STANDARDISERINGEN I SVERIGE
SWEDISH INSTITUTE FOR STANDARDS

SVENSK STANDARD SS-EN ISO 9394

Handläggande organ	Fastställd	Utgåva	Sida
Hälso- och sjukvårdsstandardiseringen, HSS	1998-10-09	1	1 (1+16)

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

The European Standard EN ISO 9394:1998 has the status of a Swedish Standard. This document contains the official English version of EN ISO 9394: 1998.

Swedish Standards corresponding to documents referred to in this Standard are listed in ”Catalogue of Swedish Standards”, issued by SIS. The Catalogue lists, with reference number and year of Swedish approval, International and European Standards approved as Swedish Standards as well as other Swedish Standards.

Ögonoptik – Kontaktlinser och skötselprodukter för kontaktlinser – Bestämning av biokompatibilitet genom provning på kaninögon (ISO 9394:1998)

Europastandarden EN ISO 9394:1998 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 9394:1998.

Motsvarigheten och aktualiteten i svensk standard till de publikationer som omnämns i denna standard framgår av ”Katalog över svensk standard”, som ges ut av SIS. I katalogen redovisas internationella och europeiska standarder som fastställts som svenska standarder och övriga gällande svenska standarder.

ICS 11.040.70

Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.
Postadress: SIS, Box 6455, 113 82 STOCKHOLM
Telefon: 08 - 610 30 00. *Telefax*: 08 - 30 77 57

Upplysningar om **sakinnehållet** i standarden lämnas av HSS.
Telefon: 08 - 702 49 00. *Telefax*: 08 - 702 49 15
E-post: hss@hss.se
Prisgrupp P
Tryckt i november 1998

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 9394

August 1998

ICS 11.040.70
Descriptors: optics, optical equipment, ophthalmic equipment, contact lenses, care products, tests, biological tests, determination, biocompatibility

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.

The European Standards exist 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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

Ref. No. EN ISO 9394:1998 E

Contents

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).

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 .

---

1) To be published.

4 Animals and husbandry

4.1 New Zealand white strain rabbits (male, female, or mixed sexes) shall be used to test each type of contact lens or contact 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 contralateral 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.

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

4.3 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.

4.4 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 5 days prior to testing.

4.5 The nictitating membrane should not be removed from the rabbit's eye, and the eyelids should not be sutured during lens wear.

NOTE 1 The albino rabbit eye is free of pigment, easily examined and has historically been used for ocular irritation studies.

NOTE 2 If the nictitating membranes are excised from the eyes of the rabbit, this should be done at least two weeks before the experiment. Such treatment shall be mentioned in the final report.

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

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

5 Reagents/Materials

5.1 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).

5.2 Contact lens care products, as recommended by the manufacturers.

5.3 Contact lenses, as recommended by the manufacturer.