Technical requirement number of the medical device product

Disposable Sterile Obstetric Kit

1. Product model / specification and its division description

1.1 Product model: delivery type, abortion type

1.2 Class II by Medical device management classification.

1.3 Supply is sterile according to supply status

2.Performance index

2.1 Configuration, and appearance requirements

Table 1

S/N	Configure product name	General specification model	Memo	
1	Surgical gown	Half body with sleeve type	/	Self-produced parts
2	Surgical mask	Branding or ear hanging type	/	bought-in components
3	Medical cap	Doctor or nuse cap	/	Self-produced parts
4	Mat cover	≥40×50cm	/	Self-produced parts
5	Draw-sheet	≥80×100cm	/	Self-produced parts
6	Hole towel	Length·Width≥50cm	/	Self-produced parts
7	Gauze bandage	5×400cm	/	Self-produced parts
8	Medical gauze block	≥3×3，number of plies 4-24 layers	/	Self-produced parts
9	Gauze pad	≥6×8，number of plies 1-24 layers	/	Self-produced parts
10	Leggings	≥60×90cm	/	Self-produced parts
11	Device drape(Wrapping drape)	≥50×60cm	/	Self-produced parts
12	The umbilical cord belt	≥10×40cm	/	Self-produced parts
13	Plastic tweezer	≥11.5cm	Have a medical device registration certificate	bought-in components
14	umbilical cord clamps	5-10cm	Have a medical device registration certificate	bought-in components

15	Disposable sterilized rubber surgical gloves	S M L	Have a medical device registration certificate	bought-in components
16	Medical skim cotton ball	≥0.2g/Grain	Have a medical device registration certificate	bought-in components
17	Non-absorbent sutures	0# 1#	Have a medical device registration certificate	bought-in components
18	The umbilical cord	≥15cm	/	self-produced parts

Description: The specification and quantity of internal accessories can be adjusted according to clinical use habits, but only for the scope in the above table.

Basic configuration of the product consisting of pad sheet, cover sheet, instruments and auxiliary configuration of surgical gown, surgical masks, surgical cap, disposable sterilized rubber surgical gloves, scarves, gauze bandage, medical gauze block, gauze pads, trouser leg, bag sheet, plastic tweezers / umbilical cord clamp, medical skimmed cotton ball, umbilical cord protection, non-absorbent suture / umbilical cord rope, etc. Different use production package according to the requirements of appropriate added accessories. The accessories in the package are pollution-free, no damage, no peculiar smell and other phenomena, and the sewn products should be uniform needle distance, no jumping needle, off needle phenomenon. Plastic tweezers should be smooth, uniform color, should not have burrs, flying edge and cracks.

2.2 Draw-sheet, mat cover, instrument cover 2.2.1 The pad sheet shall meet the following requirements:

a) Compliance with YY / T0506.2 Impermeable water resistance requirements in the standard

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

2.4.2 Mat cover、instrument cover、hole towel. It shall comply with YY / T0506.2 impermeable water resistance requirements in the standard

2.3 Surgical mask

a) The water level of the outer side of the mask should not be less than level 3 in GB / T4745-2012

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), there should be no infiltration on the inner side of the mask.

2.4 Medical cap, leggings, Wrapping cloth

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

Table1 Physical performance indicators of nonwoven fabric

Spec g/m³	15	20	25	30	40	50
Mass deviation rate of square meters(%)	±10	±10	±10	±10	±10	±10

2.5 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	
		Product key areas	Product non-critical areas	Product key areas	Product 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）	$\leq 2^C$	$\leq 2^C$	$\leq 2^C$	$\leq 2^C$
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 resistance	CmH_20	≥20	≥10	≥100	≥10
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

2.6 Medical gauze block, gauze bandage, gauze pad

a) The sinking time does not exceed 10s.

