Medical Device Product Technical Requirements Number:

Disposable Sterile Surgical Kit

1. Product model / specification and its division description

1. 1 Product models: Type I (interventional), type (ophthalmic), type (abdominal), (joint replacement), V (orthopedic), (brain)

1. 2 Category by medical device management category.

1. 3 As sterile supply status by supply status.

2. Performance index

2. 1 Configuration requirements

See the table below for details 1

Table 1

S/N	Configure product name	Model/Specification	Memo		
1	Surgical gown	S、M、L	/	Self-produced parts	
2	Surgical mask	earloop, tie belt	/	bought-in components	
3	Medical cap	Nurse's cap, doctor's cap	/	Self-produced parts	
4	Drape	Conventional type, split-way type	/	Self-produced parts	
5	Hole towel	length、width≥50cm	/	Self-produced parts	
6	Medical gauze block (gauze pad)	≥3×3, The number of layers 4~24 layers	/	Self-produced parts	
7	Large wrapping cloth	length、width≥50cm	/	Self-produced parts	

8	Small wrapping cloth	length、width≥50cm	/	Self-produced parts	
9	Cotton swab	6-35cm	Have a medical device registration certificate	Self-produced parts	
10	Tray	a square tray. kidney tray	None	bought-in components	
11	Medical skim cotton ball	≥0.2g/grain	Have a medical device registration certificate	bought-in components	
12	Disposable booster	10ml～50ml	Have a medical device registration certificate	bought-in components	
13	Plastic tweezer	≥11.5cm	Have a medical device registration certificate	bought-in components	
14	Disposable rubber surgical gloves are	6#-8#	Have a medical device registration certificate	bought-in components	
15	Scalpel	9#～36#	Have a medical device registration certificate	bought-in components	
16	Operating forceps	Oval forceps, hemostatic forceps	Have a medical device registration certificate	bought-in components	

17	Medical tape	Width 1.25～2.5cm，Length is not limited	Have a medical device registration certificate	bought-in components	
18	Band-aid stickers and infusion stickers	length、Width≥10mm	Have a medical device registration certificate	bought-in components	
19	Medical elastic bandage	width≥40cm，长≥100cm	Have a medical device registration certificate	bought-in components	
20	Counting cup	With scale	/	bought-in components	
21	Plastic test tube	2ml、3ml、5ml、10ml	/	bought-in components	
22	Plastic bowl		/	bought-in components	
23	Scissors		/	bought-in components	
24	Ruler		/	bought-in components	
25	Slide glass	25.4×76.2mm，Thickness 1-1.2mm。	/	bought-in components	
26	Waste liquid collection bag				

Note: The quantity and specification of internal accessories are not quantified according to the clinical use habits, but they are only adjusted within the scope of the above table.

2.2 Appearance requirements

产品由基础配置：手术衣、口罩、医生帽、垫单、孔巾、医用纱布块、一次性使用医用橡胶检查手套、大、小包巾和辅助配置：塑料镊子、托盘、医用脱脂棉球、一次性使用助推器、医用棉签、消毒棉球、手术刀、手术钳、医用胶带、止血带、创口贴、输液贴、医用弹性绷带、脑棉片、量杯、塑料试管、塑料碗、剪刀、尺子、载玻片组成。包内各配件应无污染、无破损、无臭、无味，经缝制的产品应针距均匀，无跳针、漏线现象。塑料配件应光洁、色泽均匀，不应有毛刺、飞边和裂纹等现象。Basic configuration: surgical clothes, masks, doctor cap, pad, hole towel, medical gauze block, disposable medical rubber examination gloves, large and small scarves and auxiliary configuration: plastic tweezers, tray, medical skim cotton ball, disposable booster, medical cotton swabs, scalpel, surgical forceps, medical tape, tourniquet, band, infusion stick, medical elastic bandage, cotton pads, measuring cup,plastic test tube, plastic bowl, scissors, ruler, slide. All accessories in the package shall be pollution-free, damaged, odorless and tasteless. The sewn products shall have uniform needle spacing and no needle jumping and line leakage. Plastic accessories should be smooth, uniform color, there should not be burrs, flying edge and cracks.

