



# SLOVENSKI STANDARD

## SIST EN 46002:1995

01-maj-1995

---

### Quality systems - Medical devices - Particular requirements for the application of EN 29002/Amendment

Quality systems - Medical devices - Particular requirements for the application of EN 29002

Qualitätssicherungssysteme - Medizinprodukte - Besondere Anforderungen für die Anwendung von EN 29002

Systemes qualité - Dispositifs médicaux - Exigences particulières relatives à l'application de l'EN 29002

<https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d86f9a61/sist-en-46002-1995>

Ta slovenski standard je istoveten z: **EN 46002:1993/AC:1994**

---

#### **ICS:**

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
11.040.01	Medicinska oprema na splošno	Medical equipment in general

**SIST EN 46002:1995**

**en**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN 46002:1995](#)

<https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d869a61/sist-en-46002-1995>

EUROPEAN STANDARD

EN 46002:1993

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 1993

UDC 615.461/.47:615.48:616-07:658.502

Descriptors: Medical device, quality assurance, quality, requirements

English version

**Quality systems - Medical devices - Particular requirements for the application of EN 29002**

Systèmes qualité - Dispositifs médicaux -  
Exigences particulières relatives à  
l'application de l'EN 29002

Qualitätssicherungssysteme - Medizinprodukte -  
Besondere Anforderungen für die Anwendung von  
EN 29002

(standards.iteh.ai)

[SIST EN 46002:1995](https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d869a61/sist-en-46002-1995)

<https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d869a61/sist-en-46002-1995>

This European Standard was approved by CEN/CENELEC on 1993-09-22. 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.

The European Standards exist 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

**CEN/CENELEC**

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Contents list

Foreword	3
0. Introduction	4
1. Scope and field of application	5
2. Normative references	5
3. Definitions	6
4. Quality system requirements	
4.1 Management responsibility	9
4.2 Quality system	10
4.3 Contract review	10
4.4 Document control	10
4.5 Purchasing	11
4.6 Purchaser supplied product	11
4.7 Product identification and traceability	11
4.8 Process control	12
4.9 Inspection and testing	14
4.10 Inspection, measuring and test equipment	14
4.11 Inspection and test status	14
4.12 Control of nonconforming product	15
4.13 Corrective action	15
4.14 Handling, storage, packaging and delivery	16
4.15 Quality records	17
4.16 Internal quality audits	17
4.17 Training	18
4.18 Statistical techniques	18
Annex A (informative) - Bibliography	19

## Foreword

This European Standard has been prepared by the Joint CEN/CENELEC Coordinating Working Group on Quality Supplements with the cooperation of CEN/TC 205 "Non-active medical devices", CENELEC/TC 62 "Electrical equipment in medical practice", CEN/TC 140 "In vitro diagnostic systems" and the Joint CEN/CENELEC Working Group on active implantable medical devices.

This document has been submitted to the Formal Vote and the result was positif.

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 June 1994, and conflicting national standards shall be withdrawn at the latest by June 1994.

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

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN 46002:1995

<https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d869a61/sist-en-46002-1995>

## 0. Introduction

EN 29002 is intended to be a general standard defining quality system requirements. EN 46002 provides particular requirements for **suppliers of medical devices** that are more specific than the general requirements specified in EN 29002.

In conjunction with EN 29002, this European Standard defines requirements for quality systems relating to the production and installation of **medical devices**. It embraces all the principles of Good Manufacturing Practice (GMP) widely used in the manufacture of **medical devices**. It can only be used in combination with EN 29002 and is not a "stand alone" standard.

There is a wide variety of **medical devices** and some of the particular requirements of this standard only apply to named groups of **medical devices**. These groups are described in clause 3, Definitions.

Particular requirements in a number of clauses of this standard are covered in detail in other European Standards. **Suppliers** should review the requirements and consider using national standards implementing harmonized European Standards in these areas.

[SIST EN 46002:1995](https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d86f9a61/sist-en-46002-1995)

To assist in the understanding of the requirements of EN 29002 and EN 46002, a series of guidance standards are being prepared for various groups of **medical devices** (see annex A).

Quality systems - Medical devices - Particular requirements for the application of EN 29002

## 1. Scope and field of application

### 1.1 Scope

This European Standard specifies, in conjunction with EN 29002, the quality system requirements for the production and, where relevant, installation of medical devices.

### 1.2 Field of application

The field of application of EN 29002 applies. In addition, this European Standard, in conjunction with EN 29002, is applicable when a medical device supplier's quality system is assessed in accordance with regulatory requirements.

As part of an assessment by a third party for the purpose of regulatory requirements, the supplier may be required to provide access to confidential data in order to demonstrate compliance with this standard. The supplier may be required to exhibit these data but is not obliged to provide copies for retention.

