SLOVENSKI STANDARD
SIST EN 46001:1995

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Quality systems - Medical devices - Particular requirements for the application of EN 29001/Amendment

Quality systems - Medical devices - Particular requirements for the application of EN 29001

Qualitätssicherungssysteme - Medizinprodukte - Besondere Anforderungen für die Anwendung von EN 29001

Systemes qualité - Dispositifs médicaux - Exigences particulieres relatives a l'application de l'EN 29001

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English version

Quality systems - Medical devices - Particular requirements for the application of EN 29001

Systèmes qualité - Dispositifs médicaux - Exigences particulières relatives à l'application de l'EN 29001

Qualitätssicherungssysteme - Medizinprodukte - Besondere Anforderungen für die Anwendung von EN 29001

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CEN/CENELEC

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Contents list

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of an identical text or by endorsement, at the latest by June 1994, and conflicting national standards shall be withdrawn at the latest by June 1994.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.

0. Introduction

EN 29001 is intended to be a general standard defining quality system requirements. EN 46001 provides particular requirements for **suppliers** of **medical devices** that are more specific than the general requirements specified in EN 29001.

In conjunction with EN 29001, this European Standard defines requirements for quality systems relating to the design/development, production, installation and servicing 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 29 001 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.

To assist in the understanding of the requirements of EN 29001 and EN 46001, 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 29001

1. Scope and field of application

1.1 Scope

This European Standard specifies, in conjunction with EN 29001, the quality system requirements for the design/development, production, and where relevant, installation and servicing of **medical devices.**

1.2 Field of application

The field of application of EN 29001 applies. In addition, this European standard, in conjunction with EN 29001, 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

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 28402:1991	Quality - Vocabulary
EN 29001:1987	Quality systems - Model for quality assurance in design/development, production, installation and servicing and installation and servicing

3. Definitions

For the purposes 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/ CEE). Definitions 3.1 and 3.5 are taken from the Council Directive 93/42/CEE of 14 June 1993 concerning medical devices. Definitions

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 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 on the physiological state, state of health or disease, or congenital abnormality thereof.

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 supplies 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 organization.

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 status.

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.

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).

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 29001:1987 applies.

4.1.2 Organization

4.1.2.1 Responsibility and authority

Clause 4.1.2.1 of EN 29001:1987 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.

4.1.2.2 Verification resources and personnel

Clause 4.1.2.2 of EN 29001:1987 applies.

4.1.2.3 Management representative

Clause 4.1.2.3 of EN 29001:1987 applies.