

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 ²		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.