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QUALITY SYSTEMS - MEDICAL DEVICES - PARTICULAR REQUIREMENTS FOR THE APPLICATION OF EN ISO 9003

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Quality systems - Medical devices - Particular requirements for the application of EN ISO 9003

Systèmes qualité - Dispositifs médicaux - Exigences particulières relatives à l'application de l'EN ISO 9003

Qualitätssicherungssysteme - Medizinprodukte - Besondere Anforderungen für die Anwendung von EN ISO 9003

This European Standard was approved by CEN/CENELEC on 1 April 1999.

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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.

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Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/CENELEC "Coordinating working group on quality supplements", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by February 2000, and conflicting national standards shall be withdrawn at the latest by February 2000.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

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.

Annex A is informative.

Introduction

EN ISO 9003 : 1994 is intended to be a general standard defining quality system requirements. EN 46003 provides particular requirements for **suppliers** of **medical devices** that are more specific than the general requirements specified in EN ISO 9003 : 1994

In conjunction with EN ISO 9003 : 1994, this European Standard defines requirements for quality systems relating to final inspection and test of **medical devices.** It can only be used in combination with EN ISO 9003 : 1994 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.

1 Scope

This European Standard specifies, in conjunction with EN ISO 9003 : 1994, the quality system requirements for the final inspection and test of **medical devices** excluding in vitro diagnostic medical devices and active implantable medical devices, and is applicable when a **medical device supplier's** quality system is assessed in accordance with regulatory requirements.

> NOTE: For sterile medical devices the relevant particular clauses in EN 46002 : 1996 apply as this standard alone is not sufficient for manufacturers of sterile medical devices seeking to comply 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 ISO 8402 : 1995
Quality management and quality assurance – Vocabulary (ISO 8402 : 1994)

EN ISO 9003 : 1994
Quality systems – Model for quality assurance in final inspection and test (ISO 9003:1994)

3 Definitions

For the purposes of this standard, the following definitions apply.

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.

> NOTE: Definition **3.1** reproduces the definition given in the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

3.2 Implantable medical device: Any **device** which is intended:

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

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered as implantable device.

NOTE: Definition 3.2 reproduces the definition given in the Council Directive 93/42/EEC, annex IX, clause 1.2 of 14 June 1993 concerning medical devices.

3.3 Supplier: The organization that provides a **product** (see **3.4**) 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 to the organization [EN ISO 8402 : 1995].

3.4 Product: Result of activities or processes.

NOTE 1: A **product** may include service, hardware, processed materials, software, or a combination thereof.

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

NOTE 3: A **product** can be either intended (e.g. offering to customers) or unintended (e.g. pollutant or unwanted effects) [EN ISO 8402 : 1995].

3.5 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**) [EN 46001 : 1996].

3.6 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 **3.7**) [EN 46001 : 1996].

3.7 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 exchange; or
- its destruction;

in accordance with the instructions contained in an **advisory notice** (see **3.6**) [EN 46001 : 1996].

4 Quality system requirements

4.1 Management responsibility

4.1 of EN ISO 9003 : 1994 applies.

4.2 Quality system

4.2.1 General

4.2.1 of EN ISO 9003 : 1994 applies.

Particular requirement for all medical devices:

The **supplier** shall establish and document the specified requirements.

NOTE: If this European Standard is used for compliance with regulatory requirements, the relevant requirements of the regulations should be included in the specified requirements.

4.2.2 Quality system procedures

4.2.2 of EN ISO 9003 : 1994 applies.

Particular requirement for all medical devices:

The **supplier** shall establish and maintain a file containing documents defining the product specifications, including inspection and test specifications for each type/model of **medical device**, or referring to the location of this information (see also **4.5.2** and **4.16**).

4.2.3 Quality planning

4.2.3 of EN ISO 9003 : 1994 applies.

4.3 Contract review

4.3 of EN ISO 9003 : 1994 applies.