



Disposable Medical Protective Coverall Manufacturer

Company Name : ZhongShan Vasaerre Technology Co.,Ltd

**Disposable Medical Protective Coverall (Sterilization)
Compliance with EN14126 TYPE4 / AAMI Level3 Standard**

Main Users Groups:

hospital groups(Switzerland, Italy, Spain,Portugal, Iran & China,etc)
private clinics, retail pharmacies, and licensed wholesalers throughout the world

Why Choose Us:

©Seamless Sealing Tape Patent Holder

(Sealing Polyester Fibre Patent No. :ZL 2018 2 1410630.6)

©Quick Delivery: 1,000,000 PCS in 10 Days.

©FOB & CIF Quotation Term

©Brand Name:OCF

Qualified Certification

©Business Licence

©Food and Drug Business License

©Product Introduction

©FDA Certification

©SGS Electrostatic Properties Testing Report

©CE by OCT (Compliance With Type4/AAMI Level 3)

©OCT Testing Data (Italian Certificate Organization)

©GTT Testing Report (China GB 19082-2009 Standard)



(The Applicant Company Name:Beautiful Nonwoven Company Limited, our Melt-Blown Fabrics Supplier)

©Declaration of Conformity Authorization Letter

HQ40" container loading q'ty: 24300pcs totally 972cases, each case 25 pcs/1size in case
Delivery time: 1-2days for 300,000 pcs

ZhongShan Vasaerre Technology Co.,Ltd

(OCF Brand Owner, Seamless Sealing Tape Patent Holder & Exporter)

统一社会信用代码 91442000MA4UNJG51Q		营 业 执 照		 扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。	
名 称	中山华沙利科技有限公司	注 册 资 本	人民币壹仟万元		
类 型	有限责任公司(自然人投资或控股)	成 立 日 期	2016年04月14日		
法定代表人	王波	营 业 期 限	长期		
经 营 范 围	新型服装功能面料、智能服装、防辐射服装、智能加热服、防弹服、防化服、防护服用具、野营装备的设计、研究、开发；纺织材料的检验、检测；设计、生产、研发、销售(含网上销售)；服装、体育运动器材、第一类医疗器械、医疗器械生产；第二类、第三类医疗器械经营；货物或技术进出口(国家禁止或涉及行政审批的货物和技术进出口除外)。(上述经营范围涉及货物进出口、技术进出口)(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	中山市沙溪镇豪吐龙山路1号3楼		
		登 记 机 关	 2020 年 3 月 15 日		

食 品 药 品 经 营 许 可 证	
经营者名称: 中山华沙利科技有限公司	许可证编号: JY94420121044596
住 所: 中山市沙溪镇豪吐龙山路1号3楼	许可范围: *****
经 营 场 所: 中山市沙溪镇豪吐龙山路1号3楼	
仓 库 地 址: 中山市沙溪镇豪吐龙山路1号3楼	
法定代表人: 王波	
负 责 人: 王波	
质量负责人: *****	
主 体 业 态: 医疗器械经营企业	
社会信用代码: 91442000MA4UNJG51Q (身份证号码)	
投诉举报电话: 12315	备案内容: 第二类医疗器械批发(长期有效)** (备案号: 粤中食药监械备20200491号)
日常监督管理机构: 中山市市场监督管理局	发证机关: 
日常监督管理人员: 由日常监督管理机构指定	签发人: *****
有效期至: 2025 年 4 月 22 日	2020 年 4 月 23 日
(注: 如需延续有效期, 应在有效期届满30日前申请延续)	
NO. 1094405	

OCF Protective Coverall Photographed at a Hospital in Italy



Coverall Material Made of:
67g White Composite Film + 30g Nonwoven Fabric
+ 35g Film + 32g Glue + 2.0cm EVA 0.12mm Sealing Line

Product Photographs





**Packing Details: 25 Units in 1 Carton**

Size	Gross Weight 1 Case	Carton Dimension W/L/H
175CM(L)	7.9 KGS	65*34*28.5CM
180CM(XL)	8.2 KGS	65*34*28.5CM
185CM(XXL)	8.6 KGS	65*34*28.5CM

*Gross Weight for Each Case: Including the Coverall & Paper Carton.

