Product Technical Requirements No:

Band-aid

## 1 Product composition, type, and its name

1.1 Product composition

The product is composed of base material, water absorption layer and isolation layer, and its shape structure is shown in Figure 1.

The base material material is generally non-woven fabric, paper based, PE film, PVC film, PU film, EVC foam, sea cotton, PET film.

Water absorbent layer material has non-woven cloth, skimmed gauze, cotton pad, PE pad layer.

The adhesive should be medical adhesives, such as acrylate copolymer, cyanoacrylate, silicone copolymer, polyvinyl ether, polyisobutylene, polyurethane, etc.
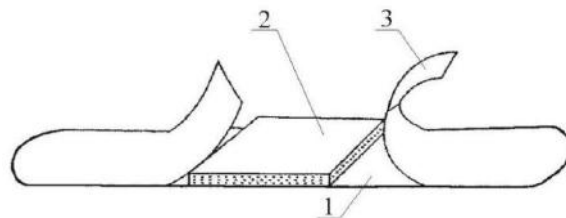
1——backing material；2——The water absorption layer；3——buttering

Figure 1 Schematic diagram of the shape structure

Note: Figure 1 is not the only structural type specified in this standard, and other structural types can be used as long as the effect is the same.

1.2 classification

According to its product grade and characteristics, it is divided into ordinary, breathable, comfortable, water resistance, elastic or inelastic type etc.

1.3   Nominate

1.3.1 Band-aids are named as follows:

□□ — □□   Type code

                 Corporate code
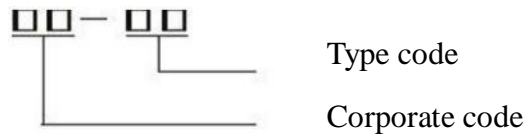
1.3.2 The meaning of symbol: it is the first letter of type syllables. For example: PT is normal; TQ is breathable.

2 Performance index

2.1 Appearance

2.1.1 The appearance of the product shall be smooth and smooth, the cutting edge shall be neat, the surface shall be clean, and there shall be no stains or damage.

2.1.2 Adhesive tape should be evenly coated without degumming, leakage and backside infiltration.

2.1.3 The absorbent layer should be located in the middle of the tape without obvious skew or dislocation.

2.1.4 The isolation layer shall be completely covered on the adhesive surface, without tape or water absorbing layer exposed.

2.2 Size

Specifications and sizes are shown in table 1

   Table 1 Specification and size   Unit：mm

2.3 Water absorption rate of the water absorption layer

Model	Specification (length and width)	allowable deviation
Ordinary type, breathable type,comfortable type, water resistance type, elastic type, inelastic type	5~200×5~200mm	±10%

The water absorption rate of the water absorption layer should not be less than 200%.

2.4 Peeling strength

The peeling strength shall conform to the average force prescribed by YY/T0148-2006 not less than 1.0N/cm.

2.5 Adhesion

The holding force shall not exceed 2.5mm in accordance with YY/T0148-2006.

2.6 Adhesive residue

There should be no residual viscous substance after the product is placed at 37°C for 30min.

2.7 Permeability

Water vapor penetration should be no less than 500g/m2 every 24h.

2.8 Comfort

The extensibility should not be greater than 14N/cm, and the permanent deformation should not be greater than 5%.

2.9 Water Resistance

When tested according to YY/T 0471.3-2004, there should be no water seepage.

2.10 Elasticity

The ratio of recovery length to full stretch length should not be greater than 80%.

2.11 Microorganisms

The total number of bacterial colonies shall not exceed 100cfu/g, and no pathogenic bacteria shall be detected.

3. Test method

3.1 Appearance

When observed with normal or corrected vision, the results shall conform to the provisions of 2.1.

3.2 Dimensions

Measuring with a general measuring tool, the result shall comply with the provisions of 2.2.

3.3 Water absorption

Take the absorbent layer 0.1g, accurately weigh (W1), completely immerse it in a container with enough water, take it out after 30 seconds, drop water naturally for 30 seconds, then accurately weigh (W2), calculate the absorbent rate according to formula (1), do two copies in parallel, take the average, the result should comply with the provisions of 2.3.

$$P = \frac{W_2 - W_1}{W_1} \times 100\% \quad \ldots\ldots(1)$$

Where: P -- water absorption, unit is percentage (%);

W1 -- Weight of water absorbing layer before water absorption, unit is g;

W2 -- Weight of absorbent layer after absorption, unit is g.

3.4 Peeling strength

Attach the sample to the center of the clean surface of the stainless steel plate so that the two sides of the sample are parallel to the two long sides of the steel plate. Apply pressure to the adhesive part of the sample with a roller and roll four times along the length of the sample at a speed of about 60 cm/min. Let it stand at standard

atmospheric pressure for 10 minutes, and determine the force required to peel the sample from the steel plate with a suitable force measuring instrument ranging from 15% to 85% of the full scale (the force Angle is 180 degrees, the peel speed is 220mm/min-330mm/min to observe the force applied at the first 25mm length, The force was observed every 30 minutes and the average of the six readings was taken. The test was repeated for the other 4 samples, and the average value of the 5 samples was calculated. The result shall comply with the provisions of 2.4.

