SLOVENSKI STANDARD
SIST EN ISO 12870:2018

01-julij-2018

Nadomešča:

SIST EN ISO 12870:2015

Očesna optika - Okviri očal - Zahteve in preskusne metode (ISO 12870:2016)

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2016)

Augenoptik - Brillenfassungen - Anforderungen und Prüfverfahren (ISO 12870:2016)

Optique ophtalmique - Montures de lunettes - Exigences et méthodes d'essai (ISO 12870:2016)

Ta slovenski standard je istoveten z: EN ISO 12870:2018

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 12870:2018 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 12870

May 2018

ICS 11.040.70

Supersedes EN ISO 12870:2014

English Version

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2016)

Optique ophtalmique - Montures de lunettes - Exigences et méthodes d'essai (ISO 12870:2016)

Augenoptik - Brillenfassungen - Anforderungen und Prüfverfahren (ISO 12870:2016)

This European Standard was approved by CEN on 26 April 2018.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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

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Ref. No. EN ISO 12870:2018 E

Contents

Page

European foreword

The text of ISO 12870:2016 has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 12870:2018 by 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of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.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 12870:2014.

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.

Endorsement notice

The text of ISO 12870:2016 has been approved by CEN as EN ISO 12870:2018 without any modification.

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.

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.

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
ISO 105-A02	—	ISO 105-A02:1993 + Cor.1:1997 + Cor.2:2005
ISO 105-B02	EN ISO 105-B02:2014	ISO 105-B02:2014
ISO 3696	EN ISO 3696:1995	ISO 3696:1987

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 7998	EN ISO 7998:2005	ISO 7998:2005
ISO 8596	EN ISO 8596:2018	ISO 8596:2017
ISO 8624:2011	EN ISO 8624:2011 + A1:2015	ISO 8624:2011 + Amd.1:2015
ISO 11380	EN ISO 11380:1996	ISO 11380:1994
ISO 11381	EN ISO 11381:2016	ISO 11381:2016
ISO/TS 24348:2014	EN 16128:2011[a]	ISO/TS 24348:2014

[a] Note that EN 16128 has recently been revised and its most recent edition is now 2015. ISO/TS 24348:2014 will be amended to align with the text of EN 16128:2015.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard 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 European Standard.

Table ZA.1 — Correspondence between this European Standard 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 EN	Remarks/Notes
7.2	4.2.2, 4.2.3	This ER is covered only for certain specific aspects and substances which are mentioned in the indicated paragraphs. This ER is covered in respect of substances migrating to the wearer only. The requirement of 4.2.3 is the requirement set forth by Entry 27 of Annex XVII to REACH. With respect to testing 4.2.3 makes reference to EN 16128. See also explanations in Annex C.
7.3	4.6, 4.7, 4.8	Only the first part of this ER applies to spectacle frames, and this is covered only for certain specific aspects which are mentioned in the indicated paragraphs.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.5	4.2.2, 4.2.3, 4.2.4, 4.7, 4.9	1st paragraph of ER 7.5 is partially covered by the overall but not specific guidance in subclause 4.2.2. Specific guidance is given for nickel, in subclause 4.2.3. The requirement of 4.2.3 (i.e. 0,5 µg/cm²/week) is the requirement set forth by Entry 27 of Annex XVII to REACH. With respect to testing 4.2.3 makes reference to EN 16128. See also explanations in Annex C. 2nd and 3rd paragraph of ER 7.5 are not applicable to spectacle frames.
9.1	4.8	Only the first sentence of ER 9.1 is covered.
9.2	4.2.1, 4.6	From the 1st bullet point of ER 9.2, the dimensional and ergonomic features are applicable to spectacle frames and are covered by 4.2.1. Volume/pressure ratio is not applicable to spectacle frames. From the 2nd bullet point of ER 9.2, temperature is applicable to spectacle frames, and is covered by 4.6. Magnetic fields, external electrical influences, electrostatic discharge, pressure, variations in pressure and acceleration are not applicable to spectacle frames. The 3rd and 4th bullet points of ER 9.2 are not applicable.
9.3	4.9	—
13.3 a)	10.4	The statement in 10.4 is mandatory for the countries of the Community. It covers the authorized representative only (where applicable).
13.3 b)	9, 10.1, 10.5, 10.6	The ER is covered only in respect of the aspects detailed in the standard.
13.3 i)	10.1	The ER is covered only in respect of the aspects detailed in the standard.
13.3 j)	10.1, 10.5, 10.6	The ER is covered only in respect of the aspects detailed in the standard.
13.3 k)	10.1, 10.5, 10.6	The ER is covered only in respect of the aspects detailed in the standard.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard 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 12870

Fourth edition
2016-11-01

Ophthalmic optics — Spectacle frames — Requirements and test methods

Optique ophtalmique — Montures de lunettes — Exigences et méthodes d'essai

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Contents

Page

