

# **GUIDE OF CONFORMITY ASSESSMENT FORMS**

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This regulation repres	sents the draft as amended
following the fifth m	neeting of the committee
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# Guide of the Conformity Assessment Forms



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#### Clause 1 - Purpose

This guide aims to present other forms for the procedures of conformity assessment followed in the Gulf Cooperation Council (GCC) countries to ensure that the products comply with their main requirements provided in the Gulf technical regulation.

#### **Clause 2 - Definitions**

The definitions, provided in the international standard ISO/IEC 17000, shall apply, as well as:

#### 1. The Council Countries

The Gulf Cooperation Council countries.

## 2. The Standardization Organization

The Standardization Organization for the GCC countries.

#### 3. Conformity Assessment

To prove that specific requirements of a product, operation, system, person or authority, are met.

## 4. Conformity Assessment Procedures

All activities and procedures followed to ensure that the product/operation/system/individuals comply with the relevant requirements.

#### 5. Conformity Assessment Model

A specific procedure for conformity assessment having specific limits as well as specific ways in and out.

## 6. Technical Regulation for the GCC Countries

A mandatory document issued by the standardization organization, specifying the main requirements for a specific category of products and specifying the necessary procedures of conformity assessment to ensure that they comply with the included main requirements in order to place the mark of conformity for the GCC countries, and it may be indicated in the technical regulation.

#### 7. Approved authority for Conformity Assessment

An authority appointed as an authority able to make all the procedures for conformity assessment within a specific limit, which are included in the technical regulation issued by the GCC Standardization Organization being usually an approved authority according to the guide of the approved authorities and may be indicated as an approved authority.

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## 8. Type

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A group of subdivisions for the same product of which the differences do not affect the security level and the other requirements of the performance.

## 9. Mark of conformity for the GCC countries:

The mark of conformity for the GCC countries, being a mark of a special form (refer to the guide of the conformity mark for the GCC countries) to be placed on the product and/or acknowledging conformity to indicate the product's compliance with the main requirements included in its own regulation, and which may be indicated as the conformity mark for the GCC countries or only as the conformity mark.

#### **Clause 3 - General Guidelines**

- 1. The main purpose of performing conformity assessment, according to the requirements of obtaining the conformity mark for the GCC countries, is to enable the authorities operating in the member states to ensure that the products, displayed in the market, comply with the safety and security requirements provided in the Gulf technical regulation, particularly in regards to the health and safety of employees and consumers.
- 2. The conformity assessment procedures are divided into different forms related either to the design phase or production phase or both phases.
- 3. And as a general base, the product shall be subject to conformity assessment forms during the phases of design and production before displaying it in the Gulf markets. The guide of conformity assessment forms shall be subject to procedures to be applied by the manufacturer as well as by the conformity assessment authorities.
- 4. Some forms are available and cover both phases of design and production with different styles as stated in clause 5, and the Gulf technical regulation shall specify the potential options for such methods which give the authorities, operating in the member states, the requested high level of safety for their products and categories.
- 5. Despite the fact of presenting a group of potential options to the manufacturer, the Gulf technical regulation will consider the compatibility of the forms with the products types as for the risks nature and the economic infrastructure of the concerned sector as well as the production type and value...
- 6. A group of options for the conformity assessment styles will be presented, according to the Gulf technical regulation, as one or more forms, to the manufacturer, ensuring that for every option the product complies with

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the main requirements provided therein, with clarification of the standards and frameworks, which make it easier for the manufacturer to select the appropriate style for his product from the list of styles provided in this regulation.

- 7. The Gulf technical regulation shall avoid imposing the application of unnecessary forms, which may be an additional charge that is not directly related to the purposes of the concerned Gulf technical regulation.
- 8. The approved authorities are encouraged to apply the forms without incurring any unnecessary charges to the manufacturers, and the Standardization Organization, with the cooperation of the member states, shall provide continuous and organized cooperation between the approved authorities in the member states including similar application of the forms.
- 9. In order to ensure protection for the manufacturers, the technical documentation, presented to the approved authorities, shall be limited to the necessary material for the purposes of the conformity assessment, and the legal protection for information confidentiality shall be provided as well.
- 10. Whereas the Gulf technical regulation provides the manufacturer with the potential use of forms according to the methods of organizing the quality management, he shall be given another option to collect from the forms which do not use the organization of quality management and the contrary is true as well unless the Gulf technical regulation specified that conformity with the requirements shall be through one model.
- 11. For the purpose of executing the forms, the member states shall declare the approved authorities which will undertake the conformity assessment procedures (according to the terms and conditions provided in the guide of the approved authorities). As well, the member states shall ensure that the approved authorities always and continuously enjoy the required technical qualifications to ensure that the missions, entrusted to them, are constantly and duly performed (refer to the guide of the approved authorities for more information about the method for regularly reviewing the works executed by the approved authorities).
- 12. In case the approved authority entered a subcontract with other authorities in order to conduct conformity assessment procedures, the approved authority shall verify:
  - The eligibility of the institution operating as subcontractor on the basis of meeting the requirements of the specification series ISO/IEC 17000 and evidence ISO/IEC.
  - The capacity of the approved authority to effectively control the works executed by the contracted authority.
  - To ensure by the approved authority that the conformity assessment works are executed by the contracted authority, and its responsibility thereof, unless this authority is previously specified by the legislative power.