3.5 Adhesion

The adhesive surface of one end of the prepared sample is contacted with the clean surface of the stainless steel plate, so that the entire width of the end of the sample is aligned with the 25mm from the end face of the steel plate, so that both sides of the sample are parallel to the long side of the steel plate. The unbonded end of the sample is suspended beyond the end face of the steel plate. When pasting the sample, it is necessary to ensure that there are no bubbles between the sample and the steel plate, apply pressure to the paste part of the sample with a roller, roll four times along the length direction of the sample at a speed of about 60 cm/min, and park it at standard atmospheric pressure for 10 minutes. Make a marking line on the end line of the sample, attach a weight to the hanging end of the sample according to the width of 0.8N (80 g) per centimeter, and the force should be evenly distributed over the entire bandwidth. The steel plate is suspended in the hot air oven at 36°C -38°C for 30 min, so that the steel plate and the vertical plane are tilted to prevent the sample from peeling off the steel plate, and the heavy object can be suspended. Repeat this step for the other four samples, and for a large elastic product, apply a non-stretchable tape of the same width between the applied gravity and the sample. When testing the elastic adhesive bandage, the elastic thread should be located in the width direction of the steel plate, and the weight should be applied in the direction of the inelastic thread. In this case, the test can be carried out under the condition that the width of the sample is at least 25 mm. If the width of the test material is 25 mm, it is necessary to paste a non-elastic adhesive tape on the sample (about 60 mm in length, the width of the sample is the same), so that the unglued part of the tape is suspended on the end of the stainless steel plate, so that it is uniform when hanging heavy objects. The result shall comply with 2.5.

3.6 Adhesive residue

Paste the product with an area of 25mm×50mm on the corresponding fabric, put it in a 37°C thermostatic box, take it out after 30min, roll it on the product twice with an 850g rubber drum at a speed of 30cm/min, and check whether there is any residual sticky substance on the fabric after peeling.

3.7 Breathability

Take five small boxes, pour about 20 ml of water into each box, and put them into an electric drying box with circulating air facilities, and keep the temperature at 36°C -38 °C, so that the relative humidity in the drying box is less than 20%. Cover the top of the opening of the box naturally with the test material strip and seal, if necessary, apply Vaseline to seal, so that the air gap between the liquid level and the placed sample is (5±1)mm, weigh the sealed box to the accuracy of mg, and place them in

the cabinet for about 18h (the recording time is accurate to 15m in). Remove the box from the cabinet, cool it at standard atmospheric pressure for 1h, and weigh it again, accurate to mg. The result shall comply with the provisions of 2.7.

$$X = \frac{(W_1 - W_2) \times 1000 \times 24}{T}$$

3.8 Comfort

Cut a representative sample (25.0±0.5) mm wide from the test material. After removing the sample from the roll or backing paper, let it relax for at least 300s. Two parallel marks with a spacing of (100±10) mm are made on the sample and the spacing is equidistant from the two ends. The distance between the two marks is measured to ±0.5mm (L1). The sample was placed outside the label in two collets of the tensile tester and extended by 20% at a tensile speed of (300±10) mm/min. Record this maximum load (ML), accurate to 0.1N. Here the stretch is held for (60±1) s, the sample is removed from the clamp and relaxed for (300±15) s. Re-measure the distance (L2) between the two markers on the sample. Repeat the above steps for the other two samples and take their average values. Then the extensibility E=ML/2.5, permanent deformability PS (%) = (L2-L1)/L1 ×100 results should meet the requirements of 2.8.

3.9 Water Resistance

The test sample should be free of folds, the sample is fixed in a horizontal position with two rings, the lower ring is a part of the pool, the pool is filled with pure water at (21±2) °C, and the sample is placed on the lower ring in a horizontal sliding way to avoid air between the surface of the water and the lower surface of the sample. Cover the upper surface of the sample with a drying filter paper larger than the test area, place an upper ring, and tighten with a thread device. Inject water into the tube to reach the required water level above the sample surface and maintain the hydrostatic pressure of (300±10) s. Check the filter paper for water seepage through the sample and record the result. The result shall comply with the provisions of 2.9.

3.10 Elasticity

The length (L) of the material is measured without tension, and one section of the material is fixed to the fixed fixture and the other end to the movable fixture of the extension device, so that the material is stretched in the elastic direction. Ensure that the material is clamped at both ends, such as with clamps on the fixture, to minimize slippage during stretching. Mark two marks (S1) about 50 cm apart on the material between the two fixtures. Apply a force of 10 N per cm width to the moving fixture and ensure that the load is completed within 5 s. Measure the distance (:) between the two marks of the material as soon as possible after loading, accurate to centimeters (cm). Maintain the tensile time of the load at 55 s-65 s to ensure no timeout and overload. The tensile force is then quickly released without tangling the material. Relax the material for 4.75 min-5.25 min. Measure the distance between the two marks (s2) I accurate to the centimeter (cm). The full drawing length was Ls1/1, the recovery length was Ls2/1, and the elastic ratio was L=S2/S1. The result shall comply with the provisions of 2.10.

3.11 Microorganisms

According to the test method of GB 15979, the result shall comply with the provisions of 2.11.