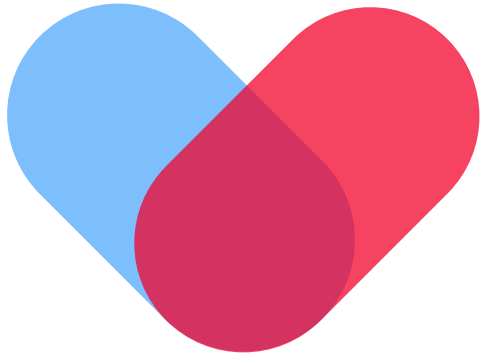


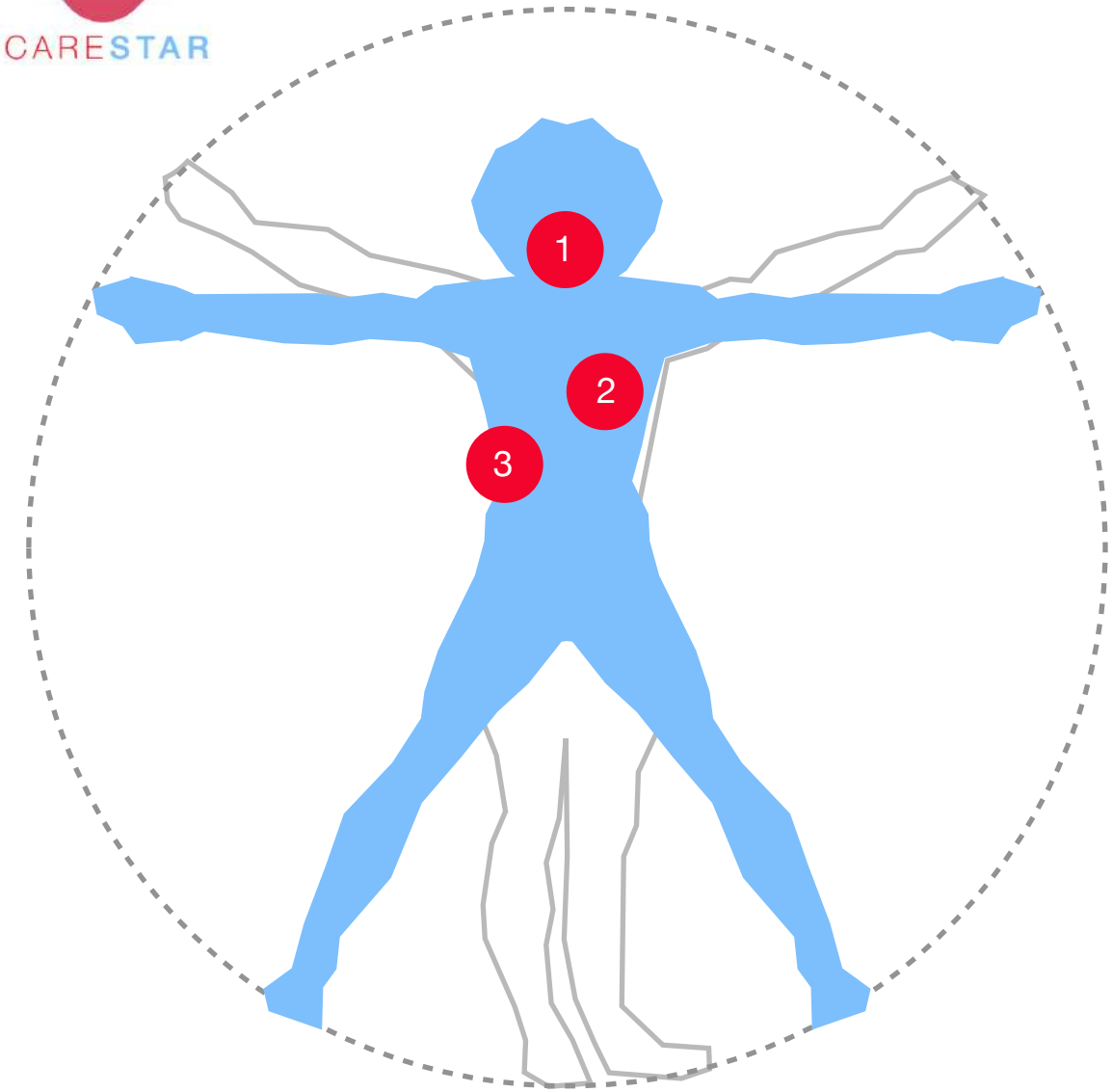
CARESTAR

carestar.com.sg

COVID-19 ESSENTIALS

CARESTAR

WE ARE PROVIDER OF COVID-19 ESSENTIAL CARE ITEMS



CARESTAR

is committed to provide COVID-19 essential items with high quality & speed-to-availability

FEATURED PRODUCTS

1 **DISPOSABLE MASK (3-PLY) & KN-95 MASK**

Most needed almost by everyone in the midst of COVID-19 pandemic situation

2 **COVID-19 TEST KIT**

Most needed Colloidal Gold Method COVID-19 TEST KIT Product for instant 15 mins early detection check

3 **COVID-19 PCR KIT**

Most needed by hospital and lab COVID-19 patients for nasal swab

DISPOSABLE **FACE MASK**

FOR CIVILIAN USE

carestar.com.sg

COVID-19 ESSENTIALS

DISPOSABLE **FACE MASK**

50-PIECE PER BOX

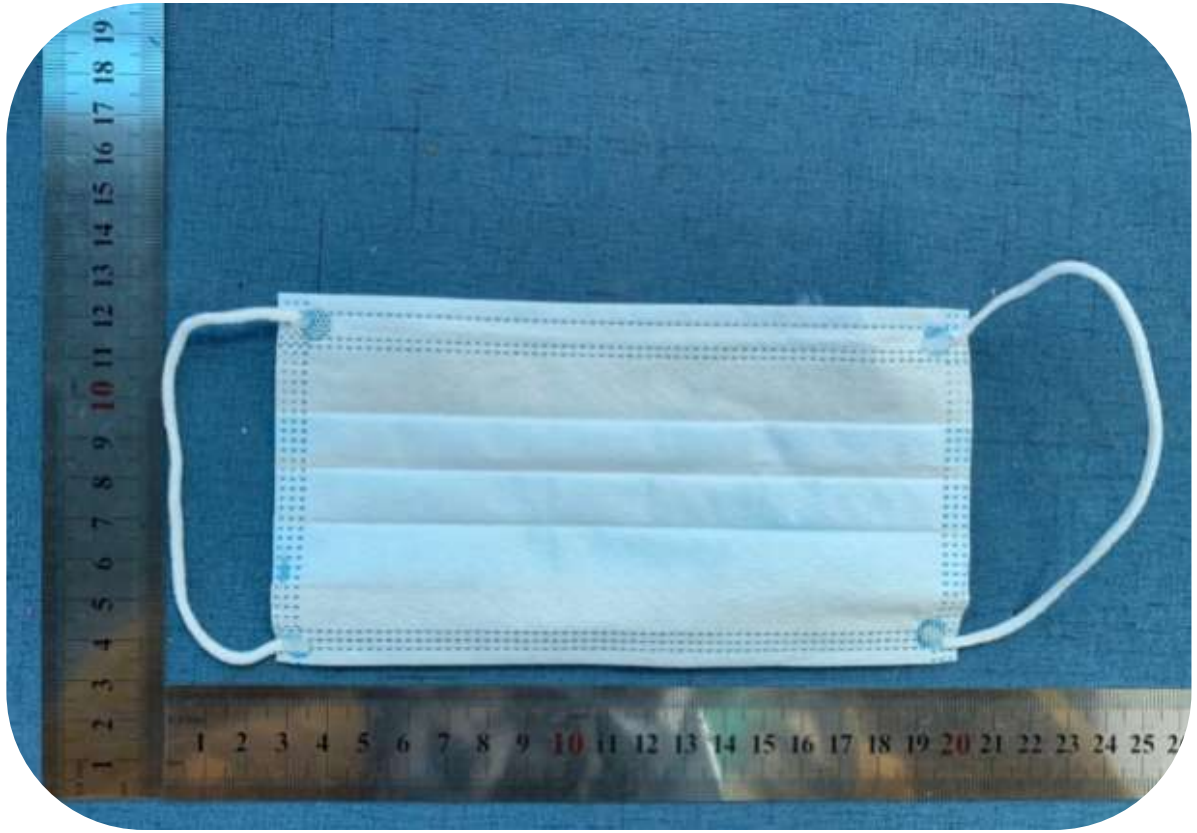
DISPOSABLE **FACE MASK**

40 BOXES OF 50PCS MASK PER CARTON

DISPOSABLE **FACE MASK**

3-PLY FACE MASK

OUTER (FRONT)



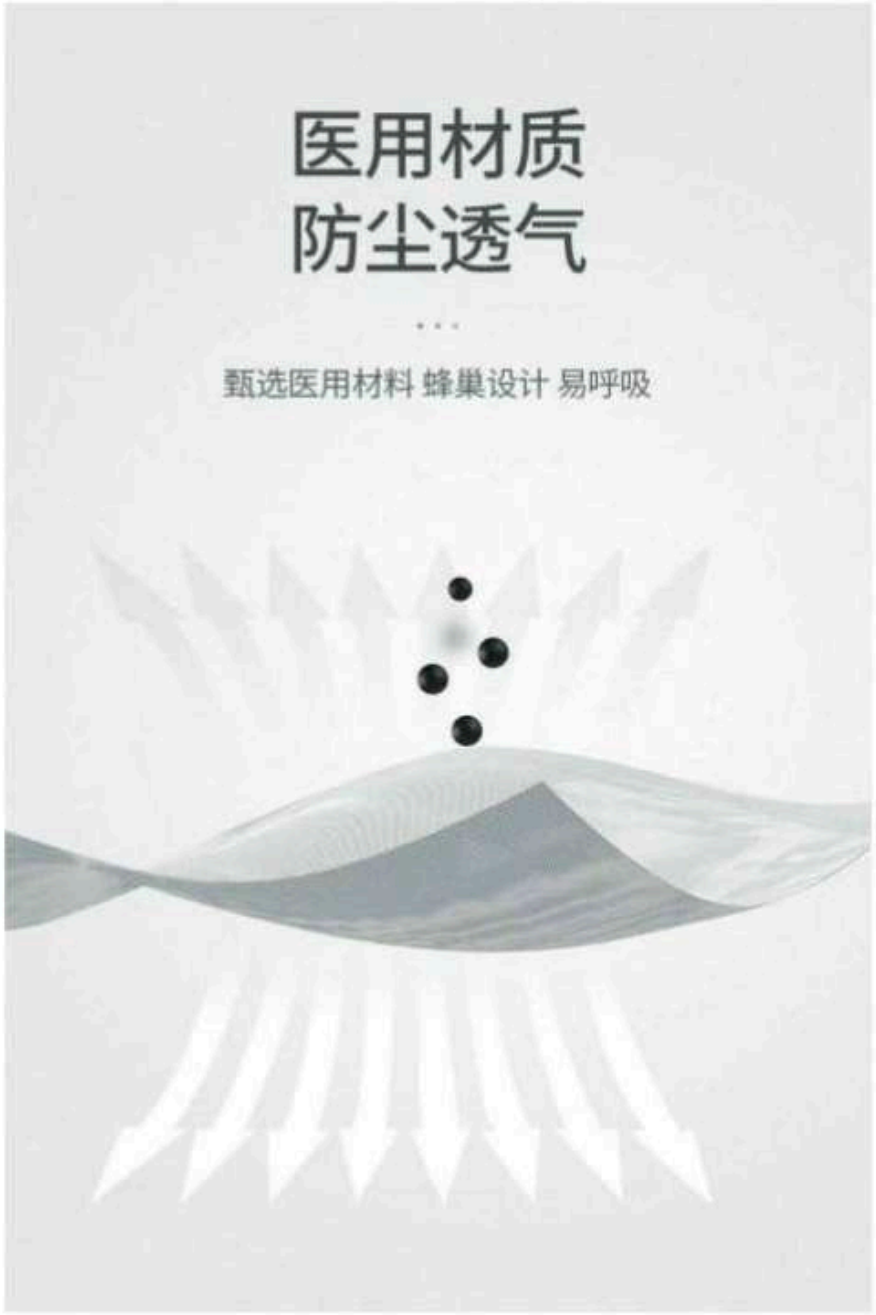
INNER (BACK)

DISPOSABLE **FACE MASK**

PROTECTION FROM

DISPOSABLE **FACE MASK**

HIGH QUALITY



DISPOSABLE **FACE MASK**

CE **CERTIFIED**

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

Form QAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 4G200325T.HJP0T80

Certificate's Holder: Hebi Junjianan Purification Technology Co., ltd.
200 meters North of the intersection of Songshan Road and Yanhe Road, Hebi city, Henan Province, P. R. C

Certification ECM Mark: Type Approved

Product: Disposable Face Mask

Model(s): J20

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

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

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE The manufacturer is responsible for the CE Marking process. 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

Issuance date: 25 March 2020

Expiry date: 24 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

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

DISPOSABLE **FACE MASK**

FDA **CERTIFIED**

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Hebi Junjianan Purification Technology Co.,Ltd
200 meters North of the intersection of SongShan Road and YanHe Road

Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807, by DongGuan TIS testing technology Co., LTD .

Owner/Operator Number: 10063545
Device Listing#: See annex
Expiration Date: December. 31, 2020

2020 TIS 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. TIS 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. TIS 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, TIS is not affiliated with the U.S. Food and Drug Administration.

