


45g/50g SMS Isolation Gown (Non-Sterile)

Level 2/3 & EN13795-1:2019

Products Specification

<p>◎Model No.: YD-G</p> <p>◎Isolation Gown (Non-Sterile)</p> <p>◎Executive Standard: AAMI ANSI/AAMI PB70-2012 Level 2/3 EN13795-1:2019</p> <p>◎Material: Level 2 by SMS polypropylene fiber: 55.5%+PE:44.5% / 45g Level 3 by SMS Polypropylene fiber 100% /45g or 50g</p> <p>◎Certificate: SGS Testing Report/FDA/CE</p>	<p>◎Quality System: ISO 13485:2006</p> <p>◎Size: XL or Customized size</p> <p>◎Place of Origin:China</p> <p>◎Sealing: Ultrasonic</p> <p>◎Color: Blue</p> <p>◎Packing: 100pcs/case</p> <p>◎Supply Ability:150,000pcs per day</p> <p>Treatment Available:</p> <p>◎Anti-Static & Soft ◎Absorbent / Hydrophilic</p> <p>◎Alcohol Repellent / Anti-bacterial</p>
	
	

Art No.	Art Name	Component	Compliance With	Sewing Type	Color	Unit net/weight t kg	Carton net weight kg	Carton Gross Weight KG	Carton Packing q'ty	Carton Dimension
YD-LT	Isolation Clothing (Non-Sterile) (One-Piece with Hood, without shoe cove)	45g SMS polypropylene fiber:57.1% PE: 42.9%	Level 1 ANSI/AAMI PB70-2012	Ultrasonic	blue	0.2	20	21.3	100 pcs	60*42*37 CM
					white	0.15	15	16.3	100 pcs	60*42*37 CM
YD-G	Isolation Gown (non-sterile)	45 SMS polypropylene fiber: 55.5% PE:44.5%	Level 2 ANSI/AAMI PB70-2012 EN13795-1:2019	Ultrasonic	blue	0.11	11	12.3	100 pcs	61*33*55CM
YD-G	Surgical Gown (non-sterile)	50g SMS Polypropylene fiber: 100%	Level 3 ANSI/AAMI PB70-2012 EN13795-1:2019	Ultrasonic	blue	0.12	12	13.3	100 pcs	61*33*55CM
		45g SMS Polypropylene fiber 100%		Ultrasonic	blue	0.14	14	15.3	100 pcs	61*33*55CM
YD-JG	Isolation Gown (non-sterile) with blue sealing Tape	50g SMS Polypropylene fiber 100%	Level 3 ANSI/AAMI PB70-2012	Sewing+ blue Sealing Tape	blue	0.14	14	15.3	100 pcs	61*33*55CM

