arnolds
OFFICE FURNITURE

DIRECT FACTORY IMPORTERS OF

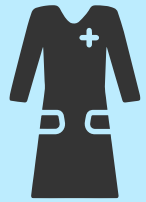
PPE

PERSONAL PROTECTIVE EQUIPMENT

SUNLINE SUPPLY

KN95 MASKS
AND
DISPOSABLE FACE MASKS

SURGICAL GOWNS
AND
ISOLATION GOWNS



NITRILE GLOVES

CAPS
AND
SHOE COVERS

FACE SHIELDS

PROTECTIVE GOGGLES

ISOLATION SUITS
AND
PROTECTION SUITS

DISPOSABLE
STETHOSCOPES

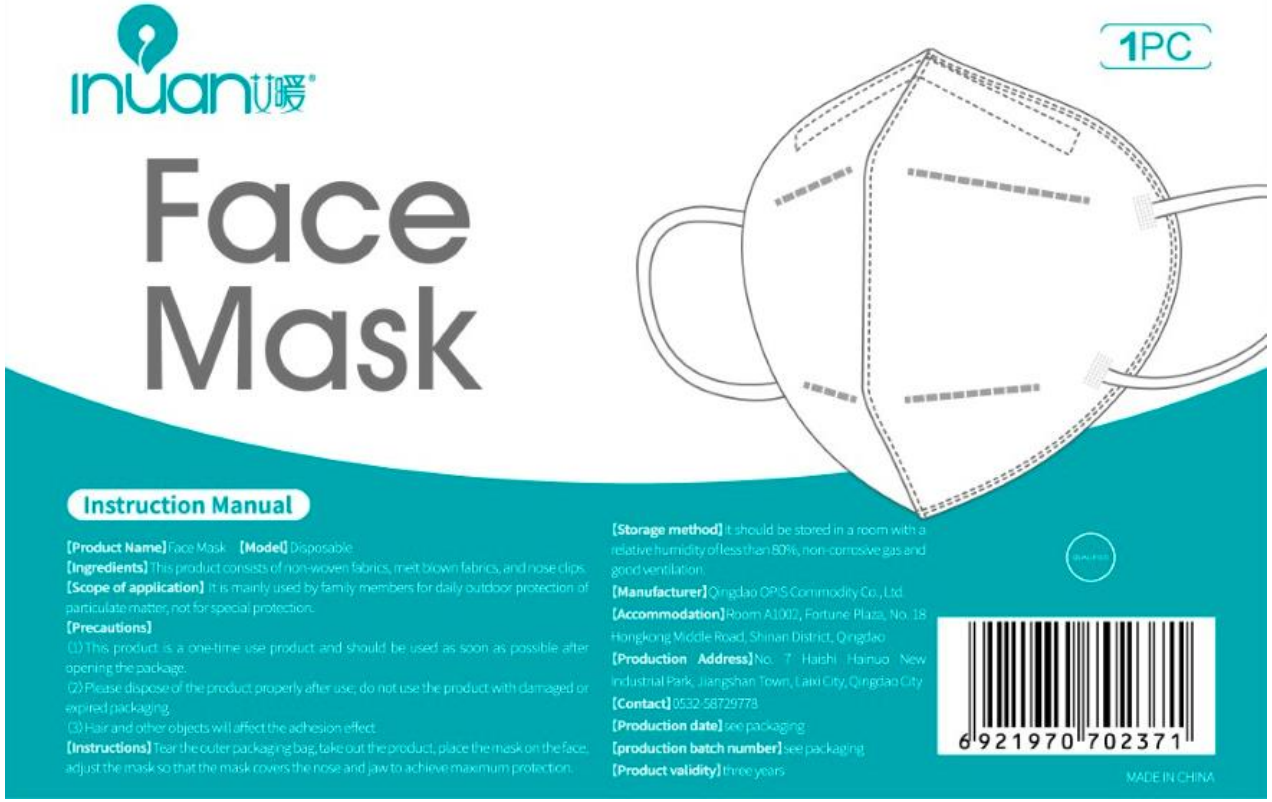
arnolds
OFFICE FURNITURE

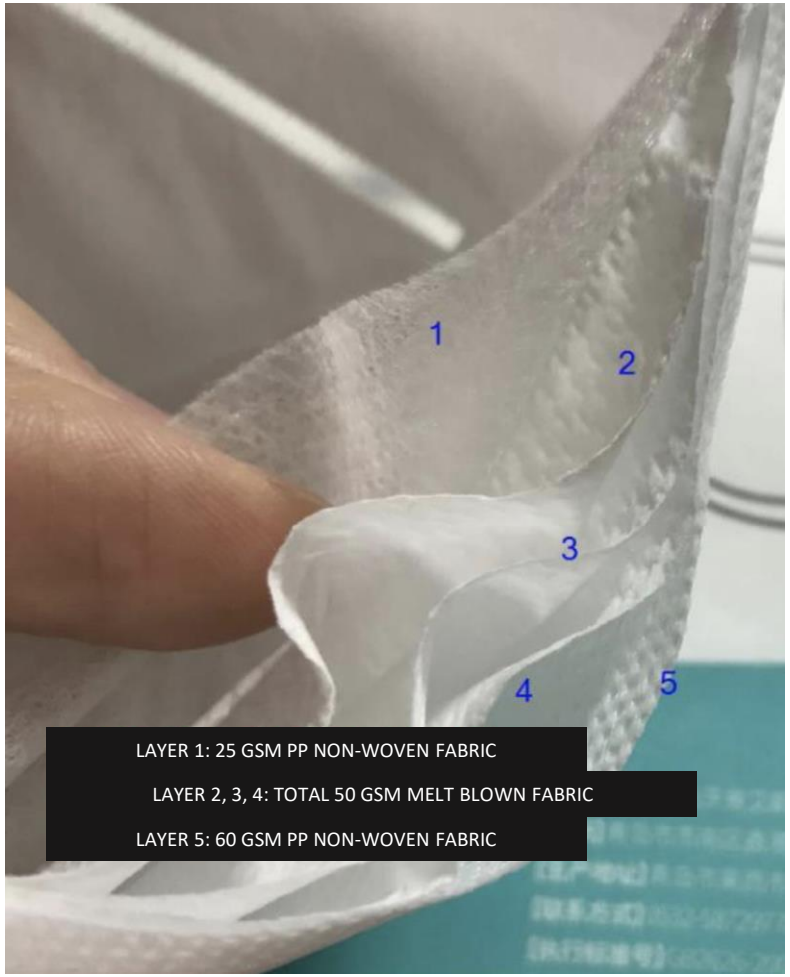
KN95 MASK

- Model and specification: Disposable type dust mask
- Ingredients: The product contains of non-woven fabrics, melt blown fabrics and interior nose clips
- Scope of application: suitable for people to cover their mouth, nose and jaw to prevent harmful particles
- It is used for daily outdoor protection; one-time use recommended
- Objects such as hair can hinder the adhesion effect
- Storage method: It should be stored in a room with a relative humidity of less than 80% non-corrosive gas and good ventilation
- Production date/batch, expire date: See packaging
- Product Validity: 3 years
- Executive Standard Number: GB2626-2006
- Filter Level: GB2626-2006-KN95
- Minimum Order Quantity: 1,000
- Carton size = 22.4” x 14.1” x 16.4”

arnolds
OFFICE FURNITURE

KN95 MASK





Material: Non-woven 60gsm PP + 25gsm BFE 95% Fliter Melt Blown Fabric +25gsm BFE 95% Fliter Melt Blown Fabric +25gsm PP, Blue, Non-sterile. With earloops and inside nose clip.

