

**Ophthalmic optics - Contact lens care products - Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses**

Ophthalmic optics - Contact lens care products - Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 14729:2001 sisaldab Euroopa standardi EN ISO 14729:2001 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 19.12.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 14729:2001 consists of the English text of the European standard EN ISO 14729:2001.</p> <p>This document is endorsed on 19.12.2001 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p><b>Käsitlusala:</b></p> <p>This Standard specifies two test methods for evaluating the antimicrobial activity of products to be marketed for contact lens disinfection by chemical means and for products that are part of a contact lens care regimen.</p> <p>This Standard is not applicable to the hygienic management of trial lenses.</p>	<p><b>Scope:</b></p> <p>This Standard specifies two test methods for evaluating the antimicrobial activity of products to be marketed for contact lens disinfection by chemical means and for products that are part of a contact lens care regimen.</p> <p>This Standard is not applicable to the hygienic management of trial lenses.</p>
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**ICS 11.040.70**

**Võtmesõnad:** contact lenses, definition, definitions, hygiene, maintenance instructions, management, microbiology, ophtalmic optics, optical equipment, preservative agents, product specification, specification (approval), specifications, testing

ICS 11.040.70

English version

**Ophthalmic optics - Contact lens care products - Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses (ISO 14729:2001)**

Optique ophtalmique - Produits d'entretien des lentilles de contact - Exigences microbiologiques et méthodes d'essai des produits et protocoles d'entretien des lentilles de contact (ISO 14729:2001)

Augenoptik - Kontaktlinsenpflegemittel - Mikrobiologische Anforderungen und Prüfverfahren für Produkte und Systeme zum Hygienemanagement von Kontaktlinsen (ISO 14729:2001)

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## **Foreword**

The text of the International Standard ISO 14729:2001 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 October 2001, and conflicting national standards shall be withdrawn at the latest by October 2001.

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 14729:2001 was approved by CEN as a European Standard without any modification.

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products — Microbiological requirements  
and test methods for products and  
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*Optique ophtalmique — Produits d'entretien des lentilles de contact —  
Exigences microbiologiques et méthodes d'essai des produits et protocoles  
d'entretien des lentilles de contact*



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## 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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14729 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annexes A to E of this International Standard are for information only.



## Introduction

Products for contact lens disinfection by chemical means are intended to reduce microbial contamination introduced during lens wear and removal, cleaning and storage and are required to contain antimicrobial agents capable of achieving this.

It is essential that all liquid contact lens care products are sterile until opened. Dry products (tablets, granules, etc.) should be subject to control of microbial contamination and should be dissolved in a suitable diluent immediately prior to use. Multidose contact lens care products must be adequately preserved or be packaged in a container designed and labelled to minimize the risk of injury resulting from in-use contamination.

Contact lenses are normally subject to a regimen of cleaning and contact lens disinfection between periods of wear. Aqueous solutions containing cleaning and/or disinfecting agents are commonly used for this purpose. These products may be marketed as solutions or as tablets for dissolution immediately prior to use in a suitable diluent such as saline.

The past 20 years of experience in the use and regulation of contact lens disinfecting products has shown distinct disinfecting antimicrobial criteria for this class of medical devices. Ocular toxicology concerns, process convenience and product comfort on the eye, have meant an evolution of products which maintain a low incidence of contact lens associated ocular infection when used as instructed by the manufacturer. This International Standard gives these distinct contact lens disinfecting antimicrobial criteria along with annexes to explain why viruses (annex C) and Acanthamoeba (annex D) are not included as challenges. Organic soil is not required for evaluation of contact lens care disinfecting products but may be used; an informative annex (annex E) is included to discuss organic soil in the context of contact lenses and contact lens care products.



# Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses

## 1 Scope

This International Standard specifies two test methods for evaluating the antimicrobial activity of products to be marketed for contact lens disinfection by chemical means and for products that are part of a contact lens care regimen.

This International Standard is not applicable to the hygienic management of trial lenses.

NOTE General disinfection product standards are not applicable to contact lens care products, e.g. EN 1040:1997 and EN 1275:1997.

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8320-1:—<sup>1)</sup>, *Contact lenses and contact lens care products — Vocabulary — Part 1: Contact lenses.*

ISO 8320-2:—<sup>1)</sup>, *Contact lenses and contact lens care products — Vocabulary — Part 2: Contact lens care products.*

## 3 Terms and definitions

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

### 3.1

#### **contact lens disinfecting product**

product that possesses cidal activity (kills, destroys and/or inactivates) meeting the primary criteria of the stand-alone test specified in this International Standard

### 3.2

#### **contact lens disinfecting regimen**

contact lens care regimen designed to meet both the secondary criteria of the stand-alone test and the regimen test as specified in this International Standard

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1) To be published. (Revision of ISO 8320:1986)