

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

Technical Regulation for Glue and Adhesive Materials

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Version (1)

Note:

Only the Arabic version of this Regulation is an original in law and applies where there are discrepancies with this translation

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Preamble

In line with the accession of KSA to the World Trade Organization (WTO), as per the Decree No. (244), of the Council of Ministers, dated 21/09/1426 AH, corresponding to 24/10/2005. On the approval of the Kingdom's accession documentation, the World Trade Organization's commitment to harmonize the relevant regulations and procedures to be in line with the principles of the WTO's agreements. In particular, the agreement on Technical Barriers to Trade (TBT), which states that no unnecessary technical requirements should be imposed on the flow of goods between member states and that no distinction should be made between products of different origins, in terms of technical requirements, the methods of conformity assessment are issued through the technical regulations that include legitimate basic requirements and standardizing work procedures.

Based on (Paragraph-1) of Article 3 of the Statute of Saudi Standards, Metrology and Quality Organization are issued by the Cabinet Resolution No. (216) the dates of 17/06/1431 AH is corresponding to 31/05/2010 AD, which states **"SASO shall issue Saudi Standards. Quality with the international standards and guides satisfy the requirements of the Worlds Trade Organization (WTO). Agreements in this regard, comply with the Islamic Sharia and fulfill the interests of the Kingdom"**;

Based on Paragraph 2 of Article 4 of the Statute of Saudi Standards, Metrology and Quality Organization, issued by the Council of Ministers No. (216), the dates of 17/06/1431 AH correspond to May 31, 2010 AD, which states, **"SASO shall issue regulations for conformity assessment procedures of commodities, products, and services according to its approved standards"**;

Based on Paragraph One of the Sixth Article of the Statute of Saudi Standards, Metrology, and Quality Organization, issued by the Council of Ministers No. (216), the dates of 17/06/1431 AH correspond to the 31st of May 2010 AD, which is subject to the Fourth Article of this Statute. **"SASO shall be the organization in charge of matters. In terms of standards, conformity assessment procedures, and the issuance of quality, metrology, and calibration marks, all public and private sectors must adhere to Saudi Standards in all purchases and works.**

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 The terms and expressions listed below, when applying the provisions of this Technical Regulation, shall have the meanings corresponding to them, unless the context requires otherwise:

KSA: The Kingdom of Saudi Arabia.

The Board: The Organization's Board of Saudi Arabia.

SASO: Saudi Standards, Metrology and Quality Organization.

Regulatory Authorities: The governmental body/bodies with regulatory tasks dictated to their specializations are consequently responsible for the implementation and enforcement of technical regulations, whether in customs ports, markets, or manufactories.

Competent Authority: The authorities concerned with implementing the provisions of this regulation and licensing the establishment and its activities

Market Surveillance Authorities: The governmental body / bodies in charge of carrying out market surveillance operations.

Market Surveillance: Activities and measures undertaken by market control authorities to verify those products. It must meet the requirements stipulated in the relevant technical regulations. They do not constitute a threat to health, safety, the environment or any other aspect of protecting the public interest.

Technical Regulation: A document approved by the Board of Directors defining the characteristics of the products, their associated processes and production methods. This includes applicable valid administrative provisions that must be adhered to. It may include or consider terms, definitions, packaging and requirements for products, services, processes or production methods.

Standard: The document specifies the characteristics of a good, material, service, or everything subject to measurement. In addition, the standard provides descriptions, characteristics, levels of quality or dimensions, and measurements of safety and security requirements. They include terms, symbols, test methods, sampling techniques, labels and packaging labels

Important Requirements: Requirements for the products may affect safety, health, and the environment, which must be adhered to in all circumstances.

Hazard(s): A hazard is any source of potential damage, harm, or other effects on something or someone.

Risk (s): Risk is the likelihood that a person will be harmed or suffer adverse health effects if they are exposed.