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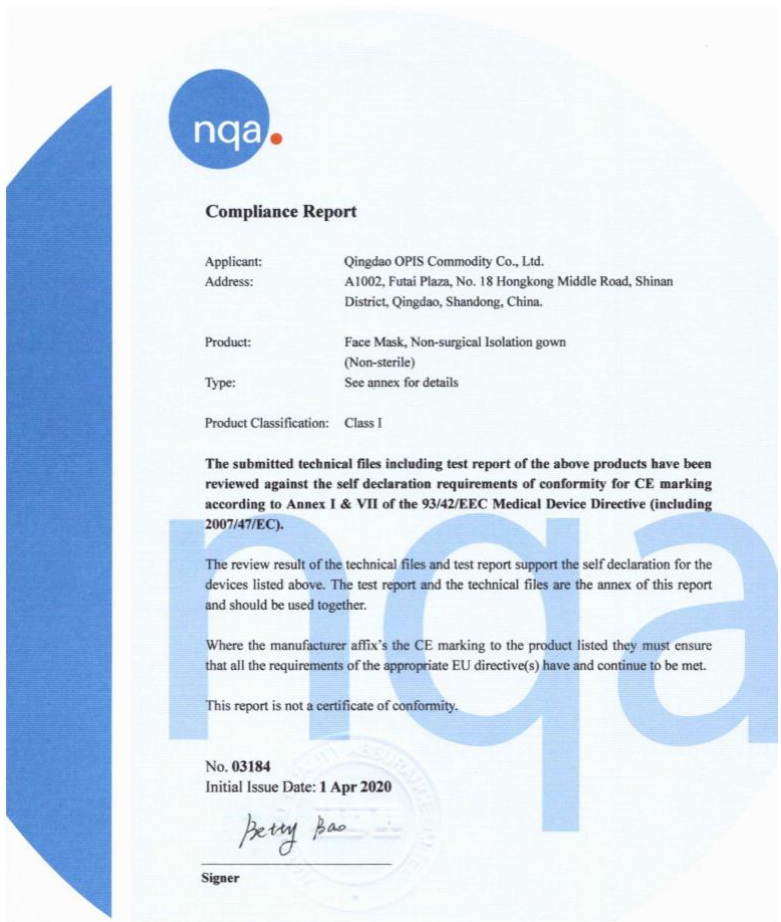
KN95 FACE MASK CERTIFICATIONS



nqa.

Compliance Report

Applicant: Qingdao OPIS Commodity Co., Ltd.
Address: A1002, Futai Plaza, No. 18 Hongkong Middle Road, Shinan District, Qingdao, Shandong, China.

Product: Face Mask, Non-surgical Isolation gown (Non-sterile)
Type: See annex for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

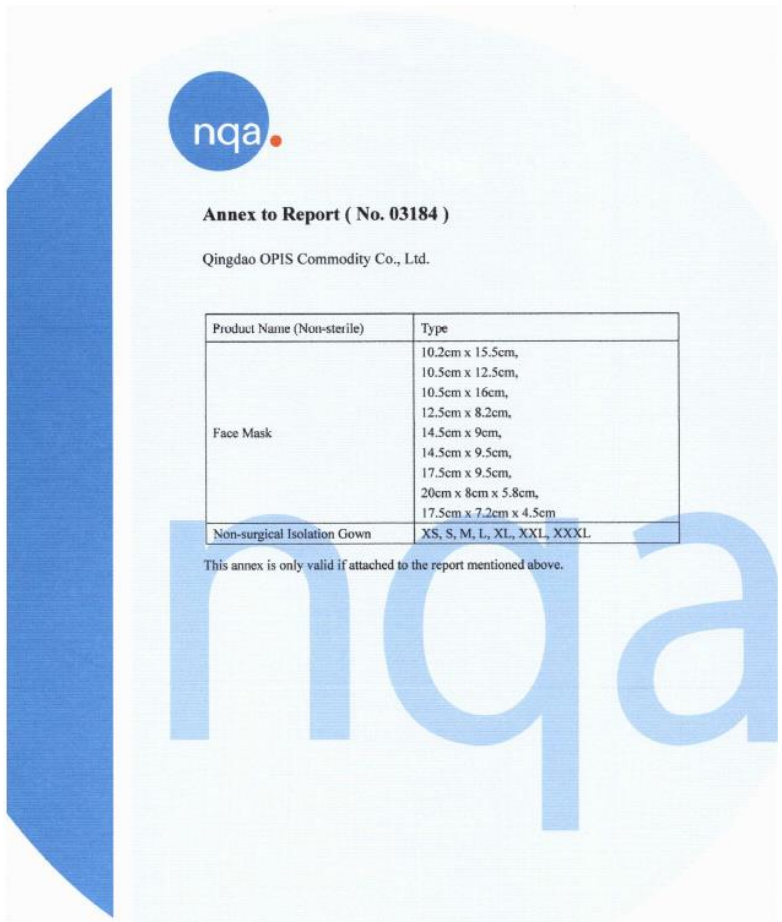
Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **03184**
Initial Issue Date: **1 Apr 2020**

Betty Bao

Signer



nqa.

Annex to Report (No. 03184)

Qingdao OPIS Commodity Co., Ltd.

Product Name (Non-sterile)	Type
Face Mask	10.2cm x 15.5cm, 10.5cm x 12.5cm, 10.5cm x 16cm, 12.5cm x 8.2cm, 14.5cm x 9cm, 14.5cm x 9.5cm, 17.5cm x 9.5cm, 20cm x 8cm x 5.8cm, 17.5cm x 7.2cm x 4.5cm
Non-surgical Isolation Gown	XS, S, M, L, XL, XXL, XXXL

This annex is only valid if attached to the report mentioned above.

CERTIFICATE

CERTIFICATE OF FDA REGISTRATION

Certification No.: CTCSD2020296

Dear Official Correspondent:
This document provides notification of the registration number assigned to your establishment:

Establishment: QINGDAO OPIS COMMODITY CO., LTD
Address: A1002, Futai Plaza, No. 18 Hongkong Middle Road, Shinan District, Qingdao, Shandong, 266071, CHINA
Owner/operator NO.: 10063386

Listing Number	Premarket Submission Number	Product Code(s)	Device Name	Activities
0376218	EXEMPT	LYU	Accessory, Surgical Apparel (disposable gloves; examination gloves)	Manufacturer
0376217	EXEMPT	KHA	MASK, SCAVENGING (dust mask;disposable mask;face mask)	Manufacturer
0377427	EXEMPT	OEA	Non-surgical isolation gown	Manufacturer
0377429	EXEMPT	IMD	PACK, HOT OR COLD,DISPOSABLE (warm patch; foot patch; moxibustion stick; steam eye mask; instant ice pack; cold patch; fever cooling patch; cold gel)	Manufacturer
0377435	EXEMPT	IME	Pack, hot or cold, Reusable (ice mat; ice pack; ice pillow; ice mattress; heat and cold gel pack)	Manufacturer

Helen Chan

General Manager
CTC REGISTRATION LLC
Email: ctc-086@hotmail.com
Web: www.ctc-086.com

CTC REGISTRATION GROUP SEAL

Validity: Dec.31,2020

FDA Official Website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

CERTIFICATE

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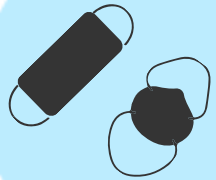
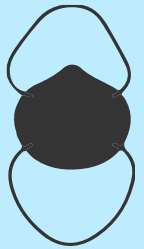


KN95 MASK COMPARISON

- Comparison between FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes
- Conducted by 3M
- Approved by CDC (read more HERE)

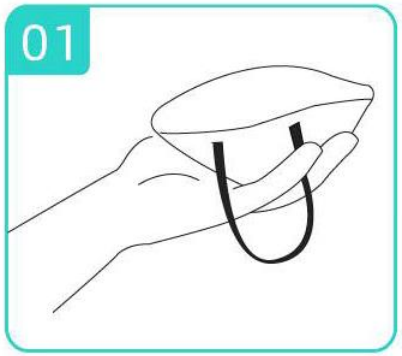
Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS (Japan JMHLW-Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO_2 clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.



HOW TO WEAR KN95 MASK

01



Open the mask fully and face the side without nose strip of the mask,hold one ear loop in each hand.

02

Hold the mask against your chin and place the nose strip on the top of the mask.

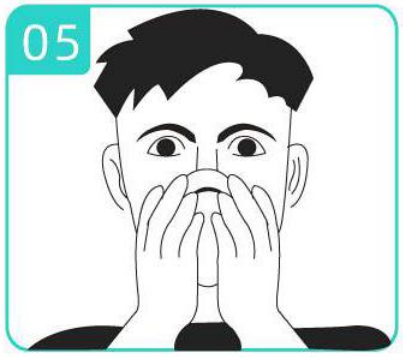
03

After straightening the ear loop, adjust it until you feel as comfortable as possible.

