Business License

(Duplicate) No: 1-1

Uniform Social Credit Code

91350300775361020 8

Scan QR code.
Login National Enterprise Credit Information Publicity System for more information on registration, filing, licensing and supervision.

Name:	PUTIAN JINLI.LAISI CLOTHTING & ACCESSORIES CO., LTD	**Registered Capital:**	USD 3,600,000,000,000
Type:	Limited Liability Company (HK, Macau& Taiwan Legal Person Sole Proprietorship)	**Date of Set-up:**	22 June. 2005
egal Representative:	YuShan Wu	**Business Term:**	From 22 June.2005 to 21 June 2055
Business Scope	Clothing manufacturing, processing, marketing, washing; Category I medical devices, category II medical devices, category III medical devices, protective equipment, sanitary supplies, medical supplies, labor protection supplies, medical equipment, disinfection supplies (excluding hazardous chemicals), the disabled supplies sales; Import and export of goods or technologies (except those prohibited by the state or involving administrative approval). [for the purpose of pre-approval, business activities are only allowed within the scope and period of validity of the approval] (for projects subject to approval according to law, business activities can only be carried out after the approval of relevant departments)	**Address:**	Fengshan Village, Huangshi Industrial Park, Licheng District, Putian City (address: the second floor of the Huangshi Town People's Government Office Building)

(Seal: Putian Market Supervision and Administration)

Issued By (Seal)

28 February, 2020

National Enterprise Credit Information Publicity System: http:// www.gsxt.gov.cn

Annual report shall be submitted Via National Enterprise Credit Information Publicity System during Jan 1 to Jun 30 every year

Supervised by State Administration for Market Regulation

Identity Card of Legal Representative

Front side

Back side

莆田市金利莱斯服饰织造有限公司

PUTIAN JINLI.LAISI CLOTHTING & ACCESSORIES CO., LTD

Account Opening License

Grant No. J3940000714203 **Serial No.** 3910 - 00875331

Through examination, PUTIAN JINLI.LAISI CLOTHTING & ACCESSORIES CO., LTD **complies with the requirements for account opening. Herein let it open a basic deposit account.**

Legal representative (responsible by): YuShan Wu **Bank Name** Branch of China Construction Bank Co., Ltd in Licheng, Putian

Account Number: 35001636207059855555

Issuing Authority(seal)

28 Dec. 2011

(Seal: Branch of China Construction Bank Co., Ltd in Licheng,Putian)

莆田市金利莱斯服饰织造有限公司

PUTIAN JINLI.LAISI CLOTHTING & ACCESSORIES CO., LTD

Temporary Registration Certificate and Production License

Item	Registration certificate	Production License
Protective Clothing	Fujian Medical Products Administration Registration Permit 20202140139 (Temporary) Application	No. 20200488 (Temporary) Application of Fujian Medical Products Administration Production License
Mask	Fujian Medical Products Administration Registration Permit 20202140140 (Temporary) Application	

莆田市金利莱斯服饰织造有限公司
PUTIAN JINLI.LAISI CLOTHTING & ACCESSORIES CO., LTD

The Government Approval of change the line of production

莆田市荔城区人民政府

荔政函〔2020〕9号

莆田市荔城区人民政府关于
商请支持荔城转产企业办理手续事宜的函

省药品监督管理局：

为全面强化疫情防控应急物资保障，我区莆田市金利莱斯服饰织造有限公司积极响应号召，发挥企业设备、技术等优势，克服困难，转型生产疫情防控医疗紧缺物资防护服、口罩。现恳请贵局对该公司转型生产医用防护服、口罩的生产许可和产品检验给予支持办理。

特此函商，恳请支持为盼。

莆田市荔城区人民政府

2020年2月17日

The information given above is true and correct.
17 Feb.
(Seal: Putian People's Government)

People's Government of Licheng district, Putian city
17 Feb. 2020
(Seal: People's Government of Licheng district, Putian city)

People's Government of Licheng district, Putian city

No. 9 (2020) Government Official Letter of Licheng district

Official Letter from People's Government of Licheng district，Putian City, on the business request to support Licheng district enterprises in handling the formalities

Fujian Medical Products Administration:

In order to comprehensively strengthen the emergency supplies for the prevention and control of the epidemic, Putian JINLI.LAISI Clothing & Accessories Company in our district has actively called on. The company makes full use of its advantages in equipment and technology to overcome difficulties and transform to produce protective clothing and masks for medical supplies in short supply. Now I sincerely request you to support the production license and product inspection of the company's transformation into the production of medical protective clothing and masks.

With words deliberate, hope for your support!

Product Name: KN95 Mask.

Implementation of technical standards: GB2626-2006.