<div style="display: flex; justify-content: space-between; align-items: center;"> <div> <p>YADI ISOLATION GOWN OPERATION INSTRUCTION</p> <p>45g SMS Isolation Gown(Full Back) Model No.: YD-G Size: XL Level 2</p>  <p>【Intended Use】 The product provides general protection. It can be used as general isolation in clinic, ward or laboratory. It is not suitable to use in hospitals for infectious control purpose. It is not intended to use in operation room.</p> <p>【Caution】 1. This product is for one-time use only. If the package is damaged, please do not use it. 2. It shall be properly treated as required and followed the local laws and regulations after use. 3. Never share your product with others. 4. Wash your hands thoroughly upon removal of the product.</p> <p>【Operation instruction】 1. Pay attention to the package, production batch number and effective date before using this product. 2. Open the package and carry out routine operation according to the requirements. 3. Handle according to the routine after use.</p> <p>【contraindication】 Use with caution when you are allergic to nonwoven fabrics.</p> <p>【Storage conditions】 Packaged finished products should be stored in a warehouse with relative humidity less than 80%, conditions of storage: between -30℃ to +70℃, ventilated and dry, clean and hygienic, and free of harmful gases</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%; text-align: center;"></td> <td>End of shelf life: 2 years after manufacture date (Check the Approved Certificate for Product)</td> </tr> <tr> <td style="text-align: center;"></td> <td>Recommended conditions of storage: between -30℃ to +70℃</td> </tr> <tr> <td style="text-align: center;"></td> <td>Recommended conditions of storage: relative humidity <80%</td> </tr> </table> <p style="text-align: right;">⊗ ⊠ ⊘</p> <p>【Manufacturer】 Foshan Yadi clothing Co., Ltd. 【Add】 No.4 building, yuanguzao porcelain factory, guzao village, Zhangcha street, Chancheng District, Foshan City China (528051)</p> <p style="text-align: right; font-size: small;">YADI TEL: 86-757-85312260 / 86-757-83136811</p> </div> <div style="width: 50%;"></div> </div>		End of shelf life: 2 years after manufacture date (Check the Approved Certificate for Product)		Recommended conditions of storage: between -30℃ to +70℃		Recommended conditions of storage: relative humidity <80%	<div style="text-align: center;"> <p>Production Certificate Level2</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">45g SMS Isolation Gown(Full Back)</td> </tr> <tr> <td colspan="2">MODELNO: YD-G</td> </tr> <tr> <td colspan="2">EXECUTIVE STSNDARD: AAMIPB70</td> </tr> <tr> <td colspan="2">BRAND NAME: YADI</td> </tr> <tr> <td>Size:</td> <td>(XL)</td> </tr> <tr> <td>COMPONENT:</td> <td>100% Polypropylene Fiber</td> </tr> <tr> <td>QUANTITY:</td> <td>1 PCS</td> </tr> <tr> <td>INSPECTOR:</td> <td>QC01</td> </tr> <tr> <td>LOTNO:</td> <td>2020102001</td> </tr> <tr> <td>PRODUCTION DATE:</td> <td>2020-10-20</td> </tr> <tr> <td>EXPIRY DATE:</td> <td>2022-09-19</td> </tr> </table> <p style="text-align: center; font-size: small;">Foshan Yadi clothing Co., Ltd. ADD: No.4 building, yuanguzao porcelain factory, guzao village, Zhangcha street, Chancheng District, Foshan Guangdong, China 528051</p> <p style="text-align: center; font-size: x-small;">The product has been inspected and meet the anticipated requirements, It is approved for shipment.</p> </div>	45g SMS Isolation Gown(Full Back)		MODELNO: YD-G		EXECUTIVE STSNDARD: AAMIPB70		BRAND NAME: YADI		Size:	(XL)	COMPONENT:	100% Polypropylene Fiber	QUANTITY:	1 PCS	INSPECTOR:	QC01	LOTNO:	2020102001	PRODUCTION DATE:	2020-10-20	EXPIRY DATE:	2022-09-19
	End of shelf life: 2 years after manufacture date (Check the Approved Certificate for Product)																												
	Recommended conditions of storage: between -30℃ to +70℃																												
	Recommended conditions of storage: relative humidity <80%																												
45g SMS Isolation Gown(Full Back)																													
MODELNO: YD-G																													
EXECUTIVE STSNDARD: AAMIPB70																													
BRAND NAME: YADI																													
Size:	(XL)																												
COMPONENT:	100% Polypropylene Fiber																												
QUANTITY:	1 PCS																												
INSPECTOR:	QC01																												
LOTNO:	2020102001																												
PRODUCTION DATE:	2020-10-20																												
EXPIRY DATE:	2022-09-19																												