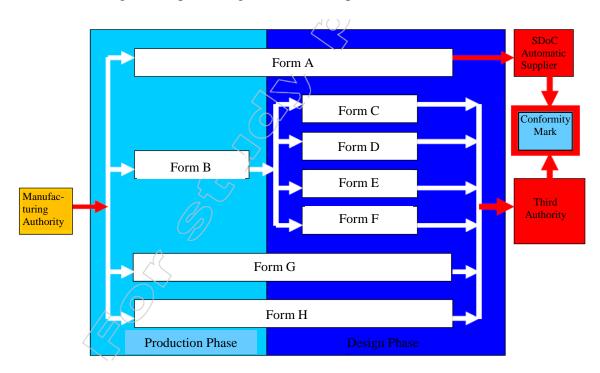
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#### **Clause 4 - Basis of the Conformity Assessment Forms**

- 1. The conformity assessment works, provided in every form, are executed with the knowledge of the manufacturing authority (First Authority) or with the intervention of an approved authority (Third Authority).
- 2. The conformity assessment works are related either to the design phase, the production phase or both phases.
- 3. In case the manufacturing authority, in subcontracting, is based on the design process or production process, such manufacturing authority is held responsible for the conformity assessment for its products.
- 4. The conformity assessment works were restricted to a limited number of forms being eight main forms (A, B, C, D, E, F, G and H) and an additional form (A1) as detailed in clause 6.
- 5. The application of the conformity assessment forms, according to the terms of the Gulf technical regulation of the products categories, leads the product to obtain the conformity mark for the GCC countries and reference in this respect can be made to the regulation of conformity mark for the GCC countries. (Refer to the following form representing the main concept of forms).



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- 6. All laboratories, either for benchmarking or testing, either independent, governmental or belonging to a manufacturing authority, shall be approved authorities within the scope of their works for conformity assessment of the products that are subject to the requirements of the Gulf technical regulation.
- 7. Certain Gulf technical regulation use forms A, C, H along with other stipulations including more requirements.
- 8. Form C was designed to be used with form B as Type Examination for the GCC countries, as well forms D, E, F are used with form B. However, in special cases, for instance when dealing with products of simplified design and structure, they may be used separately.

## **Clause 5 - Conformity Assessment Forms**

#### Form A (Internal Production Control):

- 1. A form describing the procedure by virtue of which the manufacturer or his authorized representative in the GCC countries, who executes the commitments provided in paragraph 2 below, shall confirm and acknowledge that the concerned products meet the requirements of their Gulf technical regulation. The manufacturer or his authorized representative in the GCC countries shall place the conformity mark for the GCC countries on every product and present a conformity acknowledgment.
- 2. The manufacturer shall submit technical documents, as explained in paragraph 3 below, and he or his authorized representative in the GCC countries shall keep them for a period of 10 years at least after making the last product, at the disposal of the national authorities for inspection purposes.

  And in case the manufacturer or his authorized representative is not resident in the GCC countries, the commitment of keeping the technical documents and making them available shall be the responsibility of the person who launched the products in the market of the GCC countries.
- 3. The aforementioned technical documents shall enable to assess the conformity level of the product to the relevant Gulf technical regulation and shall cover the design, manufacture and operation to the related level of such assessment.
- 4. The manufacturer and his authorized representative in the GCC countries shall keep a copy of the conformity acknowledgement with the technical documents.
- 5. The manufacturer shall take all the necessary procedures which confirm that the products manufacture processes comply with the technical documents, provided in paragraph 2 above, and with the applied requirements of the Gulf technical regulation.

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6. Form A is known as the Supplier Declaration of Conformity (SDoC).

#### Form A1

This form includes form A and the following requirements:

- 1. Every manufactured product shall be subject to one or more tests for one or more specific features of the product, either through the manufacturer or on his behalf, and such tests are conducted under the liability of an approved authority selected by the manufacturer.
- 2. Under the liability of the approved authority, the manufacturer shall confirm the identification number of the approved authority during the manufacture process.

Or

- 3. An approved authority, selected by the manufacturer, shall examine the product at random periods whereas the approved authority shall select appropriate samples of the end product in the factory and examine them and conduct appropriate tests as provided in the concerned specifications, or equivalent tests to ensure compliance with the requirements of the concerned Gulf technical regulation.
- 4. In case of non-conformity of one or more products during examination, the approved authority shall take appropriate procedures.
- 5. The product's examination shall include the following elements: (The appropriate elements shall be mentioned **here**, among which, for instance, the used statistics method and the schedule of taking samples and stating their operational characteristics...).
- 6. The manufacturer shall mention the identification number of the approved authority during the manufacture process, at the responsibility of the approved authority.

#### **Form B (Type Examination):**

- 1. A form describing that part of the procedure by virtue of which an approved authority ensures that a sample of the production meets the requirements of the Gulf technical regulation to be applied thereto.
- 2. The type examination shall be applied when the manufacturer or his authorized representative in the GCC countries files an application with an approved authority of his choice. The application shall include the following:
  - Name and address of the manufacturer, as well as the name and address of the authorized representative, if the application was filed by him.
  - Written acknowledgment that the same application was not filed before with another approved authority.

