



SLOVENSKI STANDARD

SIST EN ISO 9394:2013

01-januar-2013

Nadomešča:

SIST EN ISO 9394:2000

Očesna optika - Kontaktne leče in izdelki za vzdrževanje kontaktnih leč - Ugotavljanje biološke združljivosti z raziskavo na očeh kuncev (ISO 9394:2012)

Ophthalmic optics - Contact lenses and contact lens care products - Determination of biocompatibility by ocular study with rabbit eyes (ISO 9394:2012)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Bestimmung der Biokompatibilität durch Erprobung am Kaninchenauge (ISO 9394:2012)

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 9394:2012)

Ta slovenski standard je istoveten z: EN ISO 9394:2012

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

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en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 9394

October 2012

ICS 11.040.70

Supersedes EN ISO 9394:1998

English Version

Ophthalmic optics - Contact lenses and contact lens care products - Determination of biocompatibility by ocular study with rabbit eyes (ISO 9394:2012)

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 9394:2012)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Bestimmung der Biokompatibilität durch Erprobung am Kaninchenaug (ISO 9394:2012)

This European Standard was approved by CEN on 30 September 2012.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

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Foreword

This document (EN ISO 9394:2012) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" 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 April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.

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 9394:1998.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Endorsement notice

The text of ISO 9394:2012 has been approved by CEN as a EN ISO 9394:2012 without any modification.

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INTERNATIONAL STANDARD

**ISO
9394**

Third edition
2012-10-01

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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ISO 9394:2012(E)

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

This third edition cancels and replaces the second edition (ISO 9394:1998), which has been technically revised.

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Introduction

The ocular tissue of the rabbit is 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 Standard 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), it is recommended that this *in vivo* test be carried out after obtaining data of *in vitro* toxicological testing such as that described in ISO 10993-5.

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

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