



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

Technical Regulations for Detergents

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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: Governmental authority/ authorities 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.

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.

Market Surveillance Authorities: Governmental authority/authorities responsible for carrying out market surveys.



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.

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 the 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 replacement.
- 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 product characteristics.

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

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 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 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 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

they supply are produced in accordance with the applicable regulations, granting procedures, and the 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, 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.

Pre-packaged Containers: A product and packaging material in which detergents are packed or encapsulated, its quantity is determined prior to being offered for sale where the amount of detergent inside cannot be changed without opening the package or without the exposure to significant change in any situation.

Detergent: Any substance, mixture or solution composed of soap and/or any other active substances, which are in the form of (powder, liquid, paste, cut, mold) intended for washing and cleaning, for use or marketing for consumer purposes (domestic,/industrial, or other.).

Surfactants or Surface Active Agents: Organic materials and/or mixtures or solution used in detergents, which have effective properties, consisting of one or more hydrophilic groups in addition to one or more hydrophobic groups. In terms of type and size, which are able to reduce surface water tension and form the spread or adsorption of single layers at the water/air surface to form an emulsion and/or molecular emulsions and/or micelles and adsorb on water/solid surfaces.

MSDS: Material Safety Data Sheet

IUPAC: International Union of Pure and Applied Chemistry

CAS Number: Chemical compounds numbering system.

Article (2): Scope

 This regulation applies to detergents and materials of surface-active agent and soap, mentioned in Annex (1) of this regulation, in addition to unpackaged detergents

supplied in large containers or tanks for the purpose of re-packaging, at any stage of the supply chain, and disinfectants are excluded from the provisions of this regulation.

Article (3): Objectives.

This regulation aims to lay out the essential requirements for detergents included in the scope of this regulation, and to identify the conformity assessment procedures with which the suppliers shall comply with to ensure the conformity of the product, and preservation of the environment and the health and safety of the consumer.

Article (4): Obligation of Supplier

The supplier shall adhere to the following requirements:

4/1 Technical Requirements

4/1/1 The following technical requirements must be adhered to:

- A) The detergent fulfillment of the technical requirements contained in the standards set out in Annex (1) of this regulation.
- B) Detergents intended for washing household dishes and clothing shall meet the following additional requirements:
 - The weight of phosphorus in inorganic phosphate in the dishwashing cleaner should not exceed 0.29 g.
 - The proportion of phosphorus in a detergent should not exceed 0.49 g
- C) Carry out the required conformity assessment procedure with of the Notified (Approved) Bodies by SASO.
- d) Provide an effective quality management system at the factory, (the factory certified with a quality management system in accordance with ISO 9001 shall be considered fulfilling the requirements of this item).

4/1/2 The supplier shall cooperate with regulatory and market surveillance authorities by submitting the MSDS report, and all technical documents and information required for the product upon request.

4/1/3 The supplier must mention the detergent components in the Materials Safety Data Sheet (MSDS), according to the naming system (IUPAC), and (CAS), in a descending order by weight - except for impurities that are not among the ingredients - where the components must be divided into levels in terms of weight ratios as follows:

- A) 10% or more.
- B) 1% or more and less than 10%.

- C) 0.1% or more and less than 1%.
 - D) Less than 0.1%.
- 4/1/4 The supplier shall provide the Material Safety Data Sheet (MSDS) for the detergent components supplied as a final product upon request and in accordance with the abovementioned requirements, and shall make it available for inspection, except for the following information:
- A) Weight ratio levels.
 - B) Formulations of fragrances and essential oils.
 - C) Color material combinations (colorants).
- 4/1/5 The supplier is responsible for any violation of the requirements contained in this regulation, which may appear in detergents, except for those irregularities that appear after supply in the market resulting from poor storage or mistransportation by third parties contrary to factory instructions.
- 4/2 Packaging Requirements**
- A) Ensure that the detergent packaging is free of lead or any heavy metals.
 - B) Ensure that detergent packaging has a recycling symbol in case of using plastic containers, and shall not affect or be affected by the product.
 - C) Packing detergents in sealed and leak-proof packages, complying with any packaging requirements set by the product-related standard.
- 4/3 Metrological Requirements:**
- A) The quantities of packages shall be measured in the international system (SI units), its multiples, or its parts.
 - B) All types of detergents containers shall comply with the requirements specified in the standard (GSO OIML R 87).

