SLOVENSKI STANDARD
SIST EN ISO 15004:2000

01-januar-2000

Oftalmiļ ni instrumenti - Temeljne zahteve in preskusne metode (ISO 15004:1997)

Ophthalmic instruments - Fundamental requirements and test methods (ISO 15004:1997)

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

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

Ta slovenski standard je istoveten z: **EN ISO 15004:1997**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

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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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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Foreword

The text of the International Standard ISO 15004:1997 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 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 Directive(s), 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.

ANNEX ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

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

The following clauses of this standard, as detailed in table ZB.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZB.1: Correspondence between this European Standard and EU Directives

Clauses/sub-clauses of this European Standard	Corresponding annexes/paragraphs of Directive 93/42/EEC	Comments
§ 4	Annex IX: § 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 of this European Standard
§ 4.1	Annex IX: § II.12.7.1	---
§ 4.3	Annex IX: § II.9.1	---
§ 4.6	Annex IX: § II.10.1; II.10.2	---
§ 4.7	Annex IX: § II.12.7.5	Testing according to clause 7.2 of this European Standard
§ 4.8	Annex IX: § II.12.7.1	---
§ 5.1; 5.2	Annex IX: § 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 of this European Standard
§ 6	Annex IX: § 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 of this European Standard
§ 6.1	Annex IX: § II.12.1; II.12.6; II.12.7.4	Testing according to clause 7.4 of this European Standard
§ 6.3	Annex IX: § II.11.1; II 11.3; II.11.4	Testing according to clause 7.5 of this European Standard
§ 8	Annex IX: § I.2; II.8.1; II.11.4; II.13.1; II.13.2; II.13.3; II.13.6	---

INTERNATIONAL STANDARD

ISO 15004

First edition
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Ophthalmic instruments — Fundamental requirements and test methods

Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai

Reference number
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Contents

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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.

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.

International Standard ISO 15004 was prepared by ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments.*

Annexes A and B form an integral part of this International Standard. Annexes C and D are for information only.

Ophthalmic instruments – Fundamental requirements and test methods

1 Scope

This International Standard specifies Fundamental requirements for non-invasive, active and non-active ophthalmic instruments. This International Standard 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 International Standard takes precedence over the corresponding requirements of the other general standards cited in clause 2, if differences exist.

This International Standard does not apply to operation microscopes, endoscopes and devices intended for laser investigation or laser treatment of the eye.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9022-2:1994, *Optics and optical instruments — Environmental test methods — Part 2: Cold, heat, humidity.*

ISO 9022-3:1994, *Optics and optical instruments — Environmental test methods — Part 3: Mechanical stress.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

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

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 non-invasive ophthalmic instrument
Ophthalmic instrument which does not in whole or in part penetrate inside the body, either through a body orifice or through the surface of the body.

3.2 active ophthalmic instrument
Any ophthalmic instrument connected with a permanently installed source of electrical power energy.

3.3 manufacturer (of an ophthalmic instrument)
Natural or legal person who places the ophthalmic instrument on the market.

3.4 optical radiation hazard
Possibility of damage to the retina by optical radiation.

NOTE — The effect of the radiance of a source (see 3.6) will decrease as the light beam passes through an optical system due to filtering, absorption or other loss mechanisms. Thus, basing the optical radiation hazard on the source radiance ensures that the radiance at the retina cannot exceed the source radiance.