FDA

Executive Director
Issued: March 27, 2020

COVID-19 ESSENTIALS

DISPOSABLE **FACE MASK**

TEST REPORT

TEST REPORT

EN 149

Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Report Reference No.	**BD-PPE209305**
Tested by (name + signature)	
Compiled by (name + signature)	
Approved by (name + signature)	
Date of issue	Mar. 13, 2019
Total number of pages	6 Pages
Testing Laboratory	
Address	
Testing location	As above
Applicant's name	Hebi Junjianan Purificantion Technology Co., Ltd
Address	200 meters North of the intersection of Songshan Road and Yanhe Road, Hebi city, Henan Province, P. R. C
Test specification:	
Standard	EN 149:2001+A1:2009
Test procedure	Type approved
Non-standard test method	N/A
Test item description	Disposable Face Mask
Trade Mark	君健安 JUNJIANAN
Manufacturer	Hebi Junjianan Purificantion Technology Co., Ltd
Address	200 meters North of the intersection of Songshan Road and Yanhe Road, Hebi city, Henan Province, P. R. C
Model/Type reference	J20

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
All clauses.	10 buildings 1-5 floors of Xinligang Bay Industrial Zone, Huangtian Street, Baoan District, Shenzhen

Test item particulars

Relative Humidity	56% RH
Air Pressure	97.9 kPa
Temperature by measurement	25 °C
Information for safety use	N/A

Possible test case verdicts:

- test case does not apply to the test object: N/A
- test object does meet the requirement: P (Pass)
- test object does not meet the requirement: F (Fail)

Testing:

Date of receipt of test item	Mar. 05, 2020
Date (s) of performance of tests	Mar. 05-13, 2020

General remarks:

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 Issuing testing laboratory.
"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
Throughout this report a comma (point) is used as the decimal separator.
List of test equipment must be kept on file and available for review.

General product information:

The following test were carried out according to EN 149:2001+A1:2009 and manufacturer specification requirement.

EN 149			
Clause	Requirement - Test	Result - Remark	Verdict
4	Description		P
5	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage.	FFP2	P
6	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner		P
7	Requirements		P
7.1	In all tests all test samples shall meet the requirements.		P
7.2	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values		P
7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer.		P
7.4	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.		P
7.5	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.		P
7.6	If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.		P
7.7	The particle filtering half mask shall undergo practical performance tests under realistic conditions.		P
7.8	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges and burrs	P
7.9	Leakage		
7.9.1	The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected.	11 %	P
7.9.2	he penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	FFP2	P
7.10	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.		P
7.11	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
7.12	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average		P

DISPOSABLE **FACE MASK**

TEST REPORT

EN 149			
Clause	Requirement - Test	Result - Remark	Verdict
7.13	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.		P
7.14	The field of vision is acceptable if determined so in practical performance tests.		P
7.15	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.		P
7.16	The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.	Inhalation：0.5 Exhalation：2.1	P
7.17	Clogging		P
7.17.1	For single shift use devices, the clogging test is an optional test.		P
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks	3 mbar	P
7.17.2.2	Valveless particle filtering half masks	3 mbar	P
7.17.3	Penetration of filter material		P
7.18	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		P

Test	Required level	Test Date	Average value
Paraffin Oil penetration	<6% after 120mg exposure	Mar.12,2020	5,23%
NaCl penetration	<6% after 120mg exposure	Mar.12,2020	0,73%
Facial leakage	46 results≤11% 8 averages in 10≤8%	Mar.12,2020	Compliant
Air permeability inhalation 30l/min	≤0,7 mbars	Mar.11,2020	0,15 mbar*
Air permeability inhalation 95l/min	≤2,4 mbars	Mar.11,2020	0,65 mbar*
Air permeability exhalation 160l/min	≤3 mbars	Mar.10,2020	1,19 mbar*
Carbon dioxide content	<1,0%	Mar.10,2020	0,60%
Flammability	Must not burn or continue to burn for more than 5 seconds after the withdrawal of the flame	Mar.10,2020	Compliant

Remark:

Protection(D): protection against solid and liquid aerosols, combined with resistance higher to clogging tested with dolomite dust

*Average of the test results (Receiving State + Simulated port processing)

KN95 PROTECTIVE MASK

(FOR CIVILIAN USE WITH PFE 95%)

carestar.com.sg

COVID-19 ESSENTIALS

KN95 **PROTECTIVE MASK**

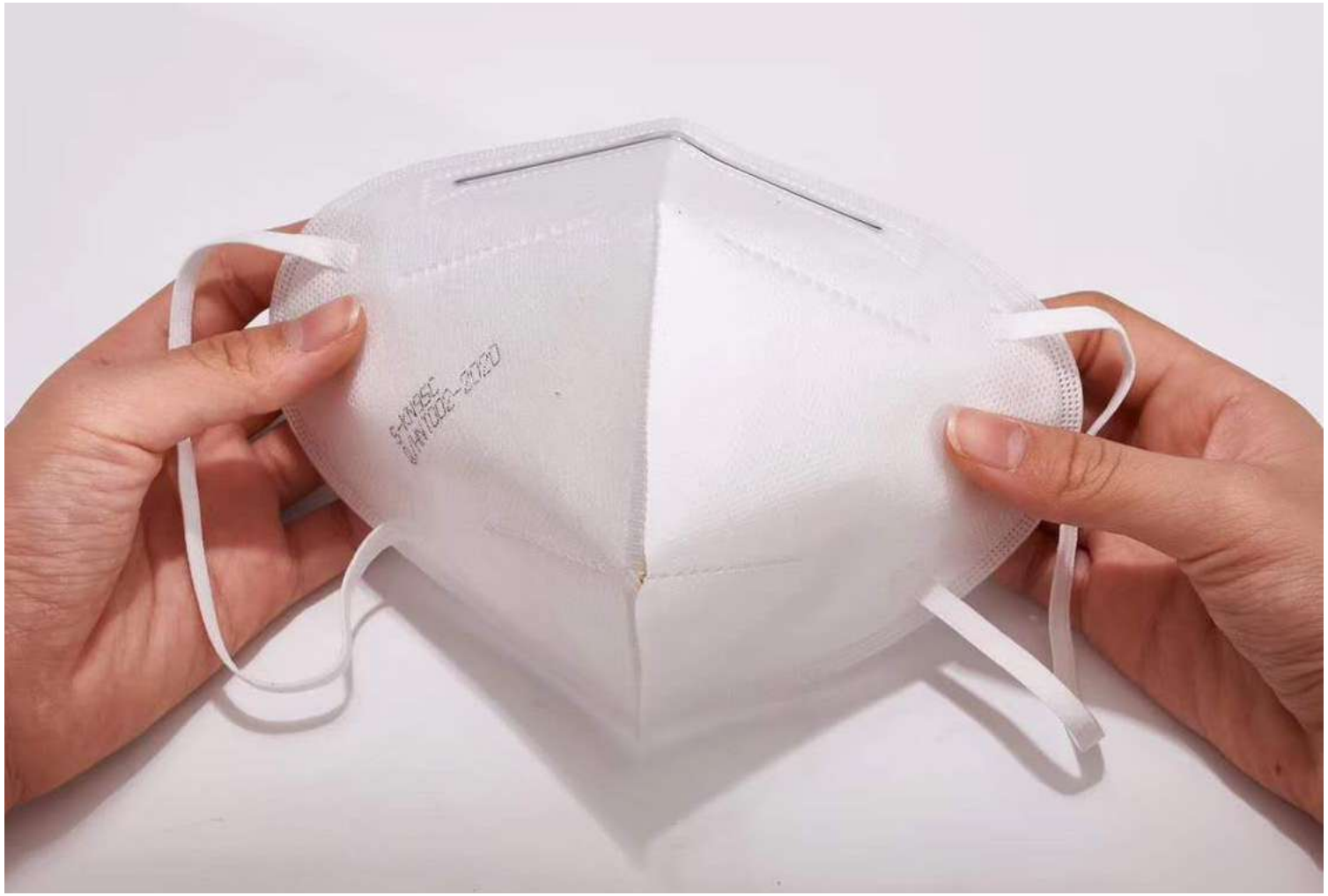
FRONT VIEW

10-PIECE PER BOX

BACK VIEW

KN95 **PROTECTIVE MASK**

KN95 PROTECTION MASK



FRONT VIEW

KN95 **PROTECTIVE MASK**

KN95 PROTECTION MASK

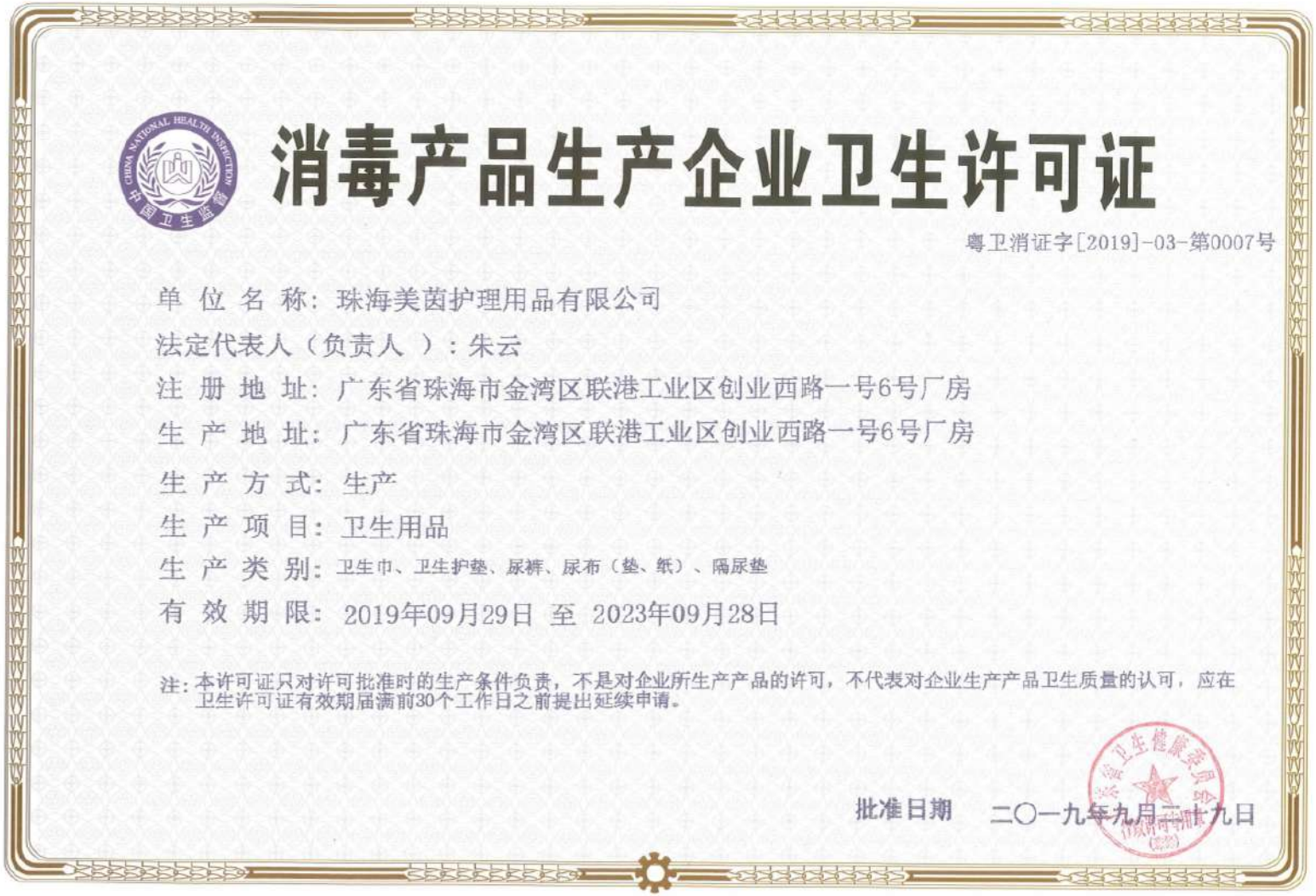
FOLDED VIEW

LEFT VIEW

RIGHT VIEW

KN95 **PROTECTIVE MASK**

CERTIFICATION FROM CHINA NATIONAL HEALTH INSPECTION



消毒产品生产企业卫生许可证

粤卫消证字[2019]-03-第0007号

单 位 名 称：珠海美茵护理用品有限公司

法定代表人（负责人 ）：朱云

注 册 地 址：广东省珠海市金湾区联港工业区创业西路一号6号厂房

生 产 地 址：广东省珠海市金湾区联港工业区创业西路一号6号厂房

生 产 方 式：生产

生 产 项 目：卫生用品

生 产 类 别：卫生巾、卫生护垫、尿裤、尿布（垫、纸）、隔尿垫

有 效 期 限：2019年09月29日 至 2023年09月28日

注：本许可证只对许可批准时的生产条件负责，不是对企业所生产产品的许可，不代表对企业生产产品卫生质量的认可，应在卫生许可证有效期届满前30个工作日之前提出延续申请。

批准日期 二〇一九年九月二十九日

KN95 PROTECTIVE MASK

CE CERTIFIED

COVID-19 ESSENTIALS

EC-Certification of Conformity

ENC

Certification of Conformity

PERSONAL PROTECTIVE EQUIPMENT - (EU) 2016/425

Registration No.: ENC2003141GZ85

Applicant	:	Foshan Ipartner Trading Co.,Ltd.
Applicant Address	:	No.1814 Building 2 Jinse Lingyu Plaza No.1 Foping Raod 3 Guicheng Street Nanhai Foshan
Product Designation	:	Self priming filter type anti particle respirator protective face mask
Model Number	:	N95, KN95, F9051, F9052, F1688, F001, F002, F118, F128, F168, F188, F198 Protective mask Protective mask cup type Protective mask butterfly type
Classification	:	FFP2
Manufacturer	:	Zhuhai Meiyin Nursing Products Co., Ltd
Manufacturer Address	:	No.6.1st West Chuangye Road, Shuanglin Area, Lian'gang Industrial Zone, Jinwan Area, Zhuhai, Guangdong.

