

Quality systems — Medical devices — Particular requirements for the application of EN ISO 9001 (revision of EN 46001:1996) (identical to ISO 13485:1996)

The European Standard EN ISO 13485:2000 has the status of a British Standard

ICS 03.120.10; 11.040.01

National foreword

This British Standard is the official English language version of EN ISO 13485:2000. It is identical with ISO 13485:1996. It supersedes BS EN 46001:1997 which will be withdrawn on 15 February 2004.

The UK participation in its preparation was entrusted to Technical Committee CH/66, Quality systems for manufacture of medical devices, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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Summary of pages

This document comprises a front cover, an inside front cover, the EN ISO title page, the EN ISO foreword page, the ISO title page, pages ii to iv, pages 1 to 10, the annex ZA page and a back cover.

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Amendments issued since publication

Amd. No.	Date	Comments

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 March 2001

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ISBN 0 580 36992 7

English version

Quality systems - Medical devices - Particular requirements for
the application of EN ISO 9001 (revision of EN 46001:1996)
(identical to ISO 13485:1996)

Systèmes qualité - Dispositifs médicaux - Exigences
particulières relatives à l'application de l'EN ISO 9001
(révision de l'EN 46001:1996) (identique à l'ISO
13485:1996)

Qualitätssicherungssysteme - Medizinprodukte - Besondere
Anforderungen für die Anwendung von EN ISO 9001
(Überprüfung der EN 46001:1996) (identisch mit ISO
13485:1996)

This European Standard was approved by CEN/CENELEC on 1 April 2000.

CEN/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 Management Centre or to any CEN/CENELEC member.

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

CENELEC Central Secretariat:
rue de Stassart, 35 B-1050 Brussels

Foreword

The text of the International Standard from Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/CENELEC "Coordinating working group on quality supplements", the secretariat of which is held by DIN.

This European Standard supersedes EN 46001:1996.

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 May 2001, and conflicting national standards shall be withdrawn at the latest by February 2004.

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).

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.

Endorsement notice

The text of the International Standard ISO 13485:1996 has been approved by CEN/CENELEC as a European Standard without any modification.

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

INTERNATIONAL STANDARD

EN ISO 13485:2000

ISO
13485

First edition
1996-12-15

Quality systems — Medical devices — Particular requirements for the application of ISO 9001

*Systèmes qualité — Dispositifs médicaux — Exigences particulières
relatives à l'application de l'ISO 9001*



Reference number
ISO 13485:1996(E)
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