JAGeeG™ Specialize in Surgical Gown

KING YON MEDICAL TECH (GUANG ZHOU)., LTD
Co.Registration No & VAT No.:914401110701730113
No.718, Blv San Yuan Li, Bai Yuan District, Guang dong,guang zhou Post Code:510403
Attn:Sam Deng(Mr) Mobile: +8615089203268
Mail: sales@King-Yon.com

Is a multi-purpose garment, worn over scrub suits during surgical procedures.It is used to protect both the patient and operating room personnel from the transfer of micro-organisms, body fluids and particulate material. It is for rather short and dry operations.

Product Name	**Sterile Surgical Suit**
Model No.	According to Customer Specification
UMDNS Code	11901
Classification (MDD Annex IX)	I Sterile, Rule 1
Conformity Assessment Route	Annex V section 3

Certificate:
CE Certificate by TUV No: G2S 073966 0008 Rev. 01
Surgical Gown FDA Registration Record
Test Report Based on EN 13795-1:2019
TUV Level 2 Test Report Based on AAMI PB70:2012
TUV Level 3 Test Report Based on AAMI PB70:2012
TUV Level 4 Test Report Based on AAMI PB70:2012

Manufacturing Center:10
Sterilization Center: 2
Employee: 4000
RD Center:2
Market: 74 Countries

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

JAGeeG™ **Specialize in Surgical Gown**

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Standard Applied:

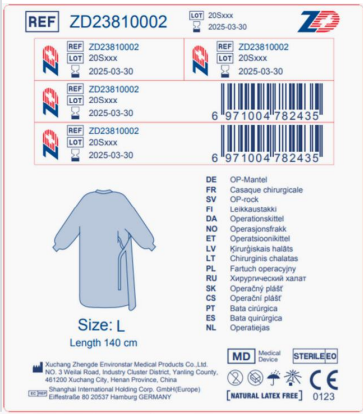
EN ISO 15223-1:2016	EN1041:2008	EN ISO 13485:2016
EN ISO 14971:2012	EN 13795:2011	

Notified Body	TüV SüD Products Service GmbH, Ridlestr. 65, 80339, Munchen, Germany
Identification Number	0123
(EC) Certificate(S)	G2S 073966 0008 Rev.01
Expire Date of the Certificate	2024-05-26
Start of CE Marking	2010-11-26
Place,Date of Issue	Xuchang, 2019-10-15

New Search | Back To Search Results

Device Classification Name	Gown, Surgical
510(K) Number	K192290
Device Name	50g SMS Standard Surgical Gown, 45g SMS Surgical Gown With Reinforcement, 68g BVB Surgical Gown, 68g BVB Splicing Surgical Gown
Applicant	Xuchang Zhengde Environstar Medical Products Co., Ltd NO.3 Weilai Road, Industry Cluster District, Yanling County Xuchang, CN 461200
Applicant Contact	Johnny Johnny
Correspondent	Mid-Link Consulting Co., Ltd P.O Box 120-119 Shanghai, CN 200120
Correspondent Contact	Diana Hong
Regulation Number	878.4040
Classification Product Code	FYA
Date Received	08/23/2019
Decision Date	04/30/2020
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General & Plastic Surgery
510k Review Panel	General Hospital
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Sterile Surgical Gown Design



