SVENSK STANDARD
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Ögonoptik – Kontaktlinser och skötselprodukter för kontaktlinser – Bestämning av biokompatibilitet genom provning på kaninögon (ISO 9394:2012)

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

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Europastandarden EN ISO 9394:2012 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 9394:2012.

Denna standard ersätter SS-EN ISO 9394, utgåva 1.

The European Standard EN ISO 9394:2012 has the status of a Swedish Standard. This document contains the official version of EN ISO 9394:2012.

This standard supersedes the Swedish Standard SS-EN ISO 9394, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Ögonoptik, SIS/TK 336.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 9394

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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 Kaninchenauge (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.

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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.

Endorsement notice

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

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.

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 both novel contact lens material 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 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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

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

ISO 18369-1, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

OECD 1997, *OECD Principles of Good Laboratory Practice, No.1*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 apply.

4 General requirements

The general principles for biological evaluation and categorization of medical devices given in ISO 10993-1 shall apply. The study shall be performed in accordance with ISO/IEC 17025 and Good Laboratory Practice (GLP) (OECD, Principles of Good Laboratory Practice, No.1).

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.

5 Animals and husbandry

5.1 New Zealand white strain rabbits (male, female or mixed sexes) or equivalent albino rabbits shall be used to test each type of contact lens or lens care product. They shall be healthy young adults from a single strain

from a single recognized source weighing > 2,5 kg. They shall have eyes free from clinically significant ocular irritation or corneal retention of fluorescein stain.

A minimum number of three rabbits shall be used, however a number of six is recommended to ensure an acceptable level of precision of the test results. If less than six rabbits are used, then the quantity shall be justified.

If control articles are included in the evaluation, use the contra-lateral eye or an additional group of animals with the same number of animals chosen as before for each control article. For contact lens care products, the control group should use the same type of contact lens which has not been treated with the test product.

Positive controls shall not be used.

NOTE In this context, “control article“ should be interpreted as being a device with defined safety and performance characteristics.

5.2 The animal welfare requirements set out in ISO 10993-2 shall be met.

5.3 The animals shall be housed individually and have free access to commercially pelted rabbit feed and tap water. Group housing is not feasible in this test since any lens found expulsed from the eye shall be matched to the specific rabbit which wore the lens and re-inserted into the same eye.

5.4 Each animal shall be identified by one of the following:

a) a numbered ear tag;

b) a tattoo;

c) a microchip; or

d) a permanent ink marking.

The animals shall be acclimatized to the laboratory conditions for at least five days prior to testing.

5.5 The nictitating membrane should not be removed from the rabbits’ eyes, and the eyelids should not be sutured during lens wear. Any deviations shall be justified and documented in the test report.

NOTE The albino rabbit eye is free of pigment, easily examined and has historically been used for ocular irritation studies.

All appropriate regulatory requirements governing the care and use of animals shall be followed.

5.6 During daily treatment, the rabbits shall be minimally restrained.

6 Reagents/materials

6.1 **Sodium fluorescein**, as specified by an appropriate pharmacopoeia.

NOTE Attention should be made to the degree of staining and the concentration of fluorescein administered to the eye (e.g. 3 µl of 1 % fluorescein in saline solution).

6.2 **Contact lens care products**, as recommended by the manufacturers.

6.3 **Contact lenses**, as recommended by the manufacturer.

7 Apparatus

7.1 **Slit lamp microscope**, with appropriate filters.

7.2 **Magnifying glass**, of minimum magnification 6×.

7.3 **Balance or weighing machine**, capable of weighing up to 5 kg to an accuracy of 100 g.

8 Test specimens

8.1 Lens parameters

Contact lenses shall be sufficiently thick to represent either

a) reasonable human use extremes; or

b) the extreme of the manufacturer's product line.

The contact lens selected shall produce a good fit to a rabbit eye.

NOTE This is necessary to minimize physical irritation and expulsion. In the case where this thickness does not allow a good fit of the contact lens, a contact lens of the greatest thickness which allows a good fit should be used.

Contact lens parameters shall be documented in the final report.

8.2 Preparation and storage

If contact lens care products are to be used in the evaluation, lenses shall be prepared, cleaned, disinfected, stored and rinsed according to the lens manufacturer's instructions using contact lens care products (6.2). If a lens falls out during the daily treatment period, it shall be rinsed with rinsing solution (6.2) and re-inserted into the rabbit's eye from which it has fallen out.

NOTE 1 Sufficient additional lenses should be treated using at least one complete daily lens care treatment to replace any lenses that are damaged or lost during the lens-wear day.

NOTE 2 Hydrogel lenses which cannot be immediately reinserted because of drying should be swapped for a similar lens which has been treated in line with the manufacturer's recommendations. Hydrogel lenses which have dried out may be re-used once cleaned and/or rehydrated.

Before insertion, contact lenses should be checked for particulate matter, physical damage and, during hydrogel lens use, for lens inversion. While inserting contact lenses, rabbits shall be observed for reactions different to that during the insertion of a control lens. Such reactions shall be recorded.

Contact lenses shall not be intermixed between rabbits in the same treatment group.

If applicable, lens storage cases shall not be intermixed between treatment groups.

For evaluation of contact lens care products, for example multipurpose solutions, testing with representative conventional and silicone hydrogel lenses should be conducted with the lens care product. The choice of lenses should be justified.

9 Test procedure

9.1 Preliminary examination of animals

9.1.1 The preliminary examination may not be made longer than 24 h before commencement of the test.

9.1.2 Using the balance (7.3), weigh the rabbits and record the mass.