*HQ40" loading Q'ty: 24300pcs

Unit Vacuum-packing







Disposable Medical Protective Coverall Manufacturer

Carton Photo



OCF Protective Coverall at China Wu Han Hospital
0% Influence Rate




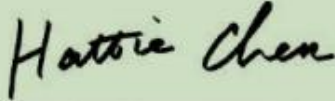



OCF Protective Coverall Photographed at a Hospital in Canadian





SGS Electrostatic Properties Testing Report
AAMI Level 3

				中国认可 国际互认 检测 TESTING CNAS L0599
Test Report	SL52025256525301TX	Date: May 11, 2020	Page 1 of 2	
ZHONGSHAN VASAERRE TECHNOLOGY CO.,LTD 3RD FLOOR,NO.1 HAOTULONGSHAN ROAD,SHAXI TOWN,ZHONGSHAN,GUANGDONG,528471 CHINA				
The following sample(s) was/were submitted and identified on behalf of the client as:				
Sample Description	: (A)Medical Protective Clothing			
Style No.	: One-piece,170cm、175cm、180cm、185cm、190cm			
Composition	: (A)PE, polyethylene polypropylene			
Sample Color	: (A)white			
Manufacturer	: ZHONGSHAN VASAERRE TECHNOLOGY CO.,LTD			
Country of Destination	: EUR			
Supplier	: ZHONGSHAN VASAERRE TECHNOLOGY CO.,LTD			
Proposed Care Instruction	: -			
Test Performed	: Selected test(s) as requested by applicant			
Sample Receiving Date	: May 06, 2020			
Testing Period	: May 07, 2020 - May 11, 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).			
Personal Protective Equipment - Protective Clothing- Electrostatic Properties- Part 5: Material Performance and Design requirements				
Conclusion	A	Remark		
Clause 4.2.1 Electrostatic Material Requirements	M			
Remark(s): M=Meet General Requirement				
Signed for and on behalf of SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center				
				
Hattie Chen (Account Executive)				
		<small>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.</small> <small>Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8387 5443, or email: CN.Operations@sgs.com</small>		
<small>SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center</small>		<small>3rd Building, No. 888, Yehou Road, Xuhui District, Shanghai, China 200233 中国·上海·徐汇区宜山路888号3号楼 邮编: 200233</small>		
		<small>t (86-21) 61402666 f (86-21) 64956763 www.sgs.com.cn t (86-21) 61402666 f (86-21) 64956763 e sgs.china@sgs.com</small>		
Member of the SGS Group (SGS SA)				



Test Report

SL52025256525301TX

Date: May 11, 2020

Page 2 of 2

Test Result

Personal Protective Equipment - Protective Clothing- Electrostatic Properties- Part 5: Material Performance and Design requirements

EN 1149-5:2008

Clause 4.2.1 Electrostatic Material Requirements

(EN 1149-1:2006; Test Condition: Applied Voltage and time: 100V for 15 seconds

Temperature: 23±1°C; Relative Humidity: 25±5%)

(A)	Unit	Face Side	Back Side	Requirement
<u>As Received</u>				
Surface Resistance	Ω	8.1x10 ⁷	7.6x10 ⁷	Max. 2.5x10 ⁹ Ω on at least one surface
Conclusion	Pass			

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



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SGS China Inspection & Testing Services
Testing Center for China

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Member of the SGS Group (SGS SA)

FDA Registration No.: 10065113

			
			
Fiscal Year 2020			
CERTIFICATION OF REGISTRATION			
This certifies that:			
ZHONGSHAN VASAERRE TECHNOLOGY CO., LTD.			
3rd floor, No.1, Haotulongshan Road, Shaxi town, Zhongshan, Guangdong, 528471, CHINA			
has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through Shenzhen Huide Medical Device Certification Service Co., Ltd.			
Owner/Operator Number: 10065113			
Listing Number:	Product Code:	Device Category	Product Name:
D380673	LYU	ACCESSORY, SURGICAL APPAREL	Medical Protective Clothing
<p>Shenzhen Huide Medical Device Certification Service Co., Ltd. will confirm that such registration remains effective upon request and presentation of this certificate until end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. Shenzhen Huide Medical Device Certification Service Co., Ltd. makes no other representations or warranties, nor does this certificate make any representation or warranties to any person or entity other than the named certificate holder, for those sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Shenzhen Huide Medical Device Certification Service Co., Ltd. assumes no liability to any person or entity in connection with the foregoing.</p> <p>Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."</p> <p>The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, Shenzhen Huide Medical Device Certification Service Co., Ltd. is not affiliated with the U.S. Food and Drug Administration.</p>			
			
