

PS- ISO 12870/2019

ICS No. 11.040.70

PAKISTAN STANDARD FOR:

**Ophthalmic optics -- Spectacle frames --
Requirements and test methods**

(IDT: ISO 12870-2016)



0. **FOREWORD**

- 0.1 International Standards are widely adopted at the regional or national level and applied by manufacturers, trade organizations, purchasers, consumers, testing laboratories, authorities and other interested parties. Since these standards generally reflect the best experience of industry, researchers, consumers and regulators worldwide, and cover common needs in a variety of countries, they constitute one of the important bases for the removal of technical barriers to trade. This has been explicitly acknowledged in the Agreement on Technical Barriers to Trade of the World Trade Organization (WTO TBT Agreement).
- 0.2 Pakistan being the signatory of TBT/WTO agreement has also re-align its Standard Development activities to meet the opportunities as well as challenges of globalization.
- 0.3 In consultation with government of Pakistan, PSQCA has adopted all ISO Standards related to various fields in 2001, which was notified through a SRO#134(KE)/2002, dated 27th November,2002.
- 0.4 This Pakistan Standard was adopted by the Authority of the Pakistan Standards & Quality Control Authority, (National Standards Body of Islamic Republic of Pakistan), after the draft prepared by the Mechanical Technical Committee (MTC-1): “Small Scale Industrial Product” which is approved and endorsed by the National Standards Committee of Mechanical on _____
- 0.5 This Pakistan Standard No. PS- ISO 12870/2001 is identical to ISO 12870:1997 “Ophthalmic optics -- Spectacle frames -- Requirements and test methods” which is acknowledged with thanks.
- 0.6 This Standard is subject to periodical review in order to keep pace with development in technology. Any suggestion for improvement will be recorded and placed before the revising committee in due course.

**Ophthalmic optics — Spectacle frames
— Requirements and test methods**

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

not for sale www.psqca.com.pk



not for sale www.psqca.com.pk



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 General	2
4.2 Physiological compatibility	3
4.2.1 Construction	3
4.2.2 General physiological compatibility	3
4.2.3 Nickel release	3
4.2.4 Clinical evaluation	4
4.3 Measurement system	4
4.4 Dimensional tolerances on nominal size	4
4.5 Tolerance on screw threads	4
4.6 Dimensional stability at elevated temperature	4
4.7 Resistance to perspiration	4
4.8 Mechanical stability	5
4.8.1 Bridge deformation	5
4.8.2 Lens retention characteristics	5
4.8.3 Endurance	5
4.9 Resistance to ignition	6
4.10 Resistance to optical radiation	6
5 Selection of test samples	6
5.1 General	6
5.2 Testing for nickel release	6
5.3 Change in spectacle frame model	6
6 Preparation and conditioning of test samples	6
6.1 Test lenses	6
6.2 Sample conditioning and test conditions	7
7 Testing, inspection and compliance	7
7.1 Testing	7
7.2 Inspection and examination	8
7.3 Compliance	8
8 Test methods	9
8.1 General	9
8.2 Test for dimensional stability at elevated temperature	10
8.2.1 Apparatus	10
8.2.2 Procedure	10
8.3 Test for resistance to perspiration	10
8.3.1 Apparatus and reagents	10
8.3.2 Procedure	11
8.4 Bridge deformation and lens retention test	11
8.4.1 Apparatus	11
8.4.2 Procedure	12
8.5 Endurance test	13
8.5.1 Apparatus	13
8.5.2 Procedure	14
8.6 Test for resistance to ignition	15
8.6.1 Apparatus	15
8.6.2 Procedure	15
8.7 Test for resistance to optical radiation	15
8.7.1 Apparatus	15

8.7.2	Procedure.....	16
9	Marking	16
10	Additional information to be supplied by the manufacturer or other person placing the product on the market	17
11	Reference to this International Standard	18
	Annex A (informative) Recommendations for the design of spectacle frames	19
	Annex B (informative) Examples of layout of test equipment	22
	Annex C (informative) European requirements and legislation on nickel release	25
	Bibliography	26

not for sale www.psqca.com.pk

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](#)).

not for sale www.psqca.com.pk

ONLY FOR SUGGESTED MANDATORY
PRODUCT FOR INCLUSION/SRO
U/S 14 OF PSQCA ACT VI OF 1996

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](#).

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 $(90 - \frac{0}{5})^\circ$ 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
- 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.

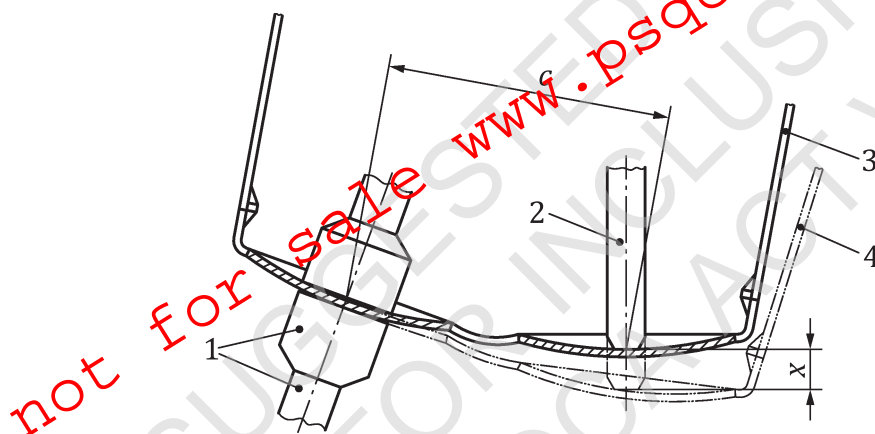
If the spectacle frame is made from natural materials and the manufacturer recommends a cream or wax for its maintenance, then, before testing, the frame(s) shall be prepared with this cream or wax in accordance with the manufacturer's instructions. At the end of the test, if the frame fails to meet 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, or
- 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 $0,02c$ (see Figure 1).



