

Wujiang Tutaike Textile & Finishing Co., Ltd

Supporting documents about TTK™ Protective Suit manufacturing qualifications

- **Manufacturer profile:**

TTK® is a research & development enterprise that has been engaged in functional anti-microbial fabric for 2 decades. It was initial devoted to research and development of high-tech military fabrics, medical antibacterial materials and civil functional fabrics. In 2003, the company served as a supplier of raw fabrics and finished goods for suits used in fighting SARS, and ever since it has viewed medical high-tech materials as one of its directions for research & development. In view of the prevailing COVID-19, the enterprise has developed as soon as possible the latest material (SSS non-woven fabric + PE highly breathable antibacterial membrane composite product) suitable for disposal medical protective suit production line and organized production of novel disposable medical protective suit made of TTK-PE disposal overall gown. The novel product can guarantee antibacterial performance and breathability of the protective suit and high strength of SSS non-woven fabric + PE highly breathable antibacterial membrane composite fabric.

- **Product usage and extensive application:**

Applicable to places potentially threatened pathogenic bacteria, such as infectious disease ward, lab, station, pasture, slaughter house and earthquake-stricken area, the fabric is able to protect users from being damaged by hazardous substances. It is frequently used in preventing SARS, plague, Ebola, Brucellosis and avian influenza.



TTK® Overall Protective Gown
Antibacterial, waterproof and breathable

● **Notes about specifications**

No.	Specification	Function
1	TTK-PE Anti-virus/Waterproof/Breathable -Protective Suit	Disposable
2	TTK-PEFE Anti-virus/Waterproof/Breathable -Protective Suit	Reusable, Washable
3	TTK- Tricot+ PFTE Highly Antistatic Yarn/Anti-Virus/Waterproof/Breathable -Protective Suit	Reusable, Washable

● **About export qualification**

Export qualification: the enterprise owns independent importing/exporting right of foreign trade

Product certification: CE certificate and FDA certificate

Standards applicable to its exported products: EN14126 Category 3, namely Category 3 for sterile and non-sterile PPE

TK™ Qualification Documents For Proof Only

CE CERTIFICATE



ISET S.r.l. Unipersonale

Sede Legale e Uffici

Via Donatori di sangue, 9 - 46024 Moglia (MN)

Tel. e fax +39 (0)376 598963

www.iset-italia.eu iset@iset-italia.com

Cap. soc. i.v.

Cod. Fisc. e P.IVA Reg. Imprese

REA

Cap. soc. i.v.

€ 10.200,00

02 332 750 369

02 332 750 369


MN 0221098

CERTIFICATE

Certificat - Certificado- Сертификат - Zertifikat - 證書

- 1) APPLICANT:** (who finally puts the product on the market)
Wujiang Tutaik Textiles & Finishing Co., Ltd.
No.1599, 3rd Southern Ring Road, Shengze Town, Wujiang City, Jiangsu Province, China
- 2) CERTIFICATE NO.:** ISETC.001420200304
FILE REFERENCE: TTK2020030301PPE
- 3) ISET MARK:**



- 4) CAUTION ABOUT CE MARKING** (Instruction for the Applicant who puts the product on the EU market):
 The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.
- 5) TYPE OF PRODUCT:** PP+PE Hooded Coveralls (Category III)
MODEL(S): S: 160-165cm M: 170-175cm L: 180-185cm
- 6) LIST OF DIRECTIVES / REGULATIONS / STANDARDS** (as declared by the manufacturer itself) Personal Protective Equipment 2016/425
EN 14126:2003/AC:2004
- 7) NOTE:** The applicant is aware about the contents and information included in the ModCOM04.06 Regulation for this type of Certificate that is considered totally accepted. The latest revision of the Regulation is available and can be downloaded from the website www.iset-italia.eu. This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.
- 8) REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark (at point 3) on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.
- 9) DATE OF ISSUE:** 04/03/2020 **EXPIRY DATE:** 03/03/2025
- 10) SIGNATURE:** Li Zhang

(On behalf of the Legal representative)



FDA CERTIFICATE



CERTIFICATION OF REGISTRATION 2020

This certifies that:

WUJIANG TUTAIKE TEXTILES&FINISHING CO., LTD
No.1599,3rd Southern Ring Road,Shengze Town, Wujiang, Jiangsu, 215200,
CHINA

Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuant to the Code of Federal Regulations 21 CFR 807, by F&W (Shanghai) Certification Co., Ltd.

Owner/Operator Number: 10063222
Device Listing#: See annex
Expiration Date: December. 31, 2020

2020 F&W will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. F&W makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose 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. F&W assumes no liability to any person or entity in connection with the foregoing.

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." 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, F&W is not affiliated with the U.S. Food and Drug Administration.