Shenzhen Huide Medical Device Certification Service Co., Ltd.		Issue Date: March 27, 2020	
16C, Building 1, Sunshine Green, No. 3003 Aiguo Road, Cuizhu Street, Luohu District, Shenzhen		Expiration Date: 31 December, 2020	

Compliance With Type 4 Standard Testing Report by OCT
(Italian Certificate Organization)

	
Certificate of Conformity	
Certification No:	OCT20200318119P
Applicant:	Zhongshan vasaerre technology co. LTD
Address:	3rd floor, no.1, haotulongshan road, shaxi town, zhongshan city
Manufacturer:	Zhongshan vasaerre technology co. LTD
Address:	3rd floor, no.1, haotulongshan road, shaxi town, zhongshan city
Certification Marking:	CE-PPE
Product Description:	Disposable Medical Protective coverall
Model:	one-piece: 175cm, 180cm, 185cm, split: 175cm, 180cm, 185cm
Sufficient samples of the product have been tested and found to be in conformity with	
Test Standards	: EN 14126:2003+AC:2004, EN ISO 13982-1:2004+A1:2010
When tested as specified, the submitted sample complies with Personal Protective Equipment (PPE) - Regulation (EU) 2016/425	
The certificate is based on a single evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test laboratory logo.	
	
Authorized Signer: 	
Manager March 17, 2020	
Oct Technology Testing Co., Ltd. 637, No. 56, zhongyun Road, Panyu District, Guangzhou, Guangdong Province, China TEL: 020-89015652, 888@ouceesting.com, www.ouceesting.com	



Test Report No.:OCT20200326008P

PPE Report**EN 14126****Protective clothing -****Performance requirements and tests methods for protective clothing against infective agents**

Testing laboratory	Oct Technology Testing Co., Ltd.
Address	637, No. 56, zhongyun Road, Panyu District, Guangzhou, Guangdong Province, China
Report body	Oct Technology Testing Co., Ltd.
Address	637, No. 56, zhongyun Road, Panyu District, Guangzhou, Guangdong Province, China
Applicant	ZHONGSHAN WARAOLI TECHNOLOGY CO. LTD.
Address	3rd floor, no.1, haotulongshan road, shaxi town, zhongshan city
Standard	EN 14126:2003/AC:2004
Test Result	Compliance with EN 14126:2003/AC:2004
Procedure deviation	N.A.
Trade Mark	N.A.
Non-standard test method	N.A.
Type of test object	Disposable Medical Protective coverall
Model/type reference	one-piece: 175cm、180cm、185cm, split: 175cm、180cm、185cm
Manufacturer	ZHONGSHAN WARAOLI TECHNOLOGY CO. LTD.
Address	3rd floor, no.1, haotulongshan road, shaxi town, zhongshan city

Oct Technology Testing Co., Ltd.
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Test Report No.:OCT20200326008P

General remarks

This report shall not be reproduced except in full without the written approval of the testing laboratory.

The test results presented in this report relate only to the item(s) tested.

"(see appended table)" refers to a table appended to the report.

"(see remark #)" refers to a remark appended to the report.

"(see Annex #)" refers to an annex appended to the report.

Throughout this report a comma (point) is used as the decimal separator.

Remark:**Photos view:**

(See appendix 1)

Copy of marking plate:

(See appendix 2)



Test Report No.:OCT20200326008P

Possible test case verdicts :	
test case does not apply to the test object	: N (.A.)
test object does meet the requirement	: P(ass)
test object does not meet the requirement	: F(ail)
Name and address of the testing laboratory: <u>Oct Technology Testing Co., Ltd.</u> <u>637, No. 56, zhongyun Road, Panyu</u> <u>District, Guangzhou, Guangdong Province, China</u>	
Reported by :  Signature	Date <u>2020.3.26</u>
Approved by :  Signature	Date <u>2020.3.26</u>

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Test Report No.:OCT20200326008P

