Medical Device Product Technical Requirements No: ：

Medical Nursing Pad

1 Specification and model division

1.1 The product model of medical nursing mat is divided according to the shape: 1. Flat type 2. paste type 3. Active type 4.S type 5.U type 6. Triangle type

1.2 Product specifications are divided according to product sizes：160*400、210*490、220*500、235*580、240*570、250*330、270*360、270*720、280*400、280*540、280*600、300*400、300*450、300*700、300*780、320*440、320*450、320*460、320*490、320*520、320*540、320*560、320*620、320*630、320*820、330*250、330*450、360*650、380*690、500*400、560*560、600*400、600*450、600*600、600*700、600*750、600*800、600*900、600*1200、600*1500、650*750、650*800、700*1100、700*1200、700*1500、700*1800、750*650、750*900、750*920、750*1000、750*1500、750*2000、800*650、800*750、800*900、800*960、800*1000、800*1200、800*1500、800*1600、820*1015、840*1030、880*750、900*900、900*1200、900*1950、1000*1500、1000*2000、1000*2300、1000*2500.The length of the special-shaped pad is 500-900 (unit: mm).

1.3 Management category is Class I.

2 Performance indicators

2.1 Appearance

The appearance of the medical nursing pad should be clean and free of foreign matter and odor, the leak-proof bottom film should be intact, without damage, soft to the touch, and reasonable in structure.

Spread the cotton evenly, without hard blocks, cut the cotton neatly, spray the right amount of glue, evenly without glue dripping, and seal firmly.

2.2 size

The basic dimensions of medical nursing pads should meet the requirements of 1.2, and the tolerance should not exceed 15%.

2.3 Water absorption rate

The water absorption rate of medical nursing pads should be ≥ 5 times.

2.4 Absorption speed

The absorption speed of medical nursing pads should be ≤60s.

2.5 pH value

The pH value of the medical nursing pad should be between 4.0 and 9.0.

2.6 Formaldehyde content

The formaldehyde content of medical nursing pads should be ≤75mg/kg.

2.7 Migratable fluorescent substances

Migratable fluorescent substances should be ≤0.60%

2.8 Microbiological indicators

Should meet the requirements of Table 1

Table 1

Total number of bacterial colonies CFU/g	coliform bacteria	Pseudomonas aeruginosa	Golden staphylococcus	hemolytic Streptococcus	total fungal colonies CFU/g
≤200	Not detectable	Not detectable	Not detectable	Not detectable	≤100

3 Test method

3.1 Appearance

Visual observation combined with sensory evaluation should meet the requirements of 2.1.

3.2 size

Measured with general measuring tools or special measuring tools, the results should meet the requirements of 2.2.

3.3 Water absorption ratio

Take a piece of sample, tear off the release paper, cut off the wings appropriately, and weigh its mass (mass before suction) with a balance with a sensitivity of 0.01g. Clamp one end of the sample with a clip, and make the clip jaws perpendicular to the longitudinal direction of the sample, and the built-in absorbent layer should not be clamped. Immerse the sample together with the clamp in distilled or deionized water at (23±1)°C, with the use side of the sample facing up. Gently press the sample, make it completely submerged for 60s, and then lift the clamp. Make the sample completely leave

the water surface, hang vertically for 90s, remove the clamp, weigh the mass of the sample after water absorption (mass after absorption), and calculate according to the following formula Water absorption rate. Test 5 samples in the same way, take the average value of 5 samples as the measurement result, and round to one decimal place. The result should comply with 2.3

Water absorption ratio = (mass after absorption - mass before absorption) / mass before absorption

3.4 Absorption speed

The absorption rate is measured according to Appendix A of GB/T 8939-2018, and the formula of the standard synthetic test solution for the determination of absorption rate is shown in Appendix B. The result should meet 2.4.

3.5 pH value

Measured according to the method specified in GB/T7573-2009, the result should meet 2.5.

3.6 Formaldehyde content

The formaldehyde content is determined by the acetylacetone visible spectrophotometric method in GB/T 34448-2017. When sampling, the outer packaging and release paper of the product are removed, and the sample is cut from both ends and the middle position. The sample should contain all layers of materials. The result should comply with 2.6.

3.7 Migratable fluorescent substances

Reagent Water: GB/T 6682, third grade Gauze: pure cotton material, about 5 cmX5 cm in size. Ammonia: 0.1%.

Hydrochloric acid solution: 10%. Extraction solution: water with a pH of 7.5-9.0 adjusted with 0.1% ammonia water

Fluorescence standard sample; the fluorescence is uniform, and the fluorescence brightness is 0.40%~0.60% Note: Except for the fluorescent standard sample, the reagents and materials used have no fluorescence phenomenon under the ultraviolet lamp.

Equipment: Balance; Sensitivity: 0.001g Erlenmeyer flask: 250 mL G1 glass sand core funnel

Glass watch glass Ultraviolet lamp: the wavelength is 254 nm and 365 nm, with a device for eye protection.

pH meter; accuracy is 0.01. Constant temperature water bath: temperature control accuracy is (40±2)C

1. Take a piece of sample randomly from the sample, remove the outer packaging, place the

sample (including release paper) and the fluorescent standard sample under the ultraviolet lamp at about 20℃, and compare and observe the fluorescence of both sides of the sample and the fluorescent standard sample Phenomenon. If the fluorescence phenomenon of the sample is weaker than that of the fluorescent standard sample, it is judged that the migratable fluorescent substance of the sample is qualified and the test is terminated;

2. Cut off the part of the sample where the fluorescence phenomenon is obvious, and cut it into small pieces of about 5mmX5mm, accurately weigh 2.0g of the sample and place it in the Erlenmeyer flask.

Note: If the mass of the obvious fluorescent part of one sample is less than 2.0 g, take samples from multiple samples.

3. Add 100 mL of extraction solution to the flask, shake the flask slowly at room temperature, take for 1 min, and then filter with a glass funnel.

4. Use hydrochloric acid solution (D.1.4) to adjust the pH of the filtrate to 3.0~5.0, immerse the gauze (D.1.2) in the filtrate, and place it in a constant temperature water bath (D.2.7) with a temperature of (40±2)C 30 min.

5. Take out the gauze with tweezers, then squeeze out the filtrate and fold it into four layers symmetrically, and place it on a glass watch glass.

6. Repeat steps 3~5 to conduct a blank test

7. Carry out two parallel determinations for each sample.

8. Place the glass surface of the sample gauze) and the blank test gauze at about 20 cm under the ultraviolet lamp, and observe the fluorescence phenomenon of the gauze.

9. If there is no obvious fluorescent phenomenon between the sample gauzes of the two parallel tests and the blank test gauze, the sample is judged to be qualified for the migratable fluorescent substance; if the two sample gauzes have obvious fluorescent phenomena, the sample is judged to be The migratable fluorescent substance is unqualified; if one of the two sample gauzes has a more obvious fluorescent phenomenon than the blank test gauze, re-test, if the sample gauze after the re-test is compared with the blank test gauze. If there is no obvious fluorescence phenomenon, the sample is judged as qualified for the migratable fluorescent substance; otherwise, it is judged as unqualified.

3.8 Microbiological indicators

Test method: Carry out the test according to the method specified in Appendix B of GB 15979-2002,

and the result should meet the requirements of 2.8.