Optika ja optikariistad. Kontaktläätsed. Säilivusaja kindlaksmääramine (ISO 11987:2012)

Ophtalmic optics - Contact lenses - Determination of shelf-life (ISO 11987:2012)

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11987:2012 sisaldab Euroopa standardi EN ISO 11987:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11987:2012 consists of the English text of the European standard EN ISO 11987:2012.
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.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.07.2012.	Date of Availability of the European standard is 15.07.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11987

July 2012

ICS 11.040.70

Supersedes EN ISO 11987:1997

English Version

Ophthalmic optics - Contact lenses - Determination of shelf-life (ISO 11987:2012)

Optique ophtalmique - Lentilles de contact - Détermination de la durée de conservation (ISO 11987:2012)

Augenoptik - Kontaktlinsen - Bestimmung der Lagerdauer (ISO 11987:2012)

This European Standard was approved by CEN on 14 July 2012.

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Ref. No. EN ISO 11987:2012: E

Foreword

This document (EN ISO 11987:2012) 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of an identical text or by endorsement, at the latest by January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.

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

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Endorsement notice

The text of ISO 11987:2012 has been approved by CEN as a EN ISO 11987:2012 without any modification.

Introduction

The tests included in this International Standard 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).

Ophthalmic optics — Contact lenses — Determination of shelf-life

1 Scope

This International Standard 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 referenced documents are indispensable for the application 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.

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.

5 General requirements and recommendations

A risk assessment shall be performed to evaluate the critical properties and parameters, and a test protocol prepared.

NOTE 1 A knowledge of the quantity and identity of extractable substances (see ISO 18369-4) is of particular help in evaluating new contact lens materials and in determining the information that needs to be obtained from the stability testing.

The specifications of the properties and parameters evaluated in the stability study, which are claimed at the time of manufacture and to the end of the proposed shelf-life, should reflect, as far as possible, the results of the stability studies, particularly in relation to any parameters which could have a bearing on efficacy, safety and product acceptability.

In designing stability tests, the manufacturer should consider any sterility requirements.

NOTE 2 Requirements for the development, validation and routine control of sterilization processes are described in other International Standards. Additionally, sterility testing is described in monographs in various pharmacopoeias.