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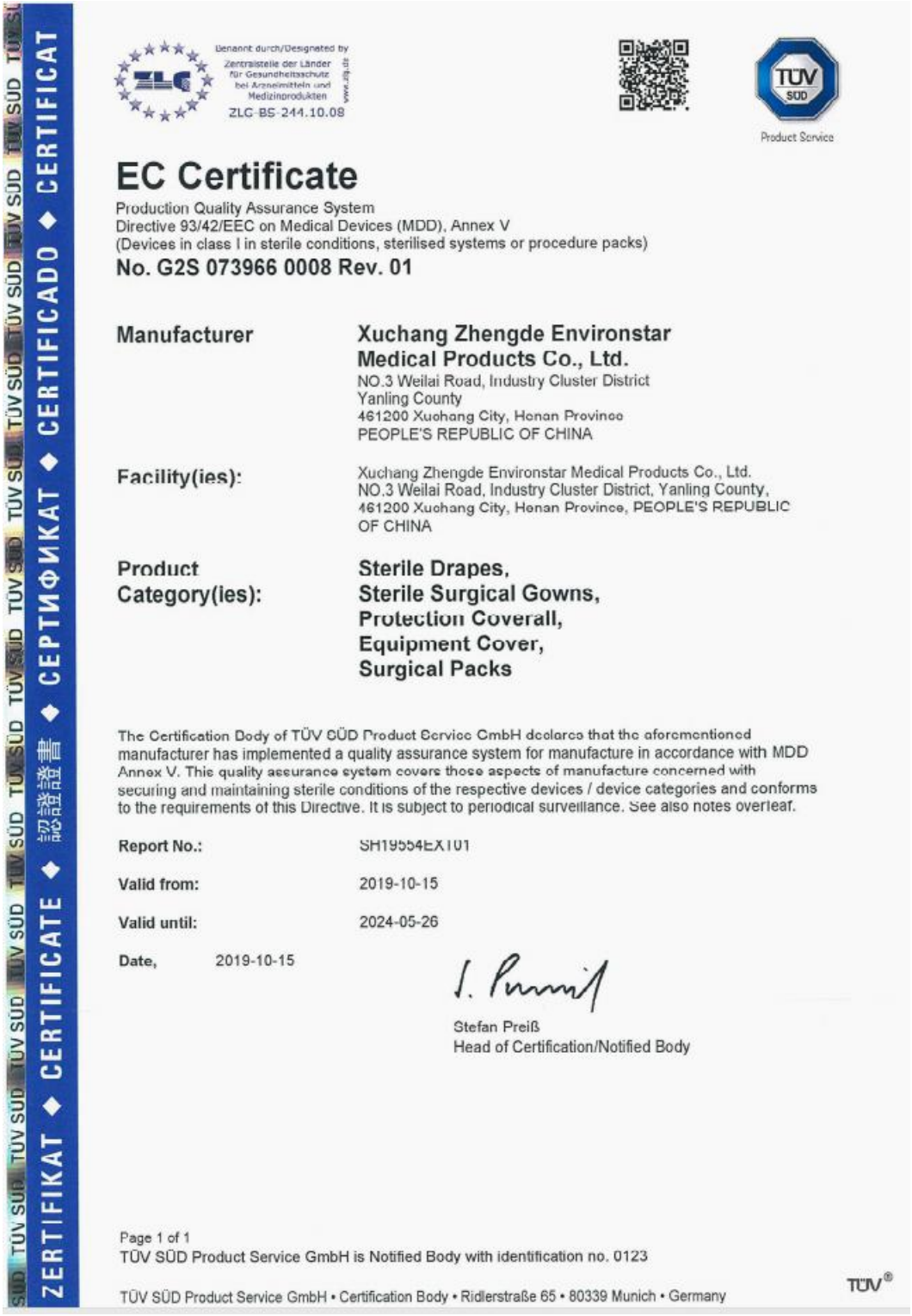
Specialize in Surgical Gown

CE Certificate by TUV No: G2S 073966 0008 Rev. 01



Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 073966 0008 Rev. 01

Manufacturer	**Xuchang Zhengde Environstar Medical Products Co., Ltd.** NO.3 Weilai Road, Industry Cluster District Yanling County 461200 Xuchang City, Henan Province PEOPLE'S REPUBLIC OF CHINA
Facility(ies):	Xuchang Zhengde Environstar Medical Products Co., Ltd. NO.3 Weilai Road, Industry Cluster District, Yanling County, 461200 Xuchang City, Henan Province, PEOPLE'S REPUBLIC OF CHINA
Product Category(ies):	**Sterile Drapes,** **Sterile Surgical Gowns,** **Protection Coverall,** **Equipment Cover,** **Surgical Packs**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:	SH19554EX101
Valid from:	2019-10-15
Valid until:	2024-05-26