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

c) The minimum fracture force of the gauze bandage shall not be less than 70N, 60N.

d) In the case of a developing gauze pad, the X-ray detection assembly shall be made of a material containing no less than 5% barium sulfate or other equivalent X-ray opaque material, which shall not fall off the fiber and shall not affect the softness of the gauze.

e) The X-ray detectable component was gently extracted from the gauze, and the length was measured and weighed. The single wire shall not be less than 0.5g / m for the medical line, and the polywire shall not be less than 0.28g / m.

f)When the X-ray impermeability is tested according to YY0594-2006 Annex B, the imaging of the sample should be obvious than the background.

2.7 The umbilical cord belt

Apply 1N force to both ends of the umbilical cord junction.

2.8 Disposable sterilized rubber surgical gloves, water permeable

Should be impermeable.2.9 plastic tweezers and umbilical cord clamp from qualified medical device units

The holding force of the plastic tweezers shall be greater than 0.5N. Its purchase shall be purchased from the qualified medical device units

2.10 Broken strength of the non-absorbable suture

It shall comply with the requirements of Table 3 below. Its purchase shall be purchased from the qualified medical device units

Table 3 Broken strength of the non-absorbable suture

Specification	Break force average/N ≥		
Routine	A class	B class	C class
2-0	14.1	10.0	17.6
0	21.2	14.2	33.3
1	26.7	17.8	46.7
2	34.5	24.9	57.8

2.11 Medical skim cotton ball

a) The character should be soft and elastic white fiber, colorless spots, stains and foreign bodies, odorless, tasteless.

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

Its purchase shall be purchased from the qualified medical device units

2.12 Sterile

The delivery pack should be sterile after the confirmed sterilization process

2.13 Ethylene oxide residue amount

The delivery pack is sterilized by ethylene oxide, and the residue of ethylene oxide should be less than or equal to 10 ug / g

3. Empirical method

3.1 Configuration, and appearance requirements

Experimental method: visual inspection, nasal smell, the result should meet the requirements of Article 2.1

3.2 Draw-sheet, mat cover, instrument cover, hole towel

Empirical method :Conduct the test according to the corresponding method of YY/T0506.2-2016, and the result shall comply with the requirements of Article 2.2

3.3 Surgical mask

Empirical method :

a)Experimentize according to the method specified in GB / T 4745-2012

b)Conduct the test according to one of the standard requirements 5.6.1 of YY0469-2011.

c)The above results shall be tested according to Article 5.5 method of YY0469-2011 to meet the requirements of Article 2.3.

3.4 Medical cap, leggings, wrapping cloth

Test method: Conduct the test according to the test method of GB / T 4669-2008, and the result shall meet the requirements of Article 2.4

3.5 Surgical gown

Experimental method: Conduct the test according to the method specified in YY/T0506.2-2016, and the result shall meet the requirements of 2.5

3.6 Medical gauze block, gauze bandage, gauze pad

Empirical method:

a)Experimentize according to the article 5.9 of YY0331-2006.

b)Experimentize according to the article 5.8 of YY0331-2006.

c)The above results according to article 5.7 of YY0331-2006 shall comply with the requirements of article 2.6

3.7 The umbilical cord belt

Experimental method: hold the umbilical cord, tear off the adhesive to the other end of the umbilical cord, apply IN force to keep the bond not loosened.

3.8 Disposable sterilized rubber surgical gloves, water permeable

Experimental method: Conduct the test according to Annex A of GB7543-2020, and the result shall comply with the requirements of Article 2.8

3.9 Plastic tweezers, umbilical cord clamping force

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

3.10 Broken strength of the non-absorbable suture

Experimental method: Conduct the test according to the method of Annex B in YY0167-2020, and the result shall meet the requirements of Article 2.10

3.11 Medical skim cotton ball

Empirical method:

a) Feel, visual inspection, nasal smell, the result should meet the requirements of 2.11

b) Conduct the test according to the method of 4.6.3 in YY0330-2015, and the result shall meet the requirements of 2,113.12 sterile

Experimental method: Conduct the test according to the method specified in Chapter 2 of GB/T14233.2-2005, and the result shall meet the requirements of Article 2.12

3.13 Ethylene oxide residue amount

Experimental method: Conduct the test according to the method of GB/T14233.1-2008, and the result shall meet the requirements of Article 2.13