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- The technical documents detailed in paragraph 3 below.
- The applicant shall put at the disposal of the approved authority a sample of the production, to be known as "Type" in this regulation (refer to clause 7 under Definitions). The approved authority shall be entitled to ask for other samples if needed to cover the testing requirements.
- 3. The technical documents shall enable the assessment of the product conformity with the requirements of the concerned Gulf technical regulation, and shall cover the design, manufacture and operation of the product whereas related to this assessment.
  - The contents of the technical documents shall be organized so that the Gulf technical regulation is in order according to the relevant products, for instance the technical documents shall include, wherever related to the assessment: general type specification; design concept, manufacture drawings, components plans, partial collectors and divisions...; specifications and necessary explanations to understand the mentioned drawings, plans and product operation; statement of technical specifications which are fully or partially applied, specification of the adopted solutions to meet the main requirements of the Gulf technical regulation when the mentioned specifications are not applied; outcomes of the accounts for the design, inspection and conducted tests.[)]
- 4. The approved authority shall perform the following:
  - 4.1 Examine the technical documents and ensure that the type was manufactured in conformity with the technical documents, specifying the elements which were designed according to the relevant technical specifications, and the components which are designed without application of the concerned requirements in these specifications.
  - 4.2 Conduct examinations and tests to ensure that, in case of non-application of the relevant specifications, the solutions adopted by the manufacturer meet the main requirements provided in the concerned Gulf technical regulation.
  - 4.3 Conduct examinations and tests to ensure that, in case the manufacturer selected to apply the relevant specifications, they are applied in fact.
  - 4.4 Agree with the applicant for the place where such examinations and tests will be conducted.
- 5. The approved authority shall issue a certificate of type conformity when the type meets the requirements of the Gulf technical regulation. The certificate shall include the name and address of the manufacturer, the results of the examination, validity terms and the necessary data to specify the acknowledged type. The relevant Gulf technical regulation may specify the validity period of the certificate. A statement of the relevant technical documents shall be enclosed to the certificate and the approved authority shall keep a copy thereof.

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In case the approved authority refused to issue the type certificate, it shall provide reasons of refusal in details and shall publish the appeal procedures.

- 6. The applicant shall notify the approved authority, who keeps the documents related to issue the type certificate with all the amendments which may be implemented to the acknowledged product, and who may need another acknowledgment if such amendments may affect the conformity of the product with the main requirements or terms stipulated to use the product. The additional acknowledgement takes place as an addition to the original certificate of type examination.
- 7. The approved authority shall deliver the information related to the certificates of type examination, their add-ons and cases of withdrawing them to the other approved authorities. Refer to the guide of approved authorities.
- 8. It might be sufficient that the other approved authorities obtain copies of the certificates of type examination and/or their add-ons, and the annexes of these certificates shall be kept at the disposal of these authorities.
- 9. The manufacturer or his authorized representative shall keep with the technical documents and their add-ons for a period of 10 years at least from the date of manufacturing the last product (the Gulf technical regulation may specify a different period).
  - Whereas the manufacturer or his authorized representative is not resident of the GCC countries, the person, who launched the product in the market of the GCC countries, shall be held responsible for keeping the technical documents available.

#### **Form C (Type Conformity):**

- 1. A form describing that part of the procedure by virtue of which the manufacturer or his authorized representative in the GCC countries ensures and acknowledges that the concerned products comply with the type described in the certificate of type examination (issued by virtue of Form B) and meet the requirements of the related Gulf technical regulation. The manufacturer or his authorized representative in the GCC countries shall place the conformity mark for the GCC countries on every product and write a conformity acknowledgment.
- 2. The manufacturer shall take all the necessary procedures to make sure that the production processes ensure that the manufactured product comply with the type described in the certificate of type examination (issued by virtue of Form B) and meet the requirements of the related Gulf technical requirements.

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3. The manufacturer or his authorized representative in the GCC countries shall keep a copy of the conformity acknowledgment for a period of 10 years at least from the date of manufacturing the last product (the concerned Gulf technical regulation may specify a different period).

In case the manufacturer or his authorized representative is not resident in the GCC countries, the person, who launched the products in the market of the GCC countries, shall be held responsible and committed to keep the technical documents and make them available.

# 4. Potential additional requirements:

The manufacturer or other authority on his behalf shall conduct one or more tests on one or more specified features of the product, and the tests shall be under the responsibility of the approved authority selected by the manufacturer, who shall, at the responsibility of the approved authority, mention its identification number during the manufacture process.

Or

The approved authority shall conduct tests for the product at random periods and shall take sufficient samples of the end products, examine them and conduct the tests provided in the relevant technical specifications or equivalent tests to ensure that the products comply with the requirements provided in the Gulf technical regulation, and in cases where one or more examined products are not compliant therewith, the approved authority shall take the appropriate procedures.

The product examination shall include the following elements:

(The appropriate elements shall be mentioned here, among which for instance, the used statistics method and the plan of taking samples and stating their operational characteristics...).

The manufacturer shall, at the responsibility of the approved authority, mention its identification number during the manufacture process.

#### **Form D (Confirm production quality):**

1. A form describing that part of the procedure by virtue of which the manufacturer or his authorized representative in the GCC countries ensures and acknowledges that the concerned products comply with the type described in the certificate of type examination (issued by virtue of Form B) and meet the requirements of the related Gulf technical regulation. The manufacturer or his authorized representative in the GCC countries shall place the conformity mark

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for the GCC countries on every product and write a conformity acknowledgment. The conformity mark shall be along with the identification number of the approved authority held responsible for controlling the conformity as mentioned in paragraph 4 below.

2. The manufacturer shall operate **an adopted quality system for production, final inspection and testing,** as mentioned in paragraph 3 below, and shall be subject to regular inspection according to paragraph 4 below.