EN 14126

Clause	Requirement – Test	Result - Remark	Verdict
4	Requirements		P
4.1	Materials requirements		P
4.1.1	General		P
	If the care instructions indicate that the clothing can be cleaned and reprocessed at least five times, protectiveclothing materials shall be submitted to five cleaning and reprocessing cycles according to the manufacturer'scare instructions before testing.		P
	If the care instructions specify a lower number of cleaning/reprocessing cycles, then materials shall besubmitted to the number of cleaning/reprocessing cycles indicated.		P
	Unless otherwise stated in the relevant test procedure, the specimens shall be conditioned for at least 24 h inan atmosphere of $(20 \pm 2) ^\circ\text{C}$ and $(65 \pm 5) \%$ relative humidity before testing. Tests shall be carried out in thesame atmosphere or within 5 min of removing the sample from the conditioning atmosphere.	20°C RH 66% conditioned 24h	P
4.1.2	Mechanical and flammability requirements		P
	The materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of EN 14325.		P
4.1.3	Chemical requirements		P
4.1.4	Performance requirements against penetration by infective agents		P
4.1.4.1	Resistance to penetration by contaminated liquids under hydrostatic pressure	Class I	P
	When tested in accordance with ISO/FDIS 16603 and ISO/FDIS 16604 the material shall be classified according to the levels of performance given in Table 1, as obtained in the bacteriophage test		P

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Test Report No.:OCT20200326008P

EN 14126

EN 14126																			
Clause	Requirement – Test	Result - Remark	Verdict																
Table 1 — Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (ISO/FDIS 16604)			--																
<table><tr><th>Class</th><th>Hydrostatic pressure at which the material passes the test</th></tr><tr><td>6</td><td>20 kPa</td></tr><tr><td>5</td><td>14 kPa</td></tr><tr><td>4</td><td>7 kPa</td></tr><tr><td>3</td><td>3,5 kPa</td></tr><tr><td>2</td><td>1,75 kPa</td></tr><tr><td>1</td><td>0 kPa ^a</td></tr><tr><td colspan="2">^a this means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell</td></tr></table>			Class	Hydrostatic pressure at which the material passes the test	6	20 kPa	5	14 kPa	4	7 kPa	3	3,5 kPa	2	1,75 kPa	1	0 kPa ^a	^a this means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell		
Class	Hydrostatic pressure at which the material passes the test																		
6	20 kPa																		
5	14 kPa																		
4	7 kPa																		
3	3,5 kPa																		
2	1,75 kPa																		
1	0 kPa ^a																		
^a this means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell																			
4.1.4.2	Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.	Class 1	P																
	When tested in accordance with Annex A the material shall be classified according to the levels of performance given in Table 2.	Breakthrough time:15min	P																
Table 2 — Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids			--																
<table><tr><th>Class</th><th>Breakthrough time, t min</th></tr><tr><td>6</td><td>$t > 75$</td></tr><tr><td>5</td><td>$60 < t \leq 75$</td></tr><tr><td>4</td><td>$45 < t \leq 60$</td></tr><tr><td>3</td><td>$30 < t \leq 45$</td></tr><tr><td>2</td><td>$15 < t \leq 30$</td></tr><tr><td>1</td><td>≤ 15 min</td></tr></table>			Class	Breakthrough time, t min	6	$t > 75$	5	$60 < t \leq 75$	4	$45 < t \leq 60$	3	$30 < t \leq 45$	2	$15 < t \leq 30$	1	≤ 15 min			
Class	Breakthrough time, t min																		
6	$t > 75$																		
5	$60 < t \leq 75$																		
4	$45 < t \leq 60$																		
3	$30 < t \leq 45$																		
2	$15 < t \leq 30$																		
1	≤ 15 min																		
4.1.4.3	Resistance to penetration by contaminated liquid aerosols	Class 1	P																
	When tested in accordance with ISO/DIS 22611 the material shall be classified according to the levels of performance given in Table 3.	Penetration ratio log 2.3	P																

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Test Report No.:OCT20200326008P

