

National Standard of the People's Republic of China

GB/T 24787—2009

Single-use non-sterile rubber surgical
gloves

一次性使用非灭菌橡胶外科手套

(English Translation)

(报批稿)

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Foreword

SAC/TC 35/SC 4 is in charge of this English translation. In case of any doubt about the contents of English translation, the Chinese original shall be considered authoritative.

This standard was proposed by China Petroleum and Chemical Industry Federation.

This standard was prepared by SAC/TC 35/SC 4 Subcommittee on rubber latex products of China National Standardization Technical Committee on Rubber and Rubber Products.

Single-use non-sterile rubber surgical gloves

1 Scope

This standard specifies the property, safety and technological requirements of single-use non-sterile rubber surgical gloves.

This standard is applicable to the packaged single-use non-sterile rubber surgical gloves which used in surgical procedures to protect the patient and the user from cross-contamination. However, the storage, safety, proper usage, sterilization procedures with subsequent handling of the gloves are outside the scope of this standard.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments (excluding corrections), or revision, of any of these publications do not apply to this standard. However parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies.

GB/T 528, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

GB/T 2828.1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

GB/T 2941, *Rubber — General procedures for preparing and conditioning test pieces for physical test methods*

GB/T 3512, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

GB/T 16886 (all parts), *Biological evaluation of medical devices*

YY 0466-2003, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

3 Classification

3.1 General

Gloves are classified by type, design, finish and adhesive materials.

3.2 Type

Two types are classified:

Type 1: gloves made primarily from natural rubber latex.

Type 2: gloves made primarily from polychloroprene rubber latex, styrene-butadiene rubber solution or emulsion, or thermoplastic elastomer solution or emulsion.

NOTE: Gloves made from mixtures or composites of materials for type 1 and type 2 gloves are designated as type 3 gloves.

3.3 Design

Two types are classified by design:

Straight type (Type R): the glove fingers are straight, and the other four fingers but the thumb are basically on the same flat surface;

Curving type (Type C): all or a part of gloves fingers are curved, and all finger and the palm are not on the same flat surface.

The glove shall be anatomically correct, with the thumb positioned towards the palm surface of the index finger rather than lying flat, and the gloves are divided into left hand and right hand. The fingers and thumb can be straight or curved in the palm direction.

3.4 Finish

Two types are classified by the finish of products latex film:

Textured surface (Type T): textured surface over part or all of the glove or roughness;

Smooth surface (Type S): smooth surface.

3.5 Separating materials

Three types are classified according to separated materials on the inner surface of gloves:

Powdered (Type P): gloves inner surface is coated with a powder;

Powder-free (Type F): gloves inner surface is treated with chlorination or other methods to be powder-free state.

Coated (Type C): Coated with polymer or other non-powder agents and lubricants.

NOTE1: Powdered gloves were made by adding the powder during manufacturing, usually to facilitate donning. Powder-free gloves were made without adding powder material.

NOTE2: The cuff termination of the glove may be cut or in the form of a rolled rim.

NOTE3: For example, powder-free gloves made from natural rubber latex with textured surface and straight fingers may be expressed as "1-RTF".

4 Materials

Gloves shall be manufactured from compounded natural latex or compounded polychloroprene rubber latex, or compounded styrene-butadiene rubber or thermoplastic elastomer solution or emulsion, or compounded styrene-butadiene rubber emulsion. To facilitate donning the gloves, any surface treatment, lubricant, powder or polymer coating may be used subject to compliance with GB/T 16886.

Any pigment used shall be non-toxic. It is essential that substances used for surface treatment which are capable of being transferred are bio-absorbable.

Gloves as supplied to the user shall comply with the relevant part(s) of GB/T 16886. The manufacturer shall make available to the purchaser, on request, data to support compliance with these requirements.

NOTE1: Other suitable polymeric material may be included in future editions of this standard.

NOTE2: Limits of extractable proteins, allergenic proteins, residual chemicals, endotoxins, and residual powder in gloves may be specified in future editions of this standard, subject to the availability of relevant standard.

