PERSONAL PROTECTIVE EQUIPMENT
PROCUREMENT

LENGHA

TABLE OF CONTENTS

LENGHA

GENERAL INFORMATION

OUR MODEL
We collaborate with a number of suppliers who provide protective equipment to the medical sector. These suppliers meet the requirements our previous counterparties have demanded regarding certifications, production capacity and lead times on large amounts of protective equipment. Furthermore, we have chosen to work with these suppliers due to positive results we have compiled from third-party inspections that we have commissioned. We have vetted these companies so you can rest assured you are receiving the highest-quality products.

FLEXIBLE SUPPLY
Since we have vetted our suppliers (with on-site inspections), we have a range of suppliers to choose from. Based on your preferences for quantity, specific certifications and urgency of delivery, we will determine the best supplier to meet your needs. Keep in mind that pictures of specific products, certifications and prices can therefore vary depending on your specific needs. Some of the products below have a range of prices. The range is based on the amount of product you are interested in purchasing: the more you want, the easier it is for us to negotiate with both the factory and shipping partner to bring down costs.

PRICING
Due to a significant increase in demand, availability and prices fluctuate on a daily basis. We guarantee a refund for non-performance of procurement but after orders are confirmed there will be a charge for cancellation.

LOGISTICS
We can assist with setting up the logistical solution based on your preferred shipping method. Shipping, customs and duties will be at your own expense, however we can and have delivered goods on a CFR basis.

PROTECTIVE MASK

LENGHA

DISPOSABLE 3 PLY MASKS

Ref: 3P001

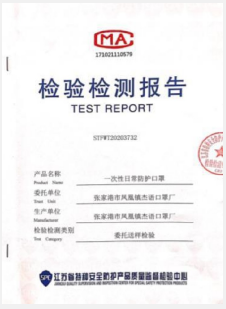
A layer of melt-blown micro- and nanofiber material has been placed between two layers of non-woven fabric. The middle layer acts as a filter which stops microbes from entering or exiting the mask

Effective in preventing the spreading of infectious deceases from the wearer to other people

Certifications: CE and Test Report

Production Capacity

5 million per week



LENGHA

DISPOSABLE 3 PLY MASKS WITH FACE SHIELD

Ref: 3PFS001

- High filtration, fluid resistant
- Clear, wraparound face shield
- Lightly-tinted to help eliminate glare
- Anti-fog and anti-static treatment
- Ear loop design

Production Capacity

2 million per week

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

HEALREG SERVICE INC

Verification of Conformity

LENGHA

SURGICAL FACE MASK

Meets CE 0121 - In reference to EN 149: 2001 FFP2 NR

- High Fluid Resistance 160 mmHG
- Filtration Efficiency BFE/PFE 99.9% @0.1 micron
- Breathability - Delta P > 5.0 mm H20/cm2
- Flame Spread Class 1

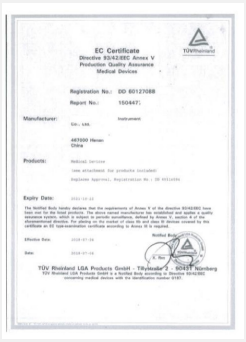
Certifications: CE and Test Report

Ref: FSFM001

10pcs per bag 50 pack 1000 pcs per carton

Production Capacity

2 million per week



LENGHA

FFP2 KN95 FACE MASK

Ref: FFP2001

Level: Civilian Level

Layers: 4 Layers
Outer two layers non-woven fabric
Inner two layers meltblown fabric
>95% non-oily particulates
Adjustable nose clip, elastic straps

5 pieces per bag

Packing Info: 90 pieces per box
1080 pieces per carton

G.W.: 8.18kg
Certifications: CE

Production Capacity

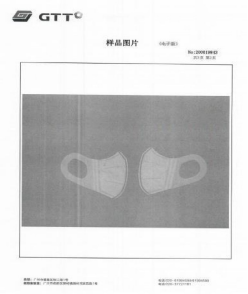
2 million per week

LENGHA

FFP2/N95 MASKS

Ref:FFP2002

Blocks at least 95% of all micro-particles (0.3 microns)
Certifications: CE and test report



