Medical Device Product Technical Requirements No: ：

Disposable Dressing Set/Kit

1、 Product model and specification

1．1 The standard of classification

It belongs to Class II according to medical device management classification.

Product specifications and models are divided into: cleaning type, debridement type, PICC (central vein catheterization) type

1．2 Configuration requirements

See the table below for details 1

Table 1

S/N	Product name	Specifications and models	Memo	
1	Wrapping cloth、Underpad	≥40×40cm	/	Self-produced parts
2	Alcohol + cotton ball	Cotton ball≥0.2/grain，75% Medicinal alcohol	/	Self-produced parts
3	Iodine volt + cotton ball	Cotton ball≥0.2/grain，0.5% Effective iodine	/	Self-produced parts
4	Medical gauze block	6×8×8layer 、8×8×8layer 、8×10×8layer	/	Self-produced parts
5	Tray	9×11cm 、10×13cm	Have a medical device registration certificate	bought-in components
6	tweezers	≥11.5cm	Have a medical device registration certificate	bought-in components

7	Sterilizing forceps	≥13cm	Have a medical device registration certificate	bought-in components
8	Nonabsorbable surgical suture	≥60cm	Have a medical device registration certificate	bought-in components
9	Medical suture needle	7×17	Have a medical device registration certificate	bought-in components
10	Operating knife blade	9#～36#	Have a medical device registration certificate	bought-in components
11	Disinfection cotton rod	2pcs	/	Self-produced parts
12	Disposable medical alcohol disinfection tablets	6×6cm， 70% Medicinal alcohol	/	bought-in components
13	Disposable sterilized rubber surgical gloves	M type/8.5×26cm	Have a medical device registration certificate	bought-in components
14	Pull the adhesive cloth	10×1.2cm	Have a medical device registration certificate	bought-in components
15	Self-adhesive transparent dressing	10×12cm	Have a medical device registration certificate	bought-in components
16	Non-woven pads	≥7×7×4 layers	/	Self-produced parts

Description: The specifications, models and configuration quantities of accessories in the package can be adjusted according to user requirements, but limited to the above table.

2、Product performance indicators

2.1 Configuration, and appearance requirements

Cleaning type: tray, tweezers, medical gauze block, iodinated cotton ball, towel, alcohol cotton ball, disinfection pliers, etc.

Degeneration: surgical blade, medical suture needle, non-absorptive surgical suture, tray, tweezers, medical gauze block, iodine cotton ball, towel, alcohol cotton ball, disinfection forceps, etc.

PICC (central venous tube) type: wrap, pad, sterilized cotton swab, disposable medical alcohol disinfection tablets, disposable sterilized rubber surgical gloves, adhesive tape, self-adhesive transparent dressing, non-woven gasket.

All accessories in the package shall be pollution-free, undamaged, odorless and tasteless. Plastic accessories should be smooth, uniform color, should not have burrs, flying edge and cracks.

2.2 The kins and pads shall meet the requirements of impermeable water resistance in YY / T 0506.2 standard

Performance name	Unit	Product is not a critical area
Impermeability resistance	CmH_20	≥10

Memo：PICC (central vein catheterization) inner wrap and pads are made of composite paper material, which is not suitable for the requirements of this clause.

2.3 Medical gauze block

a) The sinking time shall not exceed 10S

b) The quality per square meter shall not be less than 39g.

2.4 Alcohol + cotton ball

Should comply with the provisions of Table 1. Alcohol should be able to provide the disinfectant hygiene license, indicate the concentration, meet the " Disinfection Technical Specification (2002) edition: the positive control group should have more bacterial growth, the negative control group should be sterile growth, with the average killing value of natural bacteria on the skin surface of 30 batches is 1.00, can be judged as disinfection qualified

2.5 Iodine volt + cotton ball

Should comply with the provisions of Table 1. Iodophor should be able to provide the disinfectant hygiene license, indicate the concentration, meet the Disinfection Technical Specification (2002) edition: the positive control group should have more

bacterial growth, the negative control group should have sterile growth, with the average killing value of natural bacteria on the batch surface of the skin of 30 people is 1.00, can be judged as disinfection qualified.

