

Ophthalmic instruments — Fundamental requirements and test methods

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National foreword

This British Standard is the English language version of EN ISO 15004:1997. It is identical with ISO 15004:1997.

The UK participation in its preparation was entrusted by Technical Committee CH/78, Ophthalmic optics, to Subcommittee CH/78/6, Ophthalmic instruments, 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 subcommittee can be obtained on request to its secretary.

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Attention is drawn to the fact that CEN and CENELEC standards normally include an annex which lists nonnative references to international publications with their corresponding European publications. The British Standards which implement international or European publications referred to in this document 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, pages i and ii, the EN ISO title page, page 2, the ISO title page, pages ii to iv, pages 1 to 12 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority the Standard Board and comes into effect on 15 April 1998

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English version

Ophthalmic instruments — Fundamental requirements and test methods

(ISO 15004:1997)

Instruments ophtalmiques — Exigences
fondamentales et méthodes d'essai
(ISO 15004:1997)

Ophthalmische Instrumente — Grundlegende
Anforderungen und Prüfverfahren
(ISO 15004:1997)

This European Standard was approved by CEN on 4 December 1997.

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 Central Secretariat 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 Central Secretariat 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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

The text of the International Standard ISO 15004:1997 has been prepared by Technical Committee ISO/TC 194 “*Biological evaluation of medical devices*” in collaboration with Technical Committee CEN/TC 170 “*Ophthalmic optics*”, the secretariat of which is held by DIN.

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 June 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

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).

For relationship with EU Directives, see informative Annex ZA, which is an integral part of this standard.

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 15004:1997 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

**ISO
15004**

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Ophthalmic instruments — Fundamental requirements and test methods

Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai



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Descriptors: Optics, optical equipment, ophthalmic equipment, classification, specifications, tests, type testing (tests), marking.