Place the fingers of both hands in the middle of the metal nose strip and press inward as you move along the nose strip to the sides. Using only one hand to hold the nose strip may affect the mask protection effect.

04

05



Check for proper wear: press the mask lightly with both hands and breathe deliberately. Air should not leak from the edge of the mask.

DISPOSABLE FACE MASK

Description of Goods & Packing Details
Disposable 3-ply Face Masks --Model F95
Material: Non-woven 25gsm PP + 25gsm BFE 95% Fliter Melt Blown Fabric +30gsm PP, Blue, Size 17.5*9.5, Non-sterile. With earloops and inside nose clip.
Packing: 50pcs/box, 40boxes/carton, 2000pcs/carton.
Carton size: 56.8cm*35.8*41.7

- Model and specification: Disposable flat type, middle size
- Ingredients: The product contains of non-woven fabrics, melt blown fabrics and nose clips
- Scope of application: It is suitable for people to cover their mouth, nose and jaw to prevent harmful particles
- Precautions: This product is a one-time use product and should be used as soon as possible after opening the package
- Objects such as hair can hinder the adhesion effect
- Storage method: It should be stored in a room with a relative humidity of less than 80% non-corrosive gas and good ventilation
- Production date/batch, expire date: See packaging
- Product Validity: 3 years
- Executive Standard Number: Q/0285WPA 020-2020
- Filter Level: TAJ1001-2015-F95
- Minimum Order Quantity: 1,000

DISPOSABLE FACE MASK

3 LAYERS STRUCTURE

Better quality than other single layer non-medical mask

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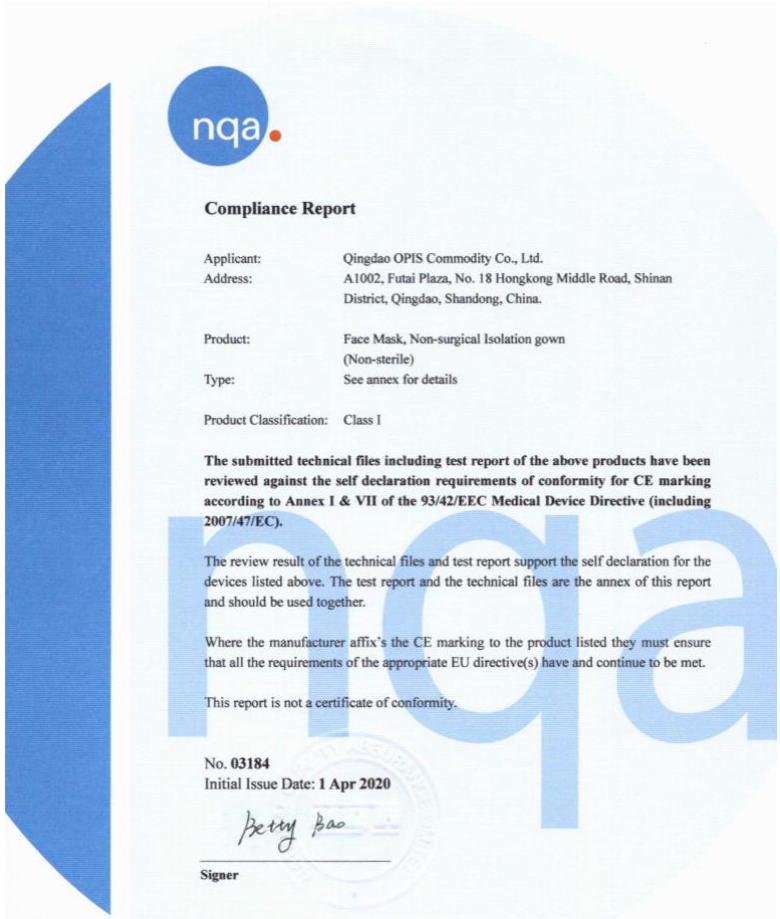
DISPOSABLE FACE MASK CERTIFICATIONS



nqa.

Compliance Report

Applicant: Qingdao OPIS Commodity Co., Ltd.
Address: A1002, Futai Plaza, No. 18 Hongkong Middle Road, Shinan District, Qingdao, Shandong, China.

Product: Face Mask, Non-surgical Isolation gown (Non-sterile)
Type: See annex for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

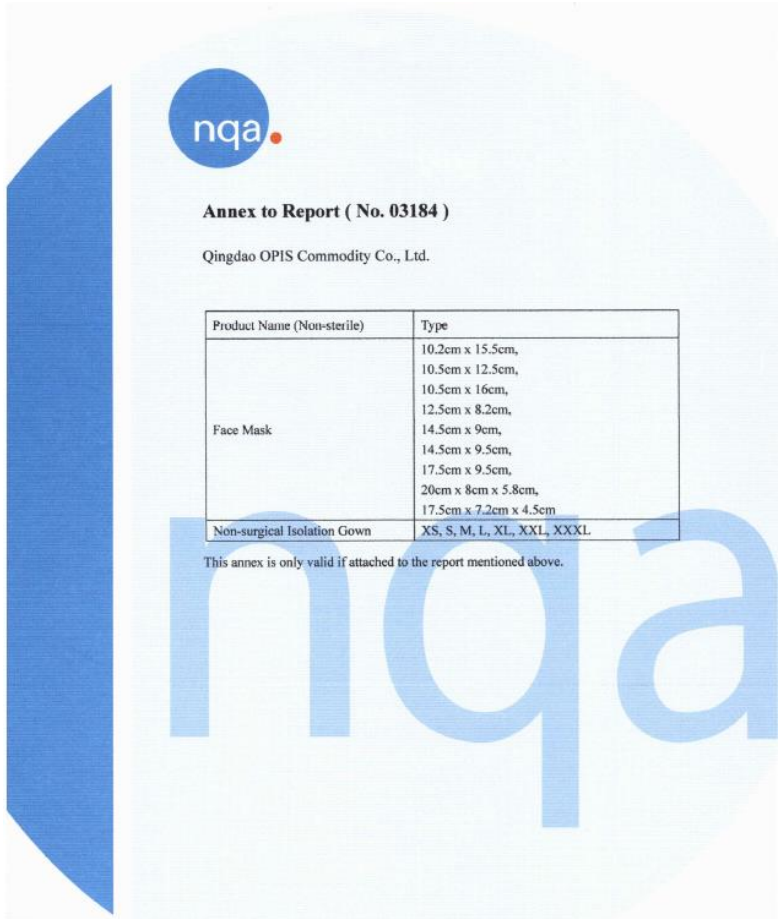
Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **03184**
Initial Issue Date: **1 Apr 2020**

Betty Bao

Signer



nqa.

Annex to Report (No. 03184)

Qingdao OPIS Commodity Co., Ltd.

Product Name (Non-sterile)	Type
Face Mask	10.2cm x 15.5cm, 10.5cm x 12.5cm, 10.5cm x 16cm, 12.5cm x 8.2cm, 14.5cm x 9cm, 14.5cm x 9.5cm, 17.5cm x 9.5cm, 20cm x 8cm x 5.8cm, 17.5cm x 7.2cm x 4.5cm
Non-surgical Isolation Gown	XS, S, M, L, XL, XXL, XXXL

This annex is only valid if attached to the report mentioned above.

