



**SLOVENSKI STANDARD
SIST EN ISO 8321-2:2000**

01-november-2000

**C YgbUcdhj_U!`GdYWZ_UWY'nUa UhYf]UYžcdh] bY]b`X]a Ybn]`g_Y`Ughbcgh]`
_cbhU_hb]`Y`!`&"XY.9bc[cf]ý bY`_cbhU_hbY`Y Y]n`]Xfc[YUf]GC', ' &%& &\$\$Ł**

Ophthalmic optics - Specifications for materials, optical and dimensional properties of contact lenses - Part 2: Single-vision hydrogel lenses (ISO 8321-2:2000)

Augenoptik - Grundanforderungen an Materialeigenschaften, optische Eigenschaften und Maße von Kontaktlinsen - Teil 2: Einstärken-Hydrogelkontaktlinsen (ISO 8321-2:2000)

(standards.iteh.ai)

Optique ophtalmique - Spécifications des propriétés des matériaux et des propriétés optiques et dimensionnelles des lentilles de contact - Partie 2: Lentilles de contact en hydrogel unifocales (ISO 8321-2:2000)

Ta slovenski standard je istoveten z: EN ISO 8321-2:2000

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 8321-2:2000 en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 8321-2:2000

<https://standards.iteh.ai/catalog/standards/sist/d116fa9d-6d57-441b-a644-a819365e90ac/sist-en-iso-8321-2-2000>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8321-2

March 2000

ICS 11.040.00

English version

Ophthalmic optics - Specifications for material, optical and dimensional properties of contact lenses - Part 2: Single-vision hydrogel lenses (ISO 8321-2:2000)

Optique ophtalmique - Spécifications des propriétés des matériaux et des propriétés optiques et dimensionnelles des lentilles de contact - Partie 2: Lentilles de contact en hydrogel unifocales (ISO 8321-2:2000)

Augenoptik - Grundanforderungen an Materialeigenschaften, optische Eigenschaften und Maße von Kontaktlinsen - Teil 2: Einstärken-Hydrogelkontaktlinsen (ISO 8321-2:2000)

This European Standard was approved by CEN on 1 March 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.



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 8321-2:2000 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 September 2000, and conflicting national standards shall be withdrawn at the latest by September 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.

EN ISO 8321 consists of the following parts, under the general title *Ophthalmic optics - Specifications for material, optical and dimensional properties of contact lenses*:

- Part 1: *Rigid corneal and scleral contact lenses*
- Part 2: *Single-vision hydrogel contact lenses*

Annex A of this part of EN ISO 8321 is for information only.

iTeh STANDARD PREVIEW (standards.iteh.ai)

Endorsement notice

The text of the International Standard ISO 8321-2:2000 was approved by CEN as a European Standard without any modification.

<https://standards.iteh.ai/catalog/standards/sist/d116fa9d-6d57-441b-a644->

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/DIS 8320-1	1997	Optics and optical instruments – Vocabulary on contact lenses and contact lens care products - Part 1: Contact lenses	prEN ISO 8320-1	1997
ISO 8599	1994	Optics and optical instruments - Contact lenses - Determination of the spectral and luminous transmittances	EN ISO 8599	1996
ISO 9337-1	1999	Contact lenses - Determination of back vertex power - Part 1: Method using focimeter with manual focusing	prEN ISO 9337-1	1999
ISO 9338	1996	Optics and optical instruments - Contact lenses - Determination of the diameters	EN ISO 9338	1998
ISO 9339-2	1998	Optics and optical instruments - Contact lenses - Determination of thickness - Part 2: Hydrogel contact lenses	EN ISO 9339-2	1998
ISO 9913-1	1996	Optics and optical instruments - Contact lenses - Part 1: Determination of oxygen permeability and transmissibility with the FATT method	EN ISO 9913-1	1998
ISO 9914	1995	Optics and optical instruments - Contact lenses - Determination of refractive index of contact lens materials	EN ISO 9914	1996
ISO 10338	1996	Optics and optical instruments - Contact lenses - Determination of curvature	EN ISO 10338	1997
ISO 10339	1997	Ophthalmic optics - Contact lenses - Determination of water content of hydrogel lenses	EN ISO 10339	1999
ISO 10344	1996	Optics and optical instruments - Contact lenses - Saline solution for contact lens testing	EN ISO 10344	1998

Page 4
EN ISO 8321-2:2000

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 these A-deviations are valid instead of the provisions of the European Standard until they have been removed.

The legislative situation in Germany requires the unit "dioptr" 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)

SIST EN ISO 8321-2:2000

<https://standards.iteh.ai/catalog/standards/sist/d116fa9d-6d57-441b-a644-a819365e90ac/sist-en-iso-8321-2-2000>

INTERNATIONAL STANDARD

ISO
8321-2

Second edition
2000-03-01

Ophthalmic optics — Specifications for material, optical and dimensional properties of contact lenses —

Part 2: Single-vision hydrogel contact lenses

iTeh **STANDARD PREVIEW**

Optique ophtalmique — Spécifications des propriétés des matériaux et des propriétés optiques et dimensionnelles des lentilles de contact —

Partie 2 : Lentilles de contact en hydrogel unifocales

[SIST EN ISO 8321-2:2000](#)

<https://standards.iteh.ai/catalog/standards/sist/d116fa9d-6d57-441b-a644-a819365e90ac/sist-en-iso-8321-2-2000>



Reference number
ISO 8321-2:2000(E)

© ISO 2000

ISO 8321-2:2000(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 8321-2:2000](https://standards.iteh.ai/catalog/standards/sist/d116fa9d-6d57-441b-a644-a819365e90ac/sist-en-iso-8321-2-2000)

<https://standards.iteh.ai/catalog/standards/sist/d116fa9d-6d57-441b-a644-a819365e90ac/sist-en-iso-8321-2-2000>

© 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
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Requirements for dimensions and optical properties	2
4.1 Test methods.....	2
4.2 Conditioning of contact lenses prior to testing.....	2
4.3 Tolerances	2
5 Requirement for finish.....	2
5.1 Criteria	2
5.2 Inclusions and surface finish	2
5.3 Edge contour and finish.....	2
Annex A (informative) Recommended method for presenting the specifications of single-vision hydrogel contact lenses.....	5
Bibliography	7

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 8321-2:2000](https://standards.iteh.ai/catalog/standards/sist/d116fa9d-6d57-441b-a644-a819365e90ac/sist-en-iso-8321-2-2000)

<https://standards.iteh.ai/catalog/standards/sist/d116fa9d-6d57-441b-a644-a819365e90ac/sist-en-iso-8321-2-2000>