检验检测项目（计量单位）[样品识别]	测试方法	标准值及允差	检验检测结果	判定	备注
细菌过滤效率 %)	YY 0469-2011 附录B 测试菌种：金黄色葡萄球菌ATCC 6538 测试面积：40cm² 气体流速：28.3L/min 平均颗粒直径：3.0μm 阳性质控值：1.9×10³ CFU 阴性质控值：<1CFU	≥95	BFE₁ 99.6 BFE₂ 99.7 BFE₃ 99.5	符合	注
大肠菌群	GB 15979-2002 附录B	不得检出	未检出	符合	注
细菌菌落总数 CFU/g)	GB 15979-2002 附录B	≤200	<20	符合	注
真菌菌落总数 CFU/g)	GB 15979-2002 附录B	≤100	<20	符合	注
绿脓杆菌	GB 15979-2002 附录B	不得检出	未检出	符合	注
金黄色葡萄球菌	GB 15979-2002 附录B	不得检出	未检出	符合	注
溶血性链球菌	GB 15979-2002 附录B	不得检出	未检出	符合	注

Production Capacity

2 million per week

LENGHA

KN95 FFP2 MASK

Ref:FFP2003

- FDA Approved FFP2 KN95 Mask
- CE Approval
- Packaged in boxes

Production Capacity

200,000

Minimum Order Quantity

100,000 unit

MOSEN

CERTIFICATE OF CONFORMITY

Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

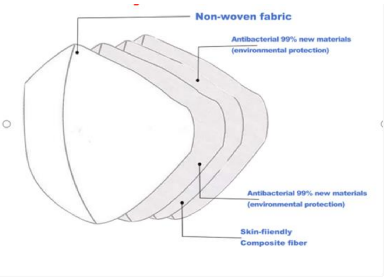
LENGHA

FFP2 KN95 4 LAYER MASK

Ref:FFP2004

- 3mm latex-free flat elastic earloop;
- plastic and wire (nosepiece);
- 45g/m² PP white spunbond (outer layer);
- 45 g/m² Bacteriostatic 99% new material (environmental protection),(two ply filter layer);
- ES Thermobonded soft (Inner layer)

- ISO 13485/CE14683/EC/RCP/FDA
- L 1000pcs/box
- size:64cm*29cm*52cm
- weight:20KG



Production Capacity
200,000

Minimum Order Quantity
100,000 unit

LENGHA

KN95 3 LAYER NON STERILE FACE MASK

Ref: FFP2003

The sizing of this CE/FDA approved surgical mask can be customised.

Offers full FFP2 protection and is compliant with GB2626-2016 Standard

Regulation (EU) 2016/425 PPE & EN 149:2001 +A1:2009.

- ✓ 20mg/m3 PP Green spun-bound outer layer
- ✓ 40mg/m3 Bacteriostatic filter layer
- ✓ ES Thermobonded soft inner layer
- ✓ Plastic & Wire Nosepiece
- ✓ 3mm latex-free round elastic ear-loop

Production Capacity

200,000 per day

Minimum Order Quantity

50,000 units

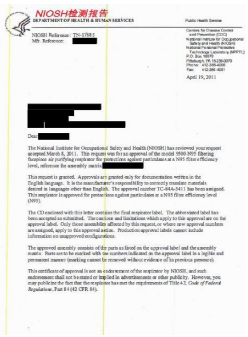

CERTIFICATION OF FDA REGISTRATION

LENGHA

FFP2/N95 NIOSH MASKS

Official CDC NIOSH Approved Manufacturer

Ref: FFPN001


NIOSH检测报告

DEPARTMENT OF HEALTH & HUMAN SERVICES

April 19, 2011

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted March 8, 2011. This request was for an approval of the model 9500-N95 filtering facepiece air purifying respirator for protection against particulates at a N95 filter efficiency level, reference the assembly matrix

This request is granted. Approval is 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. The approval number TC-84A-5411 has been assigned. This respirator is approved for particulates against particulates at a N95 filter efficiency level (N95).

The CD enclosed with this letter contains the final respirator label. The abbreviated label has been accepted as submitted. The conditions and limitations which apply to this approval are on the approved label. Only those assemblies affixed by this respirator, or where new approval numbers are assigned, apply to this approval status. 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).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that the respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

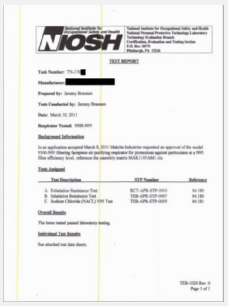
These masks are intended to be used for protection against solids, such as those from minerals, coal, iron ore, flour and certain other substances. They are extremely durable with a soft and comfortable inner surface, also have an adjustable nose piece and secured head straps to provide proper fit.

These masks have a 510(K) number for the medical market and can be used TB situations as recommended by OSHA.

