INTERNATIONAL STANDARD

ISO/IEC 17050-1

First edition
2004-10-01

Conformity assessment — Supplier's declaration of conformity —

Part 1: General requirements

Évaluation de la conformité — Déclaration de conformité du fournisseur —

Partie 1: Exigences générales

Reference number
ISO/IEC 17050-1:2004(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft International Standards are circulated to the national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC 17050-1 was prepared by the ISO *Committee on conformity assessment* (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17050-1, together with ISO/IEC 17050-2, cancels and replaces the second edition of ISO/IEC Guide 22:1996, *General criteria for supplier's declaration of conformity.*

ISO/IEC 17050 consists of the following parts, under the general title *Conformity assessment — Supplier's declaration of conformity*:

— *Part 1: General requirements*

— *Part 2: Supporting documentation*

Introduction

This part of ISO/IEC 17050 has been developed with the objective of providing general requirements for a supplier's declaration of conformity.

It addresses one of the three types of attestation of conformity, namely attestation undertaken by the first party (e.g. the supplier of a product). Other types are second-party attestation (e.g. where a user issues an attestation for the product the user is using) or third-party attestation. Each of these three types is used in the market in order to increase confidence in the conformity of an object.

This part of ISO/IEC 17050 specifies requirements applicable when the individual or organization responsible for fulfilment of specified requirements (supplier) provides a declaration that a product (including service), process, management system, person or body is in conformity with specified requirements, which can include normative documents such as standards, guides, technical specifications, laws and regulations. Such a declaration of conformity can also make reference to the results of assessments by one or more first, second or third parties. Such references are not to be interpreted as reducing the responsibility of the supplier in any way.

These general requirements are applicable to all sectors. However, these requirements might need to be supplemented for specific purposes, for example for use in connection with regulations.

A supplier's declaration of conformity of a product (including service), process, management system, person or body to specified requirements can be substantiated by supporting documentation under the responsibility of the supplier. In cases where this is desirable, or necessary, reference is made to ISO/IEC 17050-2.

Conformity assessment — Supplier's declaration of conformity —

Part 1: General requirements

1 Scope

This part of ISO/IEC 17050 specifies general requirements for a supplier's declaration of conformity in cases where it is desirable, or necessary, that conformity of an object to the specified requirements be attested, irrespective of the sector involved. For the purposes of this part of ISO/IEC 17050, the object of a declaration of conformity can be a product, process, management system, person or body.

This part of ISO/IEC 17050 does not define any particular object for the declaration of conformity.

Instead of "supplier's declaration of conformity", the term "declaration of conformity" can be used when appropriate.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 apply.

NOTE 1 "Supplier's declaration of conformity" is a "declaration" as defined in ISO/IEC 17000, i.e. first-party attestation.

NOTE 2 To avoid any confusion with attestation by certification bodies, the term "self-certification" is deprecated and should not be used.

4 Purpose of the declaration of conformity

The purpose of the declaration is to give assurance of conformity of the identified object to specified requirements to which the declaration refers, and to make clear who is responsible for that conformity and declaration. A supplier's declaration of conformity may be used alone or in conjunction with another conformity assessment procedure for regulatory or non-regulatory purposes.

5 General requirements

The issuer (issuing organization or person) of a declaration of conformity shall be responsible for issuing, maintaining, extending, reducing, suspending or withdrawing the declaration and the conformity of the object to the specified requirements.

The declaration of conformity shall be based on results of an appropriate type of conformity assessment activity (e.g. testing, measurement, auditing, inspection or examination) carried out by one or more first, second or third parties. Conformity assessment bodies involved, where applicable, should consult relevant International Standards, Guides and other normative documents.

Where a declaration of conformity is for a group of products of a similar type, it shall cover each individual product of the group. Where a declaration of conformity is for similar products delivered over a period of time, it shall cover each product as delivered or accepted.

It is recommended, as good conformity assessment practice, that the person reviewing the conformity assessment results be different from the signatory.

6 Contents of the declaration of conformity

6.1 The issuer of the declaration of conformity shall ensure that the declaration contains sufficient information to enable the recipient of the declaration of conformity to identify the issuer of the declaration, the object of the declaration, the standards or other specified requirements with which conformity is declared, and the person signing for and on behalf of the issuer of the declaration of conformity.

As a minimum, the declaration of conformity shall contain the following:

a) unique identification of the declaration of conformity;

b) the name and contact address of the issuer of the declaration of conformity;

c) the identification of the object of the declaration of conformity (e.g. name, type, date of production or model number of a product, description of a process, management system, person or body, and/or other relevant supplementary information);

d) the statement of conformity;

e) a complete and clear list of standards or other specified requirements, as well as the selected options, if any;

f) the date and place of issue of the declaration of conformity;

g) the signature (or equivalent sign of validation), name and function of the authorized person(s) acting on behalf of the issuer;

h) any limitation on the validity of the declaration of conformity.

