	Leather – Tanning of aqua lamb hides-Specifications.	SASO-ISO-5432

11	الجلود -دباغة جلد البقر الأزرق المائي – المواصفات.	Leather - Tanning of aqua cow hides- Specifications.	SASO-ISO-5433
12	الجلود – قياس المساحة.	Leather-Area measurement	SASO-ISO-11646
13	المتطلبات العامة للمصنوعات الجلدية.	General requirements for leather goods	SASO-GSO-2440
14	المصطلحات القياسية المتعلقة ببطاقة العناية بالملبوسات والمنسوجات والمفروشات والمنتجات الجلدية.	Standard terminology related to garment, textile, upholstery and leather products.	SASO-ASTM- D3136
15	المواد الضارة المستخدمة في صناعة المنسوجات	Harmful substances used in the textile industry	SASO-GSO-1956
16	الجلود –تعيين مقاومة البري للجلد- الجزء ١ : طريقة تابر	Leather-Determination of leather abrasion resistance- Part1: Taber method	SASO ISO 17076- 1
17	الجلود -التقدير الكيميائي لمحتوى الكروم سداسي في الجلود -التقادم الحراري للجلد وتعيين الكروم سداسي التكافؤ	Leather - chemical determination of hexagonal chromium content in leather - thermal aging of leather and designation of hexavalent chromium	SASO ISO 10195
18	الجلود – اختبار قوة التصاق الطبقة المجهزة	Leather-Test of adhesive strength of prepared layer	SASO ISO 11644
19	الجلود – الاختبارات الكيميائية – تعيين الأس الهيدروجيني	Leather-Chemical tests- Designation of PH	SASO ISO 4045
20	الجلود – الاختبارات الكيميائية – تعيين الأس الهيدروجيني	Leather-Chemical tests- Designation of PH	SASO ISO 2589
21	الجلود – الاختبارات الفيزيائية والميكانيكية – تحديد قوة الشد ونسبة الاستطالة	Leather - Physical and Mechanical tests - Determination of tensile strength and elongation ratio	SASO ISO 3376
22	الجلود – الاختبارات الفيزيائية والميكانيكية – تحديد قوة التمزق – الجزء ١: تمزق الطرف الواحد	Leather - Physical and Mechanical Tests - Determination of Tearing Strength - Part 1: Tearing of One End	SASO ISO 3377-1
23	الجلود – الاختبارات الفيزيائية والميكانيكية – تحديد قوة التمزق – الجزء ٢: تمزق الطرفين	Leather - Physical and mechanical tests- Determination of tearing strength - Part 2: Tearing of both ends	SASO ISO 3377-2

Note: The list of standards mentioned in this Annex is subject to review, and suppliers are responsible for ensuring that they use the latest standards through SASO's website.




B) List of Products and Customs Coding

No.	Product Categories	HS Code
1	Tanned or crust hides and skins of bovine or equine animals	4104
2	Tanned or crust skins of sheep or lambs	4105
3	Tanned or crust hides and skins of other animals	4106
4	Leather further prepared after tanning or crusting of bovine or equine animals	4107
5	Leather further prepared after tanning or crusting of sheep or lamb	4112
6	Leather further prepared after tanning or crusting of other animals	4113
7	Chamois (including combination chamois) leather; patent leather and patent laminated leather; metallized leather.	4114
8	Composition leather with a basis of leather or leather fiber, in slabs, sheets or strips	4115
9	Saddlery and harness for any animal	4201
10	Luggage transport boxes and suitcases	4202
11	Articles of apparel and clothing accessories, of genuine leather or composition leather	4203
12	Other articles of genuine leather or of composition leather	4205
13	Articles of gut	4206
14	Raw furskins	4301
15	Tanned or dressed furskins	4302
16	Articles of apparel, clothing accessories and other articles	4303
17	Headgear	6506
18	Watch straps, bands, bracelets, and parts thereof	9113

Note: The products and customs tariffs (HS Codes) found in Saber electronic platform are considered the updated and approved version.

to



Annex (2)

Conformity Assessment Form (Type 3) as per ISO/IEC 17067 (Type Approval Based on Quality Assurance of Production Process)

1 Type Approval Based on Quality Assurance of Production Process

A model of conformity assessment procedures, by which the supplier fulfills the obligations set out in the items below, while ensuring and acknowledging - on its sole responsibility - that the concerned products are in conformity with the type specified in the Type Approval Certificate and comply with the requirements of the relevant technical regulations.

