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NATIONAL STANDARD OF THE
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GB/T 7543-2020 / ISO 10282:2014

Replacing GB 7543-2006

Single-use sterile rubber surgical gloves

一次性使用灭菌橡胶外科手套

(ISO 10282:2014, Single-use sterile rubber surgical gloves - Specification,
IDT)

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Foreword

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard replaces GB 7543-2006 “Single-use sterile rubber surgical gloves - Specification”. Compared with GB 7543-2006, in addition to the editorial modifications, the main technical changes in this Standard are as follows:

- In the Scope, modified "This Standard specifies the technical requirements for packaged sterile rubber gloves used in surgical procedures to protect the patient and user and avoid cross-contamination. It is applicable to disposable gloves that are worn once and then discarded. It is inapplicable to examination gloves or procedure gloves. It includes gloves with smooth surfaces and gloves with hemp surfaces." **TO** “This Standard specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination. It is applicable to single-use gloves that are worn once and then discarded. It does not apply to examination or procedure gloves. It covers gloves with smooth surfaces and gloves with textured surfaces over part or the whole glove.” (see Chapter 1 of this Edition, Chapter 1 of Edition 2006);
- In 3.2 Type, modified "b) Type 2: gloves manufactured primarily from nitrile rubber latex, neoprene latex, styrene-butadiene rubber latex, styrene-butadiene rubber latex or thermoplastic elastomer solution." **TO** “b) Type 2: gloves made primarily from nitrile rubber latex, isoprene rubber latex, polychloroprene rubber latex, styrene-butadiene rubber solution, styrene-butadiene rubber emulsion or thermoplastic elastomer solution.” (see 3.2 of this Edition, 3.2 of Edition 2006);
- in 3.4 Finish, modified "There are four types of finishes: a) pockmarked surface; b) smooth surface; c) powdered surface; d) powder-free surface." **TO** “Two finishes are classified: a) textured surface over part or all of the glove; b) smooth surface.” (see 3.4 of this Edition, 3.4 of Edition 2006);
- in Chapter 4, modified "Gloves are made with natural rubber latex, nitrile rubber latex, neoprene latex, styrene-butadiene rubber or thermoplastic elastomer solution, or styrene-butadiene rubber latex. For ease of donning, surface treatment with ISO 10993 compliant lubricants, powders or polymeric coatings may be used." **TO** “Gloves shall be manufactured from compounded natural rubber or nitrile rubber or isoprene rubber or polychloroprene rubber latex, or compounded styrene-butadiene rubber or thermoplastic elastomer solution, 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 ISO 10993.” (see Chapter 4 of this Edition, Chapter 4 of Edition 2006);
- in 6.3.1, modified "Tensile properties shall be determined in accordance with ISO

37. Cut 3 test pieces from each glove. The result is the median value. The test piece should be taken from the palm or back of the glove.” **TO** “Tensile properties shall be measured in accordance with ISO 37, taking three type 2 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.” (see 6.3.1 of this Edition, 6.3.1 of Edition 2006).

This Standard uses translation method to identically adopt ISO 10282:2014 “Single-use sterile rubber surgical gloves - Specification”.

The Chinese documents which have consistency with the international normative references in this Standard are as follows:

- GB/T 528-2009, Rubber, *vulcanized or thermoplastic - Determination of tensile stress-strain properties* (ISO 37:2005, IDT)
- GB/T 2828.1-2012, *Sampling procedures for inspection by attribute-Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection* (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 3512-2014, *Rubber, vulcanized or thermoplastic - Accelerated ageing and heat resistance tests* (ISO 188:2011, IDT)
- GB/T 16886 (all parts), *Biological evaluation of medical devices* [ISO 10993(all parts)]
- YY/T 0466.1-2016, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements* (ISO 15223:2012, IDT)

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

This Standard shall be under the jurisdiction of National Technical Committee on Rubber and Rubber Products of Standardization Administration of China (SAC/TC 35).

The drafting organizations of this Standard: Shanghai Kebang Medical Latex Equipment Co., Ltd., Medikang Medical Products Trading (Shanghai) Co., Ltd., Anhui Hejia Medical Products Technology Co., Ltd., Guilin Zizhu Latex Products Co., Ltd., Xishuangbanna Yunmeng Xinxing Natural Rubber Co., Ltd., Shanghai Zhimei Rubber Co., Ltd., Shanghai Huaxin Medical Materials Co., Ltd., Huaxin Medical Materials (Anhui) Co., Ltd., Anhui Food and Drug Inspection and Research Institute, National Health Commission Science and Technology Research Institute, National Latex Product Quality Supervision and Inspection Center, Anhui Zhongzhike Standardization Institute Co., Ltd., Blue Sail Medical Co., Ltd., Xinjiang Uygur Autonomous Region

Single-use sterile rubber surgical gloves

1 Scope

This Standard specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination. It is applicable to single-use gloves that are worn once and then discarded. It does not apply to examination or procedure gloves. It covers gloves with smooth surfaces and gloves with textured surfaces over part or the whole glove.

This Standard is intended as a reference for the performance and safety of rubber surgical gloves. The safe and proper usage of surgical gloves and sterilization procedures with subsequent handling, packaging, and storage procedures are outside the scope of this Standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

ISO 2859-1, *Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 15223, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied*

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

3 Classification

3.1 General

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