CERTIFICATE

CERTIFICATE OF FDA REGISTRATION

Certification No.: CTCSD2020296

Dear Official Correspondent:
This document provides notification of the registration number assigned to your establishment:

Establishment: QINGDAO OPIS COMMODITY CO., LTD
Address: A1002, Futai Plaza, No. 18 Hongkong Middle Road, Shinan District, Qingdao, Shandong, 266071, CHINA
Owner/operator NO.: 10063386

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D376218	EXEMPT	LYU	Accessory, Surgical Apparel (disposable gloves; examination gloves)	Manufacturer
D376217	EXEMPT	KHA	MASK, SCAVENGING (dust mask;disposable mask;face mask)	Manufacturer
D377427	EXEMPT	OEA	Non-surgical isolation gown	Manufacturer
D377429	EXEMPT	IMD	PACK, HOT OR COLD,DISPOSABLE (warm patch; foot patch; moxibustion stick; steam eye mask; instant ice pack; cold patch; fever cooling patch; cold gel)	Manufacturer
D377435	EXEMPT	IME	Pack, hot or cold, Reusable (ice mat; ice pack; ice pillow; ice mattress; heat and cold gel pack)	Manufacturer

Helen Chan

General Manager
CTC REGISTRATION LLC
Email: ctc-086@hotmail.com
Web: www.ctc-086.com

CTC REGISTRATION GROUP SEAL

Validity: Dec.31,2020

FDA Official Website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

CERTIFICATE

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NITRILE GLOVES

- Nitrile rubber is more resistant than natural rubber to chemicals, oils and acids, and has superior strength
- Nitrile disposable gloves such as are three times more puncture-resistant than latex and are more chemical resistant than latex or vinyl
- Disposable
- Latex-free
- Standard blue/purple color

Description of Goods & Packing Details
Nitrile Exam Glove
Material: Netrile Size: S M
Packing: 50 pairs/bag, 20bags/carton.
Carton size: 32cm*25cm*25cm

GLOVE CERTIFICATIONS

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 0H200313.QSTUU46

Certificate's Holder: Qingdao Sinor Textile Co., Ltd.
Room 1020 East, No. 12, Fuzhou South Road, Shinan District, Qingdao, Shandong Province

Manufacturer: Qingdao Sinor Textile Co.,Ltd.
In Qiancheng Community Electronic Industrial Park, Shangma Street, Chengyang District, Qingdao City, Shandong Province

Certification ECM Mark: European Community – Type Approved

Product: Disposable Protective Clothing
Model(s): M, L, XL, XXL, XXXL

Verification to: Standard: EN 14126:2003+AC:2004
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it
This verification doesn't imply assessment of the production of the product(s).

Additional information: clarification about the CE Marking:
We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE *Marking Certification Procedure* through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of issue 13 March 2020 — Expiry date 12 March 2025

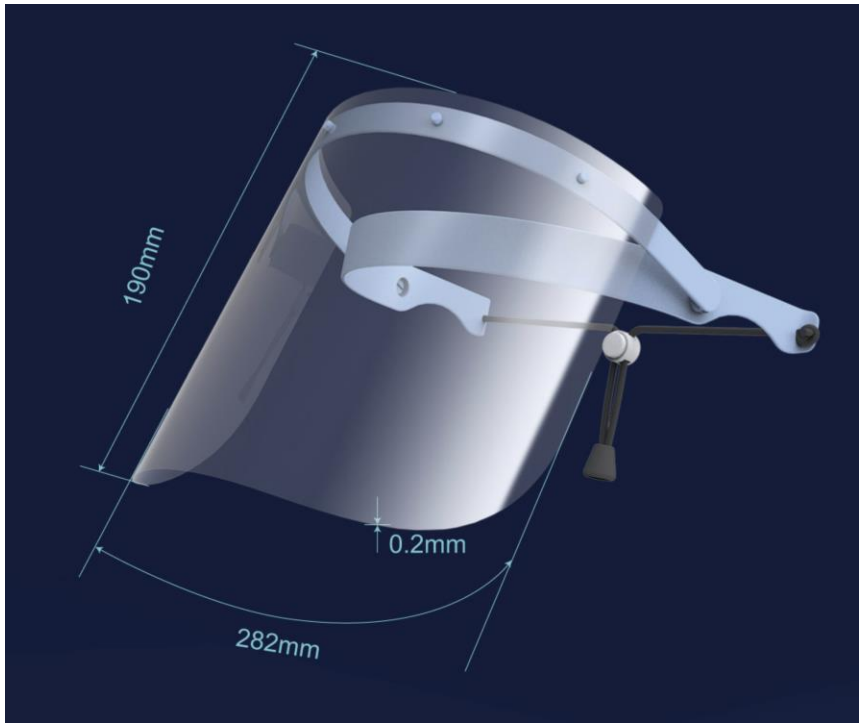
Service Manager
Luca Bedeschi

Deputy Manager
Amanda Payne

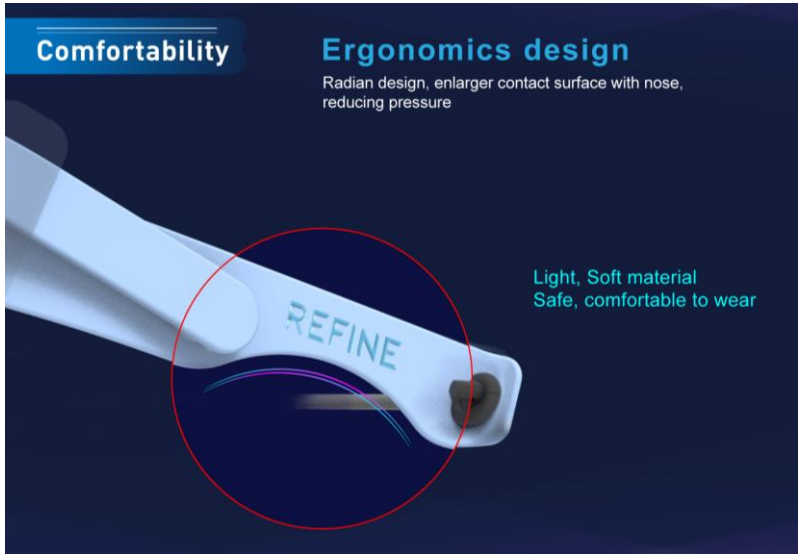
Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 ⎙ +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

FACE SHIELDS

- All-day Comfort, All-day Secure
- Double-sided antifogging PET shield provides a clear vision without dizziness
- Wider lenses protect faces effectively and isolating virus efficiently, Anti-Droplets, Anti-Virus, Anti-Fog, Anti-Spray
- 180° adjustable according to your need
- Disposable shield, more environmentally-friendly
- Headband can be sterilized by disinfectant and re-used (do not use high-temperature sterilization)
- **Can purchase (1) headband with (10) shields as a kit, or purchase headbands and shields separately, to significantly reduce per use price**
- Complies with the standard of EN166:2001, ANSI Z87.1
- Achieved CE mark and FDA registration
- Unit size: 11.1” (282mm) w x 7.48”(190 mm) h



FACE SHIELDS



FACE SHIELD CERTIFICATIONS

FDA

Certificate Of FDA Registration

Fiscal Year 2020

This is certified that:
At The Address Stated Below Has Completed U.S. FOOD And DRUG ADMINISTRATION Medical Device Registration Through MANTONG.

GUILIN REFINE MEDICAL INSTRUMENT CO., LTD.
Address:NO.8-3, INFORMATION INDUSTRIAL PARK, HIGH-TECH ZONE, QIXING DISTRICT GUILIN, GUANGXI,541004,CHINA

Owner/Operator Number 10064688

Device Listing Number See annex

- The FDA annual establishment registration fee must be paid between Oct. 1 and Dec. 31 of every year.
- You can search the FDA registration information on this website or scan QR code: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
- Cert No.: 209829MTG

Executive Director
Date: 03-30-2020

MTG STANDARDS TESTING & CERTIFICATION CENTER www.fdacn.org

FACE SHIELDS

- The Direct Splash Protection Shield comes with an anti-fog coating on both the inside and outside of the shield providing clear, direct and peripheral vision in all conditions
- The Full-Face Design provides complete coverage including the sides of the face preventing all contact with eyes, mouth, and nose
- Keeps a physical barrier between you and all airborne bugs
- The Elastic Headband allows for a custom fit no matter the size of the head and face. Comfort design is perfect for all.
- The Full-Face Shield comes with skin-friendly 1.2” forehead sponge. Fits easily goes over glasses or goggles.
- Optically clear, Anti-glare, Latex Free, No hearing limitation
- Individually packed, Antiseptic, Disposable
- Unit size: 12.6”h x 8.3”w

