

Medical Device Product Technical Requirements No: :

Medical Gauze Dressings

1 Product model/specification and division description

1.1 Model: A, gauze block; B, abdominal towel; C, cotton pad; D, gauze wrap. A, B, C and D are divided into conventional and X-ray detectable type.

Specification: See Table 1 for details.

Table 1

Unit: (cm)

Model	Specification (basic size)		Bias
	Wide × Length	× Layer	
Gauze block	2.5×10 2.5×15 2.5×20 3×3 3×4 3×5 3×6 3×8 3×10 3×15 3×20 3×25 4×4 4×5 4×6 4×8 4×10 4×15 4×20 4×25 4×30 5×5 5×6 5×7 5×8 5×9 5×10 5×12 5×15 5×20 5×25 5×30 5×35 6×6 6×7 6×8 6×9 6×10 6×12 6×15 6×18 6×20 6×25 6×30 6×35 7×7 7.5×7.5 7×8 7×9 7×10 7×12 7×25 7×30 7×35 7×40 8×8 8×9 8×10 8×12 8×13 8×14 8×15 8×16 8×20 8×25 8×30 8×35 9×9 9×10 9×12 9×15 9×20 9×25 9×30 9×40 9×45 10×10 10×12 10×13 10×14 10×15 10×18 10×20 10×25 10×28 10×30 10×35 10×38 10×40	×4/8/10/12	L: ±0.5 W: ±0.5
Abdominal towel	11×15 11×18 11×20 11×25 11×30 11×35 11×40 11×45 12×12 12×15 12×16 12×18 12×20 12×25 13×15 13×17 13×20 14×18 14×19 14×20 14×25 14×30 14×40 15×15 15×20 15×25 15×28 15×30 15×35 15×38 15×40 20×20 20×25 20×30 20×40	×2/4/6/8/10	L: ±1.0 W: ±0.8
Gauze cotton pad	25×25 25×30 25×35 25×40 30×30 30×35 30×40 35×35 35×40 35×42 35×45 35×45 40×40 40×45 40×50 40×45 40×60 80×100	×1/2/4/6/8/10/12	L: ±1.5 W: ±1.0

Gauze wrap	75×100 75×200 75×300 75×400 75×500 75×600		Any side ≤500 L:± 20 w:± 10 Any side≥500
	75×700 75×800 75×900 75×1000		
	80×100 80×200 80×300 80×400 80×500 80×600		
	80×650 80×700 80×750 80×800 80×850 80×900		
	80×950 80×1000 80×1100 80×1200 80×1500		
	84×800 84×850 84×900 84×950 84×1000 84×1200		
	90×100 90×200 90×300 90×400 90×500 90×600		
	90×700 90×800 90×900 90×1000 90×1200		
	100×1000		

1.2 According to the product structure and composition, it is divided into:

Type A gauze block: Gauze are folded into rectangular or square dressing without cut edges.

Type B abdominal towel: a surgical dressing which is made of gauze and folded into rectangular or square, no cut edge exposed, stitched all around, and a abdominal towel band can be sewn on the corner.

Type C yarn Gauze cotton pad: a rectangular or square dressing made with a layer of medical skimmed cotton folded or stitched around between the upper and lower layers of gauze.

Type D gauze wrap: transverse cut into a rectangular or square dressing of original width.

1.3 According to the different clinical principles and the particularity of materials, it is divided into conventional and X-ray detectable types.

1.4 Sterilized and non-sterilized products according to product performance.

2. Performance index

2.1 Extrinsic feature

The surface appearance of the product shall be free of stains and damage; the skim gauze used in the yarn cotton pad shall be tightly fitted and not loose.