5 Sampling and selection of test pieces

5.1 Sampling

Gloves shall be sampled and inspected in accordance with GB/T 2828.1. The inspection levels and acceptance quality limits (AQLs) shall conform to those specified in Table 1 for the characteristics listed. When a lot size cannot be determined, a lot of 35 001 pairs to 150 000 pairs shall be assumed.

Table 1 — Inspection levels and AQLs

Characteristic	Inspection level	AQL
Physical dimensions (width, length, thickness)	S-2	4.0
Water-tightness	I	1.5
Force at break and elongation at break (before and after accelerated ageing) and force at 300 % elongation (before accelerated ageing)	S-2	4.0

5.2 Selection of test pieces

Where test pieces are required, they shall be taken from the palm or back of gloves along the dip direction of the gloves.

6 Requirements

6.1 Dimensions

When measured at the points shown in **Figure 1**, gloves shall comply with the dimensions for palm width and length given in **Table 2**, using the inspection level and AQL given in **Table 1**.

The measurement of length shall be the shortest distance between the tip of the second finger and the cuff termination.

NOTE: The length measurement may be taken by hanging the glove on a suitable mandrel with a tip radius of 5 mm.

The measurement of width shall be at the midpoint between the base of the index finger and the base of the thumb. The width measurement shall be made with the glove placed on a flat surface.

The thickness of the double wall of an intact glove shall be measured in accordance with GB/T 2941, with a pressure on the foot of $22 \text{ kPa} \pm 5 \text{ kPa}$ at each of the locations shown in **Figure 2**: a point $13 \text{ mm} \pm 3 \text{ mm}$ from the extreme tip of the second finger, the approximate centre of the palm, and a point $25 \text{ mm} \pm 5 \text{ mm}$ from the cuff termination. The single-wall thickness at each point shall be reported as half the measured double-wall thickness and shall comply with the dimensions given in **Table 2**, using the inspection level and AQL given in **Table 1**.

If visual inspection indicates the presence of thin spots, then single-wall thickness measurements shall be made in such areas. The thickness at the smooth area and textured area of a single wall when measured as described in this sub-clause shall not be less than 0,10 mm and 0,13 mm respectively.

NOTE: The thickness of the cuff termination measured in accordance with GB/T 2941 should preferably not exceed 2,50 mm.

Table 2 — Dimensions and tolerances

Size code	Width (dimension w , Figure 1) mm	Minimum length (dimension l , Figure 1) mm	Minimum thickness (at the locations shown in Figure 2) mm
5	67 ± 4	250	For all sizes: Smooth area: 0,10 Textured area: 0,13
5,5	72 ± 4	250	
6	77 ± 5	260	
6,5	83 ± 5	260	
7	89 ± 5	270	
7,5	95 ± 5	270	
8	102 ± 6	270	
8,5	108 ± 6	280	
9	114 ± 6	280	
9,5	121 ± 6	280	

