

**Oftalmiline optika. Prilliraamid. Nõuded ja katsemeetodid**

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 12870:2014 sisaldab Euroopa standardi EN ISO 12870:2014 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 12870:2014 consists of the English text of the European standard EN ISO 12870:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.10.2014.	Date of Availability of the European standard is 15.10.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile [standardiosakond@evs.ee](mailto:standardiosakond@evs.ee).

ICS 11.040.70

### Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:  
Aru 10, 10317 Tallinn, Eesti; [www.evs.ee](http://www.evs.ee); telefon 605 5050; e-post [info@evs.ee](mailto:info@evs.ee)

### The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:  
Aru 10, 10317 Tallinn, Estonia; [www.evs.ee](http://www.evs.ee); phone 605 5050; e-mail [info@evs.ee](mailto:info@evs.ee)

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 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.

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.



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

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

## 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 <sup>2</sup> /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 <sup>2</sup> /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.

# Contents

Page

<b>Foreword</b>	<b>iv</b>
<b>1 Scope</b>	<b>1</b>
<b>2 Normative references</b>	<b>1</b>
<b>3 Terms and definitions</b>	<b>1</b>
<b>4 Requirements</b>	<b>2</b>
4.1 General	2
4.2 Physiological compatibility	3
4.3 Measurement system	4
4.4 Dimensional tolerances on nominal size	4
4.5 Tolerance on screw threads	4
4.6 Dimensional stability at elevated temperature	4
4.7 Resistance to perspiration	4
4.8 Mechanical stability	5
4.9 Resistance to ignition	6
4.10 Resistance to optical radiation	6
<b>5 Selection of test samples</b>	<b>6</b>
5.1 General	6
5.2 Testing for nickel release	6
5.3 Change in spectacle frame model	6
<b>6 Preparation and conditioning of test samples</b>	<b>6</b>
6.1 Test lenses	6
6.2 Sample conditioning and test conditions	7
<b>7 Testing, inspection and compliance</b>	<b>7</b>
7.1 Testing	7
7.2 Inspection and examination	8
7.3 Compliance	8
<b>8 Test methods</b>	<b>9</b>
8.1 General	9
8.2 Test for dimensional stability at elevated temperature	9
8.3 Test for resistance to perspiration	10
8.4 Bridge deformation and lens retention test	11
8.5 Endurance test	13
8.6 Test for resistance to ignition	14
8.7 Test for resistance to optical radiation	15
8.8 Nickel release	16
<b>9 Marking</b>	<b>18</b>
<b>10 Additional information to be supplied by the manufacturer or other person placing the product on the market</b>	<b>19</b>
<b>11 Reference to ISO 12870</b>	<b>20</b>
<b>Annex A (informative) Recommendations for the design of spectacle frames</b>	<b>21</b>
<b>Annex B (informative) Examples of layout of test equipment</b>	<b>23</b>
<b>Annex C (informative) Examples of locations for cutting metal spectacle frames before testing for nickel release</b>	<b>26</b>
<b>Annex D (informative) European requirements and legislation on nickel release</b>	<b>27</b>
<b>Bibliography</b>	<b>28</b>