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Očesna optika - Okviri očal - Zahteve in preskusne metode (ISO/DIS 12870:2022)

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO/DIS 12870:2022)

Augenoptik - Brillenfassungen - Anforderungen und Prüfverfahren (ISO/DIS 12870:2022)

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Foreword

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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).

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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*.

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

The main changes compared to the previous edition 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 physiological 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;

— minor changes to 4.2.1, 6.1, 8.5.2.3, 8.6, 8.7 (with a new Annex D), 9 and 10.3;

— 4.5 has been made optional, while the original 10.5 and 10.6 are now in a Note to 4.2.1;

— a new 10.5 refers to an informative Annex E on frame handling information.

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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.

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Parts of this document are applicable to custom-made frames – see 3.11 and Table 1.

NOTE See Annex A for recommendations on the design of spectacle frames.

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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 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 8624:2020, *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*

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*

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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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General terms

3.1.1
spectacle frame model
spectacle frame produced to a common design, using the same materials (but not necessarily the same pigmentation) and surface treatment

3.1.2
mass-produced frame
frame that is based on standardized dimensions/designs and is typically produced in a continuous production run or homogenous batch

Note 1 to entry: A homogeneous batch will be made to the same specifications using the same machine/equipment set-up.

Note 2 to entry: A mass-produced frame is not designed for a particular individual, but may have to be adapted to fit the wearer's facial features during dispensing and will be adapted by fitting it with spectacle lenses.

[SOURCE: Adapted from IMDRF N49: 2018, 4.7 and 4.8]

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3.1.3
custom-made frame
frame made to a written request from an authorized healthcare professional for the sole use of a particular individual to address the specific anatomo-physiological features or pathological condition of the individual for whom it is intended

Note 1 to entry: spectacle frames that are patient-matched, adaptable or mass-produced shall not be considered to be custom-made.

Note 2 to entry: A custom-made spectacle frame is intended for a case where an individual's specific needs cannot be met, or cannot be met at the appropriate level of performance, by an alternative device available on the market.

[SOURCE: IMDRF N49: 2018, 4.2, definition abbreviated to fit ISO Rules.]

3.1.4
principal components
<of a frame> rims, bridge, lugs, sides and metal nose pads

Note 1 to entry: For a frame of which the front is made of plastics materials, but the sides and/or lugs of metal, the sides and/or lugs are regarded as *principal components*.

3.1.5
non-principal components
<of a frame> all components of the spectacle frame that are not *principal components* (3.1.4)

Note 1 to entry: Typical *non-principal components* include joints, sprung joints, screws, closing blocks, solders, washers, bushings, nuts of screw assemblies, dowel pins, metal cores for plastics sides, plastics nose pads, plastics hoods, plastics end covers, plastics inner winding and cores of curl sides.[1)]

1) See ISO 7998 for a pictorial illustration of many of these terms.

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3.1.6
trained observer
person trained in testing of frames with a binocular decimal visual acuity of at least 1,0 (6/6 or 20/20) and wearing the appropriate refractive correction, if necessary, for the observation distance of the test

[SOURCE: ISO 4007: 2018, 3.11.1, modified by replacing "eye and face protectors" with "frames".]

3.1.7
test lens
lens as described in 6.1 to be mounted into the frame for testing the frame's requirements

3.2 Types of frame

3.2.1
plastics frame
frame of which the *principal parts* (3.1.4) of the front are made of a plastics material

3.2.2
frame made of natural organic materials
frame of which the *principal parts* (3.1.4) of the frame are made of *natural organic materials* (3.3.1)

Note 1 to entry: For the purposes of terminology, a frame from natural organic materials has the same construction as a plastics frame, the material having some properties similar to those of a plastic material.

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3.2.3
metal frame
frame of which the *principal components* (3.1.4) of the frame are made of metal

3.2.4
folding frame
frame hinged at the bridge, and possibly in the sides, so as to fold into a small space

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3.2.5
combination frame
frame of which the front and/or sides are made of at least two different categories of material

Note 1 to entry: The non-principal components (3.1.5) are excluded from consideration in this definition.

