ILNAS

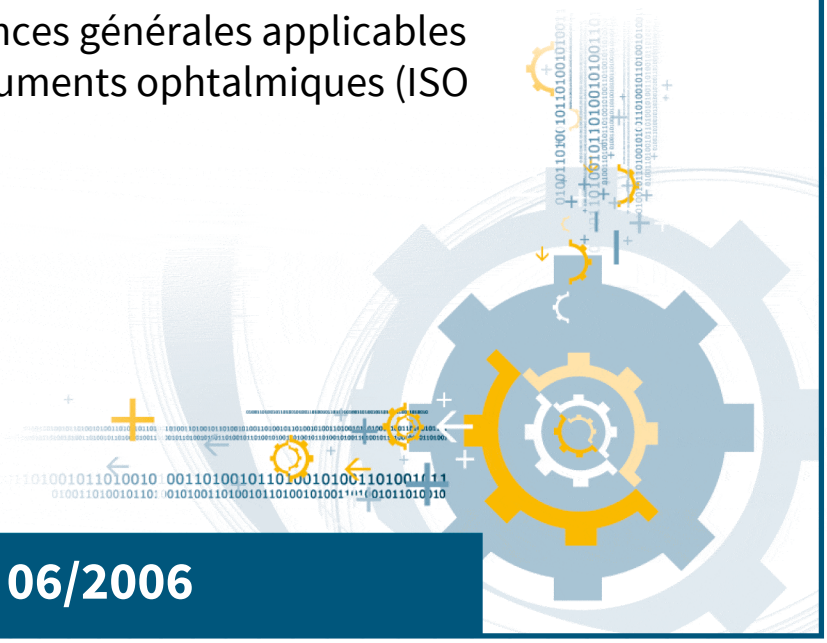
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 15004-1:2006

Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 1: Allgemeine Anforderungen an ophthalmische

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 1: Exigences générales applicables à tous les instruments ophtalmiques (ISO



06/2006

National Foreword

This European Standard EN ISO 15004-1:2006 was adopted as Luxembourgish Standard ILNAS-EN ISO 15004-1:2006.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15004-1

June 2006

ICS 11.040.70

Supersedes EN ISO 15004:1997

English Version

Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2006)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 1: Exigences générales applicables à tous les instruments ophtalmiques (ISO 15004-1:2006)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 1: Allgemeine Anforderungen an ophthalmische Instrumente (ISO 15004-1:2006)

This European Standard was approved by CEN on 9 January 2006.

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, 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 and United Kingdom.

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Ref. No. EN ISO 15004-1:2006: E

Foreword

This document (EN ISO 15004-1:2006) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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 December 2006, and conflicting national standards shall be withdrawn at the latest by December 2006.

This document, together with prEN ISO 15004-2:2006, supersedes EN ISO 15004:1997.

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 ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 and United Kingdom.

Endorsement notice

The text of ISO 15004-1:2006 has been approved by CEN as EN ISO 15004-1:2006 without any modifications.

ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International standard and Directive 93/42/EEC

Clauses/sub-clauses of this International standard	Essential requirements (ERs) of directive 93/42/EEC	Qualifying remarks/Notes
4	I.1, I.2, I.3, I.4, I.6, II.7.1, II.7.3, II.8.1, II.9.2, II.9.3, II.12.7.4	Testing according to clause 7.
4.1	II.12.7.1	—
4.3	II.9.1	—
4.6	II.10.1, II.10.2	—
4.7	II.12.7.5	Testing according to 7.2.
4.8	II.12.7.1	—
5.1, 5.2	I.1, I.3, I.4, I.5, II.7.3, II.9.2, II.10.1, II.12.7.5	Testing according to clause 7.
6	I.1, I.2, I.3, I.4, I.6, II.7.1, II.7.3, II.9.2, II.9.3, II.12.7.5	Testing according to clause 7.
6.1	II.12.1, II.12.6, II.12.7.4	Testing according to clause 7.
6.3	II.11.1, II.11.3, II.11.4	In the previous edition (EN ISO 15004: 1997) the relevant requirements and test methods were directly incorporated in the standard. In the present revised edition, these requirements and test methods have been referred to ISO 15004-2, and they are hence now incorporated in the present standard by means of a normative reference to EN ISO 15004-2.
8	I.2, II.8.1, II.11.4, II.13.1, II.13.2, II.13.3, II.13.6	—

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