Workshop Display



Ultrasonic Display



Business License & Tax No.: 91440604767347392Q

统一社会信用代码		营 业 执 照		扫描二维码，通过“国家企业信用信息公示系统”了解更多信息。	
91440604767347392Q		(副 本) (副本号: i-1)			
名 称	佛山市雅迪制衣有限公司	注 册 资 本	伍拾万元人民币		
类 型	有限责任公司(自然人投资或控股)	成 立 日 期	2004年10月19日		
法 定 代 表 人	陶四平	经 营 期 限	长期		
经 营 范 围	加工、制造：服装、床上用品；销售：服装、纺织原料（不含危险化学品），纺织品、羽绒、羽绒制品；研发、销售：熔喷布；研发、制造、销售：第一类、第二类、第三类医疗器械，卫生材料及医药用品，无纺布。（依法须经批准的项目，经相关部门批准后方可开展经营活动。）				
		住 所	佛山市禅城区张槎街道古灶村原古灶瓷厂内4号楼（住所申报）		
		登 记 机 关	禅城区市场监督管理局		
		2020 年 06 月 28 日			

国家企业信用信息公示系统网址: <http://www.gsxt.gov.cn>

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告

国家市场监督管理总局监制

SGS Testing Report Meets Level 2



中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report

SL52045312717001TX

Date: November 27, 2020

Page 1 of 3

FOSHAN YADI CLOTHING CO., LTD

BLDG 4, GUZAO PORCELAIN, ZHANGCHA, ROAD, CHACHENG DISTRICT, FOSHAN CITY, GUANG DONG PROVINCE, P.R.CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A) Isolation gown (non-sterile)

SGS Internal Ref.No. : GZF20-024835.001

Sample Color : (A) blue

Manufacturer : FOSHAN YADI CLOTHING CO., LTD

Other Info. : Type No.: YD-G

Sample Receiving Date : Nov 17, 2020

Testing Period : Nov 17, 2020 - Nov 27, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Test Performed : Selected test(s) as requested by applicant

Conclusion: the provided sample meets ANSI/AAMI PB70-2012 Level 2.

Signed for and on behalf of

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Testing Center

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

S* Building No. 888, Yienan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64956763 www.sgs.com.cn
中国·上海·徐汇区宜山路888号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64956763 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52045312717001TX

Date: November 27, 2020

Page 2 of 3

Test Result

Liquid Barrier Performance and Classification of Protective apparel and Drapes Intended for Use in Health Care Facilities

ANSI/AAMI PB70-2012

Section 4.2.1 Water Resistance: Impact Penetration Test
 (AATCC 42-2017)

As received

Weight of blotter gained (g)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	0.0	0.0	0.0	0.0	0.0
Area B (Critical zone-sleeve)	0.0	0.0	0.0	0.0	0.0
Area C (Critical zone-Back)	0.0	0.0	0.0	0.0	0.0
Seam between areas A&B	0.0	0.0	0.0	0.0	0.0
Seam between areas A&C	0.0	0.0	0.0	0.0	0.0
Seam between areas B&C	0.0	0.0	0.0	0.0	0.0

Remark:

- Level 1: all critical zone components shall have a blotter weight gain of no more than 4.5grams(g)
- Level 2: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)
- Level 3: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)

Section 4.2.1 Water Resistance: Hydrostatic Pressure Test

(AATCC 127-2018; Hydrostatic Head; Rate of increase of water pressure: 60mbar/min; temp. of distilled water: 21°C, fabric face side of water)

As received

Water Column (cmH ₂ O)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	>20.0	>20.0	>20.0	>20.0	>20.0
Area B (Critical zone-sleeve)	>20.0	>20.0	>20.0	>20.0	>20.0
Area C (Critical zone-Back)	>20.0	>20.0	>20.0	>20.0	>20.0
Seam between areas A&B	>20.0	>20.0	>20.0	>20.0	>20.0
Seam between areas A&C	>20.0	>20.0	>20.0	>20.0	>20.0
Seam between areas B&C	>20.0	>20.0	>20.0	>20.0	>20.0

Remark:

- Level 2: all critical zone components shall have a hydrostatic resistance of at least 20cmH₂O
- Level 3: all critical zone components shall have a hydrostatic resistance of at least 50cmH₂O



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8397 1443, or email: CN.Doccheck@sgs.com

