



SLOVENSKI STANDARD SIST EN ISO 11987:2000

01-januar-2000

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Optics and optical instruments - Contact lenses - Determination of shelf-life (ISO 11987:1997)

Augenoptik - Kontaktlinsen - Bestimmung der Lagerdauer (ISO 11987:1997)

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Optique et instruments d'optique - Lentilles de contact - Détermination de la durée de conservation (ISO 11987:1997)

[SIST EN ISO 11987:2000](https://standards.iteh.ai/catalog/standards/sist/113f3bd8-079c-404f-917a-8c1001a4c52f/sist-en-iso-11987-2000)

Ta slovenski standard je istoveten z: **EN ISO 11987:1997**

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 11987:2000

en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11987

December 1997

ICS 11.040.70

Descriptors: see ISO document

English version

Optics and optical instruments - Contact lenses - Determination
of shelf-life (ISO 11987:1997)

Optique et instruments d'optique - Lentilles de contact -
Détermination de la durée de conservation (ISO
11987:1997)

Augenoptik - Kontaktlinsen - Bestimmung der Lagerdauer
(ISO 11987:1997)

This European Standard was approved by CEN on 30 October 1997.

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 ISO 11987 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 June 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

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 11987:1997 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative). A-deviations are given in Annex ZB (informative).

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Annex ZA (normative)**Normative references to international publications
with their relevant European publications**

This European Standard incorporates by dated or undated reference, 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.

Publication	Year	Title	EN	Year
ISO 8321-1	1991	Optics and optical instruments - Contact lenses - Part 1: Specification for rigid corneal and scleral contact lenses	EN ISO 8321-1	1996
ISO 8599	1994	Optics and optical instruments - Contact lenses - Determination of the spectral and luminous transmittance	EN ISO 8599	1996
ISO 10338	1996	Optics and optical instruments - Contact lenses - Determination of curvature	EN ISO 10338	1997

ANNEX ZB (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard does not fall under any Directive of the EC. In the relevant CEN/CENELEC countries these A-deviations are valid instead of the provisions of the European Standard until they have been removed.

The legislative situation in Germany requires the unit "dioptré" be designated by the symbol "dpt" instead of "D".

This is to avoid conflict with the rules of ISO 1000 being the basic International Standard on symbols and units and with the respective basic resolution of the CGPM (International Conference on Weights and Measures).

Identification of the regulation:

Gesetz über die Einheiten im Meßwesen vom 02.07.1969 in der Fassung der Bekanntmachung vom 22.04.1985; and

Ausführungsverordnung zum Gesetz über Einheiten im Meßwesen (Einheitenverordnung - EinhV) vom 13.12.1985, § 1 und Anlage 1, Nr. 9

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INTERNATIONAL STANDARD

ISO
11987

First edition
1997-12-01

Ophthalmic optics — Contact lenses — Determination of shelf-life

*Optique ophtalmique — Lentilles de contact — Détermination de la durée
de conservation*

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Reference number
ISO 11987:1997(E)

ISO 11987:1997(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 11987 was prepared by 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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Introduction

The tests included in this International Standard are designed to obtain information that will enable proposals to be made for the shelf-life of the contact lens, and enable storage conditions to be recommended. However in practical terms it is the stability of the material from which the contact lens is made that is being tested, along with the integrity of the packaging that maintains the environment necessary for the contact lens.

The purpose of the stability studies is to ascertain how the quality of the contact lens varies as a function of time and under the influence of a variety of environmental factors. On the basis of the information thus obtained, storage conditions can be recommended which will guarantee the maintenance of the quality of the contact lens in relation to its safety, efficacy and acceptability, throughout the proposed shelf-life (i.e. during storage and distribution until the moment of dispensing).

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