

Medical Device Product Technical Requirements No: :

Examination Gloves

1 Product model number / specification and its description

1.1 According to 《the Medical Device Catalogue》, 14 infusion, nursing and protective devices 14-11-02, and the management category is Class I.

1.2 Specification (basic size and quality)

Table 1

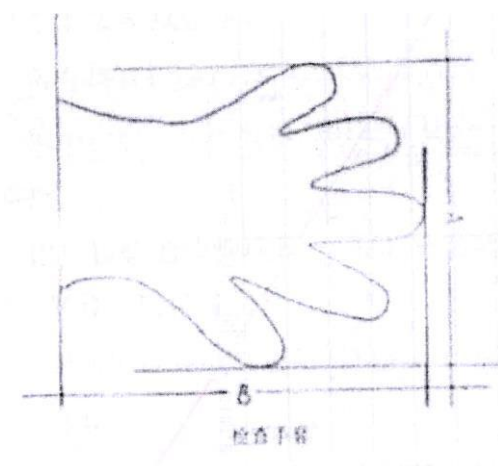
| Specification | L (Large) | M (Medium) | S (Small) |
|--------------------------------|------------|------------|------------|
| A Width (mm) $\pm 5\text{mm}$ | 240 | 230 | 220 |
| B length (mm) $\pm 5\text{mm}$ | 270 | 270 | 270 |
| Quality (g/pc) | ≥ 1.4 | ≥ 1.3 | ≥ 1.2 |

1.3 The inspection gloves can be divided into L (large), M (medium), S (small) according to their size

1.4 The inspection gloves can be divided into: ethylene oxide and gamma rays according to disinfection method.

1.5 The inspection glove's material is made of PE film, which can be divided into smooth and hemp according to the material.

1.6 Diagrammatic sketch:



2 Performance Specifications

2.1 Models, specifications and dimensions.

Shall comply with the technical requirements 1.

2.2 Appearance

Gloves should be uniform thickness, tasteless, no bubbles, no holes, stains and other defects.

2.3 Performance

The seams of gloves should be tight and firm, without penetration.

2.4 Microbiological indicators

| Product model | Total number of bacterial colonies | escherichia coli | Pathogenic pyogenic bacteria | Total number of fungal colonies |
|---------------|------------------------------------|------------------|------------------------------|---------------------------------|
| Common level | ≤200cfu/g | non-detectable | non-detectable | ≤100cfu/g |

3 Test Method

3.1 Models, specifications and dimensions.

Testing with general measuring tools and special measuring tools shall comply with the provisions of 2.1.

3.2 Appearance.

Test by sight and touch, and shall comply with the provisions of 2.2.

3.3 Usage Performance.

Pour 300ml of water into the glove. Observation after 30 seconds, there should be no penetration and cracking, which should comply with the provisions of 2.3.

3.4 Microbiological indicators.

GB15979-2002 The method specified in Appendix b of the health indicators of disposable sanitary products shall be carried out in accordance with the provisions of 2.4.

4. Sample size and decision rules

Sample inspection is carried out according to the general level of GB/T2828.1-2012 sampling scheme. (If the quantity is not enough, it can be extracted from the same batch until the inspection quantity is met), and the AQL of items 2.1, 2.2, 2.3, 2.4 and 2.5 is 0.

All items have passed the inspection, the batch of products is awarded as qualified batch, if the nominal size and shape of any unqualified sample level is III for reinspection. If the person has any of the non-conforming, the batch of products is judged as non-conforming batch.

The inspection items of factory inspection, except 2.3, other items; Formal inspection for technical requirements, all items