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GENERAL CRITERIA FOR SUPPLIER'S
DECLARATION OF CONFORMITY
(ISO/IEC GUIDE 22:1996)

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# **EUROPEAN STANDARD** NORME EUROPÉENNE **EUROPÄISCHE NORM**

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## English version

## General criteria for supplier's declaration of conformity (ISO/IEC Guide 22:1996)

Critères généraux pour la déclaration de conformité du fournisseur (Guide ISO/CEI 22:1996)

Allgemeine Kriterien für Konformitätserklärungen von Anbietem (ISO/IEC Guide 22:1996)

This European Standard was approved by CEN/CENELEC on 1 January 1998.

CEN/CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN/CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN/CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN/CENELEC members are the national standards bodies and national electrotechnical committees, respectively, of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.





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## **Foreword**

The text of the ISO/IEC Guide 22:1996 of the Committee on Conformity Assessment (CASCO) has been taken over as a European Standard by Technical Committee CEN/CLC/TC 1 "Criteria for conformity assessment bodies", the secretariat of which is held by NSF, and approved by CEN and CENELEC.

This European Standard supersedes EN 45014:1989.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

## Introduction

This Guide has been drawn up with the objective of providing general criteria for producing the supplier's declaration of conformity.

It specifies the procedures to be used when a supplier offers or is requested to declare that a product, process or service is in conformity with normative documents, which may include standards. Such a declaration of conformity issued by a supplier may also make reference to the results of assessments by one or more third parties. Such references are not to be interpreted as reducing the responsibility of the supplier in any way.

This Guide is to be regarded as a tool for the supplier's declaration procedure only. It does not define any particular subject for the declaration.

These general criteria are applicable to all sectors. However, the criteria may need to be supplemented for specific purposes, for example for use in connection with technical regulations.

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#### 1 Scope

This Guide specifies general criteria for a supplier's declaration of conformity in cases where it is desirable, or necessary, that conformity of a product, process or service to normative documents be indicated, irrespective of the sector involved. The supplier may then declare under his/her responsibility the conformity to normative documents.

#### 2 Definitions

For the purposes of this Guide, the following definitions contained in ISO/IEC Guide 2:1996, Standardization and related activities — General vocabulary, apply, except that an additional informative note (note 1) has been added to definition 2.4.

**2.1 normative document**: Document that provides rules, guidelines or characteristics for activities or their results.

#### **NOTES**

- 1 The term "normative document" is a generic term that covers such documents as standards, technical specifications, codes of practice and regulations.
- 2 A document is to be understood as any medium with information recorded on or in it.
- 3 The terms for different kinds of normative documents are defined considering the document and its content as a single entity
- **2.2 standard**: Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

NOTE — Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

**2.3** assurance of conformity: Activity resulting in a statement giving confidence that a product, process or service fulfils specified requirements.

NOTE — For a product, the statement may be in the form of a document, a label or other equivalent means. It may also be printed in or applied on a communication, a catalogue, an invoice, a user instructions manual, etc. relating to the product.

**2.4** supplier's declaration: Procedure by which a supplier gives written assurance that a product, process or service conforms to specified requirements.

#### NOTES

- 1 The supplier is the party that supplies the product, process or service and may be a manufacturer, distributor, importer, assembler, service organization, etc.
- 2 In order to avoid any confusion, the expression "self-certification" should not be used.

## 3 Objective of the declaration

The objective of the declaration is to give assurance that the product, process or service concerned is in conformity with those normative documents to which the declaration refers, and to make clear who is responsible for that conformity.

### 4 General requirements

The supplier shall be responsible for the characteristics of the products, processes or services covered by the normative documents to which the declaration refers.

The declaration shall be based on testing or assessment by a first, second or third party.

The supplier has the option of indicating in the declaration whether, for example, an accredited laboratory and/or other conformity assessment activities or programmes have been involved, or whether any certificates/marks/registrations have been obtained.

#### 5 Contents of the declaration

**5.1** The declaration shall contain sufficient information to enable the user to identify the supplier making the declaration, the products, processes and services covered,



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