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,
- 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), or
- 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

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](#).

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, for example 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 shall be selected at random and shall be conditioned and tested as specified in ISO/TS 24348 or, equivalently, EN 16128.

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 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.

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:

- for rimless frames, organic lenses of polycarbonate with a vertex power of $(0,00 \pm 0,25)$ D, a centre thickness of $(2,00 \pm 0,2)$ mm and a radius of curvature of the concave surface of (90 ± 10) mm;
- for semi-rimless frames, organic lenses of allyl diglycol carbonate¹⁾ or polycarbonate with a vertex power of $(0,00 \pm 0,25)$ D, a centre thickness of $(2,00 \pm 0,2)$ mm and a radius of curvature of the concave surface of (90 ± 10) mm;
- for all other frame types, including folding and all rimmed spectacles, either organic lenses as in b), or silicate glass with a vertex power of $(0,00 \pm 0,25)$ D, a centre thickness of $(2,25 \pm 0,25)$ mm and a radius of curvature of the concave surface of (100 ± 20) 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 $(120^{+3}_{-2})^\circ$ for spectacle frames featuring a rim with a groove.

6.2 Sample conditioning and test conditions

Immediately before starting the series of tests, the test samples shall be conditioned for at least 4 h at an ambient temperature of $(23 \pm 5)^\circ\text{C}$, in the condition as received from the manufacturer or supplier, without prior realignment, adjustment or lubrication.

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

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 $(23 \pm 5)^\circ\text{C}$.

Table 2 — Sequence of testing

Identification of test	Requirement subclause	Test method subclause	Sequence	Sample 1	Sample 2	Nickel release samples
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		*	
* Indicates that the test shall be applied.						
a This test is optional.						
b This test is a legal requirement in some countries.						

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.

Table 2 (continued)

Identification of test	Requirement subclause	Test method subclause	Sequence	Sample 1	Sample 2	Nickel release samples
Resistance to ignition	4.9	8.6	8	*		
Resistance to optical radiation	4.10	8.7	9		*a	
Nickel release	4.2.3	ISO/TS 24348 or EN 16128	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.

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.

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](#)).

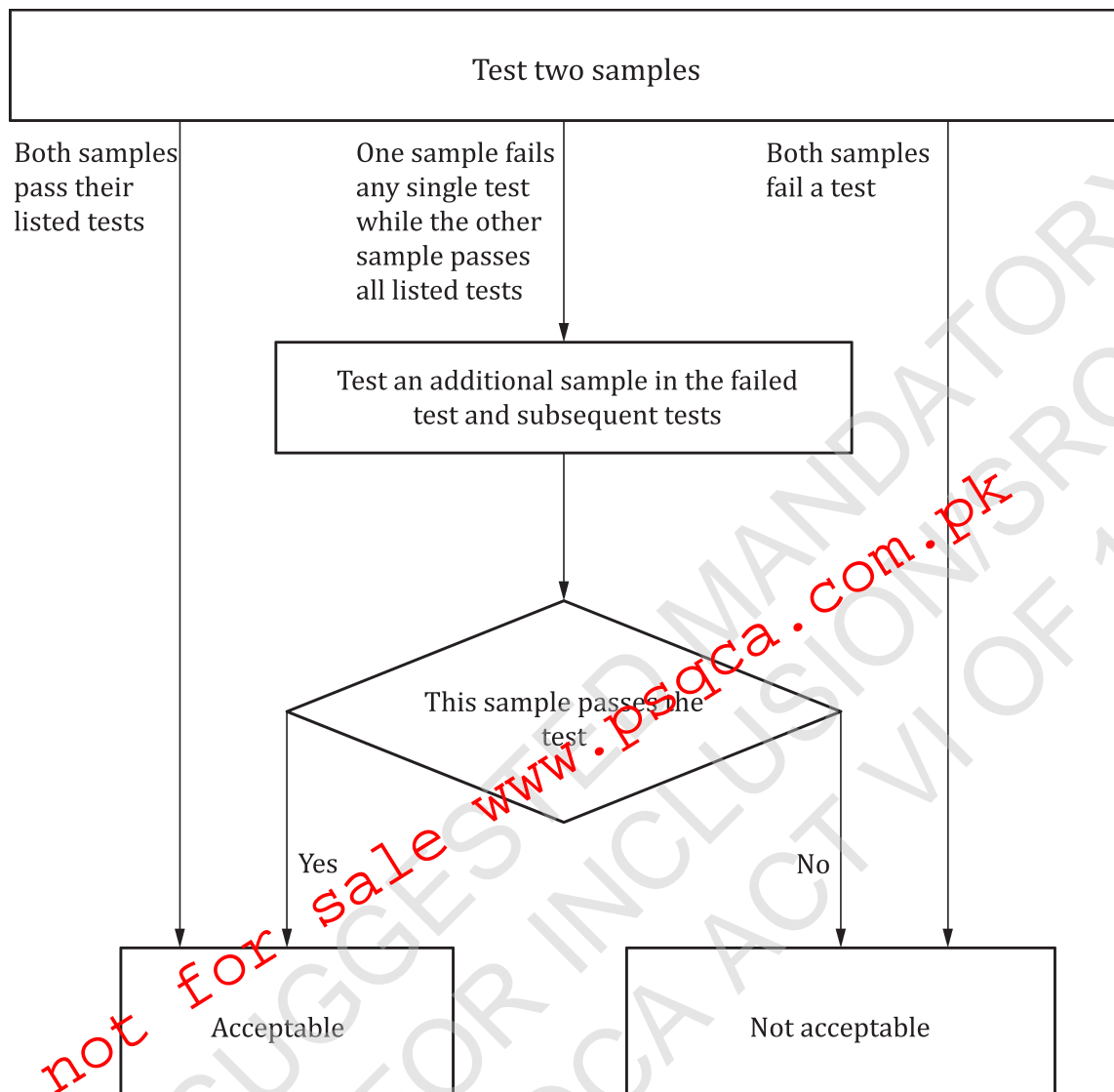


Figure 2 — Flow chart for compliance, excluding testing for nickel release

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.

