Nederlandse

norm

NEN-EN-ISO 13485 (en)

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

augustus 2003
ICS 03.120.10; 11.040.01

Vervangt NEN-EN-ISO 13485:2000; NEN-EN-ISO 13488:2000

Als Nederlandse norm is aanvaard:
- EN ISO 13485:2003,IDT
- ISO 13485:2003,IDT

Normcommissie 301 002 "301 Platform horizontale onderwerpen"

NEN

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Nederlands voorwoord

Voor de in deze norm vermelde normatieve verwijzingen bestaan in Nederland de volgende equivalenten:

vermelde norm	Nederlandse norm	titel
ISO 9000:2000	NEN-EN-ISO 9000:2000	Kwaliteitsmanagementsystemen - Grondbeginselen en verklarende woordenlijst (en,nl)

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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 13485:2003 E

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).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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 (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
ISO 9000	2000	Quality management systems – Fundamentals and vocabulary	EN ISO 9000	2000

Annex ZB
(informative)

Relationship of this document with EC Directives

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 EC Directive(s) :

- EC Directive 93/42/E(E)C

Compliance with this document provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

WARNING: Other requirements and other EC Directives may be applicable to the product(s) falling within the scope of this document.

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC.

INTERNATIONAL STANDARD

ISO 13485

Second edition
2003-07-15

Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

Reference number
ISO 13485:2003(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 13485 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This second edition cancels and replaces the first edition (ISO 13485:1996), which has been technically revised. It also cancels and replaces ISO 13488:1996. Those organizations which have used ISO 13488 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

This edition of ISO 13485 has a revised title and addresses quality assurance of product, customer requirements, and other elements of quality system management.

NEN
CONNECT

ALTIJD DE ACTUELE NORM IN UW BEZIT HEBBEN?

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Via het digitale platform NEN Connect heeft u altijd toegang tot de meest actuele versie van deze norm. Vervallen versies blijven ook beschikbaar. **U en uw collega’s** kunnen de norm via NEN Connect makkelijk raadplagen, online en offline.

Kies voor slimmer werken en bekijk onze mogelijkheden op **www.nenconnect.nl**.

Heeft u vragen?

Onze Klantenservice is bereikbaar maandag tot en met vrijdag, van 8.30 tot 17.00 uur.

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