SGS-CS (Shanghai) Technical Services Co., Ltd. 3rd Building, No. 686, Yichan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64368763 www.sgs.com.cn
 中国·上海·徐汇区宜山路686号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64368763 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52045312717001TX

Date: November 27, 2020

Page 3 of 3

Barrier performance of each component and final classification commended

	Impact Penetration Test AATCC 42(g)	Hydrostatic Pressure Test AATCC 127(cmH ₂ O)	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	Final classification
Area A (Critical zone-front)	0.0	>20.0	/	Level 2	Level 2
Area B (Critical zone-sleeve)	0.0	>20.0	/	Level 2	
Area C (Critical zone-Back)	0.0	>20.0	/	Level 2	
Seam between areas A&B	0.0	>20.0	/	Level 2	
Seam between areas A&C	0.0	>20.0	/	Level 2	
Seam between areas B&C	0.0	>20.0	/	Level 2	

Remark:

- The barrier performance of all critical zone components, including seams and points of attachments, shall be determined. The classification of isolation gown shall be a number denoting the performance of the critical zone component having the lower barrier performance.
- Level 1: Impact Penetration Test-AATCC 42: ≤4.5g;
- Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH₂O;
- Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥50cmH₂O;
- Level 4: Resistance to Bacteriophage Phi-X174-ASTM F 1671: Pass.
- Only test the barrier performance of the sample. Label request, construction and other classed in ANSI/AAMI PB70-2012 is not checked.

Sample Photo



Face

Back

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



SGS-CS (Shanghai) Technical Services Co., Ltd.
Testing Center

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing inspection report & certificate, please contact us at telephone: (86-755) 8397 1443, or email: CH.Deschack@sgs.com
3rd Building, No.889 Yishan Road, Xuhui District, Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgs.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e.sgs.china@sgs.com

Member of the SGS Group (SGS SA)

EN 13795 SGS Testing Report



中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report

SL52035286495301TX

Date: September 15, 2020

Page 1 of 11

FOSHAN YADI CLOTHING CO., LTD
BLDG 4, GUZHAO PORCELAIN, ZHANGCHA ROAD, CHANCHENG DISTRICT, FOSHAN CITY, GUANG
DONG PROVINCE, P.R. CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A) Surgical gown(non-sterile)

Sample Color : (A) blue

Style No. : YD-Y

Order No. : GZF20-017541.001

Manufacturer : FOSHAN CLOTHING CO., LTD

Sample Receiving Date : Aug 24, 2020

Testing Period : Aug 24, 2020 - Sep 15, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the
sample(s) tested, for further details, please refer to the following page(s).

Test Performed : Selected test(s) as requested by applicant



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed
overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents,
subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>.
Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is
advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of
Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a
transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced
except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or
appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the
results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755) 8307 1443,
or email: CN.Doccheck@sgs.com

SGS-CS (Shanghai) Technical Services Co., Ltd.
Testing Center

3rd Building, No. 689, Yishan Road, Xuhui District Shanghai, China 200233
中国·上海·徐汇区宜山路689号3号楼 邮编: 200233

t (86-21) 61402666
f (86-21) 61402666

f (86-21) 64958763
f (86-21) 64958763

www.sgs.com.cn
e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52035286495301TX

Date: September 15, 2020

Page 2 of 11

Comment:

Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns (EN 13795-1:2019)	(A)
Clause 4 Bursting strength-Dry	M
Clause 4 Bursting strength-Wet	M
Clause 4 Tensile strength-Dry	M
Clause 4 Tensile strength-Wet	M
Clause 4 Liquid penetration-Water Resistance	M
Clause 4 Cleanliness microbial/Bioburden	M
Clause 4 Microbial Penetration-Dry	M
Clause 4 Microbial penetration-Wet	M
Clause 4 Particle release	M

Remark: M=Meet EN 13795-1:2019 standard performance requirement

Signed for and on behalf of

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu (Authorized Signatory)



SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Testing Center - Technical Services

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing (inspection report & certificate), please contact us at telephone: (86-755) 8307 1443, or email: CN_Dispatch@sgs.com

Building No. 889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958783 www.sgs.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958783 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52035286495301TX

Date: September 15, 2020

Page 3 of 11

Test Result

Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns
(EN 13795-1:2019)

Clause 4 Bursting strength-Dry*

(EN ISO 13938-1: 1999; Dry state; Test area: 10cm²)

Material

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	128	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	120		
3	136		
4	124		
5	128		

Sleeve seam

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	140	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	114		
3	150		
4	123		
5	129		



SGS-CSI Technical Services (Shanghai) Co., Ltd.
Testing Center for Textile

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing inspection report & certificate, please contact us at telephone: (86-755) 8367 1443, or email: CN.Doccheck@sgs.com

3rd Building No. 689, Yishan Road, Xuhai District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64956763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路689号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64956763 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52035286495301TX

Date: September 15, 2020

Page 4 of 11

Clause 4 Bursting strength-Wet*(EN ISO 13938-1: 1999; Wet state; Test area: 10cm²)

Material:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	136	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	128		
3	140		
4	142		
5	137		

Sleeve seam:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
	Face		
1	144	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	148		
3	117		
4	142		
5	132		



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

S* Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgs.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52035286495301TX

Date: September 15, 2020

Page 5 of 11

Clause 4 Tensile strength-Dry

(EN 29073-3:1992; Dry state; The distance between the clamps: 200mm; Rate: 100mm/min)

(EN 29073-3:1992 eqv ISO 9073-3:1989)

Material

Sample	Length (N)	Width (N)	Requirement (N)	Conclusion
1	106.6	59.0	≥ 20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	90.8	58.2		
3	99.4	56.1		
4	94.7	57.8		
5	91.4	57.0		

Sleeve seam

Sample	(N)	Requirement (N)	Conclusion
1	45.0	≥ 20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	44.5		
3	46.6		
4	43.0		
5	39.0		



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS-CS (Shanghai) Technical Service (Shanghai) Co., Ltd.
Testing Center

13 Building No. 889, Yishan Road, Yuhai District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64956783 www.sgs.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64956783 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52035286495301TX

Date: September 15, 2020

Page 6 of 11

Clause 4 Tensile strength-Wet

(EN 29073-3: 1992; Wet state. The distance between the clamps: 200mm; Rate: 100mm/min)
(EN 29073-3:1992 eqv ISO 9073-3:1989)

Material

Sample	Length (N)	Width (N)	Requirement (N)	Conclusion
1	82.2	54.8	≥20	Pass
2	90.9	55.2	(Surgical gown: standard performance critical product area)	
3	83.3	57.8		
4	87.1	54.6		
5	81.8	59.0	EN 13795-1:2019	

Sleeve seam

Sleeve seam			
Sample	(N)	Requirement (N)	Conclusion
1	44.3	≥20	Pass
2	42.7	(Surgical gown: standard performance critical product area)	
3	43.8		
4	49.8		
	49.2		
5		EN 13795- 1:2019	



SGS-CSI (Shanghai) Technical Services Co., Ltd.
Testing Center

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com
3rd Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64956783 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64956783 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52035286495301TX

Date: September 15, 2020

Page 7 of 11

Clause 4 Liquid penetration-Water Resistance

(EN ISO 811: 2018; Rate of increase of water pressure: 10cm/min; temp. of distilled water: 20.0°C; Face side to water)

Material

Sample	Measured value (cmH ₂ O)	Requirement (cmH ₂ O)	Conclusion
1	>20	≥20	Pass
2	>20	(Surgical gown: standard performance critical product area)	
3	>20		
4	>20		
5	>20	EN 13795-1:2019	