8 Test methods

8.1 General

The test methods described are reference test methods. Variations or alternatives may be used provided their results can be shown to be equivalent to those of the relevant reference method. In case of dispute, the result obtained with the reference method shall have precedence.

8.2 Test for dimensional stability at elevated temperature

8.2.1 Apparatus

8.2.1.1 Oven, capable of producing the test temperature of $(55 \pm 5) ^\circ\text{C}$.

8.2.1.2 Flat plate, of glass or metal, mounted in the oven (8.2.1.1) either on, or parallel to, the base of the chamber.

8.2.1.3 Linear measuring device, having a measuring accuracy of at least 0,5 mm.

8.2.2 Procedure

8.2.2.1 At an ambient temperature of $(23 \pm 5) ^\circ\text{C}$, take test sample 1, with test lenses fitted and with the sides open to the fullest extent (for frames with sprung joints, opened to the fullest natural extent without activating the spring mechanism), and measure the distance between the side tips using the measuring device (8.2.1.3). Record this measurement as the pre-heating value, l_0 .

8.2.2.2 Before commencing the test, stabilize the oven (8.2.1.1) at the test temperature of $(55 \pm 5) ^\circ\text{C}$.

Place the test sample on the plate (8.2.1.2), with the sides still open to the fullest extent, and with the top edge of the front and the top edge of the sides resting on the plate surface. Place the sample on the plate in the oven, and ensure that the sample does not touch other samples or the oven wall.

8.2.2.3 When the test sample has reached the test temperature after approximately 15 min at the appropriate setting, leave it undisturbed at the test temperature for a further $2 \text{ h}^{+5 \text{ min}}_{0 \text{ min}}$.

After this period, remove the test sample, still on the plate, from the oven. Allow to cool for a period of at least 2 h at $(23 \pm 5) ^\circ\text{C}$ and repeat the measurement of the distance between the side tips as described in 8.2.2.1. Record this measurement as the post-heating value, l_1 , and calculate the difference, $l_1 - l_0$.

8.3 Test for resistance to perspiration

8.3.1 Apparatus and reagents

8.3.1.1 Oven, capable of producing the test temperature of $(55 \pm 5) ^\circ\text{C}$.

8.3.1.2 Container, of glass or inert plastic, measuring at least 200 mm across and 90 mm high, capable of being closed.

8.3.1.3 Volumetric flask, 1 l, gauged to class A.

8.3.1.4 Water, conforming to grade 3 of ISO 3696.

8.3.1.5 Artificial sweat solution, comprised of the following:

- a) lactic acid, $\rho = 1,21 \text{ g/ml}$, >85 % purity;
- b) sodium chloride (analytical reagent purity, $\geq 99 \%$);

Impurities

- 1) Pb: $\leq 0,0010 \%$;
- 2) Fe: $\leq 0,0010 \%$;

3) Br: $\leq 0,020\ 0\ \%$;

4) I: $\leq 0,010\ 0\ \%$;

c) water, conforming to grade 3 of ISO 3696.

Using suitable containers, weigh $(50 \pm 0,1)$ g of lactic acid and $(100 \pm 0,1)$ g of sodium chloride and dissolve in 900 ml of water. Using the flask (8.3.1.3), make up to 1 l with water.

8.3.1.6 Frame supports, of glass or inert plastic, fitted in the container so that the sample(s) are held above the artificial sweat solution (see Figure B.1). The supports may be designed so as to hold several samples stacked one above another, or side by side, or both, but without being in contact with each other.

8.3.2 Procedure

8.3.2.1 Cover the base of the container (8.3.1.2) with the artificial sweat solution (8.3.1.5) to a minimum depth of 10 mm so that the lowest part of the (lowest, if stacked) frame shall be not less than 12 mm above the solution.

Place test sample 1, fitted with the test lenses, on the supports (8.3.1.6), with the sides open to the fullest extent (for frames with sprung hinges, opened to the fullest natural extent without activating the spring mechanism), and with the bottom edges of the sides resting on the supports (see Figure B.1). Ensure that the spectacle frame does not touch other samples or the container walls.

Close the container, place it in the oven (8.3.1.1) and maintain at (55 ± 5) °C.

8.3.2.2 After $8\ h \pm 30\ min$, remove each sample and immediately wash with water (8.3.1.4). Dry without rubbing, using a soft cloth.

8.3.2.3 Within 30 min, examine each test sample without the aid of magnification under the inspection conditions described in 7.2. By comparison with an identical untested spectacle frame, check for and record any spots or change in colour.

8.3.2.4 Replace the test samples on the supports, close the container and maintain the test temperature of (55 ± 5) °C for a further $16\ h \pm 30\ min$. After completion of this second period, remove, clean and dry the samples as described in 8.3.2.2.

8.3.2.5 Within 30 min, examine those areas of each sample which are liable to come into prolonged contact with the skin of the wearer under the inspection conditions described in 7.2. By comparison with an identical untested spectacle frame, check for and record any corrosion, surface degradation or separation of any coating layer.

