

GLOBAL STANDARD OPERATING PROCEDURE

GSOP0013

Declaration of Conformity

Issue #3

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0. Purpose

The purpose of this procedure is to define the process used to request and complete a declaration of conformity in compliance with the requirements of EN ISO/IEC 17050-1-2004 and the ATEX Directives. It provides assurance of conformity of the identified object to specified requirements to which the declaration refers. The declaration makes clear who is responsible for that conformity and the declaration. A supplier's declaration may be used alone or in conjunction with another conformity assessment procedure for regulatory or non-regulatory purposes.

1. Scope

The declaration of conformity will be used in all cases where it is desirable or required that the conformity of an object to a specific requirement be attested. The object of the declaration can be a product or a process. Declaration of conformity will be required for all products requiring identification by certification number, serial number, or production lot number. In addition, any object that carries a certification from ATEX or IECEx must have a user manual included with the unit.

2. Definitions

Certified Product - Any item required by regulation to be assessed against a specified set of standards and identified with a unique numbering scheme.

Declaration of Conformity - A signed statement issued for a product or process declaring that said product or process conforms to the standards or documents listed in the declaration

Compliance Assessment - an evaluation by a first, second, or third party that provides assurance that a product or process conforms to the stated standards or documents

User Manual - A set of instructions written in one of the Community languages that contain information necessary for the putting into service, maintenance, inspection, checking of correct operation and where appropriate, repair of the apparatus together with all useful instructions, in particular with respect to safety.

3. Associated Reference Documents

EN ISO/IEC 17050-1:2004
EN ISO/IEC 17050-2:2004
ISO/IEC 60079-1
ATEX Directive 94/9/EC

Declaration of Conformity Template Form GSOP0013-001-1

4. Procedure

The issuer of the declaration of conformity is responsible for all aspects of that declaration including issuance, maintenance, extension, reduction, suspension, or withdrawal.

Declarations are based on the results of an appropriate conformity assessment activity.

Conformity assessments may be carried out by first, second or third parties and include inspection and test, audits or examinations. Assessments should include reference to relevant International Standards, Guides and other applicable references.

Declaration of conformity will be issued on the basis of the requirements outlined in ISO/IEC 60079-1 for components and assemblies.

The issuer of the declaration of conformity shall insure that the declaration contains the information set out below in order that the recipient of the declaration can make proper identification.

At a minimum, the declaration of conformity must contain:

- A unique identification of the declaration of conformity
- The name and contact address of the issuer of the declaration
- A full identification of the object of the declaration i.e. name, type or model number, date of production, part number and serial number, description of the process or other relevant information.
- A statement of conformity
- Certification number to be prefaced by the name of the certifying body
- A complete and clear listing of the standards or other specified requirements as well as any selected options if applicable
- Any limitations on the validity of the declaration of conformity
- If the certification is an ATEX number, including the following in this field
 - Notifying Body #0518
- The date and place of issuance of the declaration
- The signature, name and function of the person authorized to act on behalf of the issuer

The declaration of conformity shall be on the issuing company letterhead and will take the format and sequence of the Template provided in the Associated Reference Documents section of this GSOP.

Completion of a declaration of conformity shall be based on the guidance provided below.

- Every declaration of conformity shall be uniquely identified. The supplier may develop his own identification scheme.
- The responsible issuer shall be unequivocally specified. For a large organization, this may require specification of operational or departmental groups.

- The object of the declaration must be unequivocally described so that the declaration maybe related to the object in question. For pressure tested parts, this identification must include the unique test serial number.
- For mass produced products it is not required to give individual serial numbers. In such cases it is sufficient to provide the name, type, model, etc.
- The documents that form the requirements for production or process must be listed with their respective identification numbers, titles and dates of issue
- No other text need appear on the declaration unless there are limitations on the validity of the declaration.
- The full name and function of the person signing the declaration as authorized by the issuing organization management. The number of signatures or equivalent included will be determined by the minimum required by the legal form of the issuer organization.

Completed declarations must be submitted as follows:

- For components or assemblies that are declared by serial number, declaration is to be included in the packaging and attached to the individual unit
- For mass produced products (those not requiring serial numbers or individual packaging) the declaration is to be submitted to the quality representative of the ordering location for posting to JoyNet
- Any object that carries a certification from ATEX or IECEx must have a user manual included with the unit.