2 Manufacturing

The supplier shall operate with a certified Product Safety Management System, to ensure the safety of the product, including production lines, final inspection and testing of the concerned products as per Clause (3), and shall be subject to periodic surveillance as per Clause (4).

3 Product Safety Management System

3/1 The supplier shall submit a request to a Notified Body of its choice, in order to evaluate the safety management system of concerned products.

The request shall include:

- A) Name and address of the supplier, and the name and address of the official representative, in case the representative submits the request.
- B) The manufacturer shall be officially licensed by the relevant authorities in the country of origin.
- C) A written declaration not to submit the same request to any other Notified Body.
- D) All relevant information regarding the concerned product category.
- E) Documentation of the Product Safety Management System.
- F) Technical documents of the certified type, and a copy of the Type Approval Certificate.

3/2 The Product Safety Management System shall guarantee that the manufactured products are in conformity with the type specified in the Type Approval Certificate, and with the requirements of the relevant technical regulations.

3/3 All the system elements and its requirements - adopted by the supplier - shall be documented in a systematic and orderly manner in a form of written policies, procedures and instructions. The documents of the Product Safety Management System shall provide a consistent understanding of the safety programs, plans, manuals and records. Such documents shall contain, in particular, an adequate description of the following:



- A) Quality objectives, organizational structure, responsibilities and competences of the management regarding the safety of the product.
 - B) Manufacturing techniques, product safety and quality assurance procedures, and applied processes and procedures.
 - C) Executed inspections and tests; before, during, and after manufacturing, and the frequency with which they will be carried out.
 - D) Records: such as inspection, testing, calibration reports, and the qualification documents of relevant personnel, etc.
 - E) Means of control for achieving the required product safety and the effective operation of the Product Safety Management System.
- 3/4 The Notified Body, approving the Product Safety Management System, shall assess such system to determine whether it satisfies the requirements referred to in Clause (3/3), during the period of the approval of the system, which shall be three years.
- 3/5 The product shall be presumed to comply with the requirements of the technical regulations, in relation to the items of the Product Safety Management System, whenever it conforms to the standards.
- 3/6 In addition to experience in the relevant product safety, the auditing team shall have one technical expert - at least – who is experienced in the assessment of the field and techniques of manufacturing of the product, and is fully aware of the technical requirements stipulated in the relevant technical regulations.
- 3/7 The audit shall include an assessment visit to the factory. The auditing team shall review the technical documents referred to in Clause (3/3), in order to verify the manufacturer's ability to identify the requirements of the technical regulations and carry out the necessary examinations and tests to ensure compliance of the product with these requirements.
- 3/8 The manufacturer shall be notified of the decision after the end of the assessment, provided that such notice include audit findings, assessment decision, along with the justifications on which the decision was based.
- 3/9 The manufacturer shall be committed to satisfy the obligations of the Product Safety Management System, as approved, and to maintain the system so that it remains adequate and efficient.
- 3/10 The manufacturer shall notify the conformity assessment body, which approved the Product Safety Management System, of any proposed modifications to the system.
- 3/11 The Notified Body shall assess any proposed modifications and decide whether the modified Product Safety Management System will continue to satisfy the requirements referred to in Clause (3/3) or a reassessment is necessary. The Notified Body shall notify the manufacturer of its decision; the notification



shall include testing results along with the justifications of the assessment decision.

4 Periodic Surveillance Under the Responsibility of the Notified Body

4/1 The purpose of periodic surveillance is to verify the extent of which the supplier meets the obligations of the certified Product Safety Management System.

4/2 For assessment purposes, the supplier shall allow the Notified Body, during the validation period, to enter the manufacturing, inspection, testing and storage sites. The supplier shall provide the Notified Body with all necessary information, particularly, the Product Safety Management System documents and safety records, such as testing and calibration reports, and the qualification documents of relevant personnel, etc.