Article (5): Labeling

The labels (markings) of the detergents prepared to be placed or displayed in the market should be as follows:

- 5/1** The labels on the product packaging shall be in accordance with the technical requirements of the relevant standard, described in Annex (1) of this regulation.
- 5/2** The product labels shall meet the requirements of the standard "GSO 1827: Labeling For Industrial Products" which contains the following information:
 - A) Product Designation and trademark.
 - B) Name of the manufacturer, address and/or brand, or both.

- C) A special code must be placed on each packaging indicating the production batch for the purpose of tracking the product.
 - D) Country of origin, and whether the product is manufactured under a license of a registered trademark.
 - E) Ingredients included in the composition, in addition to mentioning any allergens, if any, in accordance with Annex (2).
 - F) Validity period (production and expiration date, or post-opening period of the package).
 - G) Purpose of use.
 - H) Usage and storage instructions.
 - I) Any product-related cautionary statements, if any, in accordance with the standards contained in Annex (1).
- 5/3 All information used in the labels shall be correct and verified.
- 5/4 Images and phrases used on the product packaging shall not violate the public law, morals, and the Islamic values prevailing in the KSA.

Article (6): Conformity Assessment Procedures

- 6/1 The supplier - responsible for placement of the product in the market - shall obtain a Certificate of Conformity issued by Notified (approved) body by SASO, in accordance with conformity assessment model (Type 3), as per standard ISO/IEC 17067 as shown in Annex (3).
- 6/2 The Notified (Approved) Body shall implement the conformity assessment procedures according to the specified model, in order to ensure fulfillment of the requirements of the Technical Regulation and relevant Saudi standards set out in Annex (1) of this Regulation..
- 6/3 The product shall be accompanied by a technical file, which includes the following:
- A) Supplier (manufacturer/importer) Declaration of Conformity in accordance with the attached form in Annex (4).
 - B) Risk Assessment Document.
- 6/4 The supplier shall cooperate with the Regulatory and Market Surveillance Authorities by providing the technical file documents and Certificates of Conformity, and any other documents proving the conformity of the product with the requirements of this regulation, upon request.
- 6/5 Detergents that obtained the Saudi Quality Mark or its equivalent shall be considered in conformity with the requirements stipulated in this regulation.

Article (7) Responsibilities of Regulatory Authorities (Customs Ports – Manufactories)

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

- 7/1 Regulatory Authorities shall verify the fulfillment of detergents products to the requirements of the specified conformity assessment procedures and the technical documents accompanied with the consignments.
- 7/2 Regulatory Authorities are entitled to randomly take samples of detergents products, and refer 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 are entitled 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 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 warehouses, in order to check the safety of the product and the extent of fulfillment of the requirements stipulated in this Technical Regulation and relevant standards.
- 8/2 Withdraw 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 – displayed or stored – products 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 detergents products non-conforming with the requirements of the articles stipulated in this Technical Regulation.
- 9/2** Failure to meet the requirements of this 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 consumers and to the environment, including:
- A) Non-fixing or improper fixing of conformity labels, Saudi Quality Mark, or its equivalent.
 - B) Failure to issue or incorrect issuance of the Certificate of Conformity or the Supplier Declaration of Conformity.
 - C) Unavailability, or incompleteness of the technical documentation upon request.
 - D) Unavailability, or incompleteness of product data/labels, safety guidelines, or usage instructions.
- 9/3** In case of a violation of the provisions hereof, Market Surveillance Authorities – as the case may be - 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 – 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. The product may be exported or destroyed (according to the nature of the product) within the period specified by the authorities.
 - B) Withdraw, restrain or destroy the products, or take any other necessary action to recall such products from the markets. In addition, as the case may be, Market surveillance Authorities 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 detergents 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
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conformity, while taking the necessary measures with the Notified body, which issued the certificate.

- 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 the applicable laws in Saudi Arabia.