1.Product picture:

The product consists of mask body, nose clip and mask belt. The mask body is divided into three layers: inner layer, middle layer and outer layer. The inner layer is polypropylene hot-rolled non-woven fabric, the middle layer is polypropylene melt-sprayed non-woven fabric, and the outer layer is polypropylene spinning sticky non-woven fabrics. It is made by ultrasonic heat bonding, spot welding and upper strip.

莆田市金利莱斯服饰织造有限公司
PUTIAN JINLI.LAISI CLOTHTING & ACCESSORIES CO., LTD

The purpose of this mask:

It is used to cover the user's mouth, nose and jaw.

It is not recommended to use in oily media.

Certificate of Qualification	
Trademark:	JINLI.LAISI
Product Name:	Mask
Type/Specification：	KN95
Production License：	No. 20200488 (Temporary) Application of Fujian Medical Products Administration Production License
Registration certificate：	Fujian Medical Products Administration Registration Permit 20202140140 (Temporary) Application
Implementation of standards：	GB2626-2006
Grade:	Qualified products
Instruction：	Respiratory protection for non-oily particulate matter. Contamination damage and other conditions require replacement of a new mask.
The date of production：	25 Feb.2020
Inspector：	02
Production enterprise:	Putian Jinli.laisi Clothing & Accessories CO., LTD
Production address:	Huangshi Industrial Park, Licheng District, Putian City
Tel:	0594-7560966
CN-EN	14683:2014

Packing Standard： Two per small bag

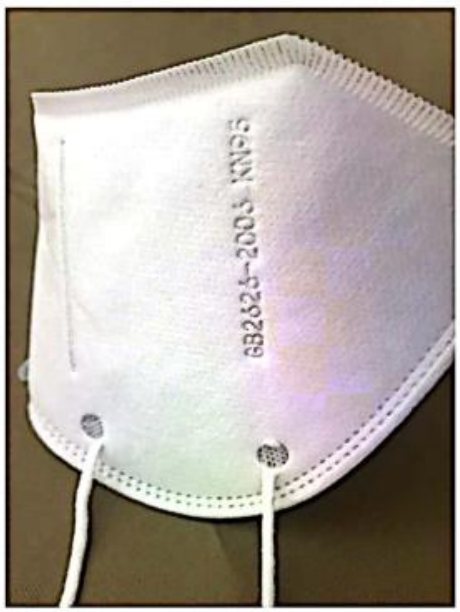
Carton Size: 700MM*40MM*300MM

Pieces Per Carton： 1000 pieces

Gross Weight： 7.3kg

Net Weight： 6.3kg


GB2626-2006 KN95


GB2626-2006 KN95

莆田市金利莱斯服饰织造有限公司

PUTIAN JINLI.LAISI CLOTHTING & ACCESSORIES CO., LTD

Certificate of Qualification

Product Name： KN95 Mask

Specification： 2 pieces per bag （ folded form）

Product Composition：

The inner and outer layers of the mask are made of spinning sticky non-woven fabric, and the middle layer is made of melt-sprayed non-woven fabric and hot air-filter cotton.

The Date of Production: 03 Mar. 2020

Inspection Date: 03 Mar. 2020

Inspector: 02

Production Enterprise: Putian Jinli.laisi Clothing & Accessories CO., LTD

Production Address: Huangshi Industrial Park, Licheng District, Putian City

莆田市金利莱斯服饰织造有限公司

PUTIAN JINLI.LAISI CLOTHTING & ACCESSORIES CO., LTD

CERTIFICATE OF CONFORMITY

Certificate No.: VIC200309-CJLL-3994

The Certification Body of

VIC TESTING AND CERTIFICATION LTD

Certifies that

Applicant:	PUTIAN JINLI.LAISI CLOTHING & ACCESSORIES CO., LTD. Add: FENGSHAN VILLAGE, HUANGSHI INDUSTRIAL PARK, LICHENG DISTRICT, PUTIAN CITY
Manufacturer:	PUTIAN JINLI.LAISI CLOTHING & ACCESSORIES CO., LTD. Add: FENGSHAN VILLAGE, HUANGSHI INDUSTRIAL PARK, LICHENG DISTRICT, PUTIAN CITY
Product:	Medical mask
Model No.:	KN95 mask, Medical disposable mask, Medical disposable surgical mask
Report No.:	DN20200309-FJLL17-CE-S

Complies with the requirements of the **Medical devices Directive 93/42/EEC (MDD)** . The submitted products have been tested by us and found in compliance with the following European Standards:

EN 14683:2014

This certificate of conformity is based on an evaluation of a sample of the above mentioned products. It does not imply an assessment of the whole production. The CE marking as shown below can be affixed on the product after preparation of necessary technical documentation.

Signature: Steven White

Steven White

Date of issue: Mar. 09, 2020

Expiry Date: Mar. 08, 2025

VIC TESTING AND CERTIFICATION LTD

Add: CHASE BUSINESS CENTRE (CHD) 39-41 CHASE SIDE LONDON, N14 5BP, U.K

Email: Info@victesting.com Website: www.victesting.com

CE

EU Declaration of Conformity

(No.: CJLL20200309-1)

We,

PUTIAN JINLI.LAISI CLOTHING & ACCESSORIES CO,.LTD.

