



SLOVENSKI STANDARD
SIST EN ISO 11986:2000
01-november-2000

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Xc`c Ub^Ydf]j nYa U]b`gdfcgh]j YgfYXghj U_{nU} cbnYfj jfUb^YGC`%%, *.% -- Ł

Ophthalmic optics - Contact lenses and contact lens care products - Guidelines for the determination of preservative uptake and release (ISO 11986:1999)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Leitfaden für die Bestimmung der Aufnahme und Wiederfreisetzung von Konservierungsmitteln (ISO 11986:1999)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Lignes directrices pour la détermination de l'absorption/adsorption et le relargage des conservateurs (ISO 11986:1999)

<https://standards.iteh.ai/catalog/standards/sist/b3114e33-f191-4138-95ad-a7360564fe5/sist-en-iso-11986-2000>

Ta slovenski standard je istoveten z: EN ISO 11986:2000

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 11986:2000 en

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EUROPEAN STANDARD
 NORME EUROPÉENNE
 EUROPÄISCHE NORM

EN ISO 11986

May 2000

ICS 11.040.70

English version

Ophthalmic optics - Contact lenses and contact lens care products - Guidelines for the determination of preservative uptake and release (ISO 11986:1999)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Lignes directrices pour la détermination de l'absorption/adsorption et le relargage des conservateurs (ISO 11986:1999)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Leitfaden für die Bestimmung der Aufnahme und Wiederfreisetzung von Konservierungsmitteln (ISO 11986:1999)

This European Standard was approved by CEN on 17 April 2000.

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 November 2000, and conflicting national standards shall be withdrawn at the latest by November 2000.

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

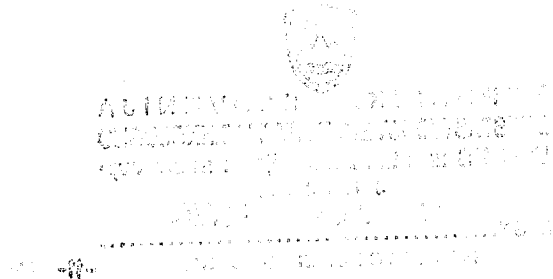
The text of the International Standard ISO 11986:1999 has been approved by CEN as a European Standard without any modification.

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.

Publication	Year	Title	EN	Year
ISO 10344	1996	Optics and optical instruments - Contact lenses - Saline solution for contact lens testing	EN ISO 10344	1998

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INTERNATIONAL STANDARD

ISO
11986

First edition
1999-05-01

Ophthalmic optics — Contact lenses and contact lens care products — Guidelines for determination of preservative uptake and release

*Optique ophtalmique — Lentilles de contact et produits d'entretien pour
lentilles de contact — Lignes directrices pour la détermination de
l'absorption/adsorption et le relargage des conservateurs*

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Reference number
ISO 11986:1999(E)

ISO 11986:1999(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 11986 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

Printed in Switzerland

Introduction

Contact lens care products are a complex mixture of organic and inorganic substances. For reasons of microbiological safety, contact lens disinfecting solutions, as well as care products in multi-use containers, contain substances with antimicrobial activity. From many years of experience in contact lens wear, it is known that irritation and sensitization problems sometimes occur due to these preservatives being absorbed and released by the matrix of the contact lens. For these reasons, it is necessary to be able to estimate the extent of preservative uptake and release by contact lenses.

The preservative uptake and release test provides general guidance on measuring the uptake of preservatives in solution by contact lenses and the release of preservatives from contact lenses in an aqueous medium. The analytical method to be used for quantification of specific preservatives is not indicated here. Chemical characteristics of the preservative as well as concentration in the contact lens care product and degree of uptake by the contact lens must be taken into consideration in selecting an appropriate analytical method. Contact lens uptake and release data may be useful in characterizing the potential for a new or modified contact lens material to produce a toxic or irritating reaction in the eye from the uptake and binding or release of preservatives from currently marketed contact lens care products.

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