SLOVENSKI STANDARD
SIST EN ISO 12870:2009

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Nadomeġļa:
SIST EN ISO 12870:2005
SIST EN ISO 12870:2005/AC:2006

Oļesna optika - Okviri oļal - Zahteve in preskusne metode (ISO 12870:2004)

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2004)

Augenoptik - Brillenfassungen - Anforderungen und Prüfverfahren (ISO 12870:2004)

Optique ophtalmique - Montures de lunettes - Exigences et méthodes d'essai (ISO 12870:2004)

Ta slovenski standard je istoveten z: **EN ISO 12870:2009**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 12870:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 12870

April 2009

ICS 11.040.70

Supersedes EN ISO 12870:2004

English Version

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2004)

Optique ophtalmique - Montures de lunettes - Exigences et méthodes d'essai (ISO 12870:2004)

Augenoptik - Brillenfassungen - Anforderungen und Prüfverfahren (ISO 12870:2004)

This European Standard was approved by CEN on 7 March 2009.

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

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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Foreword

The text of ISO 12870:2004 has been prepared by Technical Committee ISO/TC 172 “Optics and optical instruments” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 12870:2009 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 October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 12870:2004.

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 93/42/EEC, as amended by Directive 2007/47/EC.

For relationship with EU Directive 93/42/EEC as amended by Directive 2007/47/EC, see informative Annex ZA, which is an integral part of this document.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 12870:2004 has been approved by CEN as a EN ISO 12870:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the 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.

Table ZA.1 – Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All this standard.	I.1, I.2	
4	I.3	Testing according to clauses 5, 6, 7 and 8.
4.2	I.6, II.7.1, II.7.2	Testing according to clause 8.8
4.2	I.6.a)	This relevant Essential Requirement is not addressed in EN ISO 12870.
4.2.2	II.7.5	This relevant Essential Requirement is only partly addressed in EN ISO 12870; to the extent that it is covered in EN ISO 12870: Testing according to clause 8.8; The requirement of 4.2.2 (i. e. 0,5 µg/cm^2/week is the requirement set forth by Directive 94/27/EEC.) The test clause 8.8 makes reference to EN 1811 and ENV 14027. Note that ENV 14027 has been withdrawn since the publication of EN ISO 12870:2004. The correct European Standard to use instead is EN 12472.
4.7	II.7.1	Testing according to clause 8.3
4.8.2	II.7.3, II.9.1	Testing according to clause 8.4
4.9	II.7.1, II.9.3	Testing according to clause 8.6
4.8.3	I.4	Testing according to 8.5
9, 10	II.13.1, II.13.3	ER 13.3 a) is only partly addressed in EN ISO 12870 (with regard to the identification of authorized representative).

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 12870

Second edition
2004-08-01

Corrected version
2004-11-01

Ophthalmic optics — Spectacle frames — Requirements and test methods

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

Reference number
ISO 12870:2004(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 12870 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 12870:1997), which has been technically revised. As this International Standard incorporates a revision of the text of ISO 9456:1991 that International Standard is also cancelled and replaced by the current edition of ISO 12870.

This corrected version of ISO 12870:2004 incorporates the following corrections: Figure B.2 has been modified.

Ophthalmic optics — Spectacle frames — Requirements and test methods

1 Scope

This International Standard specifies fundamental requirements for unglazed spectacle frames designed for use with all prescription lenses, and is applicable to frames at the point of sale to the retailer, by the manufacturer or supplier.

It is applicable to all spectacle frame types including rimless mounts, semi-rimless mounts and folding spectacle frames. This International Standard is applicable to spectacle frames made from natural organic materials.

NOTE See Annex A for recommendations on the design of spectacle frames.

This International Standard is not applicable to complete custom-made spectacle frames or to products designed specifically to provide personal eye protection.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 105-B02:1994, *Textiles — Tests for colour fastness — Part B02: Colour fastness to artificial light: Xenon arc fading lamp test*

ISO 3160-1, *Watch-cases and accessories — Gold alloy coverings — Part 1: General requirements*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 7998, *Optics and optical instruments — Spectacle frames — Vocabulary and lists of equivalent terms*

ISO 8596, *Ophthalmic optics — Visual acuity testing — Standard optotype and its presentation*

ISO 8624, *Ophthalmic optics — Spectacle frames — Measuring system and terminology*

ISO 11380, *Optics and optical instruments — Ophthalmic optics — Formers*

ISO 11381, *Optics and optical instruments — Ophthalmic optics — Screw threads*

ISO/TS 24348, *Ophthalmic optics — Spectacle frames — Method for the simulation of wear and detection of nickel release from coated metal and combination spectacle frames*

3 Terms and definitions

For the purposes of this document, the definitions given in ISO 7998 and ISO 8624 and the following apply.

3.1
spectacle frame model
spectacle frame produced to a common design, using the same materials (but not necessarily the same pigmentation) and surface treatment

3.2
natural organic material
material that has not been synthesized from other raw organic materials and, when processed, remains essentially in its original state

NOTE 1 Processing in this case is defined as cutting, shaping, bending, polishing and heating.

NOTE 2 Examples of natural organic materials are natural horn and wood.

3.3
custom-made spectacle frame
spectacle frame made to special order for a named patient

NOTE Examples of custom-made frames are those specially manufactured for wearers with unusual facial characteristics.

4 Requirements

4.1 General

The requirements applicable to the different types of spectacle frames are given in Table 1. All spectacle frame types covered by this International Standard shall comply with the requirements identified as general (g). Requirements marked “O” are optional, but may be required by legislation in some countries.

Table 1 — Requirements applicable to the different types of spectacle frames

Frame type	**Subclause** (see Note 1)									
	4.2.1	4.2.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10
Rimless and semi-rimless mounts	g	O	O	O	g	g	g	g	g	O
All other spectacle frames (see Note 2)	g	O	g	g	g	g	g	g	g	O

Key
g Spectacle frame type shall comply with this subclause in order to pass this International Standard.
O Compliance with this subclause is optional.
4.2.1 General physiological compatibility
4.2.2 Nickel release
4.3 Measurement system
4.4 Dimensional tolerances
4.5 Tolerance on screw threads
4.6 Dimensional stability at elevated temperature
4.7 Resistance to perspiration
4.8 Mechanical stability
4.9 Resistance to ignition
4.10 Resistance to optical radiation

NOTE 1 Under European legislation, subclauses 4.2.1, 4.2.2, 4.5, 4.6, 4,7, 4.8 and 4.9 give fundamental requirements.

NOTE 2 “All other frame types” includes plastic and metal spectacle frames, including folding spectacle frames, having a rim completely surrounding the lens periphery.