SLOVENSKI STANDARD
kSIST FprEN ISO 12870:2014

01-julij-2014

Očesna optika - Okviri očal - Zahteve in preskusne metode (ISO 12870:2012)

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2012)

Augenoptik - Brillenfassungen - Anforderungen und Prüfverfahren (ISO 12870:2012)

Optique ophtalmique - Montures de lunettes - Exigences et méthodes d'essai (ISO 12870:2012)

Ta slovenski standard je istoveten z: **FprEN ISO 12870**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

kSIST FprEN ISO 12870:2014 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
FprEN ISO 12870

April 2014

ICS 11.040.70

Will supersede EN ISO 12870:2012

English Version

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2012)

Optique ophtalmique - Montures de lunettes - Exigences et méthodes d'essai (ISO 12870:2012)

Augenoptik - Brillenfassungen - Anforderungen und Prüfverfahren (ISO 12870:2012)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 170.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

CEN members are the national standards bodies of 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword **3**

Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices** **4**

Foreword

The text of ISO 12870:2012 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 FprEN ISO 12870:2014 by Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN ISO 12870:2012.

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.

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

Endorsement notice

The text of ISO 12870:2012 has been approved by CEN as FprEN ISO 12870:2014 without any modification.

Annex ZA
(informative)

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

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 Union 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 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 on Medical Devices

Clauses/sub-clauses of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
4.2.1, 4.2.2, 4.2.3	7.2	Testing according to 8.8. The requirement of 4.2.3 (i.e. 0,5 µg/cm^2/week) is the requirement set forth by Entry 27 of Annex XVII to REACH. The test in 8.8 makes reference to EN 16128 and EN 12472. See also explanations in Annex D.
4.6 to 4.9	7.3	Testing according to 8.2 to 8.6
4.2.2, 4.2.3	7.5	Testing according to 8.8. Essential Requirement 7.5 is only partly addressed in ISO 12870. To the extent that it is covered in ISO 12870, testing according to 8.8. The requirement of 4.2.3 (i.e. 0,5 µg/cm^2/week) is the requirement set forth by Entry 27 of Annex XVII to REACH. The test in 8.8 makes reference to EN 16128 and EN 12472. See also explanations in Annex D.
4.8	9.1	Testing according to 8.4 and 8.5.
4.9	9.3	Testing according to 8.6.
9,10	13.1	—
9,10	13.3	The statement in 10.4 is true for the countries of the Community [cf. ER 13.3 a)].

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

Third edition
2012-04-01

Ophthalmic optics — Spectacle frames — Requirements and test methods

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

Reference number
ISO 12870:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland