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Safety Technical Requirements for Medical Gloves

医用手套安全技术要求

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Safety Technical Requirements for Medical Gloves

1 Scope

This document specifies the safety technical requirements for medical gloves.

This document applies to disposable medical rubber examination gloves, disposable sterile rubber surgical gloves, disposable non-sterile rubber surgical gloves, and disposable polyvinyl chloride medical examination gloves.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 14233.1-2022 Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use - Part 1: Chemical Analysis Methods

GB 15979-2024 Hygienic Requirements for Disposable Sanitary Products

GB/T 21869-2008 Medical Gloves - Determination of Removable Surface Powder

GB/T 21870-2008 Medical Gloves Made from Natural Rubber Latex - Determination of Water-extractable Protein Using the Modified Lowry Method

Pharmacopoeia of the People's Republic of China (Version 2020) Volume IV

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 powder

Under test conditions, any water-insoluble adhering matter on the surface of medical gloves that can be removed by washing with water.

3.2 powdered medical gloves

Medical gloves that are typically produced through the powder coating process during the production process for ease of donning.

3.3 powder-free medical gloves

Medical gloves produced in the glove production process where the powder coating process is intentionally not used, or where the powder coating process is used, but the powder is intentionally removed.

3.4 water-extractable protein

Proteins and polypeptides that exist in natural rubber latex products and can be extracted with water.

4 Safety Technical Requirements

4.1 Limit for Water-extractable Protein

Medical gloves made from natural rubber latex shall contain no more than 200 $\mu\text{g}/\text{dm}^2$ of water-extractable protein.

4.2 Limit for Residual Surface Powder

The residual surface powder content of powdered medical gloves shall not exceed 15 mg/dm^2 . The residual surface powder content of powder-free medical gloves shall not exceed 2.0 mg/piece .

NOTE: the limit for residual surface powder does not apply to disposable polyvinyl chloride medical examination gloves.

4.3 Microbiological Indicators

4.3.1 The microbiological indicators of non-sterile medical gloves shall comply with the provisions of Table 1.

4.3.2 Sterilized gloves shall be sterile.

4.4 Ethylene Oxide Residue

The ethylene oxide residue of medical gloves sterilized with ethylene oxide shall not exceed 10 $\mu\text{g}/\text{cm}^2$.

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