2.6 Tweezers The clamp-holding force

The clamp-holding force shall be greater than 0.5N.

2.7 Sterilizing forceps Lip and tooth occlusal

Should be bite open freely.

2.8 Medical suture needle

The surface should be bright, uniform color, pinhole and needle bad should be smooth in the middle, no burr or obvious skew phenomenon.

2.9 Operating knife blade

2.9.1 The cutting edge of blade should have no gap, white mouth, curl, crack and other phenomena.

2.9.2 Both sides of the cutting lip of blade should be similar in width and no focal spots on the surface.

2.9.3 The blade shall be flat, without rust, sharp edges, burrs and obvious hemp marks.

2.10 Non-absorptive surgical sutures

The surface of the suture should be smooth, dry and smooth. The surface of multiple suture should be coated.

2.11 Adhesive tape

2.11.1 The surface of the adhesive tape shall be smooth without stains.

2.11.2 Stick holding: in the baking box, the top slide of the tape affixed on the stainless steel plate should not exceed 2.5mm.

2.11.3 Peel strength: the average force required per 1cm width shall be not less than 1.0N1.

2.12 Self-adhesive transparent dressing

2.12.1 Self-adhesive transparent dressing should be smooth and clear without stain.

2.12.2 The longitudinal comfort shall not be greater than 14N.cm-1, and the permanent deformation shall not be greater than 5%.

2.12.3 The water vapor transmittance shall not be less than 500g.m-2 every 24h.

2.13 Disposable sterilized rubber surgical gloves are water permeable

Should be impermeable.

2.14 Sterile

The dressing pack shall be sterile after the confirmed sterilization process.

2.15 Ethylene oxide residue amount

The dressing pack must be sterilized by ethylene oxide and the residual amount of ethylene oxide should be less than or equal to 10 ug / kg.

3、Product inspection method

3.1 Configuration, appearance

Experimental method: visual force observation, nasal smell.

3.2 Wrapping cloth, underpad

Experimental method: Conduct the test according to the corresponding method of YY / T 0506.2-2016, and the result shall meet the requirements of Article 2.2.

3.3 Medical gauze block

Experimental method: Conduct the test according to the 5.9 and 5.8 methods of YY0331-2006, and the results are obtained in the 2.3 requirements.

3.4 Alcohol + cotton ball (antiseptic cotton swab)

Experimental method: according to the corresponding methods in《disinfection Technical Specifications》version（2002)

3.5 Iodine volt + cotton ball

Experimental method: according to the corresponding methods in《disinfection Technical Specifications》version（2002)

3.6 Ttweezers hold force

Experimental method: hold the two sides of the tweezers handle, pick up the items greater than 0.5 weight, and keep them closed

3.7 Sterilizing forceps　Lip and tooth occlusal

Experimental method: open the handle for three times, and the result shall meet the requirements of 2.7

3.8 Medical suture needle

Experimental method: After visual inspection, the result shall meet the requirements of Article 2.8.

3.9 Operating knife blade

Experimental method: by visual inspection, the result should comply with the requirements of article 2.9

3.10 Non-absorbent sutures

Experimental method: After visual inspection, the result shall meet the requirements of Article 2.10

3.11 Experimental method of adhesive tape:

Eye-measurement

The viscosity and stripping strength shall be tested according to Annex B of YY / T0148-2006, and shall comply with the requirements of 2.11

3.12 Experimental methods for self-adhesive transparent dressing:

Day test

YY/T0471.2-2004 Contact wound dressing test method Part II Water vapor transmittance of the permeable film dressing

According to YY/T0471.4-2004 contact wound dressing test method Part IV: comfort

The above experimental results shall comply with the requirements of Article 2.12

3.13 Disposable rubber surgical gloves

Experimental method: Conduct the test according to GB / T 7543-2020 Annex A, and the result shall meet the requirements of Article 2.13

3.14 Sterile

The result shall meet the requirements of Article 2.14.

Experimental method: Conduct the test according to the method specified in chapter 2 in GB / T 14233.2-2005

3.15 Ethylene oxide residue amount

Experimental method: Conduct the test according to the method specified in GB / T 14233.1-2008, and the result shall meet the requirements of Article 2.15