Article (10): General Provisions

- 10/1** Annexes, including the terms and definitions set forth in the standards, shall be deemed an integral part of the provisions hereof. SASO may amend any of these annexes, as required.
- 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** 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, 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.

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 than six months as of the date of publication.
- 11/2** Subject to the provisions of item (1) of this Article, products, not complying with the provisions specified in this Technical Regulation may be traded for a maximum of one year as of the date of publication.
- 11/3** This Technical Regulation, when approved, shall supersede all the preceding regulations related to the scope of this regulation.

Article (12): Publication

 This Technical Regulation shall be published in the Official Gazette.

Annex No. (1)

List of Standards for Detergents

	Standard Title in Arabic	Standard Title in English	Standard No.	HS Code
1	المنظفات الاصطناعية السائلة للأقمشة والملابس	Synthetic liquid detergents for Clothing and fabrics	SASO GSO 2059	34022022
2	منظف المنسوجات الملونة	Colored textiles detergent	SASO GSO 2077	
3	المنظفات التركيبية مساحيق الغسيل التركيبية المنزلية	Synthetic detergents-detergents Powder	SASO GSO 151	34022021
4	منظفات المطبخ الصناعية	Synthetic Detergents for Kitchen	SASO GSO 1946	34022029
5	بيكربونات الصوديوم	Sodium Bicarbonate	SASO GSO 1110	28363000
6	الكور السائل (محلول هيبوكلوريت الصوديوم للاستخدامات المنزلية)	Sodium Hypochlorite Solution for Domestic uses	SASO GSO 802	28289090
7	منظف الزجاج السائل	Liquid Glass Clear	SASO GSO 884	34022022
8	منظف سائل للمسجد	Carpet cleaner liquid	SASO GSO 461	34021900
9	قشارات الصابون	Soap Flakes	SASO GSO 877	34011190
10	صابون الزينة	Ornamental soap	SASO GSO 1786	34011990
11	صابون غسيل الأيدي السائل	Hand washing liquid soap	SASO GSO 1894	34013000
12	مزيلات رائحة الحمام	bathroom odor removers	SASO 1958	34022029
13	سائل غسيل الصحون	Dishwashing liquid	SASO GSO 2238	34022022
14	زهرة الغسيل (النيلة)	Laundry Flower (indigo)	SASO 2620	32049010
15	منعمات الملابس السائلة	Liquid clothing softener	SASO GSO 1897	38099110
16	صابون الجليسرين الشفاف ونصف الشفاف والمعتم	transparent, semi-transparent and opaque Glycerol soap	SASO GSO 1944	34011120
17	الصابون الشفاف	Transparent soap	SASO GSO 1942	32049010
18	صابون التواليت للأطفال	Toilet soap for children	SASO GSO 1895	33073000
19	المنظفات الكيميائية - الهلام متعدد الاستخدامات	Chemical cleaners - mixed-use gel	SASO GSO 2161	34012020
20	المنظفات السائلة المضادة للجراثيم للأغراض العامة	antimicrobial Liquid detergent for general purpose	SASO GSO 1948	34021100
21	المنظفات الصناعية في صورة معجون للملابس	Industrial detergents in the form of paste for clothes	SASO GSO 2301	38099110
22	صابون زيت الزيتون	Olive Oil Soap	SASO GSO 2172	34011190
23	المنظفات المسحوق الكاشط	cleaners - Shiny Powder	SASO GSO 2439	34022021
24	المنظفات - مزيل البقع الدهنية للملابس والمنسوجات	cleaners - fatty patches remover for clothing and textiles	SASO GSO 2234	33074990

Annex No. (2)**First: Labeling (Markings) of Detergents Ingredients**

The markings items for detergent packaging below shall be applied; intended for sale to consumers in general:

1) Weight ratio levels below should be used to indicate the composition content of the components listed in table (1) below this annex, when added at a concentration higher than 0.2% by weight:

- Less than 5%.
- 5% or more, and less than 15%.
- 15% or more, and less than 30%.
- 30% and more.

2) When adding preservatives, they should be remembered without order, regardless of their concentration, and shall be named in accordance with the Gulf Standard "GSO 1943: Safety Requirements of Cosmetics and Personal Care Products".

