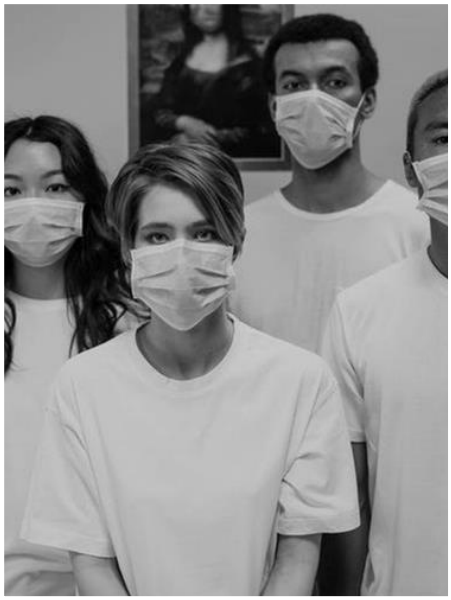
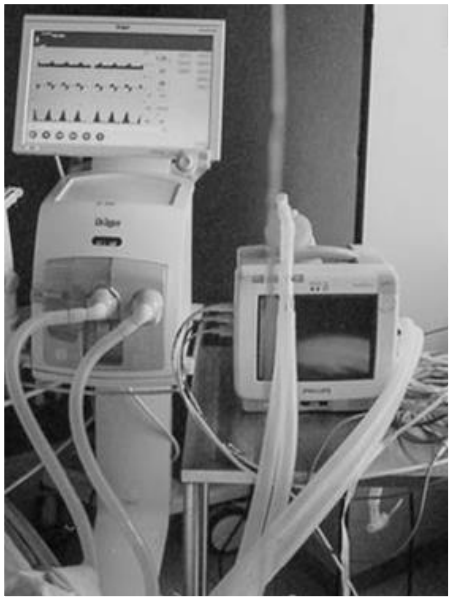
Global PPE

PRODUCT CATALOGUE

Global-PPE is your Go-to partner that ensures sustainable supplies of curated and aggregated PPE solutions for healthcare institutions across the country.

Global PPE

Our Product Categories

MASKS & RESPIRATORS

3-Ply Face Mask (Regular)

PRODUCT DESCRIPTION

The 3-Ply face mask has an outer fluid-repelling layer, a middle barrier layer for germs and an inner moisture absorbing layer.

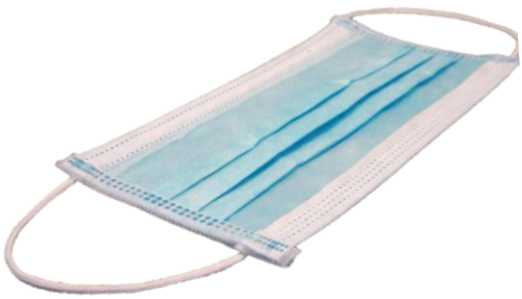
This mask can be used in order to prevent infections transmitted by respiratory droplets by limiting its spread.

We offer the Non-Sterile version as default and the Sterile version can be made available on request.

SPECIFICATIONS/FEATURES

Type	Disposable
Size	17.5 x 9.5 cm
Weight	6 gm
Specifications	Ear loops sewn or welded With nose-pin
Composition	Non-woven
Features	• BFE >= 95% • PFE >= 95% • Anti – bacteria • Odorless • Light • Non-irritant
Packaging	50 Pieces per Box Sterile versions come individually packed

PRODUCT PICTURES[1]



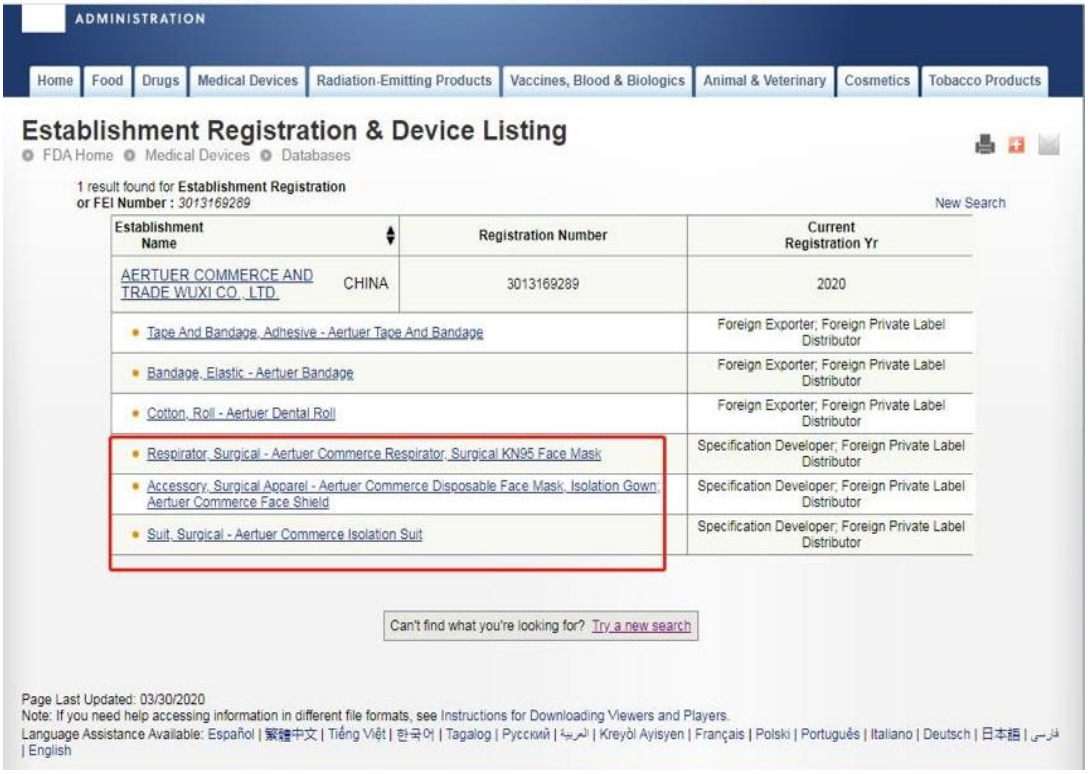
CERTIFICATIONS

Mandatory	FDA Registered
Additional[2]	CE Certified

***Note 1**. Pictures shown are for illustration purpose only. Actual product may vary due to product enhancement*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

3-Ply Face Mask (Regular)

Certifications : **FDA**



ADMINISTRATION

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home ▸ Medical Devices ▸ Databases

1 result found for **Establishment Registration** or **FEI Number** : *3013169289*

New Search

Establishment Name		Registration Number	Current Registration Yr
AERTUER COMMERCE AND TRADE WUXI CO., LTD.	CHINA	3013169289	2020
• Tape And Bandage, Adhesive - Aertuer Tape And Bandage			Foreign Exporter; Foreign Private Label Distributor
• Bandage, Elastic - Aertuer Bandage			Foreign Exporter; Foreign Private Label Distributor
• Cotton, Roll - Aertuer Dental Roll			Foreign Exporter; Foreign Private Label Distributor
• Respirator, Surgical - Aertuer Commerce Respirator, Surgical KN95 Face Mask			Specification Developer; Foreign Private Label Distributor
• Accessory, Surgical Apparel - Aertuer Commerce Disposable Face Mask, Isolation Gown; Aertuer Commerce Face Shield			Specification Developer; Foreign Private Label Distributor
• Suit, Surgical - Aertuer Commerce Isolation Suit			Specification Developer; Foreign Private Label Distributor

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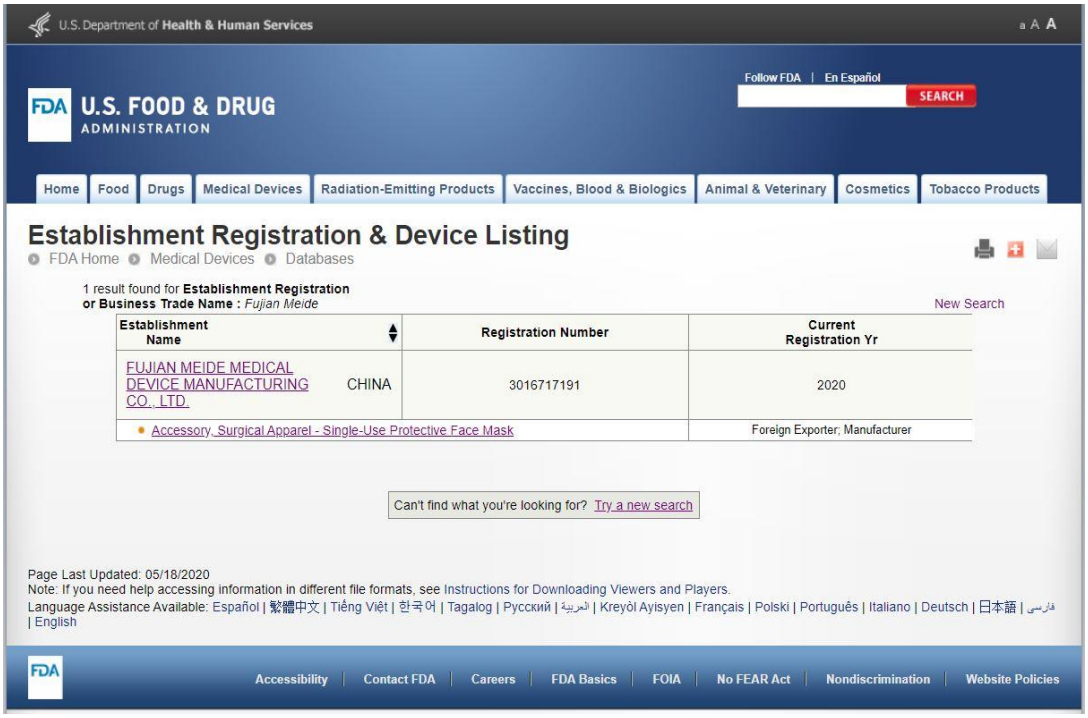
FDA



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Establishment Registration & Device Listing

FDA Home ▸ Medical Devices ▸ Databases

1 result found for **Establishment Registration** or **Business Trade Name** : *Fujian Meide*

New Search

Establishment Name		Registration Number	Current Registration Yr
FUJIAN MEIDE MEDICAL DEVICE MANUFACTURING CO., LTD.	CHINA	3016717191	2020
• Accessory, Surgical Apparel - Single-Use Protective Face Mask			Foreign Exporter; Manufacturer

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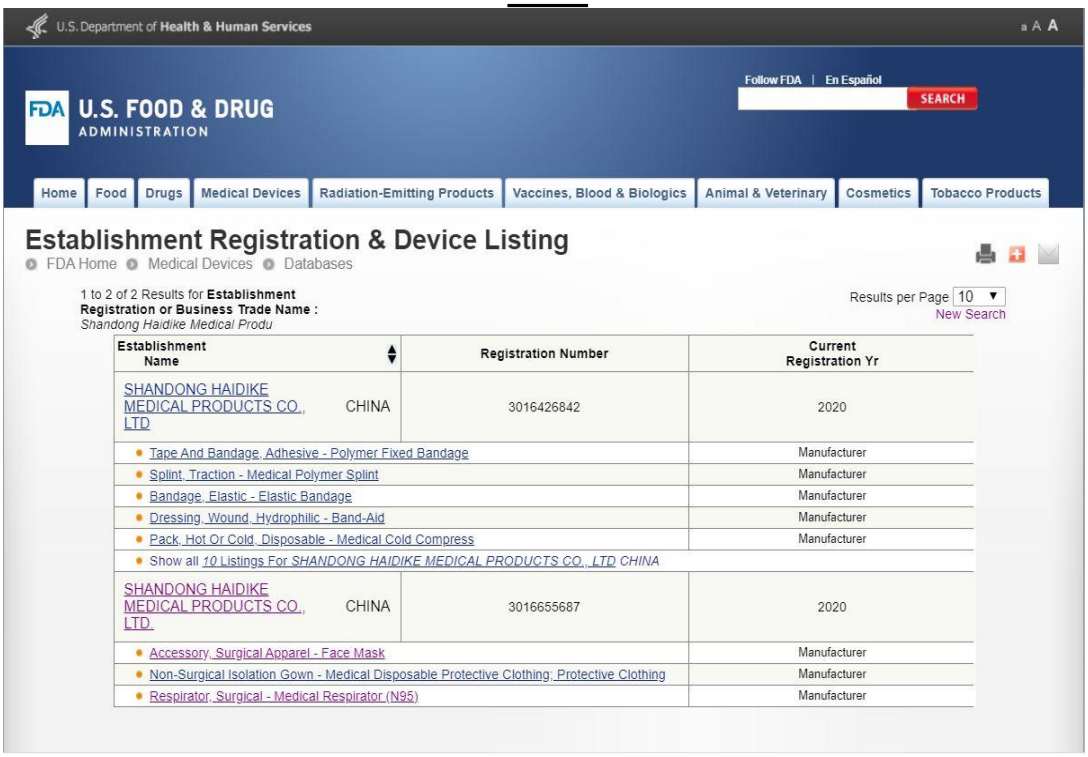
3-Ply Face Mask (Regular)

Certifications :

FDA



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Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

1 to 2 of 2 Results for **Establishment Registration or Business Trade Name :** *Shandong Haidike Medical Produ*

Results per Page 10 ▼ New Search

Establishment Name		Registration Number	Current Registration Yr
SHANDONG HAIDIKE MEDICAL PRODUCTS CO., LTD	CHINA	3016426842	2020
• Tape And Bandage, Adhesive - Polymer Fixed Bandage			Manufacturer
• Splint, Traction - Medical Polymer Splint			Manufacturer
• Bandage, Elastic - Elastic Bandage			Manufacturer
• Dressing, Wound, Hydrophilic - Band-Aid			Manufacturer
• Pack, Hot Or Cold, Disposable - Medical Cold Compress			Manufacturer
• Show all *10* Listings For *SHANDONG HAIDIKE MEDICAL PRODUCTS CO., LTD CHINA*			
SHANDONG HAIDIKE MEDICAL PRODUCTS CO., LTD.	CHINA	3016655687	2020
• Accessory, Surgical Apparel - Face Mask			Manufacturer
• Non-Surgical Isolation Gown - Medical Disposable Protective Clothing; Protective Clothing			Manufacturer
• Respirator, Surgical - Medical Respirator (N95)			Manufacturer

CE

Certificate Of Conformity NPS

Applicant :
Address :
Manufacturer
Address

DECLARE ON OUR SOLE RESPONSIBILITY THAT THE PRODUCT
Trade Name : N/A
Product : Disposable respirator
Model : 17.5*9.5CM

This EC-Declaration of conformity is following the provisions of Personal Protective Equipment (PPE) Directive (EU)2016/425
It is confirmed that a sample of the product has been tested and found in conformity with below

Test Standard : EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Classifications : FFP2
Date of issue : April 1, 2020

Detailed Specification of the tested product shown in the following test Report(s)
Certificate No. : NPS020030336-CE

CE

Technical director

NPS Laboratory Company Limited www.nps.gs e nps@nps.gs www.nps.hk e nps@nps.hk
DE Phone:+49698092918 Certificate Query http://online.nps.gs HK Phone:+852-53700017
The statement is based on a single evaluation of the sample of above mentioned products.
It does not imply an assessment of the whole production.

3-Ply Face Mask (Surgical)

PRODUCT DESCRIPTION

The surgical 3-Ply face mask has an outer layer, a middle barrier layer for germs and an inner moisture absorbing layer.

This mask is ASTM level 2 Certified and a high quality three layer structured .

