SLOVENSKI STANDARD
SIST EN ISO 14729:2002

01-maj-2002

Oļ esna optika - Kontaktne leļ e in izdelki za vzdrģevanje kontaktnih leļ ï Mikrobiologķke zahteve in preskusne metode za izdelke in postopki higienskega ravnanja s kontaktnimi leļ ami (ISO 14729:2001)

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

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

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11.040.70	Oftalmološka oprema	Ophthalmic equipment

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EUROPEAN STANDARD

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

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This European Standard was approved by CEN on 15 April 2001.

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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 Management Centre 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

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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.

INTERNATIONAL STANDARD

ISO 14729

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

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:—[1)], *Contact lenses and contact lens care products — Vocabulary — Part 1: Contact lenses.*

ISO 8320-2:—[1)], *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

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

3.3
contact lens disinfection
chemical or physical process to reduce the number of viable microorganisms as specified in the performance requirement sections of this International Standard

4 Principle

4.1 General

The stand-alone test is designed to qualify individual solutions with a suitable level of antimicrobial activity as contact lens disinfection products. The regimen test is designed to qualify individual solutions as part of a contact lens disinfecting regimen. Products meeting the regimen test criteria shall also meet the minimum performance requirements of the stand-alone test. It is fundamental that such products (unopened containers) are capable of meeting the requirements of the test throughout their labelled shelf life.

As described in Figure 1, contact lens care solutions which are designed to possess disinfecting properties shall be tested in the stand-alone test first. If the respective primary criteria are met (see 5.1), the product may be labelled as a contact lens disinfecting product. If the product fails the primary criteria of the stand-alone test, the product must exhibit sufficient antimicrobial activity to meet the secondary criteria of the stand-alone test as listed in 5.2. If these secondary criteria are met, the regimen test shall be performed in order to qualify the product as part of a contact lens disinfecting regimen by meeting the regimen criteria (see 5.3). If the product meets both the secondary criteria of the stand-alone test and the regimen test but fails the primary criteria of the stand-alone test, it shall be labelled as part of a contact lens disinfecting regimen.

The design of contact lens care products for cleaning and contact lens disinfection shall take into consideration the needs of patient compliance and the probability of non-compliance. For example, disinfecting time must be appropriate for contact lens wear.

NOTE Use of multiple or mixed microbial challenges can influence the apparent disinfecting activity of a particular product. The evaluation of these variables together with testing against a larger panel of microorganisms and testing of samples from partially used containers may be of value in developing a contact lens care product but are excluded from the scope of this International Standard. (See annexes C and D).

4.2 Stand-alone test (Inoculum challenge test)

The stand-alone test challenges a disinfecting product with a standard inoculum of a representative range of microorganisms and establishes the extent of their viability loss at pre-determined time intervals comparable with those during which the product may be used. The size of the microbial challenge chosen in this test is not intended to be representative of the likely challenge in practice but to provide countable numbers from which estimation of the rate and extent of viability loss can be determined.

In carrying out the test for antimicrobial activity the qualitative and quantitative compositions of the product have to be known at the time of testing by either analytical testing or extrapolation.

Appropriate measures shall be taken to inactivate or remove residual antimicrobial agents during culturing and counting of challenge organism survivors, and the effectiveness of these measures shall be validated. The action of this process during the test shall be demonstrated by the construction of suitable controls.

NOTE For information about virus testing, see annex C, and for *Acanthamoeba* testing, see annex D.