8.4 Bridge deformation and lens retention test

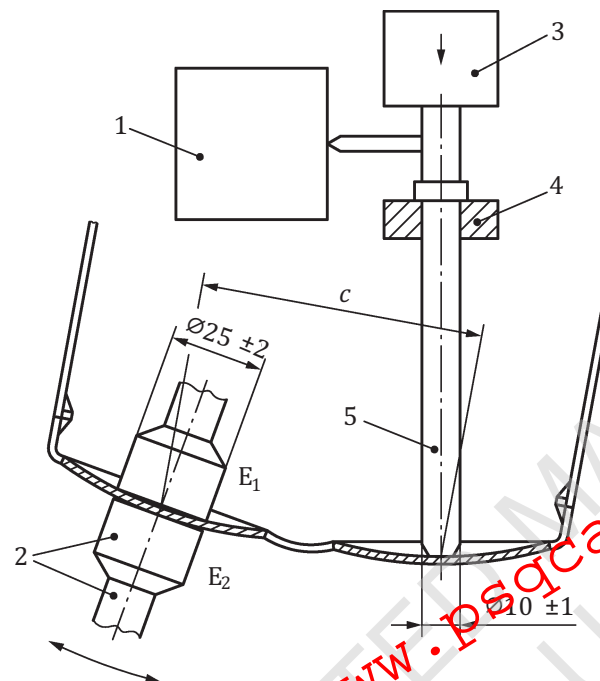
8.4.1 Apparatus

See Figure 3.

The test apparatus consists of a vertically operating annular clamp, a downward-operating pressure peg and a measuring device. The annular clamp shall be capable of holding the test sample without twist or slip and have a diameter of (25 ± 2) mm, with two contact surfaces, E_1 and E_2 , made of a firm elastic material (e.g. polyamide). The downward-operating pressure peg (see Figure 3, key item 5) shall have a diameter of (10 ± 1) mm with an almost hemispherical contact surface. The clamping surfaces can be separated at least 10 mm on either side of a horizontal line going through the apparatus and the pressure peg can travel from at least 10 mm above the horizontal line to not more than 8 mm below. To accommodate frames with a significant face form angle, the annular clamp shall also be capable of rotating about a horizontal axis so that the axis of the pressure peg remains perpendicular to the

plane of the unclamped lens at its boxed centre. The distance between the clamp and pressure peg is adjustable. The apparatus includes a linear measuring device that is accurate to at least 0,1 mm.

Dimensions in millimetres



Key

- 1 measuring device
- 2 annular clamp
- 3 direction and point of application of force (maximum 5 N)
- 4 travelling ring
- 5 pressure peg

Figure 3 — Bridge deformation test

8.4.2 Procedure

8.4.2.1 Mount test sample 2 on the device with the sides of the test sample extended and with the front of the test sample downwards. Clamp the sample within 2 mm of the boxed centre of one lens (see [Figure 3](#)).

Lower the pressure peg so that it rests on the back surface of the unclamped lens within 2 mm of its boxed centre, ensuring that there is no movement of the lens. Record this as the starting position.

Then move the pressure peg downwards slowly and smoothly, increasing the force until the first of either of the following criteria is reached:

- a) a maximum force of 5 N;
- b) a distance equal to $(10 \pm 1) \%$ of the boxed centre distance, c (see ISO 8624).

8.4.2.2 If the maximum force of 5 N is insufficient to displace the pressure peg over the distance specified in [8.4.2.1 b](#)), continue the test but record the displacement that was attained.

Retain the initial displacement for 5 s, then return the pressure peg to its starting position. After a relaxation period of 20 s, lower the pressure peg again until it just rests on the lens.

8.4.2.3 Determine, in millimetres, the movement, x , of the pressure peg from the starting position and calculate the percentage deformation using the following formula. Check that the spectacle frame shows no fracture.

$$f = \frac{x}{c} \times 100$$

where

- f is the percentage deformation;
- x is the movement of the pressure peg;
- c is the boxed centre distance.

8.4.2.4 Using the inspection conditions described in 7.2, check that neither test lens has been dislodged wholly or partially from its original location in the groove or mount.

8.5 Endurance test

8.5.1 Apparatus

The test apparatus consists of two clamping devices mounted on universal joints, which are used to restrain the sides (see Figures B.2 and B.3), and a horizontal bar forming a bridge support (see Figure 4, key item 2). The bridge support has a triangular cross-section, enclosing an angle of $30^\circ \pm 2^\circ$ and having a thickness at the top of (12 ± 1) mm with the upper edge approximately radiused.

The positions of the clamps and bridge support, relative to each other, are adjustable by at least 40 mm horizontally and vertically.

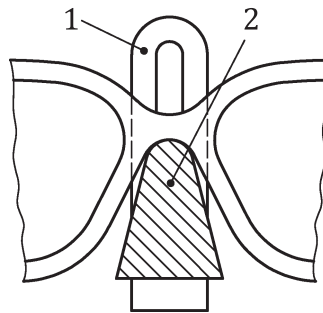
The universal joints shall not restrict the angular movement of the sides. The clamping point, defined as the edge of the clamp nearest the dowel screw centre, shall be (55 ± 1) mm from the centre of the pivot of the universal joint.

The apparatus is capable of continuously and smoothly imparting a cyclical motion to one of the universal joints:

- down $(30 \pm 0,5)$ mm;
- out $(60 \pm 1,0)$ mm;
- up $(30 \pm 0,5)$ mm;

at a rate of 40 cycles/min, with the other clamped side remaining fixed, except for the flexure of the universal joint.

For testing in frame development, manufacturers may modify the test equipment so that either the right or the left side is subject to the cyclical motion, the other remaining fixed.