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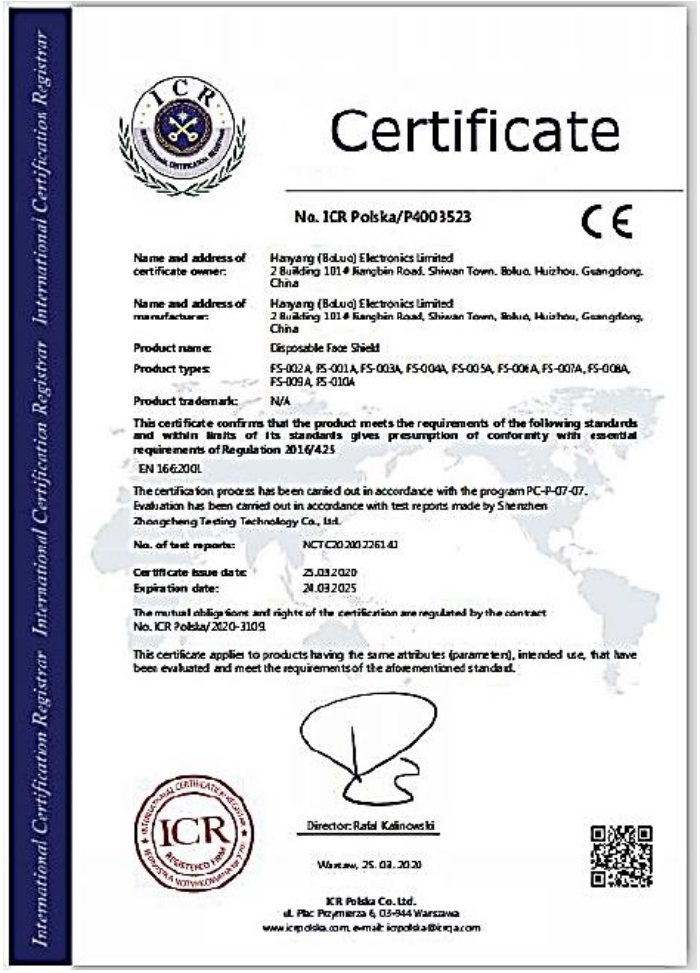
FACE SHIELD CERTIFICATIONS



International Certification Registrar International Certification Registrar International Certification Registrar International Certification Registrar

Certificate

No. ICR Polska/P4003523 CE

Name and address of certificate owner:	Hanyang (Baluo) Electronics Limited 2 Building 101# Rangbin Road, Shiwan Town, Boluo, Huizhou, Guangdong, China
Name and address of manufacturer:	Hanyang (Baluo) Electronics Limited 2 Building 101# Rangbin Road, Shiwan Town, Boluo, Huizhou, Guangdong, China
Product name:	Disposable Face Shield
Product types:	FS-002A, FS-001A, FS-003A, FS-004A, FS-005A, FS-006A, FS-007A, FS-008A, FS-009A, FS-010A
Product trademark:	N/A

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 166:2001

The certification process has been carried out in accordance with the program PC-P-07-07. Evaluation has been carried out in accordance with test reports made by Shenzhen Zhongcheng Testing Technology Co., Ltd.

No. of test reports:	NCTC20200226140
Certificate issue date:	25.03.2020
Expiration date:	24.03.2025

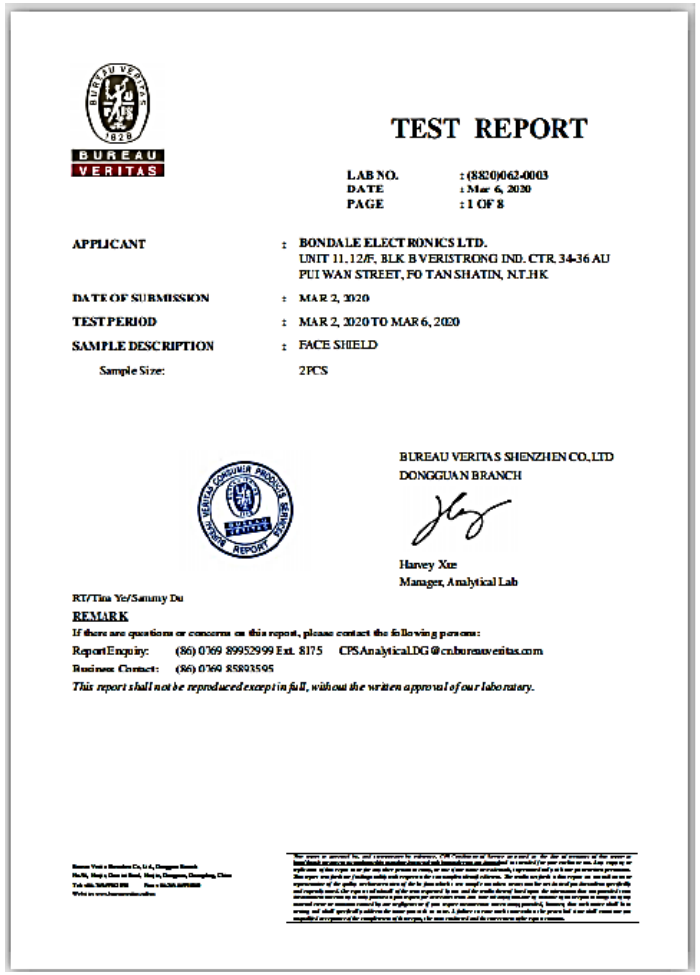
The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3109.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.

Director: Rafał Kalinowski

Warsaw, 25. 03. 2020

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com



BUREAU VERITAS

TEST REPORT

LAB NO. : (8820)062-0003
DATE : Mar 6, 2020
PAGE : 1 OF 8

APPLICANT	:	BONDALE ELECTRONICS LTD. UNIT 11, 12/F, BLK B VERISTRONG IND. CTR. 34-36 AU PUI WAN STREET, FO TAN SHATIN, N.T.HK
DATE OF SUBMISSION	:	MAR 2, 2020
TEST PERIOD	:	MAR 2, 2020 TO MAR 6, 2020
SAMPLE DESCRIPTION	:	FACE SHIELD
Sample Size:		2PCS

BUREAU VERITAS SHENZHEN CO.,LTD
DONGGUAN BRANCH

Harvey Xue
Manager, Analytical Lab

RT/Tina Ye/Sammy Du

REMARK

If there are questions or concerns on this report, please contact the following persons:

Report Enquiry: (86) 0769 89952999 Ext. 8175 CPSAnalyticalDG@cn.bureauveritas.com
Business Contact: (86) 0769 85803595

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

FDA

产权人识别号 (Ower Operator Number)
10065234

产品注册号码 (Listing Number)
D384071

查询网址 (Website)
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

arnolds OFFICE FURNITURE

INDUSTRIAL ISOLATION SUITS

- Non-CE certified, but uses same material as CE certified Medical Isolation Suit
- Non-woven, more durable material than standard suits
- Most common, mid-grade protection
- Generally used by medical personnel to avoid exposure to blood, body fluids, and other infectious materials, or to protect patients from infection
- Gown provides two-way isolation that prevents both medical personnel from being infected or contaminated and prevents the patient from being infected

Description of Goods & Packing Details
Isolation Suit --Brand Basewing
PE film + SSS non woven fabric
Packing: 1pc/bag, 40bags/carton.
Carton size: 70cm*45cm*50cm

MEDICAL ISOLATION SUITS

- CE certified
- Non-woven, more durable material than standard suits
- Most common, mid-grade protection
- Generally used by medical personnel to avoid exposure to blood, body fluids, and other infectious materials, or to protect patients from infection
- Gown provides two-way isolation that prevents both medical personnel from being infected or contaminated and prevents the patient from being infected

Description of Goods & Packing Details
Isolation Suit --Brand Basewing
PE film + SSS non woven fabric
Packing: 1pc/bag, 40bags/carton.
Carton size: 70cm*45cm*50cm

MEDICAL ISOLATION SUIT CERTIFICATIONS

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 0O200311.ZLG0N17

Certificate's Holder: ZHEJIANG LANTIAN GARMENT CO., LTD.
No. 295 Hongda Road, Xiaoshan Economic Technology Development Zone, Hangzhou