TKTMQuality.com Document for Product Only



for and on behalf of
F&W (Shanghai) Certification Co., Ltd.

executive director

Dated: March 19, 2020



CERTIFICATION OF REGISTRATION 2020


Annex to Device Listing#

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
<i>PP+PE Hooded Coveralls; Tricot+PTFE Hooded Coveralls</i>	<i>OEA</i>	<i>1</i>	<i>D375741</i>	<i>Manufacturer Foreign Exporter</i>

END OF THE ANNEX



for and on behalf of
F&W (Shanghai) Certification Co., Ltd.



executive director

Dated: March 19, 2020



Foreign Trade Operator Registration Form

Uniform social credit code: 913205097307153151

Registration form no. **04184354**

Import/Export Enterprise Code:

Operator Name (in Chinese)	吴江市涂泰克纺织后整理有限公司		
Operator Name (in English)	Wujiang Tutaike Textile & Finishing Co., Ltd		
Code of Organization		Type of Operator (filled by registration authority)	Limited liability company
Address	South Circle Road, Shengze Town		
Premise (in Chinese)	盛泽镇南环路		
Premise (in English)	South Circle Road, Shengze Town, Wujiang City		
Tel	0512-63601555	Fax	0512-63522565
Postal code	215228	Email	Zhw8866@sina.com
Business registration date	August 16, 2001	Business registration no.	-----

The enterprise applying for legal business registration shall also be liable for providing following information:

Name of legal representative	ZHANG Guizhu	Effective certificate no.	32052519670320524
Registered capital	55,000,000 Yuan	(Equivalency in USD)	

Foreign (or regional) enterprise or self-employed (sole proprietor) applying for legal business registration shall also be liable for providing following information:

Name of legal representative/self-employed	Effective certificate no.	
Registered capital	(Equivalency in USD)	

Remark	
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Please read through articles on back. Signature and seal are required hereby from legal representative or self-employed.



REGISTRATION AUTHORITY SEAL (sealed)

March 04, 2020

CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS

证书编号: 苏苏食药监械出 20200103
Certificate NO.: SSSYJXC20200103

产品名称: 紧急物资医用防护服
Product(s): PP+PE Protective Suit

规格型号: 大号、中号、小号
Model:L、M、S

产品注册或备案凭证号: 苏临 20200064
Registration certificate(s):SL20200064

生产企业: 吴江市涂泰克纺织后整理有限公司
Manufacturer: Wujiang Tutaike Textiles&Finishing Co.,Ltd

生产企业住所: 江苏省苏州市吴江区盛泽镇南三环 1599 号
Address of manufacturer: No.1599 South Suzhou 3rd Ring Road,
Shengze Town Wujiang, Jiangsu, China

生产许可或备案凭证号: /
Manufacturing License(s): /

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be
manufactured and sold in China.

证明有效日期至: 2020 年 5 月 12 日
This certification valid until:2020-5-12

备注: /
Remark: /



Product package: encapsulated and compressed package for single finished product; dimensions: 30cmx40cm

Packaging case: case size 60x40x55cm 50 suits/case

Weight per case: 16kg

● **Corporate qualification documents**

<Business License>

Uniform Social Credit Code
913205097307153151 (1/1)

**Business License
(Copy)**

No. 320584000202002100003



Scan the QR code to log in "State Business Credit Information Publicity System" to get more information concerning registration, filing, permission and supervision.

Name: Wujiang Tutaik Textile & Finishing Co., Ltd

Type: Limited Liability Company (LLC)

Legal Representative: ZHANG Guizhu

Business Scope: knitwear and textile production and sales; textile calendaring, sanding, composition and coating; self-ran and proxy of import/export business for all sorts of goods and techniques. Class I medical equipment manufacturing; Class I medical equipment wholesale; Class I medical equipment retails; Class II medical equipment manufacturing; Class II medical equipment wholesale; Class II medical equipment retails; clothing manufacturing; apparel wholesale; apparel retails (business activities demanding legal consent shall be carried out after acquiring due consent from authority)

Registered Capital: 55,000,000 Yuan only

Date of Establishment: Aug. 16, 2001

Business Term: from Aug. 16, 2001 to****

Address: South Circle Road, Shengze Town

Registration Authority: SUZHOU WUJIANG ADMINISTRATION APPROVAL BUREAU (sealed)
Feb. 10, 2020

Website of State Enterprise Credit
Information Publicity System:
<http://www.gxxl.gov.cn>

Market entity shall submit yearly report through State Enterprise Credit
Information Publicity System during Jan. 1 and Jun. 30 of each year.

Manufactured as being supervised by
State Administration for Market
Regulation

<Level 2 Emergency Medical Devices Filing>
Jiangsu Emergency Medical Protective Suit and Mask
Emergency Production and Use Filing

File no. SL 20200064

Enterprise name	Wujiang Tutaike Textile & Finishing Co., Ltd
Location	South Circle Road, Shengze Town, Wujiang, Suzhou, Jiangsu
Manufacturing address	West Side of Jinku Road, Lili Town, Suzhou, Jiangsu
Product name	Emergency materials, medical protective suit (non-antibacterial)
Model and specifications	Large, middle, small
Structure and composition	The product consists of a hoodie and a pair of trousers made of spun-bond nonwoven fabric and PE membrane composite material. It is not antibacterial.
Executive standard	Technical specifications for the product (lacking flame retardation performance in specified in GB19082-2009)
Scope of application	For separating and protecting users in contact with potentially infectious patient's blood, body fluid, secreta, and atmospheric particles.
Effective term	2 years
Filing conclusion	The product applies to emergency use against domestic pandemic. Labels and signs should be marked in conspicuous place that "For emergency use only, non-antibacterial, lacking flame retardance as specified in GB19082-2009 in technical specifications.
Mainly to	Wujiang Tutaike Textile & Finishing Co., Ltd
CC to	Medical devices Manufacturing Supervision Division, Jiangsu Food and Drug Administration; Jiangsu Food and Drug Administration Suzhou Inspection Bureau, Jiangsu Testing and Inspection Institute for Medical Devices.
Remark	Products manufactured by the enterprise during filing period are to be deployed and used uniformly by materials support agency for joint prevention and control of epidemic at all levels. The enterprise should inform local inspection bureau about yield and sales on a weekly basis.

