Medical Device Product Technical Requirements Number:

Disposable Urethral Catheter Set

1. Product model / specification and its division description

1.1 Product model: according to the model of the urinary catheter, usually 14 #, 16 #, 18 #, 20 #

1.2 Classification by medical device management: most of the components in the package are classified into 14 categories. Management posuse al al management management category II.

1.3 By supply status: sterile supply.

1.4 The configuration requirements are detailed in Table 1 below

Table 1 Note: Special requirements according to the order contract but limited in the table below

S/N	Component name	specifications and models	quantity	Memo	
1	Iodine volt + cotton ball	Cotton ball≥0.2g/grain，0.5% Effective iodine	1-3 bag	/	Self-produced parts
2	Alcohol + cotton ball	Cotton ball≥0.2g/grain，75% Medicinal alcohol	1-3 bag	/	Self-produced parts
3	Silicone oil + cotton ball	Cotton ball≥0.2g	1-3 bag	/	Self-produced parts
4	Medical gauze block	6×8×8 layer or close specifications	1-5 pcs	/	Self-produced parts
5	Wrapping cloth	50×60cm or 60×80cm	1-2 pcs	/	Self-produced parts
6	Hole towel	50×60cm or 60×60cm	1-2 pcs	/	Self-produced parts
7	Disposable silicone / latex urinary catheter	14# 16# 18# Or other specifications	1 pcs	Have a medical device registration certificate	bought-in components

8	Disposable drainage bag	1000ml	1 pcs	Have a medical device registration certificate	bought-in components
9	Plastic test tube	12×75/5ml	1-2 pcs	Have a medical device registration certificate	bought-in components
10	Disposable polyethylene film gloves	medium	1-2 pcs	None	bought-in components
11	Disposable medical rubber examination gloves	medium，large	1-5 pcs	Have a medical device registration certificate	bought-in components
12	Plastic tweezer	11.5cm	1-5 pcs	Have a medical device registration certificate	外购件
13	Tray	10x13cm	1-2 set	None	外购件
14	Disposable sterile solvent syringe	10ml or 20ml	1-2 pcs	Have a medical device registration certificate	外购件

2. Performance index

2.1 Configuration, and appearance requirements

Basic configuration: disposable latex / silicone catheter, disposable drainage bag, disposable medical rubber examination gloves, iodine cotton ball, plastic tweezers, medical gauze block, tissue, tissue and auxiliary configuration plastic test tube, disposable polyethylene film gloves, alcohol cotton ball, silicone oil ball, tray, disposable sterile soluble syringe (without needle). All the components in the package shall be undamaged, pollution-free, and neatly and clearly arranged. Plastic tweezers should be smooth, uniform color, should not have burrs, flying edge and cracks.

2.2 Hole towel, wrapping cloth

It shall comply with the impermeability water resistance requirements of YY / T 0506.2 standard.

2.3 Medical gauze block

a) The sinking time does not exceed 10s.

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

c) 2.4 Iodine + cotton balls shall 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 qualified disinfection.

2.5 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: positive control group should have more bacterial growth, 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

2.6 Disposable medical rubber examination gloves water permeability

Should be impermeable. Its purchase shall be purchased from the qualified medical device units.

2.7 Reliability of disposable latex / silicone urinary catheter balloon

The balloon shall be free of leakage and shall not affect the discharge hole. Its purchase shall be purchased from the qualified medical device units.

2.8 Leleakage of disposable drainage bag

There should be no leakage. Its purchase shall be purchased from the qualified medical device units.

2.9 Clamp-holding force of plastic tweezers

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

from the qualified medical device units

2.10 Disposable polyethylene film gloves finger sealing ability

The edge of the finger should have no open edge.

2.11 Disposable sterile solvent syringe

The capacity tolerance and residual capacity of solvent syringe shall comply with the provisions in Table 2 below.

Table 2 Nominal capacity, residual capacity and corresponding requirements

Nominal capacity of the solver V ml	Capacity tolerance		Maximum residual capacity ml
	Less than half of the nominal capacity	Equal to or greater than half of the nominal capacity	
10≤V＜20	±(1.5% of V+Exclusion of volume1%）	Exclusion of volume ±4%	0.10

a) The solvent syringe should have good sliding performance, and its pushing and pulling forces should comply with the provisions of Table 3 below

Table 3 Sliding performance

Nominal capacity of the solver V ml	Maximum initial force Fs/N	Maximum average force F/N	maximum thrust Fmax/N
2≤V＜50	25	10	≤(2.0×measure F）or the higher of （measure F+1.5N）

Its purchase shall be purchased from the qualified medical device units.

2.12 Sterile

The catheterization pack should be sterile after the confirmed sterilization process.

2.13 Ethylene oxide residue amount

The catheterization package should be sterilized by ethylene oxide, and the ethylene oxide residue should be less than or equal to 10mg / kg.

3.Method of calibration

3.1 Configuration, appearance

Inspection method: the visual inspection shall comply with the provisions of Article 2.1

3.2 Hole towel、wrapping cloth

Test method: Conduct the test according to the corresponding method of YY / T 0506.3, and the result shall comply with the provisions of Article 2.2

3.3 Medical gauze block

Test method: Conduct the test according to article 5.9 and 58 methods of YY 0331-2006, and the result shall comply with article 2.3.

3.4 Iodine volt + cotton ball

Inspection method: according to the corresponding method in 《Disinfection Technical Specification》(2002), comply to Rule 2.4 fix.

3.5 Alcohol + cotton ball

Inspection method: according to the corresponding method in 《the Technical Specification for Disinfection》 (2002) edition, it shall comply with the 2.5 rules fix.

3.6 Disposable medical rubber to check the glove water permeability

Inspection method: Conduct the impervious test according to GB 10213 Annex A, and it shall be impervious.

3.7 Reliability of disposable latex / silicone urinary catheter balloon

Test method: test the method C of YY 0325-2005, the result shall meet the provisions of 2.7.3.8 Leakiness of disposable drainage bags

Test method: according to the capacity of the drainage bag, injected with tap water, there should be no leakage.3.9 plastic tweezers, clamp-holding force.

Test method: hold both sides of the tweezers handle, pick up the weight greater than 0.5N closed, keep closed.3.10 Test method for finger sealing of disposable polyethylene film gloves: visual inspection, and the result shall comply with the provisions of Article 2.10.

3.11 Disposable sterile solvent syringe

Inspection method:

a)Capacity tolerance and residual capacity are tested according to the method specified in Annex B of GB 15810-2019.

b)Test as described in Annex E of GB 15810-2019.

All the above results shall comply with Article 2.11.

3.12 Sterile

Test method: Conduct the test according to the method specified in Chapter 2 of GB / T 14233.2-2005, and the result shall comply with the provisions of Article 2.12.

3.13 Ethylene oxide residue amount

Test method: Conduct the test according to the method specified in GB / T 14233,1-2008, and the result shall comply with the provisions of Article 2.13.