EN 14126

EN 14126											
Clause	Requirement – Test	Result - Remark	Verdict								
Table 3 — Classification of resistance to penetration by contaminated liquid aerosols <table><tr><th>Class</th><th>Penetration ratio (log)</th></tr><tr><td>3</td><td>log > 5</td></tr><tr><td>2</td><td>3 < log ≤ 5</td></tr><tr><td>1</td><td>1 < log ≤ 3</td></tr></table>			Class	Penetration ratio (log)	3	log > 5	2	3 < log ≤ 5	1	1 < log ≤ 3	--
Class	Penetration ratio (log)										
3	log > 5										
2	3 < log ≤ 5										
1	1 < log ≤ 3										
4.1.4.4	Resistance to penetration by contaminated solid particles.	Class 1	P								
	When tested in accordance with ISO/DIS 22612 the material shall be classified according to the levels of performance given in Table 4.	Penetration log cfu 2.5	P								
Table 4 — Classification of resistance to penetration by contaminated solid particles <table><tr><th>Class</th><th>Penetration (log cfu)</th></tr><tr><td>3</td><td>≤ 1</td></tr><tr><td>2</td><td>1 < log cfu ≤ 2</td></tr><tr><td>1</td><td>2 < log cfu ≤ 3</td></tr></table>			Class	Penetration (log cfu)	3	≤ 1	2	1 < log cfu ≤ 2	1	2 < log cfu ≤ 3	--
Class	Penetration (log cfu)										
3	≤ 1										
2	1 < log cfu ≤ 2										
1	2 < log cfu ≤ 3										
4.2	Performance requirements for seams, joins and assemblages		P								
	Seams, joins and assemblages of protective clothing against infective agents shall fulfil the requirements specified in the relevant clauses of prEN 14325 Seam strength shall be classified according to 5.5 of EN14325:2001.		P								
4.3	Whole suit requirements	Type 3	P								
	Protective clothing against infective agents shall fulfil the relevant requirements of EN 340 and the whole suit requirements specified in the relevant standard for chemical protective clothing (see Table 5).	Relevant standard EN 466	P								

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Clause	Requirement – Test	Result - Remark	Verdict
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Table 5 — Types of protective clothing against infective agents

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Type of clothing	Relevant standard
type 1a, 1b, 1c, 2	EN 943-1 (EN 943-2 for ET suits)
type 3	EN 466
type 4	EN 465
type 5	prEN ISO 13982-1
type 6	prEN 13034
partial body protection	EN 467

5	Marking		P
	The clothing shall be marked in accordance with the applicable requirements of the relevant standard for chemical protective clothing.		P
	The marking of protective clothing against infective agents shall contain the following additional information:		P
	a) the number of this European Standard;	EN 14126:2003	P
	b) the type of protective clothing, as specified in Table 5, with the suffix "-B", e.g. type 3-B;	Type 3	P
	c) the pictogram "protection against biological hazard"		P
			
6	Information supplied by the manufacturer		P
	The information for the user shall be worded clearly and unambiguously and be understandable by a trained person.		P
	The information for the user of protective clothing against infective agents shall contain all the information required by EN 340 and by the relevant standard for that specific type of chemical		P

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Test Report No.:OCT20200326008P

EN 14126

Clause	Requirement – Test	Result - Remark	Verdict
	protective clothing. In addition it shall contain the following information:		
	a) the number of this European Standard;	EN 14126:2003	P
	b) the type designation, e.g. type 3-B;	type 3	P
	c) the biological agents against which the protective clothing has been tested. This information shall be expressed as performance levels, as specified in 4.1.4.1 to 4.1.4.4 for the relevant types of biological challenge;		P
	d) all other relevant information on performance levels, preferably as a Table;		P
	e) the information necessary for trained persons about:		P
	application and limitations of use (temperature range, etc.);	10-40°C	P
	if relevant, checks to be carried out by the wearer before use;		P
	fitting and adjustments, and any accessories needed to provide the claimed level of protection;		P
	use;		P
	maintenance, cleaning and disinfection;		P
	storage;		P
	if relevant, a warning against problems likely to be encountered;		P
	if relevant, illustrations, part numbers and marking of spare parts, etc.		P
	disposal after use.	Concentrated destruction	P

Appendix 1

Photo of EUT





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150011112181 (2018) 国认监认字(240)号

TEST REPORT

(Electronic version)



No:200013643

VERIFICATION WEBSITE: www.gtcc.net.cn

VERIFICATION CODE: EFJJ-4606-24



ISSUE DATE 签发日期:2020-02-07

APPLICANT: Beautiful Nonwoven Company Limited

委托单位: 佛山市南海必得福无纺布有限公司

ADDRESS: Shatou Jiujiang Town, Nanhai Foshan City, Guangdong

地址: 广东省佛山市南海区九江镇沙头石江工业区

客户认定信息 APPLICANT PROVIDED SAMPLE DESCRIPTION:

LF20106 67gsm 白色SF透气复合材料 200cm×100cm

颜色 COLOR: 白色

单位质量 WEIGHT: 67gsm

DATE RECEIVED/DATE TEST STARTED: 2020-02-02

样品受理/测试开始日期: 2020-02-02

CONCLUSION 结论:

