

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

The European Standard EN ISO 9394:1998 has the status of a British Standard

ICS 11.040.70

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# National foreword

This British Standard is the English language version of EN ISO 9394:1998. It is identical with ISO 9394:1998.

The UK participation in its preparation was entrusted to Technical Committee CH/26, Biological testing of medical and dental materials and devices, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

### Cross-references

Attention is drawn to the fact that CEN and CENELEC standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

For in vivo tests, attention is drawn to the provisions of the Animals (Scientific Procedures) Act 1986.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

**Compliance with a British Standard does not of itself confer immunity from legal obligations.**

### Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN ISO title page, page 2, the ISO title page, pages ii to iv, pages 1 to 9 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 October 1998

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### Amendments issued since publication

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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.

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## CEN

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).