The submitted products have been tested by us with the listed standard and found in compliance with the following European Standards:

Directive	Applied Standards	Test Report No.
PPE (EU) 2016/425	EN 149:2001+A1:2009	ENC2003141GZ85E1

This certificate is based on an evaluation of a sample of the above mentioned product. Technical report and documentation are at the licence applicant's disposal. This certificate does not imply assessment of the series-production of the product. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.

CE

Ray Zhou / General Manager
Date of Issue: Mar. 23, 2020

East Notice Certification Service Co., Ltd.

1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City
Tel:+86-020-8256 8534 Fax:+86-020-8256 8534 E-mail:enc@enc-lab.com Web: www.enc-lab.com

KN95 **PROTECTIVE MASK**

FDA CERTIFIED
(USA APPROVED STANDARD)

COVID-19 ESSENTIALS

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

ZHUHAI MEIYIN CARE PRODUCTS CO., LTD.
No.1 Chuangye West Road, Shuanglin Area, Liangang Industrial Zone Zhuhai, Guangdong, 519000, CHINA
has completed the FDA Establishment Registration (as manufacturer , foreign exporter) 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: +1-855-057-7279 / E-mail: sungo-group@yahoo.com

Owner/Operator Number: 10064537
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. 26 2020
Cert. No.: 2007US1-55[illegible]
Expiration Date: Dec. 31 2020

KN95 **PROTECTIVE MASK**

TEST REPORT

No. FZ2005137

CMA 201719002006 | ilac-MRA | CNAS 中国认可 国际互认 检测 TESTING CNAS L0153 | AL

检 测 报 告

TEST REPORT

委托方 Commissioned by	珠海美茵护理用品有限公司 Zhuhai Meiyin Care Products Co., Ltd
生产单位 Factory	珠海美茵护理用品有限公司 Zhuhai Meiyin Care Products Co., Ltd
样品名称 Name of Sample	Butterfly type disposable face mask （N95） 鹰嘴蝶形无骨 N95 口罩
型号规格 Type, Specification	MY002
检测类别 Testing Purpose	委托检测 Commission

广东产品质量监督检验研究院
GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION

No. FZ2005137

广 东 产 品 质 量 监 督 检 验 研 究 院
GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION

检测报告
TEST REPORT

报告随机号 Security Code：JN00361　　第 1 页 共 5 页

样品名称 Name of Sample	Butterfly type disposable face mask （N95） 鹰嘴蝶形无骨 N95 口罩 送样（√） Sending / 抽样（/） sampling	样品编号 Sample number	YFZ20/005137
商标 Trade mark	美茵 Meiyin	型号规格 Type, Specification	MY002
委托方 Commissioned by	珠海美茵护理用品有限公司 Zhuhai Meiyin Care Products Co., Ltd	检测类别 Testing Purpose	委托检测 Commission
委托方地址 Address of client	珠海市金湾区联港工业区双林片创业西路一号 6 号厂房 No. 6, 1St West Chuangye Road, Shuanglin Area, Lian' gang Industrial Zone, Jinwan Area Zhuhai, Guangdong.	产品编号/批号 Product No. / batch No	——
生产单位 Factory	珠海美茵护理用品有限公司 Zhuhai Meiyin Care Products Co., Ltd	抽样单编号 Sampling list No	——
受检单位 Inspected unit	——	生产日期 Date of manufacture	——
抽样单位 Sampling unit	——	样品数量 Quantity of sample	40（个） 40（Piece）
抽样地点 Location of sampling	——	抽样基数 Basic quantity of sampling	——
抽样日期 Date of sampling	——	检验地点 Location of testing	本部实验室 Laboratory
收样日期 Date of receiving	2020 年 03 月 03 日	检验日期 Date of testing	2020 年 03 月 03 日～2020 年 03 月 10 日
检测依据 Testing reference	GB 2626-2006《呼吸防护用品 自吸过滤式防颗粒物呼吸器》 GB 2626-2006 Respiratory protective equipment. Non-powered air-purifying particle respirator		
判定依据 Judging reference	——		
检测结论 Remarks	见检测结果。 Test results are attached as below.		
备注 Notes	报告中的“——”表示此项不适用，报告中“/”表示此项空白。 “——” in the report indicates that this item is not applicable, and "/" in the report indicates that this item is blank.		

（检验检测专用章）
签发日期：检验检测专用章 (Q1)

批准： 审核： 主检：

No. FZ2005137

检 测 报 告
TEST REPORT

第 2 页 共 5 页

序号 No	检测项目[单位] Test items[Unit]	标准条款 Standard terms	标准技术要求 Standard requirements	检测结果 Result		单项结论 Conclusion	备注 Notes
1	过滤效率[%] Filtering efficiency	5.3	KN95 ≥ 95.0	未预处理 Unpretreated	99.6	合格 Pass	/
					99.4		
					99.5		
					99.4		
					99.4		
					99.4		
					99.5		
					99.5		
					99.6		
					99.4		
				预处理 Pretreated	99.3		
					98.9		
					99.0		
					99.1		
					99.3		
			氯化钠颗粒物检测 Detection of oily particles 温度 Temperature：（25±5）℃ 湿度 Humidity：（30±10）%	实测温度 Measured temperature：（23～25）℃ 实测湿度 Measured Humidity：（35～37）%			
2	吸气阻力[Pa] Inhale resistance	5.5	总吸气阻力≤350 Total inhale resistance≤350	未预处理 Unpretreated	60.6	合格 Pass	/
					60.2		
				预处理 Pretreated	65.7		
					62.5		
3	呼气阻力[Pa] Exhalation resistance	5.5	总呼气阻力≤250 Total exhalation resistance≤250	未预处理 Unpretreated	62.0	合格 Pass	/
					64.2		
				预处理 Pretreated	67.4		
					65.8		

KN95 **PROTECTIVE MASK**

TEST REPORT

No. FZ2005137

检 测 报 告

TEST REPORT

第 3 页 共 5 页

序号 No	检测项目[单位] Test items[Unit]	标准条款 Standard terms	检验检测专用章 Standard requirements	检测结果 Result		单项结论 Conclusion	备注 Notes
4	死腔[%] Dead cavity	5.7	以吸入气中二氧化碳体积分数表示时，结果平均值应≤1 When expressed as the volume fraction of carbon dioxide in the inhaled air, the average value of the results should be ≤1	平均值 Average: 0.8		合格 Pass	/
5	连接和连接部件 links and connected components	5.10	可更换式半面罩在规定检测条件下，可更换式过滤元件与面罩之间的所有连接和连接部件，在承受 50N，持续时间 10s 的轴向拉力时，不应出现滑脱、断裂或变形 When inspecting the half mask in accordance with regulations, all links and connected components between the replaceable filter element and the mask should not slip, break or deform when subjected to an axial tensile force of 50N for 10s	未预处理 Unpretreated	无此部件，此项不检 Without this part, this item is not detected	——	/
				预处理 Pretreated			
6	可燃性 Flammability	5.13	暴露于火焰的各部件在从火焰移开后，不应燃烧；如果燃烧，续燃时间不应超过 5s After being removed from the flame, the parts exposed to the flame should not burn. If burning, the after burning time should not exceed 5s	未预处理 Unpretreated	未出现燃烧现象 Unburned	合格 Pass	/
					未出现燃烧现象 Unburned		
				预处理 Pretreated	未出现燃烧现象 Unburned		
					未出现燃烧现象 Unburned		

No. FZ2005137

检 测 报 告

TEST REPORT

第 4 页 共 5 页

照片和检验检测专用章 Photos and Test Instructions

样品描述 Sample description

/

型号规格或其它说明 Type, Specification or other description

MY002

No. FZ2005137

检 测 报 告

TEST REPORT

第 5 页 共 5 页

附注 APPENDIX：

1、试验地点 Place of test：广州市黄埔区科学城科学大道 10 号

2、委托单位地址及邮编 Add.&Postcode: 珠海市金湾区联港工业区双林片创业西路一号 6 号厂房 No.6,1St West Chuangye Road, Shuanglin Area, Lian'gang Industrial Zone, Jinwan Area Zhuhai,Guangdong.

3、检测环境条件 Testing ambient conditions：检测项目均在相应标准规定的条件下进行（有注明的除外）The test items shall be carried out under the conditions specified in the corresponding standards (Unless otherwise noted)

4、抽样程序（如适用）Sampling procedure (if applicable)：————

5、偏离标准方法的说明（如适用）Statement of deviating standard method (if applicable)：————

6、检测结果不确定度说明（如适用）Uncertainty statement of test results (if applicable)：————

7、分包项目及分包方（如适用）Subcontracted items and subcontractors (if applicable)：————

KN95 3D PROTECTIVE MASK

(FOR CIVILIAN USE WITH PFE 95%)

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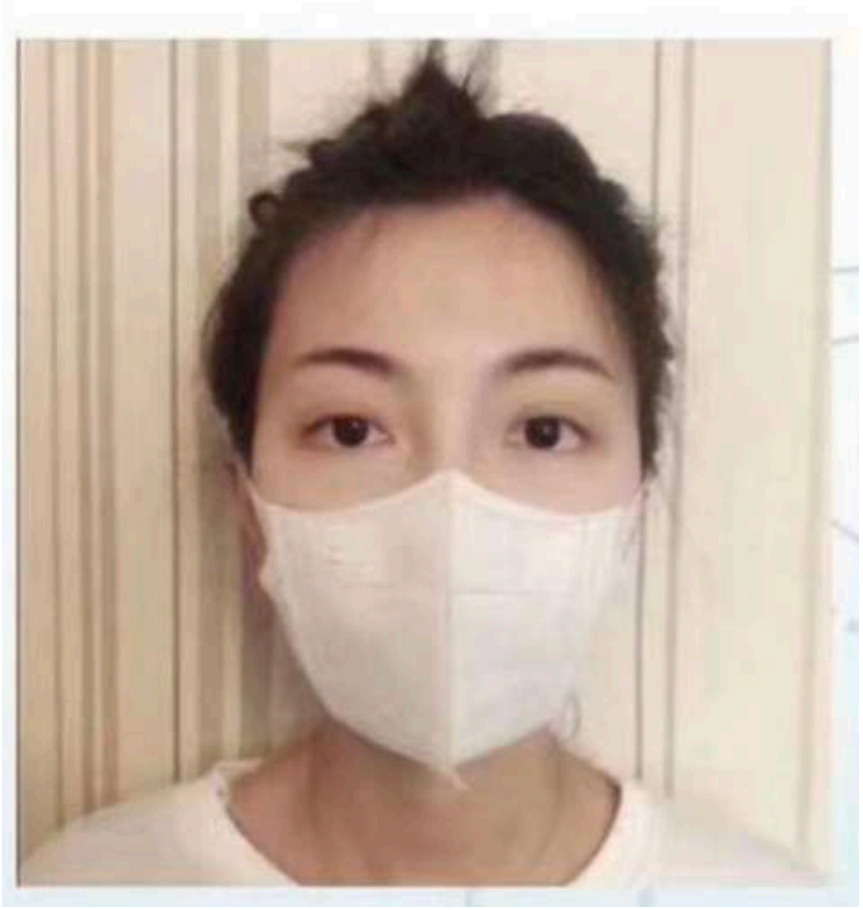
COVID-19 ESSENTIALS

