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**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*



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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 to 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:—<sup>1)</sup>, *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*

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