Note 2 to entry: Categories of material include but are not limited to metal, plastic and natural organic materials.

Note 3 to entry: This includes the original meaning of the term when the combination depended only on the construction of the front.

3.2.6
mount for rimless and semi-rimless spectacles
mount of which the front is made of metal or of a plastics material or a natural organic material (3.3.1) having similar properties, or a combination of both, and in which the lenses are not or only partially surrounded by a protecting rim

3.2.7
mixed frame
frame in which the components liable to come into close and prolonged contact with the skin are made of at least two different categories of material

Note 1 to entry: All components are included, both principal components (3.1.4) and non-principal components (3.1.5).

Note 2 to entry: Categories of material include but are not limited to metal, plastic and natural organic materials.

Note 3 to entry: This definition is used only for descriptions for testing purposes, not for frame categorization when marketing or in catalogues.

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3.2.8
clip-on
pair of lenses/filters or a one-piece lens or filter designed to clip on over the front of or behind a pair of spectacles

Note 1 to entry: for the purposes of this document, the term is restricted to designs with a rim that fit on the front.

[SOURCE: ISO 4007:2018, 3.5.1.14, modified by the addition of the note 1 to entry.]

3.2.9
prescription insert
device for carrying prescription lenses that is intended to be attached on the inside of the protector between the eyes of the wearer and the protective lens

Note 1 to entry: Prescription inserts can be used with eye and face protectors for occupational use, sunglasses, diving goggles, augmented reality devices, etc.

[SOURCE: ISO 4007:2018, 3.5.1.15, modified by the addition of the note to entry.]

3.3 Terms describing frame materials and frames made from specific metals

3.3.1
natural organic material
material that has not been synthesized from other raw organic materials and, when processed, remains essentially in its original state

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

EXAMPLE Natural horn, bamboo and wood.

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3.3.2
rolled-gold covering
covering achieved using a method by which a layer of gold alloy is bonded to a sheet or bar of base metal, the whole then being subjected to reduction by rolling

Note 1 to entry: Adapted from ISO 3160-1:1998, 3.1.

Note 2 to entry: The proportion of gold is designated by its nominal thickness, in micrometres, and by the fineness of the gold alloy covering the base metal, for example, 40 µm nominal thickness of 500 fineness gold alloy. In accordance with ISO 3160-1, the range of nominal thicknesses, in micrometres, are 5 µm, 10 µm, 20 µm, 40 µm, 80 µm, 100 µm and 120 µm, with a tolerance of –20 %, and the fineness is defined as the proportion of pure gold contained in the gold alloy, normally expressed in thousandths (41,67 thousandths = 1 carat).

Note 3 to entry: To clarify that the frame is made from rolled-gold material, the initials L or RG can also be marked on the frame.

3.3.3
rolled-gold spectacle frame
frame of which each of the metal *principal components* (3.1.4) is made of a material with a rolled-gold covering

3.3.4
titanium frame
frame of which each of the metal *principal components* (3.1.4) is made of an alloy containing at least 70% titanium by mass and has a non-nickel containing coating

3.3.5
pure titanium frame
frame of which each of the metal *principal components* (3.1.4) is made of an alloy containing at least 90 % titanium by mass and has a non-nickel containing coating

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3.3.6
memory-metal frame
frame of which some of the metal *principal components* (3.1.4) are made of an alloy containing at least 40% titanium by mass with specific flexibility characteristics

Note 1 to entry: The rims might be made of monel or similar material, or a titanium alloy.

3.3.7
titanium niobium frame
Ti-Nb frame
frame of which some of the metal *principal components* (3.1.4) are made of an alloy containing at least 50% and less than 70% titanium by mass

Note 1 to entry: The material contains niobium and other elements to decrease Young's modulus to 80 GPa or less for specific flexibility characteristics. The alloy and its surface coating do not contain the element nickel.

Note 2 to entry: The rims are probably made of titanium, usually β-titanium. β-titanium material is a titanium alloy containing at least 70% titanium by mass with specific characteristics.)

