

Medical Device Product Technical Requirements No: :

Disposable Medical Middle Sheet

1.Product model / specification and its division description

1.1 Product model:

Type A: non-woven fabric or shoe cloth;

Composite type B: non-woven fabric with PE film (polyethylene film), that is, the four corners of the peritoneal fabric tightened composite;

Sewing type B: non-woven fabric plus PE film (polyethylene film), that is, peritoneal fabric four corners tightened sewing;

Composite type C: single-layer non-woven fabric plus PE film plus absorbent paper or wood pulp cotton composite;

Sewing type C: single-layer non-woven fabric with PE film and absorbent paper or wood pulp cotton sewing;

Composite D type: non-woven fabric plus PE film plus non-woven fabric composite;

Sewing type D: non-woven fabric plus PE film and non-woven fabric sewing;

1.2 Product Specifications

Width: 200mm~5000mm

Length: 200mm~5000mm

1.3 Patient care protective devices classified by medical device management as infusion, nursing and protective devices 14-15-05.

1.4 Non-sterile supply according to state of supply.

2. Performance indicators

2.1 Size Requirements

It should meet the requirements of the nominal value, and the tolerance is within $\pm 10\%$.

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 (applicable to all models)

The physical performance requirements of non-woven fabrics are shown in Table 1

Table 1

Specification g/m ²	15	20	30	40	50
Square meter mass deviation rate (%)	± 10	± 10	± 10	± 10	± 10

2.3.2 PE film (suitable for composite type C, sewn type C)

2.3.2.1 Appearance

The surface should not affect the use of bubbles, impurities, stripes, perforations, folds and other defects.

2.3.2.2 Thickness and tensile load performance indicators meet the requirements in Table 2 below

Table 2

Nominal thickness d0 (mm)	0.010 ≤ d0 < 0.015	0.015 ≤ d0 < 0.020	0.020 ≤ d0 < 0.025
Mean thickness deviation%	+15, -12		
Tensile load (N)	≥ 1.6	≥ 2.2	≥ 3.0

2.3.3 Absorbent paper (suitable for composite type C, sewing type C)

Double layer quantity (g/m²) ≥ 20

Transverse drop height (mm/100s) ≥ 20

3. Test method

3.1 Size Requirements

Test method: Measuring with a general measuring tool or a special measuring tool shall comply with the provisions of 2.1.

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 all models)

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 1.

3.3.2 PE film (suitable for composite type C, sewn type C)

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 2.

3.3.3 Absorbent paper (suitable for composite type C, sewing type C)

Test method: Test according to GB20810-2006 6.2, 6.4 methods, should comply with the provisions of 2.3.3.