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**Ophthalmic optics — Spectacle frames —  
Method for the simulation of wear and  
detection of nickel release from coated  
metal and combination spectacle frames**

*Optique ophtalmique — Montures de lunettes — Méthode de simulation  
de l'usure et de détection de la libération du nickel de montures de  
lunettes en métal revêtu et combinées*

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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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

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An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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/TS 24348 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

## Introduction

Adverse skin reaction to nickel has been known for many decades. Nickel is now the most frequent cause of contact allergy, and a significant proportion of the female population is allergic to nickel. Skin absorption of nickel ions, which are released from some nickel-containing materials in direct and prolonged contact with the skin, causes sensitization. Further exposure to soluble nickel salts results in allergic contact dermatitis. It is known that sensitization to nickel requires higher exposure levels than does the elicitation in already sensitized individuals. Amongst individuals there is a large variation in the degree of sensitivity to nickel.

This widespread health problem has forced the introduction of a number of measures designed to reduce its prevalence. They include this Technical Specification which provides two procedures for testing those parts of metal and combination spectacle frames that come into direct and prolonged contact with the skin.

The first part specifies a method for accelerated wear to simulate two years use of coated metal and combination spectacle frames. The coatings may include rolled gold, electro- and other plating methods, varnish and other organic treatments. The second part attempts to provide an *in-vitro* chemical test that correlates as far as possible with the variable human biological reactions that occur when metallic articles containing nickel are in direct and prolonged contact with the skin. This part provides a measure of the amount of nickel release from a spectacle frame when immersed for one week in artificial sweat.

Clinical patch-testing of a small selection of nickel-containing alloys and coatings on nickel-sensitized persons indicates that high and low results achieved with the present analytical method correspond closely with patch-test reactivity. Moreover, a nickel release rate threshold of  $0,5 \mu\text{g}/\text{cm}^2/\text{week}$  has been set in European Parliament and Council Directive 94/27/EC (OJ No. L188 of 1994-07-22). In order to ensure that articles yielding values near this figure are not unnecessarily excluded from European trade as a result of the difficulties inherent in the test method, particularly when applied to intricately-shaped articles, the measured release figures are multiplied by a factor of 0,1. Materials recognized as causing sensitization to nickel would not become acceptable by use of this adjustment. Application of this Technical Specification is confidently expected to significantly reduce the development of allergic contact dermatitis due to nickel.

**NOTE** Experience of its use and further epidemiological and clinical research may justify changes to test procedure and/or interpretation of the test result.

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# Ophthalmic optics — Spectacle frames — Method for the simulation of wear and detection of nickel release from coated metal and combination spectacle frames

## 1 Scope

This Technical Specification specifies methods for simulating two years' use and for testing for the release of nickel from those parts of metal and combination spectacle frames intended to come into direct and prolonged contact with the skin, in order to determine whether such parts release nickel at a rate greater than  $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ .

This Technical Specification aims to control those frames that, if produced with materials and/or surface treatments containing nickel, can be worn by nickel-sensitized persons.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12870:—<sup>1</sup>, *Ophthalmic optics — Spectacle frames — Requirements and test methods*

## 3 Requirement

Those parts of metal and combination spectacle frames that come into direct and prolonged contact with the skin of the wearer shall have a nickel release of less than  $0,5 \mu\text{g}/\text{cm}^2/\text{week}$  when tested in accordance with this Technical Specification.

Frames having a non-nickel coating shall be subject to the wear pre-treatment described in Clause 4, which simulates two years' typical wear.

Frames that are made of homogeneous alloy or pure metal and are uncoated go direct to the nickel release test procedure described in Clauses 5 to 8.

Parts to be tested shall include:

- the rear surface of rims;
- nasal-bearing surfaces, including metal nose pads;
- sides, excluding the joints and the zone immediately around the joints, and parts intended to be protected by plastics endcovers (tips).

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1) To be published. (Revision of ISO 12870:1997)

## 4 Method for the abrasion of metal spectacle frames before the determination of nickel release

### 4.1 Materials

#### 4.1.1 Abrasive paste

Inorganic abrasive paste produced for dry tumbling barrels.

