

# SVENSK STANDARD

## SS-EN ISO/IEC 17067:2013



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### **Bedömning av överensstämmelse – Grunder för produktcertifiering och riktlinjer för produktcertifieringsordningar (ISO/IEC 17067:2013)**

### **Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes (ISO/IEC 17067:2013)**

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EUROPEAN STANDARD

EN ISO/IEC 17067

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2013

ICS 03.120.20

English version

Conformity assessment - Fundamentals of product certification  
and guidelines for product certification schemes (ISO/IEC  
17067:2013)

Évaluation de la conformité - Éléments fondamentaux de la  
certification de produits et lignes directrices pour les  
programmes de certification de produits (ISO/IEC  
17067:2013)

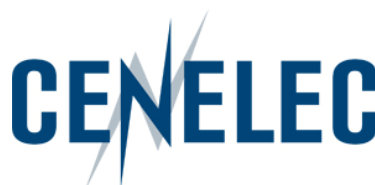
Konformitätsbewertung - Grundlagen der  
Produktzertifizierung und Leitlinien für  
Produktzertifizierungsprogramme (ISO/IEC 17067:2013)

This European Standard was approved by CEN on 12 July 2013.

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## **Foreword**

This document (EN ISO/IEC 17067:2013) has been prepared by Technical Committee ISO/CASCO "Committee on conformity assessment" in collaboration with Technical Committee CEN/CLC/TC 1 "Criteria for conformity assessment bodies" the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by February 2014, and conflicting national standards shall be withdrawn at the latest by February 2014.

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### **Endorsement notice**

The text of ISO/IEC 17067:2013 has been approved by CEN as EN ISO/IEC 17067:2013 without any modification.

## Introduction

This International Standard describes the fundamentals of product certification and provides guidelines for product certification schemes. In this International Standard references to the term “product” can also be read to mean “services” or “processes”.

As products are designed, produced, distributed, used and ultimately disposed of, they can give rise to concerns with purchasers, users and society in general. Such concerns could relate to safety, health or environmental impacts, durability, compatibility, suitability for intended purposes or for stated conditions.

Generally, these concerns are addressed by specifying the required product attributes in a normative document such as a standard.

The supplier of the product then has the task of demonstrating that the product conforms to the requirements of the normative document.

It might be sufficient for the supplier to assess and declare its product’s conformity, but in other cases the user or a regulatory authority might require that conformity be assessed by a competent and impartial third party.

Assessment and impartial third party attestation that fulfilment of specified requirements has been demonstrated for the product is referred to as product certification.

This International Standard outlines how schemes for product certification can be structured and managed. It identifies common assessment techniques that are used as a basis for product certification, such as product testing, inspection and auditing.

This International Standard is intended for use by those involved with product certification, particularly those who are, or who are considering becoming, product certification scheme owners. Product certification scheme owners can include:

- a) product certification bodies;
- b) government and regulators;
- c) purchasing agencies;
- d) non-government organizations;
- e) industry and retail associations; and
- f) consumer organizations.

This International Standard provides only guidance and does not contain requirements. It is compatible with ISO/IEC 17065, which specifies requirements for product certification bodies.

In this International Standard, the following verbal forms are used:

- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

The modal verb “shall”, which indicates a requirement, is not used because this International Standard only provides guidelines.

Further details can be found in the ISO/IEC Directives, Part 2.



# Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

## 1 Scope

This International Standard describes the fundamentals of product certification and provides guidelines for understanding, developing, operating or maintaining certification schemes for products, processes and services.

It is intended for use by all with an interest in product certification, and especially by certification scheme owners.

NOTE 1 In this International Standard the term “product” can also be read as “process” or “service”, except in those instances where separate provisions are stated for “processes” or “services”. Definitions of product, process and service are given in ISO/IEC 17065.

NOTE 2 The certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000) carried out by product certification bodies. The requirements for product certification bodies are specified in ISO/IEC 17065.

## 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*

ISO/IEC 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17065 and the following apply.

### 3.1

#### **certification system**

rules, procedures and management for carrying out certification

[SOURCE: ISO/IEC 17000:2004, 2.7, modified]

### 3.2

#### **certification scheme**

*certification system* (3.1) related to specified products, to which the same specified requirements, specific rules and procedures apply

Note 1 to entry: The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.

[SOURCE: ISO/IEC 17065:2012, 3.9, modified]

### 3.3

#### **scheme owner**

person or organization responsible for developing and maintaining a specific *certification scheme* (3.2)

Note 1 to entry: The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.

[SOURCE: ISO/IEC 17065:2012, 3.11]

## 4 Product certification

### 4.1 Concept of product certification

**4.1.1** Product certification is the provision of assessment and impartial third-party attestation that fulfilment of specified requirements has been demonstrated. Product certification is carried out by product certification bodies which should conform to ISO/IEC 17065. Specified requirements for products are generally contained in standards or other normative documents.

**4.1.2** Product certification is an established conformity assessment activity that provides confidence to consumers, regulators, industry and other interested parties that products conform to specified requirements, including for example product performance, safety, interoperability and sustainability.

**4.1.3** Product certification can facilitate trade, market access, fair competition and consumer acceptance of products on a national, regional and international level.

### 4.2 Objectives of product certification

**4.2.1** The fundamental objectives of product certification are:

- a) to address the needs of consumers, users and, more generally, all interested parties by giving confidence regarding fulfilment of specified requirements;
- b) to allow suppliers to demonstrate to the market that their product has been attested to fulfil specified requirements by an impartial third party body.

**4.2.2** Product certification should provide the following:

- confidence for those with an interest in fulfilment of requirements, and
- sufficient value so that suppliers can effectively market products.

## 5 Product certification schemes

### 5.1 Basics

**5.1.1** Product certification schemes should implement the functional approach as described in ISO/IEC 17000:2004, Annex A. The functions are:

- **selection**, which includes planning and preparation activities in order to collect or produce all the information and input needed for the subsequent determination function;
- **determination**, which may include conformity assessment activities such as testing, measuring, inspection, design appraisal, assessment of services and processes and auditing to provide information regarding the product requirements as input to the review and attestation functions;
- **review**, which means verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of specified requirements (see ISO/IEC 17000:2004, 5.1);

- **decision** on certification;
- **attestation**, which means issue of a statement of conformity, based on a decision following review, that fulfilment of specified requirements has been demonstrated (see ISO/IEC 17000:2004, 5.2);
- **surveillance** (where needed), which means systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity (see ISO/IEC 17000:2004, 6.1).

NOTE 1 Further information about the functions is given in ISO/IEC 17000.

NOTE 2 In ISO/IEC 17065, the functions of “selection” and “determination” have been combined and are referred to as “evaluation”.

NOTE 3 In ISO/IEC 17065, the function of “attestation” is related to the subclause on “certification documentation” (see ISO/IEC 17065:2012, 7.7).

**5.1.2** Whenever product certification is performed, a certification scheme (see [3.2](#)) is in place.

## **5.2 Functions and activities in product certification schemes**

**5.2.1** Product certification schemes are developed by defining specific activities for each of the applicable functions described in [5.1.1](#). [Table 1](#) shows how to build a product certification scheme by using these functions, and outlines some of the combinations of activities in use in the wide range of fields where product certification is employed. The types of product certification schemes in [Table 1](#) are further described in [5.3](#).

**5.2.2** [Clause 6](#) describes the process for deciding which activities to use for a given situation and the factors to be taken into account in making the decision.