Supplier:

- The manufacturer of the product is a resident of the Kingdom or any person who identifies himself/herself as the manufacturer of the product by naming a product in his/her name or any related commercial description. So does everyone who applies to renew a product.
- The agent is when the manufacturer in KSA in case the manufacturer is resident outside the Kingdom or the importer in the absence of a manufacturer's agent.

- Any person in the supply chain whose activities may affect the characteristics of a product.

Conformity Assessment Procedures: A document approved by the Board of Directors stating the procedures that will be used directly or indirectly for conformity assessment.

Notified Bodies: Conformity Assessment Body (“Third Party”) approved by SASO in accordance with the Regulation on Acceptance of Conformity Assessment Bodies.

Certificate of Conformity: A certificate is issued by the Saudi Standards and Metrology Organization (SASO) or the notifying body, which ensures that the product, or any batch thereof is confirmed with the requirements of the relevant standard.

Supplier Declaration of Conformity: A product declaration is an advertisement by a supplier declaring that a product complies with the requirements contained in this document and applicable legislation without mandatory third-party intervention. Neither in the design phase nor in the production phase of the manufacturing process. Advertising may be based on product testing in accordance with relevant legislation.

The Saudi Quality Mark (SQM): is a conformity mark by the Saudi Standards Metrology and Quality Organization (SASO). It is conferred on products manufactured in a facility that has a robust and effective Management System to ensure continuous compliance to Saudi Standards.

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

Supply in the Market: This means that any supply of a product for distribution in the Kingdom of Saudi Arabia as part of a business, whether paid or free, is prohibited.

Withdrawal: A product recall is any procedure that aims to prevent placing a product on the market or in a supply chain.

Recall: This procedure is intended to recall products that are provided to the end user in accordance with the recall regulation.

Product: This technical regulation applies to all types of glues and adhesives.

Adhesive: A sticky substance that is used for joining things together, usually permanently.

Pressure-sensitive tape: Pressure Sensitive Tape (PST) Pressure sensitive tape is defined as a continuous flexible tape of fabric, paper, metal or plastic coated on one or both sides with a permanently viscous adhesive at room temperature, which will adhere to a variety of surfaces with light pressure (finger pressure) No phase change (liquid to solid) and is usually on a coil. The main point that distinguishes pressure sensitive tape from other types of adhesives is that it does not need to be activated with water, solvent or heat to exert a strong adhesive force against materials as diverse as paper, glass, wood, plastic or metal.

Glue: It is an adhesive that is used to bond two surfaces. It is a mechanism of action based on flow into the pores of the surface and penetration into them.

When the glue dries, it becomes hard, bonding two opposite surfaces. Glue is

used for many uses, such as binding books, fixing wood, gluing metal and glass, making sandpaper, painting on walls, gluing PVC pipes, etc.

Label (Card): The Environmental Performance Efficiency Label for paints is owned by SASO. It includes details specified by SASO in terms of the level of environmental performance of each product. If the products meet the requirements for importation, manufacturing, or use within the Kingdom, the label is fixed or applied to them.

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

Article (2) Scope

This regulation applies to all types of glue and adhesive products (adhesive tape, liquid, powder or paste).

The following are excluded from this regulation:

- Construction and plumbing adhesives subject to other technical regulations.
- Medical adhesives, as they are subject to additional requirements from SFDA.

Article (3) Objectives

The purpose of this regulation is to specify the basic requirements for glues and adhesives covered by the scope of this technical regulation. Suppliers must follow conformity assessment procedures when placing these products in the markets of the Kingdom of Saudi Arabia to ensure conformity and preserve the environment in order to facilitate market control procedures. When assessing conformity, it is necessary to ensure that these products are safe and healthy for the consumer.

Article (4) Supplier's Obligations

The supplier shall adhere the following requirements:

4/1 Technical Requirements

To meet the requirements of this regulation, the supplier must meet glues and adhesives which have important properties as follows:

- 4/1/1 The product's fulfilment of the requirements contained in the standard specifications contained in Annex No. (1) of these regulations.
- 4/1/2 Designing and manufacturing products so that they do not pose a threat to public health or the health and safety of users and do not affect the environment and climate during use and after disposal.
- 4/1/3 The materials, adhesive tapes and glue should be suitable for the purpose for which they were designed, taking into account in particular the health and safety of the persons concerned at all stages of use.
- 4/1/4 The adhesive materials must not pose any health risks as a result of contact with them or smelling the volatile substances contained within them.

