

**Optika ja optikariistad. Kontaktläätsed.
Säilivusaja kindlaksmääramine**

Optics and optical instruments - Contact lenses -
Determination of shelf-life

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11987:1999 sisaldab Euroopa standardi EN ISO 11987:1997 ingliskeelset teksti.

Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 11987:1999 consists of the English text of the European standard EN ISO 11987:1997.

This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation.

The standard is available from Estonian standardisation organisation.

Käsitlusala:

Käesolev rahvusvaheline standard kirjeldab testimist, mis on kohustuslik, et määratleda lõplikult pakitud kontaktläätsede stabiilsust laos hoidmise ja tarnimise aja vältel.

Scope:

ICS 11.040.70

Võtmesõnad: kindlaksmääramine, kontaktläätsed, oftalmiline instrumentarium, optika, optiline instrumentarium, stabiilsus, säilivusaeg, testimine

ICS 11.040.70

Descriptors: Optics, contact lenses, shelf-life.

English version

Ophthalmic optics
Contact lenses

Determination of shelf-life
(ISO 11987 : 1997)

Optique ophtalmique – Lentilles de
contact – Détermination de la durée
de conservation (ISO 11987 : 1997)

Augenoptik – Kontaktlinsen –
Bestimmung der Lagerdauer
(ISO 11987 : 1997)

This European Standard was approved by CEN on 1997-10-30.

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 Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

International Standard

ISO 11987 : 1997 Ophthalmic optics – Contact lenses – Determination of shelf-life,

which was prepared by ISO/TC 172 'Optics and optical instruments' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 170 'Ophthalmic optics', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by June 1998 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11987 : 1997 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International publications are listed in Annex ZA (normative). A-deviations are given in Annex ZB (informative).

Introduction

The tests included in this International Standard are designed to obtain information that will enable proposals to be made for the shelf-life of the contact lens, and enable 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 which will 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).

1 Scope

This International Standard describes the testing required in order to determine the stability of contact lenses, once 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 standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8321-1:1991 *Optics and optical instruments - Contact lenses - Part 1: Specification for rigid corneal and scleral contact lenses*

ISO 8599:1994 *Optics and optical instruments - Contact lenses - Determination of spectral and luminous transmittances*

ISO 9337-1:—¹ *Ophthalmic optics - Contact lenses - Determination of back vertex power - Part 1: Focimeter*

ISO 9338:1996 *Optics and optical instruments - Contact lenses - Determination of the diameters*

ISO 9341:1996 *Optics and optical instruments - Contact lenses - Determination of inclusions and surface imperfections for rigid contact lenses*

ISO 10338:1996 *Optics and optical instruments - Contact lenses - Determination of curvature*

3 Principle

Suitable tests are described by which the stability of contact lenses under controlled storage conditions is established and their shelf-life under those conditions determined.

¹ To be published.