Certification ECM Mark: Type Approved

Product: Disposable Protective Clothing (Isolation Gown)

Model(s): LTZY-0226

Verification to: Standard: EN 14126:2003+AC:2004

related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it
This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:
We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE Marking Certification Procedure through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of issue 11 March 2020 — Chief Manager Matteo Morina

Expiry date 10 March 2025 — Deputy Manager Amanda Payne

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 +39 051 6705156 info@entecerma.it www.entecerma.it

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 0O200312.ZLG0N80

Certificate's Holder: ZHEJIANG LANTIAN GARMENT CO., LTD.
No. 295 Hongda Road, Xiaoshan Economic Technology Development Zone, Hangzhou

Certification ECM Mark: Type Approved

Product: Disposable Mask

Model(s): LTZY-0228

Verification to: Standard: EN 149:2001+A1:2009

related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it
This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:
We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE Marking Certification Procedure through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of issue 12 March 2020 — Chief Manager Matteo Morina

Expiry date 11 March 2025 — Deputy Manager Amanda Payne

Ente Certificazione Macchine Srl
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☎ +39 051 6705141 +39 051 6705156 info@entecerma.it www.entecerma.it

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Zhejiang Lantian Garment Co.,Ltd.
Hangzhou, Zhejiang, 311231, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shanghai JAT Enterprise Management Consultation Co., Ltd.

Owner Operator Number:10064662

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D379616	LYU	ACCESSORY, SURGICAL APPAREL	Disposable mask,LTZY-0228
D379617	OEA	Non-Surgical Isolation Gown	Disposable protective clothing,LTZY-0226

JAT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. JAT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. JAT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, JAT is not affiliated with the U.S. Food and Drug Administration.

JAT FDA

Chief engineer
Issued: 03/26/2020
Expiration Date:12/31/2020

arnolds OFFICE FURNITURE

MEDICAL
PROTECTIVE SUITS

- Used when treating Class A infectious diseases, reinforced w/ the plastic film, and sealed along major tear points with EVA - a rubberlike seal stripe
- Made of non-woven, non-sterile material
- Higher protection grade than standard or isolation
- Protective suit consists of hooded tops and trousers; can be divided into a one-piece structure and a separate structure
- The trouser legs and cuffs are tightened, and the protective clothing has a higher degree of protection than the gown
- Single-use recommended

Description of Goods & Packing Details
Protective Suit --Brand Basewing
PE film + antibacterial glue + SSS non woven fabric
Packing: 1pc/bag, 40bags/carton.
Carton size: 70cm*45cm*50cm

MEDICAL PROTECTIVE SUIT CERTIFICATIONS

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 0O200311.ZLG0N17

Certificate's Holder: ZHEJIANG LANTIAN GARMENT CO., LTD.
No. 295 Hongda Road, Xiaoshan Economic Technology Development Zone, Hangzhou

Certification ECM Mark: Type Approved

Product: Disposable Protective Clothing (Isolation Gown)

Model(s): LTZY-0226

Verification to: Standard: EN 14126:2003+AC:2004

related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it
This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:
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Date of issue 11 March 2020
Chief Manager Matteo Morara

Expiry date 10 March 2025
Deputy Manager Amanda Payne

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 +39 051 6705156 info@entecerma.it www.entecerma.it

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 0O200312.ZLG0N80

Certificate's Holder: ZHEJIANG LANTIAN GARMENT CO., LTD.
No. 295 Hongda Road, Xiaoshan Economic Technology Development Zone, Hangzhou

Certification ECM Mark: Type Approved

Product: Disposable Mask

Model(s): LTZY-0228

Verification to: Standard: EN 149:2001+A1:2009

related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it
This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:
We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE Marking Certification Procedure through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of issue 12 March 2020
Chief Manager Matteo Morara

Expiry date 11 March 2025
Deputy Manager Amanda Payne

Ente Certificazione Macchine Srl
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Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

Zhejiang Lantian Garment Co.,Ltd.
Hangzhou, Zhejiang, 311231, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shanghai JAT Enterprise Management Consultation Co., Ltd.

Owner Operator Number:10064662

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D379616	LYU	ACCESSORY, SURGICAL APPAREL	Disposable mask,LTZY-0228
D379617	OEA	Non-Surgical Isolation Gown	Disposable protective clothing,LTZY-0226

JAT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. JAT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. JAT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, JAT is not affiliated with the U.S. Food and Drug Administration.

JAT FDA

Chief engineer
Issued: 03/26/2020
Expiration Date:12/31/2020

arnolds OFFICE FURNITURE

SURGICAL GOWNS

- Model and specification: Level 3 AAMI
- One-piece, single-use surgical gown; non-woven
- Secure protection (ultrasonic technology), tear-resistant and flame retardant
- Anti-fluid, anti-alcohol, anti-blood, anti-static
- Durable, comfortable, lightweight, breathable material
- Ultrasonic technology in arm and sleeve/cuff; comfortable collar with soft white spun lace
- Four belts with belt card
- 35gsm standard surgical gown weight
- Available in sizes S (43.3”), M (45.2”), L (50”), XL (53.1”), XXL (55.1”), XXXL (57”)

SURGICAL GOWN CERTIFICATIONS

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10062713

Listing No.	Code	Device Name	Proprietary Names	Activities
D373299	MDM	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE	FEMALE SS 3.5MM PELLET INSERTION TRAY	Manufacturer Contract Manufacturer Contract Sterilizer Repackager/Relabeler Remanufacturer Foreign Exporter
D373300	KDD	Kit, surgical instrument, disposable	Surgical Set	
D373303	FYE	DRESS, SURGICAL	Surgical Gown	
D373304	KME	BEDDING, DISPOSABLE, MEDICAL	Surgical Drape	
D373305	FMW	COVER, MATTRESS (MEDICAL PURPOSES)	Tube Cover	
D373306	KET	FILTERS, CELL COLLECTION, TISSUE PROCESSING	Liquid Collection Pouch	
D373307	FXZ	HELMET, SURGICAL	Warm Blanket and Surgical Hood	

NOT END OF THE ANNEX

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10062713

Listing No.	Code	Device Name	Proprietary Names	Activities
D373308	OEA	Non-surgical isolation gown	Isolation Gown	Manufacturer Contract Manufacturer Contract Sterilizer Repackager/Relabeler Remanufacturer Foreign Exporter
D373309	KPY	Shield, protective, personnel	Protective Coverall	
D373310	IMD	PACK, HOT OR COLD, DISPOSABLE	Dressing Pack	

END OF THE ANNEX

Chief engineer
Issued: March 4, 2020
Expiration Date: December 31, 2020

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 18 01 83528 008

Manufacturer: Henan JoinKona Medical Products Stock Co., Ltd.
Xinxing Road
The South of Industry District
LuShan County
467300 PingDingShan, Henan Province
PEOPLE'S REPUBLIC OF CHINA

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

Product Category(ies): Surgical Set, Surgical Gown, Surgical Drape, Tube Cover, Liquid Collection Pouch, Protective Coverall, Warm Blanket and Surgical Hood

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.: SH18783EXT01
Valid from: 2018-04-23
Valid until: 2023-04-22

Date, 2018-02-15
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

◆ CERTIFICADO ◆ CERTIFICAT

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 18 01 83528 008

Facility(ies): Henan JoinKona Medical Products Stock Co., Ltd. Xinxing Road, The South of Industry District, LuShan County, 467300 PingDingShan, Henan Province, PEOPLE'S REPUBLIC OF CHINA

ISOLATION GOWNS

- Impervious material (CPE), excellent fluid repellent
- Features over-the-head neck style with open-back
- Heat or ultrasonic seam
- Thumb loop wrists feature elastic for a good gown and glove fit
- Latex-free
- Standard blue color
- Size: 47.2” x 77.1”
- Package: 25 pieces/bag, 4 bags/carton,
- Minimum order quantity: 1,000

ISOLATION GOWN CERTIFICATIONS

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

CE Documentation Review

No. 1N180615.JJMD097

Holder: Jiangsu Jiawen Medical Supplies Co., Ltd.
Zhujiang Road No.5 Economic Development Zone Xiangshui County Yancheng City Jiangsu Province, China