#### 3. Quality System

- 3.1 The manufacturer shall file an application to assess his quality system with an approved authority of his choice within the framework of the concerned products. The application shall include:
  - All relevant information about the products within the required framework.
  - Documents related to the quality system.
  - If applied, the technical documents related to the adopted type and a copy of the certificate of type examination.
- 3.2 The quality system shall ensure the conformity of the products with the type described in the certificate of type examination, and with the requirements of the relevant Gulf technical regulation.

All the elements, requirements and needs, adopted by the manufacturer, shall be formally documented and organized as policies, procedures and written guidelines. The quality system documents shall allow consistent explanation of the quality programs, plans, evidence and records, and shall particularly include the following specification:

- Quality purposes, organizational structure, responsibilities and the management authorities in regards to the product quality.
- Techniques of the quality control, quality confirmation, operations and formal actions taken in regards to the manufacture.
- Examinations and tests carried out before, during and after the manufacture process, and periodicity of execution thereof.
- Quality records such as inspection reports, test data, benchmarking data and reports of qualifying the relevant workers.
- Means of controlling the required quality control and efficient operation of the quality system.

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3.3 The approved authority shall assess the quality system to ensure that it meets the requirements provided in paragraph 3.2. It is known that if the quality system complies with a recognized specification such as ISO 9001, it is supposed to comply with these requirements as well.

The verification team shall include one member at least who has experience in the field of technology of the considered product and shall include the assessment procedure of a visit to the manufacturer's facilities. The approved authority shall notify the manufacturer of its decision and such notification shall include the examination results and the assessment decision supported with reasons.

3.4 The manufacturer shall execute all the commitments arising from the adopted quality system and shall keep it appropriate and qualified.

The manufacturer or his authorized representative shall keep the approved authority, which acknowledged the quality system, informed of any changes or amendments in the quality system and the approved authority shall assess such amendments.

The approved authority shall take a decision whether the modified quality system is still meeting the requirements provided in paragraph 3.2 or whether conducting a reassessment is needed, and shall notify the manufacturer of its decision, including the examination results and assessment decision supported with reasons.

#### 4. Regular assessment under the responsibility of the approved authority:

- 4.1 The regular assessment shall be conducted in order to ensure that the manufacturer always meet the commitments arising from the adopted quality system.
- 4.2 The manufacturer shall allow the approved authority to access the premises of manufacture, inspection, testing and storage for inspection purposes, and shall provide it with the necessary information, in particular:
  - Quality system documents.
  - Quality records such as the inspection reports, test data, benchmarking data and reports of qualifying the concerned workers...

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4.3 The approved authority shall regularly conduct an inspection to ensure that the manufacturer keeps and applies the quality system, and shall present an inspection report to the manufacturer (the Gulf technical regulation may specify the verification periodicity).

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4.4 In addition, the approved authority may conduct unexpected visits to the factory, and may also conduct tests by itself, if necessary, to ensure the right performance of the quality system, and shall provide the manufacturer with a visit report and a test report, in case of conducting tests.

- 5. The manufacturer shall, for a period of 10 years at least (the Gulf technical regulation may specify a different period) after the date of manufacturing the last product, keep the following available to the national authorities:
  - The documents provided in the second point of 3.1
  - The updates provided in the second paragraph of 3.4
  - The decisions and reports issued by the approved authority indicated in the last paragraph of 3.4, 4.3 and 4.4.
- 6. The approved authority shall provide the other approved authorities with the relevant information of quality system certificates issued thereby or those withdrawn. (The Gulf technical regulation may include arrangements other than these ones).

#### Form E (Confirm product quality):

- 1. A form describing the procedure by virtue of which the manufacturer, who meets the conditions provided in paragraph 2, ensures and acknowledges that the concerned products comply with the type described in the certificate of type examination (issued by virtue of Form B) and meet the requirements of the related Gulf technical regulation. The manufacturer or his authorized representative in the GCC countries shall place the conformity mark for the GCC countries on every product and write a conformity acknowledgment. The conformity mark shall be along with the identification number of the approved authority held responsible for controlling the conformity as mentioned in paragraph 4 below.
- 2. The manufacturer shall operate **an adopted quality system for final inspection and testing of the product,** as mentioned in paragraph 3 below, and shall be subject to regular inspection according to paragraph 4 below.

#### 3. Quality System

3.1 The manufacturer shall file an application to assess his quality system with an approved authority of his choice regarding the concerned products. The application shall include:

- All relevant information about the expected product category.
- Documents related to the quality system.

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- If appropriate, the technical documents related to the adopted type and a copy of the certificate of type examination.
- 3.2 Under the applied quality system, every product shall be examined and the relevant tests of the concerned technical specifications shall be conducted to ensure the conformity of the products with the requirements of the relevant Gulf technical regulation. All the elements, requirements and needs, adopted by the manufacturer, shall be formally documented and organized as policies, procedures and written guidelines. The quality system documents shall allow consistent explanation of the quality programs, plans, evidence and records, and shall particularly include the following specification:
  - Quality purposes, organizational structure, responsibilities and the management authorities in regards to the product quality.
  - Examinations and tests carried out after the manufacture process.
  - Means of controlling the efficient operation of the quality system.
  - Quality records such as inspection reports, test data, benchmarking data and reports of qualifying the relevant workers.
- 3.3 The approved authority shall assess the quality system to ensure that it meets the requirements provided in paragraph 3.2. It is known that if the quality system complies with a recognized specification such as ISO 9001, it is supposed to comply with these requirements as well.
  - The verification team shall include one member at least who has experience in the field of technology of the considered product and shall include the assessment procedure of a visit to the manufacturer's facilities. The approved authority shall notify the manufacturer of its decision and such notification shall include the examination results and the assessment decision supported with reasons.
- 3.4 The manufacturer shall execute all the commitments arising from the adopted quality system and shall keep it appropriate and qualified.
  - The manufacturer or his authorized representative shall keep the approved authority, which acknowledged the quality system, informed of any changes or amendments in the quality system and the approved authority shall assess such amendments.
  - The approved authority shall take a decision whether the modified quality system is still meeting the requirements provided in paragraph 3.2 or whether conducting a reassessment is needed, and shall notify the manufacturer of its decision, including the examination results and assessment decision supported with reasons.