Address: FENGSHAN VILLAGE, HUANGSHI INDUSTRIAL PARK, LICHENG DISTRICT, PUTIAN CITY

as the manufacturer declare under our sole responsibility that the product

Product: Medical mask
Model No.: KN95 mask, Medical disposable mask, Medical disposable surgical mask

to which this declaration relates is in compliance with **Medical devices Directive 93/42/EEC (MDD)** and comply with the standards listed below:

EN 14683:2014

Signature: _____

Function: manager

Place of issue : Putian, China

Date of issue : 2020-03-09

Test Report

Report No.:	**DN20200309-FJLL17-CE-S**
Applicant:	**PUTIAN JINLI.LAISI CLOTHING & ACCESSORIES CO., LTD.**
Product:	**Medical mask**
Standard(s):	**EN 14683:2014**

VIC TESTING AND CERTIFICATION LTD

VIC TESTING AND CERTIFICATION LTD

TEST REPORT
EN 14683:2014
Medical face masks
Requirements and test methods

Report Number..... :	DN20200309-FJLL17-CE-S
Tested by (name + signature)..... :	Peter Chen
Approved by (+ signature)..... :	David Zhang
Date of issue..... :	2020-03-09
Total number of pages..... :	17
Name of Testing Laboratory preparing the Report..... :	VIC TESTING AND CERTIFICATION LTD
Address..... :	CHASE BUSINESS CENTRE (CHD) 39-41 CHASE SIDE LONDON, N14 5BP, U.K
Applicant's name..... :	PUTIAN JINLI.LAISI CLOTHING & ACCESSORIES CO., LTD.
Address..... :	FENGSHAN VILLAGE, HUANGSHI INDUSTRIAL PARK, LICHENG DISTRICT, PUTIAN CITY
Manufacturer's name..... :	PUTIAN JINLI.LAISI CLOTHING & ACCESSORIES CO., LTD
Address..... :	FENGSHAN VILLAGE, HUANGSHI INDUSTRIAL PARK, LICHENG DISTRICT, PUTIAN CITY
Test specification:	
Standard..... :	EN 14683:2014
Test procedure..... :	CE
Non-standard test method..... :	-
Test item description..... :	Medical mask
Trade Mark..... :	-
Model/Type reference..... :	KN95 mask Medical disposable mask Medical disposable surgical mask

The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the Laboratory, responsible for this Test Report.

VIC TESTING AND CERTIFICATION LTD

Summary of testing:

Tests performed (name of test and test clause):

Full tests of the following standard:

- EN 14683:2014

The submitted samples were found to comply with the requirements of above standards.

Possible test case verdicts:

- test case does not apply to the test object.....: N/A

- test object does meet the requirement.....: P (Pass)

- test object does not meet the requirement.....: F (Fail)

Testing.....:

Date of receipt of test item.....: 2020-03-08

Date (s) of performance of tests.....: 2020-03-08 to 2020-03-09

General remarks:

Throughout this report a ☒ comma / ☐ point is used as the decimal separator.

General product information:

The product is intended to be used as medical face masks intended to limit the transmission of infective agents from staff to patients during surgicalprocedures and other medical settings with similar requirements..

VIC TESTING AND CERTIFICATION LTD

EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		P
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant.	☒Type I ☐Type II	P
5	**Requirements**		P
5.1	General		P
5.1.1	Materials and construction		P
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	Filter layer composed.	P
	The medical face mask shall not disintegrate, split or tear during intended use.	Not disintegrate, split or tear.	P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness (absence of particulate matter).	Cleanliness has been considered.	P
5.1.2	Design		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		P
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).		P
5.2	Performance requirements		P
5.2.1	All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.	Carried out on finished product.	P
5.2.2	Bacterial filtration efficiency (BFE)	Type I; ≥ 95 %	P
	When tested in accordance with Annex B, the bacterial filtration efficiency (BFE) of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	BFE was tested in accordance with Annex B.	P
5.2.3	Breathability	< 29,4 Pa/cm²	P
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	Breathability was tested in accordance with Annex C.	P
5.2.4	Splash resistance	Not required.	N/A