4/3 The Notified Body shall carry out periodic audit visits to verify that the manufacturer applies and maintains the Product Safety Management System, and shall provide the supplier with an audit report.

4/4 The Notified Body have the right to perform unexpected visits to the factory. During such visits, the Notified Body may, as necessary, carry out product tests, or have them carried out by a third party, in order to verify that the Product Safety Management System is properly functioning. The Notified Body shall provide the supplier with an assessment report, and testing reports, in case of testing.

5 Certificate of Conformity and Declaration of Conformity

5/1 The Notified Body shall issue a Certificate of Conformity for the product in case the supplier has an effective and certified Product Safety Management System, upon the request of the supplier, within the validity period.

5/2 The Notified Body shall identify the product details in each request, clarify such details in the issued Certificate of Conformity, and record them in the electronic portal for conformity (in SASO).

5/3 The supplier shall provide a written Declaration of Conformity for each approved product type (Type Approval), and shall put it at the Regulatory Authorities and Market Surveillance Authorities disposal for a period of ten (10) years, at least, after the placement of the product in the market. The Declaration of Conformity of the supplier shall identify the approved product type. Furthermore, a copy of the Certificate of Conformity and the Declaration of Conformity shall be provided to the Regulatory Authorities and Market Surveillance Authorities upon request.

5/4 The supplier shall put the following documents at the Regulatory Authorities and Market Surveillance Authorities disposal, for a period of ten (10) years, at least, after placement of the product in the market:



- A) Documentation referred to in Clause (3/3).
- B) The amendments referred to in Clause (3/9), as approved.
- C) Decisions and reports of the Notified Body, referred to in Clause (3/7).

5/5 Each Notified Body shall inform the Regulatory Authorities and Market Surveillance Authorities of issued or withdrawn Product Safety Management System approvals, and shall periodically or upon request, provide lists of Product Safety Management System approvals that have been rejected, suspended, or restricted by any means; on a regular basis or upon request. Each Notified Body shall inform, upon request, the other Notified Bodies of Product Safety Management System approvals it has rejected, suspended, withdrawn, or restricted; and notify such bodies of Product Safety Management System approvals issued by it.

to



Annex (3)

Conformity Assessment Form (Type 1a) as per ISO/IEC 17067

(Type Approval)

1 Type Approval

Type approval is defined as one of the conformity assessment procedures, under which a notified body reviews and verifies the technical design of the product and declares that the technical design meets the requirements of the relevant Saudi Technical Regulations.

Type approval may be conducted by one of the two following methods:

- A) Examination of a representative sample of the entire product, that represent the expected production (production model).
- B) Assessment of the conformity of the technical design of the product by auditing the relevant technical documentation and manuals (design model), and examining of a representative sample of the expected production for one part or more involving hazardous parts of the product (a combination of the production model and the design model).

2 Procedures of Type Approval

2/1 Submission of a Type Approval Request to a Notified Body

The manufacturer shall submit a request for type approval to a notified body selected by the manufacturer, such request shall include:

- A) Name and address of the manufacturer;
- B) A written declaration not to submit the same request to any other Notified Body.
- C) Technical documentation facilitating the assessment of the conformity of the product to the requirements of Saudi technical regulations. Such documentation shall include adequate analysis and evaluation of risks.
- D) Technical documentation shall identify the requirements that apply to the product. Including, as required by the assessment, the design of the product, manufacturing and operation (use) of the product.
- E) Technical documentation shall include – at least - the following:
 - 1) A general description of the product.
 - 2) Design and manufacturing drawings, horizontal projections (diagrams), components, units, subdivisions, etc.
 - 3) Description and explanations, referred to therein, necessary to understand the drawings, diagrams, and the operation (use) of the product.



