



Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 12870:2014

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)

10/2014



National Foreword

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EUROPEAN STANDARD ^{ILNAS-EN ISO 12870:2014} **EN ISO 12870**
NORME EUROPÉENNE
EUROPÄISCHE NORM

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Supersedes EN ISO 12870:2012

English Version

**Ophthalmic optics - Spectacle frames - Requirements and test
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This European Standard was approved by CEN on 3 October 2014.

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

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COMITÉ EUROPÉEN DE NORMALISATION
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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 EN ISO 12870:2014 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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

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 12870:2012.

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(s).

For relationship with EU Directive(s), 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, 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 the United Kingdom.

Endorsement notice

The text of ISO 12870:2012 has been approved by CEN as EN 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.

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