



SLOVENSKI STANDARD
SIST EN ISO 9341:2000
01-januar-2000

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Optics and optical instruments - Contact lenses - Determination of inclusions and surface imperfections for rigid contact lenses (ISO 9341:1996)

Optik und optische Instrumente - Kontaktlinsen - Bestimmung der Einschlüsse und Oberflächenfehler von formstabilen Kontaktlinsen (ISO 9341:1996)

Optique et instruments d'optique - Lentilles de contact - Détermination des inclusions et imperfections de surface des lentilles de contact rigides (ISO 9341:1996)

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Ta slovenski standard je istoveten z: EN ISO 9341:1998

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

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EUROPEAN STANDARD
 NORME EUROPÉENNE
 EUROPÄISCHE NORM

EN ISO 9341

July 1998

ICS 11.040.70

Descriptors: see ISO document

English version

**Optics and optical instruments - Contact lenses - Determination
 of inclusions and surface imperfections for rigid contact lenses
 (ISO 9341:1996)**

Optique et instruments d'optique - Lentilles de contact -
 Détermination des inclusions et imperfections de surface
 des lentilles de contact rigides (ISO 9341:1996)

Optik und optische Instrumente - Kontaktlinsen -
 Bestimmung der Einschlüsse und Oberflächenfehler von
 formstabilen Kontaktlinsen (ISO 9341:1996)

This European Standard was approved by CEN on 22 June 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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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 from Technical Committee ISO/TC 172 "Optics and optical instruments" of the International Organization for Standardization (ISO) has been taken over as an European Standard by 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 January 1999, and conflicting national standards shall be withdrawn at the latest by January 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 9341:1996 was approved by CEN as a European Standard without any modification.

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INTERNATIONAL
STANDARD

ISO
9341

First edition
1996-08-15

**Optics and optical instruments — Contact
lenses — Determination of inclusions and
surface imperfections for rigid contact
lenses**

iTeh STANDARD PREVIEW
(standards.iteh.ai)

*Optique et instruments d'optique — Lentilles de contact — Détermination
des inclusions et imperfections de surface des lentilles de contact rigides*



Reference number
ISO 9341:1996(E)

ISO 9341:1996(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.

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.

International Standard ISO 9341 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annex A forms an integral part of this International Standard.

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Optics and optical instruments — Contact lenses — Determination of inclusions and surface imperfections for rigid contact lenses

1 Scope

This International Standard describes a procedure for the assessment of inclusions and surface imperfections for rigid contact lenses. Surface markings intentionally made are not regarded as surface imperfections.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was 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 edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8320:1986, *Optics and optical instruments — Contact lenses — Vocabulary and symbols*.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8320 apply.

4 Test conditions

4.1 Resolution

For an observer with normal visual acuity, the method shall be capable of resolving any inclusion greater than $3\ \mu\text{m}$ in any direction and any surface imperfection greater than $9\ \mu\text{m}$ in any direction.

4.2 Illumination

The illumination of the contact lens to be examined shall be (350 ± 35) lx including the room illumination.

4.3 Measuring temperature

The contact lens and measuring devices shall be maintained at temperatures of (20 ± 5) °C.

5 Recommended method

A method for assessing material inclusions (e.g. bubbles, striae, fissures, residual granulates and foreign substances) and surface imperfections (e.g. scratches, matt areas and marginal chips) is described in annex A.

Other methods which fulfil the requirements of clause 4 are also allowed.

Annex A

(normative)

Inspection method for assessment of inclusions and surface imperfections of rigid contact lenses

A.1 Principle

The test is effected on a light-dark border with the apparatus according to figure A.1.

A.2 Procedure

Carry out the test with the lens in a dry state. Place the lens on the contact lens support (see figure A.1), ensuring that the lens is not deformed. With the aid of the magnifying device, view the lens at a light-dark border and record the defects as indicated in table A.1.

The observer shall be skilled in the recognition of rigid contact lens defects.

For the observation of inclusions, a $\times 6$ magnifying device shall be used and for the observation of surface imperfections, $\times 2$ magnification shall be used.

A.3 Designation of size of defects

The size and location of any defects shall be designated according to the classification given in table A.1.

Table A.1 — Rating scheme for designating the size of defects (order of magnitude)

Class	Size of defects
0	not visible under $\times 6$ magnification
1	not visible under $\times 2$ magnification
2	visible under $\times 6$ magnification
3	visible under $\times 2$ magnification

A.4 Test report

The test report shall contain at least the following information:

- a) a reference to this International Standard;
- b) the identification of the contact lens tested;
- c) description of defect (surface imperfections or inclusions);
- d) the class of defects;
- e) date of the examination.