

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

ICS 11.040.70

National foreword

This British Standard is the UK implementation of EN ISO 14729:2001+A1:2010. It is identical with ISO 14729:2001, incorporating amendment 1:2010. It supersedes BS EN ISO 14729:2001 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted by Technical Committee CH/78, Ophthalmic optics, to Subcommittee CH/78/4 Contact lenses and contact lens products.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 July 2001

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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 (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of an identical text or by endorsement, at the latest by October 2001, and conflicting national standards shall be withdrawn at the latest by October 2001.

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The text of the International Standard ISO 14729:2001 was approved by CEN as a European Standard without any modification.

Foreword to amendment A1

The text of this Amendment EN ISO 14729:2001/A1:2010 to the EN ISO 14729 from Technical Committee ISO/TC 172 “Optics and photonics” of the International Organization for Standardization (ISO) has been taken over as an amendment to the European Standard by Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 14729:2001 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2011, and conflicting national standards shall be withdrawn at the latest by April 2011.

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Endorsement notice

The text of ISO 14729:2001/Amd.1:2010 has been approved by CEN as a EN ISO 14729:2001/A1:2010 without any modification.

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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.

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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.