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4 Regular assessment under the responsibility of the approved authority:

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- 4.1 The regular assessment shall be conducted in order to ensure that the manufacturer always meet the commitments arising from the adopted quality system.
- 4.2 The manufacturer shall allow the approved authority to access the premises of manufacture, inspection, testing and storage for inspection purposes, and shall provide it with the necessary information, in particular:
  - Quality system documents.
  - Technical documents.
  - Quality records such as the inspection reports, test data, benchmarking data and reports of qualifying the concerned workers...
- 4.3 The approved authority shall regularly conduct an inspection to ensure that the manufacturer keeps and applies the quality system, and shall present an inspection report to the manufacturer (the Gulf technical regulation may specify the verification periodicity).
- 4.4 In addition, the approved authority may conduct unexpected visits to the factory, and may also conduct tests by itself, if necessary, to ensure the right performance of the quality system, and shall provide the manufacturer with a visit report and provide him with a test report, in case of conducting tests.
- 5 The manufacturer shall, for a period of 10 years at least (the Gulf technical regulation may specify a different period) after the date of manufacturing the last product, keep the following available to the national authorities:
  - The documents provided in the second point of 3.1
  - The updates provided in the second paragraph of 3.4
  - The decisions and reports issued by the approved authority indicated in the last paragraph of 3.4, 4.3 and 4.4.
- 6 The approved authority shall provide the other approved authorities with the relevant information of the issued or withdrawn quality system adoptions. (The Gulf technical regulation may include arrangements other than these ones).

#### **Form F (Product verification):**

1. A form describing the procedure by virtue of which the manufacturer or his authorized representative in the GCC countries ensures and acknowledges that the products, subject to the requirements provided in paragraph 3 below, comply with the type described in the type examination certificate and meet the requirements of the Gulf technical regulation applied thereto.

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- 2. The manufacturer shall take all the necessary procedures to ensure that the manufacture processes comply with the type described in the certificate of type examination and meet the requirements of the applied Gulf technical requirements. He shall have to place the conformity mark for the GCC countries on every product and write a conformity acknowledgment.
- 3. The approved authority shall conduct all appropriate examinations and tests to ensure that the product comply with the requirements provided in the Gulf technical regulation, either by examining and testing every product as described in paragraph 4 or examining and testing the products on statistics basis as described in paragraph 5 as determined by the manufacturer (the Gulf technical regulation may restrict this determination).
  - 3.1 The manufacturer or his authorized representative in the GCC countries shall keep a copy of the conformity acknowledgment for a period of 10 years at least from the date of manufacturing the last product (the Gulf technical regulation may specify a different period).

## 4. Verification by testing and examining every product

- 4.1 All products shall be examined separately and be subject to the appropriate tests provided in the technical specifications or equivalent tests in order to verify that they comply with the type described in the type examination certificate and the requirements of the applied Gulf technical regulation.
- 4.2 The approved authority shall mention its identification number (or ask for it to be mentioned) for every adopted product and issue a written conformity certificate in regards to the conducted tests.
- 4.3 The manufacturer or his authorized representative shall ensure his capacity to provide conformity certificates issued by the approved authority upon request.

#### 5. Statistics Verification

- 5.1 The manufacturer shall have to present his products as affinity groups and take all the necessary procedures so that the manufacture processes ensure the affinity of such products.
- 5.2 All products shall be available to be verified as affinity groups. A random sample shall be taken from every group, then the products of the sample shall be examined separately and be subject to appropriate tests provided in the technical specifications or equivalent tests in order to verify their conformity with the type described in the type examination certificate and the requirements of the applied Gulf technical regulation, and to determine whether the group is approved or rejected.

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- 5.3 The statistics procedure shall use the following elements:
  - (The appropriate elements shall be determined, for instance the used statistics method and the plan for taking samples and stating their operational features...).
- 5.4 In case of approved groups, the approved authority shall mention its identification number (or ask for it to be mentioned) on every product and issue a written conformity certificate in regards to the conducted tests. All products of the group may be launched in the market except the products of the group which were not conformed.

In case the group is rejected, the approved authority or the authority of capacity shall take the necessary procedures to prevent launching of that group in the market, and in case the groups were rejected again, the approved authority may temporarily interrupt the statistics examination.

The manufacturer may mention, under the responsibility of the approved authority, the identification number of the approved authority during the manufacture process.

5.5 The manufacturer or his authorized representative shall ensure his capacity to provide conformity certificates issued by the approved authority upon request.

## Form G (Verification of unity):

- 1. A form describing the procedure by virtue of which the manufacturer ensures and acknowledges that the concerned product, for which a certificate, provided in paragraph 2, was issued, complies with the requirements of the applied Gulf technical regulation. The manufacturer or his authorized representative, resident in the GCC countries, shall mention the conformity mark for the GCC countries and issue the conformity acknowledgment.
- 2. The approved authority shall examine every product separately and conduct appropriate tests as provided in the technical specifications or equivalent tests in order to ensure that it complies with the relevant requirements of the Gulf technical regulation.
  - The approved authority shall mention its identification number (or ask for it to be mentioned) on every product and issue an acknowledgment and a written conformity certificate in regards to the conducted tests.