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/CE Annex VIII

Product: Disposable Gloves, Disposable Apron, Disposable Gown, Work Clothes, Lab Coats, Isolation Gowns, Surgical Gowns, Coveralls, Face Masks, Caps, Sleeve Covers, Shoe Covers, Boot Covers, Beard Covers, Bed Sheets, Sauna Suit, Pillow Covers, Pants, Aprons, Slippers Shoe Cover
see the following Annex I

Model(s):

Classification: Class I
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/CE is in place for the CE Marking process. Technical File identified with the no. XJ2018052401MDD dated 05.24.2018. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 15 June 2018

Chief Manager
Marco Motta

Expiry date 14 June 2023

Deputy Manager
Amanda Tavio

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

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

Annex I

No. 1N180615.JJMD097

Product Type:	Models:
Disposable Gloves:	JW001, JW002, JW003, JW004, JW005, JW006, JW007, JW008, JW009, JW010, JW011, JW012, JW013
Disposable Apron:	70cm*120cm, 71cm*117cm, 74cm*120cm, 72cm*125cm, 80cm*115cm, 80cm*140cm
Disposable Gown:	S, M, L
Work Clothes:	S, M, L, XL, XXL, XXXL, XXXXL, XXXXXL, XXXXXXL
Lab Coats:	S, M, L, XL, XXL, XXXL, XXXXL, XXXXXL, XXXXXXL
Isolation Gowns :	S, M, L, XL, XXL, XXXL, XXXXL, XXXXXL, XXXXXXL
Surgical Gowns:	S, M, L, XL, XXL, XXXL, XXXXL, XXXXXL, XXXXXXL
Coveralls:	S, M, L, XL, XXL, XXXL, XXXXL, XXXXXL, XXXXXXL
Face Masks :	17.5cm*9.5cm, 14.5cm*9cm, 12.5cm*8.5cm, 20cm*7cm
Caps :	18'', 19'', 20'', 21'', 22'', 23'', 24'', 14*63cm, 15*62cm, 15*64cm, 16*65cm
Sleeve Covers :	20cm*40cm, 20cm*50cm, 22cm*46cm, 22cm*50cm
Shoe Covers :	15cm*36cm, 16cm*36cm, 16cm*39cm, 16cm*41cm, 16cm*46cm, 17cm*40cm, 17cm*41cm, 18cm*40cm, 18cm*41cm, 18cm*42cm
Boot Covers :	S, M, L, XL, 48cm*38cm, 48cm*42cm
Beard Covers:	18'', 19'', 20'', 21'', 22'', 23'', 24
Bed Sheets :	100cm*230cm, 140cm*190cm, 120cm*180cm, 120cm*220cm, 140cm*240cm, 120cm*220cm, 120cm*240cm, 150cm*220cm
Sauna Suit :	S, M, L, XL, XXL, XXXL, XXXXL, XXXXXL, XXXXXXL
Pillow Covers:	80cm*120cm, 50cm*75cm, 53cm*76cm
Pants:	S, M, L, XL, XXL, XXXL, XXXXL, XXXXXL, XXXXXXL
Aprons:	S, M, L, XL, XXL, XXXL, XXXXL, 24''x42'', 28''x46''
Slippers Shoe Cover:	S, M, L, XL, XXL, XXXL, XXXXL, XXXXXL, XXXXXXL

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

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

Jiangsu Jiawen Medical Supplies Co., Ltd.
Zhujiang Road NO.5 Economic Development Zone Xiangshui County Yancheng City Jiangsu Province

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications: SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.com

Registration Number: 3010650910
Device Listing#:

Listing No	Code	Device Name
D317966	LYU	ACCESSORY, SURGICAL APPAREL (Disposable glove; PE Apron; Face Masks)
D318687	FYE	DRESS, SURGICAL (CPE Gown)

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Sungo FDA

Executive Director
Issued: Mar. 26 2020
Cert. No.: 2006US608558
Expiration Date: Dec. 31 2020

SUNGO CHINA OFFICE Tel: 021-68828052 Email:Shage2008@126.com Website: www.sungoglobal.com
Add: 13th Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China

CAPS

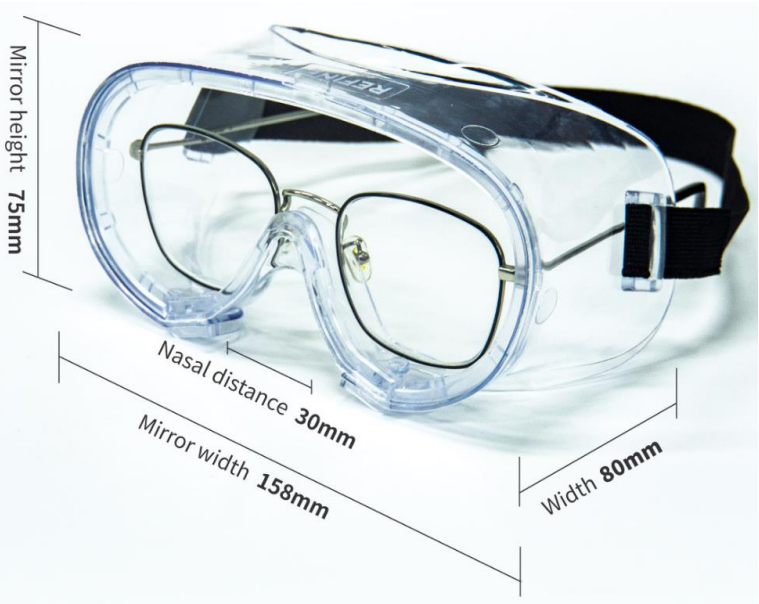
- Made of non-woven fabric, breathable & odorless.
- Protect your work from unwanted hair drop, sweat, prevent dust into hair
- Open to use, elastic band to suit head
- Perfect for hospital, labs, food service, manufacturing
- Standard blue color
- 2,800 pieces / carton size (minimum order quantity)

SHOE COVERS

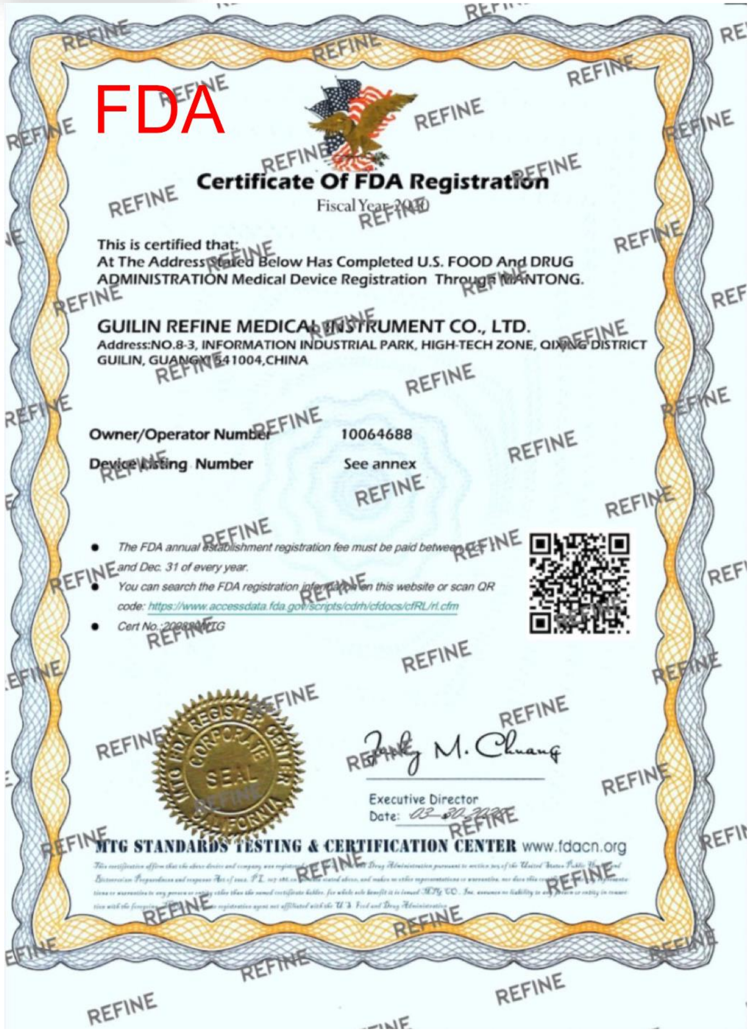
- CPE disposable surgical waterproof anti-slip shoe cover
- Use for medical, surgical, pharmaceutical, laboratorial, industrial sector, painting, cleaning room, school etc.
- Standard blue color
- One size fits most
- 2,800 pieces/carton size and Minimum Order Quantity

