

BS EN ISO 12870:2012



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

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National foreword

This British Standard is the UK implementation of EN ISO 12870:2012. It supersedes BS EN ISO 12870:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/3, Spectacles.

A list of organizations represented on this committee can be obtained on request to its secretary.

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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)

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Foreword

This document (EN ISO 12870:2012) 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of an identical text or by endorsement, at the latest by October 2012, and conflicting national standards shall be withdrawn at the latest by October 2012.

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 12870:2009.

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.

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, 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 a EN ISO 12870:2012 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EC 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 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.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

Clauses/subclauses of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
4.1, 4.2, 4.5, 4.6, 4.7, 4.8, 4.9, 9, 10	1	The requirements declared as optional in Table 1, but cited in the list given in footnote ^a , only provide presumption of conformity to their corresponding Essential Requirements if they are complied with. See below in the present table.
4.1, 4.2, 4.5, 4.6, 4.7, 4.8, 4.9, 9, 10	2	The requirements declared as optional in Table 1, but cited in the list given in footnote ^a , only provide presumption of conformity to their corresponding Essential Requirements if they are complied with. See below in the present table.
4	3	Testing in accordance with Clauses 5, 6, 7 and 8.
4.6 to 4.9	4	Testing in accordance with 8.2 to 8.6.
4.2.1, 4.2.2, 4.2.3	6	Testing in accordance with 8.8. The requirement of 4.2.3 (i.e. 0,5 µg/cm ² /week) is the requirement set forth by Directive 94/27/EEC. The test in 8.8 makes reference to EN 16128 and EN 12472. See also explanations in Annex D.
4.2.4	6 a)	—
4.2.1, 4.2.2, 4.2.3	7.1	Testing in accordance with 8.8. The requirement of 4.2.3 (i.e. 0,5 µg/cm ² /week) is the requirement set forth by Directive 94/27/EEC. The test in 8.8 makes reference to EN 16128 and EN 12472. See also explanations in Annex D.
4.6 to 4.9	7.1	Testing in accordance with 8.2 to 8.6.

Table ZA.1 (end)

Clauses/subclauses of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
4.2.1, 4.2.2, 4.2.3	7.2	Testing in accordance with 8.8. The requirement of 4.2.3 (i.e. 0,5 µg/cm ² /week) is the requirement set forth by Directive 94/27/EEC. 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 in accordance with 8.2 to 8.6.
4.2.2, 4.2.3	7.5	Testing in accordance with 8.8. Essential Requirement 7.5 is only partly addressed in ISO 12870. To the extent that it is covered in ISO 12870, testing is carried out in accordance with 8.8. The requirement of 4.2.3 (i.e. 0,5 µg/cm ² /week) is the requirement set forth by Directive 94/27/EEC. The test in 8.8 makes reference to EN 16128 and EN 12472. See also explanations in Annex D.
4.8	9.1	Testing in accordance with 8.4 and 8.5.
4.9	9.3	Testing in accordance with 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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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 third edition cancels and replaces the second edition (ISO 12870:2004) which has been technically revised.

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. It is applicable to frames at the point of sale by the manufacturer or supplier to the retailer.

This International Standard is applicable to all spectacle frame types, including rimless mounts, semi-rimless mounts and folding spectacle frames. It is also 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-A02, *Textiles — Tests for colour fastness — Part A02: Grey scale for assessing change in colour*

ISO 105-B02, *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, *Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary*

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

ISO 8624:2011, *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 terms and 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

EXAMPLES Natural horn, bamboo and wood.

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

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

EXAMPLE Spectacle frames specially manufactured for wearers with unusual facial characteristics.

4 Requirements

4.1 General

The requirements applicable to 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 different types of spectacle frames

Frame type	Subclause ^a											
	4.2.1	4.2.2	4.2.3	4.2.4	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10
Rimless and semi-rimless mounts	g	g	O	O	O	O	g	g	g	g	g	O
All other frame types ^b	g	g	O	O	g	g	g	g	g	g	g	O
Key												
g	Frame type shall meet the requirements of this subclause in order to comply with this International Standard.											
O	Compliance with this subclause is optional.											
4.2.1	Construction											
4.2.2	General physiological compatibility											
4.2.3	Nickel release											
4.2.4	Clinical evaluation											
4.3	Measurement system											
4.4	Dimensional tolerances on nominal size											
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											
^a Under European legislation, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.5, 4.6, 4.7, 4.8 and 4.9 give essential requirements.												
^b “All other frame types” includes plastics and metal spectacle frames, including folding spectacle frames, that have a rim that completely surrounds the lens periphery.												

4.2 Physiological compatibility

4.2.1 Construction

When tested under the inspection conditions given in 7.2, areas of the spectacle frame that may, either by design or accident, come into contact with the wearer should be smooth, without sharp protuberances, and all edges should be rounded.