We also offer the following masks:

Product Offered	*Standard*
Surgical Mask – Level 1	*ASTM F2100-19*
Surgical Mask – Level 2	*ASTM F2100-19*
Surgical Mask – Level 3	*ASTM F2100-19*

* *Refer to next page for more details of Levels based on ASTM Standards.*

PRODUCT PICTURES[1]

SPECIFICATIONS/FEATURES

Type	Disposable
Weight	~ 6 - 8 gm
Specifications	Ear loops sewn or welded With nose-pin
Composition	Outer Side : 22g SPP Filter Layer : 25g Melt-blown Inner Side : 18g SPP
Features	• 3 Layer • BFE >= 98% • PFE >= 98% • Anti – bacteria • Non woven protective layer • Soft skin friendly inner layer
Packaging	50 Pieces per Box

CERTIFICATIONS

Mandatory	FDA Cleared as a Class 2 Medical Device
Additional[2]	CE Certified EN14683

Note 1. *Pictures shown are for illustration purpose only. Actual product may vary due to product enhancement*
Note 2. *Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

More About Face Mask and Rating

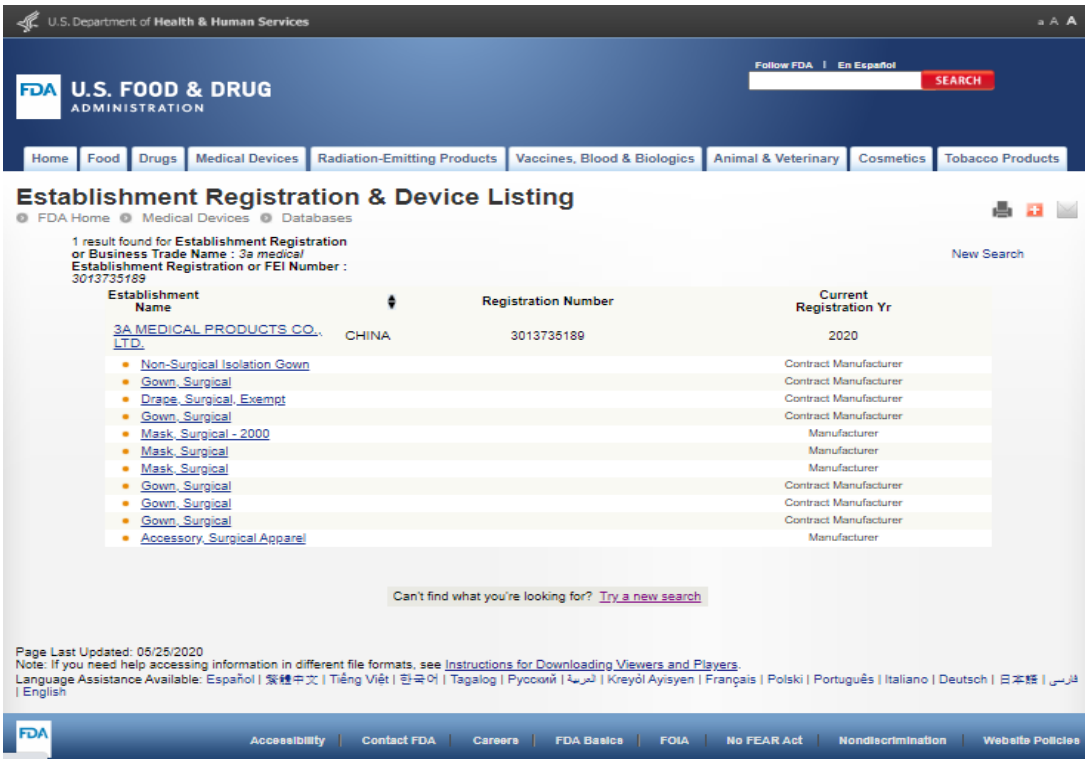
USA : ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS

EUROPE : EN 14683:2019 MEDICAL FACE MASKS - REQUIREMENTS AND TESTS METHODS

		ASTM F2100-19			EN 14683:2019 Barrier Level		
		Level 1	Level 2	Level 3	Type I	Type II	Type III
Barrier Testing	BFE % ASTM F2101, EN 14683	≥95	≥98		≥95	≥98	
	PFE % ASTM F2299	≥95	≥98		Not required		
	Synthetic Blood ASTM F1862, ISO 22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Not required		Pass at ≥16.0 kPa (>120 mmHg
Physical Testing	Different Pressure EN 14683	<5.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2		<40 Pa/cm^2		<60 Pa/cm^2
Safety Testing	Flammability 16 CFR Part 1610	Class 1 (≥3.5 seconds)			See European Medical Directive (2007/47/EC, MDD93/42/EEC)		
	Microbial Cleanliness ISO 11737 - 1	Not required			≤30 cfu/g		
	Biocompability ISO 10993	510 K Guidance recommends testing to ISO 10993			Complete an evaluation according to ISO 10993		
Sampling ANSI / ASQC Z1.4 ISO 2859 - 1		• AQL 4% for BFE, PFE, Delta P • 32 Masks for synthetic blood (Pass = ≥29 Passing, Fail = ≤ 28 Passing) • 14 masks for Flammability			• Minimum of 5 Masks up to an AQL of 4% for BFE, Delta P and Microbial Cleanliness • 32 Masks for synthetic blood (Pass = ≥29 Passing, Fail = ≤ 28 Passing)		

3-Ply Face Mask (Surgical)

Certifications : **FDA**



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Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

1 result found for **Establishment Registration or Business Trade Name :** *3a medical* **Establishment Registration or FEI Number :** *3013735189*

New Search

Establishment Name		Registration Number	Current Registration Yr
3A MEDICAL PRODUCTS CO., LTD.	CHINA	3013735189	2020
Non-Surgical Isolation Gown			Contract Manufacturer
Gown, Surgical			Contract Manufacturer
Drape, Surgical, Exempt			Contract Manufacturer
Gown, Surgical			Contract Manufacturer
Mask, Surgical - 2000			Manufacturer
Mask, Surgical			Manufacturer
Mask, Surgical			Manufacturer
Gown, Surgical			Contract Manufacturer
Gown, Surgical			Contract Manufacturer
Gown, Surgical			Contract Manufacturer
Accessory, Surgical Apparel			Manufacturer

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ZERTIFIKAT ◆ CERTIFICATE ◆ 证书 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System

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

No. G2S 16 08 96662 002

Manufacturer: 3A Medical Products Co., Ltd.
Yu An Industrial Park
230001 Liu An
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): Surgical Gown, Surgical Drape, Surgical Pack

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

Report No.: SH16111101

Valid from: 2016-10-17
Valid until: 2021-10-16

Date, 2016-10-17

Stefan Preiß

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

Page 1 of 2

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

KN95 Mask (Regular)

PRODUCT DESCRIPTION

The Regular KN95 Mask has the ability to reduce exposure to airborne particles. It has a filtration efficiency of 95% against non-oily particles.

It can be used for protection against viruses and bacteria and forms a tight seal against the face.

FDA – EUA approved KN95 Mask are available on request and subject to minimum quantity.

SPECIFICATIONS/FEATURES

Type	Disposable
Weight	13 Gm
Specifications	With nose pin With earloops
Packaging	20 Pieces per Box
Composition	Non-woven
Features	4/5 layer protection

PRODUCT PICTURES[1]

CERTIFICATIONS

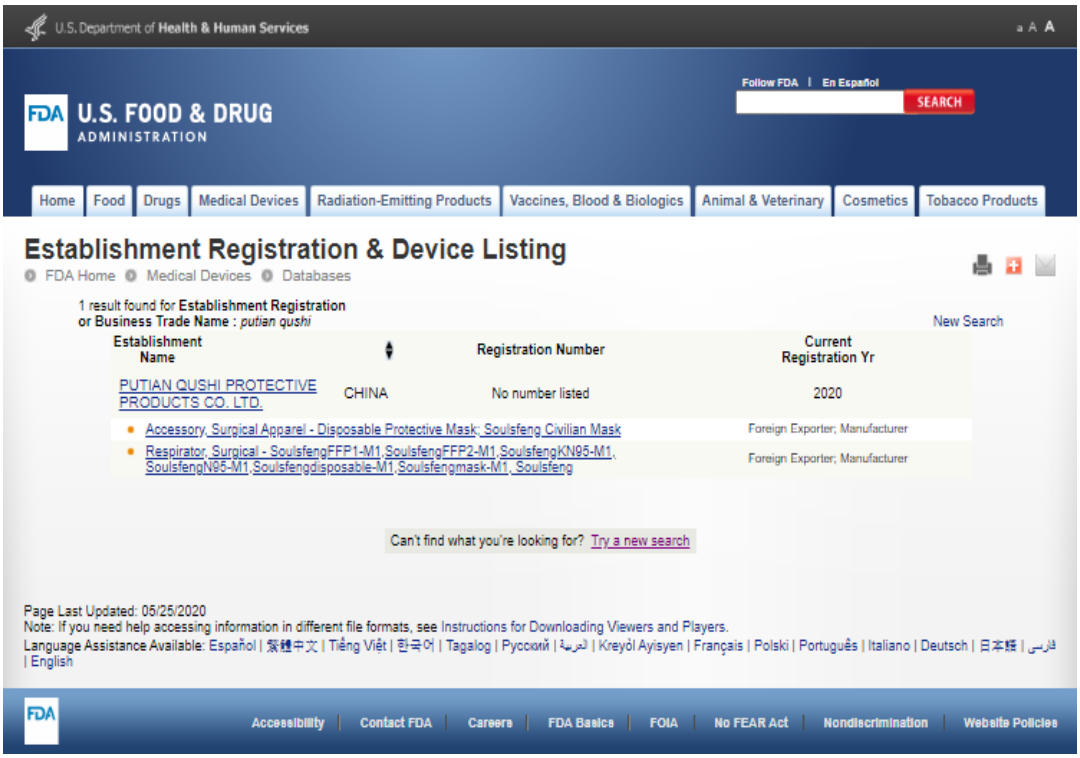
Mandatory	FDA Registered
Additional[2]	CE Certified EN 149:2001+ A1:2009 FFP2, FFP3

***Note 1**. Pictures shown are for illustration purpose only. Actual product may vary due to product enhancement*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

KN95 Mask (Regular)

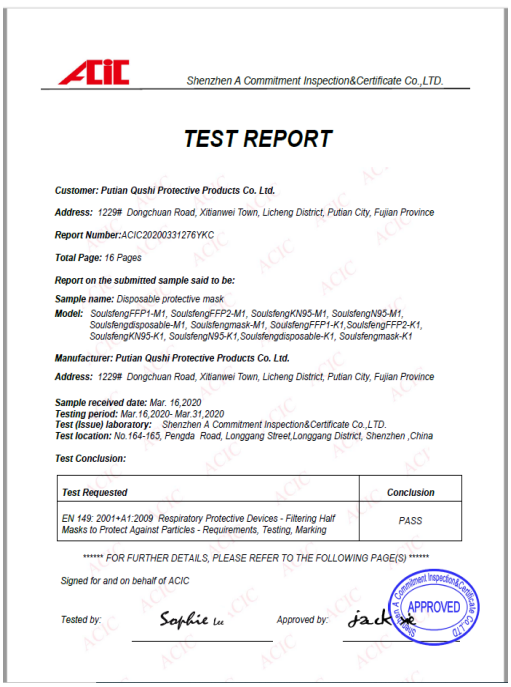
Certifications :

FDA



CE

Test Report



N95 Mask (FDA and NIOSH)

PRODUCT DESCRIPTION

N95 respirators are used to protect the wearer from airborne particles and from liquid contaminating the face. They have a filtration efficiency higher than 95%.

Generally the N95 mask comes in round molded design , but the Dasheng DTC-3X shown in this picture comes with a foldable design and head loops specifically designed for the US market.

PRODUCT PICTURES[1]

SPECIFICATIONS/FEATURES

Type	Disposable
Size	Adult
Weight	~ 12.5 gm
Packaging	20 Pieces per Box
Specifications	• Non-woven material, • 5 Layer, • BFE >= 95%, • PFE >= 95%, • With Head loops • Green box separately identifiable from Yellow box for Chinese domestic market

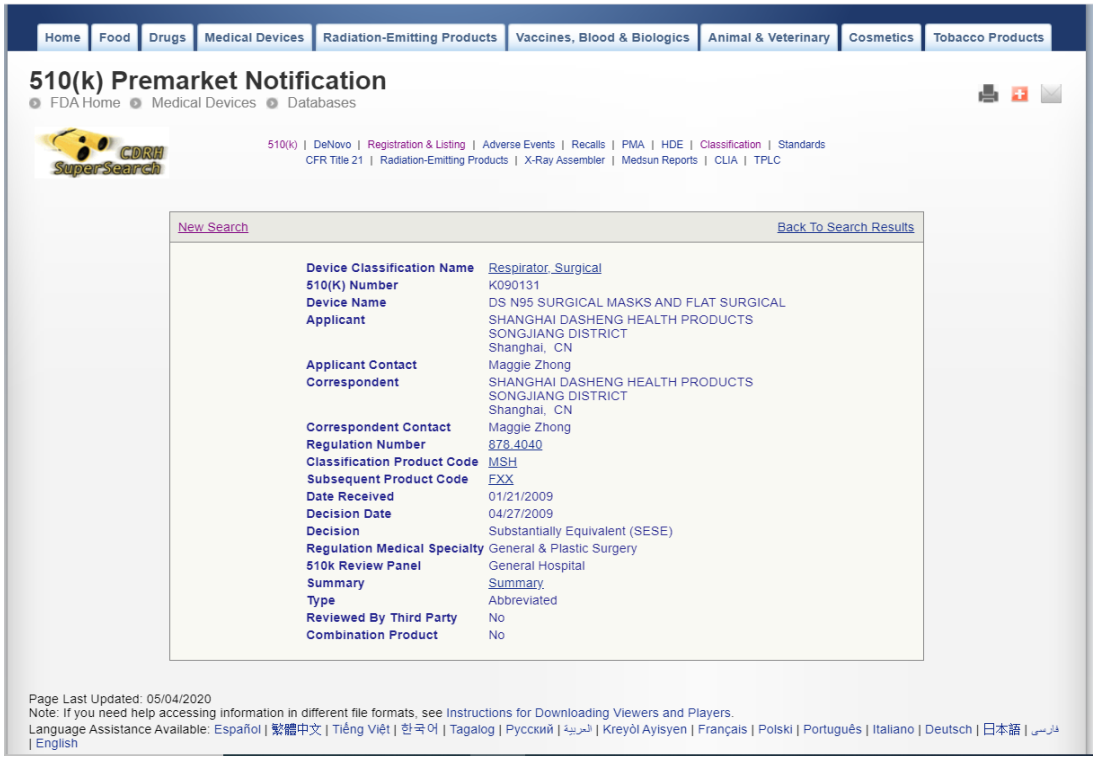
CERTIFICATIONS

Mandatory	FDA Registered NIOSH Approved NIOSH Approval no.: TC - 84A-4329
Additional[2]	CE Certified

Note 1. *Pictures shown are actual product images*
Note 2. *Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

N95 Mask (FDA and NIOSH)

Certifications : **FDA**



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510(k) Premarket Notification

FDA Home › Medical Devices › Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search — Back To Search Results

Device Classification Name	Respirator, Surgical
510(K) Number	K090131
Device Name	DS N95 SURGICAL MASKS AND FLAT SURGICAL
Applicant	SHANGHAI DASHENG HEALTH PRODUCTS SONGJIANG DISTRICT Shanghai, CN
Applicant Contact	Maggie Zhong
Correspondent	SHANGHAI DASHENG HEALTH PRODUCTS SONGJIANG DISTRICT Shanghai, CN
Correspondent Contact	Maggie Zhong
Regulation Number	878.4040
Classification Product Code	MSH
Subsequent Product Code	FXX
Date Received	01/21/2009
Decision Date	04/27/2009
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General & Plastic Surgery
510k Review Panel	General Hospital
Summary	Summary
Type	Abbreviated
Reviewed By Third Party	No
Combination Product	No

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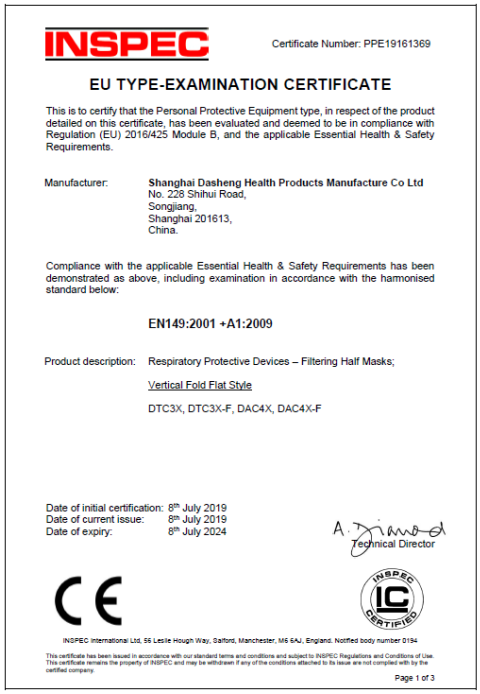

INSPEC

Certificate Number: PPE19161369

EU TYPE-EXAMINATION CERTIFICATE

This is to certify that the Personal Protective Equipment type, in respect of the product detailed on this certificate, has been evaluated and deemed to be in compliance with Regulation (EU) 2016/425 Module B, and the applicable Essential Health & Safety Requirements.