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3. The technical documents are used to ensure the product's conformity with the requirements of the Gulf technical regulation, and to understand the design, manufacture and operation of such product.

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The contents of the technical documents shall be organized so that the Gulf technical regulation is in order according to the relevant products, for instance the technical documents shall include, wherever related to the assessment: general type specification; design concept, manufacture drawings, components plans, partial collectors and divisions...; specification and necessary explanation to understand the mentioned drawings, plans and product operation; statement of technical specifications which are fully or partially applied, specification of the adopted solutions to meet the main requirements of the Gulf technical regulation when the mentioned specifications are not applied; outcomes of the accounts for the design, inspection and conducted tests[...]

#### Form H (Full quality confirmation):

- 1. A form describing the procedure by virtue of which the manufacturer, who meets the conditions provided in paragraph 2 below, ensures and acknowledges that the concerned products comply with the requirements of the related Gulf technical regulation. The manufacturer or his authorized representative in the GCC countries shall place the conformity mark for the GCC countries on every product and enclose a conformity acknowledgment. The conformity mark shall be along with the identification number of the approved authority held responsible for the regular control as mentioned in paragraph 4.
- 2. The manufacturer shall operate an adopted quality system for final design, manufacture, inspection and testing of the product, as mentioned in paragraph 3, and shall be subject to regular inspection according to paragraph 4.

#### 3. Quality System

- 3.1 The manufacturer shall file an application to assess his quality system with an approved authority of his choice regarding the concerned products. The application shall include:
  - All relevant information about the requested product category.
  - Documents related to the quality system.
- 3.2 The applied quality system shall confirm that the products comply with the requirements of the relevant Gulf technical regulation.

All the elements, requirements and conditions, adopted by the manufacturer, shall be formally documented and organized as policies, procedures and written guidelines. The quality system documents shall allow consistent explanation of the quality programs, plans, evidence and records, and shall particularly include the following specification:

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- Quality purposes, organizational structure, responsibilities and management authorities in regards to the product design and quality.
- Technical specifications of the design including the technical specifications applied to the product and, in cases of non application of the specifications, the followed means shall be enclosed to ensure conformity with the principal requirements of the Gulf technical regulation applied to the product.
- Techniques of controlling the design and verifying it, as well as the operations and the followed methodology in case of designing the products related to the covering product category.
- Techniques, operations and methodology used in the manufacture process, as well as controlling and confirming the quality.
- Examinations and tests conducted before, during and after the manufacture process and regular execution of each.
- Quality records such as inspection reports, test data, benchmarking data, and reports of qualifying the relevant workers.
- Means of controlling the design and required quality of the product, and the efficient operation of the quality system.
- 3.3 The approved authority shall assess the quality system to ensure that it meets the requirements provided in paragraph 3.2. It is known that if the quality system complies with a recognized specification such as ISO 9001, it is supposed to comply with these requirements as well.

The verification team shall include one member at least who has experience in the field of technology of the considered product and shall include the assessment procedure of a visit to the manufacturer's facilities. The approved authority shall notify the manufacturer of its decision and such notification shall include the examination results and the assessment decision supported with reasons.

3.4 The manufacturer shall execute all the commitments arising from the adopted quality system and shall keep it appropriate and qualified.

The manufacturer or his authorized representative shall keep the approved authority, which acknowledged the quality system, informed of any changes or amendments in the quality system.

The approved authority shall assess such amendments, and shall take a decision whether the modified quality system is still meeting the requirements provided in paragraph 3.2 or whether conducting a reassessment is needed, and shall notify the manufacturer of such decision, including the examination results and assessment decision supported with reasons.

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#### 4. Regular assessment under the responsibility of the approved authority:

- 4.1 The regular assessment shall be conducted in order to ensure that the manufacturer always meets the commitments arising from the adopted quality system.
- 4.2 The manufacturer shall allow the approved authority to access the premises of manufacture, inspection, testing and storage for inspection purposes, and shall provide the approved authority with the necessary information, in particular:
  - Quality system documents.
  - Quality records as seen for the design process in the quality system such as the results of analysis, accounts and tests.
  - Quality records as seen for the manufacture process in the quality system such as the inspection reports, test data, benchmarking data and reports of qualifying the concerned workers...
- 4.3 The approved authority shall conduct a regular inspection to ensure that the manufacturer keeps and applies the quality system, and shall present an inspection report to the manufacturer (the Gulf technical regulation may specify the verification periodicity).
- 4.4 In addition, the approved authority may unexpectedly visit the manufacturer, and may also conduct tests personally, if necessary, or ask for conducting tests, in order to ensure the right performance of the quality system, and shall provide the manufacturer with a visit report and with a test report, in case of conducting tests.
- 5. The manufacturer shall, for a period of 10 years at least (the Gulf technical regulation may specify a different period) after the date of manufacturing the last product, keep the following available to the national authorities:
  - The documents provided in the second point of 3.1
  - The updates provided in the second paragraph of 3.4
  - The decisions and reports issued by the approved authority indicated in the last paragraph of 3.4, 4.3 and 4.4.
- 6. The approved authority shall provide the other approved authorities with the relevant information of the issued or withdrawn quality system adoptions. (The Gulf technical regulation may include arrangements other than these ones).

