



SLOVENSKI STANDARD SIST EN ISO 21987:2017

01-november-2017

Nadomešča:
SIST EN ISO 21987:2010

Očesna optika - Vdelana stekla očal (ISO 21987:2017)

Ophthalmic optics - Mounted spectacle lenses (ISO 21987:2017)

Augenoptik - Fertig montierte Korrektionsbrillengläser (ISO 21987:2017)

Optique ophtalmique - Verres ophtalmiques montés (ISO 21987:2017)

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Ta slovenski standard je istoveten z: EN ISO 21987:2017

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ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 21987:2017 **en**

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EUROPEAN STANDARD

EN ISO 21987

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2017

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Supersedes EN ISO 21987:2009

English Version

Ophthalmic optics - Mounted spectacle lenses (ISO 21987:2017)

Optique ophtalmique - Verres ophtalmiques montés
(ISO 21987:2017)

Augenoptik - Fertig montierte Korrektionsbrillengläser
(ISO 21987:2017)

This European Standard was approved by CEN on 26 May 2017.

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

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Contents	Page
European foreword	3
Annex ZA (informative) Relationship between this document and the Essential Requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered	5

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European foreword

This document (EN ISO 21987:2017) 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of an identical text or by endorsement, at the latest by February 2018, and conflicting national standards shall be withdrawn at the latest by February 2018.

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

This document supersedes EN ISO 21987:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA', the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

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When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

EN ISO 21987:2017 (E)

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 7944	EN ISO 7944:1998 + AC:2009	ISO 7944:1998 + Cor.1:2009
ISO 8429	EN ISO 8429:1996	ISO 8429:1986
ISO 8598-1	EN ISO 8598-1:2014	ISO 8598-1:2014
ISO 8624	EN ISO 8624:2011 + A1:2015	ISO 8624:2011+ Amd.1:2015
ISO 8980-1	EN ISO 8980-1:2017	ISO 8980-1:2017
ISO 8980-2	EN ISO 8980-2:2017	ISO 8980-2:2017
ISO 13666	EN ISO 13666:2012	ISO 13666:2012
ISO 14889	EN ISO 14889:2013	ISO 14889:2013

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Endorsement notice

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The text of ISO 21987:2017 has been approved by CEN as EN ISO 21987:2017 without any modification.

Annex ZA (informative)

Relationship between this document and the Essential Requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This document has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this document.

**Table ZA.1 — Correspondence between this document and
Annex I of Directive 93/42/EEC [OJ L 169]**

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub- clause(s) of this document	Remarks/Notes
7.1	5.2, 5.3, 5.4, 5.5, 5.6	<p>5.2 of the standard only meets the requirements of Annex I, 7.1 of the Directive in respect of toxicity and flammability.</p> <p>5.3 of the standard only meets the requirements of Annex I, 7.1 of the Directive in respect of optical performance.</p> <p>5.4 of the standard only meets the requirements of Annex I, 7.1 of the Directive in respect of lens thickness.</p> <p>5.5 of the standard only meets the requirements of Annex I, 7.1 of the Directive in respect of positioning of the various lens segments.</p> <p>5.6 of the standard only meets the requirements of Annex I, 7.1 of the Directive in respect of the orientation of polarizing lenses.</p>

EN ISO 21987:2017 (E)

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this document	Remarks/Notes
9.2	5.2	5.2 of the standard only meets the requirements of Annex I, 9.2 of the Directive in respect of mechanical strength and material ageing.
9.3	5.2	5.2 of the standard only meets the requirements of Annex I, 9.3 of the Directive in respect of flammability.
11.3.1	5.2	5.2 of the standard only meets the requirements of Annex I, 11.3.1 of the Directive in respect of transmittance.
13.1	Clause 7, Clause 9	Clause 7 of the standard only meets the requirements of Annex I, 13.1 of the Directive in respect of permanent or non-permanent marking. Clause 9 of the standard only meets the requirements of Annex I, 13.1 of the Directive in respect of product identification.
13.3	Clause 9	Clause 9 of the standard only meets the requirements of Annex I, 13.3 of the Directive in respect of product trade name and manufacturer address.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this document is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

INTERNATIONAL
STANDARD

ISO
21987

Second edition
2017-07

**Ophthalmic optics — Mounted
spectacle lenses**

Optique ophtalmique — Verres ophtalmiques montés

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Contents

Page

Foreword	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	3
5 Requirements	3
5.1 Reference temperature.....	3
5.2 Lenses used in manufacturing complete spectacles.....	3
5.3 Optical requirements.....	3
5.3.1 General.....	3
5.3.2 Back vertex power.....	4
5.3.3 Direction of the cylinder axis.....	4
5.3.4 Addition power or variation power.....	5
5.3.5 Prism imbalance (relative prism error) for mounted single-vision lenses (excluding position-specific single-vision lenses) and multifocal lenses.....	5
5.3.6 Prism imbalance (relative prism error) for position-specific single-vision lenses and power-variation lenses.....	7
5.4 Requirements for thickness.....	7
5.5 Requirements for positioning.....	8
5.5.1 Multifocal lenses.....	8
5.5.2 Position-specific single-vision lenses and power-variation lenses.....	9
5.6 Orientation requirement for polarizing lenses.....	9
6 Verification methods	9
6.1 General.....	9
6.2 Verification method for back vertex power.....	9
6.3 Verification method for the direction of the cylinder axis.....	9
6.4 Verification method for addition power or variation power.....	10
6.4.1 General.....	10
6.4.2 Method for verification of addition power for multifocal lenses.....	10
6.4.3 Method for verification of variation power (including addition power) for power-variation lenses.....	10
6.5 Verification method for position and tilt.....	11
6.6 Verification method for prism imbalance (relative prism error) for mounted single-vision lenses (excluding position-specific single-vision lenses) and multifocal lenses.....	11
6.7 Verification method for planes of transmission of polarizing lenses.....	11
6.7.1 General.....	11
6.7.2 Apparatus.....	11
6.7.3 Procedure.....	12
6.8 Inspection method for material and surface quality.....	12
7 Marking for position-specific single-vision lenses and power-variation lenses	12
7.1 Permanent marking.....	12
7.2 Optional non-permanent marking.....	13
8 Recommendations on mounting	13
9 Identification	13
10 Reference to this document	13
Annex A (informative) Material and surface quality	14
Annex B (informative) Recommendations on mounting	15

ISO 21987:2017(E)

Annex C (informative) Alternative method for measuring prism imbalance (relative prism error) for mounted single-vision lenses (excluding position-specific single-vision lenses) and multifocal lenses	17
Bibliography	21

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[SIST EN ISO 21987:2017](https://standards.iteh.ai/catalog/standards/sist/abfe3d43-1a95-4e1c-8d94-48146d10b839/sist-en-iso-21987-2017)

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