



SLOVENSKI STANDARD
SIST EN ISO 11979-4:2000

01-november-2000

C Ygb]j gUX_j]f]a d`UbHUKL!`bhfUc_i`UfbY`Y Y!`("XY.`CnbU Yj Ub`Y]b]bZfa UW`Y
fiGC`%%+!(. &\$\$L

Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information (ISO 11979-4:2000)

Ophthalmische Implantate - Intraokularlinsen - Teil 4: Etikettierung und Information (ISO 11979-4:2000)

ITeH STANDARD PREVIEW
(standards.iteh.ai)

Implants ophtalmiques - Lentilles intraoculaires - Partie 4: Etiquetage et informations (ISO 11979-4:2000)

[SIST EN ISO 11979-4:2000](https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000)

[https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-](https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000)

[4e17d686fc15/sist-en-iso-11979-4-2000](https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000)

Ta slovenski standard je istoveten z: EN ISO 11979-4:2000

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 11979-4:2000

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 11979-4:2000

<https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11979-4

June 2000

ICS 11.040.70

English version

Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information (ISO 11979-4:2000)

Implants ophtalmiques - Lentilles intraoculaires - Partie 4:
Etiquetage et informations (ISO 11979-4:2000)

Ophthalmische Implantate - Intraokularlinsen - Teil 4:
Etikettierung und Information (ISO 11979-4:2000)

This European Standard was approved by CEN on 15 June 2000.

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.

This European Standard exists 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

iTeh STANDARD PREVIEW
(standards.info)

<https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000>



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Foreword

The text of the International Standard ISO 11979-4:2000 has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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 December 2000, and conflicting national standards shall be withdrawn at the latest by December 2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

European Standard EN ISO 11979-4 is part of a standards series developed by CEN/TC 170, *Ophthalmic optics*, in cooperation with ISO/TC 172/SC 7, *Ophthalmic optics and instruments*, and published in several parts under the general title *Ophthalmic implants - Intraocular lenses*:

Part 1: Vocabulary

Part 2: Optical properties and test methods

Part 3: Mechanical properties and test methods

Part 4: Labelling and information

Part 5: Biocompatibility

Part 6: Shelf-life and transport stability

Part 7: Clinical investigations

Part 8: Fundamental requirements

[SIST EN ISO 11979-4:2000](https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000)

<https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000>

Endorsement notice

The text of the International Standard ISO 11979-4:2000 was approved by CEN as a European Standard without any modification.

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

ANNEX ZA (normative)**Normative references to international publications with their corresponding European publications**

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 11979-1	1999	Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary	EN ISO 11979-1	1999

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11979-4:2000](https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000)

<https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000>

ANNEX ZB (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard does not fall under any Directive of the EC. In the relevant CEN/CENELEC countries A-deviations are valid instead of the relevant provisions of the European Standard until they have been removed.

The legislative situation in Germany requires the unit "dioptre" be designated by the symbol "dpt" instead of "D".

This is to avoid conflict with the rules of ISO 1000 being the basic International Standard on symbols and units and with the respective basic resolution of the CGPM (International Conference on Weights and Measures).

Identification of the regulation:

Gesetz über die Einheiten im Messwesen vom 02.07.1969 in der Fassung der Bekanntmachung vom 22.04.1985; and

Ausführungsverordnung zum Gesetz über Einheiten im Messwesen (Einheitenverordnung - EinhV) vom 13.12.1985, § 1 und Anlage 1, Nr. 9

STANDARD PREVIEW
(standards.iteh.ai)
<https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000>

INTERNATIONAL
STANDARD

ISO
11979-4

First edition
2000-06-15

**Ophthalmic implants — Intraocular
lenses —**

**Part 4:
Labelling and information**

*Implants ophtalmiques — Lentilles intraoculaires —
Partie 4: Étiquetage et informations*
(standards.iteh.ai)

[SIST EN ISO 11979-4:2000](https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000)

<https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000>



Reference number
ISO 11979-4:2000(E)

© ISO 2000

ISO 11979-4:2000(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 11979-4:2000](https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000)

<https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000>

© ISO 2000

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 734 10 79
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative reference	1
3 Terms and definitions	1
4 Labelling	1
5 Package insert.....	3
6 Self-adhesive label.....	3
Annex A (informative) Selected terms and definitions.....	5
Bibliography	6

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11979-4:2000](https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000)

<https://standards.iteh.ai/catalog/standards/sist/8565ce4a-6d4a-4d61-8509-4e17d686fc15/sist-en-iso-11979-4-2000>