



SLOVENSKI STANDARD
SIST EN ISO 10344:2000
01-januar-2000

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Optics and optical instruments - Contact lenses - Saline solution for contact lens testing
(ISO 10344:1996)

Optik und optische Instrumente - Kontaktlinsen - Kochsalzlösung für die Prüfung von
Kontaktlinsen (ISO 10344:1996)

Optique et instruments d'optique - Lentilles de contact - Solution saline pour les essais
des lentilles de contact (ISO 10344:1996)

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Ta slovenski standard je istoveten z: EN ISO 10344:1998

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10344

July 1998

ICS 11.040.70

Descriptors: see ISO document

English version

Optics and optical instruments - Contact lenses - Saline solution
for contact lens testing (ISO 10344:1996)

Optique et instruments d'optique - Lentilles de contact -
Solution saline pour les essais des lentilles de contact (ISO
10344:1996)

Optik und optische Instrumente - Kontaktlinsen -
Kochsalzlösung für die Prüfung von Kontaktlinsen (ISO
10344:1996)

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.

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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 10344:1996 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in Annex ZA (normative).

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ANNEX ZA (normative)**Normative references to international publications with their corresponding European publications**

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 3696	1987	Water for analytical laboratory use Specification and test methods	EN ISO 3696	1995

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INTERNATIONAL
STANDARD

ISO
10344

First edition
1996-09-01

**Optics and optical instruments — Contact
lenses — Saline solution for contact lens
testing**

iTeh STANDARD PREVIEW

(standards.iteh.ai)

*Optique et instruments d'optique — Lentilles de contact — Solution saline
pour les essais des lentilles de contact*

SIST EN ISO 10344:2000

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Reference number
ISO 10344:1996(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.

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International Standard ISO 10344 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annex A of this International Standard is for information only.

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International Organization for Standardization

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Optics and optical instruments — Contact lenses — Saline solution for contact lens testing

1 Scope

This International Standard specifies a saline solution for use when conducting specified standardized test methods to determine dimensional, physical, chemical and biological characteristics of contact lenses and contact lens materials.

The specified solution is applicable to the equilibrating of either a contact lens or a contact lens material prior to testing, and also to the immersion of the test item during testing.

The specified solution is not intended for the purpose of packaging finished contact lenses but is similar to many commercially used contact lens packaging solutions.

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 3696:1987, *Water for analytical laboratory use — Specification and test methods*.

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 Requirements

4.1 General

The standard saline solution shall be phosphate buffered at a pH of $7,4 \pm 0,1$ and have a nominal osmolarity of 310 mOsm/kg.

4.2 Ingredients

The standard saline shall be prepared using hydrated sodium phosphate salts which comply with the requirements of monographs in current official pharmacopoeia such as the US Pharmacopoeia (USP), the European Pharmacopoeia (Ph Eur) or various national pharmacopoeia. The liquid phase is water complying with ISO 3696:1987, grade 3 or any purer standardized grade. Water shall be either freshly prepared or sterilized within 24 h of preparation of the standard solution.

4.3 Formulation in molarities

The following molar concentrations shall be applicable to the finished solution.

- sodium chloride (NaCl) $1,420 \times 10^{-1}$ M
- sodium dihydrogen phosphate (NaH_2PO_4) $3,384 \times 10^{-3}$ M
- disodium phosphate (Na_2HPO_4) $1,673 \times 10^{-2}$ M