3) When adding allergenic perfume compounds with a concentration of more than 0.01% in weight, they shall be named in accordance with the Gulf Standard GSO 1943: Safety Requirements of Cosmetics and Personal Care Products". The concentration of 0.01% can be replaced by other concentration limits based on the severity of allergens.

Table (1) - Annex (2) Detergents Components

	The components of materials in English	The components of materials in Arabic
1	Phosphates	الفوسفات
2	Phosphonates	الفوسفونات
3	Anionic Surfactant	المواد ذات النشاط السطحي الأنيونية
4	Cationic Surfactant	المواد ذات النشاط السطحي الكاتيونية
5	Amphoteric Surfactants	المواد ذات النشاط السطحي الأنيونية و الكاتيونية (المتعادلة)
6	Non-Ionic Surfactant	المواد ذات النشاط السطحي غير الأيونية
7	Oxygen-based bleaching Agents	العوامل المبيضة أساسها الأوكسجين
8	Chlorine-based bleaching Agents	العوامل المبيضة أساسها الكلور
9	EDTA and Salts thereof	حمض إيثيلين ثنائي أمين رباعي الخليك و أملاحها
10	NTA (Nitrilotriacetic Acid) and Salts thereof	حمض نيتريلو تري أسيستيك و أملاحه
11	Phenols and Halogenated phenols	الفينولات و الفينولات الهالوجينية
12	Paradichlorobenzene	بارا ثنائي كلوروبنزين
13	Aromatic Hydrocarbons	الأروماتية الهيدروكربونات
14	Aliphatic Hydrocarbons	الأليفاتية الهيدروكربونات
15	Hydrocarbons	الهيدروكربونات
16	Soap	الصابون
17	Zeolites	الزيوليت
18	Polycarboxylates	عديد الكربوكسيلات
When adding the substances mentioned below, they should be mentioned without order, regardless of their concentration.		
19	Enzymes	الإنزيمات
20	Disinfectants	المطهرات
21	Optical Brighteners	البصرية المزهيات
22	Perfumes	العطورات

Second: Labeling (Markings) on Recommended Amounts of Detergents (Optional)

The markings items for detergent packaging below shall be applied; intended for washing and for sale to consumers in general:

- 1) Instructions for the recommended quantities and/or amounts; expressed in (ml) or (g); Appropriate for filling the washing machine, in accordance with the classifications of water hardness light, medium and strong; allocated to the processes of one or two wash cycles.
- 2) It is recommended to write on each package the number of washes that can be obtained from the amount of detergent; the appropriate number of washes from the detergent intended for heavy use in the washer shall be **indicated "ordinary dirty fabrics"**. The appropriate number of soft fabrics detergents in the washing machine "for fabrics that are slightly dirty"; which can be washed using the average hardness water identical to (2.5 ml/mol) of calcium carbonate for each ion (CaCO_3 /l).
- 3) When there is a measuring cup with the cleaner (detergent), the appropriate marking should be placed on the cup to indicate the amount of detergent suitable for filling the washing machine with (ml) or (g) according to the classifications of light, medium and strong water hardness.

Annex No. (3)**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 the 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 "Third party" 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 "Third Party".
- 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 reasons on which the decision was based.
- 3/9 The manufacturer shall be committed to fulfil 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 evaluate any proposed modifications and decide whether the modified Product Safety Management System will continue to fulfil 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 reasons 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 is entitled 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 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 at the Regulatory Authorities and Market Surveillance Authorities disposal 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:
- Documentation referred to in Clause (3/3).
 - The amendments referred to in Clause (9/3), as approved.
 - Decisions and reports of the Notified Body, referred to in Clause (7/3).
- 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.
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Annex No. (4)**Supplier Declaration of Conformity**

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

1) Supplier Details:

- Name: -----
- Address: -----

- Contact Person:
- E-mail: -----
- Phone Number: -----
- Fax: -----

2) Product details:

- Trade mark of the product: _____
- Model: _____
- Product description: _____
- Reference standards / The technical standards: _____

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: --/--/----