Filed by: Jiangsu Food and Drug Administration

Filed on: Mar. 13, 2020

Effective until: May 12, 2020

Product exhibition



Packaging



STERILE

TTK[®]

textiles & finishing

涂泰克

www.szttk.com.cn

SPECIALIZED FOR PROTECTIVE SUIT



● 使用说明 · PRODUCT DESCRIPTION · 사용 설명

PP+PE
透气新型防护材料

商品名:
PP+PE透气新型防护材料

产品特点:
本产品为PP+PE透气新型防护材料,采用特殊工艺,采用中空纤维,采用特殊工艺,经裁剪、热封胶条密封缝制,并制成压褶,透气性好。

适用范围:
疫病预防、生物隔离、抗菌消毒、化学实验室用途,适用于医疗机构门诊、药房、检验室等作为常规隔离使用。

型号规格:
小号:160-165cm 中号:170-175cm 大号:180-185cm

储存条件:
请避免阳光直射,本品应保存在阴凉干燥处,防潮、通风、无腐蚀性气味环境下储存。

使用方法:
1. 使用前选择并确认防护服的型号。
2. 根据自己的体型选择适合的尺码。
3. 将防护服穿好,保证口罩胶条处完全吻合,请根据实际场所需要,决定是否佩戴其他防护用品,如用胶条将袖口、手/脚腕部等开口处密封,防护效果更佳。

PP+PE
透气新型防护材料

製品名:
PP+PE透气新型防护材料

製品の特長:
本品はPP+PE透気新型防護材料を使用しています。特殊な処理技術を採用し、中空繊維を使用し、特殊な縫製技術で縫製され、熱封接着剤で縫目を密封し、透気性を向上させています。

用途:
疫病予防、生物学的隔離、抗菌・消毒防止、化学実験などの用途で、医療機関の外来診療室や病室や検診所などで一般の隔離用の防護服として使われます。

サイズ:
S:160-165cm M:170-175cm L:180-185cm

保管方法:
日光に当たらない、常温で通気性がよく、腐敗性、ガスがない乾燥した状態で保管してください。

使用方法:
1. 使用前、防護服のサイズを確認してください。
2. 自分の身長などに応じて適切なサイズを選んでください。
3. 防護服を着用し、接着テープをしっかり貼り付けます。用途に応じて必要に応じて、その他の防護用品を着用する必要があります。頭、手、足首の部分を密着させることによって、防護効果がより良くなります。

PP+PE
New Breathable Protective Material

Product Name:
PP+PE Hooded Coveralls

Product Features:
This product is a new breathable AP coating material with PP+PE. It is made of high density non-woven polyethylene fiber with a special process. After being cut, it is sealed with heat-sealing adhesive tape, and made into a structure of coveralls with hood.

Scope of Application:
It can be applied for epidemic protection, biological isolation, anti-bacterial and seepage-proofing, chemical experiment, and as routine isolation in medical outpatient, ward and laboratory.

Type Specification:
S: 160-165cm M: 170-175cm L: 180-185cm

Storage:
Avoid direct sunlight, and store in a ventilating, cool and dry place, in normal temperature, without compressive smell.

Usage:
1. Select and confirm the type of protective suit before use.
2. Choose the right size according to your frame.
3. Put on the protective suit, and make sure the flap is closed properly. Decide whether to wear other protective articles according to actual requirements. You will obtain a better protection effect if you use the adhesive tape to seal the opening part on your face, hand wrist.

PP+PE
透气新型防护材料

제품명:
PP+PE호디드 보호복 (모자 있음)

제품의 특성:
본 제품은 PP+PE통기성 신형 AP 코팅 재료입니다. 본 제품은 특수 처리된 고밀도 폴리에틸렌 섬유를 사용하여 열융착 접착제와 열융착 테이프로 밀봉 제작되었습니다.

적용범위:
전염병 예방 보호, 생물학적 격리, 항균 및 침투 방지, 화학 실험 등에 사용됩니다. 의료 기관 진료소, 병동 및 검사실의 일상적인 격리에 적합합니다.

제품규격:
Size: 160-165cm M size: 170-175cm L size: 180-185cm

보관방법:
직사광선을 피하여 보관하십시오. 온도는 적당하며 건조한 장소, 습기, 냄새가 없고 통풍이 되는 비닐이 없는 곳에서 보관하십시오.

사용방법:
1. 사용 전에 보호복의 규격과 신체를 확인하십시오.
2. 자신의 체형에 맞는 규격을 선택하십시오.
3. 보호복을 착용할 때 밀봉 테이프를 잘 밀착시켜서 밀봉하십시오. 필요에 따라 다른 보호복을 착용하여 밀봉하십시오. 얼굴, 손, 발목 등 개구부를 테이프로 밀봉하십시오.