Key

- 1 vertical support with slot to facilitate height adjustment
- 2 horizontal bar, located through a slot in the vertical support

Figure 4 — Detail of adjustable bridge support for endurance test rig

8.5.2 Procedure

8.5.2.1 Before mounting test sample 2 on the test apparatus, establish the clamping and measuring points.

Except for curl sides, ensure that the sides are clamped at a distance from the dowel-screw centre equivalent to 70 % of the overall side length ± 1 mm. Each measuring point shall be (15 ± 1) mm nearer to the dowel screw than the clamping point.

For curl sides, ensure that the clamping points are (3 ± 1) mm nearer to the dowel screw than the junction between curl and the rigid side. Each measuring point shall be (10 ± 1) mm nearer to the dowel screw than the clamping point.

8.5.2.2 Before testing, open the sides of the spectacle frame to the fullest extent, without tension, and measure the distance between the sides at the pre-determined measuring points. Record this distance, d_1 .

Mount the spectacle frame on the test device and ensure the following:

- a) that the rotating clamp (see [Figure B.2](#), key item 5) is on the same plane as the fixed clamp (see [Figure B.2](#), key item 4) and that it is positioned at the nearest point of its rotation towards the fixed clamp;
- b) that the bridge of the spectacle frame is freely supported on the bridge support (see [Figure B.2](#), key item 6, see also [Figure 4](#));
- c) that the horizontal relationship between the fixed clamp (see [Figure B.2](#), key item 4), the bridge support (see [Figure B.2](#), key item 6), and the rotating clamp (see [Figure B.2](#), key item 5) are such that the spectacle frame can be mounted with sides fully open, but not under tension, and with the bridge support midway between the clamps;
- d) that the height of the bridge support is adjusted so as to ensure that the sides are in line with the axis of the clamps and parallel to the base of the device;
- e) that the sides are clamped within 1 mm of the calculated clamping point;
- f) that the lock screw (see [Figure B.3](#), key item 5) is loosened to allow the fixed clamp to align with the inward angle of drop of the side, and then re-tightened;
- g) that the revolution counter is set to zero.

8.5.2.3 With the test sample, fitted with the test lenses, in position, set the apparatus in motion, subjecting the sample to the cyclical rotating movement described in 8.5.1 for a total of $(500 \pm 1)_0$ cycles.

After the 500 cycles have been completed, stop the motion and remove the sample from the apparatus. Measure the distance between the sides at the measuring point and record the distance, d_2 , in millimetres. Check that the difference between d_1 and d_2 does not exceed 5 mm.

Under the inspection conditions described in 7.2, inspect the spectacle frame for fractures, cracks or change in side movement (see 4.8.3).

8.6 Test for resistance to ignition

8.6.1 Apparatus

8.6.1.1 Steel rod, (300 ± 3) mm long and 6 mm in nominal diameter, with end faces that are flat and perpendicular to the longitudinal axis.

8.6.1.2 Heat source.

8.6.1.3 Thermocouple and temperature-indicating devices

8.6.1.4 Timer, capable of measuring an elapsed time of 10 s with an uncertainty no greater than $\pm 0,1$ s.

8.6.2 Procedure

8.6.2.1 Heat one end of the steel rod (8.6.1.1) over a length of at least 50 mm to a temperature of (650 ± 20) °C. Measure the temperature of the rod by means of the thermocouple (8.6.1.3) attached at a distance of (20 ± 1) mm from the heated end of the rod. Press the heated face of the rod (positioned vertically with the heated end downwards) against the surface of test sample 1 (the contact force being equal to the weight of the rod) for a period of $(5 \pm 0,5)$ s, then remove the rod.

Repeat this test on each separate component of test sample 1.

8.6.2.2 Carry out a visual inspection during the test to establish whether there is continued combustion of the test sample after removal of the rod.

8.7 Test for resistance to optical radiation

8.7.1 Apparatus

8.7.1.1 Xenon radiation apparatus, either

- specific xenon radiation apparatus, incorporating an ozone-free high-pressure xenon lamp with a nominal power of 450 W, stabilized at a lamp current of $(25 \pm 0,2)$ A, or
- any commercially available xenon radiation apparatus.

New lamps shall be burnt in for at least 150 h before use.

NOTE Suitable lamps are XBO-450 OFR and CSX-450 OFR.²⁾

8.7.1.2 Standard blue-scale radiation exposure medium, complying with ISO 105-B02.

2) XBO-450 OFR and CSX-450 OFR are examples of suitable products available commercially. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of these products. Equivalent products may be used if they can be shown to lead to the same results.

8.7.1.3 UV-B transmitting filter, transmitting wavelengths above a cut-off at 270 nm.

8.7.2 Procedure

8.7.2.1 Place the UV-B filter (8.7.1.3) in the radiation apparatus [8.7.1.1 a) or b)] to shield the test sample from shorter wavelengths. Before submitting test sample 2 to the test, cut the sample into two parts at approximately the middle of the bridge. Retain one part to serve as a control for colour comparison purposes. On the other part, separate the spectacle side from its front. Expose the front surface of the front and the outside surface of the side to xenon radiation as specified in 8.7.2.2. Carry out the determination with the test equipment operating at a temperature of $(23 \pm 5) ^\circ\text{C}$.

Forced ventilation is necessary to maintain the temperature within the specified range.

8.7.2.2 One of the following two procedures shall be followed:

- Place that/those part(s) of test sample 2 used for testing in the xenon radiation apparatus [8.7.1.1 a)]. Expose the sample for $(25 \pm 0,1)$ h to radiation from the xenon lamp at a distance of (300 ± 10) mm measured from the axis of the lamp to the nearest point on the test sample(s). Ensure that the angle of incidence of the radiation on the sample's external surface is essentially perpendicular.
- Place that part of test sample 2 used for testing in the xenon radiation apparatus [8.7.1.1 b)], together with the appropriate blue-scale radiation exposure medium (8.7.1.2). Submit each sample and the blue-scale radiation exposure medium to xenon radiation until grade 4 of the blue-scale exposure medium is bleached to stage 4,5 of the grey scale. See ISO 105-B02.

