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GB/T 10213-2025 / ISO 11193-1:2020

Replacing GB 10213-2006

Single-use medical rubber examination gloves

一次性使用医用橡胶检查手套

(ISO 11193-1:2020, Single-use medical examination gloves - Part 1: Specification for
gloves made from rubber latex or rubber solution, IDT)

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Single-use medical rubber examination gloves

Warning: Users of this document should be familiar with common laboratory procedures. This document does not address all safety issues; users are responsible for taking appropriate health precautions and complying with relevant national regulations.

1 Scope

This document specifies requirements for sterile or non-sterile, single-use medical rubber examination gloves (hereinafter referred to as "gloves"), intended for use during medical examinations and diagnostic procedures, to prevent cross-infection between patients and users. This also includes gloves used for handling contaminated medical materials. This document applies to gloves with smooth, partially textured, or fully textured surfaces.

This document specifies performance and safety requirements for gloves. However, the safe, proper use, sterilization process of gloves, as well as subsequent handling, packaging, storage, are outside the scope of this document.

2 Normative references

The contents of the following documents, through normative references, constitute essential provisions of this document. For dated references, only the version corresponding to that date applies to this document. For undated references, the latest version (including all amendments) applies to this document.

ISO 37 Rubber, vulcanized or thermoplastic - Determination of tensile stress-strain properties

Note: GB/T 528-2009 Rubber, vulcanized or thermoplastic - Determination of tensile stress-strain properties (ISO 37:2005, IDT)

ISO 188 Rubber, vulcanized or thermoplastic - Accelerated aging and heat resistance tests

Note: GB/T 3512-2014 Rubber, vulcanized or thermoplastic -- Accelerated ageing and heat resistance tests - Air-oven method (ISO 188:2011, IDT)

ISO 2859-1 Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

Note: GB/T 2828.1-2012 Sampling procedures for inspection by attributes - Part 1:

Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection (ISO 2859-1:1999, IDT)

ISO 10993 (all parts) Biological evaluation of medical devices

Note: GB/T 16886 (all parts) Biological evaluation of medical devices [ISO 10993 (all parts)]. The degree of conformity between the various parts of GB/T 16886 (all parts) and ISO 10993 (all parts) is shown in Appendix NA.

ISO 23529 Rubber - General procedures for preparing and conditioning test pieces for physical test methods

Note: GB/T 2941-2025 Rubber - General procedures for preparing and conditioning test pieces for physical test methods (ISO 23529:2016, IDT)

3 Terms and definitions

This document does not require any specific terms or definitions.

4 Classification

4.1 Overview

Gloves are classified by category and surface type, see 4.2 and 4.3.

4.2 Categories

- a) Category 1: Gloves primarily made from natural rubber latex;
- b) Category 2: Gloves primarily made from nitrile rubber latex, chloroprene rubber latex, styrene-butadiene rubber solution, styrene-butadiene rubber emulsion, or thermoplastic elastomer solution.

4.3 Surface type

- a) Partially or fully textured gloves;
- b) Smooth gloves;
- c) Powdered gloves;

Note 1: Powdered gloves are designed for easier donning and typically have powder added during manufacturing. The maximum limit for residual powder on the surface of powdered gloves is 10 mg/piece.

- d) Powder-free gloves.

Note 2: Powder-free gloves are gloves to which no powdered material is added during manufacturing. The maximum limit for residual powder on the surface of powder-free gloves is 2.0 mg/piece.

Note 3: Glove cuffs may have straight or curled edges.

5 Materials

Gloves shall be made of compounded natural rubber latex, compounded nitrile rubber latex, compounded styrene-butadiene rubber or thermoplastic elastomer solution, or compounded styrene-butadiene rubber latex. To facilitate donning, lubricants, powders, or polymer coatings meeting the requirements of ISO 10993 (all parts) may be used for surface treatment.

Any pigments, surface treatment agents, lubricants, or powders used shall be non-toxic and disclosed as required. Migratable substances used for surface treatment shall be bioabsorbable.

The materials used shall conform to the requirements of the relevant parts of ISO 10993. The manufacturer shall provide data to the purchaser, upon request, to demonstrate compliance with these requirements.

Note 1: Future parts of ISO 11193 may include other polymeric materials.

Note 2: It has been discovered that some individuals may develop sensitivities (allergic reactions) to certain rubber compounds over time, requiring the use of gloves with alternative formulations.

Limits for soluble proteins, allergenic proteins, residual chemicals, endotoxins, residual powders in gloves may be specified in future versions of this document, along with applicable method standards.