KN95 *3D* PROTECTIVE MASK

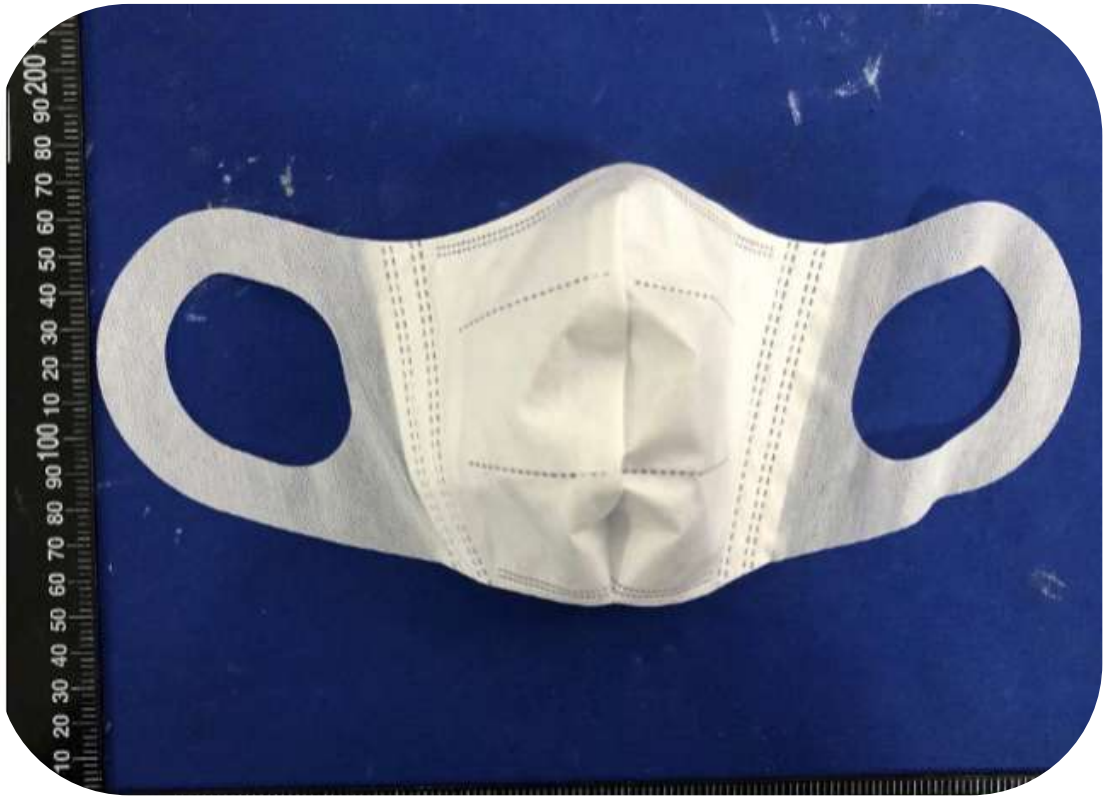
KN95 3D FRONT VIEW



KN95 3D SIDE VIEW

KN95 *3D* PROTECTIVE MASK

FRONT



BACK

KN95 *3D* PROTECTIVE MASK

INDIVIDUALLY PACKED

FRONT

BACK

KN95 3D PROTECTIVE MASK

CE CERTIFICATION

Certificate

No. ICR Polska/6301197

CE

Name and address of certificate owner:	Jinjiang Heng'an Household Tissue Products Co.,Ltd Wuli Industrial Zone, Anhai Town, Jinjiang, Fujian P.R. China
Name and address of manufacturer:	Jinjiang Heng'an Household Tissue Products Co.,Ltd Wuli Industrial Zone, Anhai Town, Jinjiang, Fujian P.R. China
Product name:	KN95 MASK
Product types:	XCL010, XCX010
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 149:2001+A1:2009

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 Monotek Technical Service Company Limited

No. of test reports:	MT20200310-018-A
Certificate issue date:	19.03.2020
Expiration date:	18.03.2025

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, 19. 03. 2020

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

KN95 *3D* PROTECTIVE MASK

TEST REPORT

Test Report

Client Name	:	Jinjiang Heng'an Household Tissue Products Co.,Ltd
Address	:	Wuli Industrial Zone, Anhai Town, Jinjiang, Fujian P.R.China
Product Name	:	KN95 MASK
Date	:	Mar. 19, 2020

Issued by : Monotek Technical Service Company Limited

TEST REPORT
EN 149
Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

Report reference No	:	MT20200310-018-A
Compiled by (+ signature)	:	Tony Xiao
Approved by (+ signature)	:	Barry Zhou
Date of issue	:	Mar. 19, 2020
Contents	:	10
Testing laboratory	:	Monotek Technical Service Company Limited
Address	:	Building A, No. 3, Huafa Road, Longgang District, Shenzhen, Guangdong, China.
Testing location	:	Same as above
Applicant	:	Jinjiang Heng'an Household Tissue Products Co.,Ltd
Address	:	Wuli Industrial Zone, Anhai Town, Jinjiang, Fujian P.R.China
Test specification		
Standard	:	EN 149:2001+A1:2009
Test procedure	:	CE Certification
Procedure deviation	:	N.A.
Non-standard test method	:	N.A.
Type of test object		
Description	:	KN95 MASK
Trademark	:	N.A.
Model/type reference	:	XCL010, XCX010
Manufacturer	:	Same as applicant
Address	:	Same as applicant

Possible test case verdicts

-- test case does not apply to the test object	:	N (Not applicable)
-- test object does meet the requirement	:	P (Pass)
-- test object does not meet the requirement	:	F (Fail)

Testing

Date of receipt of test item	:	Mar. 16, 2020
Date(s) of performance of test	:	Mar. 16, 2020 to Mar. 19, 2020

General remarks

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 testing laboratory.

Marking information

KN95 MASK
Model: XCL010
CE
EN 149:2001+A1:2009
FFP2 NR D
Jinjiang Heng'an Household Tissue Products Co.,Ltd

Marked on the packaging.

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
5	**Classification**		P
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices: FFP1, FFP2 and FFP3.	FFP2	P
6	**Designation**		P
	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner: Particle filtering half mask EN 149, year of publication, class, option .		P
7	**Requirements**		P
7.1	**General**		P
	In all tests all test samples shall meet the requirements.		P
7.2	**Nominal values and tolerances**		P
	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of ± 5 %. Unless otherwise specified, the ambient temperature for testing shall be (18 - 32) °C, and the temperature limits shall be subject to an accuracy of ± 1 °C.		P
7.3	**Visual inspection**		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.		P
7.4	**Packaging**		P
	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use. Testing shall be done in accordance with 8.2.		P
7.5	**Material**		P
	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. Three particle filtering half masks shall be tested. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. Testing shall be done in accordance with 8.2.	No mechanical failure of the facepiece or straps. Not constituted a hazard or nuisance for the wearer.	P
7.6	**Cleaning and disinfecting**		N

KN95 3D PROTECTIVE MASK

TEST REPORT

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	If the particle filtering half mask is designed for to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. Testing shall be done in accordance with 8.1.1.		N
7.7	**Practical performance**		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. Testing shall be done in accordance with 8.4.		P
7.8	Finished of parts		P
	Likely to come into contact with wearer, no sharp edges or burrs	Checked	P
7.9	**Leakage**		P
7.9.1	**Total inward leakage**		P
	The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve Leakage (if exhalation valve fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e.10 subjects x 5 exercises) for total inward leakage shall be not greater than 11 % for FFP2 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8 % for FFP2	48 out of 50 result: 21% 9 out of 10 means: 22%	P
7.9.2	**Penetration of filter material**		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	Sodium chloride 95l/min: 4.8% Paraffin oil test:95l/m: Max:5.0%	P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict

Table 1 — Penetration of filter material

Classification	(a) Maximum penetration of test aerosol (b)	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

7.10	**Compatibility with skin**		P
	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health. Testing shall be done in accordance with 8.4 and 8.5.	The materials would not cause irritation or any other adverse effect to health	P
7.11	**Flammability**		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame. The particle filtering half mask does not have to be usable after the test. Testing shall be done in accordance with 8.6.	2s after removal from flame	P
7.12	**Carbon dioxide content of the inhalation air**		P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume). Testing shall be done in accordance with 8.7.	0.4%	P
7.13	**Head harness**		P
	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device. Testing shall be done in accordance with 8.4 and 8.5.		P
7.14	**Field of vision**		P
	The field of vision is acceptable if determined so in practical performance tests. Testing shall be done in accordance with 8.4.	When test in practical performance test, the filed of vision is acceptable	P
7.15	**Exhalation Value**		N

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	After clogging the inhalation and exhalation resistances shall not exceed FFP1: 2.1 mbar FFP2: 2.4 mbar FFP3: 3 mbar at 95 l/min continuous flow. Testing shall be done in accordance with 8.9	2.31 mbar	P
7.17.3	**Penetration of filter material**		P
	All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN149, after the clogging treatment. Testing shall be done in accordance with 8.11 using EN149.		P
7.18	**Demountable parts**		N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand. Testing shall be done in accordance with 8.2.		N
8	Testing		–
8.1	General		–
8.2	Visual inspection		—
	The visual inspection is carried out where appropriate by the test house prior laboratory or practical performance tests		—
8.3	Conditioning		–
8.3.1	Simulated wearing treatment		—
	A breathing machine is adjusted to 25 cycles/min and 2.0l/stroke, the saturator being set at a temperature in excess of 37°C. The air shall be saturated at (37+/-2) °C at the mouth of the dummy head.		—
	During the test time at appro.20 min intervals the particle filter half mask shall be completely removed from the dummy head and refitted such that during the test period it is fitted ten times to the dummy head.		—
8.3.2	Temperature conditioning		—
	Expose the masks to the following thermal cycle: a) for 24h to a dry atmosphere of (70+/-3) °C b) for 24h to a dry atmosphere of (-30+/-3) °C and allow to return to room temperature for at least 4h between exposures and prior to subsequent testing. The conditioning shall be carried out in a manner which ensures that no thermal shock occurs.		—
8.3.3	Mechanical strength		—

Monotek Technical Service Company Limited
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EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	After clogging the inhalation and exhalation resistances shall not exceed FFP1: 2.1 mbar FFP2: 2.4 mbar FFP3: 3 mbar at 95 l/min continuous flow. Testing shall be done in accordance with 8.9	2.31 mbar	P
7.17.3	**Penetration of filter material**		P
	All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN149, after the clogging treatment. Testing shall be done in accordance with 8.11 using EN149.		P
7.18	**Demountable parts**		N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand. Testing shall be done in accordance with 8.2.		N
8	Testing		–
8.1	General		–
8.2	Visual inspection		—
	The visual inspection is carried out where appropriate by the test house prior laboratory or practical performance tests		—
8.3	Conditioning		–
8.3.1	Simulated wearing treatment		—
	A breathing machine is adjusted to 25 cycles/min and 2.0l/stroke, the saturator being set at a temperature in excess of 37°C. The air shall be saturated at (37+/-2) °C at the mouth of the dummy head.		—
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8.3.3	Mechanical strength		—

KN95 3D PROTECTIVE MASK

TEST REPORT

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
8.3.4	Flow conditioning		—
8.4	Practical performance		—
8.4.1	General		—
8.4.2	Walking test		—
8.4.3	Work simulation test		—
8.5	Leakage		—
8.5.1.1	Total inward leakage		—
8.5.2	Method		—
8.6	Flammability		—
8.7	Carbon dioxide content of inhalation air		—
8.8	Strength of attachment of exhalation valve housing		—
8.9	Breathing resistance		—
8.10	Clogging		—
8.11	Penetration of filter material		—
9	Marking		—
9.1	Packaging	Complied	P
9.2	Particle filtering half mask	Complied	P
10	Information supplied by the manufacture	Checked	P

Photo 1

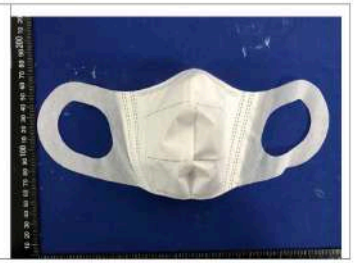
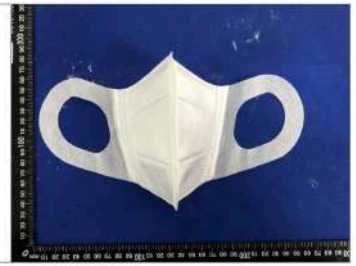


Photo 2



**** End of Report ****

MEDICAL SURGICAL **FACE MASK**

(MEDICAL GRADE WITH STERILE, BFE 95% & PFE 30%)

FOR HOSPITAL USE

carestar.com.sg

COVID-19 ESSENTIALS

MEDICAL SURGICAL **FACE MASK**

FOR HOSPITAL USE

PACKED IN STERILE PER 10-PIECE

MEDICAL SURGICAL **FACE MASK**

FOR HOSPITAL USE

50-PIECE PER BOX

MEDICAL SURGICAL FACE MASK

FOR HOSPITAL USE

CE CERTIFIED

CE EC Declaration of Conformity CE

Regarding Medical Device Regulation (EU)2017/745

Manufacturer:

Name: Shandong Zhushi Pharmaceutical Group Co., LTD
Address: No.6 Shande Road,Shan County, Heze City, Shandong, China 274300

European Authorized Representative:

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

Product::

Name: Face Mask

Model: Bandage type,Fat type,Folding type,Chi

type;22cm*9.5cm,20cm*9cm,18cm*9.3cm, .7.5cm* .16.5cm*9.5cm,1 .5*9.5 n,1

4.5cm*9cm,12cm87cm;or custo

Classification: Class I

Rule: According to le 1, Ann VIII, apter III EU Medical Device Regulation (EU)2017/7

ssment , roced e: nnex II+III

UD

Prod Mod Size	UDI-DI	Product Mod - Size	UDI-DI

We confirm our product can meet the requirement of Medical Device Regulation a the following harmonized standards:

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2008
ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN 14683:2014

Signature: Jerry Date: 2020/3/18

Position:

COVID-19 ESSENTIALS

MEDICAL SURGICAL FACE MASK

FOR HOSPITAL USE

FDA CERTIFIED


ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

兹证明:

This certifies that:

山东朱氏药业集团有限公司

Shandong Zhushi Pharmaceutical Group Co., Ltd

South Fanlou Road, Shan County Development Zone, Heze, Shandong, China 274300

已经通过美国食品药品监督管理局完成了FDA制造商注册和上市

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: 3013496867

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 global service

桑戈药监局

FDA

SUNGO

Executive Director

Issued: May 12, 2020

Cert. No.: 2006C866548

Expiration Date: Dec. 31, 2020

CERTIFIED

MEDICAL SURGICAL FACE MASK

FOR HOSPITAL USE

TEST REPORT

医疗器械产品技术要求编号：

一次性使用医用外科口罩

1.产品型号/规格及其划分说明

1.1结构、组成

一次性使用医用外科口罩（以下简称:口罩）由表层、中间层、底层、口罩带、鼻夹组成。

1.2 型号规格

根据临床需要，口罩设计样式为平面耳挂式的，规格为：17.5cm×9.5cm，其具体规格尺寸见表1。

表1 一次性使用医用外科口罩规格尺寸 单位：cm

型号规格	长	宽	展开宽	单根口罩带长（每侧各1根）
17.5cm×9.5cm	17.5	9.5	17.0	17.0

1.3 材质组成

表层材料为卫生级聚丙烯仿粘布、中间层材料为聚丙烯喷丝法制成的高效过滤熔喷布、底层材料为卫生级聚丙烯仿粘布、口罩带为涤纶线和少量氨纶线针织而成、鼻夹为可弯折可定型的聚丙烯制成。