Certifications: IFA, FDA, CDC NIOSH and Test Report

Production Capacity

1 million per week


NIOSH

TEST REPORT

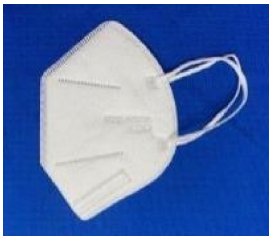

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

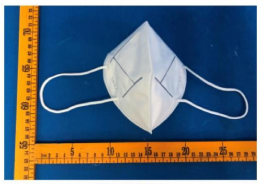
CERTIFICATE

LENGHA

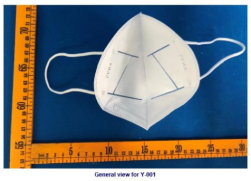
HK KN95 MASK (FFP3 STANDARD)



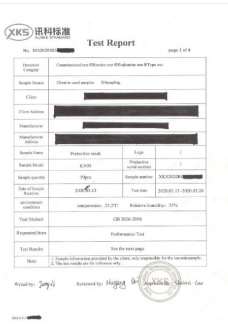
Ref: FFP3HK001

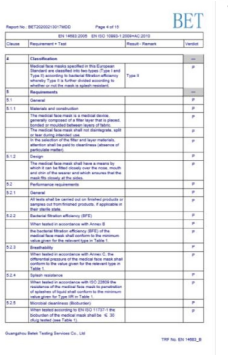


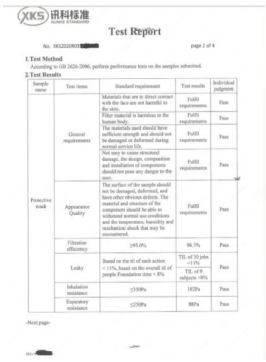
General view for Y-001



General view for Y-001

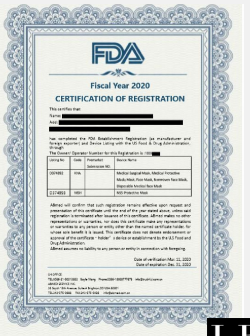






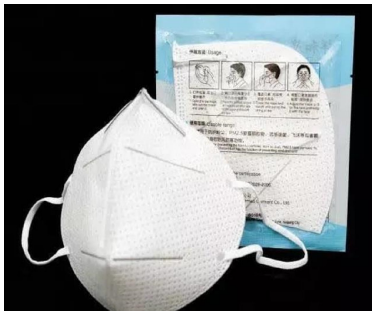
Production Capacity
250,000 per week

Minimum Order Quantity
50,000 unit



LENGHA

FFP3 FACE MASK



Ref: FFP3001

Production Capacity

2 million per wee

CURRENTLY SOLD OUT

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

HEALREG SERVICE INC

Owner/Operator Number:

Device Listing#: See annex

FDA

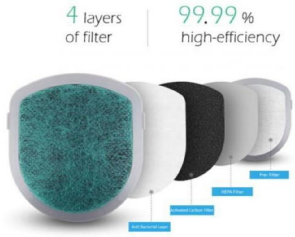
Verification of Conformity

CE Sungo

Certifications: CE and FDA

LENGHA

PORTABLE AIR PURIFICATION MASK



Ref: FEM001

Minimum Order
1000 pieces

The world's first portable Air Purification Mask. It not only deals with air pollutants, but it is your only true companion to keep out ALL pathogens which means we will protect from all Virus and Bacteria no matter where you are.

It comes with a powerful inbuilt motor which gives dedicated pollution free air no matter what the ambient air quality might be, an exhaust to push out all the exhaled Carbon Dioxide as well, hence getting over the biggest flaws of masks.

A tested and proven trio of filters used in the mask makes it the only solution for on-the-go air purification needs.

LENGHA

FACE PROTECTION

LENGHA

PROTECTIVE ISOLATION FACE SHEILD

Ref: FV002

[Name]: Protective Isolation Face shield
[Product size]: 13 * 8.6in
[PET size]: 13 * 8.6in H: 0.0098in
[Sponge size]: 8.6 * 1.37 * 1.18in
[Rubber Band Size]: 12.6 * 0.78in
[Label size]: 13 * 1.57in
[Product Net Weight]: 40g
[Packing method]: Transparent PE bag

[[Outer box size]: 18.5 * 13 * 13.38in
[Outer box weight]: 4.6kg (100pcs)
[Scope]: For daily protection
[Applicable people]: universal for men, women and children
[Certificate]: CE-EN166
[Place of Origin]: Shenzhen, China

