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Single-use Medical Poly (vinyl chloride) Examination Gloves

一次性使用聚氯乙烯医用检查手套

[ISO 11193-2:2006, Single-use Medical Examination Gloves - Part 2: Specification for Gloves Made from Poly (vinyl chloride), MOD]

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Standardization Administration of the People's Republic of China.

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Warning: users of this Standard shall be familiar with normal laboratory practices. This Standard does not involve any safety issues, even those related to it are not an exception. Users shall establish corresponding safety and health specifications; ensure the compliance with national regulations.

1 Scope

This Standard stipulates the requirements for non-sterile or packaged sterile poly (vinyl chloride) gloves used to prevent cross infection between patients and users during medical examination and diagnosis, or, the requirements for poly (vinyl chloride) gloves used to prevent cross infection during treatment of patients. It also includes poly (vinyl chloride) gloves used for the disposal of contaminated medical materials.

This Standard stipulates the performance and safety requirements for single-use medical poly (vinyl chloride) examination gloves. However, the safe and correct usage, the sterilization process and the subsequent processing, packaging and storage processes of the examination gloves are not within the scope of this Standard.

This Standard is applicable to single-use medical poly (vinyl chloride) examination gloves for medical examination, diagnosis or treatment of patients, and disposal of contaminated medical materials.

2 Normative References

Through the reference in this Standard, clauses of the following documents become clauses of this Standard. In terms of references with a specific date, all the subsequent modification sheets (excluding the corrected content) or the revised editions are not applicable to this Standard. However, all parties that reach an agreement in accordance with this Standard are encouraged to explore the possibility of adopting the latest version of these documents. In terms of references without a specific date, the latest version is applicable to this Standard.

GB/T 528 *Rubber, Vulcanized or Thermoplastic - Determination of Tensile Stress-strain Properties* (GB/T 528-2009, ISO 37:2005, IDT)

GB/T 2828.1 *Sampling Procedures for Inspection by Attribute - Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-lot Inspection* (GB/T 2828.1-2003, ISO 2859-1:1999, IDT)

GB/T 2941-2006 *Rubber - General Procedures for Preparing and Conditioning Test Pieces for Physical Test Methods* (ISO 23529:2004, IDT)

GB/T 3512 *Rubber, Vulcanized or Thermoplastic - Accelerated Ageing and Heat Resistance Tests - Air-oven Method* (GB/T 3512-2001, eqv ISO 188:1998)

GB/T 16886 (All Parts) *Biological Evaluation of Medical Devices* (all parts) [ISO 10993 (all parts), IDT]

YY 0466-2003 *Medical Devices - Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied* (ISO 15223:2000, IDT)

3 Classification

Finished gloves are classified into the following types:

a) Partial or full textured-surface gloves;

b) Smooth-surface gloves;

c) Powdered-surface gloves;

d) Powder-free-surface gloves.

NOTE 1: powdered-surface gloves: powders are added to the manufacturing process for ease of wearing; powder-free-surface gloves: no powdered materials are intentionally added during the manufacturing process.

NOTE 2: the cuff edge of the gloves may be straight edge with a regular cut, or, rolled rim.

4 Materials

The gloves involved in this Standard shall be made of poly (vinyl chloride) materials. For ease of wearing, surface treatment agents, lubricants, powders or polymer coatings may be used.

Any pigments, surface treatment agents, lubricants or powders shall be non-toxic materials and disclosed on request. Removable substances used for surface treatment shall be bioabsorbable.

Gloves provided to users shall comply with the requirements of relevant parts of GB/T 16886. If necessary, the manufacturer shall make the materials that comply with these requirements easily accessible to the buyers.

NOTE: in accordance with the existing relevant national or industrial standards on test methods, the future versions of this Standard might specify limits for extractable

b) Materials used;

c) The words “textured”, “smooth”, “powdered” or “powder-free”, or words that have such effect on finished gloves;

d) Specifications;

e) Once gloves have been treated with any surface material, there shall be a warning; before use, the surface powder shall be aseptically removed;

f) The manufacturer’s identifying lot No.;

g) “date of manufacture” or similar words, year (in four digits) and month of manufacture;

h) The words “sterile, unless this package is opened or damaged”;

i) The words “examination gloves”;

j) The words “for single-use”, or words with the same meaning;

k) The words “product contains plasticizer that may be harmful to the user (the nature of the plasticizer shall be disclosed)”.

8.2.2 Non-sterile package

Non-sterile package shall explicitly indicate the following content:

a) The manufacturer or the supplier’s name or trademark;

b) Materials used;

c) The words “textured”, “smooth”, “powdered” or “powder-free”, or words that have such effect on finished gloves;

d) Specifications;

e) The manufacturer’s identifying lot No.;

f) The words “for single-use”, or words with the same meaning;

g) “non-sterile”;

h) The words “examination gloves”;

i) “date of manufacture” or similar words, year (in four digits) and month of manufacture;

j) The words “product contains plasticizer that may be harmful to the user (the

Appendix A

(normative)
Water Impermeability

A.1 Device

A.1.1 Cylinder

The minimum diameter is 60 mm; it shall be able to hold 1,000 mL of water. In addition, it shall have sufficient length to fix the gloves, as it is shown in Figure A.1.

NOTE: the cylinder shall preferably be transparent.

A.1.2 Fixture

When filling with water, it shall be able to maintain the gloves vertical, as it is shown in Figure A.2.

A.1.3 Cylindrical measuring tool

A device with a volume of at least 1,000 mL or a device which is able to one-time transfer 1,000 mL of water.

A.2 Procedures

Use a suitable device, for example, O-shaped ring, to fix the glove on the cylinder, so that the glove does not exceed the cylinder by 40 mm.

Introduce 1,000 mL ± 50 mL of water (not exceeding 36 °C) into the device; wipe off any water on the glove. If the water cannot rise to 400 mm away from the cuff edge, raise the glove to fill the whole glove with water, excluding the part that is 40 mm away from the cuff. Immediately pay attention to any obvious leaks. If the glove does not immediately leak, then, observe for another 2 min ~ 4 min. Ignore leakage within 40 mm from the cuff edge. For ease of observation, water-soluble dyes may be used for dyeing.

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