Irish Standard
I.S. EN ISO 15004-1:2009

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

I.S. EN ISO 15004-1:2009

Incorporating amendments/corrigenda issued since publication:

This document replaces:	*This document is based on:*	*Published:*
I.S. EN ISO 15004-1:2006	EN ISO 15004-1:2009 EN ISO 15004-1:2006	8 April, 2009 4 August, 2006

This document was published under the authority of the NSAI and comes into effect on:
3 July, 2009

ICS number:
11.040.70

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I.S. EN ISO 15004-1:2009

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15004-1

April 2009

ICS 11.040.70

Supersedes EN ISO 15004-1:2006

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 7 March 2009.

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 CEN 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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 15004-1:2009: E

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Foreword

The text of ISO 15004-1:2006 has been prepared by Technical Committee ISO/TC 172 “Optics and optical instruments” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 15004-1:2009 by 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 October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 15004-1:2006.

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 93/42/EEC, as amended by Directive 2007/47/EC.

For relationship with EU Directive 93/42/EEC as amended by Directive 2007/47/EC, 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, Bulgaria, 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 the United Kingdom.

Endorsement notice

The text of ISO 15004-1:2006 has been approved by CEN as a EN ISO 15004-1:2009 without any modification.

Annex ZA
(informative)

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

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 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 European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All clauses	1, 2, 3, 4, 5, 6	Testing according to clause 7.
—	6 a)	This relevant Essential Requirement is not addressed in EN ISO 15004-1. This requirement will be addressed by the manufacturer's risk management process. See EN ISO 14971 for risk management and EN ISO 14155-1 and -2 for clinical investigation.
4.1	1, 2, 3, 4, 5, 6	
4.2	1, 2, 7.5	
4.3	3	
4.4	9.1	
4.5	7.1	
4.6	8.1	
4.7	10.1, 10.2	
4.8	12.7.5	Testing according to clause 7.2.
4.9	9.2, 12.7.1	
5.1	4, 9.2	Testing according to clause 7.
5.2	5, 9.2	Testing according to clause 7.
5.3	5, 9.2	
6.1	12.6, 12.7.4	
6.3	11.1, 11.2, 11.3, 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

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
		EN ISO 15004-2.
8.1	13.1, 13.6	Essential Requirement 13.6 is only partly addressed in EN ISO 15004-1: Essential Requirement 13.6 g) relating to instructions in the event of damage to the sterile packaging and to appropriate methods of re-sterilization is not addressed.
8.2	13.3	This relevant Essential Requirement is only partly addressed in EN ISO 15004-1: Essential Requirement 13.3 a) relating to authorized representative is not addressed.
—	12.1 a)	This relevant Essential Requirement is not addressed in EN ISO 15004-1. This requirement can be addressed by application of other standards, e.g. IEC 60601-1-4, IEC 62304.

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

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I.S. EN ISO 15004-1:2009

INTERNATIONAL STANDARD

ISO 15004-1

First edition
2006-06-01

Ophthalmic instruments — Fundamental requirements and test methods —

Part 1: General requirements applicable to all ophthalmic instruments

Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai —

Partie 1: Exigences générales applicables à tous les instruments ophtalmiques

Reference number
ISO 15004-1:2006(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 15004-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition together with ISO 15004-2 cancels and replaces ISO 15004:1997, which has been technically revised as follows:

a) all reference to light hazard (definitions 3.4 to 3.9, 6.3, 7.5, Annexes A, C and D of ISO 15004:1997) has essentially been moved to ISO 15004-2;

b) ignitability requirement/testing changed (4.5.2 and 7.1 of ISO 15004:1997);

c) environmental requirements/testing partly changed [Table 1; 5.2.2 and 8.1 f) of ISO 15004:1997];

d) normative Annex B (now informative Annex A) entirely updated;

e) normative (dated) reference updated to use IEC 60601-1:2005 edition.

ISO 15004 consists of the following parts, under the general title *Ophthalmic instruments — Fundamental requirements and test methods*:

— *Part 1: General requirements applicable to all ophthalmic instruments*

— *Part 2: Light hazard protection*

Ophthalmic instruments — Fundamental requirements and test methods —

Part 1:
General requirements applicable to all ophthalmic instruments

1 Scope

This part of ISO 15004 specifies fundamental requirements for non-invasive, active and non-active ophthalmic instruments. This part of ISO 15004 is also applicable to low-vision aids and tonometers, but not to other ophthalmic instruments which are used in contact with the globe of the eye.

This part of ISO 15004 is not applicable to operation microscopes, endoscopes and devices intended for laser investigation or laser treatment of the eye.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9022-2:2002, *Optics and optical instruments — Environmental test methods — Part 2: Cold, heat and humidity*

ISO 9022-3:1998, *Optics and optical instruments — Environmental test methods — Part 3: Mechanical stress*

ISO 15004-2:—[1)], *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-1:1992, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 60695-2-10:2000, *Fire hazard testing — Part 2-10: Glowing/hot-wire based test methods — Glow-wire apparatus and common test procedure*

IEC 60695-2-11:2000, *Fire hazard testing — Part 2-11: Glowing/hot-wire based test methods — Glow-wire flammability test method for end-products*

1) To be published. (Revision of ISO 15004:1997)