Date, 2019-10-15

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Specialize in Surgical Gown

EN ISO 13485:2006

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 073966 0010 Rev. 01

Holder of Certificate: **Xuchang Zhengde Environstar Medical Products Co., Ltd.**
NO.3 Weilai Road, Industry Cluster District
Yanling County
461200 Xuchang City, Henan Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Xuchang Zhengde Environstar Medical Products Co., Ltd.
NO.3 Weilai Road, Industry Cluster District, Yanling County,
461200 Xuchang City, Henan Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Drapes, Surgical Gowns, Protection Coverall, Equipment Cover, Surgical Packs**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1955411

Valid from: 2019-11-26
Valid until: 2022-11-25

Date, 2019-10-30

Christoph Dicks
Head of Certification/Notified Body

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Test Report No. : 721630676-R1
Report Date: 17 March 2017

SUBJECT	**Microbiological Analysis**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**XuChang ZhengDe Environstar Medical Products Co., Ltd**
CLIENT ADDRESS	NO.3 Weilai Road, Industry Cluster District, Yanling County, Xuchang City, Henan Province
TEST PERIOD	24-Feb-2017~10-Mar-2017
TEST REQUEST	Penetration of Phi-X174 Bacteriophage Test - with reference to ASTM F 1671-2013

Prepared By

(Gao Ju)
Report Drafter

Authorized By

(Chen Yue)
Authorized Signatory

Chemical/Microbiology Laboratory:
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Regional Head Office:
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

Test Report No. : 721630676-R1
Report Date: 17 March 2017

RECEIPT DATE / TEST DATE

24-Feb-2017/ 24-Feb-2017

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENTS AS:

Sample Name: 68g BVB Surgical gowns
Sample Type: /
Sample Batch: /
Manufactory: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721630676	Medical device	

TEST METHOD(S)

Penetration of Phi-X174 Bacteriophage Test
- with reference to ASTM F 1671-2013 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

REQUIREMENT

Exposure Procedure: B
Sampling Size: 75mm×75mm
Negative control: Polyethylene material
Positive control: 0.04 μm microporous membrane
Prior to testing, condition all test specimens and controls for a minimum of 24 hours at (21±5)℃ and 30%~80% relative humidity.

TEST ORGANISM(S)

Bacteriophage ATCC 13706-B1

PROCEDURE

1. Compatibility testing
   1.1. Test three specimens representing each material type to be tested.
   1.2. With the sterile cell placed horizontally on the laboratry bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
   1.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.
   1.4. With the cell remaining in the horizontal position on the laboratory bench, place a 2.0 μL aliquot of the Phi-X174 bacteriophage in bacteriophage nutrient broth, containing a total of 900-1200 PFU, near the middle of each piece of test specimen.
   1.5. Prepare a control by adding a 2.0 μL aliquot from the same suspension directly into 5.0 mL of sterile bacteriophage nutrient broth.

1.6. After 60 min, quantitatively assay by adding 5.0mL of sterile bacteriophage nutrient broth onto the surface of the specimen.
1.7. Calculate the ratio of the control assay titer to the test material assay titer using the following equation:

$$\text{ratio}=\frac{\text{control assay titer (PFU/mL)}}{\text{test material assay titer (PFU/mL)}}=1.2$$

1.8. Record the initial titer of the Phi-X174 bacteriophage challenge suspension used for the test . ((2 ±1)x10^8 PFU/mL times the ratio calculated.)

2. Test procedure
2.1. Prepare the bacteriophage challenge suspension (40-44 mN/m) for the test.
2.2. With the sterile cell placed horizontally on the laboratry bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
2.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.
2.4. Mount the test cell in the test apparatus in a vertical position and close the drain valve.
2.5. Penetration test: If liquid appears to penetrate through the test specimens at anytime during the test, terminate the test.
(1) Carefully fill the test cell reservoir with approximately 60 mL of the Phi-XI74 bacteriophage challenge suspension
(2) Step1: Observe for 5 min at 0 psi.
Step2: Slowly increase the pressure to 2.0 psi at the rate of no more than 0.5 psi/s, keep the pressure at 2.0 psi, observe for 1 min.
Step3: Slowly decrease the pressure to 0 psi at the rate of no more than 0.5 psi/s, observe for 54 min.
(3) At the end of the time period, open the drain valve and drain the test cell of the bacteriophage challenge suspension. Dilute and assay the bacteriophage concentration.
2.6. Specimen surface assay procedure
(1) With the sterile cell placed horizontally on the laboratory bench. Slowly add 5.0 mL of sterile bacteriophage nutrient broth onto the exposed surface of the specimen.
(2) Gently swirl the test cell for approximately 1 min. Assay the liquid soon after collecting.
2.7. Remove the specimen from the test cell and prepare the test cell for sterilization.