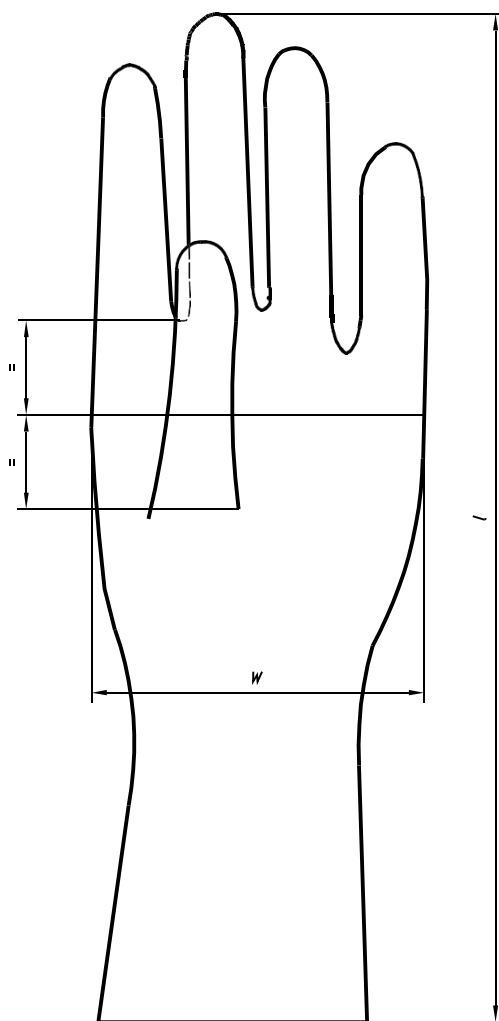
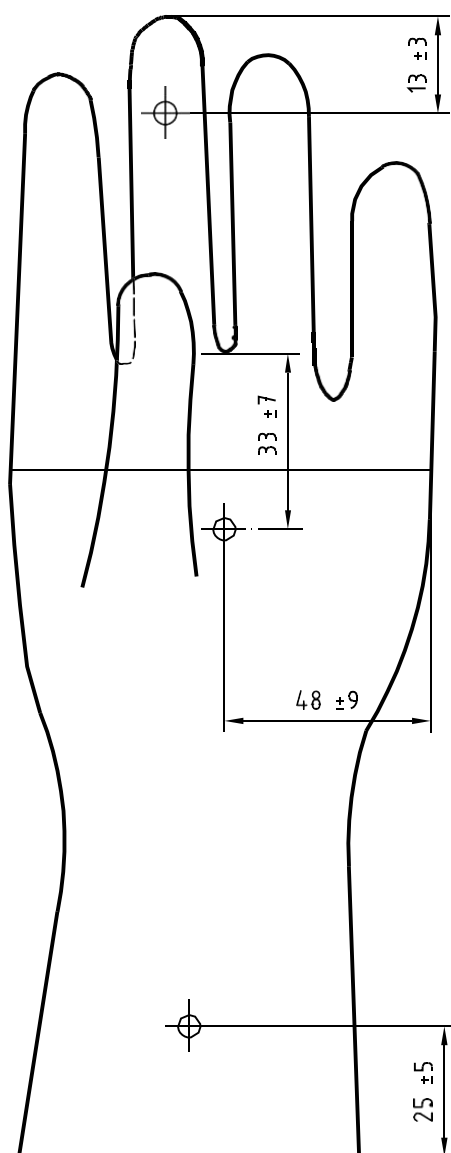


Figure 1 — Measurement points for width and length

Dimensions in millimeters



NOTE: The distance $48 \text{ mm} \pm 9 \text{ mm}$ locates the approximate centre of the palm for different glove sizes.

Figure 2 — Measurement points for thickness

6.2 Water-tightness

When gloves are tested for water-tightness as described in Annex A, the sample size and allowable number of non-conforming (leaking) gloves in the sample shall be determined in accordance with the inspection level and AQL given in **Table 1**.

6.3 Tensile properties

6.3.1 General

Tensile properties shall be measured in accordance with GB/T 528, taking three dumb-bell test pieces from each glove and using the median value as the test result. Test pieces shall be taken from the palm or back of gloves along the direction of dipping.

6.3.2 Force required to produce 300 % elongation, force at break and elongation at break before accelerated ageing

When determined in accordance with the method specified in GB/T 528, using type 2 dumb-bell test pieces, the force at break, force required to produce 300 % elongation and elongation at break shall comply with the requirements given in **Table 3**, using the inspection level and AQL given in **Table 1**.

Table 3 — Tensile properties

Property	Requirement	
	Type 1 glove	Type 2 glove
Minimum force at break before accelerated ageing, N	12,5	9,0
Minimum elongation at break before accelerated ageing, %	700	600
Maximum force required to produce 300 % elongation before accelerated ageing, N	2,0	3,0
Minimum force at break after accelerated ageing, N	9,5	9,0
Minimum elongation at break after accelerated ageing, %	550	500
NOTE: The requirement of Type 3 gloves shall refer to that of type 1 gloves.		

6.3.3 Force at break and elongation at break after accelerated ageing

Accelerated ageing tests shall be conducted in accordance with the method specified in GB/T 3512. After the test pieces cut from the gloves have been subjected to a temperature of $70\text{ °C} \pm 2\text{ °C}$ for $168\text{ h} \pm 2\text{ h}$, the value of the force at break and the elongation at break shall comply with the requirements given in Table 3, using the inspection level and AQL given in Table 1.

