INTERNATIONAL STANDARD

**ISO 12870**

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# Ophthalmic optics — Spectacle frames — Requirements and test methods

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

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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.

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# 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

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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.

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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

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**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**

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| 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.


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## 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.

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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.

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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 µg/cm$^2$/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.

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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:

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a) horizontal boxed lens size: ±0,5 mm;

b) distance between lenses: ±0,5 mm;

c) overall length of side: ±2,0 mm.

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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 $(90^{\ 0}_{-5})°$ 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


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b) no corrosion, surface degradation or separation of any coating layer on the parts liable to come into prolonged contact with the skin during wear, i.e. the insides of the sides, bottom and lower parts of the rim and the inside of the bridge, after testing for a total of 24 h.

Such defects shall be visible under the inspection conditions described in 7.2.

If the spectacle frame is made from natural materials and the manufacturer recommends a cream or wax for its maintenance, then, before testing, the frame(s) shall be prepared with this cream or wax in accordance with the manufacturer's instructions. At the end of the test, if the frame fails to meet this requirement when checked for colour change or surface degradation, use the cream or wax and wait for one day before checking again for colour change or surface degradation. If the frame has recovered its original appearance, the spectacle frame is considered to have passed the test; if the frame remains discoloured, the frame is considered to have failed the test.

## 4.8 Mechanical stability

### 4.8.1 Bridge deformation

When tested in accordance with 8.4, the spectacle frame with the test lenses fitted shall not:

a) fracture or crack at any point;

b) be permanently deformed from its original configuration by more than 2 % of the distance, $c$, between the boxed centres of the spectacle frame, i.e. the residual deformation, $x$, shall not exceed 0,02$c$ (see Figure 1).

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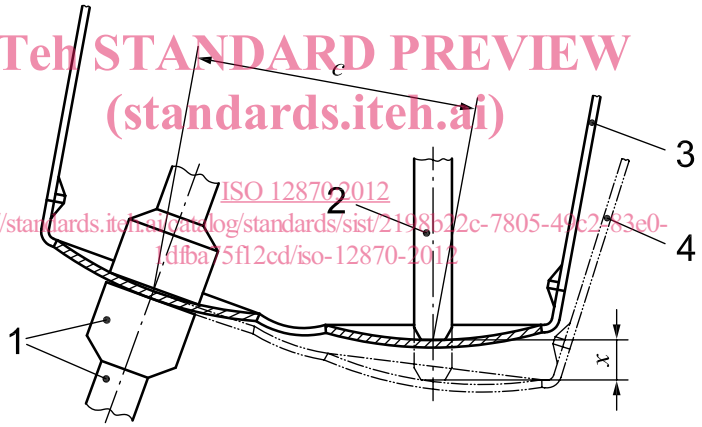


**Key**

1 annular clamp
2 pressure peg
3 original position
4 residual deformation, $x$

**Figure 1 — Permanent deformation of bridge**

### 4.8.2 Lens retention characteristics

The spectacle frame shall be considered to demonstrate acceptable lens retention characteristics if, when tested in accordance with 8.4, neither test lens is dislodged wholly or partially from its original location in the groove or mount.

### 4.8.3 Endurance

When tested in accordance with 8.5, the spectacle frame with the test lenses fitted shall not:

a) fracture at any point;

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b) be permanently deformed from its original position by more than 5 mm after 500 cycles;

c) require more than light finger pressure to open and close the sides (except for frames fitted with sprung joints);

d) have a side that closes under its own weight at any point in the opening/closing cycle (for frames not fitted with sprung joints), or for sides fitted with sprung joints, the side shall still support its weight in the open position (i.e. opened to the fullest natural extent without activating the spring mechanism).

### 4.9 Resistance to ignition

When the spectacle frame is tested in accordance with 8.6, there shall be no continued combustion after withdrawal of the test rod.

### 4.10 Resistance to optical radiation

When tested in accordance with 8.7, there shall be no:

a) colour change greater than grade 3 on the grey scale in ISO 105-A02, or

b) loss of lustre on bright surfaces,

when compared with an untested sample under the inspection conditions described in 7.2.

## 5 Selection of test samples

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### 5.1 General

The minimum level of conformity testing requires that two test specimens of each spectacle frame model shall be selected at random. These specimens shall be selected by the manufacturer or its representative, and shall be identified as test sample 1 and test sample 2. They shall be conditioned as described in Clause 6 before testing as described in Clauses 7 and 8.

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In some regions, local legislation requires a spectacle frame model to comply with regulatory requirements throughout the duration of its supply to the market. When compliance with this International Standard is claimed, the manufacturer or its representative has the responsibility, by any chosen means, e.g. use of ISO 13485, ISO 14971 and/or this International Standard, to ensure that the compliance of the spectacle frame model continues throughout its duration of supply, and not only at its first launch on the market.

### 5.2 Testing for nickel release

For metal and combination spectacle frames, two additional test samples 3 and 4 shall be selected at random and shall be conditioned as described in Clause 6 before testing as described in 8.8.