4.2.2 General physiological compatibility

Spectacle frames shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the health (and safety) of the wearer. The risks posed by substances leaking (migrating) from the device that might come into prolonged contact with the skin shall be reduced by the manufacturer to a practicable minimum and within the limits of any existing regulatory requirement. Special attention shall be given to substances that are known to be allergenic, carcinogenic, mutagenic or toxic to reproduction.

NOTE 1 The following list, which is given for information, provides examples of documents that can be examined when checking the innocuousness of materials:

- specification of the materials used;
- safety data sheets relating to the materials;
- information relating to the suitability of the materials for use with food, in medical devices, or other relevant applications;
- information relating to investigations into the allergenic, carcinogenic, toxicological or mutagenic properties of the materials, or their toxicity with regard to reproduction;
- information relating to ecotoxicological and other environmental investigations on the materials.

NOTE 2 Reactions can be generated by excessive pressure, e.g. due to a poor fit on the face, chemical irritation or allergy. Rare or idiosyncratic reactions can occur to any material and indicate the need for the individual to avoid particular types of frames.

NOTE 3 In some countries, specific material properties are mandatory.

4.2.3 Nickel release

Those parts of metal spectacle frames and those metal parts of combination spectacle frames that come into direct and prolonged contact with the skin of the wearer shall not have a nickel release greater than $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ when tested in accordance with 8.8.

The parts to be tested shall include:

- the rear surface of both rims (for full-rim designs, the top part of the rim need not be tested provided the lower part is tested and the whole rim is manufactured from the same design and material);
- the rear and lower surface of the bridge (except when a non-metallic insert bridge has been fitted), the rear and upper surface of any brace bar and any other nasal bearing surfaces, including metal nose pads;
- sides, including metal collets, but excluding the joints and the zone immediately around the joints, and parts intended to be protected by plastics end covers (tips);
- metal decorative trims, if fitted, on the inside of plastics sides and plastics end covers.

Each of these sets of components shall be tested separately for nickel release, and each set shall pass in order for the frame to pass. If both sides are tested, the results for each side, not their average, shall be used to determine whether or not the sides pass.

Heads of screws on folding frames, or holding plastics components onto metal frames, that might come into contact with the skin shall also be tested as part of the front or side to which they are screwed.

Metal frames that are uncoated and made of homogeneous alloys or metals do not require a wear pre-treatment (such as that specified in 8.8.2) and shall be tested directly in accordance with 8.8.3 or 8.8.4. Unless the manufacturer certifies that a component is homogeneous and uncoated, the component shall be assumed to be coated.

If only indicative information on the extent of nickel release is required, such information can be obtained by performing one of the tests specified in CEN/CR 12471:2002^[3].

4.2.4 Clinical evaluation

If a spectacle frame is manufactured using materials (e.g. plastics, alloys, coatings or pigments) not previously used in spectacle frame manufacture, the clinical evaluation shall be made according to the appropriate International Standard(s), either using the spectacle frame itself or using studies where the identical material is used in other medical devices.

4.3 Measurement system

The stated nominal dimensions of the spectacle frame shall be in accordance with the measuring system specified in ISO 8624.

4.4 Dimensional tolerances on nominal size

When measured with a linear measuring device that is accurate to at least 0,1 mm, the following tolerances shall apply to the marked dimensions of the unglazed spectacle frame using the boxed lens measurement method described in ISO 8624:

- a) horizontal boxed lens size: $\pm 0,5$ mm;
- b) distance between lenses: $\pm 0,5$ mm;
- c) overall length of side: $\pm 2,0$ mm.

To improve the accuracy of measurement of overall length of side, it is recommended that the drop be physically straightened. Sinuosity in the intended vertical plane, or pronounced curvature in the intended horizontal plane in the part of the side before the earbend, should be ignored. The overall length of side should be taken as the length of the straight line between the dowel screw and the end of the side. Gentle bowing of the side to go round the width of the head should be straightened. For sides without a hinged joint, the side should be held open at $(90_{-5}^0)^{\circ}$ to the front or to that part of the side that is attached to the front, and the length is measured from the end of the side to the front, minus 10 mm. See ISO 8624:2011, Figures 2 and 3 for an illustration of overall length of side.

To simplify the edging of lenses for any single frame model, tighter tolerances in the lens aperture size from one frame to another of the same nominal size may be a matter of agreement between supplier and purchaser.

4.5 Tolerance on screw threads

The tolerances on the screw threads used in the spectacle frame shall conform to ISO 11381.

4.6 Dimensional stability at elevated temperature

When the spectacle frame with test lenses fitted is tested in accordance with 8.2, the distance between the tips of the sides shall not alter by more than +6 mm or -12 mm. For small spectacle frames where the tip of the side is less than 100 mm from the back plane of the front, these tolerances are reduced to +5 mm or -10 mm.

4.7 Resistance to perspiration

When the spectacle frame is tested in accordance with 8.3, there shall be

- a) no spotting or colour change (except for loss of gloss on surface) anywhere on the frame, excluding joints and screws, after testing for 8 h, and