3. Test controls
3.1. The negative control was negative for bacteriophage penetration.
3.2. The positive control was positive for bacteriophage penetration.
3.3. Record the final titer of the bacteriophage challenge at the conclusion of the 60 min test.

TEST RESULT(S)

Test Items		Initial titer PFU/ml	Final titer PFU/ml	Test Results				
				Step1	Step2	Step3	Assay titer (PFU/ml)	Pass/Fail
Penetration of Phi-X174 Bacteriophage	Control(+)	1.6x10^3	1.6x10^6	None Seen	Seen	-	-	Acceptable
	Control(-)	1.6x10^3	1.6x10^6	None Seen	None Seen	None Seen	<1	Acceptable
	-1	1.6x10^3	1.6x10^6	None Seen	None Seen	None Seen	<1	Pass
	-2	1.6x10^3	1.6x10^6	None Seen	None Seen	None Seen	<1	Pass
	-3	1.6x10^3	1.6x10^6	None Seen	None Seen	None Seen	<1	Pass

Note:
PFU: Plaque Forming Unit.
This report replaces report 721630676, 721630676 is obsolete

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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Webpage: www.tuv-sud.cn

Regional Head Office:
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No.151 Heng Tong Road Shanghai
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JAGeeG™

Specialize in Surgical Gown

Test report for 45g SMS (level 3) surgical gown with reinforcement

Based on AAMI PB70:2012

中国认可 国际互认 检测 TESTING CNAS L5413

Test Report No. 70.405.20.19094.01

Dated 2020-06-17

China

ORIGINAL

Applicant:	Xuchang Zhengde Environstar Medical Products Co., Ltd.
Address:	No.3 Weilai Road, Industry Cluster District, Yanling Country, Xuchang City, Henan Province
Sample Name:	45g SMS Surgical Gown With Reinforcement
Sample Lot:	M20200522
Receipt Date of Sample:	Received on 2020-06-12
Date of Testing:	From 2020-06-12 to 2020-06-17
Sample Submitted:	The sample(s) was (were) submitted by applicant and identified. The product's function is declared by the applicant. The testing point(s) was (were) selected by the applicant.
Test Result:	Refer to Next Page.

TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch
Testing Center

Prepared by:

Kathy Xu
Softlines Department

Authorized by:

Andy Wang
Softlines Department

Note: (1) The TÜV SÜD Certification and Testing (China) Co., Ltd. "General Terms & Conditions" applied.
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中国认可
国际互认
检测
TESTING
CNAS L5413

Test Report No. 70.405.20.19094.01
Dated 2020-06-17

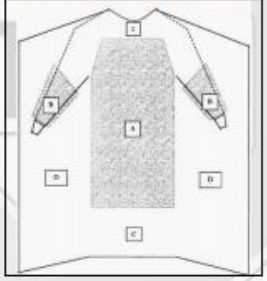
China
ORIGINAL

Description of The Test Subject

Sample	Description	Photo
001	45g SMS Surgical Gown With Reinforcement in blue	

Test Position List:
A: 001-part A
B1: 001-sleeve seam of part B
B2: 001-sleeve fabric of part B
C: 001- part C
D: 001- part D

Photo of testing position



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中国认可 国际互认 检测 TESTING CNAS L5413

Test Report No. 70.405.20.19094.01

Dated 2020-06-17

China

ORIGINAL

Conclusion

Test Items		Test Position	Conclusion
1.	Water Resistance-Impact Penetration Test	A	Pass
		B1	Pass
		B2	Pass
		C/D	Pass
2.	Hydrostatic head Test	A	Pass
		B1	Pass
		B2	Pass
		C/D	Pass

Remarks: Pass = Meet Applicant's Requirement Fail = Below Applicant's Requirement

Disclaimer Measurement Uncertainty:
Unless otherwise agreed upon, Pass or Fail verdicts are given based on the measured values without any considerations of measurement uncertainties. Please note, every test method has a measurement uncertainty which has been evaluated by the laboratory according to ISO/IEC 17025 requirements. By taking measurement uncertainties into account it might happen that measured values can neither be assessed as Pass nor as Fail.