Manufacturer: **Shanghai Dasheng Health Products Manufacture Co Ltd**
No. 228 Shihui Road,
Songjiang,
Shanghai 201613,
China.

Compliance with the applicable Essential Health & Safety Requirements has been demonstrated as above, including examination in accordance with the harmonised standard below:

EN149:2001 +A1:2009

Product description: Respiratory Protective Devices – Filtering Half Masks;

Vertical Fold Flat Style

DTC3X, DTC3X-F, DAC4X, DAC4X-F

Date of initial certification: 8th July 2019
Date of current issue: 8th July 2019
Date of expiry: 8th July 2024

Technical Director

INSPEC International Ltd, 56 Leslie Hough Way, Salford, Manchester, M6 6AJ, England. Notified body number 0194

This certificate has been issued in accordance with our standard terms and conditions and subject to INSPEC Regulations and Conditions of Use. This certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with by the certified company.

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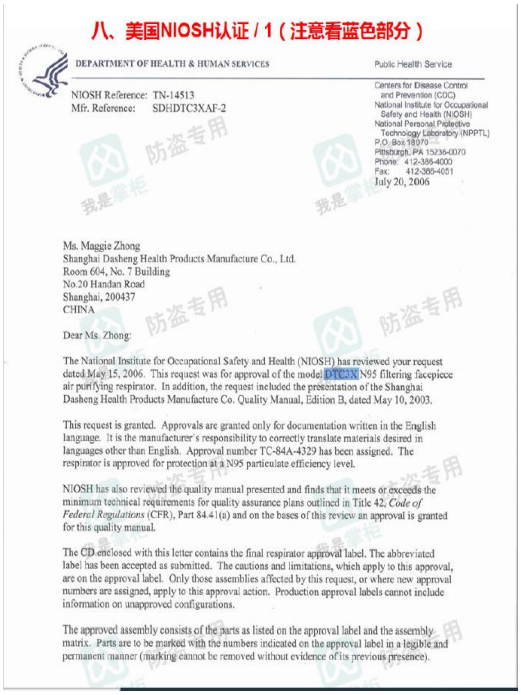
NIOSH



八、美国NIOSH认证 / 1（注意看蓝色部分）

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4651

NIOSH Reference: TN-14513
Mfr. Reference: SDHDTC3XAF-2

July 20, 2006

Ms. Maggie Zhong
Shanghai Dasheng Health Products Manufacture Co., Ltd.
Room 604, No. 7 Building
No.20 Handan Road
Shanghai, 200437
CHINA

Dear Ms. Zhong:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated May 15, 2006. This request was for approval of the model DTC3X N95 filtering facepiece air purifying respirator. In addition, the request included the presentation of the Shanghai Dasheng Health Products Manufacture Co. Quality Manual, Edition B, dated May 10, 2003.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-4329 has been assigned. The respirator is approved for protection at a N95 particulate efficiency level.

NIOSH has also reviewed the quality manual presented and finds that it meets or exceeds the minimum technical requirements for quality assurance plans outlined in Title 42, *Code of Federal Regulations* (CFR), Part 84.41(a) and on the bases of this review an approval is granted for this quality manual.

The CD enclosed with this letter contains the final respirator approval label. The abbreviated label has been accepted as submitted. The cautions and limitations, which apply to this approval, are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

N95 Mask (FDA)

PRODUCT DESCRIPTION

The N95 AirQueen mask has a nano membrane filter that completely blocks particles as small as 1µm, while most bacteria are 3 – 10µm.

AirQueen mask maintains its 95% protection up to 24 hrs. Even talking, spitting, and forced breathing do not reduce it's efficiency.

SPECIFICATIONS

Type	Disposable Molded design
Size (L*W)	7.5 * 20.7 cm
Weight	4.38 Gm
Features	• Nano Membrane • UV protection with more then 90 % • Triple Layer structure • BFE >= 95%, • PFE >= 95% • With comfort Head loops

PRODUCT PICTURES[1]

CERTIFICATIONS

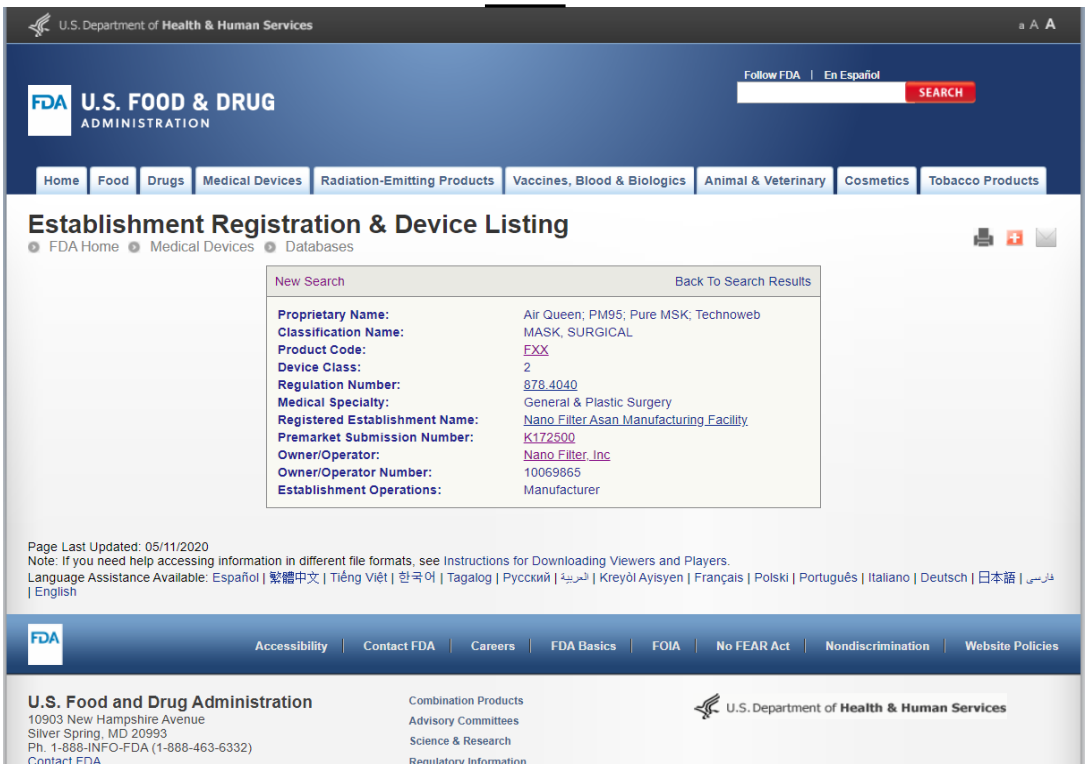
Mandatory	FDA Cleared as a Class 2 Medical Device
Additional[2]	CE Certified FFP2

***Note 1**. Pictures shown are actual product images*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

N95 Mask (FDA)

Certifications :

FDA



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Establishment Registration & Device Listing

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Proprietary Name:	Air Queen; PM95; Pure MSK; Technoweb
Classification Name:	MASK, SURGICAL
Product Code:	FXX
Device Class:	2
Regulation Number:	878.4040
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	Nano Filter Asan Manufacturing Facility
Premarket Submission Number:	K172500
Owner/Operator:	Nano Filter, Inc
Owner/Operator Number:	10069865
Establishment Operations:	Manufacturer

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Combination Products
Advisory Committees
Science & Research
Regulatory Information

U.S. Department of Health & Human Services

Cloth Mask

PRODUCT DESCRIPTION

The cloth face mask is a reusable face mask and comes in a four different variants. The function of face mask is workable for about 20 times of normal washing (gently wash w/o bleach). We also offer customization options.

PRODUCT OFFERED

Product	Specifications
Woven Shell mask	• Water Repellent (WR) • Middle layer is Dust filler padding • Inner layer is cotton knitted with anti-bacterial (A-B) treatment • Cloth ear-loop or elastic ear-loop
2 layers knitted	• Stretch fabric with tight fit • Outer layer with WR treatment • Inner layer with A-B treatment • Cloth-shell ear-loop
3 layers knitted	• WR, Dust filter padding, A-B treatment • stretchable seam for better fitting • Ear-loop by fabric or soft elastic
2 layers knitted mask with pleat	• Double layer of fabric with A-B function • Shell fabric ear-loop

PRODUCT PICTURES[1]

CERTIFICATIONS

Mandatory	No Certification required
Additional[2]	FDA Registered

Note 1. *Pictures shown are actual product images*
Note 2. *Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Global PPE

Our Product Categories

GLOVES, GOWNS, COVERALLS , SHOE COVERS, HEAD COVERS, GOGGLES AND FACE SHIELDS

Disposable Nitrile Gloves (Piece): GLV-NTR-1
Disposable Latex Gloves (Piece) : GLV-LTX-1

Gloves (Nitrile)

PRODUCT DESCRIPTION

Examination non sterile gloves are disposable gloves that help prevent cross contamination between patients and healthcare professionals during examinations or medical procedures.

The default product offered is the Nitrile Gloves, we also offer Vinyl and Latex options.

PRODUCT PICTURES[1]

SPECIFICATIONS/FEATURES

Type	Disposable
Sizes (l*w) (in cm)	24*9.5(M), 24*10.5(L), 24*11.5(XL)
Thickness (Finger : Palm : Cuff)	0.09:0.08:0.05 mm (M,L,XL)
Packaging	100 Pieces per Box
Specifications	Examination/ Surgical

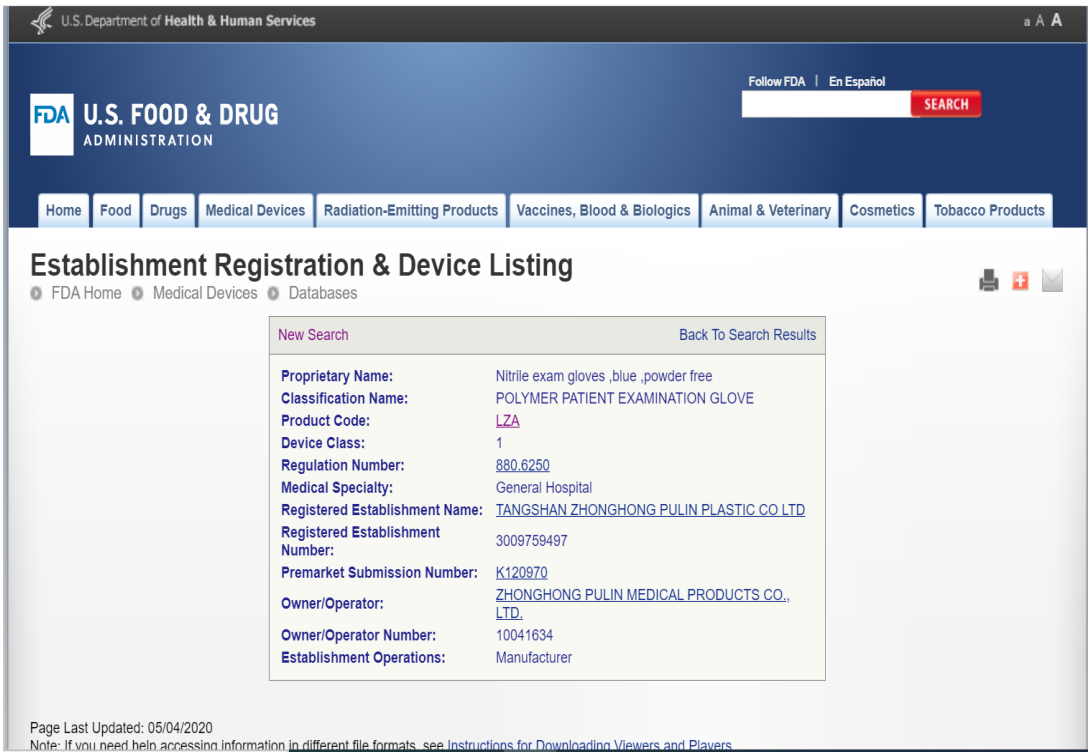
CERTIFICATIONS

Mandatory	FDA Cleared
Additional[2]	CE Certified ASTM Conformant

***Note 1**. Pictures shown are for illustration purpose only. Actual product may vary due to product enhancement*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Gloves (Nitrile)

Certifications : **FDA**



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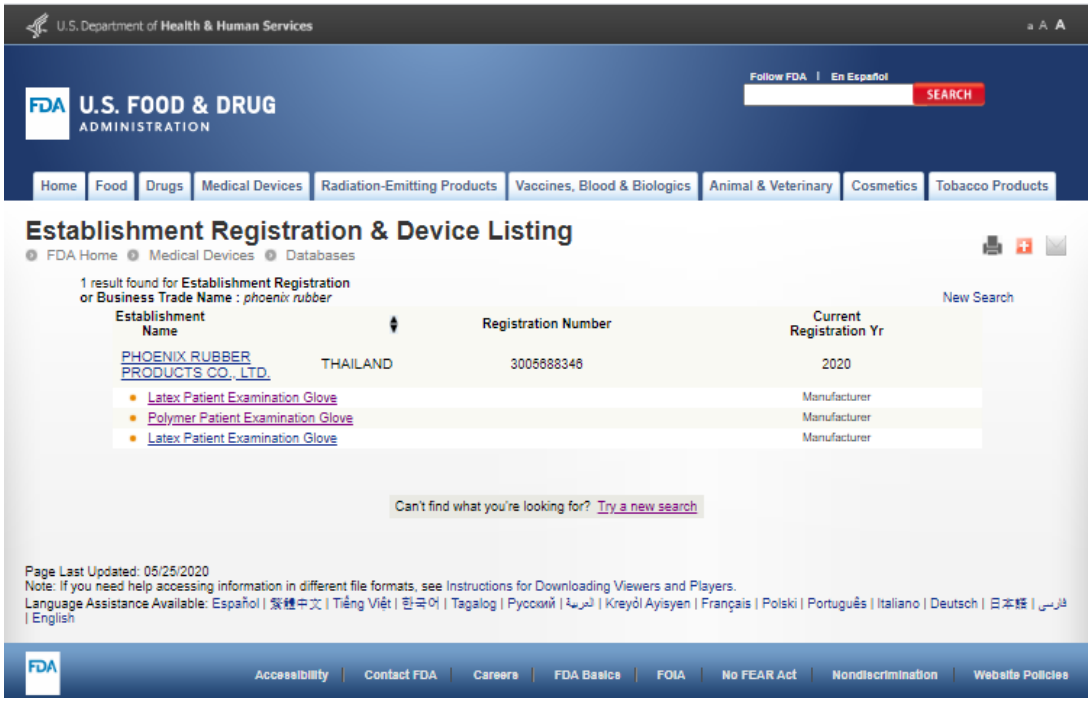
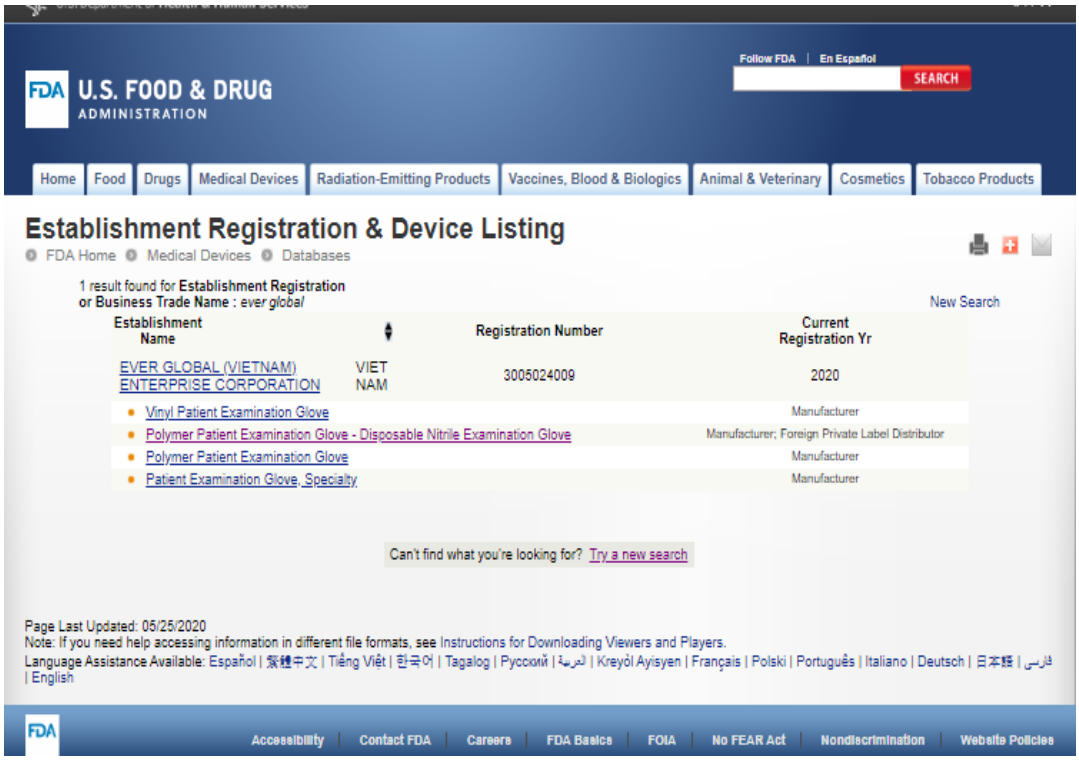