6.4 Qualification

Gloves shall be considered to meet this standard if all the test results do not exceed the acceptance quality limits (AQLs) specified in **Table 1**. If one item of test results exceeds the acceptance AQLs specified in **Table 1**, testing shall be repeated on the unqualified item with double samples according to GB / T 2828.1. If it is still not qualified, this batch of products is deemed to be not qualified.

7 Packaging

Gloves shall be packaged in an appropriate manner.

8 Marking

8.1 General

The marking shall include a reference to this standard. Appropriate symbols in YY 0466 may be used for labeling.

The language used for marking shall be as agreed upon between the interested parties.

8.2 Unit-package

The outer wrapping for each unit package of an individual of pair of gloves shall be clearly marked with the following:

- a) the name or trademark of the manufacturer or supplier;
- b) the material used;
- c) the words "STRAIGHT FINGERS" or "CURVED FINGERS" or words to that effect for the appropriate glove design;
- d) the words "TEXTURED" or "SMOOTH", "PRE-POWDERED" or "POWDER-FREE" or words to that effect for the appropriate glove finish;
- e) the size;
- f) the manufacturer's identifying lot number;
- g) the words "DATE OF MANUFACTURE" or words to that effect, and the year in four digits and month of manufacture;
- h) the words "NON-STERILE";
- i) the words "SHALL BE STERILED ACCORDING TO THE STERILIZATION CODE OF PRACTICE FOR MEDICAL DEVICE PRIOR TO USE";
- j) the words "FOR SINGLE USE";
- k) the words "RUBBER SURGICAL GLOVES";
- l) the words "PRODUCT IS MADE FROM NATURAL LATEX WHICH CAN CAUSE ALLERGIC REACTIONS" or words to that effect for type 1 gloves.

8.3 Multi-unit package

Multi-unit package is one containing a predetermined number of unit packages of the same size gloves, intended to facilitate safe transport and storage. Multi-unit packages shall be marked in accordance with 8.2 a) ~ 8.2 h) and 8.2 j), and the quantity of the gloves in a package shall be marked.

Annex A

(normative)

Test for water-tightness

A.1 Apparatus

A.1.1 Circular hollow mandrel, of minimum external diameter 60 mm and adequate length to hold the glove and, with the glove attached, to accommodate 1 000 mL of water. An example is given in Figure A.1.

NOTE: A transparent circular hollow mandrel would be suitable.

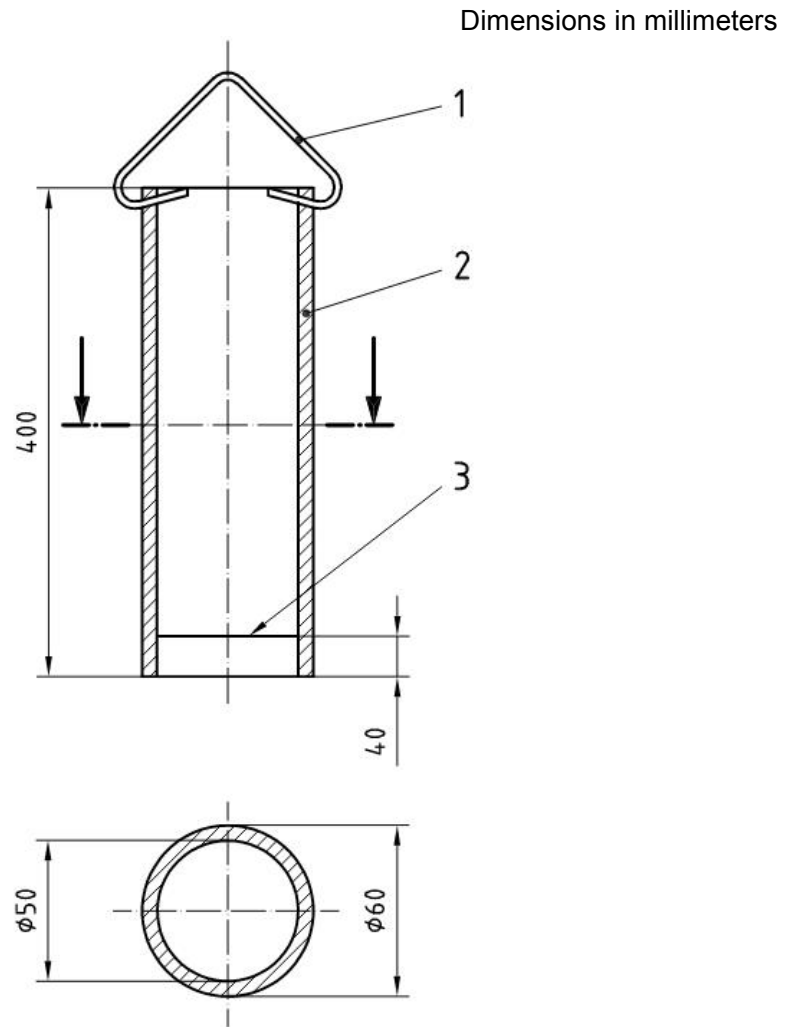
A.1.2 Holding device, designed to hold the glove in vertical position when filled with water. An example is given in Figure A.2.