Size Chart

SPECIALIZED
FOR
PROTECTIVE
SUIT



防护服尺寸表 Size

单位 cm	S (160-165)	M (170-175)	L (180-185)
衣长(连帽) Length (with hood)	186	196	206
胸围 Chest	119	127	135
袖长 Sleeve Length	86	89	92
袖口 Wrist Length	18	18	18
脚围 Ankle length	24	24	24

Product packaging

A single set of finished packaging: 30cm×40cm

Carton size: 67 × 30 × 65cm

50 sets / carton

16kg/carton



<Testing and Inspection Institute for Medical Devices—Emergency Materials-Medical
Protective Suit Test Report>

Test Report

(2020) ZC No. 0308

Product Name: Emergency Medical Protective Suit

Specifications: Small

Test Category: Registration Test

Entrusting Unit: Wujiang Tutaik Textile & Finishing Co., Ltd

**JIANGSU TESTING AND INSPECTION INSTITUTE FOR MEDICAL
DEVICES Special Seal for Test Report (sealed)**

Jiangsu Testing and Inspection Institute for Medical Devices

Jiangsu Testing and Inspection Institute for Medical Devices

Test Report (Front Page)

Report no. 2020ZC0308

1 Front Page, 2 Page W, 1 Page Z, 4 Pages in total

Sample name	Emergency medical protective suit		Sample no.	SLZC2002289
	Sample delivered (√)	Sample collected ()		
Trade mark	/		Specifications	Small
Entrusting unit	Wujiang Tutaik Textile & Finishing Co., Ltd		Test category	Registration test
Correspondence address of entrusting unit	West Ride of Jinku Road, Lili Town, Suzhou, Jiangsu		Product no/batch no.	20200206
Labelled manufacturer	Wujiang Tutaik Textile & Finishing Co., Ltd		Sample form no.	/
Tested unit	Wujiang Tutaik Textile & Finishing Co., Ltd		Date of manufacture	
Sample unit	/		Sample number	10 pieces
Sample site	/		Sampling basic number	
Sample date	/		Test site	Lab of the Institute
Received on	Feb. 28, 2020		Tested on	From Mar. 2 to Mar. 9, 2020
Test items	2.1-2.9			
Test basis	Technical specifications for Wujiang Tutaik Textile & Finishing Co., Ltd, Emergency Medical Protective Unit			
Test conclusions	The product turns out to be completely in compliance with the technical specifications for Wujiang Tutaik Textile & Finishing Co., Ltd, Emergency Medical Protective Unit			
Remark	1) “-” in the Report means it is inapplicable, while “/” indicates blankness 2) “W” in header indicates physics, while “Z” indicates photo.			

Approved by: GAO Jingxian (signed)

Title: Authorized signatory

Test Report

Report no. 2020ZC0308

W Page 1 of 2

No.	Test item	Article	Requirements	Test result	Individual conclusion	Remark
				1~3		
1	Appearance	2.	1.1. Emergency medical protective suit should be dry, clean and free from any mold spot. No such defects adhesion, crack, and hole are allowed on the surface.	Conforming	Conforming	/
			2.1. Joints on the protective suit may adopt a variety of processing ways such as sewing, adhesion and heat sealing.	Conforming		
			2.2. Stitch gap should be sealed.	9 stitches/3 cm~ 10 stitches/3 cm		
			Needle tracking should remain uniform, level and straight without a skipping stitch.	Conforming		
			Those adhered or thermal sealed parts should remain flat and sealed without any air bubble.	Conforming		
			2.3. Zipper on protective suit shouldn't be exposed and its puller should be of self-locking type if any.	Conforming		
2	Structure	2.	2.1. Protective suit consists of a hoodie and a pair of trousers. It is of overall style as shown in Fig. 1.	Conforming	Conforming	/
			2.2. The protective suit should have a reasonable structure so that it is convenient to be put on and off. Joints should remain tight.	Conforming		
			2.3. Cuffs and ankle openings should be flexibly tightened, while hat's facial part and waist should be tightened with flexibility, cord pull or buckle.	Flexibly tightened confirming		
3	Specifications (small)	2.	2.3. Height: 180cm±5cm	181.0cm~182.0cm	Conforming	/
			Chest circumference: 132cm±5cm	- Without significant chest demarcation		
			Sleeve length: 83cm±5cm	81.2cm~82.1cm		
			Cuff opening: 20cm±5cm	20.0cm~21.6cm		
			Ankle opening: 29cm±5cm	31.0cm~31.8cm		
Sampling plan: n=3 [Ac=0, Re=1]						