Gloves (Nitrile)

Certifications : **FDA**



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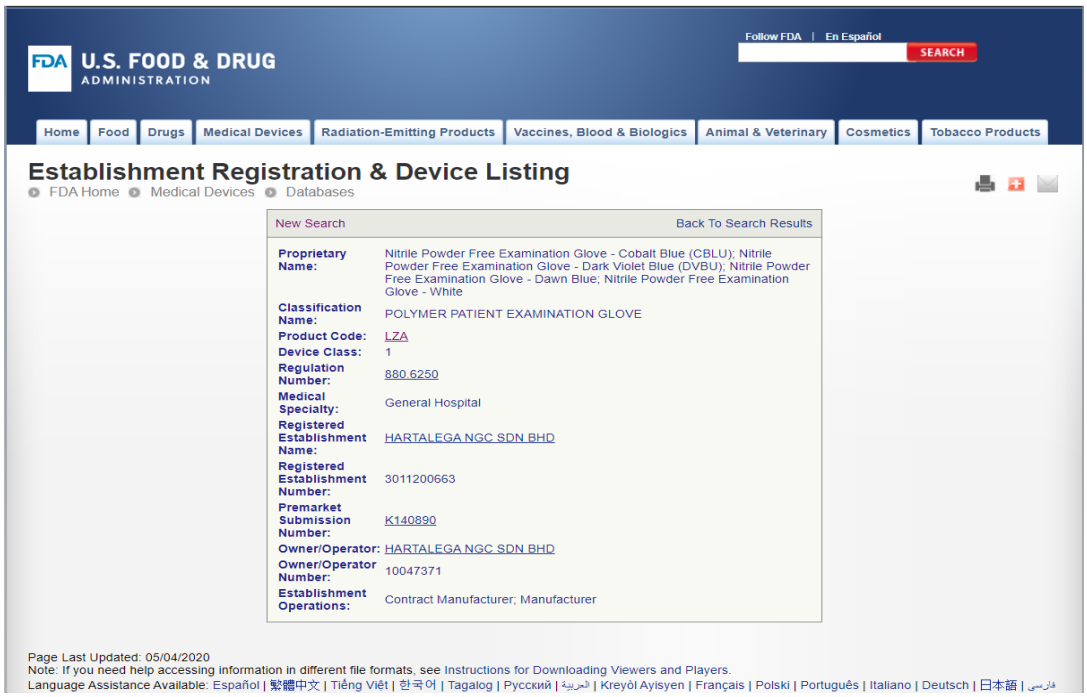
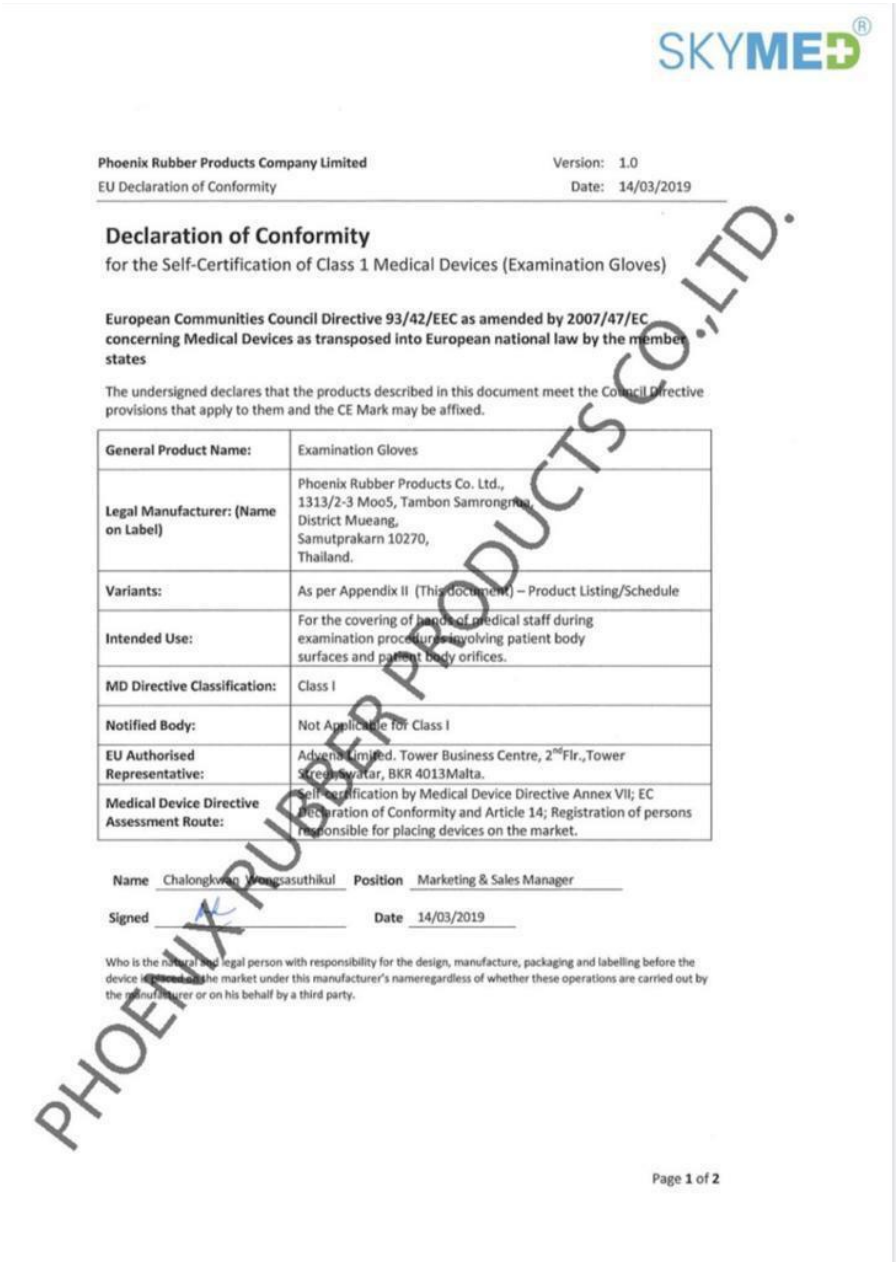


Gloves (Nitrile)

Certifications : **CE**



SKYMED®

Phoenix Rubber Products Company Limited Version: 1.0
EU Declaration of Conformity Date: 14/03/2019

Declaration of Conformity

for the Self-Certification of Class 1 Medical Devices (Examination Gloves)

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Examination Gloves
Legal Manufacturer: (Name on Label)	Phoenix Rubber Products Co. Ltd., 1313/2-3 Moo5, Tambon Samrongnua, District Mueang, Samutprakarn 10270, Thailand.
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	For the covering of hands of medical staff during examination procedures involving patient body surfaces and patient body orifices.
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr.,Tower Street,Swatar, BKR 4013Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name Chalongkwan Wongsasuthikul **Position** Marketing & Sales Manager

Signed **Date** 14/03/2019

Who is the natural or legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's nameregardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

PHOENIX RUBBER PRODUCTS CO.,LTD.

Page 1 of 2

Disposable General Isolation Gowns

PRODUCT DESCRIPTION

Disposable General Isolation Gowns are fluid resistant and are used for general isolation in out-patient departments, wards and laboratories of medical institutions.

A Premium version of 42GSM also available.

Customizations such as Knit cuffs are also available.

PRODUCT PICTURES[1]

SPECIFICATIONS

Type	General, Disposable
Sizes	Unisize
Weight	< 0.10 Kg
Composition	Non-woven fabric (SMS)
GSM / Thickness	Typically 22 to 28 grams per square meter (GSM)
Features	• Water resistant • Hydrophobic • Breathable

CERTIFICATIONS

Mandatory	No Certification required
Additional[2]	FDA Registered CE Certified

***Note 1**. Pictures shown are actual product images*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Disposable Medical Isolation Gowns (Level 1) : GWN-MED-PEPP-NST-L1-MIX
(Level 2) : GWN-MED-PEPP-NST-L2-MIX
GWN-MED-PEPP-NST-L2-MIX-HW

Disposable Medical Isolation Gowns

PRODUCT DESCRIPTION

These gowns are used for medical isolation by varied medical professionals depending upon category of use. The American National Standards Institute (ANSI) and the Association of the Advancement of Medical Instrumentation (AAMI): ANSI/AAMI PB70:2003 describes liquid barrier performance & classification of protective apparel Level 1 and Level 2 gowns are specified below.

Sterile version is also available at extra cost.

PRODUCT PICTURES[1]

Level 2

SPECIFICATIONS

Type	Level 1
Standard	AATC 42 Impact Penetration[2]
Weight	65 gm
Size	Unisize
Option	Wrist : Knit Cuffs or elastic cuffs Neck Closure : String tie or Sticky tape Tie options are also available
Type	Level 2
Standard	AATC 42 Impact Penetration[2] / AATCC 127 Hydrostatic Pressure[3]
Weight	75 gm
Size	Unisize
Option	Wrist : Knit Cuffs or elastic cuffs Neck Closure : String tie or Sticky tape Tie options are also available

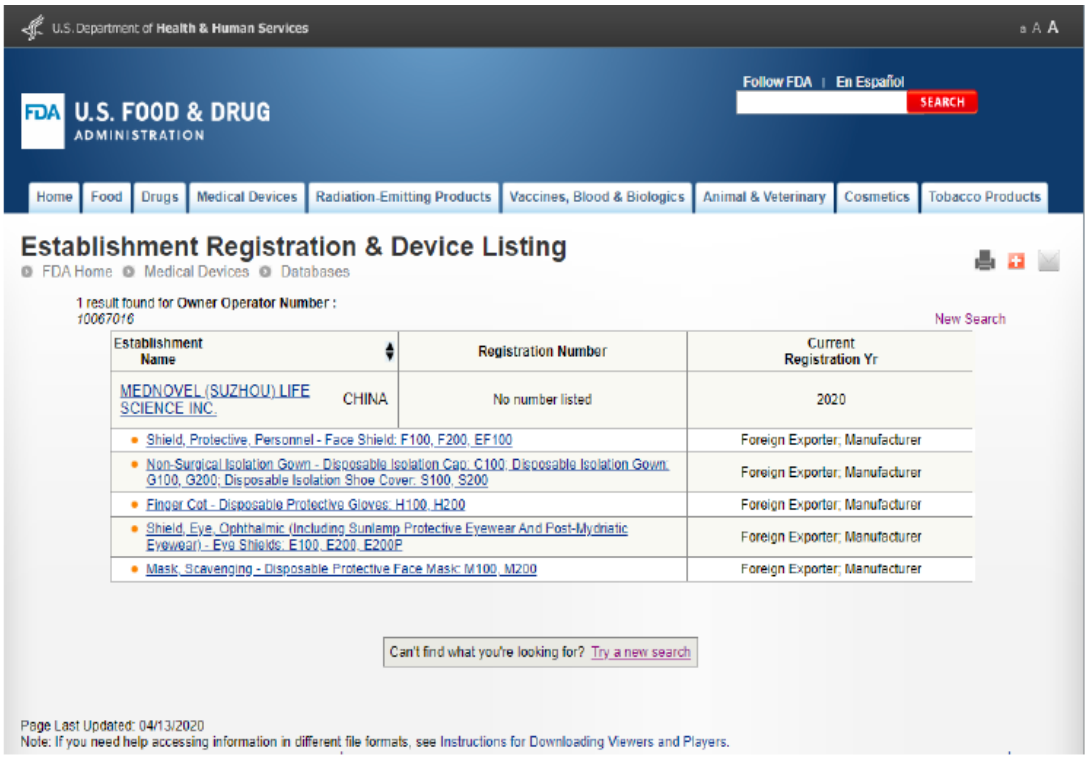
CERTIFICATIONS

Mandatory	FDA Registered
Additional[2]	CE Certified, ISO 13485:2016 EN14605

Note 1. *Pictures shown are actual product images*
Note 2. *Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Disposable Medical Isolation Gowns

Certifications : **FDA**



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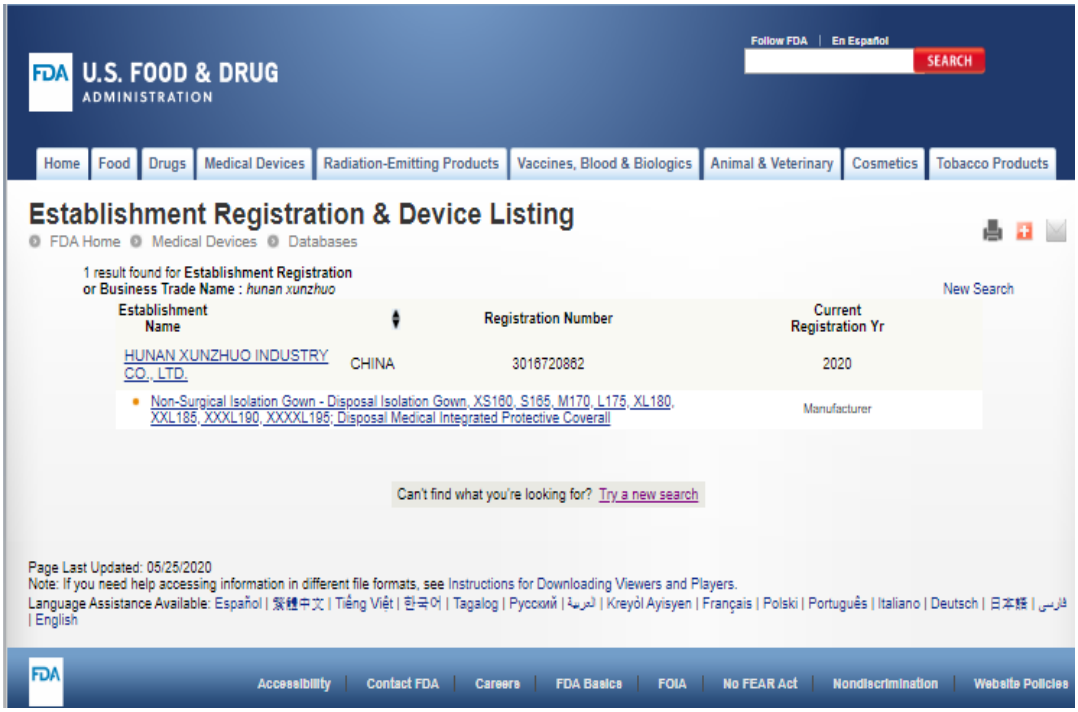


Disposable Medical Isolation Gowns (Level 3) : GWN-MED-PEPP-NST-L3-MIX
(Level 4) : GWN-MED-PEPP-NST-L4-MIX

Disposable Medical Isolation Gowns

PRODUCT DESCRIPTION

These Disposable Medical Isolation Gowns are Level 3 & 4 Gowns categorized by The American National Standards Institute (ANSI) and the Association of the Advancement of Medical Instrumentation (AAMI): ANSI/AAMI PB70:2003 which describes liquid barrier performance & classification of protective apparel & drapes. Level 3 and Level 4 gowns are specified below.

Sterile version is also available at extra cost.