2.2 Specifications and basic dimensions

Should comply with the provisions of Table 1

2.3 Medical skim gauze

The skim cotton gauze used for medical gauze dressing shall comply with the specified material requirements of YY0331-2006

2.4 Medical skim cotton

The intermediate material of cotton yarn pad shall comply with the material requirements of YY / T0330-2015

2.5 Abdominal band and suture material

It shall be made of cotton yarn and / or adhesive yarn, and the fluorescent substance of abdominal towel band and suture shall meet the requirements of test A in Appendix D of YY0594-2006.

2.6 Minimum breaking force of the abdominal band

Should not be less than 50N

2.7 Soluble material in the suture water

The total amount does not exceed 0.5%

2.8 Structure and sewing

The folding of medical gauze dressing should make the cutting edge of gauze not exposed, and the sewing requires no less than 2 stitches per 1cm without jumping needle throwing phenomenon.

2.9 Mass of the X-ray detectable components

2.9.1 The X-ray detectable assembly shall be made of materials containing no less than 55% sulfuric acid or other equivalent X-ray opaque materials that shall not shed the fibers and shall not affect the softness of the gauze.

2.9.2 Gently extract the X-ray detection components from the gauze, measure the length and weigh the quality. The single wire shall not be less than 0.5g / m, and the polywire shall not be less than 0.28g / m.

2.9.3 When the X-ray impermeability is tested according to Annex B of YY0594-2006, the imaging of the sample should be significantly lower than the background.

2.10 Colour fastness

Staining products should not stain white cotton cloth

2.11 Microbial indicators

2.11.1 Medical gauze dressings supplied without sterilization shall be tested according to the GB/T19973.1-2015 standard, and their initial bacterial content shall not exceed 100 cfu / g, and no pathogenic bacteria shall be detected.

2.11.2 Sterilized medical gauze dressing should be tested according to the B/T1433.2-2005 standard

2.12 Ethylene oxide residue amount

Medical gauze dressing shall be sterilized by ethylene oxide, and the residual ethylene oxide amount during the test as specified in GB/T14233.1-2008 shall not be greater than 10 ug / g.

3. Method of calibration

3.1 Extrinsic feature

Visual inspection, it shall comply with the provisions of 2.1;

3.2 Specifications and basic dimensions

The measurement with special measuring tools or general measuring tools shall comply with the provisions of Table 1;

3.3 Medical skim gauze

Medical dressing materials shall be tested according to the requirements of YY0331-2006 and shall comply with the provisions of 2.3

3.4 Medical skim cotton

The intermediate material of yarn cotton pad shall be tested according to the requirements of YYO330-2015 and shall comply with the provisions of 2.4

3.5 Abdominal band、 Sewing material

The test according to the requirements of Test A in Annex D of YY0594-2006 shall comply with Article 25

3.6 Minimum breaking force of the abdominal towel band

When using the tension test machine, the force required for breaking the tape, the junction of the belt and the abdominal towel, the joint of the band, or the breaking of the abdominal towel shall comply with the provisions of Article 2.6

3.7 Soluble material in the suture water

When testing according to Annex E of YY0594-2006, the requirements of soluble materials in water shall comply with the provisions of Article 2.7

3.8 Structure and sewing

Select one position at the gauze suture position for visual observation, and measure with a special measuring tool, which shall comply with the provisions of 2.8

3.9 Quality of the X-ray detectable components

The test according to the requirements of Appendix A and B of YY0594-2006 shall comply with the provisions of 2.9

3.10 Colour fastness

According to the experiment A test specified in Appendix C of YY0594-2006, the white cotton cloth shall not be dyed;

According to the experiment B experiment in Appendix C of YY0594-2006, the color of the two white cotton cloth should not be significantly different.

3.11 Microbial indicators

3.11.1 The test according to the method specified in GB19973.1-2015 shall comply with the provisions G30 of 2.11.1

3.11.2 The test according to the method specified in GB/T14233.2-2005 shall comply with the provisions of 2.11.2

3.12 Ethylene oxide residue amount

All the test as specified in GB/T14233.1-2008 shall comply with the provisions of 2.12