

Medical Device Product Technical Requirements No: :

# Disposable Medical Cap

## Specifications:

### 1.Product model / specification and its division description

1.1 Product model: doctor cap, nurse cap.

1.2 Classification by medical device management: classification code is 14-13, management category II.

1.3 Classification by supply status: sterile supply.

1.4 Medical caps can be divided into mechanical type and manual type according to the production process

### 2. Performance index

2.1 The dimensional requirements shall comply with the requirements of Table 1.

Table 1

Unit: mm

Name	Model / specification	length allowance±%	width allowance ±%	Belt length	Pine tight belt length allowance±%
Medical Cap	Medical cap /140×640	10	10	80	10
	Nurse cap /520×520	10	10	400	10

### 2. 2 Appearance requirements

Medical cap should be clean, pollution-free, undamaged, smooth suture, even needle distance, moderate tightness, no needle jumping, needle removal, needle leakage and other defects, the product color should be consistent, odorless and odor-less.

### 2. 3 Material characterization requirements

The requirements of the physical and mechanical performance indicators of non-woven fabrics are shown in Table 2 below.

Specification g/m <sup>2</sup>		15	20	25	30	40	50
Mass deviation rate of square meters (%)		±10	±10	±10	±10	±10	±10
breaking strength (N)	Longitudinal direction	≥10	≥20	≥20	≥30	≥37	≥52
	Transverse landscape	≥7	≥14	≥14	≥23	≥27	≥45

#### 2.4 Sterile

Sterically supplied medical caps shall undergo a confirmed sterilization process.

#### 2.5 Ethylene oxide residue amount

If the medical cap is sterilized by ethylene oxide, the ethylene oxide residue shall not be greater than 10mg / kg.

Note: Non-woven fabric has a high adsorption capacity for ethylene oxide. Because ethylene oxide has a toxic effect on human body, it is recommended not to use ethylene oxide sterilization as far as possible.

### 3 Inspection method

#### 3.1 Dimensional requirement

Test method: for measuring with general measuring tool or special measuring tool, it shall comply with the provisions of Table 1.

#### 3.2 Appearance requirements

Test method: visual observation, hand feel and nasal smell shall comply with the provisions of Article 2.2.

#### 3.3 Material characterization requirements

Test method: the mass of square meters shall be determined according to the test method of FZ / T60003-1993, and the fracture force shall be determined according to the test method of FZ / T60005-1991 in accordance with the provisions of Article 2.3.

#### 3.4 Sterile

Test method: the method specified in Chapter 2 of GB/T14233.2-2005 shall be conducted in accordance with Article 2.4.

### 3.5 Ethylene oxide residue amount

Test method: The test according to the method specified in GB/T14233.1-2008 shall comply with the provisions of article 2.5.