PRODUCT PICTURES[1]

Level 3

Level 4

SPECIFICATIONS

Type	Level 3
Standard	AATC 42 Impact Penetration[2] / AATCC 127 Hydrostatic Pressure[3]
Weight	110 gm
Size	Unisize
Option	Ankle for increase in wearer comfort Knit Cuffs with elastic waist
Type	Level 4
Standard	ASTM F1670 Synthetic Blood Penetration / ASTM F1671 Viral Penetration Test
Weight	140 gm
Size	Unisize
Features	• Elastic Cuffs • Stich Tightly • Two ropes fasten clothing

* *Check next page for Gowns rating and testing.*

CERTIFICATIONS

Mandatory	FDA Registered
Additional[2]	CE Certified, ISO 13485:2016 EN14605

***Note 1**. Pictures shown are actual product images*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

More About AAMI Rating (Level 1, 2, 3, 4)

Standard AAMI PB70:2012, for Liquid Barrier Performance *classifies a gown's ability to act as a barrier to penetration by liquids or liquid-borne pathogens based on four levels. The critical protective zones for surgical and non-surgical gowns are defined differently by the standard. While the critical zones designate different protective areas for the different gowns, the levels of protection are the same for both surgical and non-surgical gowns*

Applicability: *Liquid barrier performance is not related to the strength of the material. This standard references several other standards*
Liquid barrier performance is not related to the strength of the material.
This standard references several other standards

Sub headings	Description	Applicability
Level 1	•Used for MINIMAL risk situations •Provides a slight barrier to small amounts of fluid penetration •Single test of water impacting the surface of the gown material is conducted to assess barrier protection performance.	basic care, standard hospital medical unit
Level 2	•Used in LOW risk situations •Provides a barrier to larger amounts of fluid penetration through splatter and some fluid exposure through soaking •Two tests are conducted to assess barrier protection performance: • Water impacting the surface of the gown material • Pressurizing the material	Blood draw from a vein, Suturing, Intensive care unit, Pathology lab
Level 3	•Used in MODERATE risk situations •Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soaking than Level 2 •Two tests are conducted to test barrier protection performance: • Water impacting the surface of the gown material • Pressurizing the material	Arterial blood draw, Inserting an IV, Emergency Room, Trauma
Level 4	•Used in HIGH risk situations •Prevents all fluid penetration for up to 1 hour •May prevent VIRUS penetration for up to 1 hour •In addition to the other tests conducted under levels 1-3, barrier level performance is tested with a simulated blood containing a virus. If no virus is found at the end of the test, the gown passes.	Pathogen resistance, Infectious diseases (non-airborne), Large amounts of fluid exposure over long periods

Source: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns

Tests for Level 1 to 4 Medical Gowns

The ANSI/AAMI PB70 standard includes four standard tests to evaluate the barrier effectiveness of surgical gowns, isolation gowns, and surgical drapes. Based on the results of these standardized tests, four levels of barrier performance are defined, with Level 1 being the lowest level of protection, and Level 4 being the highest level of protection. Table 3 summarizes the requirements of ANSI/AAMI PB70:2012 regarding the classification of barrier performance of surgical gowns, isolation gowns, and surgical drapes.

Table 3: ANSI/AAMI PB 70:12 classification of barrier performance of surgical gowns, other protective apparel, surgical drapes and drape accessories

Level1

Level[1]	Test	Liquid Challenge	Result	Expected Barrier Effectiveness
1	AATCC 42 Impact Penetration[2]	Water	= 4.5 g	Minimal water resistance (some resistance to water spray)
2	AATCC 42 Impact Penetration	Water	= 1.0 g	Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)
	AATCC 127 Hydrostatic Pressure[3]	Water	= 20 cm	
3	AATCC 42 Impact Penetration	Water	= 1.0 g	Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)
	AATCC 127 Hydrostatic Pressure	Water	= 50 cm	
4	ASTM F1670 Synthetic Blood Penetration Test (for surgical drapes)	Surrogate Blood	no penetration at 2 psi(13.8 kPa)	Blood and viral penetration resistance (2 psi)
	ASTM F1671 Viral Penetration Test (for surgical and isolation gowns)	Bacteriophage Phi-X174	no penetration at 2 psi(13.8 kPa)	

[1] In order of increasing protection

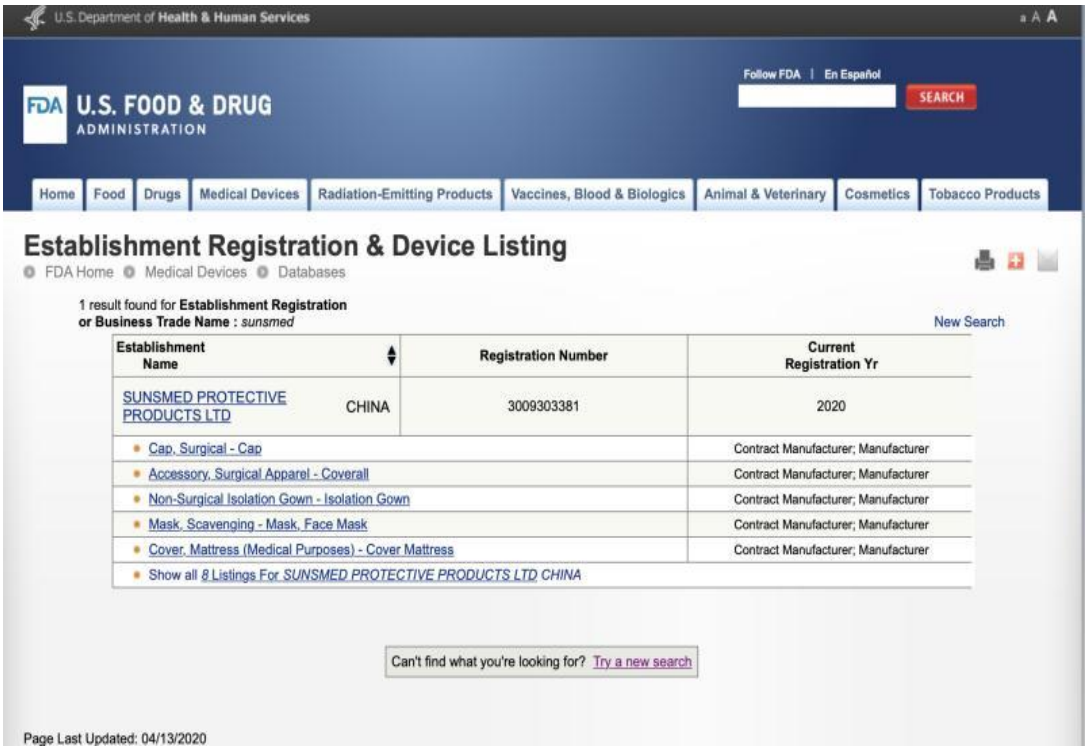
[2] American Association of Textile Chemists and Colorists (AATCC) 42 Water resistance: impact penetration test determines the ability of a material to resist water penetration under spray impact [AATCC 2000]

[3] AATCC 127 Water resistance: hydrostatic pressure test determines the ability of a material to resist water penetration under constant contact with increasing pressure [AATCC 1998]

Source: ttps://wwwn.cdc.gov/PPEInfo/Standards/Info/ANSI/AAMIPB70Class3

Disposable Medical Isolation Gowns

Certifications : **FDA**



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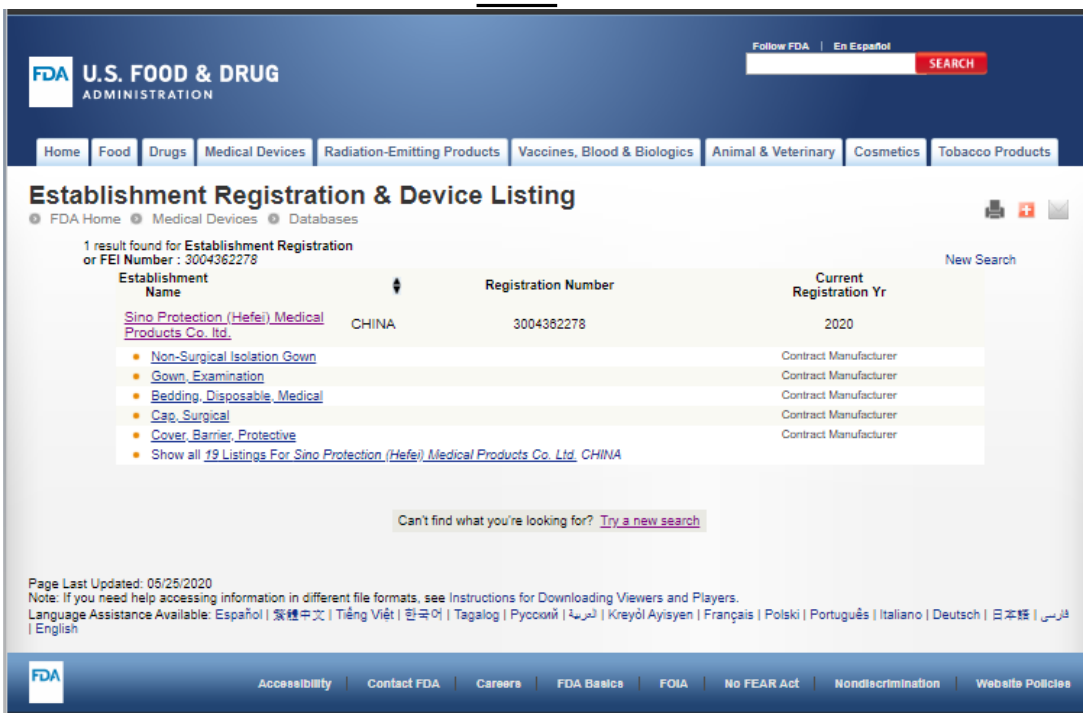


Disposable Medical Isolation Gowns

Certifications : **CE**

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System

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

No. G2S 17 02 62151 011

Manufacturer: Sino Protection (Hefei) Medical Products Co., Ltd.
Area B, Xinzhan Industrial Park
XingHuo Road
230011 Hefei
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): Surgical Gown, Surgical Drape, Surgical Pack, Coverall, Non-woven Swabs

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

Report No.: SH17364EXT01

Valid from: 2017-04-25
Valid until: 2022-04-24

Date, 2017-03-09

Stefan Preiß

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

Page 1 of 2

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TEST REPORT

NELSON LABORATORIES

Sponsor:
Slinda Ma
Sino Protection Medical Products Co., Lt
Area B New Station Industrial Park
Hefei, Anhui, 230051
CHINA

Viral Penetration ASTM Method F 1671 Final Report

Test Article: SPI-15-008
Purchase Order: Sino-2017001
Study Number: 997514-S01
Study Received Date: 19 Oct 2017
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0062 Rev 15
Deviation(s): None

Summary: This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at 21 ± 5°C and 30-80% relative humidity (RH), and then tested for viral penetration using a ΦX174 bacteriophage suspension. At the conclusion of the test, the observed side of the test article was rinsed with a sterile medium and assayed for the presence of ΦX174 bacteriophage. The viral penetration method complies with ASTM F1671; sampling was at the discretion of the sponsor. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 3
Number of Test Articles Passed: 3
Test Article Side Tested: Either Side
Test Article Preparation: Cut from the Material at Random
Test Article Sealed: Paraffin Wax
Exposure Procedure: B (Retaining Screen: Woven Polyester Mesh, with >50% Open Area)
Compatibility Ratio: 1.1
Environmental Plate Results: Acceptable

Results:

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1-3	1.6×10^8	1.3×10^8	<1[a]	None Seen	Pass
Negative Control	1.6×10^8	1.3×10^8	<1[a]	None Seen	Acceptable
Positive Control	1.6×10^8	1.3×10^8	TNTC[b]	Yes	Acceptable

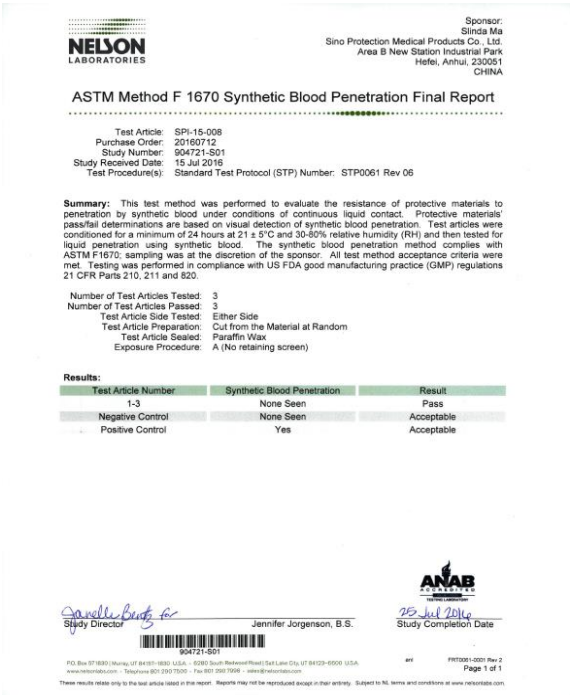
[a] A value of <1 plaque forming unit (PFU)/mL is reported for assay plates showing no plaques.
[b] TNTC = PFUs were too numerous to count.

Study Director — Jennifer Jorgenson, B.S.
06 NOV 2017 — Study Completion Date

997514-S01

FRT0062-0001 Rev 8
Page 1 of 1

TEST REPORT



NELSON LABORATORIES

Sponsor:
Slinda Ma
Sino Protection Medical Products Co., Ltd.
Area B New Station Industrial Park
Hefei, Anhui, 230051
CHINA

ASTM Method F 1670 Synthetic Blood Penetration Final Report

Test Article: SPI-15-008
Purchase Order: 20160712
Study Number: 904721-S01
Study Received Date: 15 Jul 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0061 Rev 06

Summary: This test method was performed to evaluate the resistance of protective materials to penetration by synthetic blood under conditions of continuous liquid contact. Protective materials' pass/fail determinations are based on visual detection of synthetic blood penetration. Test articles were conditioned for a minimum of 24 hours at 21 ± 5°C and 30-80% relative humidity (RH) and then tested for liquid penetration using synthetic blood. The synthetic blood penetration method complies with ASTM F1670; sampling was at the discretion of the sponsor. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 3
Number of Test Articles Passed: 3
Test Article Side Tested: Either Side
Test Article Preparation: Cut from the Material at Random
Test Article Sealed: Paraffin Wax
Exposure Procedure: A (No retaining screen)

Results:

Test Article Number	Synthetic Blood Penetration	Result
1-3	None Seen	Pass
Negative Control	None Seen	Acceptable
Positive Control	Yes	Acceptable

Study Director — Jennifer Jorgenson, B.S.
25 Jul 2016 — Study Completion Date

904721-S01

FRT0061-0001 Rev 2
Page 1 of 1

Disposable General Protective Coverall Suit (Mixed Sizes): COV-GEN-1MIX
Disposable Medical Protective Coverall Suit (Mixed Sizes): COV-MED-1MIX

Disposable Coverall Suit

PRODUCT DESCRIPTION

Disposable Coveralls are used by clinical medical personnel when coming in contact with patients with potentially infectious blood, fluids, or secretions in order to create a barrier and provide protection.