8.7.2.3 Switch off the radiation, remove each sample and inspect under the conditions described in 7.2, ignoring any changes adjacent to the cut surface at the bridge. Compare the exposed sample to the control sample and record as a failure if the exposed sample displays any of the changes specified in 4.10.

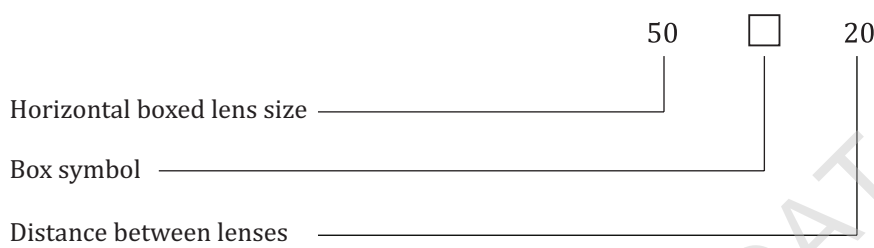
9 Marking

Spectacle frames shall be marked with the minimum information given in Table 3 at the locations indicated.

Table 3 — Marking of spectacle frames

Marking	Location
Identification of manufacturer or his/her agent or supplier	Not specified
Model identification	Not specified
Colour identification	Not specified
Horizontal boxed lens size with box symbol □	On the front, whenever practicable
Distance between lenses	On the front, whenever practicable
NOTE 1 All dimensions used are given in ISO 8624.	
NOTE 2 Marking of horizontal boxed lens size and distance between lenses is optional for three-piece rimless mounts.	
NOTE 3 National legislation in some countries can require additional information, e.g. country of origin, to be marked on the frame.	

Table 3 (continued)

Marking	Location
Overall length of side	On the side
Specified order of marking of the dimensions of the front:	
	
<p>NOTE 1 All dimensions used are given in ISO 8624.</p> <p>NOTE 2 Marking of horizontal boxed lens size and distance between lenses is optional for three-piece rimless mounts.</p> <p>NOTE 3 National legislation in some countries can require additional information, e.g. country of origin, to be marked on the frame.</p>	

10 Additional information to be supplied by the manufacturer or other person placing the product on the market

10.1 The manufacturer, or his/her agent or supplier, shall make available, with the spectacle frame, information on particular processing conditions that can be required when fitting lenses or manipulating the spectacle frame for adjustment purposes.

10.2 The following information shall be made available in catalogues.

Range available (sizes and colours) including other side lengths available.

10.3 The following information shall be made available upon request:

- vertical boxed lens size (dimension shown in ISO 8624);
- bridge width (dimension shown in ISO 8624);
- bridge height (dimension shown in ISO 8624);
- effective diameter (dimension shown in ISO 8624);
- a list of components that are available separately.

10.4 Legislation in some countries can require that, for spectacle frames imported into those countries where the manufacturer does not have a registered place of business, the packaging or labelling shall state the name and address of the authorized representative.

10.5 Legislation in some countries can require that, for spectacle frames intended for children younger than 36 months, warnings be provided regarding the possibility of parts becoming detached or an asphyxiation hazard.

NOTE 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 71-1.

10.6 Legislation in some countries can require that, for example, for spectacle 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.

NOTE 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.

11 Reference to this International Standard

If the manufacturer or supplier claims compliance with this International Standard, reference shall be made to this International Standard either on the packaging or in available literature. Marking ISO 12870 on the frame is optional.

Any claim for compliance with subclauses of this International Standard which are optional for the type of frame (e.g. 4.10) shall be accompanied by a reference to this International Standard, i.e. ISO 12870:2016, and if the requirement in 4.2.3 (nickel release) applies, a reference to ISO/TS 24348 or, equivalently, EN 16128.

not for sale www.psqca.com.pk

Annex A (informative)

Recommendations for the design of spectacle frames

A.1 Design considerations

The spectacle frame should be designed to provide secure placement and retention of the lenses in the prescribed position relative to the eyes, and should be capable of being worn without discomfort for prolonged periods. It is therefore necessary that, in addition to meeting the requirements contained in this International Standard, the spectacle frame have the following capabilities.

A.2 Materials

As well as being sufficiently stable to meet the requirements of [Clause 4](#), the materials used should also allow for professional adjustment at final fitting and should retain both their shape and relative position when worn. Materials should also resist degradation well enough to make the spectacle frame acceptable for use over a reasonable period.

The following information can be made available either in documentation accompanying the frame, in catalogues or upon request:

- materials of the principal components, for example, type of plastic and whether it has a protective coating;
- for metal frames, the type of plating and whether it has a protective coating.

A.3 Assembly

The method of assembly should ensure that unintentional separation of the various components from each other (e.g. separation of sides from fronts or trims from fronts) cannot occur either during fitting or in normal wear.

A.4 Range of sizes and facility for adjustment

In order to provide a comfortable fit on a wide range of wearers, the spectacle frame should be available in a minimum of two lens sizes, each in a minimum of two bridge widths.

Apart from the general need for adjustment identified in [A.2](#), it should be possible to vary the side length on any given front. A minimum of three side lengths should be achievable, with a 5 mm difference between each, by, for example, shortening the side tips or by replacing the whole side.

A.5 Mass

It is recommended that the mass of the unglazed spectacle frame not exceed 32 g.

A.6 Contact areas

Areas intended as bearing surfaces should generally be as large as possible. In the case of pads and nasal bearing areas, it is recommended that the total area be the following:

- a) at least 200 mm² for a spectacle frame weighing up to 25 g;
- b) at least 250 mm² for a spectacle frame weighing over 25 g.