Application:	Used in laboratories, chemical plants, domestic and public places, etc.
Features:	1. Double-sided anti-fog, long-lasting 2. Transparent high-definition, anti-dizziness 3. Safe and lightweight, easy to carry 4. High temperature resistance, impact resistance
Precautions:	Before use, please remove the transparent protective film on both sides of the lens.If it is dirty, you can rinse it with water and do not wipe it directly (recommended to wear a mask, the more detailed and safer)

Production Capacity

1 million per week


MOSEN
CERTIFICATE OF CONFORMITY
CE

LENGHA

PROTECTIVE GOGGLES

- Medical grade
- Lens made of polycarbonate
- Optical frame made of silica gel
- Weight: 60 g
- Size: 15 * 9 * 6 cm

Ref: G001

Production Capacity

500,000 per week


DIN CERTCO

Test Report No. 1283-PZA-15 Main Part Page 4 of 5

Type:	Goggle with ultraviolet protective filter, type "GB1304"
Test mark:	12832-PZA-15
Number of delivered parts: 18	Number of test samples: 18

Test-sequence	Requirements	according to DIN EN	Clause	Tests according to DIN EN	Clause	Sample 5283-18 to 5283-36
1	User information	166	10	166	10	+
2	Design and manufacturing requirements	166	6	166	6	+
3	Lateral protection	166	7.2.6	166	19	+
4	Field of vision	166	7.5.1	166	19	+
5	Quality of material and surface	166	7.1.3	167	5	+
6	Diffusion of light	166	7.1.2.3	167	4	+
7	Spherical refractive power and astigmatic refractive power	166	7.1.2.1	167	3	+
8	Prismatic refractive power	166	7.1.2.1	167	3	+
9	Transmittance	170	5	167	5	--
10	Variations in transmittance	166	7.1.2.2.3	167	7	/
11	Stability at an elevated temperature	166	7.1.5.1	166	5	/
12	Resistance to UV radiation	166	7.1.5.2	166	6	/
13	Minimum robustness	166	7.1.4.1	166	4	/
14	Increased robustness -5°C / +55°C	166	7.1.4.2	166	3	/
15	Protection against high-speed particles (120 m/s)	166	7.2.2	166	9	/
17	Resistance to ignition	166	7.1.7	166	7	/
18	Resistance to corrosion	166	7.1.6	166	8	/

Individual results of each test sample see annex 2

* Contains no metal components.

Marking:

Frame:	V EN 166 B CE CROSS 551
Oculars:	None

DIN CERTCO

Test Report No. 1283-PZA-15 Main Part Page 5 of 5

Type:	Goggle with ultraviolet protective filter, type "GB1304"
Test mark:	12832-PZA-15
Number of delivered parts: 30	Number of test samples: 18

Test-sequence	Requirements	according to DIN EN	Clause	Tests according to DIN EN	Clause	Sample 5283-37 to 5283-54
1	Quality of material and surface	166	7.1.3	167	5	+
2	Diffusion of light	166	7.1.2.3	167	4	+
3	Spherical refractive power and astigmatic refractive power	166	7.1.2.1	167	3	+
4	Prismatic refractive power	166	7.1.2.1	167	3	+
5	Transmittance	170	5	167	5	--
6	Variations in transmittance	166	7.1.2.2.3	167	7	/
7	Stability at an elevated temperature	166	7.1.5.1	166	5	/
8	Resistance to UV radiation	166	7.1.5.2	166	6	/
9	Minimum robustness	166	7.1.4.1	166	4	/
10	Increased robustness -5°C / +55°C	166	7.1.4.2	166	3	/
11	Protection against high-speed particles (120 m/s)	166	7.2.2	166	9	/
12	Resistance to ignition	166	7.1.7	166	7	/
13	Resistance to corrosion	166	7.1.6	166	8	/

Individual results of each test sample see annex 2

* Contains no metal components.

