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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

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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.