4 Requirements

4.1 General

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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.

Spectacle frames shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.

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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 document is claimed, the manufacturer or its representative has the responsibility, by any chosen means, 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.

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Table 1 — Requirements applicable to different types of spectacle frame

Production method	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	9
Mass-produced [b]	Rimless and semi-rimless mounts	g	g	O	g	O	g [c]	O	g	g	g	g	O	g
	Rimmed clip-ons, prescription inserts	g	g	O	g	g	g	N	N	g	N	g	O	O
	All other frame types [d]	g	g	O	g	g	g	O	g	g	g	g	O	g
Custom-made [b]	Rimless and semi-rimless mounts	g	g	O	g	O	N	O	N	N	N	g	O	O
	Rimmed clip-ons, prescription inserts	g	g	O	g	g	O	N	N	N	N	g	O	O
	All other frame types [d]	g	g	O	g	g	O	O	N	N	O[e]	g	O	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.
N	Not applicable

4.2.1	Construction	4.6	Dimensional stability at elevated temperature
4.2.2	General physiological compatibility	4.7	Resistance to perspiration
4.2.3	Nickel release	4.8	Mechanical stability
4.2.4	Clinical evaluation	4.9	Resistance to ignition
4.3	Measurement system	4.10	Resistance to optical radiation
4.4	Dimensional tolerances on nominal size	9	Marking, also 10.2, 10.3 and 10.4
4.5	Tolerance on screw threads		

[a] Under European legislation, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.5, 4.6, 4.7, 4.8, 4.9 and 9 cover some essential requirements.

[b] The production method shall be declared by the manufacturer.

[c] Horizontal boxed lens size is optional for rimless mounts

[d] "All other frame types" include plastics, metal, combination spectacle frames and frames made of natural organic materials, including folding spectacle frames, that have a rim that completely surrounds the lens periphery.

[e] Only 4.8.1 and 4.8.2 can be applied

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4.2 Physiological compatibility

4.2.1 Construction

The solutions adopted by the manufacturer for the design and construction of spectacle frames must conform to safety principles, taking account of the generally acknowledged state of the art.

When tested under the inspection conditions given in 7.2, areas of the spectacle frame that might, during intended use come into contact with the wearer shall be smooth and without sharp protrusions.

NOTE 1 If a frame incorporates magnets, e.g., for attachment of clip-ons or prescription inserts, then risk management must ensure that there will not be any interference with other medical devices, e.g. hearing aids, and shall not compromise health, e.g., the possibility of being swallowed. The risk of swallowing magnets by children can be tested, e.g., according to the Toys Directive and EN 71-1.

NOTE 2 Legislation in some countries can require that, e.g., for frames fitted with headbands that help retain the spectacles in the correct position in front of the eyes, the headband shall not be capable of causing a strangulation hazard. See, for example, Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, and EN 14682.

4.2.2 General physiological compatibility

Spectacle frames shall be designed, manufactured and packaged in such a way that, when used under normal conditions and according to the intended use as foreseen by the manufacturer, they shall not compromise the health and safety of the patient, healthcare professional or lay person.

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The manufacturer shall perform an appropriate risk management analysis.

Special attention shall be given to substances that are known to be allergenic, carcinogenic, mutagenic or toxic to reproduction.

NOTE 1 ISO 14971 gives guidance on risk management.

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NOTE 2 Attention must be paid to any regulatory limits. In some countries, restrictions on specific materials or their chemical constituents are mandatory, e.g., European REACH, Californian Proposition 65.

NOTE 3 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 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 4 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 frames made from that particular material.

NOTE 5 In some countries, additional regulations may be relevant, e.g., CPSIA (Consumer Product Safety Improvement Act), or for wearers aged 36 months or less, e.g., Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

NOTE 6 Testing according to ISO 10993-5 gives useful information on biocompatibility.

NOTE 7 For mixed-frames, where more than one material is liable to come into close and prolonged contact with the skin, the manufacturer needs to consider the physiological properties of each material.

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