6.2 Additional supporting information may be provided to relate the declaration to the conformity assessment results on which it is based, for example:

a) the name and address of any conformity assessment body involved (e.g. testing or calibration laboratory, inspection body, certification body);

b) reference to relevant conformity assessment reports, and the date of the reports;

c) reference to any management systems involved;

d) reference to the accreditation documents of conformity assessment bodies involved where the scope of accreditation is relevant to the declaration of conformity;

e) reference to the existence of associated supporting documentation, such as that described in ISO/IEC 17050-2;

f) additional information regarding certificates, registrations or marks that have been obtained;

g) other activities or programmes of the conformity assessment body (e.g. membership in an agreement group).

References in the documentation to conformity assessment results shall not misrepresent their applicability nor mislead the recipient of the declaration of conformity.

7 Form of declaration of conformity

See Annex A for an example of a declaration of conformity. The declaration of conformity may be in hardcopy, electronic media, or any other suitable medium.

8 Accessibility

A copy of the declaration of conformity may be included in other documentation, such as a statement, catalogue, invoice, user's instructions or website, relevant to the object of the declaration of conformity.

9 Product marking

If any marking is placed on the product to indicate the existence of a declaration of conformity, such marking shall be in such a format that it will not be confused with any certification mark. Such marking shall be traceable to the declaration of conformity.

10 Continuing validity of the declaration of conformity

10.1 The issuer of the declaration of conformity shall have procedures in place to ensure the continued conformity of the object, as delivered or accepted, with the stated requirements of the declaration of conformity.

10.2 The issuer of the declaration of conformity shall have procedures in place to re-evaluate the validity of the declaration of conformity, in the event of

h) changes significantly affecting the object’s design or specification,

i) changes in the standards to which conformity of the object is stated,

j) changes in the ownership or structure of management of the supplier, if relevant, or

k) relevant information indicating that the object may no longer conform to the specified requirements.

Annex A
(informative)

Supplier's declaration of conformity

A.1 Guidance to complete the form of declaration of conformity

NOTE Numbers 1) to 7) refer to the form shown in A.2.

1) Every declaration of conformity should be uniquely identified.

2) The responsible issuer should be unequivocally specified. For large organizations, it may be necessary to specify operational groups or departments.

3) a) The “object” should be unequivocally described so that the declaration of conformity may be related to the object in question.

3) b) For mass-produced products, it is not necessary to give individual serial numbers. In such cases it is sufficient to give the name, type, model number, etc.

4) For products, an alternative conformity statement may be: “As delivered, the object of the declaration described above is in conformity with the requirements of the following documents”.

5) Requirements documents should be listed with their identification numbers, titles and dates of issue.

6) Text should appear here only if any limitation on the validity of the declaration of conformity and/or any additional information are given. The latter information may, for example, correspond to 6.2 or may make reference to related product marking in accordance with Clause 9. Such product marking or other indication (e.g. on the product) may be an attachment to the declaration of conformity.

7) Full name and function of the signing person(s) authorised by the issuer's management to sign on its behalf should be given. The number of signatures, or equivalent, included will be the minimum determined by the legal form of the issuer’s organization.

A.2 Example of form of declaration of conformity

Supplier's declaration of conformity (in accordance with ISO/IEC 17050-1)

1) **No.** .....

2) **Issuer's name:** .....

Issuer's address: .....

.....

3) **Object of the declaration:** .....

.....

.....

4) **The object of the declaration described above is in conformity with the requirements of the following documents:**

	Documents No.	Title	Edition/Date of issue
5)	.....	.....	.....
	.....	.....	.....
	.....	.....	.....

Additional information:

6) .....

.....

.....

Signed for and on behalf of:

.....

.....

(Place and date of issue)

7) ....

(Name, function) (Signature or equivalent authorized by the issuer)

Bibliography

[1] ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

[2] ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*

[3] ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection*

[4] ISO/IEC 17021:—[1)], *Conformity assessment — General requirements for bodies providing assessment and certification for management systems*

[5] ISO/IEC 17024:2003, *Conformity assessment — General requirements for bodies operating certification of persons*

[6] ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*

[7] ISO/IEC 17040:—[2)], *General requirements for peer assessment of conformity assessment bodies and accreditation bodies*

[8] ISO/IEC 17050-2:2004, *Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation*

[9] ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*

1) To be published. (Revision of ISO/IEC Guide 62:1996 and ISO/IEC Guide 66:1999)

2) To be published.

ICS 03.120.20

Price based on 6 pages