SVENSK STANDARD
SS-EN ISO 13485:2012

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

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

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Europastandarden EN ISO 13485:2012 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 13485:2012.

Denna standard ersätter SS-EN ISO 13485, utgåva 2; SS-EN ISO 13485/AC:2007, utgåva 1 och SS-EN ISO 13485/AC:2009, utgåva 1.

The European Standard EN ISO 13485:2012 has the status of a Swedish Standard. This document contains the official version of EN ISO 13485:2012.

This standard supersedes the Swedish Standard SS-EN ISO 13485, edition 2; SS-EN ISO 13485/AC:2007, edition 1 and SS-EN ISO 13485/AC:2009, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Medicintekniska kvalitetssystem, SIS/TK 355.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13485

February 2012

ICS 03.120.10; 11.040.01

Supersedes EN ISO 13485:2003

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)

Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2003)

This European Standard was approved by CEN on 24 January 2012.

CEN and 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 CEN-CENELEC Management Centre or to any CEN and CENELEC 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 and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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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-CENELEC Management Centre (CCMC) with the assistance of the CEN-CENELEC Technical Committee 3 "Quality Management and corresponding general aspects for 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 August 2012, and conflicting national standards shall be withdrawn at the latest by August 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports quality system requirements of EU Medical Devices Directives. Compliance with EN ISO 13485 does not provide a presumption of conformity with all the aspects of the quality systems of the Medical Devices Directives. It is important that the organization and the Notified Body identify the regulatory requirements that are not covered by the standard. The Annexes Z of this standard shall be used for this purpose, describing the relationship between this European Standard and the conformity assessment requirements of the Medical Devices Directives.

This document supersedes EN ISO 13485:2003.

NOTE The following is specifically intended for organizations that need to comply with one or more of the 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 for other parties involved in that process whilst other Directives might also require a CE marking.

Where organizations wish to implement quality systems[1)] in conformance with Directives 90/385/EEC, 93/42/EEC and 98/79/EC, they may use EN ISO 13485:2012. EN ISO 13485:2012 provides a framework to enable a manufacturer to meet some of the quality system requirements for an EC Declaration of Conformity (Annex 2 and Annex 5 of Directive 90/385/EEC; Annex II, V and VI of Directive 93/42/EEC; or Annex III, IV and VII of Directive 98/79/EC).

In seeking compliance with the quality systems requirements of the Medical Devices Directives, organizations may exclude specific requirements from EN ISO 13485. The table below shows the exclusions that are permitted.

1) The European Directives use the term "quality system" whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Directive 90/385/EEC	Directive 93/42/EEC	Directive 98/79/EC
For Annex 2, no exclusions are permitted	For Annex II, no exclusions are permitted	For Annex III and IV, no exclusions are permitted
For Annex 5, exclusion of 7.3 of EN ISO 13485 is permitted	For Annex V, exclusion of 7.3 from EN ISO 13485 is permitted	For Annex VII, exclusion of 7.3 from EN ISO 13485 is permitted
	For Annex VI, exclusion of 7.3, 7.5.1 and 7.5.2 from EN ISO 13485 are permitted	

It should be noted that where the exclusions described in 1.2 of EN ISO 13485:2012 are exceeded, conformity to EN ISO 13485:2012 shall not be claimed.

The requirements in ISO 13485:2003 describe a systematic approach, within which manufacturers can identify, review and decide on the appropriate manner to incorporate regulatory requirements, other standards, and regulatory guidance documents into their quality management system. In this context, EN ISO 13485 requires the manufacturer to provide quality management system elements including: necessary resources, infrastructure and competent personnel; documentation and records for the operation of the quality management system; systems of internal audit and management review; systems to address nonconformity, corrective action and preventive action.

It should be noted that EN ISO 13485:2012 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 13485:2012 has the same format as EN ISO 9001:2000 and most of the same requirements, compliance with EN ISO 13485:2012 does not provide conformity with EN ISO 9001:2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 13485:2003 has been approved by CEN as a EN ISO 13485:2012 without any modification.

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.*