Test Report

Report no. 2020ZC0308

W Page 2 of 2

No.	Test item	Article	Requirements	Test result	Individual conclusion	Remark
4	Waterproof property	2.4.1	Hydrostatic pressure at key parts of protective suit shouldn't be lower than 1.67kPa (17cmH ₂ O)	Joint-free Joint	32.93 kPa 26.32 kPa	Conforming
5	Water vapor transmission (WVT)	2.4.2	Protective suit's WVT should be no lower than 2,500g/(m ² ·d)		4,672 g/(m ² ·d)	Conforming
6	Anti-synthetic-blood permeability	2.4.3	Protective suit's anti-synthetic-blood permeability should be no inferior to Level 2 (1.75kPa) requirements.	Level 5-6	Conforming	/
7	Surface moisture resistance	2.4.4	Lateral surface of protective suit should meet Level 3 spray requirements for the minimum.	Level 4	Conforming	/
8	Breaking strength	2.5	Break strength of key parts of protective suit should be no lower than 45N.	Longitudinal Crosswise	128.8 N 61.6 N	Conforming
9	Elongation at break	2.6	Elongation at break of key parts of protective suit should be no lower than 15%.	Longitudinal Crosswise	54.2 % 110.4 %	Conforming
10	Filter efficiency	2.7	Materials and joints at key parts of protective suit should be able to filter at least 70% of non-oily particles.	Key part 1 Key part 2 Joint	99.95 368% 99.85 303% Highly resistant 99.90 948%	Conforming
11	Antistatic property	2.8	Electric charge of protective suit should be no higher than 0.6μC/piece.	0.58μC/piece	Conforming	/
12	Electrostatic attenuation performance	2.9	Protective suit's electrostatic attenuation shouldn't exceed 0.5s.	+5kV -5kV	Conforming 0.13s ~0.18s	Conforming
Remark: as declared by entrusting unit, the protective suit is made of spun-bond nonwoven fabric and PE membrane composite.						
Following space is left blank.						

Tested by: WEN Jiqin (signed) Approved by: QIN Li (signed)

Test Report (Photo Page)

Report no. 2020ZC0308

Z Page 1 of 1

Photo and notes



Sample Description

Specifications or others

The product hereby is of small size.

No. Technical specifications for medical devices

Emergency Medical Protective Suit

1. Product model/specifications and classification notes

1.1 Scope

The technical specifications apply to emergency protective medical suit (hereinafter referred to as protective suit) that is used to separate and protect medical staff in contact with potentially contagious patient blood, body fluid, secretions and atmospheric particles in work.

1.2 Specifications

There are three sizes, namely large, middle and small.

1.3 Materials

The product is made of spun-bond nonwoven fabric and PE membrane composite material, zipper and adhesive tape.

2. Performance indicators

2.1 Appearance

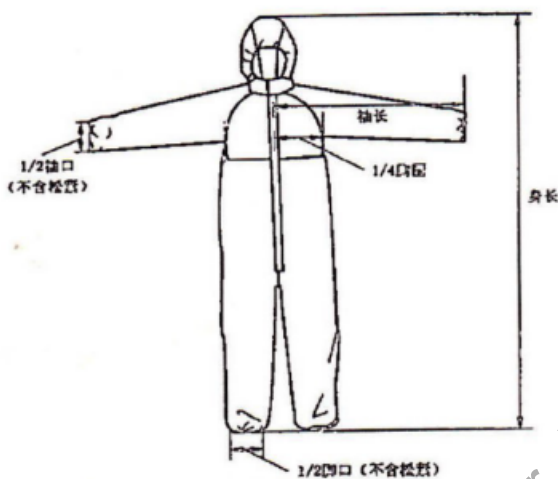
2.1.1 Emergency medical protective suit should be dry, clean and free from any mold spot. No such defects as adhesion, crack, and hole are allowed on the surface.

2.1.2 Joints on the protective suit may adopt a variety of processing ways such as sewing, adhesion and heat sealing. Stitch gap should be sealed. Stitch length should be 8-14 stitches within every 3cm. Needle tracking should remain uniform, level and straight without a skipping stitch. Those adhered or thermal sealed parts should remain flat and sealed without any air bubble.

2.1.3 Zipper on protective suit shouldn't be exposed and its puller should be of self-locking type if any.

2.2 Structure

2.2.1 Protective suit consists of a hoodie and a pair of trousers. It is of overall style as shown in Fig. 1.



1/2 Cuff opening (exclusive of elastic cord)

Sleeve length

Height

1/2 ankle opening (exclusive of elastic cord)

Fig. 1 Overall-structured Protective Suit

2.2.2 The protective suit should have a reasonable structure so that it is convenient to be put on and off. Joints should remain tight.

2.2.3 Cuffs and ankle openings should be flexibly tightened, while hat's facial part and waist should be tightened with flexibility, cord pull or buckle.

2.3 Specifications

The protective suit is divided into three sizes, namely large, middle and small. As for detailed specifications, see Table 1.

Table 1 Specifications

Unit: cm

Size	Height	Chest circumference	Sleeve length	Cuff opening	Ankle opening
Large	200	152	89	24	33
Middle	190	140	86	22	31
Small	180	132	83	20	29
Deviation	±5	±5	±5	±5	±5

2.4 Fluid resistance

2.4.1 Waterproof property

Hydrostatic pressure at key parts of protective suit shouldn't be lower than 1.67kPa (17cmH₂O).

2.4.2 Water vapor transmission (WVT)

Protective suit's WVT should be no lower than 2,500g/(m² d)

2.4.3 Anti-synthetic-blood permeability

Protective suit's anti-synthetic-blood permeability should be no inferior to Level 2 in Table 2.

Table 2 Anti-synthetic-blood permeability levels

Level	Intensity of Pressure kPa
6	20
5	14
4	7
3	3.5
2	1.75
1	0 ^a

^a It means pressure applied to the material is equal to that generated by synthetic blood within test flume.

2.4.4 Surface moisture resistance

Lateral surface of protective suit should meet Level 3 spray requirements for the minimum.

2.5 Breaking strength

Break strength of key parts of protective suit should be no lower than 45N.

2.6 Elongation at break

Elongation at break of key parts of protective suit should be no lower than 15%.