VIC TESTING AND CERTIFICATION LTD

EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
	When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		N/A
5.2.5	Microbial cleanliness (Bioburden)	≤ 30 cfu/g	P
	When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested.	Bioburden was tested according to EN ISO 11737-1.	P
	EN ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation of the population of viable microorganisms on or in a medical device, component, raw material or package.		P
	To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below:		P
	•..... The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.	5 specimens	P
	Weigh each mask prior testing.	Weights were recorded.	P
	The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl & 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]).	Extraction liquid: 300 ml.	P
	The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.	Shaken: 250 rpm.	P
	After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µ filter and laid down on a TSA plate for the total viable aerobic microbial count.	Filter: 0,45 µ	P
	Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration.		P
	The plates are incubated for 3 days at 30 °C and 7 days at (20 – 25) °C for TSA and SDA plates respectively.	30 °C: 3 days; 20 °C– 25 °C: 7 days.	P
	The total bioburden is expressed by addition of the TSA and SDA counts.		P
	In the report, indicate the total bioburden per mask and based on the mask weigh, the total bioburden per gram tested.		P
5.2.6	Biocompatibility	In accordance with EN ISO 10993-1.	P
	According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact.		P

VIC TESTING AND CERTIFICATION LTD

EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine the applicable toxicology testing regime.	In accordance with EN ISO 10993-1.	P
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		P
	The test results shall be available upon request.		P
	As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered. 5.2.7 Summary of performance requirements		P
5.2.7	Summary of performance requirements	a Bacterial filtration efficiency (BFE): ≥ 95%; b Differential pressure: < 29,4 Pa/cm²; c Splash resistance pressure: Not required; d Microbial cleanliness: ≤ 30 cfu/g.	P

Table 1 - Performance requirements for medical face masks			
Test	Type I[a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm²)	< 29,4	< 29,4	< 49,0
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.
Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

6	**Labelling and information to be supplied**		P
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) specifies the information that has to be specified on the packaging in which the medical face mask is supplied.		P
	The following information shall be supplied in addition:		P
	a).... umber of this European Standard;	EN 14683:2014	P
	b).... type of mask (as indicated in Table 1).	Type I	P
	EN ISO 15223-1 and EN 1041 should be considered.		P

VIC TESTING AND CERTIFICATION LTD

EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
A	**Information for users**		P
	When breathing, speaking, coughing, sneezing etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose.		P
	The majority of the nuclei are between 0,5 µm and 12 µm in diameter and especially the larger droplets can contain micro-organisms from the source site.	Nuclei: 0,5 µm - 12 µm.	P
	Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.		P
	The medical face masks intended to be used in operating rooms and health care settings with similar requirements are designed to protect the entire working environment.	It was designed to protect the entire working environment.	P
	This standard describes two types of medical face masks with associated protection levels.	Type I medical face mask.	P
	As a minimum, Type I medical face masks are used for patients in order to reduce the risk of the spread of infections, particularly in epidemic or pandemic situations.		P
	Type II masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements.	Type I medical face mask.	N/A
	A special case, also covered by the European Medical Devices legislation, is that in which the wearer wishes to protect him/herself against splashes of potentially contaminated fluids and particles that are created in the surgical environment, e.g. by the use of electro-cautery devices.		P
	If the intended use of the mask is to protect the wearer against infective agents (bacteria, viruses or fungi), the use of a respirator device should be considered.		N/A
	Performance requirements for respirators are the scope of EN 149.	In accordance with EN 149.	P
	The level of efficiency offered by a mask depends on a number of factors such as the filtration efficiency, quality of the material and the fit of the mask on the wearer's face.		P
	Different designs are suited for different applications and the careful choice of mask is therefore important in order to achieve the desired result.		P
	The filtration capacity of mask materials can vary depending on the filter media.		P

VIC TESTING AND CERTIFICATION LTD

EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
	The fit of masks varies considerably from those which are held in place by ear loops fastened behind the wearer's ears to those with tie bands around the head and a nose clamp that can be shaped to the wearer's nose.	Can be shaped to the wearer's nose.	P
	The effect of a very good or less good fit can be tested in vivo whereas the filtration efficiency may be reproducibly tested in vitro.	Effect can be tested in vivo.	P
	The considerable variations in results when masks are tested in vivo results in the need for large groups of test subjects and observations.	No any variations.	N/A
	It is thus usual to characterise mask performance using in vitro tests of the material from which the mask is made.		P
	It is, however, important to consider the fit of the mask carefully when a mask for a certain application is chosen. Users should request such information from their suppliers.		P
	A further factor to be considered is the capacity of the mask to absorb moisture from the exhaled air and thereby to maintain its performance over a longer period of time.		P
	The more advanced designs easily maintain their performance throughout even very long operations whereas the less advanced ones are intended only for short procedures.		P
	The contamination risk resulting from hand contact with a used mask means that it is essential that the mask is taken off and disposed of when no longer worn over nose and mouth.	No longer worn over nose and mouth.	P
	When there is a further need for protection then a new mask should be put on.	No further need for protection.	N/A
	Touching a used face mask or putting on a new one should always be followed by a full hand disinfection procedure and a used mask should always be disposed of when no longer needed or between two procedures.		P
	In summary, to use an appropriate mask is an effective means to protect the working environment from droplet contamination from nose and throat during health care procedures.		P
	Masks with very different performance are, however, available.	Without very different performance.	N/A
	Therefore such factors as infection risk and mask fit should be carefully considered when choosing a mask.		P