- 4/1/5 Adhesives should not pose any health risks from coming into contact with or smelling the volatile substances they contain.
- 4/1/6 Any product containing toluene shall contain a proportion of substances that shall not exceed a maximum of 0.1%, which is the total weight of the product.
- 4/1/7 Each product must be provided with a safety data sheet or explanatory statement containing the information.
 - A) The legal person who is responsible for placing the product on the market.
 - B) Identification of the substance or preparation.
 - C) Product ingredients/information on ingredients.
 - D) Determine the current risks and project risks of the product.
 - E) When a hazard appears on using the product, first aid must be used to avoid damage as soon as possible.
 - F) Firefighting precautionary statements.
 - G) Determine the actions to specify in some circumstances and anticipate the risk from the product.
 - H) Information on the toxicity of the product (if exists).
 - I) Methods of disposing or recycling product packages.
 - J) Adhere to the required conformity assessment procedures.

4/2 Environmental Requirements

- 4/2/1 The product must be free from toxic and hazardous substances that affect the environment.
- 4/2/2 Commitment to the environmental system and its executive regulations issued by the relevant authorities.
- 4/2/3 Availability of an effective environmental management system in the manufacturer in accordance with the requirements of the competent authorities.
- 4/2/4 Products must be designed and manufactured to sustainably use natural materials. Achieving the purpose for which it was manufactured, taking into account the reuse or recycling of those materials and their parts, and not using primary or secondary materials incompatible with the environment.

4/3 Metrological requirements

In the International, system of units (SI Units), multiples or parts thereof should be used during designing, manufacturing or trading.

4/4 Packaging requirements

The supplier must comply with the following packaging requirements:

- A) Products intend to pack in an appropriate packaging.
- B) Products must be packed in suitable, tightly closed, non-hazardous packages. When using it, there should be no leakage of materials that have been cracked or damaged.
- C) Ensure that the product packaging materials are free from substances harmful to human health as well as substances harmful to the environment.

- D) Ensure that product packaging bears a recycling symbol, especially when using recyclable packaging materials.

Article (5) Metadata

The following marking is required for glues and adhesives intended for market placement:

- 5/1 It must the technical requirements contained in this Technical Regulation and the relevant standards set fourth in Annex No. (1).
- 5/2 The products should have written, legible and non-erasable marks. The manufacturer must use text and font sizes compatible with the product.
- 5/3 The data should be in Arabic or in both Arabic and English.
- 5/4 All information in the tag must be true, specific and verifiable.
- 5/5 Pictures and phrases that are placed on the product packaging must not violate the public morals, and Islamic values prevailing in the kingdom of Saudi Arabia.
- 5/6 The metadata of the product intended to be placed on the market must meet the following requirements:
 - The product's name and type.
 - The supplier's name
 - The name of the manufacturer or its trademark.
 - The country of origin.
 - The classification of the product and its intended use.
 - The ingredients (the products' main components).
 - The physical characteristics of the product (condition, dimensions, quantity, size, color).
 - The chemical substances required declaration.
 - The methods of utilization and storage.
 - The safety precautionary statements.

Article (6) Conformity Assessment Procedures

- 6/1 The supplier is responsible for placing the products subject to this technical regulation on the market and must obtain a certificate of conformity issued by a body accredited by SASO. According to the conformity assessment form (Type 3), the ISO/IEC 17067 set out in Annex (2), for wax glue products and liquid glue products
- 6/2 The supplier is responsible for placing the products subject to this technical regulation on the market and must obtain a certificate of conformity issued by a body accredited by SASO. According to the conformity assessment form

(Type 1A), the ISO/IEC 17067 set out in Annex (3), for the rest of products fall under the scope of the regulation.

