



National Standard of the People's Republic of China

GB 24788—2009

Limit for the removable surface powder and
water-extractable protein of medical gloves

医用手套表面残余粉末、水抽提蛋白质限量

(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.

Limit for the removable surface powder and water-extractable protein of medical gloves

1 Scope

This standard specifies the limit for removable surface powder and water-extractable protein of medical gloves.

This standard is applicable to the single-use rubber medical examination gloves, single-use sterile rubber surgical gloves, single-use nitrile rubber medical examination gloves, single-use polyvinyl chloride medical examination gloves and single-use non-sterile rubber surgical gloves.

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 21869 — 2008 *Medical gloves-determination of removable surface powder*(ISO 21171: 2006, IDT)

GB/T 21870—2008 *Medical gloves made from natural rubber latex - Determination of water-extractable protein using the modified Lowry method* (ISO 21443:2003, IDT)

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

powder

under testing conditions, all water-insoluble attachments that can be removed from the surface of the medical glove by water.

3.2

powdered glove

to facilitate donning, usually made by a coating powder process during manufacturing.

3.3**powder-free glove**

gloves produced during manufacturing consciously not coating powder process or consciously removing powder after coating powder process.

3.4**water-extractable protein**

water-extractable protein and protein-like substances (such as polypeptides) existed in natural latex products.

4 Requirements**4.1 The limit of water-extractable protein content**

The content of water-extractable protein in medical gloves made from natural rubber latex shall be not more than 200 $\mu\text{g}/\text{dm}^2$.

4.2 The limit of removable surface powder content

The limit of removable surface powder content of powdered medical gloves shall be not more than 10 mg/dm^2 . The limit of removable surface powder content of the powder-free medical gloves shall be not more than 2.0 mg /one glove.

5 Test method**5.1 The determination of water-extractable protein content**

The determination of water-extractable protein content for natural latex medical gloves shall be conducted in accordance with method A specified in GB/T 21870—2008.

5.2 The determination of removable surface powder content

The determination of removable surface powder content of gloves shall be conducted in accordance with GB/T 21869—2008.

Calculate the surface area of glove as follows:

$$S = \frac{4 \times W \times L}{10000}$$

Where

S is the surface area of the glove, in dm^2 ;

W is the width of the glove, 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, in mm ;

L is the length of a glove, measure the shortest distance from the top of the second finger to the edge of the cuff, in mm .

Note: The surface area of glove includes four sides: the outside and inside of the back of the glove, the outside and inside of the the palm of the glove.

Convert the unit of the result to mg/dm^2 according to the total area calculated.