Security on wearing can, in part, be provided by lateral pressure on the head. The elasticity of both front and sides should therefore be durable and contact surfaces should be as large as possible.

A.7 Sprung joints

The spring tension of sprung joints should be similar on both sides when the sides are subjected to identical deflection. The spring tensions should become active immediately at the side tip in the wearing position when the side is deflected out of its starting position.

A.8 Symmetry of spectacle frame

In a mirror-symmetric spectacle frame design, the let-back of side, the angle of side and the overall side length should be the same.

A.9 Claims for material composition

A.9.1 General

If the frame is claimed to be manufactured from rolled-gold or titanium material, then the materials used shall comply with the following definitions.

A.9.2

principal components of metal or combination spectacle frame

rim, bridge, lugs, sides and metal nose pads

NOTE 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.

A.9.3

non-principal components of metal or combination spectacle frame

all components of the spectacle frame that are not principal components

NOTE Typical non-principal components include joints, sprung joints, screws, closing blocks, solders, washers, bushings, nuts of screw assemblies, dowel pins, plastics nose pads, plastics coverings, plastics inner winding and cores of curl sides.

A.9.4

rolled-gold spectacle frame

frame of which each of the principal metal components is made of a material with a rolled-gold covering

A.9.5

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 Adapted from ISO 3160-1:1998, 3.1.

NOTE 2 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 clarify that the frame is made from rolled-gold material, the initials L or RG can also be marked on the frame.

A.9.6

titanium spectacle frame

frame of which each of the principal metal components is made of an alloy containing at least 70 % titanium by mass

A.9.7

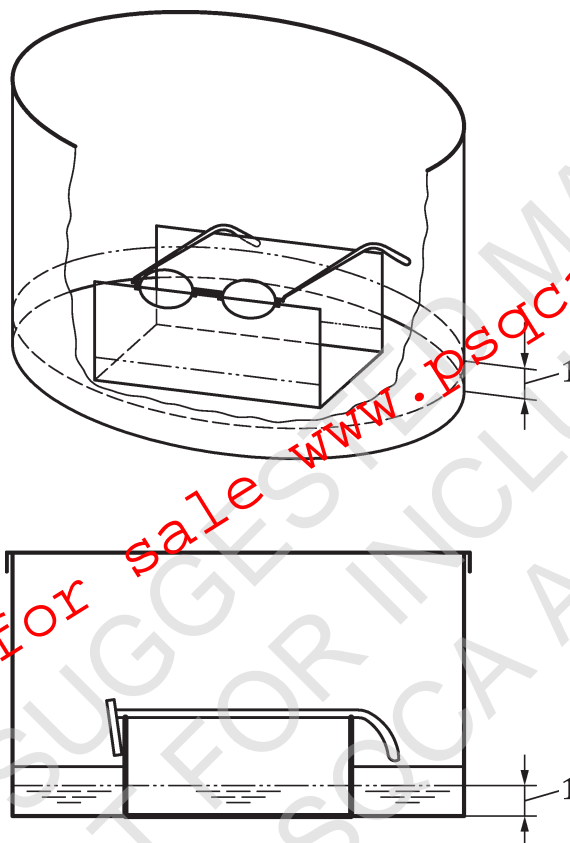
pure titanium spectacle frame

frame of which each of the principal metal components is made of an alloy containing at least 90 % titanium by mass

Annex B (informative)

Examples of layout of test equipment

B.1 Example of frame support for the resistance to perspiration test



Key

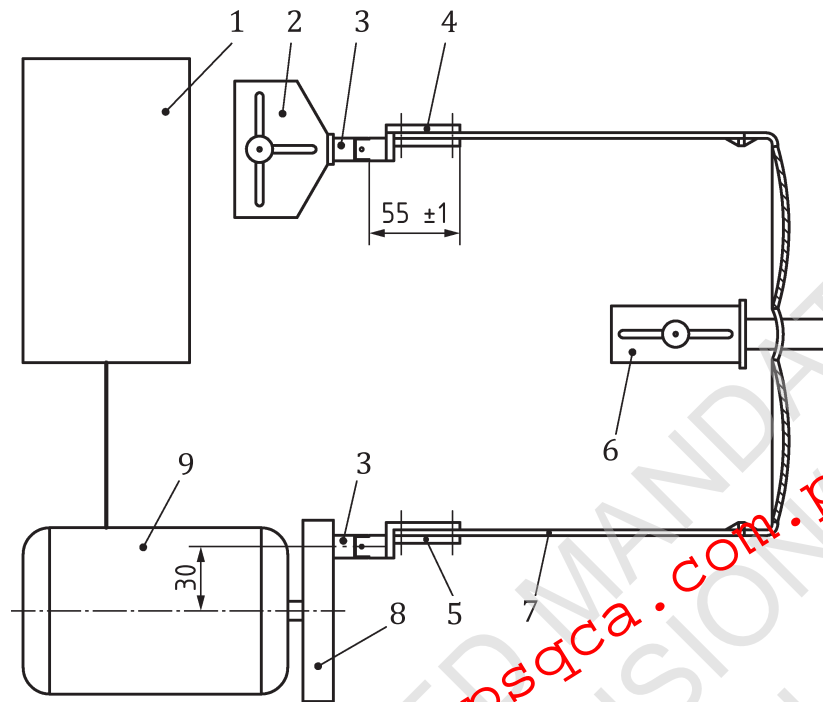
1 artificial sweat

Figure B.1 — Diagram of a typical frame support

B.2 Examples of the equipment layout for the endurance test

NOTE For testing in frame development, manufacturers might wish to modify the test equipment so that either the right or the left side can be subject to the cyclical motion, the other remaining fixed.