- 6/3 The accredited body should implement the conformity assessment procedures according to the specified form. Ensuring that the requirements of this technical regulation and the relevant Saudi standards set out in Annex (1) are met.
- 6/4 A technical file must be attached to the product that includes the following.
- The supplier (manufacturer/importer) declaration of conformity, according to the form attached in Annex (4).
 - The risk assessment document.
 - The certificate of origin.
 - The testing reports requested in the technical regulation.
 - The list of specifications applicable to the product.
 - The product-marking manual in case the label could not be affixed to the product.
- 6/5 Products with the Saudi Quality Mark or its equivalent must be considered as complying with the requirements stipulated in this technical regulation.

Article (7) Responsibilities of Regulatory Authorities

The supervisory authorities, within their competencies and powers, shall do the following:

- 7/1 Verify that products meet specified conformity assessment requirements for availability of technical documents attached to the consignments.
- 7/2 Taking random samples from the products subject to this regulation and referring them to them to the competent laboratories to verify their compliance with requirements specified here.
- 7/3 Charge suppliers, manufacturers, and importers of costs and fees associated with conducting the tests.
- 7/4 When a product non-conformity is discovered, the regulatory authority must remove the relevant products from the warehouse and take legal action against them.

Article (8) the Responsibilities of Market Surveillance Authorities

Market Surveillance Authorities takes as a part of their competence and powers to carry out the following:

- 8/1 Apply market surveillance procedures to the products supplied in the markets. In addition to the products stored in the traders, and manufacturers and warehouses in order to verify their integrity to the extent that they meet the basic requirements stipulated in this regulation and related standard specifications.



- 8/2 Taking some product samples, whether from the market or from the warehouses of suppliers (manufacturers and importers), conduct the required tests and ensure that they comply with the requirements stipulated herein.
- 8/3 In some situation that the supplied or stored product does not comply with the requirements of this regulation, the market control authorities shall take all administrative measures, including the withdrawal and retrieval of the relevant product. The procedures and penalties referred to in Article (9) shall be applied after taking the necessary measures.

Article (9) Violations and Penalties

- 9/1 It is prohibited to manufacture, importer, place, and offer or advertise products are not to the requirements of the articles stipulated herein.
- 9/2 Failure of the product to meet the requirements of this Technical Regulation is sufficient reason for the Market Surveillance Authorities and Regulatory Authorities to consider the product as non-conforming. This means that the product may pose a threat to the consumer health and to tamper the environment, In this following cases:
- A) Failure to install, conformity cards, the 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) Lack, unavailability or incompleteness of technical documentation.
 - D) Lack, unavailability or incompleteness of product data/labels or usage instructions.
- 9/3 In case of a violation of the provisions hereof, the market survey authorities shall take all necessary measures to remove such violations and their effects from the market, as the case may be. To this end, the market survey authorities may:
- A) Obligating the violating body responsible for placing or displaying the non-conforming product in the market. Withdrawing such a violating product from warehouses or from the market in order to correct these violations, if possible, or exporting or destroying the product (depending on the nature of the product) during the period determined by the market control authorities.
 - B) Withdraw, impound or destroy the products, or taking any further action to recall such products from the market. Market surveillance authorities as the case may be announced the product withdrawal from the markets, with the violating body bearing all associated expenses.

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- 9/4 When a violation is discovered, SASO should take the necessary measures against the products that violate the requirements herein. For instance, cancelling the relevant certificate of conformity for the necessary measurement with the authorized body issuing the certificate. According to the regulations for accepting conformity assessment bodies.
- 9/5 Without prejudice to any severer penalty stipulated in the regulations. Anyone who violates any of the provisions of this system shall be liable to the penalties stipulated in the Anti-Commercial Fraud Law.