2.3 The pad shall meet the following requirements:

a) Compliance with the requirements in YY / T0506.2.

b) Liquid control: the% fluid retention rate is greater than the nominal value.

2.4 Surgical mask

a)The water level on the outer side of the mask should not be less than Grade 3 in GB / T4745-1997.

b)The bacterial filtration efficiency of the mask should not be less than 95%.

c)After 2ml of synthetic blood is sprayed to the outer side of the mask sample at 16.0kPa (120mmHg) pressure, there should be no infiltration into the inner side of the mask.

2.5 Medical cap, Large and small wrapping cloth, hole towel

The requirements of the physical properties of non-woven fabrics are shown in Table 1 below.

Table 1 Physical performance indicators of nonwoven fabric

Specification g/m^2	15	20	25	30	40	50
Mass deviation rate of square meters(%)	±10	±10	±10	±10	±10	±10

2.6 Surgical gown

Performance requirements of critical and non-critical areas

Table 2 Performance requirements for critical and non-critical areas

Performance name	Unit	Standard performance		High-performance	
		Key areas	non-critical areas	Key areas	non-critical areas
Blocking microbial penetration, dry state	log_{10} CFU	Do not require	≤2[a, c]	Do not require	≤2[a, c]
Blocking microbial penetration, hygrometric state	I_B	≥2.8[b]	Do not require	6.0[b, d]	Do not require
Cleanliness, and microorganisms	log_{10} (CFU/dm^2)	≤2[C]	≤2[C]	≤2[C]	≤2[C]
Cleanliness, particulate matter	IPM	≤3.5	≤3.5	≤3.5	≤3.5
Falling flocculant	log_{10} (Floc counting)	≤4.0	≤4.0	≤4.0	≤4.0
Impermeability	CmH_2O	≥20	≥10	≥100	≥10

resistance					
Break-out strength, dry state	Kpa	≥40	≥40	≥40	≥40
Break-out strength, the wet state	Kpa	≥40	Do not require	≥40	Do not require
Tensile strength, and the dry state	N	≥20	≥20	≥20	≥20
Tensile strength, and is present in the wet state	N	≥20	Do not require	≥20	Do not require
a Experimental conditions: the challenge bacteria concentration was 108 CFU / g talc powder, and the vibration time was 30min. b The minimum significant difference in IB at the 95% confidence level was 0.98 when tested with YY / T0506.6. This is the minimal difference that distinguishes differences between the two materials. Less than 0.98IB is probably worse (95% confidence level means 20 trials, at least 19 are correct). c In this section, log10 (CFU) ≤2 means a maximum of 300 CFU. d IB=6.0 in this part, which means no penetration. IB=6.0 is the maximum acceptable value.					

2.7Medical gauze block (gauze pad)

a)The sinking time does not exceed 10s.

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

2.8 Requirements for outsourcing accessories

2.8.1 Disposable sterilized rubber surgical gloves are water permeable

Should be impermeable.

2.8.2 Clamp-holding force of plastic tweezers

The clamp-holding force of the plastic tweezers shall be greater than 0.5N.

2.8.3 Medical skim cotton ball

a) The character should be soft and elastic white fiber, no color spots, stains and foreign bodies, odorless, tasteless;

b) The water absorption per gram of the sample should not be less than 23g.

2.8.4 The disposable booster should be crack-free. Push whether the core rod is to massage freely.

2.8.5 The tray should be pollution-free, without holes and without impurities.

2.8.6 The scalpel shall meet the following requirements.

a) The blade cutting edge should have no gap, white mouth, curl, crack and other phenomena;

b) Blade cutting lip on both sides of the width should be similar, the surface without focal spots;

c) The blade should be flat, and there should be no rust, sharp edges, burrs and obvious hemp points;

d) The blade edge shall be sharp and when cutting 3-0 wire (0.21mm~0.22mm), the cutting force shall not be greater than 0.8N.