# **Further potential requirements:**

#### **Design verification**

1. The manufacturer shall have to file an application to examine the product with one approved authority.

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- 2. The application shall enable understanding the design, manufacture and operation of the product, as well as verifying the conformity with the requirements of the Gulf technical regulation.
  - The application shall include:
- The technical specifications of the design including the specifications, already applied.
- The necessary support evidence for conformity, particularly when not fully using the provided specifications, and such support evidence shall include the results of the conducted tests through appropriate laboratories of the manufacturer or on his behalf.
- 3. The approved authority shall examine the application, and if the design meets the requirements of the Gulf technical regulation, then the approved authority shall issue to the applicant a design examination certificate, including the examination results, acknowledgment terms and necessary data distinguishing the adopted design and whether such design has a specification link to the product performance.
- 4. The applicant shall always notify the approved authority, which issued the design examination certificate, of any modifications made to the adopted design. An additional adoption shall be made for the modifications that were implemented to the design adopted by the approved authority, which issued the design examination certificate, in case such modifications would affect the conformity with the Gulf technical regulation or affect the aforementioned terms of using the product. Such further adoption shall be given as an add-on to the original design examination certificate.
- 5. The approved authority shall notify the other approved authorities of the following:
  - The issued design examination certificates and issued add-ons,
  - The design adoptions and related withdrawn add-ons.

#### Clause 6 - Annexes

- 1. Annex 1 illustrates the general chart of the interaction and content of the forms to verify the conformity provided in clause 5.
- 2. Annex 2 illustrates a list the responsibilities for the manufacturer and/or his authorized representative and/or the approved authority.

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#### **Clause 7 - References**

- 1. List of the conformity mark for the GCC countries.
- 2. The Gulf technical regulation.
- 3. The guide of the approved authorities.
- 4. The international specifications and evidence ISO/IEC for verifying the conformity, issued by the Conformity Verification Committee CASCO in ISO Organization.
- 5. The documents and guidelines issued by the European Commission in regards to Global Approach for Certification and Testing, particularly the Commission's decision No. 93/465/EEC of July 22, 1993.

A. Internal **B. Type Examination** G. Unity H. Complete Production **Quality System** Verification Authority of providing product certificate acting according to ISO/IEC Guide Control 65 or inspection authority of type A acting according to the international Laboratory of specification ISO/IEC 17020 and shall be an approved authority Authority of Authority of approved test providing product providing certificate acting acting according certificate acting according to to the **Type Examination Certificate** according to the ISO/IEC Guide 65 international international or inspection specification authority of type A specification ISO/IEC 17025 C. Type acting according to ISO/IEC 17021 F. Product D. Quality Confirmation E. Product Quality and shall be an Conformity the international Verification and shall be an Confirmation Certificate approved specification Authority of approved Authority of **ISO/IEC 17020** Authority of authority providing product Laboratory of authority providing certificate acting and shall be an providing approved test certificate acting according to approved authority certificate acting acting according ISO/IEC Guide 65 according to the according to the or inspection to the international international authority of type A international specification specification acting according to specification ISO/IEC 17021 the international ISO/IEC 17021 specification ISO/IEC 17025 and shall be an and shall be an ISO/IEC 17020 and and shall be an approved approved shall be an Test every product approved authority authority annroved authority or at random authority Verification of Certificate ISO periods every product and 9001-2000 Verification of providing every product and Testing every conformity Certificate ISO Certificate ISO providing product or at 9001-2000 9001-2000 conformity random periods

**Annex 1: Chart Summary for the Conformity Verification Forms** 

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**Annex 2: List of responsibilities in the Conformity Verification Forms** 

The Form	The Manufacturer	The Manufacturer or his Authorized Representative	The Approved Authority (Third Party)
A	<ul> <li>Establish the technical documents in regards to the design, manufacture and production process.</li> <li>Take all necessary procedures to ensure that the manufacture process ensures the conformity of the products with the technical documents and with the applicable requirements (that is to say quality system application)</li> </ul>	<ul> <li>Ensure and declare the conformity of the concerned products with the requirements.</li> <li>Place the Gulf conformity mark on every product.</li> <li>Draw out the conformity acknowledgment.</li> <li>Keep a copy of the conformity acknowledgment and the technical documents, and at the disposal of the control authorities.</li> </ul>	
A1	<ul> <li>In addition to the responsibilities mentioned in Form A.</li> <li>Conduct by himself, or on his behalf, one or more tests for every product.</li> <li>Select the approved authority held responsible for conducting the test.</li> </ul>	<ul> <li>In addition to the responsibilities mentioned in Form A.</li> <li>Place the identification number of the approved authority related to the Gulf conformity mark, if the approved authority intervened during the production phase.</li> </ul>	<ul> <li>Control the tests conducted by the manufacturer.</li> <li>Control the process of placing its identification number upon intervention in verification the conformity during the production phase.</li> <li>Keep a record of the related information.</li> <li>Contact other approved authorities having related information (upon request).</li> </ul>
В	Establish the technical documents in regards to the design, manufacture and production process	<ul> <li>File an application for the type tests related to the GCC countries.</li> <li>Put at the disposal of the approved authority one or more samples representing the expected product.</li> <li>Inform the approved authority of all the modifications implemented to the adopted product.</li> </ul>	<ul> <li>Confirm, by conducting examinations and tests, that the sample(s) comply with the requirements and is manufactured according to the technical documents.</li> <li>Issue a type examination certificate for the GCC countries.</li> </ul>