Article (10) General Provisions

- 10/1 The supplier bear full legal responsibility for implementation the requirements of this Technical Regulation, and is subject to the penalties stipulated in the Anti-Commercial Fraud Law and any other related laws, in case any violation of the articles herein is proven.
- 10/2 This technical regulation does not prevent the supplier from complying with all other laws or regulations in force in the Kingdom of Saudi Arabia. It is concerned with the trade, transportation and storage of the product and the rules and regulations related to the environment, security and safety.
- 10/3 All suppliers of the products covered in the scope of this regulation and subject to its provisions that shall provide inspectors of regulatory and market surveillance authorities with all facilitation and necessary information. When it is required, in order to carry out their assigned tasks.
- 10/4 When new issues arise, that cannot be dealt with under the provisions of this law, or when a dispute arises due to the application of these provisions. The matter is referred to a competent committee of the authority to issue the appropriate decision in the case or dispute, taking into account the public interest.
- 10/5 After making the necessary corrections, the supplier may submit a new application and incur any additional expenses determined by SASO.
- 10/6 SASO receives complaints to study those regarding products that have a certificate of conformity or a quality mark. Verify the validity of these complaints and take the necessary legal measures in the event that a violation is proven. If the supplier violates the provisions herein, SASO shall revoke the Certificate of Conformity or Quality Mark License and take legal measures to ensure that SASO's rights are preserved.
- 10/7 If any modifications have been made to the product during the validity period of the Certificate of Conformity or Quality Mark License to use the Quality Mark (excluding morphological modifications). The product's certification or license must be revoked when a new order is placed.
- 10/8 The Saudi Standards and Metrology Organization (SASO) alone has the right to interpret the provisions of this law. All beneficiaries of the application of this technical regulation must abide by the interpretations of the authority.

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Article (11) Transitional Provisions

- 11/1 The supplier shall abide by the provisions of this Technical Regulation within a period not exceeding 180 days (6 months) from the date of publication in the Official Gazette.
- 11/2 Subject to the provisions of Paragraph (1) of this Article, suppliers shall give them a grace period to consolidate their position in the market. In accordance with the requirements contained in this law within a period not exceeding 365 days (annually) from the date of publication in the Official Gazette.
- 11/3 This regulation, as soon as it comes into force, shall replace all previous regulations issued within the scope of this regulation.

Article (12) Publication

This technical regulation shall be published in the Official Gazette.



Annex (1)

A) List of Glue and Adhesive Products and Related Standards

#	Standard Title in Arabic	Standard Title in English	Standard No.
1	مواد لاصقة ذات طبيعة فينولية وأمينوبلاستيكية ، للهياكل الخشبية الحاملة -متطلبات التصنيف والأداء	Adhesives, phenolic and amino plastic, for load-bearing timber structures- Classification and performance requirements	EN 301
2	المواصفة القياسية للأسمنت المذيب لأنابيب ووصلات البلاستيك المكورة (كلوريد الفينيل)(CPVC)	Standards for solvent cements for chlorinated poly(Vinyl Chloride) (CPVC) plastic pipe and fittings	SASO-ASTM-F493
3	المواصفات القياسية للطلاءات الأولية المستخدمة مذيبات غراء الوصلات لأنابيب والوصلات البلاستيكية من (كلوريد الفينيل)(PVC)	Standards for primers for use in solvent cement joints of poly(vinyl chloride) (PVC) plastic pipe and fittings	SASO-ASTM-F656
4	لاصق مستحلب خلاص عديد الفينيل	Polyvinyl acetate emulsion adhesive	SASO-798
5	المواد اللاصقة -المصطلحات والتعاريف	Adhesives-Terms and definitions	EN 923
6	الغراء للأغراض العامة	Adhesives for general purposes	SASO-2070
7	المواصفات القياسية لمذيب غراء الأنابيب البلاستيكية ووصلاتها (ABS)	Standards for solvent cement for acrylonitrile-butadiene-styrene (ABS) plastic pipe and fittings	SASO-ASTM-D2235
8	أشرطة اللصق الحساسة بالضغط للغلق والاحكام	Pressure sensitive adhesive closing and sealing tapes	SASO-2272
9	التصنيف القياسي لتحديد مواد السيليكون اللاصقة وموانع التسرب لتطبيقات النقل	Standard classification for specifying silicone adhesives and sealants for transportation applications	SASO-ASTM-F2468
10	المواصفة القياسية للمذيب الأسمنتي لأنظمة الأنابيب البلاستيكية من عديد (كلوريد الفينيل)(PVC)	Standard for solvent cements for poly(vinyl chloride) (PVC) plastic piping systems	SASO-ASTM-D2564
11	المواصفة القياسية للوصلات لأنابيب IPS PVC باستخدام الأسمنت المذيب	Standard for joints for IPS PVC pipe using solvent cement	SASO-ASTM-D2672
12	الرقائق اللاصقة لنوافذ المركبات	Adhesive film of vehicles windows	SASO-2912