VIC TESTING AND CERTIFICATION LTD

EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
B	**Method for in-vitro determination of bacterial filtration efficiency (BFE)**		P
	WARNING:		P
	• Staphylococcus aureus is a pathogen.		P
	• The relevant national provisions by law and hygienic instructions when dealing with pathogens shall be complied with.		P
B.1	Principle		P
	A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber.		P
	An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum.		P
	The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.		P
B.2	Reagents and materials		P
B.2.1	General		P
	B.2.2 and B.2.3 describe commercially available solutions of tryptic soy agar and tryptic soy broth.		P
	Other variants may be suitable.		P
B.2.2	Tryptic soy agar		P
	Formula/liter:		P
	• Enzymatic digest of casein:	15 g	P
	• Enzymatic digest of soybean meal:	5 g	P
	• Sodium chloride:	5 g	P
	• Agar:	15 g	P
	• Final pH:	7,3 ± 0,2 at 25 °C	P
B.2.3	Tryptic soy broth		P
	Formula/liter		P
	• Enzymatic digest of casein:	17 g	P
	• Enzymatic digest of soybean meal:	3 g	P
	• Sodium chloride:	5 g	P
	• Dipotassium phosphate:	2,5 g	P
	• Dextrose:	2,5 g	P
	• Final pH:	7,3 ± 0,2 at 25 °C	P

VIC TESTING AND CERTIFICATION LTD

EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
B.2.4	Peptone water		P
	Formula/liter		P
	• ..... Peptone ..... :	10 g	P
	• ..... Sodium chloride ..... :	5 g	P
	• ..... Final pH ..... :	7,2 ± 0,2 at 25 °C	P
B.2.5	Culture of Staphylococcus aureus ATCC 6538, growing on tryptic soy agar slants		P
B.3	Apparatus		P
B.3.1	Six stage cascade impactor		P
B.3.2	Nebulizer, capable of delivering particles with a mean size of (3,0 ± 0,3) µm when in contact with the impactor	3,1 µm	P
B.3.3	Aerosol chamber, glass, 600 mm long and 80 mm in external diameter	Long: 600 mm; Diameter: 80 mm.	P
B.3.4	Flow meters, capable of measuring a flow rate of 28,3 l/min	Flow rate: 28,3 l/min.	P
B.3.5	Pressure gauge, capable of measuring a pressure of 35 kPa to an accuracy of ± 1 kPa	35 kPa	P
B.3.6	Erlenmeyer flasks, 250 ml and 500 ml capacity		P
B.3.7	Peristaltic or syringe pump, capable of delivering 0,01 ml/min	0,01 ml/min	P
B.3.8	Vacuum pump, capable of maintaining a flow rate of 57 l/min	Flow rate: 57 l/min.	P
B.4	Test specimens		P
	Test specimens shall be cut from complete masks.		P
	Each specimen shall be minimum 100 mm by 100 mm and shall include all layers of the mask in the order in which they are placed in the complete mask.		P
	The number of specimens that shall be tested is minimum 5 (five), but can be greater and shall be increased if necessary to allow for an AQL of 4 %.	5 specimens	P
	All specimens tested shall be taken from representative areas to incorporate all/any variation in construction.		P
	Unless otherwise specified, the testing shall be performed with the inside of the medical face mask in contact with the bacterial challenge.		P
	Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.		P

VIC TESTING AND CERTIFICATION LTD

EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
B.5	Preparation of bacterial challenge		P
	Staphylococcus aureus (see B.2.4) shall be inoculated into 30 ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at a temperature of (37 ± 2) °C for (24 ± 2) h.	37 °C for 24 h.	P
	The culture shall then be diluted in peptone water to give a concentration of approximately 5×10^5 cfu/ml.	5×10^5 cfu/ml	P
	The bacterial challenge shall be maintained at (2 200 ± 500) cfu per test.	2300 cfu	P
	The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see B.6.3) and the dilution of the challenge suspension adjusted accordingly.		P
	The mean particle size in the bacterial challenge shall be maintained at (3,0 ± 0,3) µm (see B.6.9).	3,1 µm	P
B.6 B.6.1	Procedure		P
	Assemble the apparatus in accordance with the flow chart shown in Figure B.1.		P
B.6.2	Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.		P
B.6.3	Perform a positive control run without a test specimen. Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28,3 l/min.	Flow rate: 28,3 l/min.	P
	Deliver the bacterial challenge for 1 min.		P
	Maintain the airflow through the impactor for 2 min.	2 min	P
	Then remove the plates from the impactor.		P
	Ensure that each plate is numbered to indicate its position in the impactor.		P
B.6.4	Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.		P
B.6.5	Repeat this procedure for each test specimen.		P
B.6.6	After the last test specimen has been tested, perform a further positive control run.		P
B.6.7	Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.	2 min	P
B.6.8	Incubate all the plates at (37 ± 2) °C for (48 ± 4) h.	37 °C for 48 h.	P