The abrasive paste shall be made of the following components:

- a) pumice (Al and Si oxides) powder, where the abrasive particles have dimensions of  $200 \mu\text{m} \pm 15 \mu\text{m}$ ;
- b) mixture of emulsifying agents, mineral oils and water, having the following physical properties:
  - softening point:  $30 \text{ }^\circ\text{C}$  to  $35 \text{ }^\circ\text{C}$
  - flash point:  $> 250 \text{ }^\circ\text{C}$
  - pH: 6 to 7

The ratio of a) to b) shall be 4:1.

NOTE Information on sourcing a suitable paste is available from the ISO Central Secretariat.

#### 4.1.2 Wood granules

This material shall be made of the following components.

Outer shells of coconuts, walnuts, peanuts, almond, mixed in a ratio 1:1:1:1 by weight, ground and sieved to give a mixture of particles having dimensions between 0,8 mm and 1,3 mm.

Equilibrium moisture at a temperature of  $30 \text{ }^\circ\text{C}$  and a relative humidity of 75 % shall be 14 %.

Before use, the required amount of granulate shall be conditioned in standard laboratory conditions for at least 24 h.

NOTE Information on sourcing suitable granules is available from the ISO Central Secretariat.

#### 4.1.3 Tumbling barrel

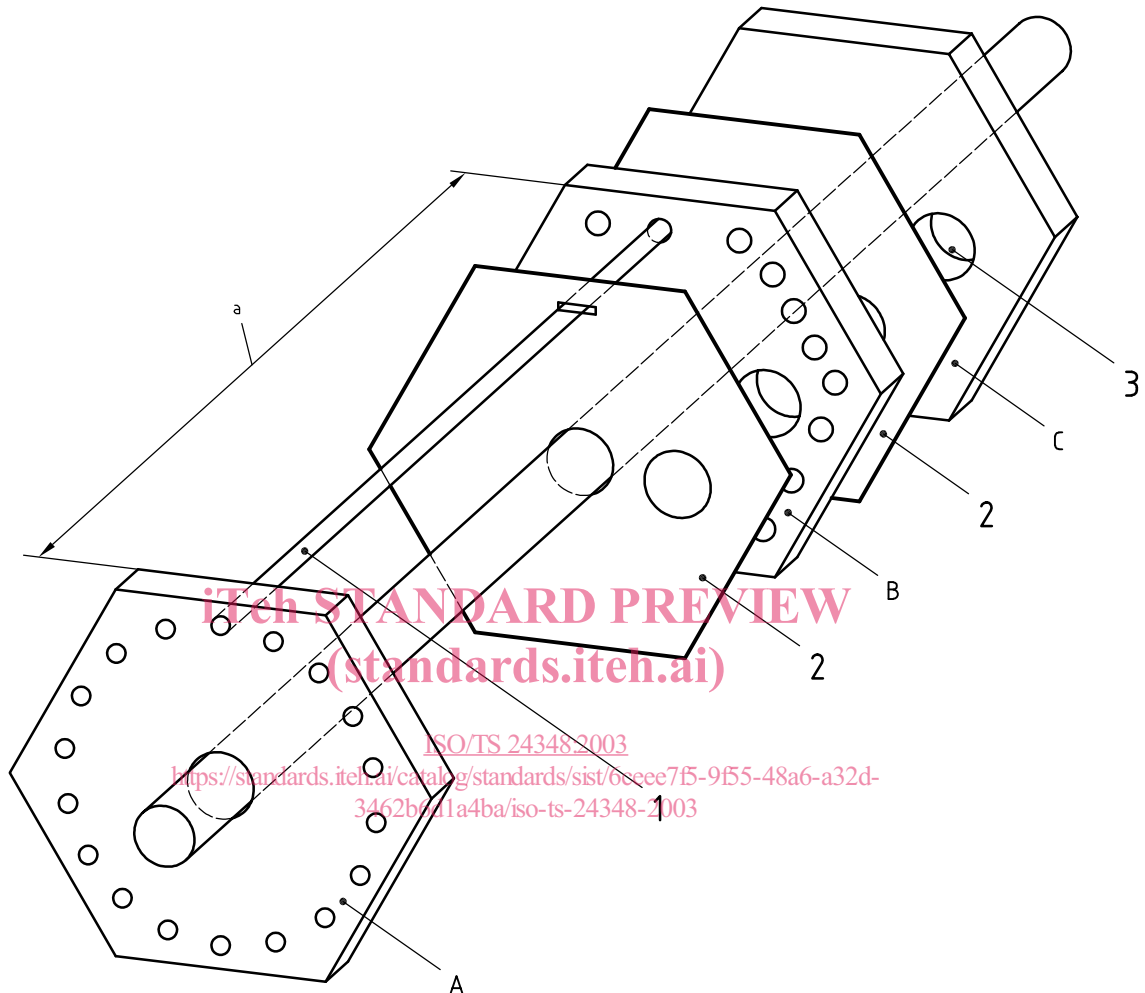
The tumbling barrel and retaining assembly shall be in accordance with the following description.