Marking:

Frame:	V EN 166 B CE CROSS 551
Oculars:	None

LENGHA

GOGGLES

Ref:

Production Capacity

1 million per week

LENGHA

FULL BODY PROTECTION

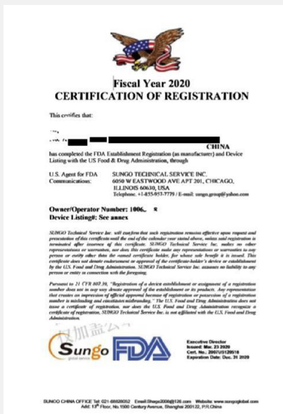
LENGHA

ISOLATION GOWNS

Ref: ISCV001

Production Capacity

500,000 per week



Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

[redacted]
CHINA

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. +1-855-953-7779 / E-mail: sungo.group@yahoo.com

Owner/Operator Number: 1006_ 8
Device Listing#: See annex

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. 23 2020
Cert. No.: 2007US120518
Expiration Date: Dec. 31 2020

SUNGO CHINA OFFICE Tel: 021-68828052 Email:Shago2008@126.com Website: www.sungoglobal.com
Add: 13th Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China

LENGHA

DISPOSABLE PROTECTIVE CLOTHING FOR MEDICAL USE

- Provide barrier and protection for medical staff to contact potentially infectious patients' blood, body fluids, secretions and the particles in the air.

Production Capacity

500,000 per week

LENGHA

DISPOSABLE PROTECTVE CLOTHING

Ref: 0I001

Production Capacity

1 million per week


Certificate – Сертификат – 證明書 – Certificat – 인증서

Certificate of Compliance

Certificate's Holder:

Manufacturer:

Certification ECM Mark:

Product: Disposable protective clothing for medical use

Model(s): 160, 165, 170, 175, 180, 185, 190

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


FDA Medical Device Registration & Listing

Establishment

Owner/Operator

Official Correspondent

US Agent

Device Listing Information

GTS

LENGHA

CHEMICAL PROTECTIVE COVERALL

Ref: CPC001

Ref: CPC002 Same model as above but with shoe cover

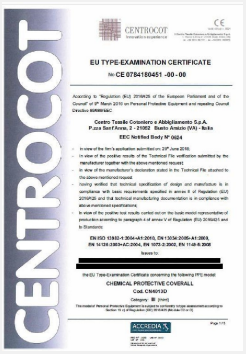
One-piece coverall white colour, with hood, zipper at front opening covered by flap, knitted cuffs, elasticated ankles, hood and waist.

Fabric:	Microporous 54% polypropylene + 46% polyetylene, 65 g/m2 white colour. Cut and sewn seams.
Knitted cuffs:	100% Polyester
Sizes:	S, M, L, XL, XXL, XXXL

EN ISO 13688:2013	Protective clothing - general requirements
EN ISO 13982-1:2004 +A1:2010	Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates
EN 13034:2005+A1:2009	Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals
EN 1073-2:2002	Protective clothing against radioactive contamination - Requirement and test methods for non-ventilated protective clothing against particulate radioactive contamination
EN 14126:2003+AC:2004	Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN 1149-5:2008	Protective clothing – Electrostatic properties – Part 5 ; Material performance and design requirements

Production Capacity

500,000 per week

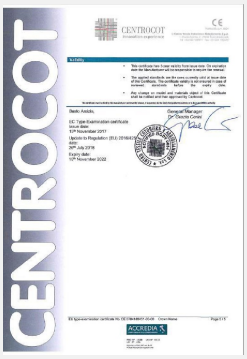

CENTROCOT

EU TYPE-EXAMINATION CERTIFICATE

No CE 0784180451 -00 - 00

CHEMICAL PROTECTIVE COVERALL

Cod. CHAP150


CENTROCOT

LENGHA

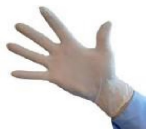
GLOVES

Ref: GLMDE001B

Medical Disposable Nitrile Gloves

Medical Disposable Nitrile Examination Gloves

Disposable Nitrile Gloves are a popular alternative to latex gloves



Ref: GLDPVC001W

Disposable PVC Gloves

Disposable PVC Gloves

Disposable PVC Gloves that are ideal for use as medical gloves, surgery gloves and food handling gloves. Made from Polyvinyl Chloride (PVC), our Disposable PVC Gloves do not use latex, making them ideal for people who have latex allergies and preventing contamination as far as possible.

Ref: GLDV001B

Disposable Vinyl Examination Gloves

Disposable Vinyl Gloves,

Latex-Free, the most cost-effective among all types of gloves which are widely used in any industry, such as hospital,

Production Capacity

5 million per week


SATRA

EU Type-Examination Certificate


EU DECLARATION OF CONFORMITY

LENGHA

DISPOSABLE SHOE COVERS

Ref:DSC001

Disposable Shoe Cover

Single elastic or double elastic

Machine made or hand made

Standard or Anti-slip

Production Capacity

3 million per week

Verification of Conformity

LENGHA

DISPOSABLE CAP

Ref: C001

Disposable Nonwoven Bouffant Cap

The Disposable Bouffant Cap are ultrasonically sealed and prevent less movement of hair which contains a large number of microorganisms that are transferred at the time of surgery.