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EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
B.6.9	For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of cfu collected by the impactor using the "positive hole" conversion table1) in accordance with the instructions of the cascade impactor manufacturer (stages 3 to 6).		P
	For the two positive control runs, take the mean of the two totals.		P
	From the positive control plates calculate the mean particle size of the bacterial challenge aerosol using the "positive hole" conversion table in accordance with the instructions of the cascade impactor manufacturer.		P
B.7	Calculation of bacterial filtration efficiency		P
	For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the formula..... :	$B = (C - T) / C \times 100$ C is the mean of the total plate counts for the two positive control runs; T is the total plate count for the test specimen.	P
B.8	Test report	a number and date of this European Standard; b lot number or batch code of the masks tested; c dimensions of the test specimens and the size of the area tested; d which side of the test specimen was facing towards the challenge aerosol; e flow rate during testing; f mean of the total plate counts of the two positive controls; g mean plate count of the negative controls; h bacterial filtration efficiency for each test specimen.	P

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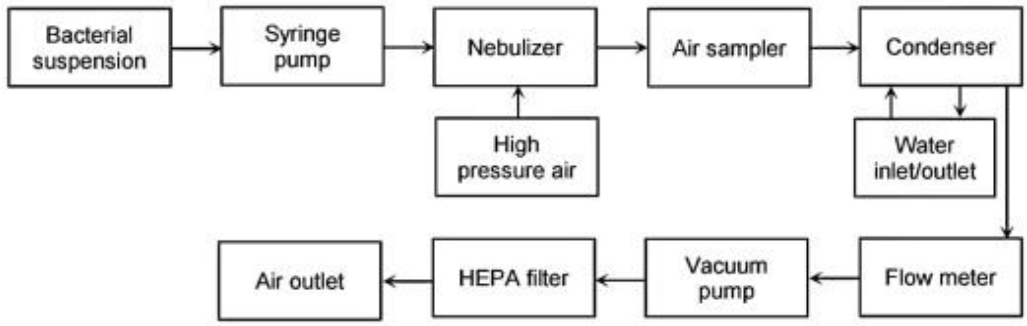
EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict

Principle of BFE test apparatus



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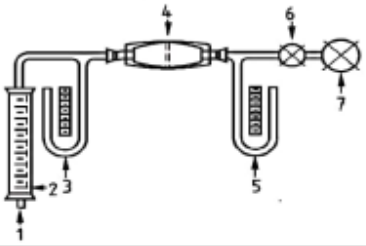
EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
C	**Method for determination of breathability (differential pressure)**		P
C.1	Principle		P
	A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure C.1. 		P
	Water-filled manometers (M1 and M2) are used to measure the differential pressure.		P
	A flow meter is used for measurement of the airflow.		P
	An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the airflow rate.		P
C.2	Apparatus		P
C.2.1	Flow meter, capable of measuring an airflow of 8 l/min	Airflow: 8 l/min.	P
C.2.2	Manometers, M1 and M2 or differential manometer		P
C.2.3	Electric vacuum pump		P
C.2.4	Valve		P
C.3	Test specimens		P
	Test specimens are complete masks or shall be cut from masks.	Complete mask.	P
	Each specimen shall be able to provide 5 different circular test areas of 2,5 cm in diameter.	Diameter: 2,5 cm	P
	If one specimen cannot provide 5 test areas of 2,5 cm in diameter, the number of test areas retrieved should be representative for the entire mask.	Diameter: 2,5 cm	P
	The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL of 4 %.	5 specimens	P
	All specimens tested shall be taken from areas representative from the mask to incorporate all/any variation in construction.		P

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EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
	Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.	(21 ± 2) °C; (85 ± 2) %	P
C.4	Procedure		P
C.4.1	The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm^2) and clamped into place so as to minimise air leaks and that the tested area of the specimen will be in line and across the flow of air.	Area: 4,9 cm^2	P
C.4.2	The pump is started and the flow of air adjusted to 8 l/min.		P
C.4.3	The manometers M1 and M2 are read and recorded.		P
C.4.4	The procedure described in steps C.4.1 through C.4.3 is carried out on 5 (or appropriate number of) different areas of the mask and the readings averaged.		P
C.5	Calculation of differential pressure		P
	For each test specimen calculate the differential pressure ΔP as.....:	ΔP = (Xm1 – Xm2)/4,9	P
C.6	Test report	a number and date of this European Standard; b lot number or batch code of the masks tested; c flow rate during testing; d differential pressure for each test specimen.	P

ZA	**Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices**		P
	This European Standard has been prepared under a mandate given to CEN by the European Commission Union to provide a means of conforming to the essential requirements of New Approach EU Directive 93/42/EEC concerning medical devices.		P
	Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.		P