2.7 Filter efficiency

Materials and joints at key parts of protective suit should be able to filter at least 70% of non-oily particles.

2.8 Antistatic property

Electric charge of protective suit should be no higher than 0.6 μ C/piece.

2.9 Electrostatic attenuation performance

Protective suit's electrostatic attenuation shouldn't exceed 0.5s.

2.10 Microbiological indicators

The protective suit must comply with corresponding microbial indicators in GB15979-2002 (see Table 3)

Table 3

Total bacterial colonies CFU/g	Coliform	Pseudomonas aeruginosa	Staphylococcus aureus	Hemolytic streptococcus	Total fungal colonies CFU/g
≤ 200	None	None	None	None	≤ 100

3. Ways of test

3.1 Appearance

3.1.1 Visual check: refer to 2.1.1

3.1.2 Visual check: stitch length measured with general tool should comply with 2.1.2.

3.1.3 Each sample of protective suit should be zippered on and off for 5 times and altogether 3 pieces should be tested. Results should be consistent with 2.1.3.

3.2 Structure

Visual check: refer to 2.2

3.3 Specifications

General tool should be used to measure 3 samples of each size. Results should be consistent with 2.3.

3.4 Fluid resistance

3.4.1 Waterproof property

Collect samples from key parts of protective suit and conduct hydrostatic test according to GB/T4744. Results should be consistent with 2.4.1.

3.4.2 WVT

Protective suit should be tested according to Approach A moisture absorption in GB/T12704. Results should be consistent with 2.4.2.

3.4.3 Anti-synthetic-blood permeability

Test the protective suit in accordance with Annex A to GB 19082. Results should be consistent with 2.4.3

3.4.4 Surface moisture resistance

Perform spray test on lateral surface of protective suit as specified in GB/T4745. Results should be consistent with 2.4.4.

3.5 Breaking strength

Test materials of key parts from protective suit according to strip method specified in GB/T3923.1. Results should be consistent with 2.5.

3.6 Elongation at break

Test materials of key parts from protective suit according to strip method specified in GB/T3923.1. Results should be consistent with 2.6.

3.7 Filter efficiency

At least 3 protective suit samples should undergo the test. Results should be consistent with 2.7. The test should be carried out with sodium chloride aerosol or equivalent solid aerosol [count mean diameter (CMD): $0.075\mu\text{m}\pm 0.020\mu\text{m}$; geometric standard deviation of particle distribution: ≤ 1.86 ; concentration: $\leq 200\text{mg}/\text{m}^3$] in an environment with relative humidity of $30\pm 10\%$ and temperature of $25\pm 5^\circ\text{C}$. Airflow rate is set to be $15\text{L}/\text{min}\pm 2\text{L}/\text{min}$ and cross section where air flows through to be 100cm^2 .

3.8 Antistatic property

Carry out test in accordance with 7.2 in GB/T12703. Results should be consistent with 2.8.

3.9 Electrostatic attenuation performance

3.9.1 Test environment

Before being tested, the sample is left in the environment with relative humidity of $50\pm 3\%$ and temperature of $23\pm 1^\circ\text{C}$, for 24h. The test process adopts same conditions.

3.9.2 Sampling

Collect one $89\text{mm}\times(152\pm 6)\text{mm}$ sample from each key part of the protective suit. Wear latex or cotton-weaved gloves during sampling process to prevent causing pollution to sample surface.

3.9.3 Test

Fix first the test samples onto an electrostatic attenuation instrument that can generate $\pm 5000\text{V}$ at least as specified in IST40.2(01); then apply 5000V voltage to the materials; measure the time for charge to attenuate. The attenuation time for 5 test samples should comply with 2.9.

3.10 Microbiological indicators

Perform test on protective suit samples as specified in Annex B to GB 15979. Results should be consistent with 2.10.1.

4. Terminology

None

Annex 1 Normative References and Notes

Following documents constitute an inseparable part for the document when being referred to. For dated references, only dated editions apply to the document; while for undated ones, their latest editions (including all revisions) apply.

GB/T 2828.1-2012 *Sampling procedure for inspection by attribute-Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

GB/T 4744-2013 *Textiles — Testing and evaluation for water resistance — Hydrostatic pressure method*

GB/T 4745-2012 *Textiles - Testing and evaluation for water resistance - Spray test method*

GB/T 9969-2008 *General principles for preparation of instructions for use of industrial products*

GB/T 12704.1-2009 *Textiles - Test method for water-vapor transmission of fabrics - Part 1: Desiccant method*

GB/T 15979-2002 *Hygienic STANDARD for disposable sanitary products*

GB/T 19082-2009 *Technical requirements for single-use protective clothing for medical use*

GB/T 3923.1-2013 *Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using the strip method*

YY/T 0466.1-2016 *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements*

FZ/T 64005-2011 *Sanitary thin nonwoven*

<PE Fabric Test Report>



Test Report (e-version)

