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Optics and optical instruments — Microscopes — Slides —

Part 2:

Quality of material, standards of finish and mode of packaging

Optique et instruments d'optique — Microscopes — Lames porte-objet — Partie 2: Qualité des matériaux, normes de finition et mode d'emballage

Document Preview

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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.

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.

International Standard ISO 8037-2 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 5, *Microscopes and endoscopes*.

ISO 8037 consists of the following parts under the general title *Optics and optical instruments* — *Microscopes* — *Slides* —

Part 1: Dimensions, optical properties and marking

Part 2: Quality of material, standards of finish and mode of packaging

Annex A forms an integral part of this part of ISO 8037. Annexes B to D are for information only.

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Introduction

The data given in this part of ISO 8037 on optical microscope slides are intended to provide for safety of the end user as well as for adequate performance of the product. (Dimensions and optical properties are described in ISO 8037-1.)

Requirements for smoothness of edges and perhaps rounding of corners, reducing the risk to technicians of finger cuts or abrasions, have become increasingly urgent. This is especially important because of the possibility of infection during research or diagnostic work involving blood or other bodily fluids, since these might be contaminated with HIV virus related to AIDS. Cut-edge slides should not be used because of these hazards.

The data given in this part of ISO 8037 are applicable to most products in use and have been adapted to take into account relevant national standards in force.

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Optics and optical instruments — Microscopes — Slides —

Part 2:

Quality of material, standards of finish and mode of packaging

1 Scope

This part of ISO 8037 specifies requirements and test methods for the quality of material, standards of finish and mode of packaging of silicate microscope slides for use in transmitted light microscopy in the visible spectrum range (400 nm to 760 nm).

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8037. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8037 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2859-1:1989, Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection

ISO 4287-1:1984, Surface roughness — Terminology — Part 1: Surface and its parameters

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ISO 8037-1:1986, Optics and optical instruments — Microscopes — Slides — Part 1: Dimensions, optical properties and marking

ISO 11455: 1995, Raw optical glass — Determination of birefringence

3 Definitions

For the purposes of this part of ISO 8037, the following definitions apply.

3.1 seed

Small bubble in glass, sometimes elongated.

3.2 stone

Containment or solid inclusion in glass resulting from poor melting of batch or particle from furnace wall.

3.3 cord

Vitreous compositional inhomogeneities in glass (also known as striae, ream or glassy knots).

3.4 line

Fine parallel line on glass surface in direction of draw.

3.5 nick

Place where minute piece(s) of glass have been removed from the edge of the glass, giving rise to poor edge finish.

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3.6 cleanliness

Freedom from visible surface contamination such as fingerprints, particulate matter or residue left from cleaning process.

3.7 cloudiness; haze

Light scattering or reduced transparency due to surface deterioration, typically as a result of atmospheric attack in the presence of humidity and CO_2 .

3.8 abrasion

Surface damage and pitting, typically caused by vibration of one slide surface on another during packaging or during shipment and handling.

3.9 AQL

Acceptable Quality Level, as defined in ISO 2859-1.

3.10 lux

Unit of illumination equal to one lumen per square metre.

3.11 vision 1,0; standard visual acuity

Ability to see an object so small that the angle subtended at the eye is only one minute of arc (1/60 of a degree).

NOTE 1 At 0,6 m the size of a test object is about 1,75 mm.

NOTE 2 Since slight colour variation is permitted, definition of colour vision quality of the observer is not critical.

3.12 non-flatness; waviness

Sum of the maximum positive and negative profile departures (see 4.18 of ISO 4287-1:1984), of the real profile to the reference line, over the evaluation length (see 4.17 of ISO 4287-1:1984).

3.13 real profile

Equally spaced points, separated by not more than 1 mm, parallel to the long edge of the slide and approximately centred on the surface being evaluated (see 4.9 of ISO 4287-1:1984).

NOTE This definition allows continuous curves, which may be filtered to remove roughness, if so desired.

3.14 reference line

Nominal profile or any arithmetical mean line of the profile (see 4.20 of ISO 4287-1:1984), including the least squares mean line of the profile (see 4.19 of ISO 4287-1:1984).

NOTE 1 The particular reference line selected from these options is at the discretion of the evaluator and is to be identified.

NOTE 2 See also 4.15 of ISO 4287-1:1984.

3.15 nominal profile

Reference line joining the ends of the real profile.

3.16 evaluation length

See the definition given in 4.17 of ISO 4287-1:1984.

NOTE For the purposes of this part of ISO 8037, the evaluation length is 60 mm for slides of 76 mm length and 30 mm for slides of 46 mm length. The evaluation length consists of one sampling length (see 4.16 of ISO 4287-1:1984).

3.17 thickness variation

Difference between the largest and smallest thickness measurements, within a slide.

4 Requirements

4.1 Transparency and colour

Slides shall be transparent and colourless. They may have a slight greenish tint when viewed edgewise. Colour and transparency shall be evaluated as described in 6.5.

