ICS 11.040.70 SLOVENSKÁ TECHNICKÁ NORMA November 2025

STN	**Očná optika Okuliarové rámy Požiadavky a skúšobné metódy (ISO 12870: 2024)**	**STN EN ISO 12870** 19 5041

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/25

Obsahuje: EN ISO 12870:2025, ISO 12870:2024

Oznámením tejto normy sa ruší
STN EN ISO 12870 (19 5041) z novembra 2018

141351

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 12870

August 2025

ICS 11.040.70 Supersedes EN ISO 12870:2018

English Version

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2024)

Optique ophtalmique - Montures de lunettes - Exigences et méthodes d'essai (ISO 12870:2024)

Augenoptik - Brillenfassungen - Anforderungen und Prüfverfahren (ISO 12870:2024)

This European Standard was approved by CEN on 17 November 2024.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 12870:2025 E

Contents

Page

European foreword **3**

Annex ZA (informative) **Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered** **4**

European foreword

This document (EN ISO 12870:2025) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with 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 February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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 12870:2018.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

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

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 12870:2024 has been approved by CEN as EN ISO 12870:2025 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

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 Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance 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 Regulation (EU) 2017/745 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/notes
1	4	Clause 4 of the standard only meets the requirements of Annex I, GSPR 4 of the Regulation in respect of detailing the requirements for spectacle frames.
3 a)	4.3	4.3 of the standard only partially meets the requirements of Annex I, GSPR 3 (a) of the Regulation in respect of risk management since it gives only general guidance.
4 (a)	4.2	4.2 of the standard only partially meets the requirements of Annex I, GSPR 4 (a) of the Regulation in respect of construction since it gives only guidance.
5 (a)	4.2, 4.12	4.2 and 4.12 of the standard only partially meet the requirements of Annex I, GSPR 5 (a) of the Regulation in respect of reducing risk (4.2) and mechanical stability (4.12).
6	4.10, 4.11, 4.12	4.10, 4.11 and 4.12 of the standard only partially meet the requirements of Annex I, GSPR 6 of the Regulation in respect of possible changes in shape caused by raised temperature (4.10), surface quality (4.11) and mechanical strength (4.12).
7	4.10	4.10 of the standard only meets the requirements of Annex I, GSPR 7 of the Regulation in respect of temperature when in use but not in packaging or transport. The test temperature is, however, greater than any likely to be met during transport.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/notes
10.1 (a)	4.4, 4.13	4.4 and 4.13 of the standard only meet the requirements of Annex I, GSPR 10.1 (a) of the Regulation in respect of flammability (4.13) and only partially met with respect to toxicity by the guidance on materials in 4.4.
10.1 (b)	4.4, 4.5, 4.11	4.5 of the standard only meets the requirements of Annex I, GSPR 10.1 (b) of the Regulation in respect of nickel allergy (4.5); 4.4 and 4.11 of the standard only partially meet the requirements of Annex I, GSPR 10.1 (b) of the Regulation in respect of manufacture since while 4.4 gives guidance on the materials that can be used, it does not specifically address the aspects of chemicals from the frame being absorbed, distributed, metabolised and excreted. 4.11 covers damage to the surface by perspiration, which might be a two-way process, allowing damaged constituents of the frame to enter the skin.
10.1 (d)	4.5	4.5 of the standard only meets the requirements of Annex I, GSPR 10.1 (d) of the Regulation in respect of nickel release – the welding of metals to construct a spectacle frame can result in changes to the original material properties of the metals.
10.1 (f)	4.12	4.12 of the standard only meets the requirements of Annex I, GSPR 10.1 (f) of the Regulation in respect of all listed mechanical properties except ductility which is not relevant to spectacle frames.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/notes
10.1 (g)	4.2, 4.11	4.2 and 4.11 of the standard only meet the requirements of Annex I, GSPR 10.1 (g) of the Regulation in respect of surface quality when new by 4.2 and after wear by 4.11
10.4.1	4.5	4.5 of the standard only partially meets the requirements of Annex I, GSPR 10.4.1 of the Regulation in respect of nickel release
10.4.3	4.4	4.4 of the standard only partially meets the requirements of Annex I, GSPR 10.4.3 of the Regulation in respect of phthalates which are not specifically mentioned; manufacturers are aware of these substances.
14.1	4.12.2	4.12.2 of the standard only meets the requirements of Annex I, GSPR 14.1 of the Regulation in respect of retaining spectacle lenses.
14.2 (a)	4.8	4.8 of the standard only partially meets the requirements of Annex I, GSPR 14.2 (a) of the Regulation in respect of dimensional tolerances.
14.2 (b)	4.10	4.10 of the standard only partially meets the requirements of Annex I, GSPR 14.2 (b) of the Regulation in respect of temperature. All the other external influences are not applicable.
14.3	4.13	4.13 of the standard only partially meets the requirements of Annex I, GSPR 14.3 of the Regulation in respect of the risk of catching fire.
14.5	4.12.2	4.12.2 of the standard only meets the requirements of