SPECIFICATIONS/FEATURES

Type	Disposable
Sizes	M – XXL
Weight	0.30-0.45 Kg
Composition	Non-woven fabric
Features	• Water-proof • Moisture permeable • Bacteriostatic • Material equivalent to Tyvek

PRODUCT PICTURES[1]

CERTIFICATIONS

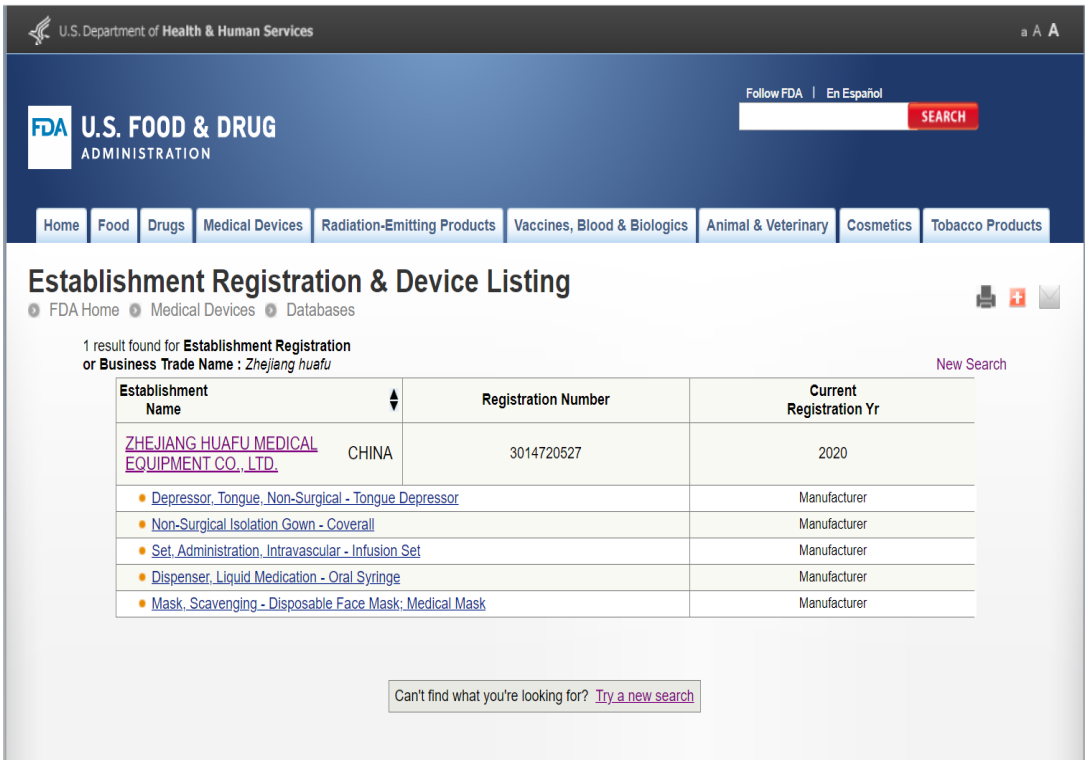
Mandatory	FDA Registered
Additional[2]	CE Certified, EN 14126 : 2003

***Note 1**. Pictures shown are for illustration purpose only. Actual product may vary due to product enhancement*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Disposable Coverall Suit

Certifications :

FDA



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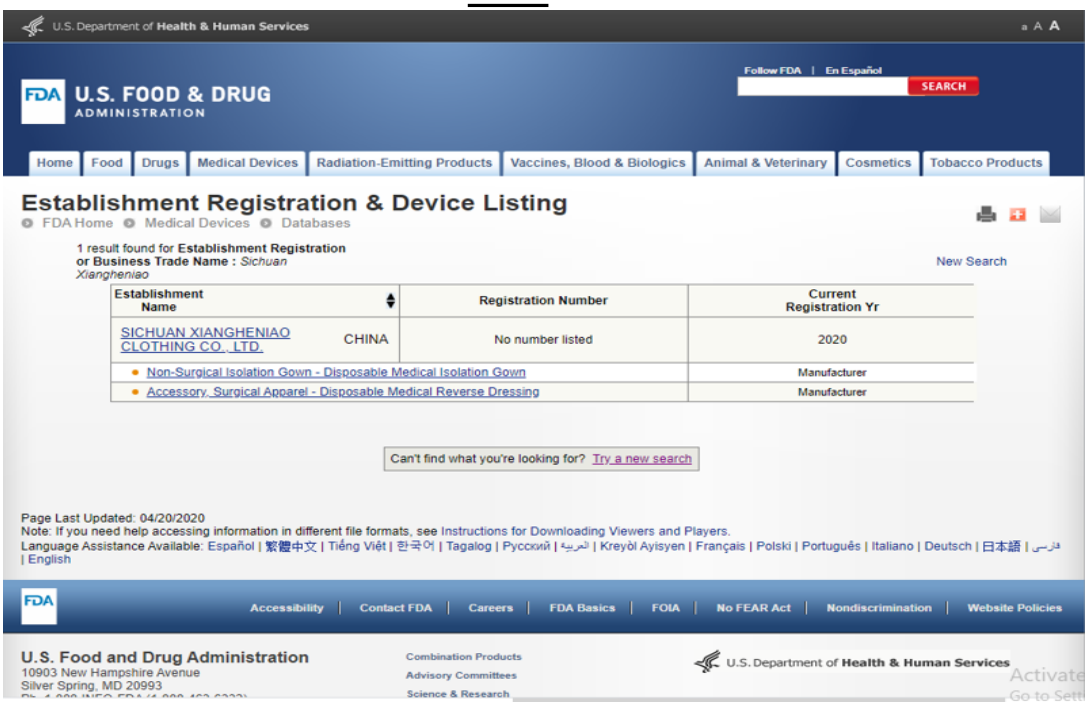


Disposable Coverall Suit

Certifications : **EN 14126 : 2003**

Testing Center

Report No: QA2020031302

Institute of Textile Technology Testing Center

EN 14126:2003

Protective clothing — Performance requirements and tests methods for protective clothing against infective agents

Report Number:	QA2020031302
Tested by (name + signature):	Qinggang
Approved by (+ signature):	Zengtao
Date of issue:	2020-03-13
Total number of pages:	21
Name of Testing Laboratory preparing the Report:	Institute of Textile Technology Testing Center
Address:	No.498 Fenghua Road, Jiangbei District, Ningbo, China
Applicant's name:	Sichuan Xiangheniao Clothing Co.,Ltd
Address:	No. 558, Mengqiao Road, Section 3 Wenquan Avenue, Cross-Strait Industrial Park, Wenjiang District, Chengdu, Sichuan Province
Manufacturer's name:	Sichuan Xiangheniao Clothing Co.,Ltd
Address:	No. 558, Mengqiao Road, Section 3 Wenquan Avenue, Cross-Strait Industrial Park, Wenjiang District, Chengdu, Sichuan Province
Test specification:	
Standard:	EN 14126:2003
Test procedure:	CE
Non-standard test method:	N/A
Test item description:	Protective clothing
Trade Mark:	N/A
Model/Type reference:	XS-4XL

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.

Disposable Shoe Covers (Pairs) : COV-SHO-1
Disposable Protective Over-boot (Pairs) COV-SHO-2

Shoe Coverings

PRODUCT DESCRIPTION

Shoe-covers are used to keep surroundings sterile and prevent cross-contamination. They are made to be anti-skid and anti-static and are tightened by an elastic band.

SPECIFICATIONS/FEATURES

Type	Disposable
Weight	25 Gm
Option	• Over boot type • Shoe cover type
Composition	Non-woven fabric
Features	• Waterproof • Antibacterial • Anti-slip

PRODUCT PICTURES[1]

Shoe Cover

Booties

CERTIFICATIONS

Mandatory	FDA Registered
Additional[2]	CE Certified

***Note 1**. Pictures shown are for illustration purpose only. Actual product may vary due to product enhancement*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Disposable Protective Cap : COV-HEAD-1
Medical Protective Hood : COV-HEAD-2

Head Covers

PRODUCT DESCRIPTION

Hoods, caps and other head covers are used to completely cover the hair in order to prevent contamination in a clean room.

They have an elastic band around the rim that keeps them secured on the head.

SPECIFICATIONS/FEATURES

Type	Medical Hood/ Head Cap Surgical / Regular
Sizes	Medium
Weight	Cap : 25 gm Hoodies : 50 gm
Composition	42 GSM material,
Features	• Anti- bacterial • Hydrophobic • Bouffant type cap

PRODUCT PICTURES[1]

Head Caps

Hoodies

CERTIFICATIONS

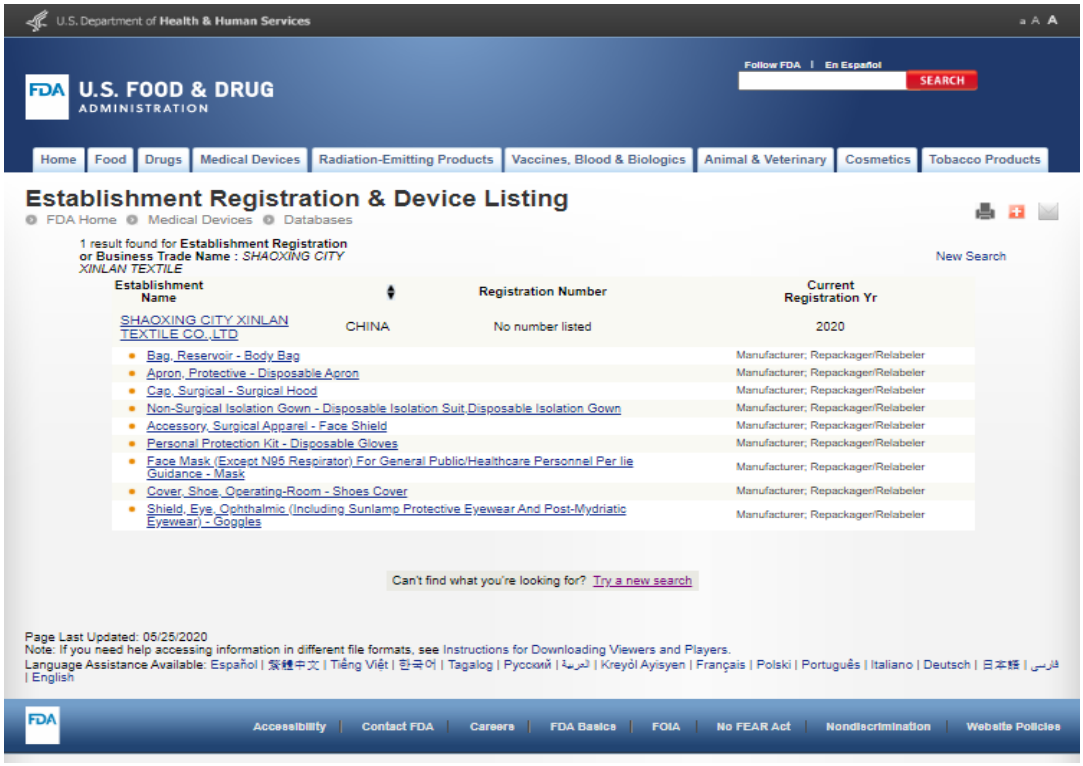
Mandatory	FDA Registered
Additional[2]	CE Certified

***Note 1**. Pictures shown are for illustration purpose only. Actual product may vary due to product enhancement*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Disposable Shoe Covers (Pairs) : COV-SHO-1
Disposable Protective Over-boot (Pairs) COV-SHO-2
Disposable Protective Cap : COV-HEAD-1
Medical Protective Hood : COV-HEAD-2

Shoe Covering & Head Covers

Certifications : **FDA**



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

1 result found for **Establishment Registration or Business Trade Name :** *SHAOXING CITY XINLAN TEXTILE*

New Search

Establishment Name		Registration Number	Current Registration Yr
SHAOXING CITY XINLAN TEXTILE CO.,LTD	CHINA	No number listed	2020

Bag, Reservoir - Body Bag	Manufacturer; Repackager/Relabeler
Apron, Protective - Disposable Apron	Manufacturer; Repackager/Relabeler
Cap, Surgical - Surgical Hood	Manufacturer; Repackager/Relabeler
Non-Surgical Isolation Gown - Disposable Isolation Suit,Disposable Isolation Gown	Manufacturer; Repackager/Relabeler
Accessory, Surgical Apparel - Face Shield	Manufacturer; Repackager/Relabeler
Personal Protection Kit - Disposable Gloves	Manufacturer; Repackager/Relabeler
Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per Iie Guidance - Mask	Manufacturer; Repackager/Relabeler
Cover, Shoe, Operating-Room - Shoes Cover	Manufacturer; Repackager/Relabeler
Shield, Eye, Ophthalmic (Including Sunlamp Protective Eyewear And Post-Mydriatic Eyewear) - Goggles	Manufacturer; Repackager/Relabeler

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CE

Review Report – 审查报告 – 검토 보고서 – Rapport d'Evaluation

Form QAT_10-M06, version 00, effective since March 25th, 2020

CE Documentation Review

ECM

No. SD200413.SCXTC37

Holder: Shaoxing City Xinlan Textile Co., Ltd.
West of Zhongxing Avenue, East of Tanggong Road, southeast of No. 1 Plant, Shaoxing City, Zhejiang Province

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable Isolation Suit (Not Sterile)
Model(s): *(this certificate certifies only the product without its own specific models)*

Classification: Class I (Not Sterile) (accordingly to the Manufacturer's declaration)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 07 April 2020
Approver
ECM Service Director
Luca Bedonni

Expiry date 06 April 2025
Technical Expert
Amanda Sarno

Ente Certificazione Macchine
Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.0516705141 🖷 +39.0516705156 ✉ info@entecerma.it 🌍 www.entecerma.it

Goggles

PRODUCT DESCRIPTION

Protective Goggles are used in medical institutions to prevent bodily fluids, blood splashes and other splashes from contaminating during treatment or examinations.

PRODUCT PICTURES[1]

SPECIFICATIONS/FEATURES

Type	Protective
Sizes	Standard
Weight	90 gm
Composition	PVC Frame + PC Lens
Features	• Anti-fog, • Anti- scratch • Isolation Protection • High-definition • Ultra-transparent

CERTIFICATIONS

Mandatory	FDA Registered
Additional[2]	EN 166 : 2001 ANSI/ISEA Z87.1

***Note 1**. Pictures shown are for illustration purpose only. Actual product may vary due to product enhancement*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Face Shields

PRODUCT DESCRIPTION

Medical face shields provide over the top, side and front face protection against blood, fluid and other spatters that may carry the risk of contamination.

PRODUCT PICTURES[1]

SPECIFICATIONS/FEATURES

Type	Protective
Sizes	Standard
Weight	50 gm
Thickness	0.5 mm
Specifications	With brow guard/ visor
Composition	Medical polymer
Features	• Anti-fog • Anti- scratch • Isolation protection • High definition • Ultra transparent

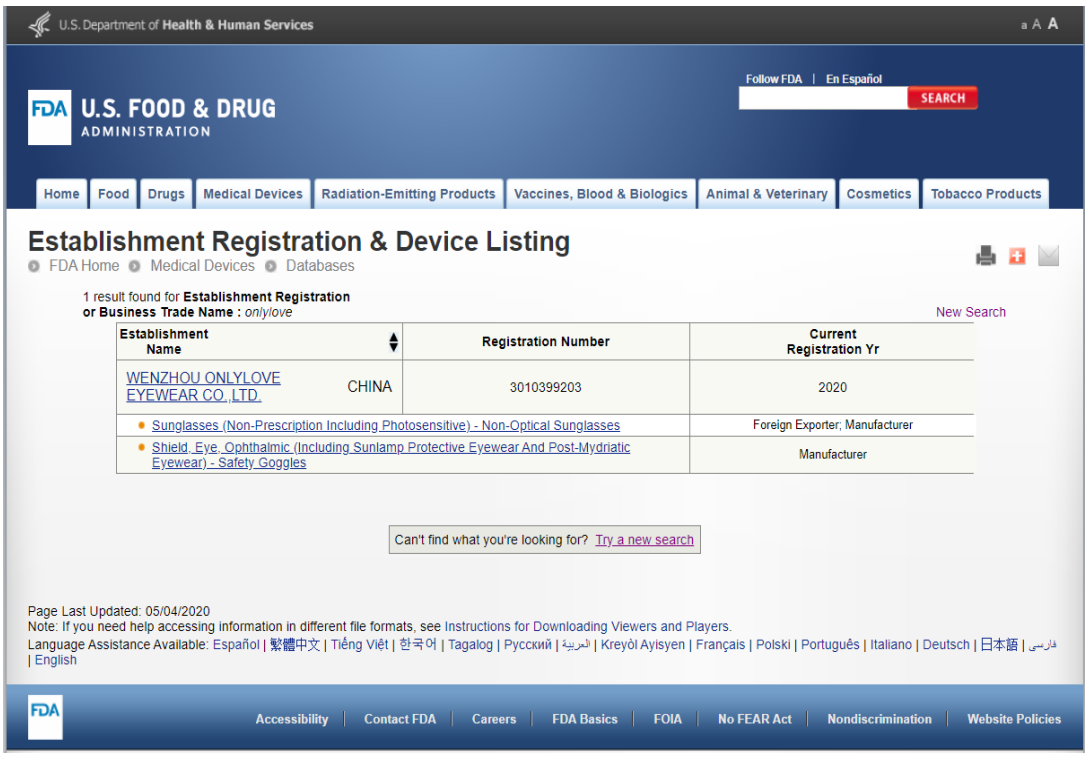
CERTIFICATIONS

Mandatory	FDA Registered
Additional[2]	EN 166 : 2001 ANSI/ISEA Z87.1

***Note 1**. Pictures shown are for illustration purpose only. Actual product may vary due to product enhancement*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Goggles & Face Shields

Certifications : **FDA**


U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

1 result found for **Establishment Registration or Business Trade Name :** *onlylove* New Search

Establishment Name		Registration Number	Current Registration Yr
WENZHOU ONLYLOVE EYEWEAR CO.,LTD.	CHINA	3010399203	2020
• Sunglasses (Non-Prescription Including Photosensitive) - Non-Optical Sunglasses			Foreign Exporter; Manufacturer
• Shield, Eye, Ophthalmic (Including Sunlamp Protective Eyewear And Post-Mydriatic Eyewear) - Safety Goggles			Manufacturer

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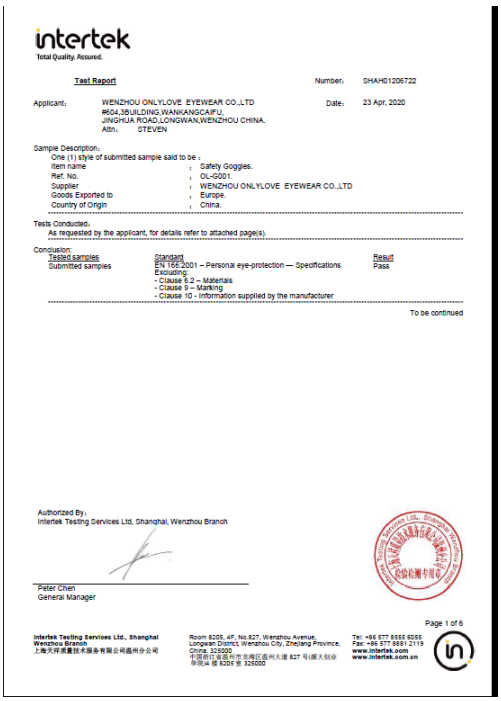
Test Report : Goggle


intertek
Total Quality. Assured.