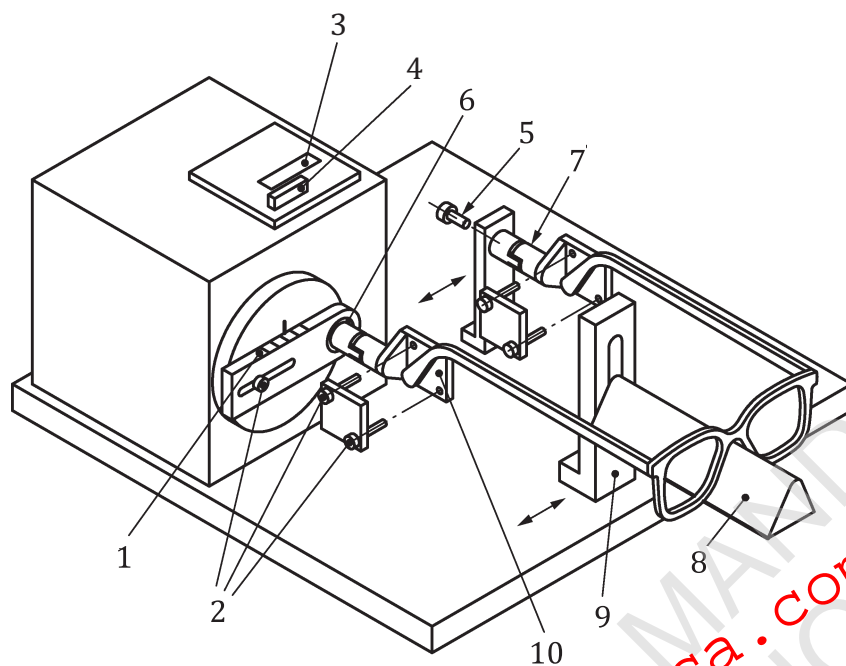
Dimensions in millimetres



Key

- 1 control panel and counter
- 2 side clamp adjustment
- 3 universal joint
- 4 fixed clamp
- 5 rotating clamp
- 6 adjustable spectacle bridge support assembly
- 7 test sample
- 8 rotating disc
- 9 geared motor

Figure B.2 — Diagram of a typical test apparatus



Key

- 1 side displacement amplitude scale
- 2 finger screws
- 3 counter window
- 4 control switch
- 5 lock screw
- 6 ball bearing
- 7 universal joint
- 8 adjustable spectacle frame bridge support
- 9 adjustable bracket to match various spectacle frame sizes
- 10 clamping point

Figure B.3 — General test arrangement showing clamping device

Annex C (informative)

European requirements and legislation on nickel release

European legislation³⁾ refers to the following European Standards:

- EN 1811, *Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin*;
- EN 12472, *Method for the simulation of wear and corrosion for the detection of nickel release from coated items*;
- EN 16128, *Ophthalmic optics — Reference method for the testing of spectacle frames and sunglasses for nickel release*.

Of these, EN 12472 and EN 16128 are applicable to spectacle frames.

ISO/TS 24348 is equivalent to EN 12472 and EN 16128.

NOTE 1 ISO/TS 24348:2014, Clause 4, is textually similar to EN 12472:2005, while ISO/TS 24348:2014, Clause 5, is textually similar to EN 16128:2011⁴⁾. EN 16128 specifies the use of the simulation of wear test in EN 12472, which is why there is no (direct) reference to EN 12472 in the body of the present International Standard.

NOTE 2 For the sake of simplicity and as an indication of whether or not a sample is likely to pass the nickel release requirements, following the simulation of wear and corrosion specified in ISO/TS 24348:2014, Clause 4, the DMG test specified in CEN/CR 12471 can be used to test the components of a spectacle frame for nickel release. The test methods are based on the formation of a coloured complex when nickel ions come into contact with a mixture of ammonia and dimethylglyoxine. There are three tests described in CEN/CR 12471, of which the laboratory test is recommended as it gives the best indication of the possible nickel release. If all the components pass without giving a pink colouration to the cotton bud, then there is a significant probability that the frame complies with the requirements of 4.2.3.

3) European REACH regulations state that nickel or its compounds shall not be used in articles intended to come into direct and prolonged contact with the skin if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm²/week. For articles which have a non-nickel coating, such coating shall be sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm²/week for a period of at least two years of normal use of the product.^[2]

4) EN 16128:2011 has recently been revised and ISO/TS 24348:2014 will be amended to align with the new text.

Bibliography

- [1] EN 71-1, *Safety of toys — Part 1: Mechanical and physical properties*
- [2] EN 1811, *Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin*
- [3] CEN/CR 12471, *Screening tests for nickel release from alloys and coatings in items that come into direct and prolonged contact with the skin*
- [4] EN 12472, *Method for the simulation of wear and corrosion for the detection of nickel release from coated items*
- [5] EN 14682, *Safety of children's clothing — Cords and drawstrings on children's clothing — Specifications*
- [6] EN 16128, *Ophthalmic optics — Reference method for the testing of spectacle frames and sunglasses for Nickel release*
- [7] European REACH Regulations. (EC No. 1907/ 2006), Annex XVII, entry 27. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20120601:en:PDF>
- [8] ISO 3160-1:1998, *Watch-cases and accessories — Gold alloy coverings — Part 1: General requirements*
- [9] ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*
- [10] ISO 14971, *Medical devices — Application of risk management to medical devices*

not for sale www.psqca.com.pk

ONLY FOR SUGGESTED MANDATORY
PRODUCT FOR INCLUSION SRO
U/S 14 OF PSQCA ACT VI OF 1996

not for sale www.psqca.com.pk