Medical Device Product Technical Requirements No:

## Medical Elastic Bandage

## 1 Product model / planning and its division description

1.1 Product model: belly support type, fetal monitoring retention type, emergency dressing type, conventional type, neck type, wrist joint type, knee joint type

1.2 Specifications of the medical elastic bandage

Model	Specification	% deviation	assembly	
Abdominal type	waistline/Abdominal bottom M: 75-110cm L: 110-125cm		Adjust the buckle or the self-adhesive cloth	
Fetal supervision and fixation type			fastener	
First aid dressing type	(W×L) 1~110cm×100~1000cm	±10	Ultra-elastic bandage, water absorption pad medical skim cotton, medical gauze piece, plastic film, plastic clip, plastic eye piece, self-adhesive cloth and other components	
conventional type	nal type		Aluminum buckle or self-adhesive cloth, water-absorbing pad 10cmX8cm、12cmX12cm、 18cmX18cm	

## Table 1

Size (cm)	S (L×w)			allowable
Model	S (L×W)	M (L×w)	L (L×w)	deviation%
Neck type	10×10	12×12	15×15	±10
Carpal joint type	35×6	36×8	42×9	±10
Knee type	45×10	60×15	70×18	±10

1.3 Medical elastic bandage material:

1.3.1 Belly support type: pure cotton, mesh cloth composition;

1.3.2 Fetal monitoring retention type: polyester, human cotton composition;

1.3.3 First aid dressing type: add water suction pad, medical skim cotton, medical gauze piece, plastic film, plastic clip, plastic eye piece, self-adhesive cloth and other components to the bandage.

1.3.4 Conventional: cotton: cotton yarn; wrinkles: spandex, cotton; super elastic: spandex, polyester,

cotton, cotton composition; self-adhesive: cotton yarn, spandex, self-adhesive composition;

## 1.4 Components

1.4.1 Absorbent pad at one end of the bandage, sew fixed components, such as medical absorbent cotton, medical gauze, can be sewn and fixed at the same time.

1.4.2 The two ends of the plastic eye lens are sewn on the back of the bandage, and the protruding point is toward the bandage.

1.4.3 Medical gauze (wrinkles) and plastic film are placed between the bandage and the absorbent pad.

1.4.4 Plastic clip to the inner end of the bandage, sewn fixed.

1.4.5 The self-adhesive cloth is sewn and fixed in the middle part of the outer end of the bandage.

1.4.6 Aluminum buckle/button on the outer end of the bandage

2 Performance indicators.

2.1 Model: Specifications and dimensions shall comply with Table 1 and Table 2 of this technical requirement.

2.2 Appearance Specifications

2.2.1 Should be soft, odorless, tasteless, no obvious stains can be distinguished by foreign debris.

2.2.2 With elasticity, moderate tightness.

2.3 Warp density (applicable to models with gauze material)

The number of warp strands within a width of 10cm measured at rest and calculated according to the total number of warp threads and the publicized width, its unit is expressed in roots per 10cm, and should be within the range of  $\pm 5\%$  of the stated nominal value.

2.4 Weft density (suitable for models with gauze material)

When measuring the 10cm width of the inner weft in the stretched state, the unit is expressed by the root per 10cm and should be within the range of  $\pm 5\%$  of the stated nominal value.

2.5 Tensile length Tensile rate

The drawing length shall meet the following requirements,

The stretching rate of abdominal support type, fetal fixation type, neck type, wrist type and knee type should not be less than 60%, and the stretching rate of cotton type bandage, wrinkle type bandage and super elastic bandage should not be less than 80%.

2.6 Microbiological indicators should meet the requirements in the following table.

Total number of bacterial colonies CFU/g	Coliform bacteria	Bacillus pseudomonas aeruginosa	Golden yellow staphylococc us	hemolytic streptococcu s	Total number of fungal colonies CFU/g
≤200	non-detectabl e	non-detectable	non-detectable	non-detectabl e	≤100

3 Test Method

3.1 Models, specifications and dimensions

Measuring and counting with general measuring tools shall comply with the provisions of 2.1.

3.2 Appearance

Sight and smell shall comply with provisions 2.2.

3.3 Warp Density

According to method 5.6 of YY/T 0507-2009, the test complies with the provisions of 2.3.

3.4 weft density

Method tests in 5.7 of YY/T 0507-2009 shall comply with 2.4.

3.5 Tensile length Tensile ratio

Test according to 5.8 method in YY/T 0507-2009 shall comply with 2.5.

3.6 Microbiological indicators

It shall be carried out in accordance with the method specified in Appendix B of the hygiene index of disposable sanitary products in GB 15979-2002, and shall comply with the provisions of 2.6.