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Qualitätssicherungssysteme - Medizinprodukte - Besondere Anforderungen für die Anwendung von EN ISO 9002

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CEN/CENELEC

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Contents

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 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of an identical text or by endorsement, at the latest by February 1997, and conflicting national standards shall be withdrawn at the latest by February 1997 .

According to the CEN/CENELEC Internal Regulations,the national standards orgganizations of 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 and United Kingdom.

0 Introduction

EN ISO 9002 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 ISO 9002.

In conjunction with EN ISO 9002, this European Standard defines requirements for quality systems relating to the 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 ISO 9002 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 ISO 9002 and EN 46002, a series of guidance standards are being prepared for various groups of medical devices (see annex A).

1 Scope

This European Standard specifies, in conjunction with EN ISO 9002, the quality system requirements for the production, and where relevant, installation of medical devices.

The field of application of EN ISO 9002 applies. In addition, this European Standard, in conjunction with EN ISO 9002, 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 ISO 8402:1995
Quality management and quality assurance - Vocabulary (ISO 8402:1994)

EN ISO 9002 : 1994
Quality systems – Model for quality assurance in production, installation and servicing (ISO 9002:1994)

3 Definitions

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

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/EEC of 14 June 1993 concerning medical devices.

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 30 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 provides a product (see 3.11) to the customer [EN ISO 8402:1995].

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 organisation.

3.9 verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled [EN ISO 8402:1995].

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: The term '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.

3.11 product: Result of activities or processes [EN ISO 8402:1995].

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).

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 exchange; or
- its destruction;

in accordance with the instructions 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 of EN ISO 9002 : 1994 applies.

4.2 Quality system

4.2.1 General

4.2.1 of EN ISO 9002 : 1994 applies.

Particular requirements 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 9002 : 1994 applies.

Particular requirements for all medical devices:

The supplier shall establish and maintain a file containing documents defining the product specifications, including complete manufacturing and quality assurance 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 9002 : 1994 applies.

4.3 Contract review

4.3 of EN ISO 9002 : 1994 applies.

4.4 Design control

The scope of this European Standard does not include quality system requirements for design control. This clause is included to align the clause numbering with EN ISO 9001.

4.5 Document and data control

4.5.1 General

4.5.1 of EN ISO 9002 : 1994 applies.

4.5.2 Document and data approval and issue

4.5.2 of EN ISO 9002 : 1994 applies.

Particular requirement for all medical devices:

The supplier shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that specifications to which medical devices have been manufactured are available for at least the lifetime of the medical device as defined by the supplier (see 4.16).

4.5.3 Document and data changes

4.5.3 of EN ISO 9002 :1994 applies.

4.6 Purchasing

4.6.1 General

4.6.1 of EN ISO 9002 :1994 applies.

4.6.2 Evaluation of sub-contractors

4.6.2 of EN ISO 9002 :1994 applies.

4.6.3 Purchasing data

4.6.3 of EN ISO 9002 :1994 applies.

Particular requirement for all medical devices:

To the extent required by the particular requirements for traceability in 4.8, the supplier shall retain copies (see 4.16) of relevant purchasing documents.

4.6.4 Verification of purchased product

4.6.4 of EN ISO 9002 :1994 applies.

4.7 Control of customer-supplied product

4.7 of EN ISO 9002 :1994 applies.

4.8 Product identification and traceability

4.8 of EN ISO 9002 :1994 applies.

a) Identification:

Particular requirement for all medical devices:

The supplier shall establish and maintain procedures to ensure that medical devices received for refurbishing are identified and distinguished at all times from normal production.

b) Traceability

Particular requirement for all medical devices:

The supplier shall establish, document and maintain procedures for traceability. The procedures shall define the extent of traceability and facilitate corrective action (see 4.14.2).

Additional requirements for active implantable medical devices and implantable medical devices:

The extent of traceability shall include all components and materials used, and records of the environmental conditions (see 4.9 B)d), when these could cause the medical device not to satisfy its specified requirements.

4.9 Process control

4.9 of EN ISO 9002 :1994 applies.

Particular requirement for all medical devices:

A) Personnel

The supplier shall establish, document and maintain requirements for health, cleanliness and clothing of personnel if contact between such personnel and product or environment could adversely affect the quality of product.

B) Environmental control in manufacture

For medical devices:

a) that are supplied sterile; or

b) that are supplied non-sterile and intended for sterilization before use; or

c) where the microbiological and/or particulate cleanliness or other environmental conditions are of significance in their use; or

d) where the environmental conditions are of significance in their manufacture;

the supplier shall establish and document requirements for the environment to which product is exposed. If appropriate, the environmental conditions shall be controlled and/or monitored.

C) Cleanliness of product

The supplier shall establish, document and maintain requirements for cleanliness of product if:

a) product is cleaned by the supplier prior to sterilization and/or its use; or

b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use;or

c) product is supplied to be used non-sterile and its cleanliness is of significance in use; or

d) process agents are to be removed from product during manufacture.

If appropriate, product cleaned in accordance with a) or b) above need not be subject to the preceding particular requirements, i.e. A) Personnel and B) Environmental control in manufacture, prior to the cleaning procedure.

D) Maintenance

The supplier shall establish and document requirements for maintenance activities when such activities may affect product quality.