A.1.3 Graduated cylinder, capacity at least 1 000 mL or other dispensing apparatus capable of delivering 1 000 mL at a time.

A.2 Procedure

Attach the glove to the circular hollow mandrel by a suitable device, e.g. an O-ring, so that the glove does not extend more than 40 mm over the mandrel.

Introduce 1 000 mL \pm 50 mL of water at a maximum temperature of 36 °C into the hollow mandrel. Remove any water that has inadvertently splashed on to the glove. If the water does not rise to within 40 mm of the cuff end, raise the glove to ensure that the whole of the glove, excluding the part 40 mm from the cuff end, is tested. Note any leaks immediately evident. If the glove does not leak immediately, make a second observation for leaks 2 min to 4 min after pouring the water into the glove. Disregard leakage within 40 mm of the cuff end. To assist observation, the water can be coloured with a water-soluble dye.

**Key**

- 1 hook
- 2 cylinder
- 3 score line on inside surface of wall

Figure A.1 — Mandrel

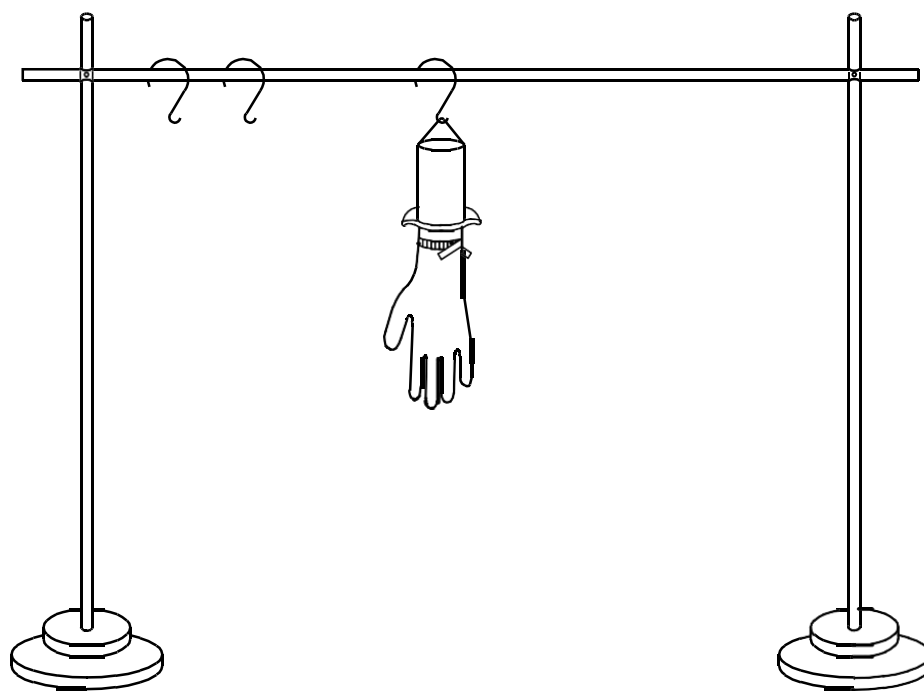


Figure A.2 — Holding device