RESISTANCE TO WATER PENETRATION M

抗渗水性

SURFACE WATER REPELLENCY M

表面抗湿性

BREAKING STRENGTH M

断裂强力

ELONGATION AT BREAK M

断裂伸长率

ELECTROSTATIC DECAY M

静电衰减性能

RESISTANCE AGAINST PENETRATION BY SYNTHETIC BLOOD M

抗合成血液穿透性

FILTRATION EFFICIENCY M

过滤效率

WATER-VAPOUR TRANSMISSION RATE M

透湿量

APPROVED BY (签发):

胡万丽 工程师

WanLi Hu ENGINEER

总部: 广州市番禺区珠江路1号
花都实验室: 广州市花都区狮岭镇旗岭河西路1号电话: 020-61994598/61994599
电话: 020-37721161



170000113982



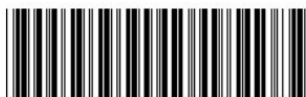
150011112181



(2018) 国认监认字(240)号

TEST REPORT

(Electronic version)



No:200013643

VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: EFJJ-4606-24



ISSUE DATE 签发日期:2020-02-07

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT

"---" -NO COMMENT

备注: "M" -符合标准要求 "F" -不符合标准要求

"---" -此项目不判定

REMARK:

ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).

本报告中检验检测项目均在相应标准规定的环境条件下进行(有注明的除外)。

COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.

复印件、副本未重新加盖报告书确认章无效。

THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P. R. CHINA.

本报告检验检测地址为广州市番禺区珠江路1号。

APPROVED BY(签发):

胡万丽 工程师

WanLi Hu ENGINEER



总部: 广州市番禺区珠江路1号

花都实验室: 广州市花都区狮岭镇旗岭河滨西路1号

电话:020-61994598/61994599

电话:020-37721161



TEST REPORT

(Electronic version)

No:200013643

RESISTANCE TO WATER PENETRATION(kPa)
抗渗水性(kPa)

(GB/T 4744-1997, STEADILY INCREASING WATER PRESSURE 增压法:6.0kPa/min, TEMPERATURE OF THE WATER 水温:20.0℃, FACE DOWN AND FACE SIDE TESTED 正面向下接触水面)

		REQUIREMENT 要求
1#	40.0	≥1.67
2#	37.9	(GB 19082-2009)
3#	37.5	
4#	34.7	
5#	33.9	
AVERAGE 平均值	36.8	

SURFACE WATER REPELLENCY
表面抗湿性

(GB/T 4745-1997)

(GB/T 4745-1997 EQV等效采用 ISO 4920-1981)

		REQUIREMENT 要求
1#	4 GRADE 级	≥3 GRADE 级
2#	4 GRADE 级	(GB 19082-2009)
3#	4 GRADE 级	

BREAKING STRENGTH
断裂强力

(GB/T 3923.1-1997, STRIP METHOD 条样法, THE DISTANCE BETWEEN THE CLAMPS 夹距:100mm, RATE 速度:100mm/min)

		REQUIREMENT 要求
LENGTH 纵向	128N	≥45N
WIDTH 横向	62N	≥45N
		(GB 19082-2009)

ELONGATION AT BREAK
断裂伸长率

(GB/T 3923.1-1997, STRIP METHOD 条样法, THE DISTANCE BETWEEN THE CLAMPS 夹距:100mm, RATE 速度:100mm/min)

		REQUIREMENT 要求
LENGTH 纵向	72%	≥15%
WIDTH 横向	101%	≥15%
		(GB 19082-2009)

ELECTROSTATIC DECAY
静电衰减性能

(GB 19082-2009 5.10, TEMP 温度:23.5℃, RH 相对湿度:50.1%, VOLTAGE APPLIED 施加电压:±5000V)

		REQUIREMENT 要求
MAXIMUM 最大值	0.05s	≤0.5s
		(GB 19082-2009)

RESISTANCE AGAINST PENETRATION BY SYNTHETIC BLOOD
抗合成血液穿透性

(GB 19082-2009 ANNEX A 附录A SURFACE TENSION OF SYNTHETIC BLOOD 合成血液表面张力:0.042N/m)

		REQUIREMENT 要求
	6 GRADE 级	≥2 GRADE 级
		(GB 19082-2009)



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150011112181 (2018) 国认监认字(240)号

TEST REPORT

(Electronic version)

No:200013643

FILTRATION EFFICIENCY

过滤效率

(GB 19082-2009 5.7, AIR FLOW 空气流量:15L/min, AEROSOL 气溶胶颗粒:NaCl, AEROSOL
CONCENTRATION 气溶胶浓度:15mg/m³, TEMP 温度:23.5℃RH 相对湿度:38.5%)