Test Results

1 Water Resistance-Impact Penetration Test

AATCC 42:2017

Test Component	Weight of blotter gained(g) 1#	2#	3#	4#	5#	Applicant's Requirement
A	0.0	0.0	0.0	0.0	0.0	≤1.0g
B1	0.0	0.0	0.0	0.0	0.0	≤1.0g
B2	0.0	0.0	0.0	0.0	0.0	≤1.0g
C/D	0.0	0.0	0.0	0.0	0.0	≤1.0g

2 Hydrostatic head Test

AATCC 127:2017 Option 2;

Hydrostatic Head; Rate of Increase Of Water Pressure: 60cm/min., Face Side Facing Water

Test Component	Result (cm.H_2O) 1#	2#	3#	4#	5#	Applicant's Requirement
A	197.9	195.8	199.9	190.7	193.8	≥50cm.H_2O
B1	195.8*	198.9*	196.9*	193.8*	192.8*	≥50cm.H_2O
B2	193.8	196.9	194.8	189.7	191.8	≥50cm.H_2O
C/D	74.2	74.6	73.3	72.8	74.0	≥20cm.H_2O

Remarks: *=water leakage was found on fabric

-End of The Test Report-

Laboratory:
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JAGeeG™

Specialize in Surgical Gown

Test report for 50g SMS (level 3) standard surgical gown Based on AAMI PB70:2012

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检测
TESTING
CNAS L5413

Test Report No. 70.405.20.19093.01

Dated 2020-06-17

China

ORIGINAL

Applicant:	Xuchang Zhengde Environstar Medical Products Co., Ltd.
Address:	No.3 Weilai Road, Industry Cluster District, Yanling Country, Xuchang City, Henan Province
Sample Name:	50g SMS Standard Surgical Gown
Sample Lot:	M20200522
Receipt Date of Sample:	Received on 2020-06-12
Date of Testing:	From 2020-06-12 to 2020-06-17
Sample Submitted:	The sample(s) was (were) submitted by applicant and identified. The product's function is declared by the applicant. The testing point(s) was (were) selected by the applicant.
Test Result:	Refer to Next Page.

TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch
Testing Center

Prepared by:

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Softlines Department

Authorized by:

Andy Wang
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TESTING
CNAS L5413

Test Report No. 70.405.20.19093.01
Dated 2020-06-17

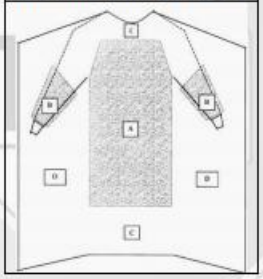
China
ORIGINAL

Description of The Test Subject

Sample	Description	Photo
001	50g SMS Standard Surgical Gown in blue	

Test Position List:
A: 001-part A
B1: 001-sleeve seam of part B
B2: 001-sleeve fabric of part B
C: 001- part C
D: 001- part D

Photo of testing position



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Test Report No. 70.405.20.19093.01

Dated 2020-06-17

TÜV SÜD China

ORIGINAL

Conclusion

Test Items		Test Position	Conclusion
1.	Water Resistance-Impact Penetration Test	A	Pass
		B1	Pass
		B2	Pass
		C/D	Pass
2.	Hydrostatic head Test	A	Pass
		B1	Pass
		B2	Pass
		C/D	Pass

Remarks: Pass = Meet Applicant's Requirement Fail = Below Applicant's Requirement

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Please note, every test method has a measurement uncertainty which has been evaluated by the laboratory according to ISO/IEC 17025 requirements.
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Test Results

