

Quality systems — Medical devices — Particular requirements for the application of EN ISO 9002 (revision of EN 46002:1996) (identical to ISO 13488:1996)

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

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- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
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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 9, the annex ZA page, an inside back cover and a back cover.

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**Quality systems - Medical devices - Particular requirements for
the application of EN ISO 9002 (revision of EN 46002:1996)
(identical to ISO 13488:1996)**

Systèmes qualité - Dispositifs médicaux - Exigences
particulières relatives à l'application de l'EN ISO 9002
(révision de l'EN 46002:1996) (identique à l'ISO
13488:1996)

Qualitätssicherungssysteme - Medizinprodukte - Besondere
Anforderungen für die Anwendung von EN ISO 9002
(Überprüfung der EN 46002:1996) (identisch mit ISO
13488:1996)

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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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 46002:1996.

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 13488:1996 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 13488:2000

**ISO
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Quality systems — Medical devices — Particular requirements for the application of ISO 9002

*Systèmes qualité — Dispositifs médicaux — Exigences particulières
relatives à l'application de l'ISO 9002*



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