ICS 11.040.70 SLOVENSKÁ TECHNICKÁ NORMA Apríl 2026

STN	**Očná optika Kontaktné šošovky a prostriedky na ošetrovanie kontaktných šošoviek Stanovenie absorpcie a uvoľňovania konzervačných látok (ISO 11986: 2026)**	**STN EN ISO 11986** 19 5226

Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release (ISO 11986:2026)

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

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/26

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Oznámením tejto normy sa ruší
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EN ISO 11986

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ICS 11.040.70 Supersedes EN ISO 11986:2017

English Version

Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release (ISO 11986:2026)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Détermination de l'absorption et de la libération des conservateurs (ISO 11986:2026)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Bestimmung der Aufnahme und Wiederfreisetzung von Konservierungsmitteln (ISO 11986:2026)

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European foreword

This document (EN ISO 11986:2026) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" 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of an identical text or by endorsement, at the latest by July 2026, and conflicting national standards shall be withdrawn at the latest by July 2026.

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Endorsement notice

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International Standard

ISO 11986

Ophthalmic optics — Contact lenses and contact lens care products — Determination of preservative uptake and release

Optique ophtalmique — Lentilles de contact et produits d'entretien pour lentilles de contact — Détermination de l'absorption et de la libération des conservateurs

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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 of 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 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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 11986:2017), which has been technically revised.

The main changes are as follows:

— Editorial update of the whole document.

— An additional sentence in the Scope clarifies the circumstances when the test method is to be applied. In particular this test method is only considered for use during the development phase of new or modified contact lens materials or new contact lens care products.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Contact lens care products are a complex mixture of organic and inorganic substances. For reasons of microbiological safety, contact lens disinfecting solutions, as well as care products in multi-use containers, contain substances with antimicrobial activity. From many years of experience in contact lens wear, it is known that irritation and sensitization problems sometimes occur due to these preservatives being absorbed and released by the matrix of the contact lens. For these reasons, it is necessary to be able to estimate the extent of preservative uptake and release by contact lenses.

The preservative uptake and release test provides a general method for measuring the uptake of preservatives in solution by contact lenses and the release of preservatives from contact lenses in an aqueous medium. The analytical method to be used for quantification of specific preservatives is not indicated here. Chemical characteristics of the preservative, as well as concentration in the contact lens care product and degree of uptake by the contact lens, can be taken into consideration in selecting an appropriate analytical method. Contact lens uptake and release data can be useful in characterizing the potential for a new or modified contact lens material to produce a toxic or irritating reaction in the eye from the uptake and binding or release of preservatives from currently marketed contact lens care products.

International Standard **ISO 11986:2026(en)**

Ophthalmic optics — Contact lenses and contact lens care products — Determination of preservative uptake and release

1 Scope

This document provides general procedures for the selection of methods, preparation of samples, and the conduct of testing for the uptake and release of preservatives from contact lenses.

Preservative uptake and release testing is not intended as a routine test of production contact lenses or contact lens care products nor are testing results meant to establish finished goods specifications in any way.

Such testing is carried out when developing new contact lens materials and/or contact lens care products.

NOTE 1 Due to the manifest difficulties of reproducibility when coating contact lenses with mineral and organic deposits encountered during lens wear, these methods are only applicable to new and unused contact lenses.

NOTE 2 Preservative depletion by a contact lens in the limited volume of a lens case could compromise disinfection performance. This document does not measure disinfection performance.

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 18369-3:2017, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*