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ISO 11987

Ophthalmic optics — Contact lenses — Determination of shelf-life

Optique ophtalmique — Lentilles de contact — Détermination de la durée de conservation

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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 instrument*, 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 third edition cancels and replaces the second edition (ISO 11987:2012), which has been technically revised.

The main changes are as follows:

— Editorial update of the whole document.

— An additional sentence in Clause 4 clarifies the circumstances when the test method has to be applied. In particular a variation of a lens design does not require a new shelf-life study.

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.

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Introduction

The tests included in this document are designed to obtain information that enables proposals to be made for the shelf-life of a contact lens, and storage conditions to be recommended. However, in practical terms, it is the stability of the material from which the contact lens is made that is being tested, along with the integrity of the packaging that maintains the environment necessary for the contact lens.

The purpose of the stability studies is to ascertain how the quality of the contact lens varies as a function of time and under the influence of a variety of environmental factors. On the basis of the information thus obtained, storage conditions can be recommended that guarantee the maintenance of the quality of the contact lens in relation to its safety, efficacy and acceptability throughout the proposed shelf-life (i.e. during storage and distribution until the moment of dispensing).

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Ophthalmic optics — Contact lenses — Determination of shelf-life

1 Scope

This document specifies test procedures for determining the stability of contact lenses once they are placed in their final packaging during storage and distribution.

NOTE The results obtained can be used for determining the expiry date.

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*

ISO 18369-2, *Ophthalmic optics — Contact lenses — Part 2: Tolerances*

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

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 Principle

The stability of contact lenses, packaging solution and packaging is established under controlled storage conditions in order to determine their shelf-life under those conditions.

The design of the stability tests is based on the known properties of the material from which the contact lens is made, the packaging system, and the recommendations for storing the contact lens.

Stability assessment, with respect to contact lens, refers to material, not design. Having demonstrated the stability of a single material and packaging system with one or more lens designs, risk assessments shall be examined to determine whether or not additional stability testing should be performed for any substantial change to lens designs.

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