2.性能指标

2.1外观

口罩外观应整洁、形状完好、表面不得有破损、污渍。

2.2 结构与尺寸

2.2.1 口罩佩戴好后，应能罩住佩戴者的口、鼻至下颌。

2.2.2 规格尺寸应符合表1的规定，最大误差不超过±5%。

2.3 鼻夹

2.3.1 口罩上应配有鼻夹，鼻夹由可塑性材料制成。

2.3.2 鼻夹长度应不小于8.0cm。

2.4 口罩带

2.4.1口罩带应戴取方便。

2.4.2每根口罩带与口罩体连接点的断裂强力应不小于10N。

2.5合成血液穿透

2mL合成血液以16.0kPa(120mmHg)压力喷向口罩外侧面后，口罩内侧面不应出现渗透。

2.6 过滤效率

2.6.1 细菌过滤效率（BFE）

口罩的细菌过滤效率应不小于95%。

2.6.2 颗粒过滤效率（PFE）

口罩对非油性颗粒的过滤效率应不小于30%。

2.7 压力差(Δp)

口罩两侧面进行气体交换的压力差Δp应不大于49Pa/cm²。

2.8 阻燃性能

口罩材料应采用不易燃材料，口罩离开火焰后燃烧不大于5s。

2.9 环氧乙烷残留量

采用环氧乙烷灭菌，环氧乙烷残留量应不超过10μg/g。

2.10 无菌

口罩应无菌。

3. 检验方法

3.1 外观

随机取3个口罩，正常视力或矫正视力检查，应符合2.1的要求。

3.2结构与尺寸

3.2.1 随机取3个口罩，实际佩戴验证，结果应符合2.2.1的要求。

3.2.1 以通用或专用量具测量，结果应符合2.2.2的要求。

3.3 鼻夹

3.3.1随机取3个口罩，检查鼻夹材质并手试弯折，均应符合2.3.1的要求。

3.3.2随机取3个口罩，取出鼻夹，以通用或专用量具测量，均应符合2.3.2的要求。

3.4 口罩带

3.4.1随机取3个口罩，通过佩戴检查其调节情况，均应符合2.4.1的要求。

3.4.2随机取3个口罩，以10N的静拉力进行测量，持续5s，均应符合2.4.2的要求。

3.5 合成血液穿透

3.5.1 样品数量：取5个样品进行试验。

3.5.2 预处理条件：样品在21℃±5℃，相对湿度85%±5%环境试验箱中预处理至少4h。样品从环境箱中取出1min内作测试。

3.5.3 按照YY/T0691-2008的试验方法进行，合成血液的配制方法见附录。结果应符合2.5的要求。

3.6 过滤效率

分别随机取3个口罩，分别按照YY0469-2011中细菌过滤效率和颗粒过滤效率测试方法进行试验，结果应符合2.6.1和2.6.2的要求。

3.7压力差(Δp)

随机抽取5个样品进行试验，按照YY0469-2011中压力差测试方法进行试验，结果应符合2.7的要求。

3.8 阻燃性能

随机抽取3个样品进行试验，按照YY0469-2011中阻燃性测试方法进行试验，结果应符合2.8的要求。

3.9 环氧乙烷残留量

环氧乙烷残留量按GB/T14233.1-2008中规定的方法进行，以第九章规定极限浸提的气相色谱法为仲裁方法，结果应符合2.9的规定。

3.10 无菌

按照《中华人民共和国药典》(2015年版 四部）通则1101“无菌检查法”中的“直接接种法”进行试验，结果应符合2.10的要求。

4术语

细菌过滤效率（BFE）

在规定的流量下，口罩材料对含菌悬浮粒子滤除的百分数。

MEDICAL SURGICAL FACE MASK

FOR HOSPITAL USE

TEST REPORT

附录

（资料性附录）

合成血液配制方法

1 试剂

按照如下配方制备 1L 合成血液：

羧甲基纤维素钠[例如，CMC-Sigma 9004-32-4 中粘度]	2g
聚氧乙烯（20）山梨糖醇酐单月桂酸酯（例如，吐温 20[Fluka9377]）	0.04g
氯化钠（分析纯）	2.4g
苋菜红染料[例如，Sigma915-67-3]（915-67-3）	1.0g
磷酸二氢钾（KH_2PO_4）	1.2g
磷酸氢二钠（Na_2HPO_4）	4.3g
蒸馏水或去离子水	加至 1L

注 1：可在合成血液中加入 2-甲基-4-异噻唑啉-3-酮盐酸盐（MIT）（0.5g/L）以延长溶液的贮存期。

注 2：Sigma 9004-32-4，Fluka 915-67-3 以及 Fluka 9377 是合适的商用产品举例。给出这一信息是为了方便本标准的使用者，并不代表对该产品的认可。

2配制方法

将羧甲基纤维素钠溶解在 0.5L 水中，在磁力搅拌器上混匀 60min。

在一个小烧杯中称量吐温 20，加入水混匀。

将吐温 20 溶液加到羧甲基纤维素钠溶液中，用蒸馏水将烧杯洗几次加到前溶液中。

将 NaCl 溶解在溶液中，将 KH_2PO_4 和 Na_2HPO_4 溶解在溶液中。

加入 MIT（如使用）和苋菜红染料。

用水将溶液稀释近 1000ml。

用磷酸盐缓冲液将合成血液的 pH 调节至 7.3±0.1，定容至 1000ml。

按照 GB/T5549-1990 测量合成血液的表面张力，结果应是 0.042N/m±0.002N/m。

一次性使用医用外科口罩使用说明书

【产品名称】一次性使用医用外科口罩

【规格型号】17.5cm×9.5cm 允差：±5%

【注册人名称】山东未氏药业集团有限公司

【注册人住所】单县经济技术开发区葵楼路南

【联系方式】电话：0530-4285777

【售后服务单位】山东未氏药业集团有限公司

【生产企业名称】山东未氏药业集团有限公司

【生产企业住所】单县经济技术开发区葵楼路南

【生产企业地址】山东单县经济技术开发区

【联系方式】电话：0530-4285777

【生产许可证编号】

【产品注册证编号】

【产品技术要求编号】

【执行标准号】YY0469-2011 医用外科口罩

【产品性能】1. 2mL 合成血液以 16.0kPa（120mmHg）压力喷向口罩外侧面后，口罩内侧面不应出现渗透；2. 口罩的细菌过滤效率应不小于 95%；3. 口罩对非油性颗粒的过滤效率应不小于 30%；4. 口罩两侧面进行气体交换的压力差 Δp 应不大于 49Pa/cm²；5. 口罩材料应采用不易燃材料，口罩离开火焰后燃烧不大于 5s；6. 采用环氧乙烷灭菌，环氧乙烷残留量应不超过 10μg/g；7. 口罩应无菌。

【主要结构组成或者成分】由表层、中间层、底层、口罩带、鼻夹组成。表层材料为聚丙烯纺粘布，中间层材料为聚丙烯喷丝法制成的过滤熔喷布，底层材料为聚丙烯纺粘布，口罩带为涤纶线和少量氨纶线针织而成，鼻夹为可弯折可定型的聚丙烯制成。

【适用范围】供临床医务人员在有创操作过程中佩带，覆盖住使用者的口、鼻及下颌，为防止病原体微生物、体液、颗粒物等的直接透过提供物理屏障。

【注意事项、警示】

1. 医用外科口罩只能一次性使用；
2. 口罩潮湿后，应及时更换；
3. 每次佩戴医用防护口罩进入工作区域之前，应进行密合性检查；
4. 口罩受到患者血液，体液污染后，应及时更换；
5. 包装破损后禁止使用；
6. 产品开封后应尽快使用；
7. 产品使用后应按医疗垃圾相关规定进行处理。

【禁忌症】

材料过敏者禁止使

【使用说明】

1. 打开产品包装，取出口罩，将有鼻夹一端向上，有包边一面朝外，轻拉耳带将口罩挂于双耳，应避免手部接触口罩内侧。

2. 轻按鼻夹使其与鼻梁贴合，然后按住鼻夹。将口罩下端向下拉至下颌处，使折叠边完全展开。

3. 整理口罩佩戴效果，使口罩能罩住使用者的鼻、口至下颌并保证口罩的密闭性。

【运输贮存】运输工具应清洁卫生、隔离火源。本产品应存放在干燥阴凉处，注意防水，避免阳光直射，严禁与有毒有害物质共同存放。本产品应贮存在阴凉干燥，清洁、避光、无腐蚀性气体、通风良好的室内。

【生产日期】见单包装

【使用期限】经环氧乙烷灭菌后，有效期两年。

【标签、包装标识】

STERILE	无菌
STERILE EO	经环氧乙烷灭菌
2	不得二次使用
	包装破损禁止使用

【编制日期】2019年01月30日

MEDICAL SURGICAL FACE MASK

FOR HOSPITAL USE

TEST REPORT

最小销售单元标签设计样稿

商标

STERILE STERILEO ② ⊘

【产品名称】一次性使用医用外科口罩

【型号规格】17.5cm×9.5cm 允差：±5%

【包　　装】　个/袋

【企业名称】山东朱氏药业集团有限公司

【生产企业住所】单县经济技术开发区樊楼路南

【生产企业地址】山东单县经济技术开发区

【联系方式】0530-4235777

【售后服务单位】山东朱氏药业集团有限公司

【生产许可证编号】

【产品注册证编号】

【产品技术要求编号】

【执行标准号】YY0469-2011 医用外科口罩

【适用范围】供临床医务人员在有创操作过程中佩带，覆盖住使用者的口、鼻及下颌，为防止病原体微生物、体液、颗粒物等的直接透过提供物理屏障。

【使用说明】

1. 打开产品包装，取出口罩，将有鼻夹一端向上，有包边一面朝外，轻拉耳带将口罩挂于双耳，应避免手部接触口罩内侧。
2. 轻按鼻夹使其与鼻梁贴合，然后按住鼻夹。将口罩下端向下拉至下颌处，使折叠边完全展开。
3. 整理口罩佩戴效果，使口罩能罩住使用者的鼻、口至下颌并保证口罩的密闭性。

【运输贮存】运输工具应清洁卫生、隔离火源。本产品应存放在干燥阴凉处，注意防水，避免阳光直射，严禁与有毒有害物质共同存放。本产品应贮存在阴凉干燥，清洁、避光、无腐蚀性气体、通风良好的室内。

【标签所用的图形符号说明】

STERILE	无菌
STERILEO	经环氧乙烷灭菌
②	不得二次使用
⊘	包装破损禁止使用

【生产批号】

【生产日期】

【失效日期】

其他内容详见说明书。

中华人民共和国医疗器械注册证

注册证编号：鲁械注准 20192140064

注册人名称	山东朱氏药业集团有限公司
注册人住所	单县开发区樊楼路南
生产地址	山东单县经济技术开发区
代理人名称	（“进口医疗器械适用”）
代理人住所	（“进口医疗器械适用”）
产品名称	一次性使用医用外科口罩
型号、规格	17.5cm×9.5cm
结构及组成	由表层、中间层、底层、口罩带、鼻夹组成。表层材料为卫生级聚丙烯仿粘布、中间层材料为聚丙烯喷丝法制成的高效过滤熔喷布、底层材料为卫生级聚丙烯仿粘布、口罩带为涤纶线和少量氨纶线针织而成，鼻夹为可弯折可定型的聚丙烯制成。
适用范围	供临床医务人员在有创操作过程中佩带，覆盖住使用者的口、鼻及下颌，为防止病原体微生物、体液、颗粒物等的直接透过提供物理屏障。
附件	注册产品技术要求：鲁械注准 20192140064
其他内容	
备注	原《医疗器械分类目录》产品分类编码：II类：6864 医用卫生材料及敷料

审批部门：山东省食品药品监督管理局　　批准日期：2019 年 03 月 19 日

有效期至：2024 年 03 月 18 日

イーノビ enovata® 意诺唯

99% ウィルス飛沫カット 抗菌率 光触媒技術採用 Certified by Eurovats

PHOTOCATALYTIC **FACE MASK**

(PHOTOCATALYST PATENTED TECHNOLOGY)

WE ARE AN AUTHORIZED AGENT FOR イーノビ enovata® 意诺唯

carestar.com.sg

COVID-19 ESSENTIALS

PHOTOCATALYTIC FACE MASK

Patented Technology

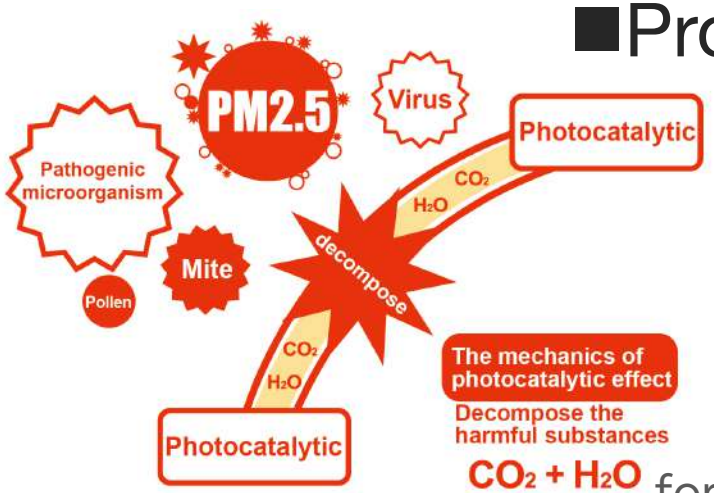
ENOVATA PHOTOCATALYTIC MASKS SERIES

for order enquiries contact: sales@carestar.com.sg

PATENTED TECHNOLOGY

PATENTED PHOTOCATALYTIC TECHNOLOGY

- Decomposing 99% of harmful substances
- Sterilization and Purification
- Anti-haze, Anti-allergy, Safe and Harmless
- Latest technology: photocatalyst response to visible light (555nm)
- Producing Oxygen Anions, Anti-ultraviolet



for order enquiries contact: sales@carestar.com.sg

Patented Technology

3D PHOTOCATALYTIC FACE MASK

PHOTOCATALYTIC 3D FACE MASK

99% ウイルス飛沫カット 抗菌率 光触媒 技術採用

Certified by Enovata®

3D MASK FOR CHILDREN

3D MASK FOR ADULTS

■ Photocatalytic 3D masks for children (medium size, 3 pieces)

