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Utgåva 2

Medicintekniska produkter – Ledningssystem för kvalitet – Krav för regulatoriska ändamål
(ISO 13485:2003)

Medical devices – Quality management systems – Requirements for regulatory purposes
(ISO 13485:2003)

ICS 03.120.10; 11.040.01

Språk: engelska

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Europastandarden EN ISO 13485:2003 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 13485:2003.

Denna standard ersätter SS-EN ISO 13488, utgåva 1.

Den svenska standarden SS-EN ISO 13485, utgåva 1 (2001), gäller ej fr.o.m. 2006-07-31.

The European Standard EN ISO 13485:2003 has the status of a Swedish Standard. This document contains the official English version of EN ISO 13485:2003.

This standard supersedes the Swedish Standard SS-EN ISO 13488, edition 1.

The Swedish Standard SS-EN ISO 13485, edition 1 (2001), is not valid from 2006-07-31.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13485

July 2003

ICS 03.120.10; 11.040.01

Supersedes EN ISO 13485:2000 and EN ISO 13488:2000

English version

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)

Dispositifs médicaux - Systèmes de manegement de la qualité - Exigences à des fins réglementaires (ISO 13485:2003)

Qualitätssicherungssysteme - Medizinprodukte - Systemanforderungen zur Erfüllung gesetzlicher Anforderungen (ISO 13485:2003)

This European Standard was approved by CEN on 16 June 2003.

CEN 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 Management Centre or to any CEN member.

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 member into its own language and notified to the Management Centre has the same status as the official versions.

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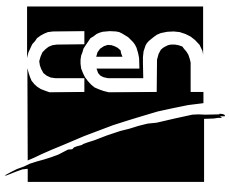

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of the International Standard ISO 13485:2003 has been prepared by Technical Committee ISO/TC 210 "*Quality management and corresponding general aspects for medical devices*, Working Group 1". The transposition into a European Standard has been managed by the CEN Management Centre (CMC) with the assistance of the CEN/CENELEC Co-ordinating Working Group on quality supplements for medical devices.

This European Standard supersedes EN ISO 13485:2000 and EN ISO 13488:2000.

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 January 2004, and conflicting national standards shall be withdrawn at the latest by July 2006.

This document 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 ZB, which is an integral part of this document.

NOTE The following is specifically intended for organisations that need to comply with one or more of the "New Approach" European Directives for medical devices (90/385/EEC, 93/42/EEC, and 98/79/EC) in order to affix CE marking on their products and to other parties involved in that process.

The publication of EN ISO 13485:2003 has implications for Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives. It is important to note that the modules used in individual technical harmonization directives may vary in some respects compared to those described in Council Decision 93/465/EEC. In all cases, it is the annex of the applicable directive(s) which is legally binding. The principles set out in this foreword remain valid regardless of these variations.

Two of the modules cited in Council Decision, i.e. modules D and H, require that "*the manufacturer must operate an approved quality system*". The scope of the quality systems required by these modules addresses:
- Production, final inspection and testing (module D),
- Design manufacture and final product inspection and testing (module H).

Where organizations wish to implement quality management systems in conformance with modules D or H, they may use EN ISO 13485:2003. In seeking compliance with modules D or H organizations may exclude specific requirements.

Where organizations wish to implement quality management systems in conformance with module E, they may use EN 46003:1999 (which is in the process of being revised into the format of EN ISO 13485:2003)

Module D Permissible exclusions	Module H Permissible exclusions
Sub-clause 7.3: design and development	NO exclusions permitted
Module D is the basis for annex V of 93/42/EEC directive and the basis for annex VII of 98/79/EC directive. Module H is the basis for annex 2 of 90/385/EEC directive, for annex II of 93/42/EEC directive and for annex II of 98/79/EC directive.	

It should be noted that EN ISO 13485:2003 is a Quality Management System for medical devices specifically for regulatory purposes. It is based on EN ISO 9001:2000 but in particular the requirements for “customer satisfaction” and “continual improvement” have been modified. Therefore, while EN ISO 13485:2003 has the same format as EN ISO 9001:2000 and most of the same requirements, compliance with EN ISO 13485:2003 does not provide conformity with EN ISO 9001:2000.