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EN 14683:2014			
Clause	Requirement + Test	Result - Remark	Verdict
ZA.1	Correspondence between this European Standard and EU Directive 93/42/EEC concerning medical devices		P
	Clause/subclause of this European Standard; 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.2.3, 6.....:	Corresponding Essential Requirement of Directive 93/42/EEC: 8.1	P
	Clause/subclause of this European Standard; 5.2.2..... :	Corresponding Essential Requirement of Directive 93/42/EEC: 9.2	P
	Clause/subclause of this European Standard; 6....:	Corresponding Essential Requirement of Directive 93/42/EEC: 13	P
	WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.		P

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Photo document

Fig. 1 Overview

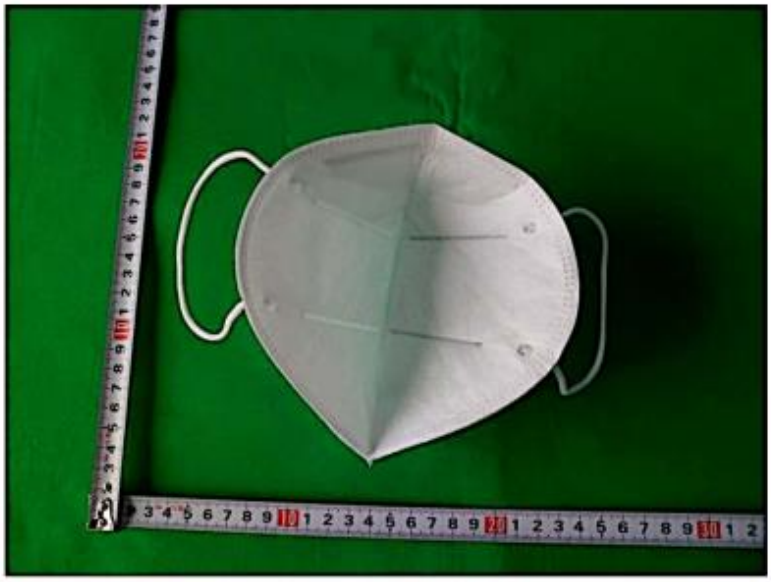

Fig. 2 Overview

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Photo document

Fig. 3 Overview

--- End of report ---

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Add：CHASE BUSINESS CENTRE (CHD) 39-41 CHASE SIDE LONDON, N14 5BP, U.K

VIC

佛山中纺联检验技术服务有限公司
CNTAC Testing Service Co.,Ltd.(Foshan)

Testing Report	Security website：www.fcl-sz.org.cn Security code：1232502503
Report No：ZFLJ2616849A	Page 1 of 4

Applicant Information

Applicant Name : JINLILAISI CLOTHING WEAVING CO, LTD
Applicant Address : Fengshan village, huangshi industrial park, licheng district, putian city, fujian province
Manufacturer : JINLILAISI CLOTHING WEAVING CO, LTD

Sample Information

Sample Description : KN95
Sample Quantity : 50 pieces

- Sample Receiving Date : 2020-04-26
- Report Date : 2020-04-30
- The original sample is sticked on the last paper.

Test Performed

Judgement according to:
GB 2626-2006 Respiratory protective equipment—— Non-powered air-purifying particle respirator .
- Selected test(s) as requested by applicants. For details, refer to attached page(s).

Pronounce

The results shown in this report refer only to sample(s) tested unless otherwise stated.
All the items are performed in the standard conditions, except the noted cases.
Except for the requirement of the client, the test results and the conformity judgement of this report do not take the uncertainty of the test results into account.

Signed for and on behalf of
CNTAC Testing Service Co.,Ltd.(Foshan)
Approved by

张志荣

佛山中纺联检验技术服务有限公司
CNTAC Testing Service Co.,Ltd.(Foshan)

Testing Report	Security website：www.fcl-sz.org.cn Security code：1232502503
Report No：ZFLJ2616849A	Page 2 of 4

--- Test Result ---

	Test Result	Requirements	Judgement
1. Filtration Efficiency[1] *GB 2626-2006 Section 6.3*[2]			
Air flow: 85L/min, Aerosol: NaCl			
Unit: <**%**>			
Before pretreatment		(KN95) ≥ 95.0	Pass
sample 1#	99.3		
sample 2#	99.7		
sample 3#	98.9		
sample 4#	99.0		
sample 5#	99.5		
sample 6#	99.6		
sample 7#	99.1		
sample 8#	98.2		
sample 9#	98.6		
sample 10#	97.6		
2. Head harness *GB 2626-2006 Section 6.11*			
Disposable mask with tensile force of 10N, lasting for 10s			
Result	No slippage or fracture	There should be no slippage or fracture	Pass
3. Exhalation Resistance[1] *GB 2626-2006 Section 6.6*[3]			
Air flow: 85 L/min			
Unit: <**Pa**>			
Before pretreatment		≤ 250	Pass
sample 1#	131.9		
sample 2#	128.3		
4. Inhalation Resistance[1] *GB 2626-2006 Section 6.5*[3]			
Air flow 85 L/min			
Unit: <**Pa**>			
Before pretreatment		≤ 350	Pass
sample 1#	147.0		
sample 2#	138.3		