■ Photocatalytic 3D masks for adutls (5 pieces)

for order enquiries contact: sales@carestar.com.sg

Patented Technology

PHOTOCATALYTIC ADULT FACE MASK

99% ウィルス飛沫カット 抗菌率 光触媒 技術採用

Certified by Enovata®

PHOTOCATALYTIC FACE MASK FOR ADULTS

■ Photocatalytic masks for adults (10 pieces) PINK

■ Photocatalytic masks for adults (10 pieces) WHITE

■ Photocatalytic masks for adults (10 pieces) BLUE

for order enquiries contact: sales@carestar.com.sg

Patented Technology

PHOTOCATALYTIC KIDS FACE MASK

PHOTOCATALYTIC FACE MASK FOR KIDS

■ Photocatalytic masks for kids (10 pieces) PINK

■ Photocatalytic masks for kids (10 pieces) BLUE

for order enquiries contact: sales@carestar.com.sg

CERTIFICATIONS

FDA APPROVED

for order enquiries contact: sales@carestar.com.sg

HIGH QUALITY & HIGHLY RECOMMENDED

COVID-19 **TEST KIT** sensing.self

(COLLOIDAL GOLD METHOD)

WE ARE AN AUTHORIZED AGENT FOR sensing.self

carestar.com.sg

COVID-19 ESSENTIALS

European CE certified

ICMR Certified

10 MINUTES

DETECTION TIME

>No lab visits, no doctors

>**Just one finger prick of blood**

Very Cost Effective Solution

for order enquiries contact: sales@carestar.com.sg

CARESTAR

Pre-screening

Concerned **Citizens**

Self-conducted
Pre-screen test

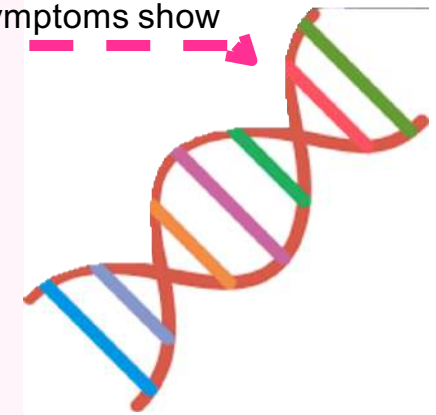
No symptoms, **no need to worry**

Negative

if symptoms show

Postive

Early Stage Detection



Lab test
conducted

Final Results
Positive or Negative

European CE certified

for order enquiries contact: sales@carestar.com.sg

CARESTAR

CARESTAR

for order enquiries contact: sales@carestar.com.sg

Detection Period

10 MINUTES

>**Easy operation** without requirement of any Doctor or Professional Nurse

>No special equipment storage and transportation conditions required

> Works with whole blood, serum, and plasma

>**Tests for 2 antibodies** IgM and IgG simultaneously

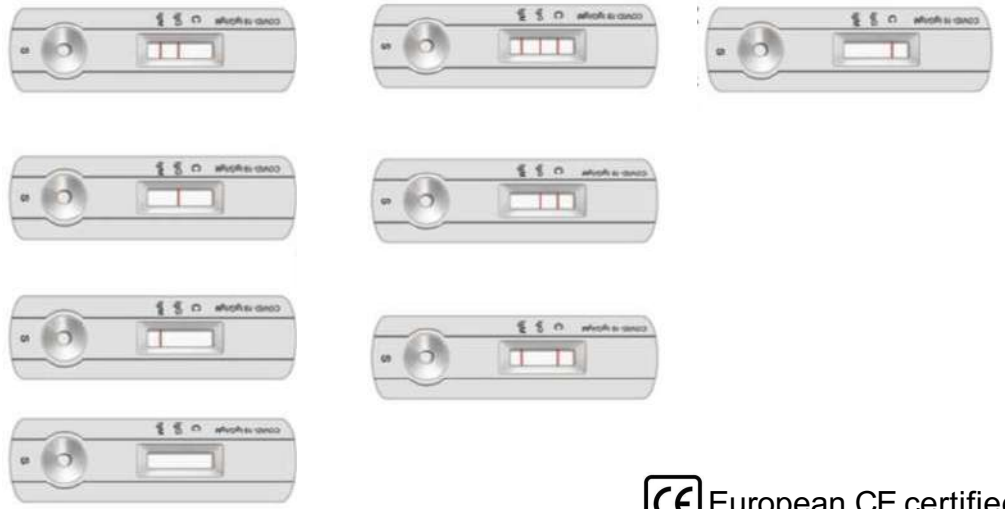
> **Instant Field screening**

Step.1
Drop of
whole blood

Step.2
Drops of
buffer

Step.3
Wait for result

INVALID	POSTIIVE	NEGATIVE



92%+ ACCURACY

CE European CE certified

Certification

- **Certified by accredited CE**
- FDA EUA Submitted - Under Review

European CE certified

ICMR Certified, National Institute Of Virology - India

for order enquiries contact: sales@carestar.com.sg

CARESTAR

CE & FDA CERTIFICATION

Verification of CE Registration

Certificate No.:C-WC-20200318-001

This is to certify that during the examination of the Technical Documentation provided by the manufacturer:

CONFIDENTIAL
Name disclosure upon order

On its product as follows:

Product Name: COVID-2019 ANTIGEN RAPID TEST KIT (Colloid Gold Immunochromatography)
COVID-19 IgG/IgM ANTIBODY RAPID TEST KIT (Colloidal Gold Immunochromatography)

Classification: Other IVD Product

No Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected, and the aforementioned device complies with Directive including all essential requirements.

The manufacturer has provided all the appropriate declaration according to the Directive 98/79/EC - article 10 requirements including the EC Declaration of Conformity confirming that this In vitro diagnostics medical device, as stipulated above, is fulfilling the applicable requirements of the Directive 98/79/EC.

The notification of aforementioned device has been completed by the European Representative in Germany. The German Competent Authority is notified of the manufacturer's in vitro medical devices and has allocated registration.

Issue Date: Mar. 18, 2020
Date of expiry: May 25, 2022

SIGNATURE

CE

ABMED SERVICE INC.
Room 608, No. 738 Shangcheng Rd., Pudong, 200120 Shanghai, China
E-mail: info@abmed.com.cn

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

SENSING SELF PTE LTD
160, Robinson Road, #20-03, Singapore Business Federation Ctr, 068914, SINGAPORE
has completed the FDA Establishment Registration (as manufacturer , foreign exporter) 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

Owner/Operator Number: 10061635
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

SUNGO Executive Director
Issued: Nov. 5 2019
Cert. No: 2005U8571618
Expiration Date: Dec. 31 2020
CERTIFIED

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CARESTAR

for order enquiries contact: sales@carestar.com.sg

Technical Review

2019-nCOV IVD Solution

	Fluorescence PCR	CLIA	Colloidal Gold Method (our method)
Detection substance	Nucleic acid	Antibody	Antibody
Type of sample	Nasopharyngeal swabs, sputum, alveolar lavage fluid	Serum/ Plasma	Serum/ Plasma/ Whole blood
Time to get result	2 hrs	20 mins	**Fastest 10 minutes**
Instrument needed or not	Yes	Yes, i 3000, i 1000	**Not needed**
Laboratory requirement	High	Relatively high	Average
Product Usage	Confirming diagnosis	Nucleic acid negative sample reviewing or high-volume sample detection	Nucleic acid negative sample reviewing or basic hospital sample testing

Colloidal Gold Method: The 2019-nCOV IgG/IgM Rapid Test Device using this Method is a rapid chromatographic immunoassay for the qualitative detection of IgG & IgM antibody of Coronavirus in human whole blood, serum, or plasma

Clinical Report Summary

2019-nCOV IgG/IgM Rapid Test Device

CARESTAR

for order enquiries contact: sales@carestar.com.sg

Comparative Test Report

SARS-CoV-2 IgM Ab Rapid Test Vs PCR

(Immunochromatographic)

1. Method

In this trial, 1300 clinical samples were selected. There were 300 positive samples and 1000 negative samples.

The SARS-CoV-2 IgM Ab rapid test and the SARS-CoV-2 PCR test were detected simultaneously, and the positive coincidence rate, negative coincidence rate, and total coincidence rate were calculated.

2. Result

（1）300 cases of positive samples confirmed by Nucleic Acid Test (RT-PCR): tested with SARS-CoV-2 IgM Ab rapid test, 246 cases were positive, 54 cases were negative.

（2）1000 cases of negative samples confirmed by Nucleic Acid Test (RT-PCR): tested with SARS-CoV-2 IgM Ab rapid test, 960 cases were negative, 40 cases were positive.

3. Analysis

（1） Results statistics table

SARS-CoV-2 IgM Ab Rapid Test	PCR Test		Total
	Positive	Negative	
Positive	246	40	286
Negative	54	960	1014
Total	300	1000	1300

（2） Analysis of coincidence rate of SARS-CoV-2 IgM Ab rapid test and PCR test in serum samples

Positive coincidence rate=246/（246+54）x 100%=**82% (Sensitivity)**
Negative coincidence rate=960/（40+960）×100%=**96% (Selectivity)**
Total coincidence rate=（246+960）/（246+54+40+960）×100%=**92.8% (Accuracy)**

4. Conclusion

SARS-CoV-2 IgM Ab rapid test and PCR test positive coincidence rate **(Sensitivity)** of 82%, negative coincidence rate **(Selectivity)** of 96%, total coincidence rate **(Accuracy)** of 92.8%.

Clinical Report Summary

2019-nCOV IgG/IgM Rapid Test Device

CARESTAR

for order enquiries contact: sales@carestar.com.sg

Comparative Test Report

SARS-CoV-2 IgG Ab Rapid Test
(Immunochromatographic)

1. Method

In this trial, 1300 clinical samples were selected. There were 300 positive samples and 1000negative samples.

The SARS-CoV-2 IgG Ab rapid test and the SARS-CoV-2 PCR were detected simultaneously, and the positive coincidence rate, negative coincidence rate, and total coincidence rate were calculated.

2. Result

（1）300 cases of positive samples confirmed by PCR Test: tested with SARS-CoV-2 IgG Ab rapid test, 279 cases were positive, 21 cases were negative.

（2）1000 cases of negative samples confirmed by PCR Test: tested with SARS-CoV-2 IgG Ab rapid test, 975 cases were negative, 25 cases were positive.

3. Analysis

（1） Results statistics table

SARS-CoV-2 IgG Ab Rapid Test	PCR Test		Total
	Positive	Negative	
Positive	279	25	304
Negative	21	975	996
Total	300	1000	1300

（2） Analysis of coincidence rate of SARS-CoV-2 IgG Ab rapid test and PCR test in serum samples

Positive coincidence rate=279/（279+21）×100%=**93% (Sensitivity)**
Negative coincidence rate=975/（25+975）×100%=**97.5% (Specificity)**
Total coincidence rate=（279+975）/（279+21+25+975）×100%=**96.5% (Accuracy)**

4. Conclusion

SARS-CoV-2 IgG Ab rapid test and PCR test positive coincidence rate **(Sensitivity)** of 93%, negative coincidence rate **(Specificity)** of 97.5%, total coincidence rate of 96.5% **(Accuracy).**

Clinical Report Summary

2019-nCOV IgG/IgM Rapid Test Device

CARESTAR

for order enquiries contact: sales@carestar.com.sg

5. Cross Reactivity Study:

Specimens which tested positive with following various agents from patients were investigated with SARS-CoV-2 IgM Ab Rapid Test (Lateral Flow Method). The results showed no cross reactivity.

Parainfluenza virus antibody
Influenza A antibody
Influenza B antibody
Chlamydia pneumonia antibody
Mycoplasma pneumoniae antibody
Adenovirus antibody
Respiratory syncytial virus antibody
Hepatitis B surface antibody
Hepatitis C virus antibody
Treponema pallidum antibody
HIV antibody
EB virus antibody
Measles virus antibody
Cytomegalovirus antibody
Enterovirus type 71 antibody
Mumps antibody
Varicella-zoster virus positive sample

6. Interferences Study:

The test result of SARS-CoV-2 IgM Ab Rapid Test (Lateral Flow Method) does not interfere with the substance at the following concentration:

Substance	Concentration
Bilirubin	250 umol/L
Hemoglobin	9 g/L
Triglyceride	15 mmol/L
Rheumatoid factors	80 IU/mL
Antinuclear antibody (ANA) titer	1:240
Anti-mitochondrial antibody (AMA)	80 U/mL
Mouse IgG	1000 ug/ml

COVID-19 **TEST KIT (V2)**

(COLLOIDAL GOLD METHOD)

carestar.com.sg

COVID-19 ESSENTIALS

COVID-19 TEST KIT

COLLOIDAL GOLD METHOD

nCoV Test Kit (Colloidal Gold Method)
Common name: Novel coronavirus antibody detection kit (colloidal gold method)

Intended Use

The kit is intended for the vitro qualitative determination of IgG and IgM antibodies of the novel coronavirus in human serum, plasma or blood.

