
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.

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This fourth edition cancels and replaces the third edition (ISO 12870:2012), which has been technically revised with the following change:

- 8.8 and Annex C are now covered in more specific standards (ISO/TS 24348:2014 and EN 16128:2015, respectively) and are now included as appropriate reference to this International Standard (see [4.2.3](#) and [Annex C](#)).

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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

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 3696, *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 24348:2014, *Ophthalmic optics — Spectacle frames — Method for the simulation of wear and detection of nickel release from 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

Note 1 to entry: Processing in this case is defined as cutting, shaping, laminating, bonding, bending, polishing and heating.

EXAMPLES Natural horn, bamboo and wood.

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 can 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	0	0	0	0	g	g	g	g	g	0
All other frame types ^b	g	g	0	0	g	g	g	g	g	g	g	0
Key												
g	Frame type shall meet the requirements of this subclause in order to comply with this International Standard.											
0	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 cover some essential requirements.												
^b “All other frame types” include 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 can, 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 appropriate 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, for example, 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 µg/cm²/week when tested in accordance with ISO/TS 24348 or, equivalently, EN 16128.

The parts to be tested shall include the following:

- the front (rims, bridge and, if applicable, brace bar and any nasal bearing surfaces including metal nose pads), excluding pad arms and lugs;
- the sides including metal collets, but excluding the joints and areas intended to be protected by plastic end covers (tips);
- metal decorative trims, if fitted on the inside of plastic sides and plastic end covers.

See ISO/TS 24348 or, equivalently, EN 16128 for further details.

NOTE 1 [Annex C](#) provides brief information about European requirements and legislation.

NOTE 2 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. See NOTE 2 of [Annex C](#).