SLOVENSKI STANDARD
SIST EN ISO 9394:2000

01-januar-2000

Oļesna optika - Kontaktne leļe in izdelki za vzdrģevanje kontaktnih leļ - Ugotavljanje biološke združljivosti z raziskavo na oļeh kuncev (ISO 9394:1998)

Ophthalmic optics - Contact lenses and contact lens care products - Determination of biocompatibility by ocular study using rabbit eyes (ISO 9394:1998)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Bestimmung der Biokompatibilität durch Erprobung am Kaninchenauge (ISO 9394:1998)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Détermination de la biocompatibilité par évaluation de la tolérance oculaire chez le lapin (ISO 9394:1998)

Ta slovenski standard je istoveten z: **EN ISO 9394:1998**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 9394:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 9394

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English version

Ophthalmic optics - Contact lenses and contact lens care products - Determination of biocompatibility by ocular study using rabbit eyes (ISO 9394:1998)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Détermination de la biocompatibilité par évaluation de la tolérance oculaire chez le lapin (ISO 9394:1998)

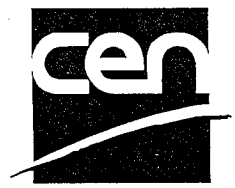
Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Bestimmung der Biokompatibilität durch Erprobung am Kaninchenauge (ISO 9394:1998)

This European Standard was approved by CEN on 14 August 1998.

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

Foreword

The text of the International Standard ISO 9394:1998 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 February 1999, and conflicting national standards shall be withdrawn at the latest by February 1999.

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 9394:1998 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

ANNEX ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 8321-1	1991	Optics and optical instruments - Contact lenses - Part 1: Specification for rigid corneal and scleral contact lenses	EN ISO 8321-1	1996
ISO 10993-1	1992	Biological evaluation of medical devices - Part 1: Guidance on selection of tests (Technical Corrigendum 1:1992)	EN 30993-1	1994
ISO 10993-10	1995	Biological evaluation of medical devices - Part 10: Tests for irritation and sensitization	EN ISO 10993-10	1995

INTERNATIONAL STANDARD

ISO 9394

Second edition
1998-08-15

Ophthalmic optics — Contact lenses and contact lens care products — Determination of biocompatibility by ocular study with rabbit eyes

Optique ophtalmique — Lentilles de contact et produits d'entretien pour lentilles de contact — Détermination de la biocompatibilité par évaluation de la tolérance oculaire chez le lapin

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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 9394 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 9394:1994), which has been technically revised.

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

Introduction

The ocular tissue of the rabbit is the system traditionally used to evaluate the irritant properties of materials which come in contact with ocular tissue.

The use of the device under evaluation is governed by the nature, degree, duration, frequency and conditions of exposure of humans to the device in normal intended use.

It is incumbent upon the investigator to conduct such evaluations using good scientific laboratory practices, complying with regulations related to animal welfare and the general principles set forth in the normative references.

ISO 10993-1 is the basic horizontal International Standard for biological evaluation of medical devices, and serves as a framework for planning biological evaluation tests.

ISO 10993-10 assesses possible contact hazards from device-released chemicals that may produce skin and mucosal irritation, eye irritation and delayed contact sensitization.

Usage tests for specific devices are defined in vertical standards. This International Standard describes one of several specific usage tests for contact lenses and contact lens care products.

The existence of this International Standards does not imply that rabbit-eye testing is a requirement in the determination of biocompatibility of contact lenses and contact lens care products, nor that this test is sufficient by itself to determine the biocompatibility of contact lenses and contact lens care products. Taking into consideration animal welfare requirements (ISO 10993-2:1992), it is recommended that this *in vivo* test be carried out after obtaining data of *in vitro* toxicological testing such as described in ISO 9363-1, ISO 10340 and ISO 11986.

Testing by ocular study with rabbit eyes is to be regarded as a "disaster check" before entering human trials; it might be useful in certain situations (e.g. testing of new materials), but will not be required in many cases.

Care should be taken when extrapolating the test results to the human eye.

Ophthalmic optics — Contact lenses and contact lens care products — Determination of biocompatibility by ocular study with rabbit eyes

1 Scope

This International Standard specifies an *in vivo* method of test to assess the ocular safety of contact lenses and contact lens care products. The test assesses the degree of irritation to the ocular tissue produced by the device under test. The test method is described in application to rabbit eyes.

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 8321-1:1991, *Optics and optical instruments — Contact lenses — Part 1: Specification for rigid corneal and scleral contact lenses.*

ISO 8321-2:—[1)], *Optics and optical instruments — Contact lenses — Part 2: Specification for single-vision hydrogel contact lenses.*

ISO 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

ISO 10993-2:1992, *Biological evaluation of medical devices — Part 2: Animal welfare requirements.*

ISO 10993-10:1995, *Biological evaluation of medical devices — Part 10: Tests for irritation and sensitization.*

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories.*

3 General requirements

The general principles for biological evaluation and categorization of medical devices given in ISO 10993-1 shall apply. Tests shall be performed in accordance with ISO/IEC Guide 25.

Tests for irritation and sensitization of contact lenses and contact lens care products shall be carried out in accordance with ISO 10993-10.

The assessment of the results shall be carried out by appropriately experienced and competent personnel .

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1) To be published.