- 4) A list of the Saudi standards or any other relevant technical specifications adopted by SASO, whether fully or partially applied, and a description of the adopted solutions to meet the essential requirements of the Saudi technical regulations in case of non-application of the aforementioned standards. In case of partial application of Saudi standards, the technical documentation shall clarify the applied clauses.
- 5) Report results (graph calculations) of the design, operation control, conducted tests, etc.
- 6) Test reports.
- 7) Representative samples of the planned production. The notified body may request additional samples, if necessary.
- 8) Evidences (proofs) supporting the appropriateness of the technical solutions applied in the design. Such evidence shall refer to all documents, particularly in case of non-application of the Saudi standards and/or the aforementioned appropriate technical specification. Supporting evidences – as applicable - shall include results of test conducted in the suitable laboratory in the manufacturer or any other laboratory under the responsibility of manufacturer.

2/2 Tasks of the Notified Body

2/2/1 With regard to the product, the notified body shall:

Study the technical documentation and supporting evidence for the purpose of assessment of the technical design of the product.

2/2/2 With regard to the samples, the notified body shall:

- 1) Ensure that the manufacturing of samples is conformant to the technical documentation, in addition to identifying the elements designed in accordance with the Saudi standards, and the elements designed in accordance with other standards.
- 2) Carry out appropriate examinations and tests, or outsource them in order to verify that the technical solutions adopted by the manufacturer meet the essential requirements specified in the standards, in case of non-application of the relevant standards.
- 3) Carry out appropriate tests or outsource them, in order to verify that – in case of non-application of Saudi standards and/or other appropriate standards - the technical solutions adopted by the manufacturer meet the essential requirements of the Saudi technical regulations.



- 4) Be in agreement with the manufacturer on the venue where tests should be conducted.

2/2/3 As for decisions made by the Notified Body:

- 1) The notified body shall issue an assessment report of the procedures carried out and their outputs. The notified body shall not publish, fully or partially, the report without the approval of the manufacturer.
- 2) In case the type meets the requirements of the Saudi technical regulations relevant to the concerned product, the Notified Body shall issue a Type Approval Certificate for the manufacturer. Such certificate shall include the name and address of the manufacturer, test results, the validity conditions thereof, if any, and all information required for identification of the certified type. The certificate may also include attachments.
- 3) The certificate, along with its attachments, shall include all necessary information required to assess the conformity of manufactured products, according to the tested type and for monitoring during operation.
- 4) In case the type is non-conforming to the requirements of the Saudi Technical Regulations applicable to the product, the Notified Body shall not issue the Type Approval Certificate and shall notify the applicant of its decision, stating detailed justifications for such decision.
- 5) The Notified Body shall follow all recognized technological developments. Whenever such developments indicate that the possibility that the certified type may no longer comply with the requirements of the Saudi Technical Regulations, the Notified Body shall determine to what extent further tests are required, and it shall inform the manufacturer accordingly.
- 6) The manufacturer shall inform the Notified Body, holding the technical documentation related to the Type Approval Certificate, of all modifications of the certified type, which may affect the conformity of the product to the requirements of the Saudi Technical Regulations, or to the terms of validity of the Type Approval Certificate. As such modifications require additional approval other than the primary Type Approval Certificate.
- 7) Notified bodies shall inform SASO of the Type Approval Certificates and any additions issued or withdrawn, and shall periodically, or upon request, provide a list of the Type Approval Certificates and any additions that has been rejected, suspended, or restricted in any way.
- 8) Each Notified Body shall inform the other accredited Notified Bodies of the Type Approval Certificates and any additions that has been rejected, suspended, or restricted in any way. In addition, they shall be informed, upon request, about Type Approval Certificates or any additions released.



- 9) Upon request, SASO and other Notified Bodies can obtain copies of the Type Approval Certificates and/or additions thereto. SASO may obtain copies of technical documentation and testing results carried out by the Notified Body, upon request. The Notified Body shall keep a copy of the Type Approval Certificate, its annexes and additions, in addition to the technical documentation (including documents attached by the manufacturer) up until the certificate's expiration date.
- 10) The manufacturer shall keep a copy of the Type Approval Certificate, its annexes and additions thereto, in addition to the technical documentation. Furthermore, the manufacturer shall make all documents available to Regulatory Authorities and Market Surveillance Authorities for ten (10) years after placement of the product in the market.
- 11) The supplier may submit the request mentioned in Clause (2/1/1), and carry out the aforementioned tasks on behalf of the manufacturer, on the condition of the manufacturer's consent.

to