Production Capacity

3 million per week

Verification of Conformity

LENGHA

RELATED PRODUCTS

LENGHA

INFRARED THERMOMETERS

Ref:THK002AG

Ref:TH001AG

Production Capacity

100,000 per week

Minimum Order Quantity

100,000 units

LENGHA

DISPOSABLE 3 PLY MASKS

Ref:

-More effective and efficient than sprays and towels.
-Lint free and highly absorbent for an optimal clean.
-Water based formula safe to use on plastics, laminates, metals,
-Plexiglas screens and rubber surfaces.
-Independently lab certified to quickly disinfect.
-Kills Staph (MRSA), Influenza A Virus, Norovirus and 99.9% of bacteria when used as directed.

WipesPlus® Disinfecting Wipes have demonstrated effectiveness against viruses similar to 2019 Novel Coronavirus (2019-nCoV) on hard, non-porous surfaces.

Therefore, WipesPlus® Disinfecting Wipes can be used against 2019 Novel Coronavirus (2019-nCoV) when used in accordance with the directions for use against Norovirus on hard, non-porous surfaces.

Refer to the CDC Website https://www.cdc.gov/coronavirus/2019-ncov/index.html for additional information.

Production Capacity

3 million per week

Minimum Order Quantity

500,000 packs

WIPES										
ITEM#	DESCRIPTION	CASE PACK	SHEET SIZE	UPC CASE/ UPC UNIT	WEIGHT	CUBE	DIMENSIONS	PALLET PATTERN	CASES/ PALLETS	PALLET WEIGHT
1	WipesPlus® Disinfecting Surface Wipes, Resealable Refill Pack, 80CT	12	7" x 8"	Case: 10 83426 00006 95	16.8 lbs.	0.68	19" x 8" x 7.75"	10 x 6	60	1,058 lbs.
				Item: 0 83426 00069 4	1 lb. 6.4 oz.	0.05	7.5" x 2.5" x 4.25"			

LENGHA

OXFORD PVC BODY BAG

Ref:OPB001

LENGHA

DISPOSABLE CADAVER BAG

Ref: DCB001

Disposable cadaver bags are made of plastic and work as a great temporary aid in carrying and covering a body in a funeral, mortuary or emergency situation.

Size: Adult

SGS Test Report Available

SGS

Test Report

[redacted]

No. KA/2019/503072 Date: 2019/01/18 Page: 1 of 4

The following sample(s) was/were submitted and identified by/on behalf of the client as :

Sample Description	:	LLDPE
Style/Item No.	:	21699
Sample Receiving Date	:	2019/01/16
Testing Period	:	2019/01/16 TO 2019/01/18

Test Requested	:	In accordance with the RoHS Directive 2002/95/EC, and its amendment directives.
Test Method	:	With reference to IEC 62321Ed1 CDV (111/96/CDV) Procedures for the Determination of Levels of Regulated Substanc in Electrotechnical Products.
	:	(1) With reference to IEC 62321Ed1 CDV (111/95/CDV) Clau 8. Determination of Cadmium by ICP-AES.
		(2) With reference to IEC 62321Ed1 CDV (111/95/CDV) Clau 9. Determination of Lead by ICP-AES.
		(3) With reference to IEC 62321Ed1 CDV (111/95/CDV) Clau 7. Determination of Mercury by ICP-AES.
		(4) With reference to IEC 62321Ed1 CDV (111/95/CDV) Anne C. Determination of Hexavalent Chromium for non-metallic 10. Determination of Hexavalent Chromium by UV-VIS.
		(5) With reference to IEC 62321Ed1 CDV (111/95/CDV) Anne A. Determination of PBBs and PBDEs by GC/MS.
Test Result(s)	:	Please refer to next page(s).