#	Standard Title in Arabic	Standard Title in English	Standard No.
13	المواصفة القياسية لاصق قار الفحم	Standard for coal tar adhesive	SASO-ASTM-D6753
14	المواد اللاصقة للبلاط -- المتطلبات وتقييم المطابقة والتصنيف والتميز	Adhesives for tiles – Requirements, evaluation of conformity, classification and designation	SASO-GSO-EN-12004
15	الأشرطة اللاصقة -المصطلحات	Self-adhesive tapes-Terminology	EN 12481
16	تصنيف المواد اللاصقة الصلبة للخشب للاستخدامات غير الهيكلية	Classification of thermosetting wood adhesives for non-structural applications	EN 12765
17	المواد اللاصقة لأنظمة الأنابيب البلاستيكية الحرارية غير المضغوطة - المواصفات	Adhesives for non-pressure thermoplastics piping systems- Specifications	EN 14680
18	المواد اللاصقة لأنظمة الأنابيب البلاستيكية الحرارية للسوائل تحت الضغط -المواصفات	Adhesives for thermoplastic piping systems for fluids under pressure-Specifications	EN 14814
19	مواد لاصقة إنشائية للتطبيقات العامة - المتطلبات وطرق الاختبار	General purpose adhesives for structural assembly- Requirements and test methods	EN 15274
20	المواد اللاصقة -مواد لاصقة من مادة البولي يوريثين (PUR) أحادية المكون للهياكل الخشبية الحاملة -متطلبات التصنيف والأداء	Adhesives- One component polyurethane (PUR) for load-bearing timber structures. Classification and performance requirements	EN 15425
21	مواصفات المواد اللاصقة المستخدمة لمفاصل الإصبع في منتجات الخشب غير الإنشائية	standards for adhesives used for finger joints in non-structural lumber products	SASO-ISO-17087
22	مواصفات الأشرطة اللاصقة الحساسة للضغط للأغراض الكهربائية -الجزء ١: المتطلبات العامة	standards for pressure-sensitive adhesive tapes for electrical purposes – Part 1: General requirements	SASO-IEC-60454-1
23	المواصفة القياسية للمواد اللاصقة الإيبوكسية (المرنة) للمواد الرابطة المعدنية وغير المعدنية	Standard for Epoxy (Flexible) Adhesive For Bonding Metallic And Nonmetallic Materials	SASO-ASTM-D6412

Note: The list of standards mentioned in this annex is subject to review, and suppliers shall ensure from SASO's website that they are using the latest standard specifications.

B) List of Products and Customs Coding

#	Product categories	Customs item
1	Dextrins and other modified starches (for example, pregelatinised or esterified starches); glues based on starches, or on dextrins or other modified starches.	3505
2	Prepared glues and other prepared adhesives- not elsewhere specified or included; products suitable for use as glues or adhesives- put up for retail sale as glues or adhesives- not exceeding a net weight of 1 kg.	3506
3	Self-adhesive plates- sheets- film- foil- tape- strip and other flat shapes- of plastics- whether or not in rolls.	3919
4	Self-adhesive	4811
5	Adhesive tapes	5906
6	casein glues	3501
7	Other glues	3503

Note: The list of products and customs codes available on SABER electronic platform is the updated and adopted 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 form of conformity assessment procedure, by which the supplier fulfills the obligations stipulated in the clauses below with the assurance and acknowledgment (on its sole responsibility) that the products in question comply with the type specified in the certificate of approval of the equipment 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 the concerned products.