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The Form	The Manufacturer	The Manufacturer or his Authorized Representative	The Approved Authority (Third Party)
		Keep the technical documents, including a copy of the type testing for the GCC countries, and at the disposal of the control authorities.	<ul> <li>Keep a copy of the certificate and a record of the relevant technical information.</li> <li>Contact other approved authorities specialized in the information related to the type testing certificates for the GCC countries (upon request).</li> </ul>
С	Take all the necessary procedures to make sure that the manufacture process ensures the products conformity with the type as detailed in the type testing certificate for the GCC countries, and with the applied requirements (such as management of the quality control including the establishment of the necessary documents).	<ul> <li>Ensure and declare (acknowledge) the conformity of the concerned products with the type testing certificate for the GCC countries, and with the applied requirements.</li> <li>Place the Gulf conformity mark on every product.</li> <li>Draw out the conformity acknowledgment.</li> <li>Keep the relevant technical information and a copy of conformity acknowledgment upon the request of the control authorities.</li> </ul>	
D	Apply an approved quality system for production and inspection, to the end product and testing including the establishment of the technical documents (that is to say the relevant information such as the expected product category and the documents of the quality system and update, and the	* *	<ul> <li>Assess the quality system to decide about its conformity with the applied requirements and take a decision in this respect.</li> <li>Supervise the process of placing its identification number on the product related to the Gulf conformity mark.</li> </ul>

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	technical documents of the adopted type and a copy of the type examination certificate for the GCC countries, as well as the decisions and reports of the approved authority).  • Ask for the calendar of the quality system for the concerned products.  • Ensure and declare (acknowledge) the conformity of the concerned products with the type testing certificate for the GCC countries, and with the applied requirements.  • Commit to achieve the obligations arising in consequence of the approved quality system and support it to keep it appropriate and efficient.  • Support the procedure taken by the approved authority for controlling purposes.  • Keep the documents of the quality system	<ul> <li>Inform the approved authority of any planned update for the quality system.</li> <li>Keep a copy of the conformity acknowledgment upon the request of the control authorities.</li> </ul>	unexpected and regular visits.

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	and the details of any update for the quality system, decisions and reports of the approved authority, upon the request of the control authorities.		
E	• As detailed in Form (D), and operate the approved quality system related to the examination and testing of the end product.	As detailed in Form (D).	As detailed in Form (D).
F	Take all necessary procedures to make sure that the manufacture process ensures the conformity of the products with the type as detailed in the type examination certificate for the GCC countries, and with the applied requirements (such as the management of the quality control including drawing out the necessary documents).  And wherever the statistics assessment is used:  Present the products as affinity groups and take all the necessary procedures so that	<ul> <li>File an application for conformity certificate.</li> <li>Inspect and certify the conformity of the products with the type specified in the type examination certificate for the GCC countries, and with the applied requirements.</li> <li>Place the Gulf conformity mark on every product.</li> <li>Place the identification number of the approved authority related to the Gulf conformity mark.</li> <li>Draw out the conformity acknowledgment.</li> </ul>	<ul> <li>Conduct appropriate examinations and tests to ensure the conformity of the product with the applicable requirements, either by examining and testing every product or by examining and testing the products on statistics basis.</li> <li>Supervise the process of placing its identification number.</li> <li>Draw out the conformity certificate related to the conducted tests.</li> </ul>

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The Form	The Manufacturer	The Manufacturer or his Authorized Representative	The Approved Authority (Third Party)
	the manufacture process ensures the affinity of every production group.	Keep a copy of the conformity acknowledgment and relevant technical information (such as the conformity certificate for the approved authority) at the disposal of the control authorities.	<ul> <li>Take the appropriate procedures to prevent launching the group in the markets in case they were rejected.</li> <li>Keep a record of the relevant technical information.</li> <li>Communicate the relevant information to the approved authorities (upon request).</li> </ul>
G	<ul> <li>Establish the technical documents related to the design, manufacture and production process.</li> <li>Ensure and acknowledge the conformity of the concerned product with the applied requirements.</li> </ul>	<ul> <li>Apply to obtain the conformity certificate.</li> <li>Place the Gulf conformity mark on every product.</li> <li>Place the identification number of the approved authority followed by the Gulf conformity mark.</li> <li>Keep a copy of the conformity acknowledgment, the technical documents and the conformity certificate of the approved authority and put them all at the disposal of the control authorities.</li> </ul>	<ul> <li>Examine all the product unites and conduct the appropriate tests to ensure the conformity with the relevant requirements.</li> <li>Supervise the process of placing its identification number.</li> <li>Keep a record of the relevant information.</li> <li>Issue a conformity certificate in regards to the conducted tests.</li> <li>Contact the approved authorities and communicate the relevant information (upon</li> </ul>

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The Form	The Manufacturer	The Manufacturer or his Authorized Representative	The Approved Authority (Third Party)
			request).
H	<ul> <li>Apply an approved quality system for designing, manufacturing and testing the end product for production, including the establishment of the technical documents (that is to say the information related to the product design and category, the documents of the quality system and update, and the decisions and reports of the approved authority).</li> <li>File an application to assess the quality system of the concerned product.</li> <li>Commit to achieve all the obligations of the approved quality system and commit to keep the system appropriate and efficient.</li> <li>Support the procedures taken by the approved authority for controlling purposes.</li> <li>Put at the disposal of the control authorities all the documents related to the quality system, and the details of any update process for this system, as well as the decisions and reports of the approved authority.</li> </ul>	As mentioned in Form D.	As mentioned in Form D.