Anti-counterfeiting website: www.gttc.net.cn

Security code: XGOR-0493-34



No. 200019288

Page 1 of 3

Entrusting unit	Wujiang Tutaik Textile & Finishing Co., Ltd Address: No. 1599 South 3 rd Circle Road, Shengze Town, Wujiang		
Client-confirmed information	Disposable protective suit's fabric 3m Color: white Manufacturer: Wujiang Tutaik Textile & Finishing Co., Ltd		
Nature of inspection	Entrusted test	Sample accepted/tested on	Feb 18, 2020 Report issued on Feb. 22, 2020
Judgment basis	GB 19082-2009 <i>Technical requirements for single-use protective clothing for medical use</i>		
Comprehensive inspection conclusions	---		
Inspection and test results	Test item	Judgment basis	Judgment
	Waterproof property	GB 19082-2009	Conforming
	Surface moisture resistance	GB 19082-2009	Conforming
	Breaking strength	GB 19082-2009	Conforming
	Elongation at break	GB 19082-2009	Conforming
	Electrostatic attenuation performance	GB 19082-2009	Conforming
	Anti-synthetic-blood permeability	GB 19082-2009	Conforming
	Filter efficiency	GB 19082-2009	Conforming
	WVT	GB 19082-2009	Conforming
Remark	All test items in this report are carried out in the ambient conditions as specified accordingly (unless otherwise noted). Copies and duplicates without bearing report confirming seal shall all be viewed as invalid. The test address is No. 1 Zhujiang Road, Fanyu District, Guangzhou.		

Issued by: Engineer Fang Ming (signed)

Headquarter: No. 1 Zhujiang Road, Fanyu District, Guangzhou Tel: 020-61994598/61994599
Huadu Lab: No. 1 Hebin West Road, Qiling, Shiling Township, Huadu District, Guangzhou Tel: 020-37721161

Sample Photos (e-version)

No, 200019288

Page 2 of 3



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Sheet Attached to Test Report (e-version)

No. 200019288

Page 3 of 3

Test item (unit of measure) [Sample identification]	Way of test	Standard value and allowance	Test result	Judgment	Remark
● Water permeability	GB/T 4744-1997 Supercharge method Water temperature: 20.0°C Touch the surface with face down	≥ 1.67	1# 26.0 2# 25.6 3# 25.8 4# 27.0 5# 26.2 Average: 26.2	Conforming	
● Surface moisture resistance (level)	GB/T 4745-1997	≥ 3	1# 4 2# 4 3# 4	Conforming	
● Breaking strength	GB/T 3923.1-1997 Clamping distance: 100mm Speed: 100mm/min	Longitudinal: ≥ 45N Crosswise: ≥ 45N	Longitudinal: 123N Crosswise: 59 N	Conforming	
● Elongation at break	GB/T 3923.1-1997 Clamping distance: 100mm Speed: 100mm/min	Longitudinal: ≥ 15% Crosswise: ≥ 15%	Longitudinal: 93% Crosswise: 99%	Conforming	
● Electrostatic attenuation performance (s)	GB/T 19082-2009 5.10 Temperature: 23.0°C Relative humidity: 50.1% Applied voltage: ±5000V	≤ 0.5	Max. 0.01	Conforming	
● Anti-synthetic blood permeability (level)	GB/T 19082-2009 Annex A Synthetic blood surface tension: 0.042N/m	≥ 2	6	Conforming	
● Filter efficiency (%)	GB 19082-2009 5.7 Airflow rate: 15L/min Aerosol particles: NaCl Aerosol concentration: 15mg/m ³ Temperature: 23.0°C Relative humidity: 35.6%	≥ 70	Min. 100	Conforming	
● WVT (g/m ²) d)	GB/T 12704-1991 Test case environment: 38.0°C, 90.0% Moisture-absorbing time: 1h Method: moisture absorption method	≥ 2500	4790	Conforming	
Remark	(The column is intentionally left blank)				

---End of Report---

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Huadu Lab: No. 1 Hebin West Road, Qiling, Shiling Township, Huadu District, Guangzhou Tel:
020-37721161

<PTFE Fabric Test Report>

Test Report (e-version)

Anti-counterfeiting website: www.gttc.net.cn

Security code: LACF-2926-34



No. 200008593

Page 1 of 3

Entrusting unit	Wujiang Tutaik Textile & Finishing Co., Ltd Address: No. 1599 South 3 rd Circle Road, Shengze Town, Wujiang				
Client-confirmed information	Disposal protective suit fabric for medical use 1000cm x 150cm Color: white Unit weight: 92g/m ²				
Nature of inspection	Entrusted test	Sample accepted/tested on	Feb 6, 2020	Report issued on	Feb. 7, 2020
Judgment basis	GB 19082-2009 <i>Technical requirements for single-use protective clothing for medical use</i> , as required by the client				
Comprehensive inspection conclusions	---				
Inspection and test results	Test item		Judgment basis	Judgment	
	WVT		GB 19082-2009	Conforming	
	Water permeability		GB 19082-2009	Conforming	
	Surface moisture resistance		GB 19082-2009	Conforming	
	Mass per unit		As required by the client	Conforming	
	Breaking strength		GB 19082-2009	Conforming	
	Anti-synthetic-blood permeability		GB 19082-2009	Conforming	
	Filter efficiency		GB 19082-2009	Conforming	
Remark	All test items in this report are carried out in the ambient conditions as specified accordingly (unless otherwise noted). Copies and duplicates without bearing report confirming seal shall all be viewed as invalid. The test address is No. 1 Zhujiang Road, Fanyu District, Guangzhou.				