Test Report Number: SHAH01206722

Applicant: WENZHOU ONLYLOVE EYEWEAR CO.,LTD #604,3BUILDING,WANKANGCAIFU, JINGHUA ROAD,LONGWAN,WENZHOU CHINA. Attn: STEVEN Date: 23 Apr, 2020

Sample Description:
One (1) style of submitted sample said to be :
Item name : Safety Goggles.
Ref. No. : OL-G001.
Supplier : WENZHOU ONLYLOVE EYEWEAR CO.,LTD
Goods Exported to : Europe.
Country of Origin : China.

Tests Conducted:
As requested by the applicant, for details refer to attached page(s).

Conclusion:
Tested samples: Submitted samples — Standard: EN 166:2001 – Personal eye-protection — Specifications. Excluding: - Clause 6.2 – Materials - Clause 9 – Marking - Clause 10 – Information supplied by the manufacturer — Result: Pass

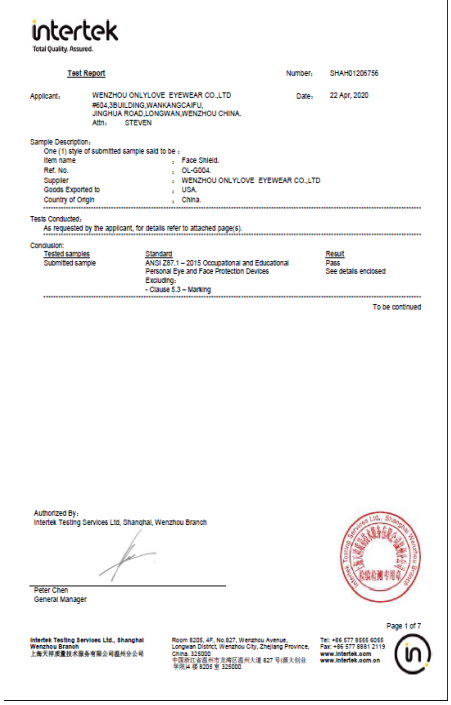
To be continued

Authorized By:
Intertek Testing Services Ltd, Shanghai, Wenzhou Branch
Peter Chen
General Manager

Page 1 of 6

Intertek Testing Services Ltd., Shanghai Wenzhou Branch 上海天祥质量技术服务有限公司温州分公司 Room 8205, 4F, No.827, Wenzhou Avenue, Longwan District, Wenzhou City, Zhejiang Province, China. 325000 Tel: +86 577 8666 6055 Fax: +86 577 8881 2119 www.intertek.com www.intertek.com.cn

Test Report : Face Shield


intertek
Total Quality. Assured.

Test Report Number: SHAH01206756

Applicant: WENZHOU ONLYLOVE EYEWEAR CO.,LTD #604,3BUILDING,WANKANGCAIFU, JINGHUA ROAD,LONGWAN,WENZHOU CHINA. Attn: STEVEN Date: 22 Apr, 2020

Sample Description:
One (1) style of submitted sample said to be :
Item name : Face Shield.
Ref. No. : OL-G004.
Supplier : WENZHOU ONLYLOVE EYEWEAR CO.,LTD
Goods Exported to : USA.
Country of Origin : China.

Tests Conducted:
As requested by the applicant, for details refer to attached page(s).

Conclusion:
Tested samples: Submitted sample — Standard: ANSI Z87.1 – 2015 Occupational and Educational Personal Eye and Face Protection Devices. Excluding: - Clause 5.3 – Marking — Result: Pass. See details enclosed

To be continued

Authorized By:
Intertek Testing Services Ltd, Shanghai, Wenzhou Branch
Peter Chen
General Manager

Page 1 of 7

Intertek Testing Services Ltd., Shanghai Wenzhou Branch 上海天祥质量技术服务有限公司温州分公司 Room 8205, 4F, No.827, Wenzhou Avenue, Longwan District, Wenzhou City, Zhejiang Province, China. 325000 Tel: +86 577 8666 6055 Fax: +86 577 8881 2119 www.intertek.com www.intertek.com.cn

Protective Face Shield with Mask

PRODUCT DESCRIPTION

This Protective shield come with a 3 Ply mask for protecting the full face.
It is easy and convenient to use and comes with a very affordable price.

PRODUCT PICTURES[1]

SPECIFICATIONS

Type	Anti-fog, Anti-dust, with 3-layer disposable mask
Weight	75 gm
Material	Non - woven
Features	• Unisize • Ear loops with nose-pin

CERTIFICATIONS

Mandatory	FDA Registered

***Note 1**. Pictures shown are for illustration purpose only. Actual product may vary due to product enhancement*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Global PPE

Our Product Categories

TESTING AND DIAGNOSTICS

COVID-19 Test Kit (RT-PCR)

PRODUCT DESCRIPTION

The LabGun™ COVID-19 Assay PCR Kit is intended for the detection of COVID-19 strain SARS-CoV-2, in patients that meet the clinical criteria for COVID-19 This RT-PCR Test kit is used to directly detect the presence of an antigen / Viral RNA.

Needs a compatible PCR Analyser i.e. BioRad and Thermo Fisher (CFX96 & AB7500)

Refer to the Global-PPE FAQ on COVID RT-PCR Test kits for more information.

SPECIFICATIONS

Type	Real-time Reverse-transcription PCR test for detection of SARS-CoV-2 coronavirus (COVID-19) gene RdRp
Features	• Accurate – 99.9% specificity and sensitivity • Fast - results in 4-6 hours • Scalable - can be deployed to screen hundreds or thousands of subjects easily
Packaging	Sizes available: • 1000 Tests per box • 3000 Tests per box • 7000 Tests per box • 20000 Tests per box

PRODUCT PICTURES[1]

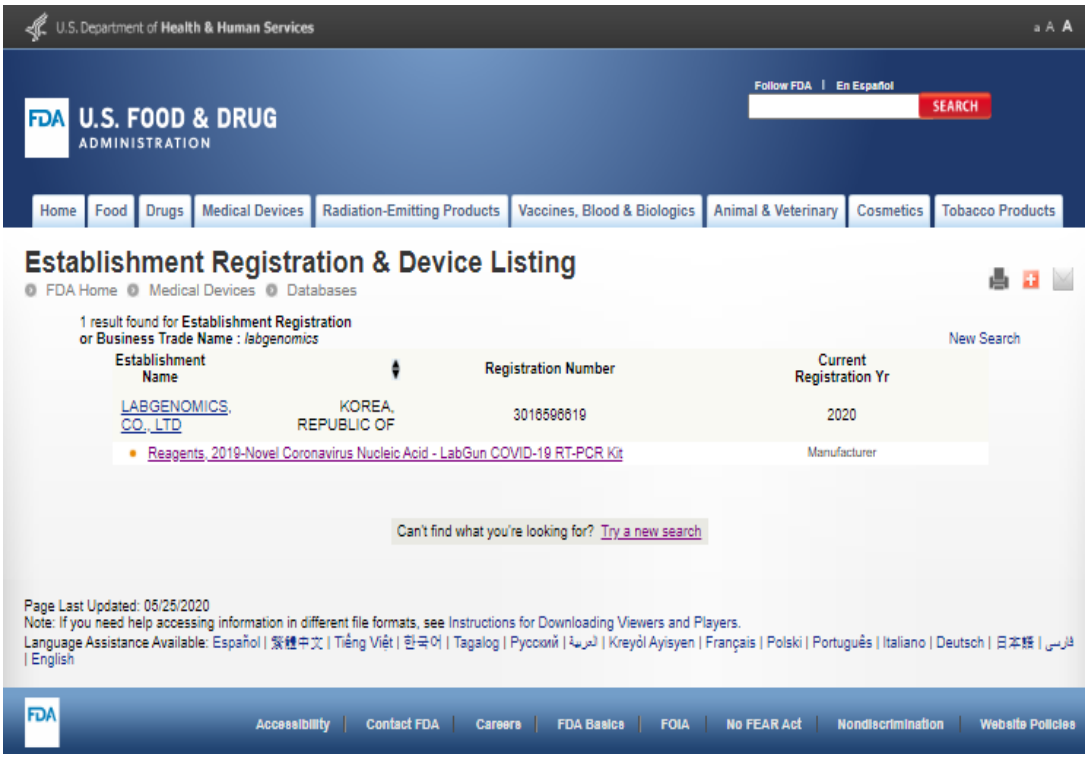
CERTIFICATIONS

Mandatory	FDA EUA
Additional[2]	CE Certified

***Note 1**. Pictures shown are actual product images*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

COVID-19 Test Kit (RT-PCR)

Certifications : **FDA**



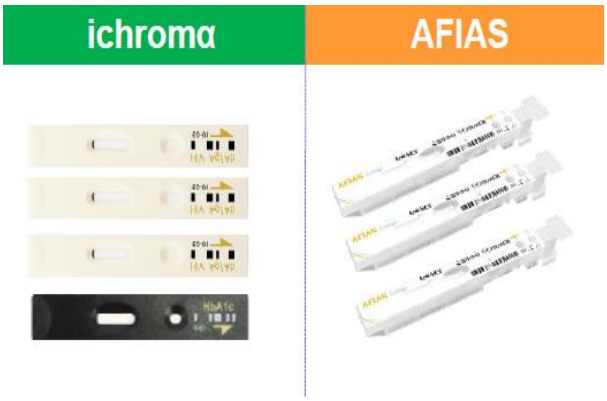
COVID-19 Test Kit (Antibody)

PRODUCT DESCRIPTION

The AFIAS COVID-19 ab and iChroma COVID-19 Ab antibody Kit is intended for the detection of COVID-19 strain SARS-CoV-2, in patients that meet the clinical criteria for COVID-19 .
This antibody kit tests for IgG/IgM in blood sample.

Refer to the Global-PPE FAQ on COVID Antibody Test kits for more information.

PRODUCT PICTURES[1]



SPECIFICATIONS

Type	AFIAS COVID-19Ab & ichroma COVID-19 Ab
Features	• Target – Antiviral IgM/IgG • Fast - results in 10 minutes only • Sample type – Whole blood / Serum / Plasma

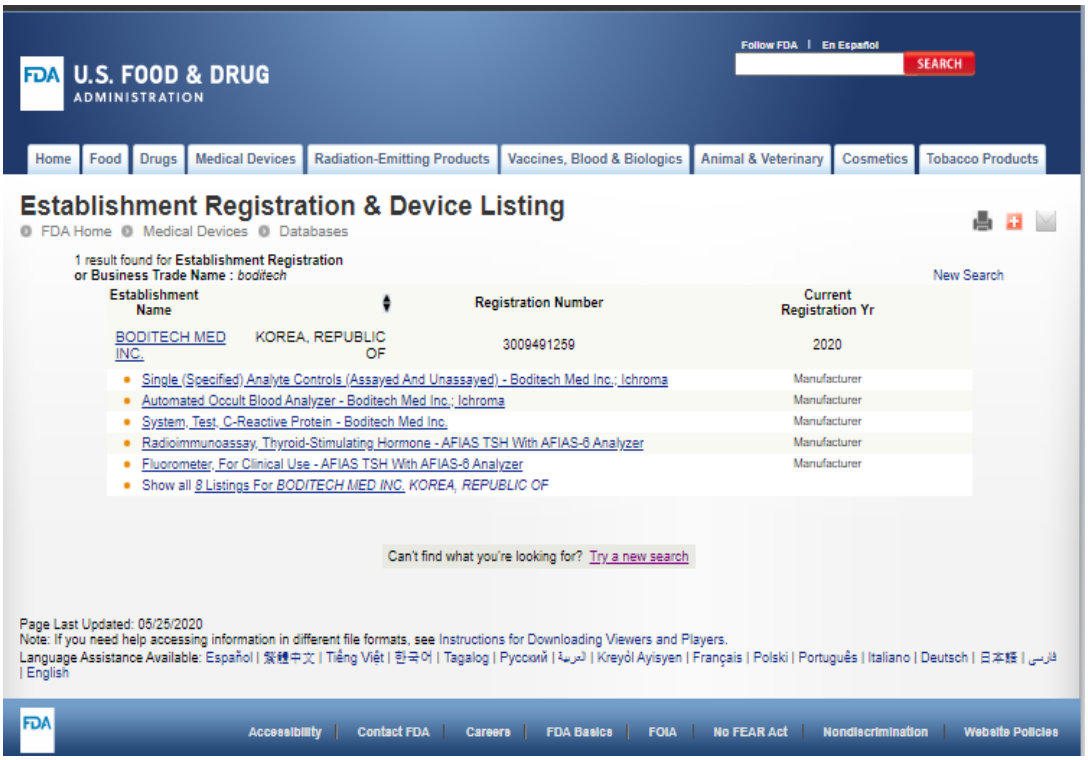
CERTIFICATIONS

Mandatory	FDA EUA
Additional[2]	CE Certified

***Note 1**. Pictures shown are actual product images*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

COVID-19 Test Kit (Antibody)

Certifications : **FDA**



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Establishment Registration & Device Listing

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1 result found for **Establishment Registration or Business Trade Name :** *boditech*

New Search

Establishment Name		Registration Number	Current Registration Yr
BODITECH MED INC.	KOREA, REPUBLIC OF	3009491259	2020

- Single (Specified) Analyte Controls (Assayed And Unassayed) - Boditech Med Inc.; Ichroma — Manufacturer
- Automated Occult Blood Analyzer - Boditech Med Inc.; Ichroma — Manufacturer
- System, Test, C-Reactive Protein - Boditech Med Inc. — Manufacturer
- Radioimmunoassay, Thyroid-Stimulating Hormone - AFIAS TSH With AFIAS-6 Analyzer — Manufacturer
- Fluorometer, For Clinical Use - AFIAS TSH With AFIAS-6 Analyzer — Manufacturer
- Show all 8 Listings For *BODITECH MED INC., KOREA, REPUBLIC OF*

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Swab Kits (1) : ***SWB-KIT-1***
Swab Kits (2) : ***SWB-KIT-2***

Swab Kits

PRODUCT DESCRIPTION

The disposable Swab Kits are used to sample collection, and then sent for testing.

Easy to use for anyone with provide How-to-Use.

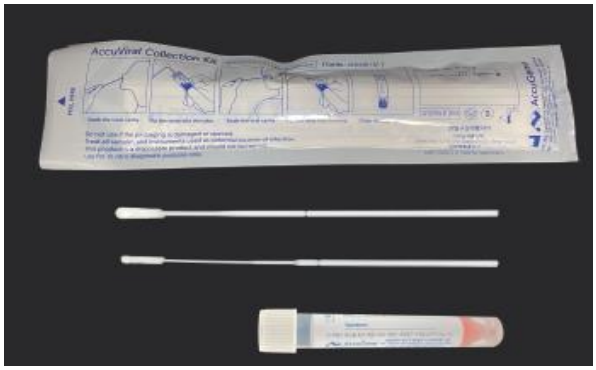
Its Simultaneous collect Nasal and Oral samples.

