

## Product Technical Requirements No: XTFDA Certified 20140010

### Bandage

#### 1. Product model / specification and its division description

1.1 They are divided into type A (skimmed gauze material) and type B (water thorn nonwovens).

1.2 Product specifications shall comply with the provisions of Table 1, and special specifications shall be stipulated in the order contract.

Table 1 Basic size unit of bandage: cm

Model	Width tolerance	Length tolerance	Model	Width tolerance	Length tolerance	Model	Width tolerance	Length tolerance
4.8×600	±5%	±6%	6×600	±5%	±6%	8×600	±5%	±6%
4.8×550	±5%	±6%	6×550	±5%	±6%	8×550	±5%	±6%
4.8×500	±5%	±6%	6×500	±5%	±6%	8×500	±5%	±6%
4.8×450	±5%	±6%	6×450	±5%	±6%	8×450	±5%	±6%
4.8×400	±5%	±6%	6×400	±5%	±6%	8×400	±5%	±6%
4.8×350	±5%	±6%	6×350	±5%	±6%	8×350	±5%	±6%
4.8×300	±5%	±6%	6×300	±5%	±6%	8×300	±5%	±6%
5.5×600	±5%	±6%	7.5×600	±5%	±6%	10×x600	±5%	±6%
5.5×550	±5%	±6%	7.5×550	±5%	±6%	10×x550	±5%	±6%
5.5×x500	±5%	±6%	7.5×500	±5%	±6%	10×500	±5%	±6%
5.5×450	±5%	±6%	7.5×450	±5%	±6%	10×450	±5%	±6%
5.5×400	±5%	±6%	7.5×400	±5%	±6%	10×400	±5%	±6%
5.5×350	±5%	±6%	7.5×350	±5%	±6%	10×350	±5%	±6%
5.5×300	±5%	±6%	7.5×300	±5%	±6%	10×300	±5%	±6%

1.3 It belongs to the medical health materials according to the medical device management

classification

1. 4 It is a non-sterile supply by supply status.

2. Performance indicators

2.1 Appearance

Bandages should be pure white nonwoven gauze or spunlaced nonwovens, gauze materials should feel soft, odorless, tasteless, no burrs; Nonwoven fabric should be uniform, flat, no obvious creases, broken edges and holes, no oil stains, no defects.

2.2 Dimensions

The requirements of Table 1 shall be met.

2.3 Nonfat gauze material

Article 4 of YY 0331-2006 shall be complied with.

2.4 Spunlace material properties:

2.4.1 Mass per unit area: The mass per unit area of the non-woven fabric in contact with trauma is 30-150g/m<sup>2</sup>.

2.4.2 Breaking strength: meet the requirements of Table 2 below.

2.4.3 Water absorption meets the requirements in Table 2 below

Table 2

Project		request	
		superior product	Standard product
breaking force	$M \leq 30$	10	6
	$30 < M \leq 40$	15	7
	$40 < M \leq 50$	20	9
	$50 < M \leq 60$	25	14
	$60 < M \leq 70$	30	18
	$70 < M \leq 80$	40	22
	$M > 70$	50	26
Mass per unit area	$M \leq 50$	7	
	$M \leq 70$	5	
The mass deviation rate per unit area shall not exceed		$\pm 7$	
Water absorption	$M \leq 80$	700	
	$M > 80$	500	
Note 1: longitudinal and transverse fracture strength assessment; Note 2: M represents the mass per unit area, the unit is g/m <sup>2</sup> ;			

Note 3: Water absorption capacity is only assessed for products that require water absorption.

### 3. Test conditions:

- a) Room temperature: 15°C-30°C; b Relative humidity: 65%±20%,
- b) Water for the preparation of test liquid: PH value is 6.5-7.5.

### 4. Test method

#### 4.1 Appearance

Test method: Visual inspection shall comply with the provisions of 2.1.

#### 4.2 Dimensions

Test method: Through the special measuring tool measurement, where the number of layers with scissors cut measurement, should comply with the provisions of 2.2.

#### 4.3 Performance of nonfat gauze

Test method: According to the standard method of YY 0331-2006, which shall comply with Article 2.3.

#### 4.4 Spunlaced nonwovens performance test.

##### 4.4.1 Mass per unit area shall comply with the provisions of 2.4.1.

Test method: According to FZ/T 60003-1993, the nominal value is used as the reference value. The deviation rate is calculated according to formula (1), expressed as a percentage, with one decimal place reserved.

Deviation rate (%) = [measured value - reference value/reference value] \*100 ---(Formula 1 )

##### 4.4.2 The breaking strength shall comply with the provisions of 2.4.2.

Test method: According to FZ/T 60005-1991 related methods.

##### 4.4.3 Water absorption shall comply with the provisions of 2.4.3.

Test method: Cut the sample, the size is 100mmx100mm, and the cumulative total weight is not less than 1g as a sample. Weighing after equilibrium in the standard atmosphere stipulated by GB6529, accurate to 0.01g as the original mass of the sample. After the sample is impregnated in distilled water or under the three levels of water surface, the sample is taken out after (50+1) s, hung vertically, dripping water) 120+3) S, weighed as the sample mass after water absorption, and the water absorption rate is calculated according to formula (2). Keep one decimal place.

Water absorption rate (%) - [(quality of sample after water absorption - original quality of sample)/original quality of sample] \*100... (Formula 2) The average value of 5 samples is taken as the test result