Sleeve seam

Sample	Measured value (cmH ₂ O)	Requirement (cmH ₂ O)	Conclusion
1	>20	≥20	Pass
2	>20	(Surgical gown: standard performance critical product area)	
3	>20		
4	>20		
5	>20		
		EN 13795-1:2019	

Clause 4 Cleanliness microbial/Bioburden

(EN ISO 11737-1: 2018; Membrane Filtration Method)

Sample	total plate count (CFU/100cm ²)	Requirement (CFU/100cm ²)	Conclusion
1	6	≤300 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	18		
3	12		
4	6		
5	3		



SGS-CTI (Shanghai) Technical Services Co., Ltd.
Testing Center for Textiles and Apparel

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
Attention: To check the authenticity of testing (inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com
3rd Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958783 www.sgs.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958783 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52035286495301TX

Date: September 15, 2020

Page 8 of 11

Clause 4 Microbial Penetration-Dry*

(EN ISO 22612:2005, The fourth generation of spores of bacillus subtilis ATCC 9372, The concentration of the spores: 1.8×10^8 CFU/g talcum powder, Sample: 12, Vibration frequency: 20800 times/min, Vibration time: 30min)

Material

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	3	≤ 300 (Surgical gown: standard performance less critical product area) EN 13795-1:2019	Pass
2	6		
3	6		
4	3		
5	5		
6	2		
7	2		
8	4		
9	3		
10	7		

Sleeve seam

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	11	≤ 300 (Surgical gown: standard performance less critical product area) EN 13795-1:2019	Pass
2	15		
3	7		
4	9		
5	9		
6	3		
7	8		
8	8		
9	12		
10	6		



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing (inspection report & certificate), please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS-CS (Shanghai) Technical Services (Shanghai) Co., Ltd. 13 Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgs.com.cn
 中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52035286495301TX

Date: September 15, 2020

Page 9 of 11

Clause 4 Microbial penetration-Wet*

(EN ISO 22610:2006, Temp:24.5°C, RH:56.0% ,The distance of agar to plates brim:3mm, Carrier material:30µm polyurethane (PU))

Material

Sample	Barrier index	Requirement Barrier index	Conclusion
1	4.5	≥ 2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	4.6		
3	4.5		
4	4.5		
5	4.5		

Sleeve seam

Sample	Barrier index	Requirement Barrier index	Conclusion
1	4.3	≥ 2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	4.3		
3	4.3		
4	4.4		
5	4.4		



SGS-CHINA Technical Services (Shanghai) Co., Ltd.
Testing Center

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

3rd Building, No.888, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgs.com.cn
中国·上海·徐汇区宜山路888号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52035286495301TX

Date: September 15, 2020

Page 10 of 11

Clause 4 Particle release*

(EN ISO 9073-10: 2004; Size of particles counted: 3um-25um)
(EN ISO 9073-10:2004 idt ISO 9073-10:2003)

Material

Size of particles counted (μm)	Sample	Measured value Coefficient of linting \log_{10}	Requirement Coefficient of linting \log_{10}	Conclusion
3~25	A: Face	1	2.4	≤ 4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019 Pass
		2	2.1	
		3	2.4	
		4	2.3	
		5	2.4	
	A: Back	1	2.3	
		2	2.4	
		3	2.4	
		4	2.4	
		5	2.3	

Sleeve seam

Size of particles counted (μm)	Sample	Measured value Coefficient of linting \log_{10}	Requirement Coefficient of linting \log_{10}	Conclusion
3~25	A: Face	1	2.4	≤ 4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019 Pass
		2	2.2	
		3	2.3	
		4	2.4	
		5	2.3	
	A: Back	1	2.3	
		2	2.4	
		3	2.1	
		4	2.3	
		5	2.3	

*This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment).