Barrel of hexagonal cross-section designed to rotate around its axis of symmetry, which is orientated horizontally. The spectacle fronts or sides are mounted in a retaining assembly that slides into the barrel.

For use with spectacle sides, the assembly consists of a threaded rod which carries three metal hexagonal plates (see Figures 1 and 2). The end plate (A) is drilled part way through with holes of nominal diameter 1,5 mm or, as appropriate, to take the ends of the tips of the sides. The next plate (B) is perforated with holes of nominal diameter 5,0 mm or, as appropriate, to take the joint ends of the sides, together with an aperture of 40 mm nominal diameter to act as a filling hole for the abrasive mixture. The final plate (C) is undrilled apart from the filling hole. Threaded nuts either side of the last two plates secure them at the required distance from plate A, while silicone rubber sheets hold the sides firmly to prevent them from rotating in the assembly. The volume between the first and second plates is approximately  $5 \text{ l} \pm 0,5 \text{ l}$ .



There are two proposed assemblies for retaining spectacle fronts. In the first, short pieces of side are attached to the front half joints in the usual manner, and these pieces of side are inserted in a similar assembly. In the second, the central threaded rod carries two six-sided "spiders" carrying six radiating threaded rods (see Figure 3). The fronts are attached to these rods by means of holes in the test lenses, and are held at the appropriate distance of 80 mm from the axis of the barrel by nuts.

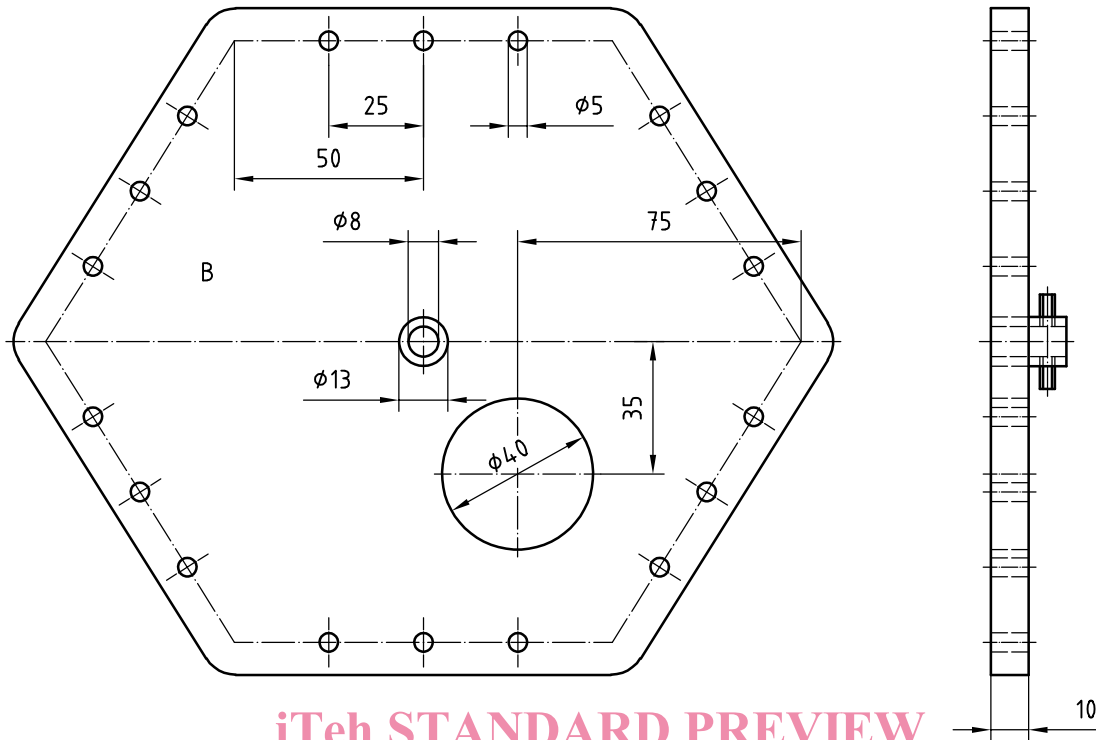


#### Key

- 1 sample side
- 2 silicone sheet
- 3 filling hole
- a Adjust as required.

