



SLOVENSKI STANDARD
SIST EN ISO 13212:2000

01-januar-2000

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Ophthalmic optics - Contact lens care products - Guidelines for the determination of shelf-life (ISO 13212:1999)

Augenoptik - Kontaktlinsenpflegemittel - Leitfaden für die Bestimmung der Lagerdauer (ISO 13212:1999)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Optique ophtalmique - Produits d'entretien pour lentilles de contact - Lignes directrices pour la détermination de la durée de conservation (ISO 13212:1999)

<https://standards.iteh.ai/catalog/standards/sist/f70ae953-3295-4e35-b6b1-2a7c05014560/sist-en-iso-13212-2000>

Ta slovenski standard je istoveten z: EN ISO 13212:1999

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 13212:2000

en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 13212

May 1999

ICS 11.040.00

English version

Ophthalmic optics - Contact lens care products - Guidelines for the determination of shelf-life (ISO 13212:1999)

Optique ophtalmique - Produits d'entretien pour lentilles de contact - Lignes directrices pour la détermination de la durée de conservation (ISO 13212:1999)

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This European Standard was approved by CEN on 1 May 1999.

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

Page 2
EN ISO 13212:1999

Foreword

The text of the International Standard ISO 13212:1999 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 November 1999, and conflicting national standards shall be withdrawn at the latest by November 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.

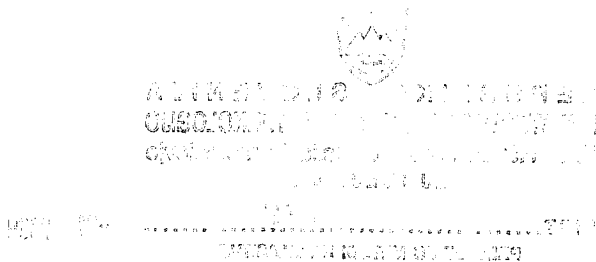
Endorsement notice

The text of the International Standard ISO 13212:1999 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 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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 14534	1997	Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements	EN ISO 14534	1997

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INTERNATIONAL
STANDARD

ISO
13212

First edition
1999-05-01

Corrected and reprinted
1999-12-01

**Ophthalmic optics — Contact lens care
products — Guidelines for determination
of shelf-life**

*Optique ophtalmique — Produits d'entretien pour lentilles de contact —
Lignes directrices pour la détermination de la durée de conservation*

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Reference number
ISO 13212:1999(E)

ISO 13212:1999(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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 13212 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
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

Printed in Switzerland

Introduction

The purpose of stability tests of contact lens care products is to obtain sufficient information to enable the manufacturer to establish an appropriate shelf-life and identify any unique storage conditions required to appear on the labelling for the product.

The quality of a contact lens care product is determined by its content of active ingredient(s), its purity and its physicochemical and microbiological properties. Due account should be taken of possible interaction of the container/closure with the contents.

The stability studies should ascertain how the quality of a product 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 are recommended which will guarantee maintenance of the quality of the product, in relation to its safety, performance and acceptability, throughout the proposed shelf-life.

The design of the finished-product stability studies for a contact lens care product is based on knowledge obtained from studies on the active ingredient(s) and from the development studies.

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