It should be noted that where the exclusions described in sub-clause 1.2 of EN ISO 13485:2003 are exceeded, conformity to EN ISO 13485:2003 shall not be claimed.

According to 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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 13485:2003 has been approved by CEN as EN ISO 13485:2003 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

0 Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation and servicing of medical devices, and the design, development, and provision of related services.

It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements.

Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

It is emphasized that the quality management system requirements specified in this International Standard are complementary to technical requirements for products.

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

There is a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.

0.2 Process approach

This International Standard is based on a process approach to quality management.

Any activity that receives inputs and converts them to outputs can be considered as a process.

For an organization to function effectively, it has to identify and manage numerous linked processes.

Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

0.3 Relationship with other standards

0.3.1 Relationship with ISO 9001

While this is a stand-alone standard, it is based on ISO 9001.

Those clauses or subclauses that are quoted directly and unchanged from ISO 9001 are in normal font. The fact that these subclauses are presented unchanged is noted in Annex B.

Where the text of this International Standard is not identical to the text of ISO 9001, the sentence or indent containing that text as a whole is shown in italics (in blue italics for electronic versions). The nature and reasons for the text changes are noted in Annex B.

0.3.2 Relationship with ISO/TR 14969

ISO/TR 14969 is a Technical Report intended to provide guidance for the application of ISO 13485.

0.4 Compatibility with other management systems

This International Standard follows the format of ISO 9001 for the convenience of users in the medical device community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management.

However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Medical devices — Quality management systems — Requirements for regulatory purposes

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of this International Standard is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001 (see Annex B).

1.2 Application

All requirements of this International Standard are specific to organizations providing medical devices, regardless of the type or size of the organization.

If regulatory requirements permit exclusions of design and development controls (see 7.3), this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this International Standard reflect exclusion of design and development controls [see 4.2.2 a) and 7.3].

If any requirement(s) in Clause 7 of this International Standard is(are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system [see 4.2.2 a)].

The processes required by this International Standard, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system [see 4.1 a)].

In this International Standard the terms "if appropriate" and "where appropriate" are used several times. When a requirement is qualified by either of these phrases, it is deemed to be "appropriate" unless the organization can document a justification otherwise. A requirement is considered "appropriate" if it is necessary in order for

— *the product to meet specified requirements, and/or*

— *the organization to carry out corrective action.*

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 9000:2000*, Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this *document*, the terms and definitions given in ISO 9000 apply, *together with the following.*

The following terms, used in this edition of *ISO 13485* to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier ----------> organization ----------> customer

The term "organization" replaces the term "supplier" used in ISO 13485:1996, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

Wherever requirements are specified as applying to "medical devices", the requirements apply equally to related services as supplied by the organization.

The following definitions should be regarded as generic, as definitions provided in national regulations can differ slightly and take precedence.

3.1
active implantable medical device
active medical device 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

3.2
active medical device
medical device 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
advisory notice
notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in

— *the use of a medical device,*

— *the modification of a medical device,*

— *the return of the medical device to the organization that supplied it, or*

— *the destruction of a medical device*

NOTE Issue of an advisory notice might be required to comply with national or regional regulations.

3.4
customer complaint
written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market

3.5
implantable medical device
medical device 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, and 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.

3.6
labelling
written, printed or graphic matter

— *affixed to a medical device or any of its containers or wrappers, or*

— *accompanying a medical device,*

related to identification, technical description, and use of the medical device, but excluding shipping documents

NOTE Some regional and national regulations refer to "labelling" as "information supplied by the manufacturer."

3.7
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— *diagnosis, prevention, monitoring, treatment or alleviation of disease,*

— *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*

— *investigation, replacement, modification, or support of the anatomy or of a physiological process,*

— *supporting or sustaining life,*

— *control of conception,*

— *disinfection of medical devices,*

— *providing information for medical purposes by means of in vitro examination of specimens derived from the human body,*

and which does not achieve its primary 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 This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [15].