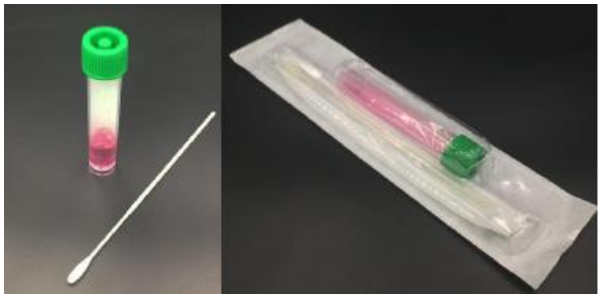
SPECIFICATIONS

Type	Disposable
Weight	Vendor 1 : ~ 18 gm Vendor 2: ~ 30 gm
Specifications	Vendor 1 : 1 Viral Transportation Media (VTM) tube and 1 Nasal swab and Oral swab each. Vendor 2 : 1 VTM and 1 swab
Features	• Compatible with various other nucleic acid extraction kits. • Convenient self-collection, storage and transport

PRODUCT PICTURES[1]

Vendor 1





Vendor 2

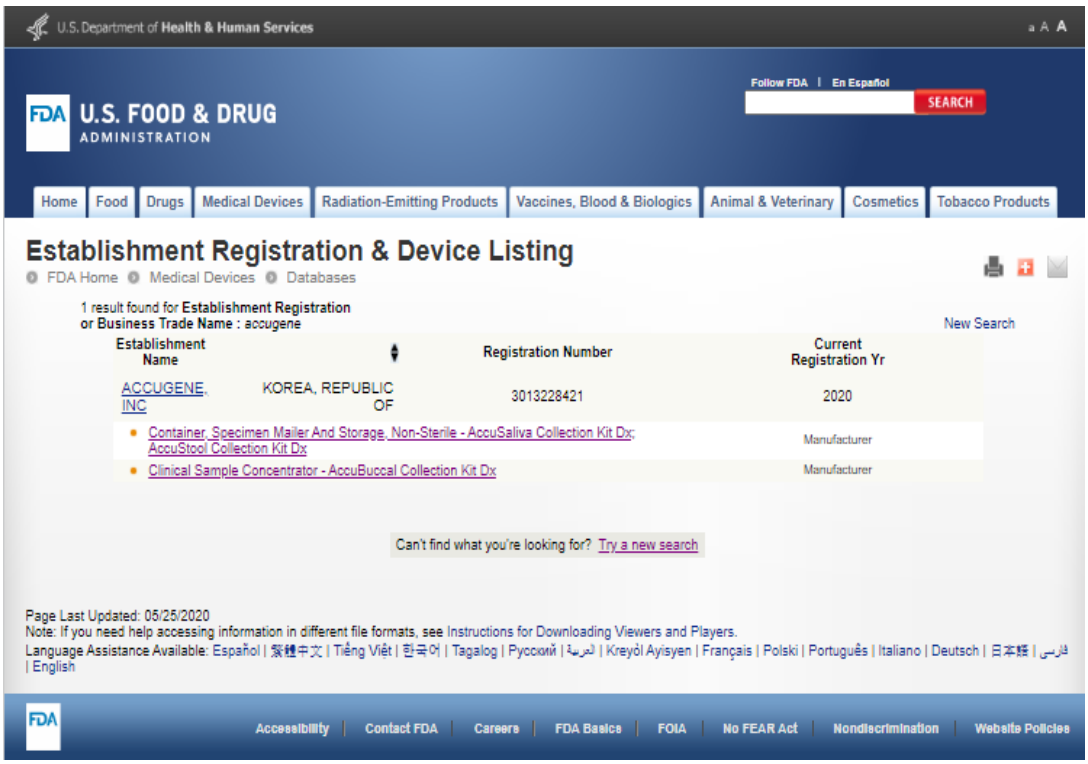
CERTIFICATIONS

Mandatory	FDA Registered
Additional[2]	Certificate of Free Sales (They are under FDA - EUA)

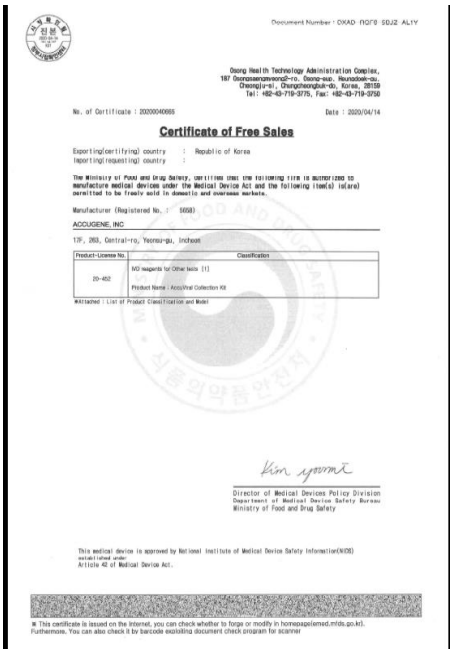
Note 1. *Pictures shown are actual product images*
Note 2. *Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Swab Kits

Certifications : **FDA**



Additional Certificate



Global PPE

Our Product Categories

SANITIZATION & OTHERS

HAND SANITIZER (500ml): STZ-500-1
HAND SANITIZER (237ml): STZ-237-1

Hand Sanitizer

PRODUCT DESCRIPTION

This alcohol -based hand sanitizer works against a wide variety of microorganisms.
It has 65% Ethyl Alcohol.

For bulk usage, 1 Gallon Jugs with 78% Ethyl Alcohol (Made in USA) are available.

PRODUCT PICTURES[1]

SPECIFICATIONS

Type	Sanitizer with 65% Ethyl Alcohol, PET bottle with pump
Packaging	Case of 12 Bottles (500 ml) Case of 24 Bottles (237 ml)
Variations	1 Gallon Jugs with 78% Ethyl Alcohol (Made in USA)

CERTIFICATIONS

Mandatory	FDA Registered

***Note 1**. Pictures shown are actual product images*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

DISINFECTANT WIPES (box) : DISINF-WIPES-TB-50
DISINFECTANT WIPES (Can) : DISINF-WIPES-CAN-110

Disinfectant Wipes

PRODUCT DESCRIPTION

These alcohol based disinfectant wipes are proven to kill most microorganisms such as bacteria, yeast & viruses.
A mixture of ethanol diluted in water is effective against a wide spectrum of microorganisms.
It come in two variants i.e wipes in a box and in a canister.

PRODUCT PICTURES[1]

SPECIFICATIONS

Type	Alcohol pad (non-woven) with 70-75 % Ethyl Alcohol
Weight	167 gm (box) 667 gm(canister)
Size	12*15cm (Box wipe) 13*17cm(Canister wipe)
Packaging	50 Wipes in Canister 110 Wipes in Box
Features	• Paper aluminium bag sachet • Wipes Material 45g/m^2

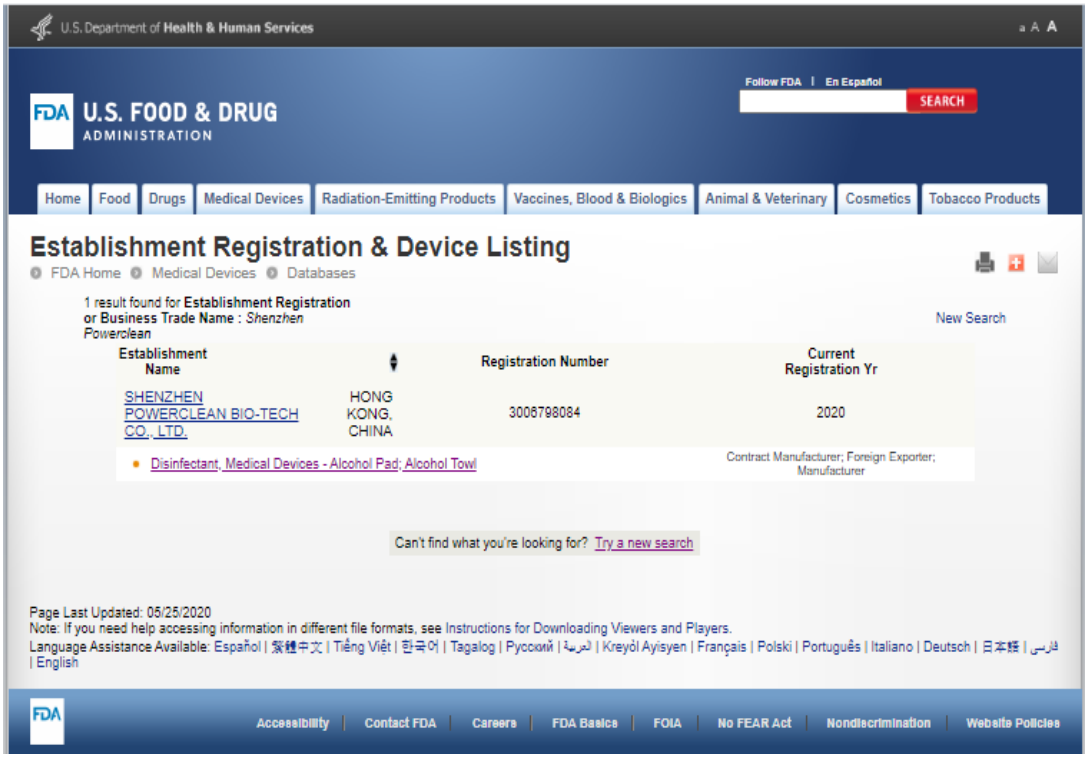
CERTIFICATIONS

Mandatory	FDA Registered
Additional[2]	CE Certified

***Note 1**. Pictures shown are actual product images*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

Disinfectant Wipes

Certifications : **FDA**



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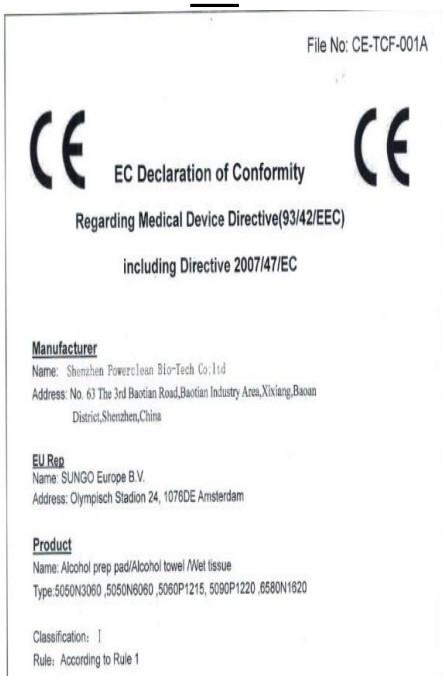

File No: CE-TCF-001A

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Manufacturer
Name: Shenzhen Powerclean Bio-Tech Co.,ltd
Address: No. 63 The 3rd Baotian Road,Baotian Industry Area,Xixiang,Baoan District,Shenzhen,China

EU Rep
Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam

Product
Name: Alcohol prep pad/Alcohol towel /Wet tissue
Type:5050N3060 ,5050N6060 ,5060P1215, 5090P1220 ,6580N1620

Classification: I
Rule: According to Rule 1

Thermometer – DET 306

PRODUCT DESCRIPTION

Non-contact thermometers allow a person's temperature to be taken with minimal (tympanic) or no (Non-contact infrared thermometer [NCIT], thermal scanner) contact with the person.

PRODUCT PICTURES[1]

SPECIFICATIONS

Type	Infrared Non Contact Forehead Thermometer
Weight	135 gm
Features	• 10 memory • Fever Alarm • Auto shut off • Low battery indicator • Backlight - Optional
Measure Time Accuracy	1 second measurement Forehead: 34 C, ~ 43 C Object Mode: 0C ~ 100C 0.1 C or 0.1 F
Display Resolution LCD Size	24 * 22 mm

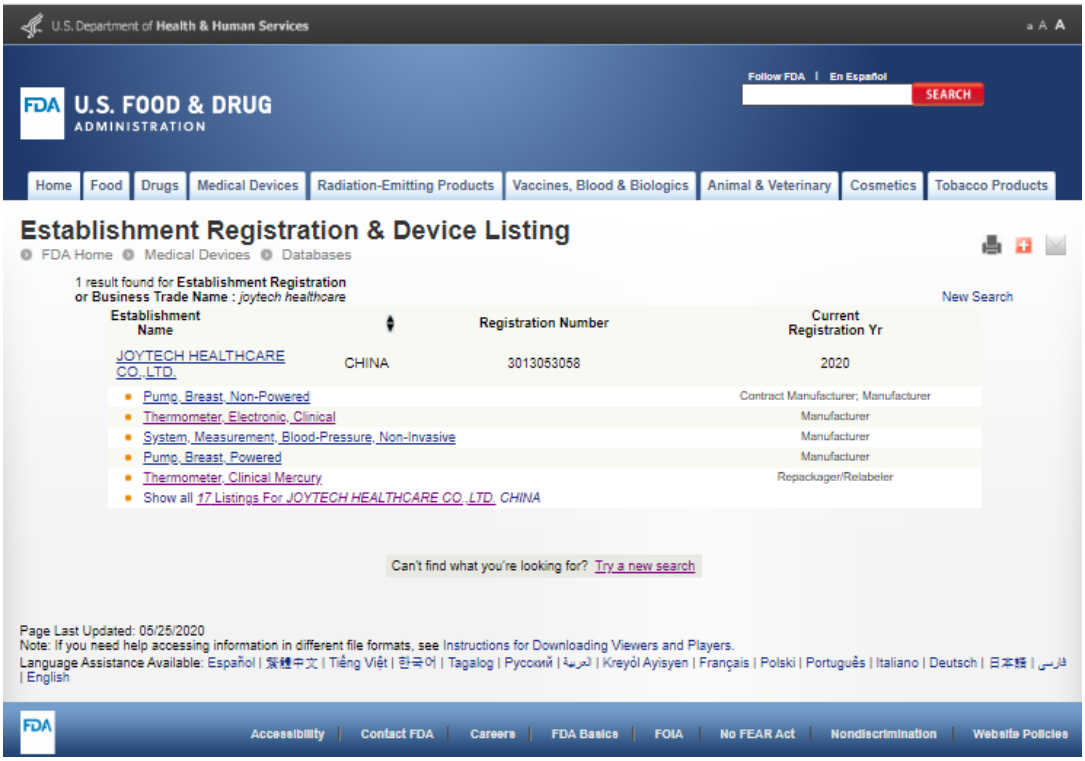
CERTIFICATIONS

Mandatory	FDA Registered
Additional[2]	CE Certified EN ISO 13485 : 2016

***Note 1**. Pictures shown are actual product images*
***Note 2**. Additional Certificate are not mandatory, the product with these additional certificates can be made available for specific requirements.*

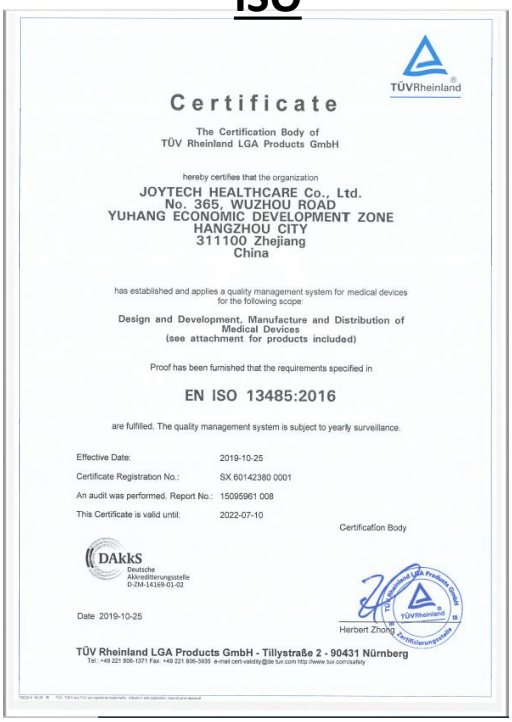
Thermometer – DET 306

Certifications : **FDA**



CE

ISO



About Global-PPE

As the entire world fights the COVID-19 pandemic, the sudden and huge influx of infected patients has resulted in severe shortages of personal protective equipment (PPE) in medical facilities across the country, severely risking the safety and lives of our healthcare professionals. Global-PPE is committed to creating rapid and sustainable supplies of certified diagnostic/testing kits and medical consumables.

Our marketplace assists governments, healthcare institutions and hospitals to procure aggregated kits comprised of the highest quality certified products from verified manufacturers, supplier-partners & exporters and innovative 3D printer-based solution providers from across the globe.

Global-PPE is guided by professionals with rich experience in public healthcare, rapid emergency response, global supply chain and innovative entrepreneurship. Our team is active 24/7, sourcing PPE supplies from various parts of the country and meeting demand cost effectively.

Contact: enquiry@global-ppe.com

Call: +1-703-488-6912

Contact Us

enquiry@global-ppe.com | www.global-ppe.com

11490, Commerce Park Drive, Suite #520
Reston, Virginia 20191

Google Location Link

+1-703-488-6912

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