**Figure 1 — Exploded schematic illustration of the assembly for holding sides, which inserts into the tumbling barrel**

Dimensions in millimetres

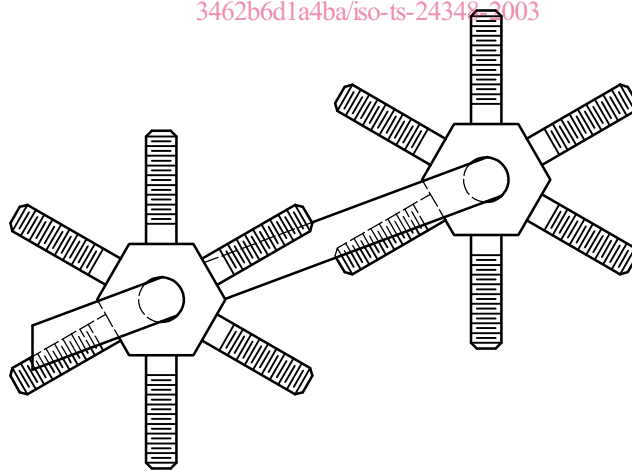


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**Figure 2 — Plan view of the upper part of the tumbling barrel — Component B**

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**Figure 3 — Spiders for carrying spectacle fronts**

## 4.2 Test method

### 4.2.1 Preparation

Weigh a sufficient quantity of wood granules in order to fill the tumbling barrel (4.1.3) to half its volume (approximately 2,5 l). Add 7,5 g of abrasive paste (4.1.1) for every kg of wood granules (4.1.2) and homogenize by rotating in the barrel for 48 h.

NOTE This coats the granules with the abrasive paste, thus forming the abrasive material that is used to simulate wear.

After 10 h of use, add a further 7,5 g of abrasive paste for every kg of wood granules.

After 20 h of use, discard the abrasive material and prepare fresh material.

Spectacle sides and fronts shall be separated from each other, and side tips (endcovers) removed from sides, where appropriate.

Before testing, spectacle fronts shall be glazed with test lenses in accordance with ISO 12870.

### 4.2.2 Tumbling

Fix the test samples into the two hexagonal plates (A and B) of the barrel, positioning them with the inside face of sides or the posterior face of fronts turned towards the rotation axis. The samples shall be fitted so that they do not move. Fill any vacant positions with waste samples.

Half fill the tumbling barrel with the abrasive mixture (4.2.1).

Close the tumbling barrel and place it on the rotating system.

Rotate the tumbling barrel at a speed of  $(30 \pm 2)$  rotations per minute (approx.  $0,5 \text{ s}^{-1}$ ) for  $5 \text{ h} \pm 5 \text{ min}$ .

When the tumbling process is completed, remove the test samples and clean them with a smooth cloth without further damaging the surface with the abrasive.

Following this, the samples shall be subject to the determination of nickel release given in Clauses 5 to 8.

## 5 Method for the determination of nickel release

### 5.1 Principle

The parts of the spectacle frame to be tested for nickel release are placed in an artificial sweat test solution for one week. The concentration of dissolved nickel in the solution is determined by atomic absorption spectrometry, inductively-coupled plasma spectrometry or other appropriate analytical method. The nickel release is expressed in micrograms per square centimetre per week ( $\mu\text{g}/\text{cm}^2/\text{week}$ ).

The value of the measured nickel release multiplied by an adjusting factor of 0,1, shall not be greater than  $0,5 \mu\text{g}/\text{cm}^2/\text{week}$  after the test samples treatments and evaluations according to the procedure described in Clause 7.

### 5.2 Reagents

Except where indicated, all reagents shall be of recognized pro-analysis, per analytical grade or better and shall be free from nickel.