Medical Device Product Technical Requirements No: ：

Disposable Surgical Gown

1. Product model / specification and its division description

1.1 Product name: disposable surgical gown

1.2Classification by medical device management: classification code is 14-13, management category II. Sterile supply.

1.3 The product surface can be divided into critical and non-critical areas according to its infection degree; front chest and sleeve are key areas, and hat and back are non-critical areas.

1.4 According to the performance level, the products can be divided into two types: standard performance and high performance.

1.5 According to the product production process,the product can be devided into: sewing type, hot combination type

1.6 According to the different size of the product can be divided into: small / S, medium / M, large / L, large / XL, plus / XXL, three plus / XXXL。

1.7 Basic structure of the surgical gown: the surgical gown is made of SMS non-woven fabric, the cuff is treated with elastic mouth, the back is fully opened by the cloth belt tightening, and the cloth belt is heat combined with non-woven cloth.

2、Performance index

2.1 The materials used shall comply with the FZ/T 64005-2011 standard and shall be manufactured in accordance with the approved drawings and documents according to the prescribed procedures.。

2.2 Dimensional requirement

It shall meet the requirements of Table 1.

Table 1 Specification and basic size of surgical gown

Model / Size	S(160)	M(165)	L(170)	XL(175)	XXL(180)	XXXL(190)
L×W(cm)	110～120×110～119	120～130×120～130	131～144×120～130	145～149×120～130	150～159×120～130	160～170×120～140
shoulder breadth (cm)	55	55	56	56	57	58
outside sleeve (cm)	54	56	56	58	58	60
deviation(cm)	±3cm	±3cm	±3cm	±3cm	±3cm	±3cm

2.3 Appearance requirements

2.3.1 The operating coat is flat, with no holes, stains, and no splicing phenomenon.

2.3.2 The heating or sewing mouth is uniform and straight, and the sewing shall not be less than 3 stitches per centimeter.

2.3.3 Hot closing or sewing place does not allow wool edges, leakage, cracking and other phenomena.

2.4 Structure

2.4.1 The structure of the surgical garment should be reasonable, convenient to wear and take off, and the structure of the joint should is consistent.

2.4.2 The cuff is elastic and tight.

2.5 Performance requirements of the surgical clothes

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 is in non-critical areas	Product key areas	Product is in non-critical areas
Blocking microbial penetration, dry state	$\log_{10}$ CFU	Do not require	$\leq 2^{a,\ c}$	Do not require	$\leq 2^{a,\ c}$

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 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

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 between the two materials. Less than 0.98IB may vary (a 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.

2.6 Breathability

The air rate (mm/s) is greater than the nominal value.

2.7 Sterile

After the procedure is sterilized, the product shall be sterile.

2.8 Ethylene oxide residue amount

If the surgical coat is sterilized by ethylene oxide, the ethylene oxide residue is less than or equal to 10mg / kg.

2.9 Skin irritatin

Surgical clothes should be of minimal reaction.

2.10 Delayed hypersensitivity

Surgical gown should have no delayed hair-type hypersensitivity reaction.

3、Experimental method

3.1 Material requirements

Test method: Conduct the test according to FZ / T 64005-2011, it shall comply with the requirements of 2.1.

3.2 Dimensional requirement

Test method: Measure with a general measuring tool or a special measuring tool, and the result shall meet the requirements of 2.2.

3.3 Appearance requirements

Test method: visual and hand feel, and the result shall meet the requirements of Article 2.3.

3.4 Structural requirement

Test method: visual and feel, and the result shall meet the requirements of Article 2.4.

3.5 Performance requirements of critical and non-critical areas

Test method: The impermeable water shall be tested according to the hydrostatic method of GB / T4744-2013 textiles, and the result shall meet the requirements of non-critical areas in Article 2.5.

Cleanliness and microorganisms shall be tested in accordance with the methods specified in YY / T 0506.7-2014 standards for patients,《medical personnel and instruments for operation sheets, surgical clothes and Clean clothes-Part 7: Cleanliness-Microbiological Test Methods》, and the results shall meet the corresponding requirements of Article 2.5.

The cleanliness and particulate matter shall be tested according to the methods specified in YY / T 0506.4-2016 Standard for Patients, Medical Personnel and Instruments, Surgical Clothes and Clean Service-Part 4: Dry Test Methods for Falling catkins, and the results shall meet the corresponding requirements of Article 2.5.

The tensile strength, dry state and wet state shall be tested in accordance with the methods specified in YY / T 0506.2-2016 Standard for Patients《Medical personnel and instruments-Part 2: Performance Requirements and Test Methods》and the results shall meet the corresponding requirements in Article 2.5.

Breaking strength dry state, humidity shall be tested according to the method specified in GB/T7742.1-2005 《Part 1: Determination of breaking strength and breaking degree by hydraulic method》and the result shall meet the corresponding requirements of Article 2.5.

The catkins shall be tested according to YY / T 0506.4-2016 《Operation sheets, Surgical Clothes and Clean Clothes for Patients, Medical Personnel and Instruments-Part 4: Dry Method》and the result shall meet the corresponding requirements in Article 2.5.

The dry state of resistant microorganisms shall be tested according to YY/T0506.5-2009 《Operation sheets, surgical clothes and clean clothes for Patients, Medical Personnel and Instruments-Part 5: Test method for penetration of dry resistant microorganisms》 and the results shall meet the corresponding requirements of Article 2.5.

The wet state of resistant microorganisms shall be tested according to YY/T0506.6-2009 《Operation sheets, surgical clothes and clean clothes for Patients, Medical Personnel and Instruments-Part 6: Test Method for damp resistant microorganisms》and the results shall meet the corresponding requirements of Article 2.5.

3.6 Breathability

Test method: calculate the air permeability according to the test method specified in GB / T5453, and the result shall meet the requirements of 2.6.

3.7 Sterile

Test 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 2.7.

3.8 Ethylene oxide residue amount

Test method: Conduct the test according to the method specified in GB/T14233.1-2008, and the result shall meet the requirements of Article 2.8.