Issued by: Engineer HU Wanli (signed)

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Huadu Lab: No. 1 Hebin West Road, Qiling, Shiling Township, Huadu District, Guangzhou Tel: 020-37721161

Sheet Attached to Test Report (e-version)

No. 200008593

Page 3 of 3

Test item (unit of measure) [Sample identification]	Way of test	Standard value and allowance	Test result	Judgment	Remark
● WVT	GB/T 12704-1991 Method A: moisture absorption method Test case environment: 38.0°C, 90.0%	≥2500	8240	Conforming	
● Water permeability (kPa)	GB/T 4744-1997 Supercharge method: 6.0kPa/min Water temperature: 20.0°C Touch the surface with face down	≥1.67	1# 127.3 2# 119.8 3# 131.4 4# 125.6 5# 139.4 Average: 128.8	Conforming	
● Surface moisture resistance (level)	GB/T 4745-1997	≥3	1# 4 2# 4 3# 4	Conforming	
● Mass per unit (g/m ²)	GB/T 24218.1-2009	92±5% (as required by the client)	96.10	Conforming	
● Breaking strength	GB/T 3923.1-1997 Strip method Sample width: 50mm Clamping distance: 200mm Speed: 100mm/min	Warp-wise ≥45N Broad-wise ≥45N	Warp-wise 590N Broad-wise 408N	Conforming	
● Anti-synthetic blood permeability (level)	GB/T 19082-2009 Annex A Synthetic blood surface tension: 0.042N/m	≥2	6	Conforming	
● Filter efficiency (%)	GB 19082-2009 Airflow rate: 1.5L/min Aerosol particles: NaCl Aerosol concentration: 15mg/m ³ Temperature: 24.0°C Relative humidity: 38.0%	≥70	Min. 100	Conforming	
Remark	(The column is intentionally left blank)				

---End of Report---

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<System Document Certificate>

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POSTFACH 2156
8002 ZÜRICH, SWITZERLAND

OEKO-TEX®
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CERTIFICATE

The company

Wujiang Tutaike Textiles & Finishing Co., Ltd.
No. 1599 South 3rd Ring Road, Shengze Town
Wujiang, Jiangsu,
China

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report **SH050 157495.2**

for the following articles:

Commission coating and laminating:
Woven fabrics made of 100% polyester or 100% polyamide, with transparent and white PU coating; 100% polyester woven fabric laminate with transparent TPU film and 100% polyester knitted polar fleece fabric

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Annex 4, **product class I** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Annex 4 for baby articles.

The certified articles fulfil requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA, with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use the STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

The certificate SH050 127861 is valid until 15.06.2020

Zurich, 11.10.2019

Matz Bachmann
Matz Bachmann
Managing Director

Mary Rose Egloff
Mary Rose Egloff
Customer Service Ecology Manager

OEKO-TEX® Association | Genferstrasse 23 | P.O. Box 2006 | CH-8027 Zurich

INGER CERTIFICATION ASSESSMENT SERVICES

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管理体系认证证书

认证编号: 117 18 QU 0119-11 ROM

兹证明 **吴江市涂泰克纺织后整理有限公司**
统一社会信用代码 **913205097307153151**

注册地址 **江苏省苏州市吴江区盛泽镇南环路**
审核地址 **江苏省苏州市吴江区盛泽镇南三环 1599 号**

经现场评审满足: **GB/T19001-2016/ISO9001:2015 质量管理体系要求**

认证范围 **纺织品 (机织布) 涂层的加工**

核准: *[Signature]*

初次发证: 2018 年 11 月 09 日
有效期至: 2021 年 11 月 08 日

上海英格尔认证有限公司
国家认监委批准号: CNCA-R-2003-117
电话: 400-182-9001 / 86 21-51147000
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ENVIRONMENT MANAGEMENT SYSTEM CERTIFICATE

Registration Number: 04819E40252R0M

This is to certify that

Unified Social Credit Code:913205097307153151

WUJIANG TUTAIKE TEXTILE FINISHING CO.,LTD.

Registered Address:South ring road, shengze town
Production/Business Address:No.1599 south third ring road, shengze town, wujiang district, suzhou city, jiangsu province

has implemented an environment management system for compliance with this standard:

GB/T24001-2016 / ISO14001:2015

The environment management system for the following scope:

Processing and related management activities of textiles (woven cloth) coating.

Valid date: 2019-08-27 — 2022-08-26
Issued date: 2019-08-27

Signed By: *[Signature]*

2020-08 First Stock
2021-08 Second Stock

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OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEM CERTIFICATE

Registration Number: 04819S20221R0M

This is to certify that

Unified Social Credit Code:913205097307153151

WUJIANG TUTAIKE TEXTILE FINISHING CO.,LTD.

Registered Address:South ring road, shengze town
Production/Business Address:No.1599 south third ring road, shengze town, wujiang district, suzhou city, jiangsu province

has implemented an occupational health & safety management system for compliance with this standard:

GB/T28001-2011 / OHSAS18001:2007

The occupational health & safety management system for the following scope:

Processing and related management activities of textiles (woven cloth) coating.

Valid date: 2019-08-27 — 2021-03-11
Issued date: 2019-08-27

Signed By: *[Signature]*

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TTK® Protective suit manufacturing originates from raw material end. The whole production process, from antibacterial PE membrane to SSS nonwoven fabric, is completely under independent control with intra-company equipment so as to maximize quality, delivery term and high cost performance.