## 2. Normative references [SIST EN 46002:1995](#)

[https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-](https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d869a61/sist-en-46002-1995)

[6a69d869a61/sist-en-46002-1995](#)

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references subsequent amendments to or revisions of any of these publications apply to this European standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 29002:1987 Quality systems - Model for quality assurance in production and installation

EN 28402:1991 Quality - Vocabulary

### 3. Definitions

For the purpose of this standard, the definitions given in EN 28402:1991 apply, together with the following.

**NOTE :** Definitions 3.2 and 3.3 are taken from the Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC). Definitions 3.1 and 3.5 are taken from the Council Directive 93/42/CEE of 14 June 1993 concerning medical devices. Definitions 3.8, 3.9 and 3.11 are taken from EN 28402:1991.

#### 3.1 Medical Device

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

#### 3.2 Active medical device

Any **medical device** (see 3.1) relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

#### 3.3 Active implantable medical device

Any **active medical device** (see 3.1 and 3.2) which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.



### 3.4 Implantable medical device

Any medical device (see 3.1) intended

- to be totally or partially introduced into the human body or a natural orifice; or
- to replace an epithelial surface or the surface of the eye

by surgical intervention, which is intended to remain after the procedure for at least thirty days and which can only be removed by medical or surgical intervention.

NOTE : This definition applies to implantable medical devices other than active implantable medical devices.

### 3.5 In vitro diagnostic device

Any device which is a reagent, reagent product, kit, instrument, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of samples derived from the human body with a view to providing information the physiological state, state of health or disease, or congenital abnormality thereof.

[SIST EN 46002:1995  
https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d869a61/sist-en-46002-1995](https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d869a61/sist-en-46002-1995)

### 3.6 Non-active medical device

Any medical device (see 3.1) which is neither an active medical device (see 3.2) nor an in vitro diagnostic device (see 3.5).

### 3.7 Sterile medical device

Any medical device labelled "STERILE".

NOTE : Requirements for labelling a medical device "STERILE" appear in European Standards.

### 3.8 Supplier

The organization that provides a product (see 3.11) to the customer.

NOTE 1 : In a contractual situation, the supplier may be called the contractor.

NOTE 2 : The supplier may be for example the producer, distributor, importer, assembler, or service organisation.

NOTE 3 : The supplier can be either external or internal.

### 3.9 Verification

Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

NOTE 1 : In design and development, **verification** concerns the process of examining the result of a given activity to determine conformity with the stated requirement for that activity.

NOTE 2 : "Verified" is used to designate the corresponding state.

### 3.10 Label

All written, printed or graphic matter

a) on a **medical device** or any of its containers or wrappers or

b) accompanying a **medical device**

relating to identification, technical description and use of the **medical device** but excluding shipping documents.

[SIST EN 46002:1995](https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d86f9a61/sist-en-46002-1995)

<https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d86f9a61/sist-en-46002-1995>

### 3.11 Product

The result of activities or processes.

NOTE 1 : **Product** includes service, hardware, processed materials, software or combination thereof.

NOTE 2 : A **product** can be tangible (e.g. assemblies or processed materials) or intangible (e.g. information or concepts), or a combination thereof.

NOTE 3 : **Products** can be intended (e.g. offered to customers) or unintended (e.g. pollutants or unwanted effects).

### 3.12 Refurbishing

The processing or reprocessing to specified requirements of a **medical device** which has been previously released.

NOTE : Refurbishing applies also to repacking and/or resterilization of **medical devices** intended to be **sterile medical devices**, for example when a container that maintains sterility has been opened or damaged.

### 3.13 Customer complaint

Any reported allegation, written or verbal, from a customer of deficiencies related to the identity, quality, durability, reliability, safety or performance of a **medical device** (see 3.1).

### 3.14 Advisory notice

A notice issued to provide information and/or advice on what action should be taken in the use, modification, disposal or return of a **medical device** (see 3.1 and 3.15)

### 3.15 Recall

When there is a risk of death or serious deterioration to the state of health:

- the return of a **medical device** to the **supplier**;
- its modification by the **supplier** at the site of installation;
- its exchanges; or
- its destruction;

in accordance with the instruction contained in an **advisory notice** (see 3.14).

<https://standards.iteh.ai/catalog/standards/sist/d14e186f-666c-4b48-8b50-6a69d869a61/sist-en-46002-1995>

### 3.16 Labelling

The process of combining labels (see 3.10) with **medical devices**.

## 4. Quality system requirements

### 4.1 Management Responsibility

#### 4.1.1 Quality policy

Clause 4.1.1 of EN 29002:1987 applies.

#### 4.1.2 Organization

##### 4.1.2.1 Responsibility and authority

Clause 4.1.2.1 of EN 29002:1987 applies.

#### Particular requirement for all medical devices:

The **supplier** shall document the responsibility, authority and the interrelationship of all personnel who manage, perform and verify work affecting quality.