PROTECTIVE GOGGLES

- Intended Use: protecting eyes against droplets and splashes of liquids and impact
- Suitable for various head circumference
- Anti-Fog, Anti-Impact, Anti-Scratch, Anti-Dust, Anti-Liquid Spray
- Materials: Soft TPU for all day comfort
- Polycarbonate lens for wider and clearer vision
- Cloth strap- adjustable, flexible; Ensures proper fit for adequate protection
- Soft Nosepiece
- Compatibility with other glasses
- Standards: China: GB 14866-2006, EU: EN166:2001, USA: ANSI Z87.1



PROTECTIVE GOGGLES CERTIFICATIONS


FDA

Certificate Of FDA Registration

Fiscal Year 2020

This is certified that:
At The Address Stated Below Has Completed U.S. FOOD And DRUG ADMINISTRATION Medical Device Registration Through MANTONG.

GUILIN REFINE MEDICAL INSTRUMENT CO., LTD.
Address:NO.8-3, INFORMATION INDUSTRIAL PARK, HIGH-TECH ZONE, QIXING DISTRICT GUILIN, GUANGXI 541004,CHINA

Owner/Operator Number	10064688
Device Listing Number	See annex

- The FDA annual establishment registration fee must be paid between Oct. 1 and Dec. 31 of every year.
- You can search the FDA registration information on this website or scan QR code: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
- Cert No: 209829MTG

Executive Director
Date: 03-30-2020

MTG STANDARDS TESTING & CERTIFICATION CENTER www.fdacn.org


Certificate Of FDA Registration

Fiscal Year 2020

Annex to Cert No.: 209829MTG

Listing Number	Product Code	Device Name
D379683	HOY	Safety Goggle Face Shield

END OF THE ANNEX

Executive Director
Date: 03-30-2020

MTG STANDARDS TESTING & CERTIFICATION CENTER www.fdacn.org


CERTIFICATE OF CONFORMITY

Date of Issuance	:	March 23, 2020
Item name	:	Safety Goggles
Model No.	:	EP01
Manufacturer	:	Guilin Refine Medical Instrument Co., LTD
Manufacturer Address	:	NO.8-3,Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R. China
Applicable Standards	:	EN 166: 2001 Personal eye – protection Specifications; EN 167: 2001 Personal Eye-Protection – Optical test methods; EN 168: 2001 Personal eye-protection - Non-Optical test methods;
Applicable EC Regulation	:	(EU) 2016/425-Personal Protective Equipment (PPE)
Test Report Number	:	C80132072 Performed by UL VS Shanghai Limited Shenzhen Branch

After inspection of the technical documentation issued by the customer, we express our opinion that the above-mentioned product complies with the requirements of the above applicable EC regulation.

The following manufacturer documents were inspected:

Presence of Declaration of conformity	OK
Test report using valid Harmonized standard as indiated in the declaration of conformity	OK
Presence "CE" Symbol in the label or product	OK
Presence Instruction manual	OK
Presence product description in the technical construction file	OK

The manufacturer has the responsibility for ensuring that all serial manufacture of the product is in compliance with the specification of the sample submitted.

For and on behalf of :
UL VS Shanghai Limited Shenzhen Branch

Hedy Li
Consumer Engineering Manager
Eyewear Testing Department

CE
CE符合性声明

DISPOSABLE STETHOSCOPES

- Disposable stethoscope
- Length: 28.9”
- Weight: 60g
- Tubing length: 21.6”
- Tubing diameter: 1.96”
- Tubing material: PVC
- Chest piece diameter: 1.7”
- Chest piece material: Plastic
- Binaural material: Aluminum
- Includes 2 soft earplugs

DISPOSABLE STETHOSCOPE CERTIFICATIONS

CERTIFICATE OF FDA

Facility Registration and Device Listing of Medical Device

Ningbo Yongjin Medical Instruments Manufacture Co., Ltd.

Owner/Operator Number: 10061688
Registration/FEI Number: 3012541976

Address: Zhixi'ao, Lubu Town, Yuyao City, Ningbo, Zhejiang, 315421, China

has completed the Facility Registration and Device Listing (as manufacturer) with the US FDA, through
HUMISS INC. (U.S. Agent)

Address: 4845 Pearl East Cir Ste 118, Boulder, CO, 80301, USA
E-mail: cc401vip@126.com
Tel: 001-720-759-5888

HUMISS INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of calendar year stated above, unless said registration is terminated after issuance of this certificate. HUMISS INC. makes no other representations or warranties, nor does this certificate make any representation or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's product(s) or establishment by the U.S Food and Drug Administration. HUMISS INC. assumes no liability to any person or entity in connection with foregoing.
The U.S Food and Drug Administration does not issue a certificate of registrations, nor does the U.S Food and Drug Administration recognize a certificate of registration, HUMISS INC. is not affiliated with the U.S Food and Drug Administration.

FDA

Certificate Nº: HU-M-191231001

Issue date: Jan. 1, 2020
Expire date: Dec. 31, 2020

Fiscal Year 2020

Device Listing of Medical Device

Annex to cert No. HU-M-191231001

Listing Number	*Premarket Submission*	*Product Code(s)*	*Device Name(s)*	*Activities*	*Models*
D361669	*Exempt*	*LDE*	*Stethoscope, Manual*	*Manufacturer*	*S1101, S1102, S1103, S1204A, S2114, S2224, S2324, S2424, S2514-GB, S2524-GB, S2614-BB, S2624-BB, S3104, S3214, S3204, S3303, S3414, S4101, S4101C, S4102, S4102C, S4111, S4111C, S4211-B, S4201-B, S4311-W, S4301-W, S5114, S5214, S5314*
D361670	*Exempt*	*FZY*	*Hammer, Surgical*	*Manufacturer*	*Percussion hammer: PH01, PH02, PH03, PH04, PH05, PH06*
D361671	*Exempt*	*KYT*	*Light, Examination, Medical, Battery Powered*	*Manufacturer*	*Medical penlight: PL01, PL02, PL03 Medical headlight*
D361672	*Exempt*	*GWX*	*Fork, Tuning*	*Manufacturer*	*Tuning fork: TF01*
D361673	*Exempt*	*ERA*	*Otoscope*	*Manufacturer*	*Otoscope: OT01*
D361674	*Exempt*	*FMA*	*Depressor, Tongue, Nonsurgical*	*Manufacturer*	*Tongue depressor*
D361675	*Exempt*	*FNJ*	*Bed, Manual*	*Manufacturer*	*General hospital bed*
D361676	*Exempt*	*FQM*	*Bandage, Elastic*	*Manufacturer*	*Bandage*

End of the annex.

Humiss Inc. | 4845 Pearl East Cir Ste 118, Boulder, CO, 80301, USA | cc401vip@126.com | 001-720-759-5888

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

CE Documentation Review

No. 3J190624.NYMTD11

Holder: Ningbo Yongjin Medical Instruments manufacture Co., Ltd.
Zhixi'ao, Lubu Town, Yuyao City, Zhejiang Province, China 315400

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Stethoscopes: Class I
Model(s): S2224/S4101/S2114/S4111/S1204/S5214/ S3303/S3104/S5314/S3214

Classification: Class I
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 03 July 2019
Chief Manager
Marco Martini

Expiry date 23 June 2024
Deputy Manager
Amanda Payne

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

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- Utilizing our importing expertise and supply chain connections to import PPE's without any added layers and provide them directly to our clients at reasonable, competitive prices

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Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
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David Lennarz
Executive Director
Registrar Corp
Dated: April 6, 2020

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