Coronavirus (CoV) belongs to the Coronaviridae, and is divided into four genera: alpha, beta, gamma and delta.

Only the alpha and beta genera are pathogenic to mammals. The gamma genus mainly causes avian infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route.

So far, there are 7 human coronaviruses (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and now this new coronaviruse (2019) is an important pathogen of human respiratory infections.

This new coronavirus (2019), now commonly called the "novel coronavirus" or CoVID-19 was discovered due to the Wuhan viral pneumonia cases in 2019. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough and dyspnea, etc., which can rapidly develop into severe pneumonia, with respiratory failure. A distress syndrome, with septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. is equally life-threatening.

Principle of the method

The kit uses immunochromatography and the test card is contained.

1) Colloidal gold-labeled recombinant novel coronavirus antigen and quality control antibody gold markers;
2) A nitrocellulose membrane fixed with two detection lines (G and M lines) and one quality control line (C line). The M line is immobilized with a monoclonal anti-human IgM antibody for detecting a new coronavirus IgM antibody; the G line is immobilized with a monoclonal anti-human IgG antibody for a novel coronavirus IgG antibody; the C line is immobilized with a quality control antibody.

When an appropriate amount of the test sample is added to the sample hole of the test card, the sample will move forward along the test card under capillary action. If the sample contains an IgM antibody, the antibody will bind to the colloidal gold-labeled novel coronavirus antigen, and the immune complex will be captured by the anti-human IgM antibody immobilized on the membrane to form a purple-red M line, showing that the new coronavirus IgM antibody is positive.

If the sample contains an IgG antibody, the antibody will bind to the colloidal gold-labeled novel coronavirus antigen, and the immune complex will be captured by the reagent immobilized on the membrane to form a purple red G line, indicating that the new coronavirus IgG antibody is positive. If the test lines G and M are not colored, a negative result is displayed. The test card also contains a quality control line C. The fuchsia quality control line C should appear regardless of whether a test line appears. The QC line is the color band of the QC antibody immune complex. If the quality control line C does not appear, the test result is invalid, and the sample needs to be tested again with another test card.

Main ingredient

1. One-time test card
2. Sample Diluent (1 bottle, 1 mL / bottle)
3. user's manual

Storage conditions and validity

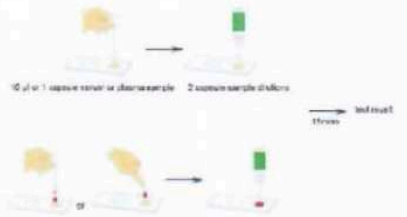
1. Store in a dry environment at 2-30 °C, protected from light.
2. After opening the inner package, the test card will become invalid due to moisture absorption if not used within 1 hour.
3. Valid for 18 months if stored correctly.

Sample collection, handling and storage

1. Suitable for human serum, plasma or whole blood samples, including plasma or whole blood samples prepared by commonly used anticoagulants (EDTA, heparin, sodium citrate).
2. The samples should be collected and tested immediately. If the test cannot done detected immediately, the serum and plasma samples to be tested can be stored at 2 ~ 8 °C for 5 days. For long-term storage, store at -20 °C. Avoid repeated freeze-thaw cycles. Anticoagulated whole blood samples should not be stored for more than 72 hours at room temperature; not more than 7 days at 2-8 °C.
3. Before testing, slowly return the refrigerated or frozen samples to room temperature and mix them carefully. When clearly visible particulate matter is present in the sample, it should be centrifuged to remove sediment before testing.
4. If the sample contains a large amount of lipid, hemolysis or turbidity, please do not use it, as this can affect the reading of the result.

Testing method

1. If the sample has been stored refrigerated or frozen, remove the test sample and the required reagents from the storage conditions and equilibrate to room temperature (15 ~ 30 °C). After thawing and equilibration, mix the samples thoroughly before testing.
2. When preparing to test, open the aluminum foil bag along the tear line. Remove the test card and lay it flat on a horizontal table.
3. Mark the sample number on the test card.
4. Use a sample gun or a dropper to draw 10 µl of the test sample (serum, plasma or whole blood sample) from the sample tube and immediately add 2 drops (about 70 ~ 100 µL) of sample into the sample well. Dilute the solution as shown below and ensure that no air bubbles are generated during the operation.
5. Set the time counter for interpretation of results in 15 minutes



Note: Do not read the results later than that initial 15 minutes. After

COVID-19 **TEST KIT**

POSITIVE RESULT IF
ANY PEMUTATION LINES APPEAR ON C/G/M

FOR BLOOD SAMPLE

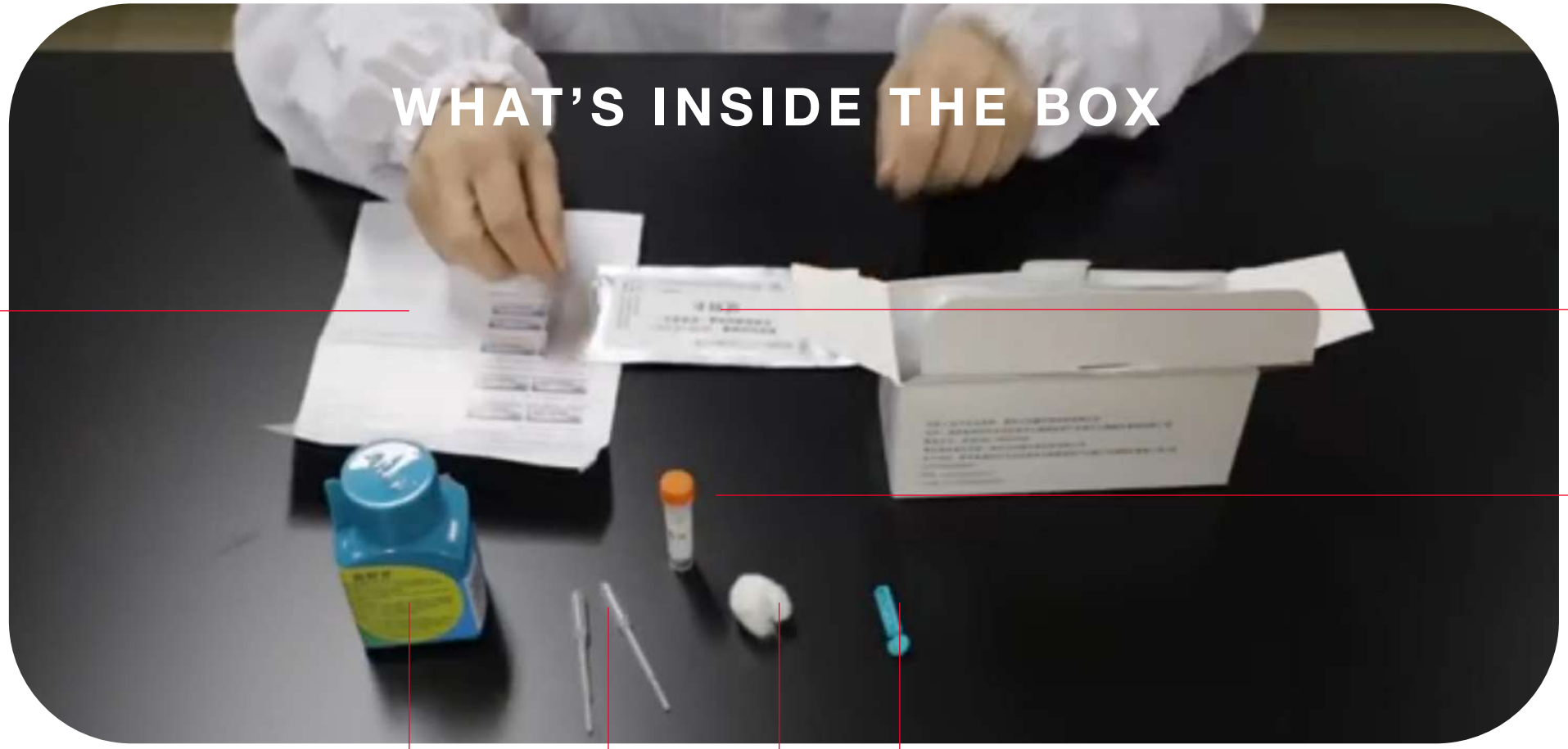
NEGATIVE RESULT IF:
ONLY LINE APPEAR ON C

