Medical Device Product Technical Requirements No: XTFDA Certified 20140010：

Standard disposable bed Sheet & Cover

1. Product model / specification and its division description

1.1 Product model：

Single-layer type: for the non-woven fabric

Sewing double layer: for non-woven cloth with PE film (polyethylene film) that is, peritoneal cloth suture;

Thermal combined bilayer type: for non-woven cloth with PE membrane (polyethylene film), that is, peritoneal cloth heat combined;

Sewing multilayer type: a single layer of non-woven cloth plus PE film and absorbent paper or non-woven cloth plus PE film and non-woven cloth suture;

Thermal multilayer: single layer non-woven which add PE film and absorbent paper or non-woven and PE membrane and non-woven fabric.

1.2 Product specification

400×500、600×800、800×1200、800×1500、800×1700

Special specifications are made according to customer requirements, special size are made according to the order contract, in the actual operation, the middle of the pad commonly known as hole scarves, used for the delivery surgery women wear on the legs of the pad commonly known as leggings, wrapped in the package products commonly known as wrapping towel).

1.3 It belongs to classI14-15 according to the medical device management.

1.4 It belongs to non-sterile supply by supply status.

2. Performance standard

2.1 Dimensional requirement

It shall meet the requirements of Table 1

Table 1 Unit：mm

Specification Model	Length tolerance ±%	Width tolerance±%	Specification Model	Length tolerance ±%	Width tolerance±%
1500×2500、A，B，C	6	6	600×900、A	8	8
1500×2000、A，B，C	6	6	600×800、A，B，C	8	8
1200×2000、A，B，C	6	6	600×700、A，B，C	8	8
1400×2200、A，B，C	6	6	500×700、A，B，C	8	8
900×2150、A，B，C	6	6	500×550、A，B，C	8	8
860×2120、A，B，C	6	6	450×750、A，B，C	10	10
750×2200、A，B，C	6	6	400×600、A，B，C	10	10
800×1000、A，B，C	6	6	400×500、A，B，C	10	10
800×1200、A，B，C	6	6			
800×1400、A，B，C	6	6			
800×1500、A，B，C	6	6			
800×1700、A，B，C	6	6			

** Special size According to the order contract, in actual operation, the pad with the hole dug in the middle is commonly known as the hole towel, the pad worn on the leg of the maternity operation is commonly known as the pant leg, and the pad wrapped in the bag products is commonly known as the wrap towel.

2.2 Appearance Requirements

The product should be clean, pollution-free, no damage, smooth stitching, uniform needle spacing, moderate tightness, no skipping needle, needle, needle leakage and other defects, the product color is consistent, no odor, no odor.

2.3 Material characterization requirements

2.3.1 Non-woven fabric (suitable for single-layer non-woven fabric without peritoneum)

The physical and mechanical properties of non-woven fabrics are shown in Table 2

Table 2

Specification g/㎡		15	20	30	40	50
Square meter mass deviation rate（%）		±10	±10	±10	±10	±10
Breaking	portrait	≥10	≥20	≥30	≥37	≥52

strength（N）	Landscape orientation	≥7	≥14	≥23	≥27	≥45

2.3.2 PE film

2.3.2.1 Thickness and tensile load performance indicators meet the requirements in Table 3 below (applicable to single-layer unbonded PE film)

表 3

thickness（mm）	0.008	0.010	0.012	0.014	0.020
Mean thickness deviation%	±15	±15	±15	±15	±15
Tensile load（N）	≥1.6	≥2.0	≥2.5	≥2.5	≥2.8

2.3.2.2 Waterproof performance

When the hydrostatic pressure is 1.67kpa, there should be no leakage.

2.3.3 Absorbent paper

Quantitative (g/㎡) 24.0±2.0

Horizontal suction height (mm/100s) ≥15

3. Test method

3.1 Size Requirements

Test method: Measuring with general measuring tool or special measuring tool, should comply with the provisions of Table 1.

3.2 Appearance Requirements

Test methods: Visual, hand feel, and nasal smell shall comply with the provisions of Article 2.2.

3.3 Material characterization requirements

3.3.1 Non-woven fabric (applicable to single-layer non-woven fabric without peritoneum)

Test method: Cut no less than 10 circles with a diameter of 10cm at any place of the cloth, weigh them with an electronic balance, and take their average value. The breaking strength of the electronic fabric is measured by the strength instrument, and the breaking strength of the special specification is referred to the nearby low index value, and the two values should comply with the provisions of Table 2.

3.3.2 PE film

Test method: The test shall be carried out according to methods 6.3 and 6.7 of GB 13735-2017, which shall comply with the provisions of Table 3.

The test shall be carried out according to GB/T 4744-2013 textile fabric impermeability measurement and hydrostatic pressure measurement, which shall comply with the provisions of 2.3.2.2.

3.3.3 Absorbent paper

Test method: The test shall be carried out according to methods 6.2 and 6.4 in GB/T 20810-2018, which shall comply with the provisions of 2.3.3.