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions. If any, The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com
 3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402866 f (86-21) 64958763 www.sgs.com.cn
 中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402866 f (86-21) 64958763 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)

SGS

Test Report

SL52035286495301TX

Date: September 15, 2020

Page 11 of 11

Sample Photo



Face

Back

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



SGS-CHINA Technical Service Co., Ltd.
Testing Center: Shanghai

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8507 1443, or email: CN_Qcscheck@sgs.com

3rd Building, No. 889, Yishan Road, Xuhui District, Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958783 www.sgs.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958783 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)

FDA



U.S. FOOD & DRUG
ADMINISTRATION

[Follow FDA](#) | [En Español](#)

SEARCH

Home

Food

Drugs

Medical Devices

Radiation-Emitting Products

Vaccines, Blood & Biologics

Animal & Veterinary

Cosmetics

Tobacco P

Establishment Registration & Device Listing

[FDA Home](#) [Medical Devices](#) [Databases](#)

1 result found for **Owner Operator Number :**
10076526

New Search

Establishment Name		Registration Number	Current Registration Yr
FOSHAN YADI CLOTHING CO., LTD	CHINA	3017417657	2021
• Non-Surgical Isolation Gown - Surgical Gown(Non-Sterile) YD-LY.YD-Lg			Manufacturer
• Suit, Surgical - Isolation Clothing(Non-Sterile) YD-LT			Manufacturer

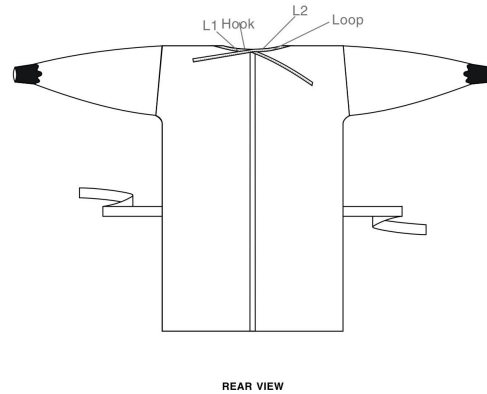
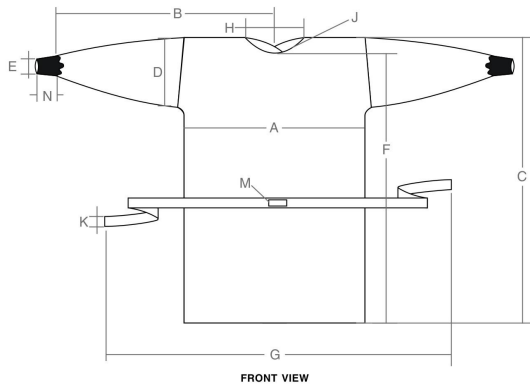
QCC ISO Certificate No.: QCC638ISOQ



European & USA Size Comparison Chart

Size	Measuring (unit:inch)										
	A	B	C	D	E	F	G	H	M	N	J

UL	27	35	47	10	2 1/4	43	70	7	1 3/8	2 1/2	2 1/2	1 1/2
XL	28	37	48	10 1/2	2 1/4	44	70	7	1 3/8	2 1/2	2 1/2	1 1/2
Tolerance	±1	±1	±1	±1	±1/4	±1	NA	±1	±1/2	±1/2	±1/8	±1/4


Guangzhou King Yon Medical Tech Co.,Ltd

Address: No.718, Blv San Yuan Li, Bai Yuan
District, Guang Zhou City, Guang Dong
Province, P.R.China

Post Code: 510403

Website: www.King-Yon.com (Head Office)

Attn: Sam Deng (Mr.)

G.Manager

E-Mail: sales@King-Yon.com

Mobile Phone: +86-15089203268

WeChat ID:


Foshan Yadi Clothing Co.,Ltd

Address:Bldg 4,Guzhao Porcelain, Zhangcha
Road, Chancheng District, Foshan City,
Guang Dong Province, P.R. China

Post Code: 528051

Website: www.YadiSuits.com (Manufacture base)

Attn: Zeego (Mr.)

Sales Manager

E-Mail: sales@King-Yon.com

Mobile Phone: +86-13802807828

WeChat ID:

