

Medical Device Product Technical Requirements No: :

Gauze and Cotton tissue

1 Specification and model division

1.1 Cotton sheet product models are divided into: dry type; Wet type.

1.2 Product specifications According to the product size: 5×6cm, 6×6cm, 12×15cm, 12×18cm, 13×15cm, 15×18cm, 15×20cm, 16×20cm, 18×18cm, 18×20cm, 20×20cm, 20×25cm, 25×25cm.

2 Performance Specifications

2.1 Appearance

The appearance of the cotton sheet should be clean and free of foreign bodies, no odor and no damage, feel soft, reasonable structure, uniform cotton laying, no hard block.

2.2 Dimensions

The basic size of the cotton sheet shall comply with the provisions of 1.2, tolerance $\pm 10\%$.

2.3 Water Absorption

Water absorption time of cotton sheet $\leq 5s$.

2.4 PH value

The PH value of the cotton sheet should be between 4.0 and 9.0.

2.6 Dry and wet state vertical and horizontal fracture strength

The dry and wet state vertical and horizontal fracture strength of the cotton sheet is $\geq 20N$.

2.7 Purified water (for wet type)

The purified water used for wet type shall meet the requirements of the Chinese Pharmacopoeia.

2.8 Microbiological indicators

Shall comply with Table 1

Table 1

Total number of bacterial colonies CFU/g	Coliform bacteria	Bacillus pseudomonas aeruginosa	Golden yellow staphylococcus	hemolytic streptococcus	Total number of fungal colonies CFU/g
≤ 200	non-detectable	non-detectable	non-detectable	non-detectable	≤ 100

3 Test methods

3.1 Appearance

Visual observation combined with sensory assessment shall meet the requirements of 2.1.

3.2 Dimensions

Measuring with a general measuring tool or a special measuring tool, the result shall meet the requirements of 2.2.

3.3 Water Absorption

According to the method specified in 4.5 of GB/T 24218.6-2010, the results shall meet the requirements of 2.3.

3.4 PH value

According to the method specified in GB/T 7573-2009, the results shall meet the requirements of 2.4.

3.5 Dry and wet state vertical and horizontal fracture strength

Measured according to the method specified in GB/T 24218.3-2010, the result shall meet the requirements of 2.6.

3.6 Purified water (for wet type)

According to the method specified in the Chinese Pharmacopoeia, the results should meet the requirements of 2.7.

3.7 Microbiological Indicators

Test method: The test shall be carried out according to the method specified in Appendix B of GB 15979-2002, and the results shall meet the requirements of 2.8.