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/notes
		Annex I, GSPR 14.5 of the Regulation in respect of compatibility with spectacle lenses required by the lens retention test in 4.12.2.
20.1	4.12	4.12 of the standard only meets the requirements of Annex I, GSPR 20.1 of the Regulation in respect of mechanical performance.
22.1	4.2, 4.4 ,4.10, 4.11 4.12	4.2, 4.4, 410, 4.11 and 4.12 of the standard together only meet the requirements of Annex I, GSPR 22.1 of the Regulation in respect of performance requirements from the wearer's point of view. Spectacle frames are intentionally designed for use by lay persons and as a Class I product have no information for users.
23.1 (a)	9	9 of the standard only meets the requirements of Annex I, GSPR 23.1 (a) of the Regulation in respect of the labelling to be put on a spectacle frame.
23.1 (b)	9	9 of the standard only meets the requirements of Annex I, GSPR 23.1 (b) of the Regulation in respect of the labelling to be put on a spectacle frame.
23.2 (c)	10.4	10.4 of the standard only partially meets the requirements of Annex I, GSPR 23.2 (c) of the Regulation in respect of the manufacturer's or agent's name and address. Spectacle frames do not have labels but are usually mounted on an accompanying card. If not, information can be provided on the packaging or in catalogues or electronic database.

Table ZA.2 — Normative references from clause 2 of this document and their corresponding European publications

Column 1 **Reference in** Clause 2	**Column 2** **International Standard edition**	**Column 3** **Title**	**Column 4** **Corresponding European Standard Edition**
ISO 105-A02	ISO 105-A02:1993 ISO 105-A02:1993/Cor 1:1997 ISO 105-A02:1993/Cor 2:2005	Textiles — Tests for colour fastness — Part A02: Grey scale for assessing change in colour	EN 20105-A02:1994 For applicable standard edition see Column 2.
ISO 3696	ISO 3696:1987	Water for analytical laboratory use — Specification and test methods	EN ISO 3696:1995
ISO 7998	ISO 7998:2005	Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary	EN ISO 7998:2005
ISO 8624	ISO 8624:2020	Ophthalmic optics — Spectacle frames — Measuring system and vocabulary	EN ISO 8624:2020
ISO 11380	ISO 11380:1994	Optics and optical instruments — Ophthalmic optics — Formers	EN ISO 11380:1996
ISO 11381	ISO 11381:2016	Ophthalmic optics — Spectacle frames — Screw threads	EN ISO 11381:2016
EN 16128	None	Ophthalmic optics — Reference method for the testing of spectacle frames and sunglasses for Nickel release	EN 16128:2015 Note – a revision is at the FprEN stage.
ISO 14971	EN ISO 14971:2019	Medical devices. Application of risk management to medical devices	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

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 product(s) falling within the scope of this standard.

International Standard

ISO 12870

Ophthalmic optics — Spectacle frames — Requirements and test methods

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

Fifth edition
2024-11

Reference number
ISO 12870:2024(en)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword ..... **v**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **2**
3.1 General terms 2
3.2 Types of frame 3
3.3 Term describing frame materials 4

4 Requirements **5**
4.1 General 5
4.2 Construction 7
4.3 Risk management 7
4.4 Biological compatibility 7
4.5 Nickel release (optional) 8
4.6 Clinical evaluation 8
4.7 Measurement system 8
4.8 Dimensional tolerances on nominal size 8
4.9 Tolerance on screw threads (optional) 9
4.10 Dimensional stability at elevated temperature 9
4.11 Resistance to perspiration 9
4.12 Mechanical stability 10
4.12.1 Bridge deformation 10
4.12.2 Lens retention characteristics 10
4.12.3 Endurance 11
4.13 Resistance to ignition 11
4.14 Resistance to optical radiation (optional) 11