Kitharine Hu / Supervisor
Signed for and on behalf of
SGS Taiwan Limited

SGS

Test Report

[redacted]

No. KA/2019/503072 Date: 2019/01/18 Page: 6 of 6

KA/2019/503072

** End of Report **

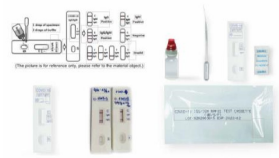
LENGHA

TESTING KITS

LENGHA

COVID-19 LGG/LGM RAPID TEST KIT (WHOLE BLOOD/SERUM/PLASMA)

Ref:CT001



COVID-19 lgG/lgM Rapid Test Kit (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of lgG and lgM antibodies to 2019 Novel Coronavirusi in human whole blood, serum or plasma. This test provides only a preliminarv test result.
Therefore, anv reactive specimen with the COVID-19 lgG/I9.M Rapid Test_ kit (Whole Blood/Serum/Plasma) must be confirmed with-alternative testing method(s) and clinical findings.
Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses -229E, 0(43, NL63, and HKU1 -are prevalent and typically cause common cold symptoms in immunocompetent ind1viduals.4

The three other strains -severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) -are zoonotic in origin and have been linked to sometimes fatal illness. lgG and lgM antibodies to 2019 Novel Coronavirus can be detected with 2-3 weeks after expo

Production Capacity
500,000k+ per week

Minimum Order Quantity
100,000 units


EC Certificate


Declaration of Conformity

Manufacturer:

European Representative: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: COVID-19 IgG/IgM Rapid Test Kit
Model: Strip, Cassette
Classification (IVDD, Annex II): Others
Conformity Assessment Route: Annex III

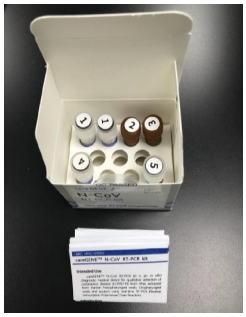
We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards, under our solo responsibility. All supporting documentations are retained under the premises of the manufacturer.

Signature:
Name: Su Lingling
Position: Management Representative

Date: 13 March 2020

LENGHA

N-COV RT-PCR KIT

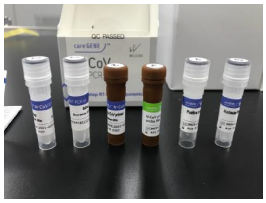


Ref:CT003

GENERAL FEATURES
Real-time PCR • Taqman probe based qPCR kit

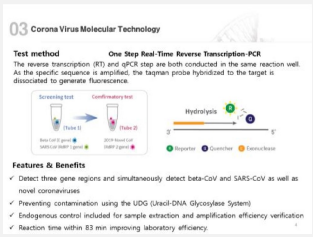
careGENETM N-CoV RT-PCR kit is an in vitro diagnostic medical device for qualitative detection of novel coronavirus (2019-nCoV) from RNA extracted from human Nasopharyngeal swab, Oropharyngeal swab and sputum using real-time RT-PCR (Reverse transcription-Polymerase Chain Reaction).

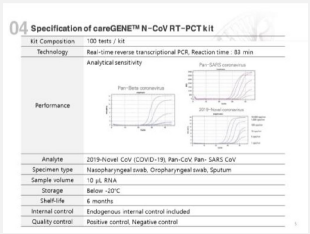
Features
• Detect three gene regions and simultaneously detect beta-CoV and SARS-CoV as well as novel coronaviruses
• Endogenous control included for sample extraction and amplification efficiency verification
• Preventing contamination using the UDG (Uracil-DNA Glycosylase System)
• Reaction time within 83 min. Improving laboratory efficiency



Production Capacity
100,000k

Minimum Order Quantity
50,000 units /2500 per shipment





LENGHA

SARS-COV-2 IgM TEST

Ref: CTOO4V

First approved COVID-19 rapid test by CFDA.
Total Clinical Study includes 596 specimens, positive specimen 361 (includes 101 early diagnosed patients) ; Sensitivity 86.43%, Specificity 99.57%; Clinical study done in 6 different facilities including Wuhan

One million purchased by UK Government

CE Approval received
Listed with FIND (Foundation for Innovative New Diagnostics.)

Product Listed at FIND-COVID-19 DIAGNOSTIC PIPELINE, await further validation.
Product widely use in domestic market, daily supply 300,000 Test.

Shelf Life
- CFDA approved Product – 6 Months
- CE approved Product – 12 Months

Production Capacity

10,000,000
300,000 per day

Minimum Order Quantity

1 million units

MANUFACTURER STATEMENT

To whom it may concerned,

According to the classification of EU IVD Directive, the classification of rapid testing reagents includes: *Self-testing, List A, List B, and others.* Wondfo SARS-CoV-2 Antibody Rapid Test is intended for professional use, it belongs to the category of "others".

