

Očná optika Kontaktné šošovky Hygienické zaobchádzanie so skúšobnými kontaktnými šošovkami určenými pre viac ako jedného pacienta (ISO 19979: 2018)

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Ophthalmic optics - Contact lenses - Hygienic management of multipatient use trial contact lenses (ISO 19979:2018)

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

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Ophthalmic optics - Contact lenses - Hygienic management of multipatient use trial contact lenses (ISO 19979:2018)

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EN ISO 19979:2023 (E)

European foreword

The text of ISO 19979:2018 has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 19979:2023 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of an identical text or by endorsement, at the latest by December 2023, and conflicting national standards shall be withdrawn at the latest by December 2023.

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The text of ISO 19979:2018 has been approved by CEN as EN ISO 19979:2023 without any modification.

INTERNATIONAL STANDARD

ISO 19979

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Ophthalmic optics — Contact lenses — Hygienic management of multipatient use trial contact lenses

Optique ophtalmique — Lentilles de contact — Entretien de l'hygiène des lentilles de contact d'essai à usage multipatient





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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition of ISO 19979:2018 cancels and replaces ISO/TS 19979:2014, which has been technically revised. In addition to the change in document type from a Technical Specification to an International Standard, the main changes compared to ISO/TS 19979:2014 are as follows:

- the specific processes of hygienic management have been presented as tables;
- a flow chart of the hygienic management process has been introduced;
- the example of disinfection procedure using hydrogen peroxide has been moved to Annex A;
- editorial revisions have been implemented.

Introduction

Wherever possible, a trial contact lens should be used only on one individual. While the current trend in contact lens development is toward disposable and extended wear lenses, conventional lenses including rigid gas-permeable (RGP) contact lenses, composite contact lenses and hydrogel contact lenses in special designs and parameters are necessary to meet individual patient needs.

The reconditioning of multipatient use contact lenses involves cleaning, disinfection and storage of the contact lenses. The cleaning step is not specified in this document, as it does not differ from the cleaning of contact lenses for end-users.

The hygienic management for multipatient use differs from the requirements of hygienic management for contact lenses for individual use and from surface disinfection used in hospitals.

This document gives guidance for the development of instructions for manufacturers of multipatient use contact lenses, in order to mitigate the risk of pathogen transfer between patients.

Ophthalmic optics — Contact lenses — Hygienic management of multipatient use trial contact lenses

1 Scope

This document provides guidance to manufacturers for the development of information to be provided to eye care practitioners for the hygienic management of trial hydrogel, composite and rigid gaspermeable (RGP) contact lenses intended for multipatient use.

This document does not apply to:

- labelling of contact lenses;
- the inactivation of prions and viruses since there are no standardised methods available for contact lenses.

This document can be used as guidance for the development of a hygienic management procedure for multipatient use.

NOTE ISO 14729 does not cover multipatient use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18369-1, Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications

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