Medical Device Product Technical Requirements No: :

Medical Tape

1. Specifications and models

- 1.1 Medical tape are divided into ordinary type, desensitization type, breathable type according to the material characteristics
- 1.2 The tape are infusion, nursing and protective devices 14-11-02, and the management category is Class I.
- 1.3 Material composition: the tape is made of non-woven fabric or PE film, PU cloth, rubber paste and paper as the substrate, and the adhesive layer is made of medical non-toxic polyacrylic coating as the main raw material.

1.4 Specifications

The basic size of the tape shall comply with the provisions in Table 1, and the special specifications shall be stipulated by both parties.

Table 1 Unit: (cm)

specifications	basic size		
	Width	Length	Tolerance%
1~50×100~1000	1~50	100~1000	±10

2 Performance indicators

- 2.1 The appearance of the tape should be clean, tidy, flat, free of grease spots, impurities, and stains.
- 2.2 The basic size of the tape should meet the requirements in Table 1, and the length of the tape should not exceed two joints within 10m.
- 2.3 The peel strength of the tape should not be lower than 1.4N/cm.
- 2.4 The stickiness of the tape should not exceed 2.5mm.
- 2.5 The paste content of the adhesive layer of the tape should not be less than 25g/m2.
- 2.6 The air flow of the tape should not be less than 50% of the normal air flow value.
- 2.7 After the tape is placed at 37°C for 30 minutes, there should be no residual sticky substance.

3 Test method

3.1 Appearance requirements

Under natural light, visual observation should meet the requirements of 2.1.

3.2 Basic dimensions

Measured with general measuring tools or special measuring tools, it should meet the requirements of 2.2.

3.3 Peel strength test

According to 5.3 in YY 0148-2006, the result should meet the requirements of 2.3.

3.4 Holding viscosity test

According to 5.4 in YY 0148-2006, the result should meet the requirements of 2.4.

3.5 Ointment content test

Accurately measure 100cm tape, weigh it with a balance with a sensitivity of 0.001g (W1), then place it in a 250ml beaker, add solvent acetone and soak it for 30min, stir constantly, scrape off the coating with a blade, and wash it with acetone for several Once, until it is cleaned, take out the substrate and place it in a thermostat at 37°C, dry it for 30 minutes, then cool it in a desiccator for 30 minutes at room temperature and weigh it (W2). The calculation result should meet the requirements of 2.5.

The paste content is calculated according to the following formula:

$$C= (W_1-W_2) \times 100$$

In formula:

C — content of paste, g / m2;

W1 —tape weight, g;

W2 —substrate weight, g.

3.6 Air permeability test

Connect the matching flow meter to the exhaust pipe of the oxygen cylinder (twice the internal pressure of the indoor pressure value), and open the switch and exhaust for 1min to record the air flow value. Then take 25mm 200mm tape to the exhaust hole, exhaust for 1min, record the airflow value, do 5 tests to take the arithmetic average value, the result should meet the requirements of 2.6.

3.7 Residue test

Operation according to 5.7 in YY 0148-2006, and the result shall be 2.7.

Preparation instructions of medical tape

The medical tape produced by our company has no skin allergies, non-toxicity, no side effects, good air permeability, no skin stains, and long-lasting stickiness. At present, it has been widely used in medical clinical work. Medical adhesive tape has changed the disadvantages of traditional zinc oxide adhesive plaster such as allergies and poor air permeability. Since there is currently no national standard to refer to, and no industry standard to implement, this standard is formulated for the safety, effectiveness, and quality assurance of this product as the quality basis for tape production, inspection, and sales.

—, Citing of standards and materials

YY 0148-2006 Medical adhesive tape, general requirements

___. Determine the criteria for the management category

According to the classification of medical equipment management, the tape belongs to injection, nursing and protective equipment 14-11-02, and the management category is Class I.

三、Product overview and basis for determination of main technical terms Medical tape is for use in surgical trauma. Its compilation refers to the provisions of YY 0148-2006 "General Requirements for Medical Tape".