

SLOVENSKI STANDARD oSIST prEN ISO 11979-1:2018

01-marec-2018

Očesni vsadki (implantati) - Intraokularne leče - 1. del: Slovar (ISO/DIS 11979-1:2018)

Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO/DIS 11979-1:2018)

Ophthalmische Implantate - Intraokularlinsen - Teil 1: Vokabular (ISO/DIS 11979-1:2018)

Implants ophtalmiques - Lentilles intraoculaires - Partie 1: Vocabulaire (ISO/DIS 11979-1:2018)

Ta slovenski standard je istoveten z: prEN ISO 11979-1

SIST EN ISO 11979-1:2019

ICS:

01.040.11 Zdravstveno varstvo Health care technology

(Slovarji) (Vocabularies)

11.040.70 Oftalmološka oprema Ophthalmic equipment

oSIST prEN ISO 11979-1:2018 en

oSIST prEN ISO 11979-1:2018

iTeh Standards (https://standards.iteh.ai) Document Preview

<u>SIST EN ISO 11979-1:2019</u>

oSIST prEN ISO 11979-1:2018

DRAFT INTERNATIONAL STANDARD ISO/DIS 11979-1

ISO/TC **172**/SC **7**

Secretariat: DIN

Voting begins on: **2018-01-22**

Voting terminates on:

2018-04-16

Ophthalmic implants — Intraocular lenses —

Part 1: **Vocabulary**

Implants ophtalmiques — Lentilles intraoculaires — Partie 1: Vocabulaire

ICS: 11.040.70; 01.040.11

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 11979-1:2019

https://standards.iteh.ai/catalog/standards/sist/2310ed91-42e1-4aa1-a7d6-d93d1fd0f093/sist-en-iso-11979-1-2019

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING



Reference number ISO/DIS 11979-1:2018(E)

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 11979-1:2019

https://standards.jteh.aj/catalog/standards/sist/2310ed91-42e1-4aa1-a7d6-d93d1fd0f093/sist-en-iso-11979-1-2019



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Ch. de Blandonnet 8 • CP 401 CH-1214 Vernier, Geneva, Switzerland Tel. +41 22 749 01 11 Fax +41 22 749 09 47 copyright@iso.org www.iso.org

Con	tents	Page
Forew	vord	iv
	duction	\
1	Scope	1
2	Normative references	1
3	Torms definitions and abbreviated terms	1

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 11979-1:2019

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 third edition cancels and replaces the second edition (ISO 11979-1:2012), which has been technically revised.

A list of all parts in the ISO 11979- series can be found on the ISO website.

Introduction

This document contains definitions of terms related to intraocular lenses and methods to evaluate them.

Terms are given alphabetically in the englisch version.

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 11979-1:2019

oSIST prEN ISO 11979-1:2018

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 11979-1:2019

Ophthalmic implants — Intraocular lenses —

Part 1:

Vocabulary

1 Scope

This document defines terms applicable to intraocular lenses and to the methods used to evaluate them.

2 Normative references

No normative references are given in this document.

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions 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 http://www.iso.org/obp

3.1.1

accelerated shelf-life study

stability study designed to increase the rate of chemical or physical degradation of a product by using exaggerated storage conditions (e.g. temperature, humidity) to determine kinetic degradation parameters to predict the tentative expiration dating period

3.1.2

accommodating intraocular lens

AIOL

intraocular lens which provides continuous focusing from far point to near point by changing the dioptric power of the eye

3.1.3

accommodative amplitude

difference in refractive power between the near point and the far point of the eye

3.1.4

additional wrapping

container used in addition to the primary packaging and which could be used to maintain sterility of the intraocular lens

3.1.5

addition power

difference between the distance power and the near power of the lens portion, measured under specified conditions

3.1.6

anterior chamber lens

anterior chamber intraocular lensintraocular lens designed to be placed entirely in the anterior chamber of the eye

3.1.7

aspheric intraocular lens

intraocular lens having at least one surface with a monotonically continuously variable curvature from the vertex to the periphery

3.1.8

axis mark

indicator of the meridian of lowest optical power

3.1.9

base power

distance power

far power

power that is intended to provide an in-focus image of an object at infinite distance

3.1.10

best-case subject

subject with no pre-operative ocular pathology, no macular degeneration detected at any time, and no previous surgery for the correction of refractive errors

3.1.11

body

central part of an intraocular lens incorporating the optic

Note 1 to entry: See Figure 1.

iTeh Standards

acorporating the optic

SIST EN ISO 11979-1:2019