6 Sampling and test piece selection

6.1 Sampling

During arbitration, gloves shall be sampled and inspected in accordance with the requirements of ISO 2859-1. The inspection levels and acceptance quality limits (AQLs) shall be as specified in Table 1.

When the batch size cannot be determined, a batch size of 35001 ~ 150000 pieces shall be assumed.

6.2 Selection of test pieces

Test pieces shall be cut from the palm or back of the glove.

7 Requirements

7.1 Dimensions

When measured at the positions shown in Figure 1, the length and palm width of the glove shall conform to the requirements specified in Table 2. The inspection levels and acceptance quality limits (AQLs) are shown in Table 1.

The length shall be the shortest distance from the tip of the middle finger to the edge of the cuff.

The length can be measured by hanging the glove from a suitable round rod, which has a top radius of 5 mm.

To measure the width, lay the glove flat and measure the distance from the inside of the index finger to the outside of the ring finger. The width is measured midway between the base of the index finger and the base of the thumb.

The double-layer thickness of gloves shall be measured in accordance with ISO 23529, applying a foot pressure of $22\text{ kPa} \pm 5\text{ kPa}$. Measurements shall be taken at each location shown in Figure 1: $13\text{ mm} \pm 3\text{ mm}$ from the tip of the middle finger and approximately at the center of the glove palm. Half of the double-layer thickness measured at each point is recorded as the single-layer thickness. Dimensions shall conform to Table 2; the inspection level and acceptance quality limit (AQL) shall conform to Table 1.

If thin spots are detected during visual inspection, the single-layer thickness shall be measured at these locations. The single-layer thickness of the smooth and textured surfaces, when measured in accordance with this clause, shall be no less than 0.08 mm and 0.11 mm, respectively.

When gloves are tested for waterproofness according to Appendix A. The sample size and the number of gloves permitted to fail (leak) shall be determined according to the inspection level and acceptance quality limit (AQL) in Table 1.

7.3 Tensile properties

7.3.1 General

Tensile properties shall be measured in accordance with ISO 37. Three Type 2 dumbbell specimens shall be cut from each glove; the median value of the test result shall be taken. Specimens shall be cut from the palm or back of the hand.

7.3.2 Breaking strength and elongation at break before accelerated aging

Test according to ISO 37 using Type 2 dumbbell specimens. Breaking strength and elongation at break shall comply with Table 3. The inspection level and acceptance quality limit (AQL) shall comply with Table 1.

7.3.3 Breaking strength and elongation at break after accelerated aging

Accelerated aging tests shall be conducted in accordance with ISO 188. Specimens may be cut from gloves after accelerated aging at $(70 \pm 2) ^\circ\text{C}$ for (168 ± 2) hours, OR they may be cut from gloves and then accelerated aged under the above conditions. Tensile testing shall be conducted in accordance with 7.3.2. The results shall comply with Table 3. The inspection level and acceptance quality limit (AQL) shall comply with Table 1.

Gloves manufactured more than 6 months after their date of production, or whose date of manufacture is unknown, shall not be subjected to accelerated aging testing. Tensile properties shall only comply with the "after accelerated aging" values in Table 3. The 6-month period should be calculated from the first day of the month following the month in which the gloves were manufactured.

7.4 Sterilization

If gloves are sterilized, the type of sterilization treatment shall be marked as required.

8 Packaging

If gloves are sterilized, they shall be packaged individually or in pairs.

9 Marking

9.1 General

Marking shall include a reference to this document. Appropriate symbols from ISO 15223-1 and ISO 15223-2 may be used on the label.

The language used for marking shall be agreed upon by all parties involved.

9.2 Unit packaging

9.2.1 Sterile packaging

A single glove or pair of gloves placed in a bag constitutes a unit packaging. The unit packaging shall be clearly labeled with the following:

- a) The manufacturer's or supplier's name or trademark;
- b) The material used;
- c) "Partially textured or fully textured", "smooth", "powdered", "powder-free", or other terms indicating the glove's surface treatment;
- d) Size code/specification;
- e) For gloves treated with any surface material, a warning to sterilely remove the surface powder before wearing;
- f) The manufacturer's batch number;
- g) "Date of manufacture" or similar, the four-digit year, the month of manufacture;
- h) Wording that "Sterile, unless package is opened or tampered with";
- i) Wording of "Single use" or equivalent;
- j) Wording of "Examination gloves";
- k) For Category 1 gloves, "Made from natural rubber latex that may cause an allergic reaction" or similar.

9.2.2 Non-sterile packaging

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