MINIMUM 最小值 100%

REQUIREMENT 要求
≥70%
(GB 19082-2009)

WATER-VAPOUR TRANSMISSION RATE

透湿量

(GB/T 12704-1991, METHOD A 方法A: DESICCANT METHOD 吸湿法,
TEST CONDITION 试验箱环境:38.0℃, 90.0%)

3770g/(m² · d)

REQUIREMENT 要求
≥2500g/(m² · d)
(GB 19082-2009)



——本报告结束(End of Report)——

PAGE 4 OF 4

Zhongshan vasaerre technology co. LTD

Declaration of Conformity

Zhongshan vasaerre technology co. LTD

3rd floor, no.1, haotulongshan road, shaxi town, zhongshan city

We declare that the following product :

Disposable Medical Protective coverall

Models No: one-piece : 175cm、180cm、185cm , split : 175cm、180cm、185cm

Described above is in conformity with the following directive (s) :

Personal Protective Equipment 2016/425

Relevant standard (s):

EN 14126:2003+AC:2004, EN ISO 13982-1:2004+A1:2010

The reference of the File identified with the No:

MESTTCF-PPE

And we are aware about the contents and information included in the ModCOM04.06 Regulation that is considered totally accepted.



Date of issue

2020.03.18

Stamp and Signature of authorized personnel





检验检测报告



No:200027852

防伪查询网址: www.gtcc.net.cn

防伪码: EJKT-0692-34

共3页 第1页



委托单位	中山华沙利科技有限公司 地址: 中山市沙溪镇豪吐龙山路1号3楼		
客户认定信息	医用一次性防护服 3件		
检验性质	委托检测	样品受理/测试开始日期	2020-03-13
		报告签发日期	2020-03-18
判定依据	GB 19082-2009 《医用一次性防护服技术要求》		
综合检验结论	——		
检验检测结果	检验检测项目	判定依据	判定
	断裂强力	GB 19082-2009	符合
	断裂伸长率	GB 19082-2009	符合
	表面抗湿性	GB 19082-2009	符合
	抗渗水性	GB 19082-2009	符合
	透湿量	GB 19082-2009	符合
	抗合成血液穿透性	GB 19082-2009	符合
	过滤效率[关键部位]	GB 19082-2009	符合
	过滤效率[接缝处]	GB 19082-2009	符合
备注	本报告中检验检测项目均在相应标准规定的环境条件下进行(有注明的除外)。 复印件、副本未重新加盖报告书确认章无效。 本报告检验检测地址为广州市番禺区珠江路1号		







中国认可
国际互认
检测
CNAS L10314




TEST REPORT

检验检测报告





广州检验检测认证集团有限公司
 Guangzhou Inspection Testing and Certification Group Co., Ltd.
 广州广检纺织服装服饰检测研究院有限公司
 Guangzhou Guangjian Textile Garment and Accessories Testing and Research Institute Co., Ltd.
 国家纺织品服装服饰产品质量检验中心(广东)
 National Quality Inspection and Testing Center for Textile Garment and Accessories (Guangdong)
 国家皮革制品质量检验中心(广东)



样品图片

No: 200027852

共3页 第2页





检验检测报告附页

No: 200027852

共3页 第3页

检验检测项目 (计量单位) [样品识别]	测试方法	标准值及允差	检验检测结果	判定	备注
●断裂强力(N)	GB/T 3923.1-1997 夹距:100mm 速度:100mm/min	纵向 ≥ 45 横向 ≥ 45	纵向 145 横向 76	符合	
●断裂伸长率(%)	GB/T 3923.1-1997 夹距:100mm 速度:100mm/min	纵向 ≥ 15 横向 ≥ 15	纵向 117 横向 105	符合	
●表面抗湿性(级)	GB/T 4745-1997	≥ 3	1# 4 2# 4 3# 4	符合	
●抗渗水性(kPa)	GB/T 4744-1997 增压法:6.0kPa/min 水温:20.0℃ 正面向下接触水面	≥ 1.67	1# 19.7 2# 20.0 3# 21.2 4# 20.0 5# 22.0 平均值 20.6	符合	
●透湿量 (g/(m ² ·d))	GB/T 12704-1991 方法A: 吸湿法 试验箱环境: 38.0℃, 90.0% 透湿时间: 1h	≥ 2500	6340	符合	
●抗合成血液穿透性(级)	GB 19082-2009 附录A 合成血液表面张力: 0.042N/m	≥ 2	6	符合	
●过滤效率(%) [关键部位]	GB 19082-2009 5.7 空气流量: 15L/min 气溶胶颗粒: NaCl 气溶胶浓度: 15mg/m ³ 温度:24.1℃ 相对湿度:38.2%	≥ 70	最小值 100	符合	
●过滤效率(%) [接缝处]	GB 19082-2009 5.7 空气流量: 15L/min 气溶胶颗粒: NaCl 气溶胶浓度: 15mg/m ³ 温度:24.3℃ 相对湿度:38.2%	≥ 70	最小值 99	符合	
备 注	(本栏空白)				