佛山中纺联检验技术服务有限公司
CNTAC Testing Service Co.,Ltd.(Foshan)

Testing Report	Security website：www.fcl-sz.org.cn Security code：1232502503
Report No：ZFLJ2616849A	Page 3 of 4

	Test Result	Requirements	Judgement
5. Appearance Inspection *GB 2626-2006 Section 6.1~6.2*			
Result	Accordance	The surface should not be damaged, deformation and other obvious defects.	Pass
	Accordance	Component materials and structures shall be able to withstand normal operating conditions and possible temperature, humidity and mechanical shocks.	
	Accordance	Headband should be adjustable.	
	Accordance	After temperature and humidity pretreatment and mechanical strength pretreatment, components should not fall off, damage and deformation.	
6. Flammability *GB 2626-2006 Section 6.15*			
Unit: <s>			
Before pretreatment		After flame time ≤ 5	Pass
sample 1#	0		
sample 2#	0		

Remark：1. [1]=The client requires that only before pretreatment results be issued, And according to GB 2626-2006 standard.
2. [2]=This method is beyond the scope of CMA and CNAS accreditation and have no valid in law.
3. [3]=This method is beyond the scope of CNAS accreditation .

Testing Report	Security website：www.fcl-sz.org.cn Security code：1232502503
Report No：ZFLJ2616849A	Page 4 of 4

Original Sample

======= End of Report ======

Fiscal Year 2020

CERTIFICATE OF REGISTRATION

This Certifies that:

PUTIAN JINLI.LAISI CLOTHING & ACCESSORIES CO.,LTD
Address: Fengshan Village, Huangshi Industrial Park, Licheng District, Putian, Fujan, 351144, CHINA

Was registered with US Food & Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807. Such registration has been verified, with the registrant's authorization, by Ningbo Dano Youxin Testing Service Co Ltd

Registration Number: No Number Listed
Owner/Operator Number: 10063062

Listing Number	Product Code(s)	Device Name
D375220	LYU	ACCESSORY, SURGICAL APPAREL
D375221	OEA	Non-surgical isolation gown

Issued: March 16,2020 **Expiration Date: December 31,2020**

This Certificate affirms that Ningbo Dano Youxin Testing Service Co Ltd has verified that the above stated facility is registered with the US Food & Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807, on the date stated above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. Ningbo Dano Youxin Testing Service Co Ltd assume no liability to any person or entity in connection with the foregoing. Ningbo Dano Youxin Testing Service Co Ltd is a private registration agent and is not affiliated with the US Food and Drug Administration.

Ningbo Dano Youxin Testing Service Co Ltd DANO

Signature:

FDA website: www.fda.gov
Professional FDA Registration Services,by Ningbo Dano Youxin Testing Service Co Ltd
More details on the website: www.danotest.com Service hotline: 400-0088-852

Help (./help/index.html)

DRLM Home (mainMenu.htm) > Change Registration Information for a Facility

✔ Facility

✔ Products Listing

Update Registration Successful

Facility: PUTIAN JINLI.LAISI CLOTHING & ACCESSORIES CO.,LTD , Putian , Fujian, CHINA

The Owner/Operator Number for this Registration is: 10063062.

Facility Information

Registration Number:

Initial Importer:
N

Facility Name:
PUTIAN JINLI.LAISI CLOTHING & ACCESSORIES CO.,LTD

Address:
Fengshan Village,Huangshi Industrial Park,Licheng District,
Putian, Fujian, 351144, CHINA

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Owner/Operator Information

Owner/Operator Number:
10063062

Contact Name:
YuShan Wu

Company:
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Putian, FUJIAN, 351144, CHINA

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86 - 159 - 59890888

Fax:
-

E-mail: putianjl@eac-trcu.com

DUNS Number:

Official Correspondent Information

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YuShan Wu

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Putian, FUJIAN, 351144, CHINA

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Fax:
-

E-mail: putianjl@eac-trcu.com

DUNS Number:

United States Agent Information

Contact Name:
Tao Zhang

Contact Title:
Mr

Business Name:

Address: 3850 Coleman Rd , Apt 0613A
East Lansing, Michigan, 48823, UNITED STATES

Phone:
734 - 7308016

Fax:

DUNS Number:

E-mail: us.sec@sec-cert.com

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D375220	Exempt	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer	
D375221	Exempt	OEA	Non-surgical isolation gown	Manufacturer	

Date of Initial Registration: 2020-03-16 05:58:36.0