The request shall include:

- A) The 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 conform to the type specified in the Type Approval Certificate, and with the requirements of the relevant technical regulations.

3/3 All system elements and requirements adopted by the supplier must be documented in a systematic and organized manner in the form of written policies, procedures and instructions. Product Safety Management System documentation should provide a consistent understanding of safety programs, plans, manuals, and records. For example, documents should specifically contain an appropriate description of the following:

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- A) Quality objectives, organizational structure, responsibilities and competencies of management in relation to product safety.
- B) Manufacturing techniques, product safety, quality assurance procedures, processes and procedures applied.
- C) Carrying out and inspections and tests; Before, during and after manufacturing, and how often it is performed.
- D) Records such as inspection, testing, calibration reports, 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, which approves the product safety management system, must evaluate this system to determine whether it meets the requirements referred to in item (3/3), during the approval period of the system, which will be three years.
- 3/5** It is assumed that the product complies with the requirements of the technical regulations in relation to the items of the product safety management system, when it conforms to the standard specifications.
- 3/6** In addition, relevant product safety experience. The audit team should have one technical expert who is experienced in evaluating the field and techniques of product manufacturing. Full familiarity with the technical requirements stipulated in the relevant technical regulations.
- 3/7** The review should include an assessment visit to the factory. The audit team shall review the technical documents referred to in clause (3/3) to verify the manufacturer's ability to determine the requirements of the technical regulations. Conducting the necessary checks and tests to ensure that the product complies with these requirements.
- 3/8** The manufacturer shall be notified of the decision after the evaluation is completed. It includes providing notification of audit findings, evaluation decision, and justification based on the decision.
- 3/9** The manufacturer shall fulfill the obligations of the Product Safety Management System, as approved, and maintain the system so that it remains relevant and effective.
- 3/10** The manufacturer shall notify the conformity assessment body, which has approved the Product Safety Management System, of any proposed modifications to the system.
- 3/11** The Notified Body shall assess any proposed amendments and decide whether the revised Product Safety Management System will continue to meet the requirements referred to in Clause (3/3) or a reassessment is necessary. The Notified Body must notify the manufacturer of its decision; the notification



must include the test 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 to 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 needs to provide the Notified Body with the 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 should carry out periodic audit visits to verify the maintain manufacturer's application. The Product Safety Management System should provide the supplier with an audit report.
- 4/4 The Notified Body has the right to make unexpected visits to the factory. During visits, the notified body may, as necessary, perform product tests or perform them by a third party to verify that the Product Safety Management System is operating properly. The Notified Body shall provide the supplier with an assessment report and test reports for testing.

5 Certificate of Conformity and Declaration of Conformity

- 5/1 The notified body shall issue a certificate of conformity for the product in the circumstance that the supplier has an effective and approved product safety management system, upon the supplier's request, during 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 inform the Regulatory Authorities and Market Surveillance Authorities of its issuance or withdrawal. Periodically, Product Safety Management System approvals provide lists of Product Safety Management System approvals that have been denied, 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 that it has refused, suspended, withdrawn, or restricted; notifying those bodies of Product Safety Management System approvals issued by them.



Annex (3)

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

1/1 Type Approval

Type approval is defined as a conformity assessment procedure, according to which the 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 conformity of the technical design of the product by checking the relevant technical documentation and manuals (design model). Examination of a representative sample of the expected production of one or more parts that include hazardous parts of the product (a combination of a production model and a design model).