4.1.1 Non-flatness; waviness

The maximum acceptable non-flatness is 50 μ m for slides of 76 mm length and 25 μ m for slides of 46 mm length when measured as described in 6.11 (AQL 1.0).

4.1.2 Thickness variation

For a 76 mm slide, the thickness variation tolerance is 50 μ m [times the ratio of the working length to the total length (L_w/L) in the case of frosted-end slides]. For a 46 mm slide, the thickness variation tolerance is 30 μ m.

Measurement shall be carried out as described in 6.12 (AQL 1,0).

4.2 Durability

The glass shall have a surface of sufficient chemical durability to pass the solubility test described in 6.9.

4.3 Surface quality and inclusions

Slides shall be visibly free of pits, seeds, cords, stones, lines, abrasions, scratches or cracks when observed as described in 6.4 (AQL 1,5).

4.4 Edge finish

All edges and corners shall be finished in order to be free from dangerous cutting edges, roughness or nicks when examined as described in 6.6 (short edges and corners AQL 1,0; long edges AQL 4,0). Short edges shall be straight (not curved) when examined as described in 6.6.4.

NOTE Slides with unfinished edges (as-cut) are available. Because of danger of infection from contaminated bodily fluids, such slides should never be used in any hospital diagnostic laboratory or health-related research facility. For this reason, they are not recommended and are not within the scope of this part of ISO 8037.

4.5 Cloudiness and cleanliness

Slides shall be clean and free of cloudiness, fingerprints or particulate matter on their surfaces when observed as described in 6.3 (AQL 1,5).

4.6 Adhesion

Slides shall be free from adhesion when tested as described in 6.2 (AQL 0,65).

4.7 Wettability

Glass should be fully wettable when tested as described in 6.8 (Inspection Level S-2, AQL 1,0).

4.8 Frosted end

If specified, one end of one or both surfaces shall be frosted for a distance of $19 \text{ mm} \pm 3 \text{ mm}$ from the end. Alternatively both ends may be frosted for a distance of $9 \text{ mm} \pm 2 \text{ mm}$. Frosting shall allow marking with a 2B pencil,

felt-tip pen or drawing pen with India ink. Frosting shall pass the test described in 6.7 (Inspection Level S-2, AQL 1,0).

4.9 Residual stress/birefringence

Slides designated for use with polarized light shall not exhibit an optical path difference greater than 5 nm when measured through the principal plane of the slide as described in 6.10 (Inspection Level S-2, AQL 1,0).

5 Sampling

NOTE Meeting the requirements in subclause 5.1 may be sufficient to assure compliance if the manufacturer's certificate of conformance with ISO 9000 to ISO 9003 has been accepted by the purchaser or user.

5.1 Quality measurement for microscope slides for conformance with this part of ISO 8037

The sampling methods, inspection levels and AQLs specified in this part of ISO 8037 are required for finished-lot inspection. If a producer has a "Quality System", as described in ISO 9000 (all parts), ISO 9001, ISO 9002 and ISO 9003 and this system meets the quality expectations of the purchaser or user, the supplier's certificate of conformance with the quality requirements of ISO 8037-2 may be acceptable to the purchaser or user. Manufacturers may carry out in-process inspection to assure compliance. Cloudiness and cleanliness might be worth evaluating with inspection levels and AQL on a lot-by-lot basis. In-process inspection may be used by the manufacturer to assure compliance with other criteria to qualify lots for certification.

Even if the supplier's certificate of conformance is acceptable to the purchaser or user, such lots shall not be marked, "Conforms with ISO 8037-2", unless tested as specified in clause 6 with samples drawn as in 5.2.

5.2 Drawing of samples and units of inspection

Samples shall be drawn at random from a lot of slides according to procedures outlined in ISO 2859-1, Normal Inspection, General Inspection level I or, when specified, inspection level S-1, S-2, S-3 or S-4 with sample sizes chosen according to tables A.1 and A.2, unless a specific number of samples selected from the total sample population is specified. To assure that sufficient samples are provided for each test, including "unit package" tests and "groups of 10" tests, the following three-step procedure shall be used to determine the size of a sample which will serve for all tests.

Step 1: Determine, from tables A-1 and A-2 of ISO 2859-1, the number of slides corresponding to General Inspection Level I, AQL 0,65.

Step 2: Divide the number determined in step 1 by 10, and randomly select that number of packages from the lot.

Step 3: After the "package" tests (average count and thickness variation within a package), draw "the sample" (General Inspection Level I, AQL 0,65) for "slide" tests as described in 6.2.

The unit of inspection shall be one slide, except for packaging requirements, in which case the unit of inspection shall be one package. The samples should be handled in a way which does not affect their cleanliness or cause them to stick together.

The population for individual tests shall be randomly selected from within the sample chosen by the method described in paragraph one of this clause, when fewer than the total sample are required for a test. Samples may be reused in subsequent tests. A slide with multiple defects within a single attribute [such as a chipped corner and nicks (see 3.5)] shall be considered a single defective item.