5 Selection of test samples **11**
5.1 General 11
5.2 Testing for nickel release 11
5.3 Change in spectacle frame model 11

6 Preparation and conditioning of test samples **12**
6.1 Test lenses 12
6.2 Sample conditioning and test conditions 12

7 Testing, inspection and conformity **12**
7.1 Testing 12
7.2 Inspection and examination 13
7.3 Conformity 13

8 Test methods **14**
8.1 General 14
8.2 Test for dimensional stability 14
8.2.1 Apparatus 14
8.2.2 Procedure 15
8.3 Test for resistance to perspiration 15
8.3.1 Apparatus and reagents 15
8.3.2 Procedure 16
8.4 Bridge deformation and lens retention 16
8.4.1 Apparatus 16
8.4.2 Procedure 17
8.5 Endurance test 18
8.5.1 Apparatus 18
8.5.2 Procedure 19
8.6 Test for resistance to ignition 20
8.6.1 Apparatus 20

8.6.2 Procedure 20
8.7 Test for resistance to optical radiation 21
8.7.1 Apparatus 21
8.7.2 Procedure 21
9 Marking **22**
10 Additional information to be supplied by the manufacturer or other person placing the product on the market **23**
11 Reference to this document **23**
Annex A (informative) **Recommendations for the design of spectacle frames** **24**
Annex B (informative) **Chemicals that can be harmful to health** **26**
Annex C (informative) **European requirements and legislation on nickel release** **27**
Annex D (informative) **Examples of layout of test equipment** **28**
Annex E (normative) **Long wavelength pass filter** **31**
Annex F (informative) **Identification marking or labelling of handling requirements (optional)** **35**
Bibliography **36**

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fifth edition cancels and replaces the fourth edition (ISO 12870:2016), which has been technically revised.

The main changes are as follows:

— rimmed clip-ons, prescription inserts, and frames made by additive manufacture are now included in the scope;

— additional terms and definitions;

— clarification of the tests to be applied for the biological properties of custom-made frames in Table 1 (in 4.1);

— some re-arrangement of and additional text in 4.2;

— simplification of the text in 4.2 to make it more general, and addition of a note on magnets;

— additional wording has been added to 4.12.3 and 8.5 to emphasize that the apparatus prevents rotational movements of the "fixed" side;

— minor changes to 4.2, 6.1, 8.5.2.3, 8.6, 8.7 (with a new Annex E), Clause 9 and 10.3;

— 4.5 and 4.9 have been made optional, while the original 10.5 and 10.6 are now in a Note to 4.2;

— 10.1 refers to an informative Annex F on frame handling information.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

International Standard **ISO 12870:2024(en)**

Ophthalmic optics — Spectacle frames — Requirements and test methods

1 Scope

This document specifies fundamental requirements and their test methods for unglazed spectacle frames designed for use with prescription lenses. It is applicable to spectacle frames at the point of sale by the manufacturer or supplier to the retailer.

This document is applicable to:

— all mass-produced spectacle frame types, including rimless mounts, semi-rimless mounts and folding spectacle frames;

— spectacle frames made with additive manufacturing, for example, 3D printing;

— spectacle frames made from natural organic materials;

— the frame or mount of clip-ons designed specifically for attachment to particular models of spectacle frame, but not to their lenses or filters to which ISO 16034 or ISO 12312-1 apply;

— prescription inserts designed for attachment to particular models of, for example, eye protector, sunglass or diving mask.

Parts of this document are applicable to custom-made frames – see 3.1.3 and Table 1.

NOTE See Annex A for recommendations on the design of spectacle frames and terms to be used when describing metal frames.

This document is not applicable to spectacle frames used in eye protection, where ISO 16321-1 applies, or to sunglasses with afocal filters, where ISO 12312-1 applies.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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-A02, *Textiles — Tests for colour fastness — Part A02: Grey scale for assessing change in colour*

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

ISO 7998, *Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary*

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

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

ISO 11381, *Ophthalmic optics — Spectacle frames — Screw threads*

EN 16128, *Ophthalmic optics — Reference method for the testing of spectacle frames and sunglasses for Nickel release*