2/1 Procedures of Type Approval

2/1/1 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 documents that facilitate the assessment of product compliance with the requirements of Saudi technical regulations. These documentations should include appropriate analysis and risk assessment. Technical documentation should specify the requirements that apply to the product. Including what is required for evaluation, product, design, manufacturing, and operations (use) of the product.
- D) Technical documentation must include at least the following:
 - 1) A general description of the product.
 - 2) Designing 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. The description of this adopted solution to meet the essential requirements of the Saudi technical regulations in case of non-application of the

aforementioned standards is given below. In the partial application of Saudi standards, the technical documentation should clarify the applicable 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) Evidence supports the appropriateness of the technical solutions applied in the design. These manuals should refer to all documents, especially if the Saudi standards and/or the appropriate technical specifications mentioned not applied. Supporting evidence shall include as applicable, the result of the test performed in the appropriate laboratory of the manufacture or any other laboratory under the responsibility of the manufacturer.

2/1/2 Tasks of the Notified Body

A) With regard to the product, the notified body shall:

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

B) With regard to the samples, the notified body shall:

- 1) Ensure that the manufacturing of samples is conformant to the technical documentation; identify the elements designed in accordance with the Saudi standards and the elements designed in accordance with other standards.
- 2) Perform appropriate checks and tests, or outsource, to verify that technical solutions approved by the manufacturer meet the essential requirements specified in the standards, if relevant standards are not applied.
- 3) Perform appropriate tests or outsource to verify that in the event that Saudi standards and/or other appropriate standards are not applied, the technical solutions approved by the manufacturer meet the essential requirements of Saudi technical regulations.
- 4) Be in agreement with the manufacture where the tests will be performed.

C) As for decisions made by the Notified Body:

- 1) The notified body should issue an assessment report of the procedures to carry out their outputs. The notified body should publish, fully or partially, the report without the approval of the manufacturer.



- 2) In this case, the product 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 a certificate shall include the name and address of the manufacturer, test results, and the validity conditions thereof. If any, all the information required for identification of the certified type The certificate may also include attachments.
- 3) The certificate, along with its attachments, shall include all the necessary information required to assess the conformity of manufactured products according to the tested type and for monitoring during operation.
- 4) In the event that 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 the detailed justification for such decision.
- 5) The notified body must keep abreast of all recognized technological developments. When these developments indicate the possibility that the approved type may not be in compliance with the requirements of the Saudi technical regulations, the notifying body shall determine the extent to which further testing is required, and 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 to the certified type which may affect the conformity of the product to the requirements of the Saudi Technical Regulations or 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. Any additions issued or withdrawn, and shall periodically, or upon request, provide a list of the Type Approval Certificates and any additions that have been rejected, suspended, or restricted in any way.
- 8) Each Notified Body shall inform the other accredited Notified Bodies of the Type Approval Certificates. Any additional that have been rejected suspended, or restricted in any way. As a result, they shall be informed upon request about Type Approval Certificates or any additions released.
- 9) Upon request, SASO and other Notified Bodies may obtain copies of Type Approval Certificates and/or additions to it. SASO may obtain copies of technical documentation and results of the tests conducted by the Notified Body, upon request. The Notified Body must keep a copy of the Type Approval Certificate for the equipment, its accessories and add-ons, as well as the technical documentation (including those attached by the manufacturer), until the expiry date of the certificate.

- 10) The manufacturer shall keep a copy of the Type Approval Certificate, its annexes and additions thereto, in addition to the technical documentation. Furthermore, for ten (10) years after the product is placed on the market, the manufacturer must make all documents available to regulatory authorities and market surveillance authorities.
- 11) The supplier may submit the request mentioned in item (2/1/1), and carry out the above-mentioned tasks on behalf of the manufacturer with the approval of the manufacturer.

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Annex (4)

Supplier Declaration of Conformity Form

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

1) Supplier data:

- Name:
- Address:
.....
.....
- Contact person:
- Email:
- Tel. No.:
- Fax. No.:

2) Product details:

- Trademark:.....
- Type:.....
- Product Description:.....
- Category (according to the standards):.....
- Reference standards/ technical specifications:
.....

We, hereby, acknowledge that the above-mentioned product is conforming to the Saudi technical regulation (), and the Saudi standards included therein.

- Person in Charge:
- Company:
- Signature: Date:--/--/-----