Product under this category, manufacturer self-declaration of conformity and registration with EU competent authority are required for the approval of CE. The following harmonized standards applies:

EN ISO 13485:2016		EN ISO 14971:2012	EN 13612:2002
EN ISO 15223-1:2016		EN ISO 18113-1:2011	EN ISO 18113-2:2011
EN ISO 23640:2011		EN 13641:2002	EN 62366:2008

We hereby confirm that Wondfo SARS CoV-2 antibody rapid test compliance with the directive, the product packaging will carry the CE mark and to be sold freely in European Union.

For your further information, kindly check the Annex for the declaration of notification as well as EC declaration of Conformity.

DECLARATION OF NOTIFICATION

Date: March 5, 2020

The undersigned, Sara Van Wouwe, Device Compliance Assistant of Qarad BVBA, hereby declares that:

[redacted]

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Name Device	Catalogue numbers
Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)	W195
Finecare™ SARS-CoV-2 IgM Test	W277
Finecare™ SARS-CoV-2 Antibody Test	W276

The notification to the Belgian Competent Authorities has been carried out on March 5, 2020 by Qarad BVBA, the appointed Authorized Representative of [redacted].

Information on the notification to the competent Authorities of other European countries is available upon request.

Sara Van Wouwe
Device Compliance Assistant
Qarad BVBA
Authorized Representative

LENGHA

SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD

Ref: ATOO1V

Production Capacity

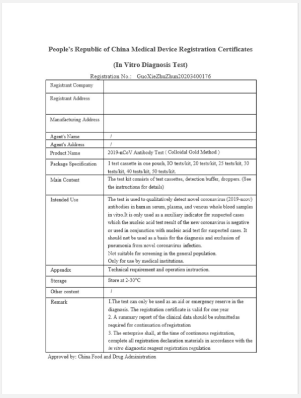
10,000,000
300,000 per day

Minimum Order Quantity

1 million units

Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) is based on the principle of capture immunoassay for determination of SARS-CoV-2 IgG/IgM antibodies in human whole blood, serum and plasma. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the SARS-CoV-2 antigen-dye conjugate and flows across the pre-coated membrane. When the SARS-CoV-2 antibodies level in the specimen is at or above the target cut-off (the detection limit of the test), the antibodies bound to the antigen-dye conjugate are captured by anti-human IgG antibody and anti-human µ chain antibody immobilized in the Test Region (T) of the device, and this produces a coloured test band that indicates a positive result. When the SARS-CoV-2 antibody level in the specimen is zero or below the target cut-off, there is not a visible coloured band in the Test Region (T) of the device. This indicates a negative result.

Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG/IgM antibody in human whole blood, serum or plasma sample. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2. The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.



People's Republic of China Medical Device Registration Certificates

(In Vitro Diagnosis Test)

Registration No.: GuoXieZhuZhun20204400176

Registrant Company	
Registrant Address	
Manufacturing Address	
Agent's Name	/
Agent's Address	/
Product Name	2019-nCoV Antibody Test (Colloidal Gold Method)
Package Specification	1 test cassette in one pouch, 20 tests/kit, 25 tests/kit, 50 tests/kit, 40 tests/kit, 30 tests/kit
Main Content	The test kit consists of test cassettes, detection buffer, droppers. (See the instructions for details)
Intended Use	The test is used to qualitatively detect novel coronavirus (2019-nCoV) antibodies in human serum, plasma, and venous whole blood samples in vitro.It is only used as a auxiliary indicator for suspected cases which the nucleic acid test result of the new coronavirus is negative or used in conjunction with nucleic acid test for suspected cases. It should not be used as a basis for the diagnosis and exclusion of pneumonia from novel coronavirus infection. Not suitable for screening in the general population. Only for use by medical institutions.
Appendix	Technical requirement and operation instruction.
Storage	Store at 2-30℃
Other content	/
Remark	1.The test can only be used as an aid or emergency reserve in the diagnosis. The registration certificate is valid for one year. 2. A summary report of the clinical data should be submitted as required for continuation of registration. 3. The enterprise shall, at the time of continuous registration, complete all registration declaration materials in accordance with the in vitro diagnostic reagent registration regulation.

Approved by: China Food and Drug Administration

qarad

DECLARATION OF NOTIFICATION

Date: March 5, 2020

The undersigned, Sara Van Wouwe, Device Compliance Assistant of Qarad BVBA, hereby declares that:

[redacted]

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

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Sara Van Wouwe
Device Compliance Assistant
Qarad BVBA
Authorized Representative

LENGHA