BS EN ISO 9394:2012

BSI Standards Publication

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

This British Standard is the UK implementation of EN ISO 9394:2012. It supersedes BS EN ISO 9394:1998, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/9, Contact lenses and contact lens care products.

A list of organizations represented on this committee can be obtained on request to its secretary.



ISBN 978 0 580 74794 6

ICS 11.040.70

**Compliance with a British Standard cannot confer immunity from legal obligations.**

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 October 2012.

**Amendments issued since publication**

| Date | Text affected |
|---|---|

# EUROPÄISCHE NORM

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 Kaninchenauge (ISO 9394:2012)

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

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Ref. No. EN ISO 9394:2012: E

# 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of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.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.

# Contents

## 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.

## 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