1 Water Resistance-Impact Penetration Test
AATCC 42:2017

Test Component	Weight of blotter gained(g) 1#	2#	3#	4#	5#	Applicant's Requirement
A	0.0	0.0	0.0	0.0	0.0	≤1.0g
B1	0.0	0.0	0.0	0.0	0.0	≤1.0g
B2	0.0	0.0	0.0	0.0	0.0	≤1.0g
C/D	0.0	0.0	0.0	0.1	0.0	≤1.0g

2 Hydrostatic head Test
AATCC 127:2017 Option 2;
Hydrostatic Head; Rate of Increase Of Water Pressure: 60cm/min., Face Side Facing Water

Test Component	Result ($cm.H_2O$) 1#	2#	3#	4#	5#	Applicant's Requirement
A	80.9	82.4	80.3	81.1	81.6	≥50$cm.H_2O$
B1	81.8*	80.5*	81.2*	80.9*	80.1*	≥50$cm.H_2O$
B2	80.5	78.2	79.7	78.8	79.9	≥50$cm.H_2O$
C/D	78.2	76.7	80.2	81.0	81.8	≥20$cm.H_2O$

Remarks: *=water leakage was found on fabric

-End of The Test Report-

Laboratory:
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Specialize in Surgical Gown

Container Loading Details

Ref.No.	Description	Szie	Packing in a Case	Box/Carton (Unit)	G/W in a Case/kgs	N/W in a Case/kgs	Carton Dimension(cm)	40"HQ Container Loading Q'ty/Case	40"HQ Container Total Loading (Unit)	Lead-Time	Order Q'ty
ZD23101K	Reinforced Surgical Gown, 45g/㎡ SMMS, **Level 3**	M	Individually Packed	28	6.68	5.32	60X45.5X29CM	882	24696	30 Days	3M
ZD23102K		L	Individually Packed	28	6.96	5.6		882	24696		
ZD23103K		XL	Individually Packed	26	6.82	5.46		882	22932		
ZD23104K		XX	Individually Packed	26	7.6	6.24		882	22932		
ZD23105K		XXXL	Individually Packed	24	7.12	5.76		882	21168		
ZD23106K		XXXL-XL	Individually Packed	24	7.6	6.24		882	21168		
ZD23001K	Standard Surgical Gown, 50g/㎡ SMMS, **Level 3**	M	Individually Packed	28	6.12	4.76	60X45.5X29CM	882	24696	30 Days	3M
ZD23002K		L	Individually Packed	28	6.26	4.9		882	24696		
ZD23003K		XL	Individually Packed	26	6.3	4.94		882	22932		
ZD23004K		XX	Individually Packed	24	6.4	5.04		882	21168		
ZD23005K		XXXL	Individually Packed	24	6.64	5.28		882	21168		
ZD23006K		XXXL-XL	Individually Packed	24	7	5.64		882	21168		

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ZD24201K	Surgical Gown, 68g/㎡ BVB, Splicing, **Level 4**	M	Individually Packed	28	6.4	5.04	60X45.5X29CM	882	24696	45-90 Days	2M
ZD24202K		L	Individually Packed	26	6.43	5.07		882	22932		
ZD24203K		XL	Individually Packed	26	6.69	5.33		882	22932		
ZD24204K		XX	Individually Packed	24	6.88	5.52		882	21168		
ZD24205K		XXXL	Individually Packed	24	7.12	5.76		882	21168		
ZD24206K		XXXL-XL	Individually Packed	24	7.48	6.12		882	21168		
ZD24301K	Surgical Gown, 68g/㎡ BVB, **Level 4**	M	Individually Packed	28	7.1	5.74	60X45.5X29CM	882	24696	45-90 Days	2M
ZD24302K		L	Individually Packed	26	6.95	5.59		882	22932		
ZD24303K		XL	Individually Packed	26	7.47	6.11		882	22932		
ZD24304K		XX	Individually Packed	24	7.6	6.24		882	21168		
ZD24305K		XXXL	Individually Packed	24	7.84	6.48		882	21168		
ZD24306K		XXXL-XL	Individually Packed	24	8.56	7.2		882	21168		

Packing & carton

Packing　　Case