### 5.3 Change in spectacle frame model

If a range of spectacle frame models is made from the same material(s), following the same manufacturing procedures, including surface treatments, it is acceptable to perform, from Table 2, test sequences 4 (see 8.3), 8 (see 8.6) and, if required, 9 (see 8.7) and/or 10 (see 8.8) on only one of the spectacle frame models.

## 6 Preparation and conditioning of test samples

### 6.1 Test lenses

Prior to testing for the requirements described in 4.6 to 4.10, test samples 1 and 2 shall be fitted with a pair of suitable test lenses.


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The test lenses shall preferably be supplied or specified by the manufacturer. If these are not supplied or specified, then the following types shall be used depending upon the type of spectacle frame:

a) for rimless frames, organic lenses of polycarbonate with a vertex power of 0,00 D ± 0,25 D, a centre thickness of 2,00 mm ± 0,2 mm and a radius of curvature of the concave surface of 90 mm ± 10 mm;

b) for semi-rimless frames, organic lenses of allyl diglycol carbonate[1)] or polycarbonate with a vertex power of 0,00 D ± 0,25 D, a centre thickness of 2,00 mm ± 0,2 mm and a radius of curvature of the concave surface of 90 mm ± 10 mm;

c) for all other frame types, including folding and all rimmed spectacles, either organic lenses as in b) above, or silicate glass with a vertex power of 0,00 D ± 0,25 D, a centre thickness of 2,25 mm ± 0,25 mm and a radius of curvature of the concave surface of 100 mm ± 20 mm.

Prior to any wear pre-treatment for nickel release as specified in 4.2.3, test samples 3 and 4 shall, if they are not already fitted with dummy or demonstration lenses, be fitted with a pair of suitable organic lenses within the range of –1,00 D to +1,00 D and with an edge thickness of between 1,5 mm and 2,5 mm.

For all test samples, these test lenses shall be edged either in accordance with the manufacturer's electronic instructions or with a digitally controlled edging machine that uses the tracing made of the individual test sample or, where appropriate, using a mechanical former in accordance with ISO 11380.

The bevel angle of the edged lens shall be $(120\ ^{+3}_{-2})°$ for spectacle frames featuring a rim with a groove.

### 6.2 Sample conditioning and test conditions

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Immediately before starting the series of tests, the test samples shall be conditioned for at least 4 h at an ambient temperature of 23 °C ± 5 °C, in the condition as received from the manufacturer or supplier, without prior realignment, adjustment or lubrication.

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Carry out the testing in an atmosphere maintained within the same temperature range.

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## 7 Testing, inspection and compliance

### 7.1 Testing

The testing shall be carried out with the conditioned test samples (see 6.2) in the sequence specified in Table 2 at an ambient temperature of 23 °C ± 5 °C.

1) A trade name for this polymer is CR 39. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

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**Table 2 — Sequence of testing**

| Identification of test | Requirement subclause | Test method subclause | Sequence | Sample 1 | Sample 2 | Samples 3 and 4 |
|---|---|---|---|---|---|---|
| Construction | 4.2.1 | 4.2.1 | 1 | * | | |
| Dimensional tolerance | 4.3; 4.4 | 4.4 | 2 | * | | |
| Dimensional stability | 4.6 | 8.2 | 3 | * | | |
| Resistance to perspiration | 4.7 | 8.3 | 4 | * | | |
| Bridge deformation | 4.8.1 | 8.4 | 5 | | * | |
| Lens retention | 4.8.2 | 8.4 | 6 | | * | |
| Endurance | 4.8.3 | 8.5 | 7 | | * | |
| Resistance to ignition | 4.9 | 8.6 | 8 | * | | |
| Resistance to optical radiation | 4.10 | 8.7 | 9 | | *[a] | |
| Nickel release | 4.2.3 | 8.8 | 10 | | | *[b] |

* Indicates that the test shall be applied.

[a] This test is optional.

[b] This test is a legal requirement in some countries.

## 7.2 Inspection and examination

Where visual inspection is required, the inspection and examination of test samples shall be carried out, without the aid of a magnifying lens, by an observer with a visual acuity of at least 1,0, when tested using optotypes conforming to ISO 8596. Any visual correction required for the observation distance shall be worn.

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During the examination, expose the test specimen to an illuminance of 1 000 lx to 2 000 lx and carry out the inspection against a matt black background.

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## 7.3 Compliance

If all test samples of the spectacle frame model pass the tests specified in Table 1 and listed in Table 2, the product shall be deemed to comply with this International Standard (see Figure 2).

If either sample 1 or sample 2 fails any one of the tests in the complete test sequence, an additional sample shall be used to repeat the test that was failed. If this additional sample passes the previously failed test and subsequent tests specified in Table 1 and listed in Table 2, the product shall be deemed to comply with this International Standard. If one or more tests in the sequence result in failure, the product shall be deemed not to comply with this International Standard.

If two or more of the tests carried out on the first set of test samples result in failure, no additional samples shall be tested and the product shall be deemed not to comply with this International Standard.

In the case of non-compliance, this clause does not preclude resubmitting the frame for testing after improvements have been made to its design or manufacture.


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