2.8.7 The detachment force of the surgical forceps is not less than 6N.

2.8.8 Infusion post (band-aid stick) and medical tape shall meet the following requirements.

a) Requirements for stickiness: during the test in the oven, the top slide of the adhesive tape affixed on the stainless steel plate shall not exceed 2.5mm.

b) Peel strength requirement: the average force required per 1cm width shall not be no less than 1.0N.

2.8.9 The medical elastic bandage width is consistent with the nominal

width.

2.9 Sterile

The surgical pack supplied with sterile equipment shall be sterilized and shall be sterile.

2.10 Ethylene oxide residue amount

The surgical package must be sterilized by ethylene oxide, and the residue of ethylene oxide is less than or equal to 10mg / kg.

3 Experimental method

3.1 Configuration requirements

Experimental method: Visual inspection according to the product.

3.2 Appearance requirements

Experimental method: visual inspection, nasal smell.

3.3 Draw-sheet

Experimental method: Conduct the test according to the corresponding method of YY / T0506.3, and the result shall meet the requirements of Article 2.3.

3.4 Medical surgical mask

Empirical method :

a) Test with the method specified in GB / T 4745-1997.

b) Conduct the test according to one of the methods specified in Annex B according to the standards of YY0469-2004.

c) Conduct the test according to clause 5.5.1 of YY0469-2004.

All the above results shall comply with the requirements of Article 2.4.

3.5 Medical cap, Large and small wrapping cloth, hole towel

Test method: Conduct the test according to the test method of FZ / T60003-1993, and the result shall meet the requirements of Article 2.5.

3.6 Surgical gown

Experimental method: test according to the method specified in YY / T0506 standard, and the result shall meet the requirements of 2.6.

3.7 Medical gauze block (gauze pad)

Empirical method:

a)Test according to the 5.9 method of YY0331-2006.

b)Test according to the 5.8 method of YY0331-2006.

c)Test according to the 5.7 method of YY0331-2006.

All the above results shall comply with the requirements of Article 2.7.

3.8 Test method of purchased parts (if the purchased parts can be provided with the product qualification and validity period, testing can be exempted)

3.8.1 Disposable sterile rubber surgical gloves are impermeable

Experimental method: Follow the test in Annex A of GB7543-2006.

3.8.2 Medical skimmed cotton ball characteristics

Experimental method: hand feel, visual inspection, nose smell.

3.8.3 Clamp-holding force of plastic tweezers

Experimental method: hold both sides of the tweezers handle, pick up the weight greater than 0.5N closed, keep closed.

3.8.4 Disposable booster

Experimental method: Visual inspection, hand to push the core rod.

3.8.5 Tray

Experimental method: Visual inspection.

3.8.6 The scalpel shall be tested according to the experimental method of YY0174, and shall comply with the requirements of 2.8.6.

3.8.7 The surgical forceps shall be tested according to the experimental method of YY / T0452-2003, and it shall comply with the requirements of 2.8.7.

3.8.8 The viscosity and stripping strength of infusion tape and medical tape shall be tested according to the method specified in YY / T0148-2006,

and shall comply with the requirements of 2.8.8

3.8.9 The medical elastic bandage shall be tested according to the experimental method of YY / T0507-2009, and it shall comply with the requirements of 2.8.9.

3.8.10 The medical elastic bandage shall be tested according to the experimental method of YY / T0507-2009, and it shall comply with the requirements of 2.8.10

3.8.11 Medical cotton swab

Experimental method

a) Conduct the experiments according to the method specified in Article 4.63 of YY0330-2015 standard

b) Fixed the cotton stick, apply IN force to the cotton head, the cotton head should not fall

All the above results shall meet the requirements of 2.8.11. Check the medical device registration certificate.

3.9 Sterile

Experimental method: Conduct the test according to the method specified in Chapter 2 of GB14233.2-2005.

3.10 Ethylene oxide residue amount

Experimental method: Conduct the test according to the method specified in GB/T14233.1-2008.