6 Test methods

All observations shall be made by the unaided eye corrected to vision 1,0 (without magnification). Illumination shall be diffuse uniform artificial light produced by a "cool white" fluorescent lamp or equivalent, with intensity of 1500 lux \pm 150 lux.

All testing, to be valid, shall be performed within six months of the date of packaging.

Tests shall be carried out in the following order:

- a) packaging suitability, and average quantity of slides and thickness variation within package;
- b) adhesion;
- c) cloudiness and cleanliness;
- d) surface quality inclusions;
- e) transparency and colour;
- f) edge finish;
- g) frosting;
- h) non-flatness; waviness
- i) wettability;
- j) durability (chemical durability of the surface and resistance to atmospheric attack; solubility);
- k) residual stress / birefringence.

6.1 Package

Individual packages, selected as described in 5.2, of for example 50, 72 or 100 slides, shall be examined according to the sampling plan. The average number of slides per package shall be at least as many as the quantity stated on the label. Inspection level shall be S-3.

NOTE 1 ISO 2859 -1 gives a sampling plan for inspection by attributes. Because count is not an attribute, but a variable, references to AQL do not apply to count.

NOTE 2 While not included in this part of ISO 8037, specifications for packaging and packing for protection from moisture and contaminants during shipment and storage, as well as suitability for product handling, should be agreed upon by purchaser or user and supplier. Shelf-life requirements and storage conditions should also be agreed upon.

Within a package, slides judged visually to be the thickest and thinnest shall be measured near the centre of the slide. These slides shall not deviate by more than \pm 0,10 mm from the thickness marked on the label. For thickness variation testing, use Inspection Level S-2. AQL 1,0.

6.2 Adhesion

The contents of freshly opened packages randomly selected as described in 5.2 shall be examined for adhesion of their interfaces (two or more slides adhering together, not coming apart with slight flexing or riffling). No more than one group of ten pieces shall be taken from one package to make up the test sample for this and subsequent tests. This examination shall be done concurrently with the original counting of slides described in 6.1. Rubber or plastic finger-covers or inspection gloves shall be used to avoid introducing moisture or other foreign matter which could affect adhesion. The slides shall be handled by their edges and should not be pressed together. Each adhered interface shall be considered a defect.

6.3 Cloudiness and cleanliness

Hold slides individually against a half matte black, half matte white split background under an illumination of 1500 lux (see figure 1). The inspector shall observe each slide with the unaided eye for 5 s at a distance of 30 cm. Observation should be made at the black-white interface. There shall be an absence of haze, cloudiness, fingerprints, abrasion marks or particulate matter. Defects within 6 mm of short edges or 3 mm of long edges shall not be considered.

6.4 Surface quality and inclusions

Observe 10 microscope slides as a group, under conditions as in 6.3. There shall be no observable pits, seeds, cords, stones, lines, scratches or cracks. The same samples as used for the test described in 6.3 may be used. Other than cracks, defects within 6 mm of short edges or 3 mm of long edges shall not be considered.

6.5 Transparency and colour

Lay out in a single layer a random selection of 50 slides taken from the sample described in clause 5 onto a sheet of white paper on which there is typed or printed material in lieu of the split black-white background. The same samples as used for the test described in 6.3 may be used. When observed under illumination in accordance with 6.3, there shall be no observable colour tint or decrease in legibility of the printed matter. When viewed edgewise, a slight greenish tint to the glass is permitted.



Figure 1 — Background surface for observation of cloudiness/cleanliness

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6.6 Edge finish

Examine the edges of the microscope slides in groups of about 20 under the same illumination as specified in 6.3.

6.6.1 There shall be no chipped corners exceeding 1 mm in length and 0,5 mm in depth.

6.6.2 Nicks in the short edges shall not exceed 0,5 mm in length or depth, and shall not extend into the intersection between the short edge and the plane surface.

6.6.3 Nicks in the long edges shall not exceed 1 mm in length and 0,5 mm in depth.

6.6.4 Short edges shall be straight, not curved. Observations may be made against a plane surface. There shall be no light visible when the slide edge is held in contact with the surface, except within 2 mm of a corner, where curvature is permitted.

6.6.5 For the following test, select one slide for long-edge testing and two slides for short-edge testing from each group of 20 slides as described in 6.6. Scratch one long or one short edge/surface interface on each slide for each test. For frosted-end slides, test the unfrosted end only. To determine roughness, the intersection between the edge and the plane surface of the slides shall be lightly scratched with a fingernail. It shall not feel rougher than the same light scratch on a standard surface finish comparitor of 0,8 μ m for a ground surface. See ISO 468:1982, table 2.

NOTE See the note in annex C for surface roughness 32.

6.7 Frosted end

If a frosted end is specified, take the quantity of sample slides indicated in 5.2 at random from the population of samples used in previous testing. The size of the frosted end shall be as specified in 4.8. Write the numbers 1, 2