——本报告结束——

Sealing Polyester Fibre Patent No. :ZL 2018 2 1410630.6)

证书号第8937294号



实用新型专利证书

实用新型名称：一种衣服接缝高强度胶条

发 明 人：王贵;王志勇;相里海霞

专 利 号：ZL 2018 2 1410630.6

专利申请日：2018年08月30日

专 利 权 人：中山华沙利科技有限公司

地 址：528471 广东省中山市沙溪镇隆盛路巨邦产业园第一幢7楼

授权公告日：2019年06月07日 授权公告号：CN 208949173 U

国家知识产权局依照中华人民共和国专利法经过初步审查，决定授予专利权，颁发实用新型专利证书并在专利登记簿上予以登记。专利权自授权公告之日起生效。专利权期限为十年，自申请日起算。

专利证书记载专利权登记时的法律状况。专利权的转移、质押、无效、终止、恢复和专利权人的姓名或名称、国籍、地址变更等事项记载在专利登记簿上。



局长
申长雨



第1页(共2页)



Disposable Medical Protective Coverall Manufacturer

中山市突发公共卫生事件一级响应期间 应急医疗器械生产备案凭证

备案编号：粤中市监应急械生产备 2020005 号

企业名称	中山华沙利科技有限公司			
住 所	中山市沙溪镇豪吐龙山路 1 号 3 楼			
生产地址	中山市沙溪镇豪吐龙山路 1 号 3 楼			
法定代表人	王波	企业负责人	王贵	
生产范围	14-14-02：医用一次性防护服			
生产产品 列表	产品名称	产品备案/注册号	登载日期	备注
	医用一次性防护服	粤中市监应急械备 2020005 号	2020 年 2 月 15 日	
	以下空白			
备注	本备案仅在防控新冠肺炎疫情期间有效			


备案部门（公章）

备案日期：



中山市突发公共卫生事件一级响应期间 应急医疗器械备案信息表

备案号：粤中市监应急械备 2020005 号

备案人名称	中山华沙利科技有限公司
备案人社会信用代码	91442000MA4UNJG51Q
备案人注册地址	中山市沙溪镇豪吐龙山路 1 号 3 楼
生产地址	中山市沙溪镇豪吐龙山路 1 号 3 楼
产品名称	医用一次性防护服
分类编码	14-14-02
型号/规格	型号：连身式、分身式 规格：160、165、170、175、180、185。
产品描述	由一种或多种对病毒气溶胶、含病毒液体等具有隔离作用的面料加工而成的衣服。脱下时，防护衣的外表面不与人体接触。为非灭菌产品，一次性使用。
预期用途	用于医疗机构医护人员穿的职业防护衣。阻止来自患者的病毒随空气或液体向医务人员传播。
适用标准	GB 19082-2009 医用一次性防护服技术要求
备案单位和日期	 中山市市场监督管理局 备案日期：2020 年 2 月 15 日
变更情况	
备注	本备案仅在防控新冠肺炎疫情期间有效

3/7

中山市突发公共卫生事件一级响应期间 应急医疗器械备案凭证

中山华沙利科技有限公司：

在重大突发公共卫生事件一级响应期间，我局根据《广东省药品监督管理局办公室关于重大突发公共卫生事件一级响应期间对医用口罩等防控急需器械实施特殊管理的通知》（粤药监办许〔2020〕39号）及其补充通知（粤药监办许〔2020〕42号）、《广东省药品监督管理局办公室关于明确疫情防控所需第二类医疗器械应急审批备案有关事宜的通知》（粤药监办许〔2020〕65号）对你单位申请的疫情应急医疗器械：医用一次性防护服予以备案，备案号：粤中市监应急械备 2020005 号。

本备案仅在防控新冠肺炎疫情期间有效。



日期： 2020 年 2 月 15 日