

This document is a preview generated by EVS

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



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 19979:2023 sisaldab Euroopa standardi EN ISO 19979:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 19979:2023 consists of the English text of the European standard EN ISO 19979:2023.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 07.06.2023.	Date of Availability of the European standard is 07.06.2023.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.70

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation and Accreditation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

ICS 11.040.70

English Version

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

Optique ophtalmique - Lentilles de contact - Entretien de l'hygiène des lentilles de contact d'essai à usage multipatient (ISO 19979:2018)

Augenoptik - Kontaktlinsen - Hygienemanagement für Kontaktlinsen zur Anwendung bei mehreren Personen (ISO 19979:2018)

This European Standard was approved by CEN on 28 May 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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.

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

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

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

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Methods of hygienic management for multipatient use trial contact lenses	2
5 Options for hygienic management of multipatient use trial contact lenses	2
5.1 General.....	2
5.2 Disinfection procedure with moist heat.....	4
5.3 Disinfection procedures using an 3 % ophthalmic hydrogen peroxide for 3 h or equivalent.....	5
5.4 Storage of disinfected lenses.....	5
6 Flowchart to describe the use of multipatient use trial contact lenses	5
Annex A (informative) Disinfection procedure using an 3 % ophthalmic hydrogen peroxide solution	7
Bibliography	8

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 gas-permeable (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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1

trial contact lens

diagnostic contact lens

contact lens only used by a practitioner or fitter for the purpose of selecting the appropriate contact lens parameters for the intended wearer

[SOURCE: ISO 18369-1:2017, 3.1.10.8]

3.2

multipatient use trial contact lens

trial contact lens permitted to be used on more than one person

[SOURCE: ISO 18369-1:2017, 3.1.10.9, modified — Note 1 to entry has been deleted.]