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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

Issued on: December 15, 2009 **Implemented on: October 1, 2010**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine;
Standardization Administration of the PRC

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Foreword

GB/T 24787-2009 was issued on 15 December 2009 by the General Administration of Quality Supervision, Inspection and Quarantine and the Standardization Administration of the People's Republic of China, and has been in force since 1 October 2010. The /T in the designation marks it as a recommended rather than a compulsory national standard.

This is the official English translation published by openstd, the national public service platform for standards information. SAC/TC 35/SC 4 is in charge of the English translation; where the English and the Chinese differ, the Chinese original is the authoritative text.

The standard was proposed by the China Petroleum and Chemical Industry Federation and prepared by SAC/TC 35/SC 4, the Subcommittee on rubber latex products of the China National Standardization Technical Committee on Rubber and Rubber Products.

1 Scope

China's national standard for single-use rubber surgical gloves supplied non-sterile. A surgical glove is a barrier in both directions: it protects the patient from the surgeon and the surgeon from the patient, and the whole of its value rests on the film staying intact for the length of a procedure. This standard fixes the properties, the safety and the technological requirements that make that barrier trustworthy, and it does so for gloves that leave the factory in a packaged but non-sterile state, to be sterilized by the user before the operation. It classifies gloves by material - natural rubber latex, synthetic latices and solutions, or a mixture of the two - and by design, finish and separating material, so that a product can be designated unambiguously in a purchase order. It then sets the sampling scheme and acceptance quality limits for each characteristic, the palm width, length and single-wall thickness for every size code, a water-tightness test in which each glove is filled with water on a mandrel and observed for leaks, and the tensile requirements, which are checked both on fresh test pieces and after accelerated ageing, because a glove that is strong when new but degrades on the shelf offers a barrier that fails at the worst possible moment. It closes with packaging and marking, including the warnings that a natural latex product can cause allergic reactions and that the gloves must be sterilized before use. Storage, safety in use, correct usage and the sterilization procedure itself lie outside its scope.

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

It applies to packaged single-use non-sterile rubber surgical gloves used in surgical procedures to protect the patient and the user from cross-contamination. Storage, safety, proper usage and the sterilization procedure with the subsequent handling of the gloves are outside its scope.

2 Normative references

For dated references, subsequent amendments excluding corrections, or revisions, do not apply; parties to agreements based on the standard are nevertheless encouraged to investigate the possibility of applying the most recent editions. For undated references the latest edition 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

Gloves are classified by type, design, finish and adhesive materials, and the four axes combine into a short designation: a powder-free glove of natural rubber latex with a textured surface and straight fingers, for example, is written as 1-RTF.

3.2 Type

Type 1 gloves are made primarily from natural rubber latex. Type 2 gloves are made primarily from polychloroprene rubber latex, from styrene-butadiene rubber solution or emulsion, or from thermoplastic elastomer solution or emulsion. Gloves made from mixtures or composites of type 1 and type 2 materials are designated type 3.

3.3 Design

Two designs are distinguished. In the straight type (type R) the fingers are straight and the four fingers other than the thumb lie essentially on one flat surface; in the curving type (type C) all or part of the fingers are curved and the fingers and palm do not lie on one flat surface.

In either design the glove shall be anatomically correct, with the thumb positioned towards the palm surface of the index finger rather than lying flat, and gloves are made as left-hand and right-hand pairs.

3.4 Finish

Two finishes of the latex film are distinguished: textured surface (type T), textured or roughened over part or all of the glove, and smooth surface (type S).

3.5 Separating materials

Three classes are distinguished according to the material on the inner surface: powdered (type P), whose inner surface is coated with a powder added during manufacture, usually to make donning easier; powder-free (type F), whose inner surface is chlorinated or otherwise treated to reach a powder-free state; and coated (type C), coated with polymer or other non-powder agents and lubricants. The cuff termination may be cut or rolled.

4 Materials

Gloves shall be manufactured from compounded natural latex, compounded polychloroprene rubber latex, compounded styrene-butadiene rubber or thermoplastic elastomer solution or emulsion, or compounded styrene-butadiene rubber emulsion. Any surface treatment, lubricant, powder or polymer coating used to ease donning is permitted subject to compliance with GB/T 16886.

Any pigment used shall be non-toxic, and substances used for surface treatment that are capable of being transferred shall be bio-absorbable.

Gloves as supplied to the user shall comply with the relevant parts of GB/T 16886, and the manufacturer shall make the supporting data available to the purchaser on request.

5 Sampling and selection of test pieces

Gloves shall be sampled and inspected in accordance with GB/T 2828.1, using the inspection levels and acceptance quality limits given in Table 1 for the characteristics listed there - physical dimensions, water-tightness, and the tensile properties before and after accelerated ageing. Where a lot size cannot be determined, a lot of 35 001 pairs to 150 000 pairs is assumed.

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

6.1 Dimensions

Measured at the points shown in Figure 1, gloves shall comply with the palm width and length given in Table 2 for each size code, using the inspection level and AQL of Table 1. Length is the shortest distance between the tip of the second finger and the cuff termination; width is measured at the midpoint between the base of the index finger and the base of the thumb, with the glove laid on a flat surface.

The double-wall thickness of an intact glove is measured in accordance with GB/T 2941 at three locations shown in Figure 2 - near the tip of the second finger, at the approximate centre of the palm, and near the cuff termination - under a defined foot pressure. The single-wall thickness at each point is reported as half of the measured double-wall thickness and shall comply with Table 2; where visual inspection shows thin spots, measurements shall also be made there.

6.2 Water-tightness

Gloves are tested for water-tightness by the method of Annex A, and the sample size and the allowable number of leaking gloves are determined from the inspection level and AQL given in Table 1.