15-MIN INSTANT RESULTS

COVID-19 ESSENTIALS

COVID-19 TEST KIT

15-MIN INSTANT RESULTS



INSTRUCTION MANUAL

TEST KIT

SAMPLE DILUENT

STERILIZING ALCOHOL WITH COTTON BALL

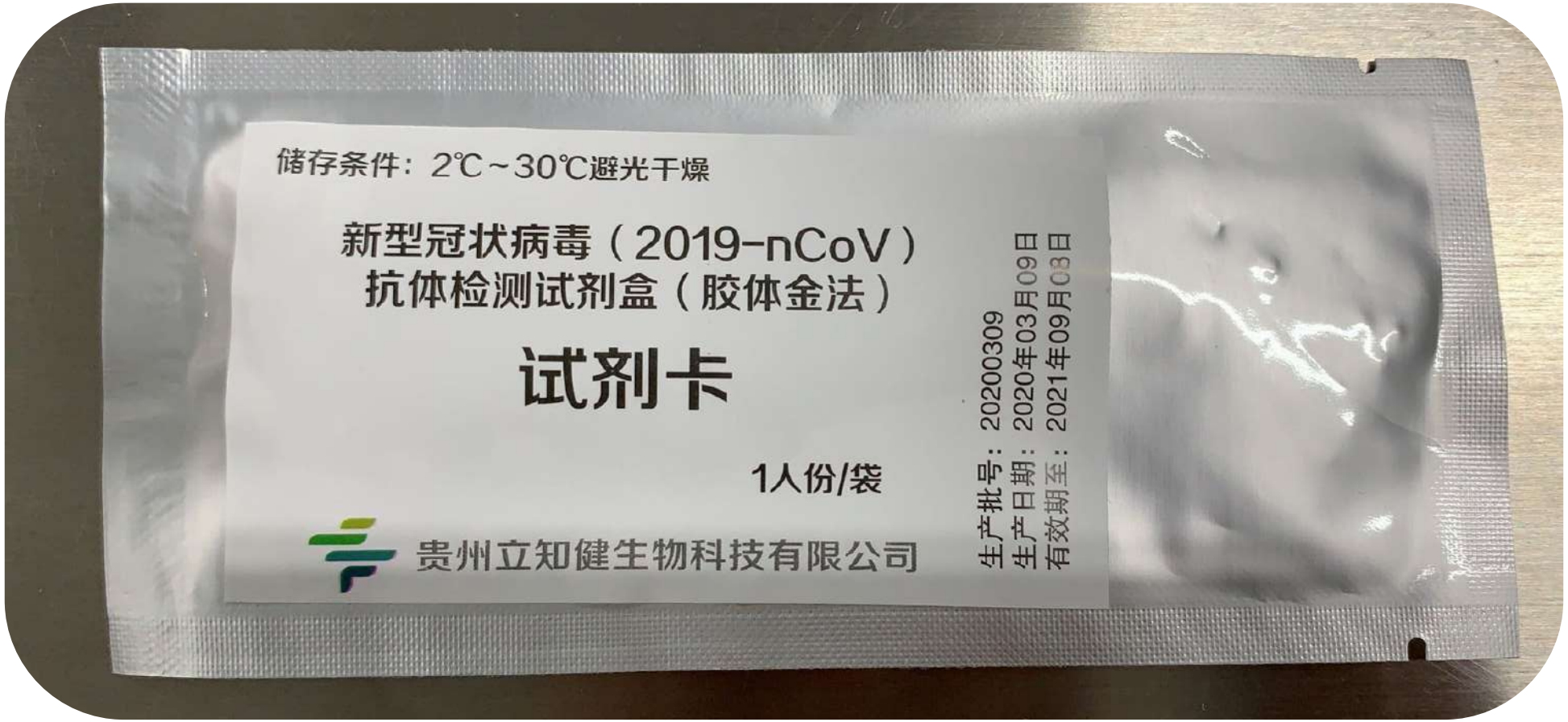
BLOOD SUCTION TUBE

COTTON BALL

MEDICAL GRADE NEEDLE

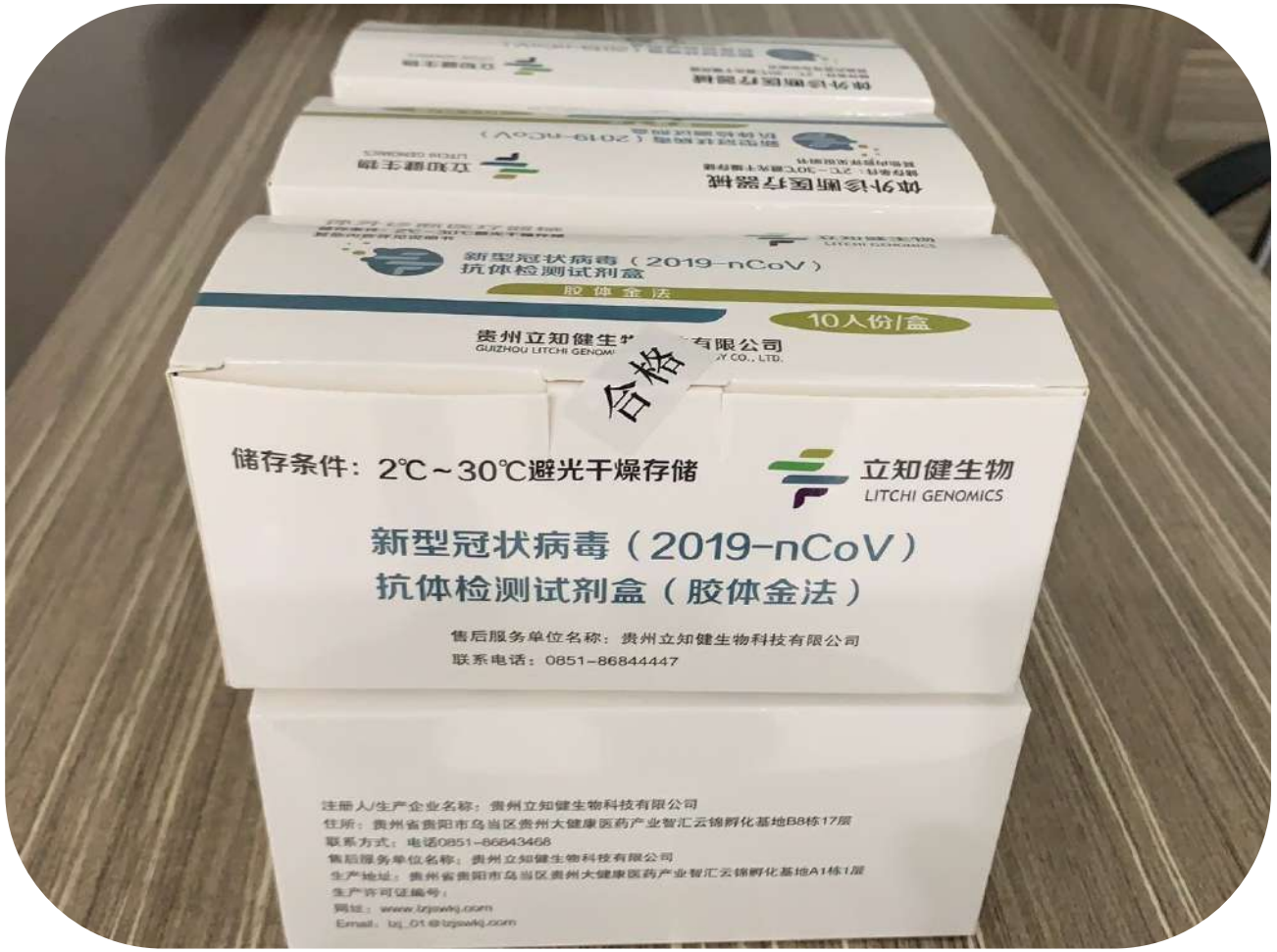
COVID-19 TEST KIT

SEALED PACKAGING



COVID-19 TEST KIT

OUTER BOX



COVID-19 TEST KIT

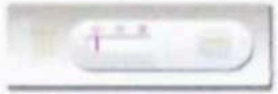
HOW TO USE COVID-19 TEST KIT VIDEO

COVID-19 **TEST KIT**

HOW TO READ TEST RESULT?

Interpretation of test results

1. Negative results: If only the quality control line C appears, and the detection lines G and M do not show color, it means that no novel coronavirus antibody is detected and the result is negative (see the figure below).



2. Positive results:

2.1 If both the quality control line C and the detection line M appear, it means that the novel coronavirus IgM antibody is detected, and the result is that the IgM antibody is positive (see the figure below).

2.2 If both the quality control line C and the detection line G appear, it indicates that the novel coronavirus IgG antibody is detected, and the result is positive for IgG antibody (see the figure below).

2.3 If both the quality control line C and the detection lines G and M appear, it indicates that the novel coronavirus IgG and IgM antibodies have been detected, and the results are positive for IgG and IgM antibodies (as shown below)

3. Invalid result: If the quality control line C is not observed, it will be invalid regardless of whether the detection line is displayed (see the figure below), and the test should be performed again.

COVID-19 ESSENTIALS

COVID-19 TEST KIT

CERTIFIED BY MEDICINE & HEALTH AUTHORITY

医疗器械生产许可证

许可证编号：黔食药监械生产许 20190004 号

企业名称：贵州立知健生物科技有限公司

生产地址：贵州省贵阳市乌当区贵州大健康医药产业智汇云锦孵化基地 A1 栋 1 层

法定代表人：张远波

生产范围：II 类：22-04-免疫分析设备，6840-体外诊断试剂

企业负责人：张远波

住　　所：贵州省贵阳市乌当区贵州大健康医药产业智汇云锦孵化基地 B8 栋 17 层

发证部门：贵州省药品监督管理局

有效期限：至　2024 年 09 月 28 日

发证日期：2019 年 09 月 29 日

COVID-19 **PCR KIT**

ProTect™

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COVID-19 ESSENTIALS

COVID-19 PCR KIT

WHY PCR KIT? (SUITABLE FOR HOSPITAL & LAB USE)

COVID-19 **PCR KIT**

MADE IN SINGAPORE

Intended Use

The ProTect™ Coronavirus Disease 2019 (COVID-19) RT-qPCR kit by JN Medsys provides all necessary reagents for the *in vitro* qualitative detection of the SARS-CoV-2 virus from upper respiratory nasopharyngeal specimens. The test is compatible with the US CDC protocol, targeting the SARS-CoV-2 N1, N2 and N3 genes and the human RNase P control gene.

This assay has received Provisional Authorisation from the Health Sciences Authority in Singapore

IVD

Product Information

Test Principle	One-step RT-qPCR (TaqMan®-based detection)
Targets	N1, N2, N3 (SARS-CoV-2 virus) and RNase P (Human)
Number of Tests	50/ kit (Cat No. 10024) or 100/kit (Cat. No. 10027)
Compatible Specimen Type	Upper respiratory nasopharyngeal specimens (i.e. nasopharyngeal swabs)
Limit of Detection^	10 copies RNA per reaction (N1, N2, N3)
Precision^	<2%
Specificity	Detects only SARS-CoV-2 based on *in silico* sequence validation

^Validated on QuantStudio™ 3 Real-Time PCR System (Applied Biosystem)

Reagents Supplied

Each kit provides reagents sufficient for performing 50 tests and consists of the following:

1. ProTect™ one-step RT-qPCR reagent
2. Ready-to-use primer and probe mixes for N1, N2, N3 and RNase P
3. Nuclease-free water
4. Positive Controls

Ordering Information

Product Name	Description	Catalogue Number
ProTect™ COVID-19 RT-qPCR Kit	50 Tests	10024
ProTect™ COVID-19 RT-qPCR Kit	100 Tests	10027

COVID-19 PCR KIT

INTENDED USE

The ProTect™ Coronavirus Disease 2019 (COVID-19) RT-qPCR kit by JN Medsys provides all necessary reagents for the *in vitro* qualitative detection of SARS-CoV-2 from upper respiratory nasopharyngeal specimens. The test is compatible with the US CDC protocol, targeting SARS-CoV-2 N1, N2 and N3 genes and the human RNase P control gene.

This assay has received Provisional Authorisation from the Health Sciences Authority in Singapore IVD

KIT FEATURES

Test Principle	One-step RT-qPCR (TaqMan®-based detection)
Targets	N1, N2, N3 (SARS-CoV-2) and RNase P (Human)
Number of Tests	50/kit (Cat. No. 10024) or 100/kit (Cat. No. 10027)
Compatible Specimen Type	Upper respiratory nasopharyngeal specimens (i.e. nasopharyngeal swabs)
Limit of Detection^	10 copies RNA per reaction (for N1, N2, N3)
Precision^	<2%
Specificity	Detects only SARS-CoV-2 based on *in silico* sequence validation

^Validated on QuantStudio™ 3 Real-Time PCR System (Applied Biosystems)

Limit of Detection (LoD)

LoD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all replicates test positive. The LoD was determined to be 10 copies/reaction based on limiting dilution studies. The results are summarised as follow:

Target	Concentration	Number of replicates tested positive	Mean Ct	Standard Deviation	Relative Uncertainty (%)*
N1	10 copies/reaction	20/20	34.27	0.36	1.06
N2	10 copies/reaction	20/20	33.16	0.54	1.64
N3	10 copies/reaction	20/20	34.35	0.30	0.89

** Relative uncertainty = Standard deviation/Mean*

Precision

Precision studies determine the reproducibility and robustness of the test. Three independent tests were conducted for N1, N2 and N3 assays in 10 replicates for each test. The results demonstrate that these assays achieved a relative uncertainty of <2%.

Test	N1			N2			N3		
	Mean Ct	Standard Deviation	Relative Uncertainty (%)	Mean Ct	Standard Deviation	Relative Uncertainty (%)	Mean Ct	Standard Deviation	Relative Uncertainty (%)
1	25.47	0.41	1.64%	26.52	0.47	1.79%	25.71	0.07	0.25%
2	24.76			25.96			25.77		
3	25.49			26.90			25.84		

** Relative uncertainty = Standard deviation/Mean*

PCR KIT SPECIFICATION

KIT CONTENTS

Each kit includes reagents sufficient to perform 50 tests (Cat No. 10024) or 100 tests (Cat No. 10027). Each test includes 4 separate RT-qPCR assays, which target the N1, N2, N3 and RNase P genes, respectively.

Reagents Supplied	50 Tests (10024) Volume (µL)	100 Tests (10027) Volume (µL)
Box 1 (Mastermix)		
ProTect™ Probe qPCR Mastermix (2X)	2000	4000
ProTect™ RT Mix (50X)	200	200
Nuclease Free Water	1000	2000
Box 2 (Primer/Probe Mix, Positive Controls)		
N1 Primer & Probe Mix (FAM)	85	170
N2 Primer & Probe Mix (FAM)	85	170
N3 Primer & Probe Mix (FAM)	85	170
RNase P Primer & Probe Mix (FAM)	85	170
COVID-19 Positive Control^*	35	70
RNase P Positive Control^	15	30

^Sufficient for 10 tests (10024) and 20 tests (10027), dilute 5X using TE Buffer (pH8) prior to use
** The COVID-19 Positive Control is a plasmid consisting of N1, N2 and N3 target sequences and serves as a control for the N1, N2 and N3 tests.*
+ The RNase P Positive Control is a plasmid consisting of the RNase P target sequence and serves as a control for the RNase P test.

STORAGE AND STABILITY

The ProTect™ COVID-19 RT-qPCR kit should be stored at -20°C upon receipt. Avoid repeated freezing and thawing of kit contents. The kit is stable through the expiry date indicated on the kit label.

GENERAL CONSIDERATIONS

1. Laboratory personnel should be familiar with the protocol and instruments used, and are required to wear appropriate personal protective equipment (e.g. gowns, gloves, eye protection) when performing the tests
2. Use only aerosol-resistant pipette tips
3. Do not open tube strips or reaction plates after amplification is completed to minimize risks of contaminating subsequent reactions with the amplified product
4. Clean and decontaminate all work surfaces, pipettes, equipment prior to use using cleaning agents against RNase

EXPERIMENTAL SETUP

1. Thaw reagents at room temperature and maintain reagents on ice when thawed. Mix reagents gently and briefly centrifuge to collect contents at the bottom of the tubes.
2. Prepare each reaction mix as shown in the table below:

COVID-19 PCR KIT

PCR KIT SPECIFICATION

No.	Reagents	Volume (µL)
1	ProTect™ Probe qPCR Mastermix (2X)	10
2	ProTect™ RT Mix (50X)	0.4
3	Primer & Probe Mix for N1, N2, N3 or RNase P	1.5
4	Nuclease free water	3.1
5	RNA Sample/Positive control	5
	Total Vol	20

❗ Positive and no template controls should be run concurrently with all test samples
❗ Dilute Positive Controls 5X using TE Buffer (pH8) prior to use

3. Pipette 20 µL of the reaction mix into the required reaction tube strip or 96-well plate.
4. Centrifuge to collect contents at the bottom of the tube strip/plate.
5. Transfer tube strip/plate to qPCR instrument and perform one-step RT-qPCR according to the following protocol. Fluorescence data for FAM should be collected during the 55°C annealing & extension step.

Step	Cycle	Temperature	Time
Reverse Transcription	1	45°C	15 min
Reverse Transcriptase Inactivation & DNA Polymerase Activation	1	95°C	2 min
Denaturation	40	95°C	3 sec
Annealing & Extension		55°C	30 sec

DATA ANALYSIS AND INTERPRETATION

1. No Template Control - No fluorescence signal should be detected
2. Positive Control – Fluorescence signal should be detected with Ct value below 30
3. Results for the respective targets may be interpreted as follow:

N1	N2	N3	RNase P	Outcome
+	+	+	±	SARS-CoV-2 detected
Any two out of three targets positive			±	SARS-CoV-2 detected
-	-	-	+	SARS-CoV-2 not detected
If only one of these targets is positive			±	Inconclusive result. Repeat test
-	-	-	-	Invalid result. Repeat test

COVID-19 **PCR KIT**

APPROVED BY HEALTH & SCIENCE AUTHORITY OF SINGAPORE

Health Sciences Authority
11 Outram Road Singapore 169078
Tel: 65 6213 0838 Fax: 65 6213 0749
Website: www.hsa.gov.sg

HSA 600:36/01

25 March 2020

JN Medsys Pte Ltd
217 Henderson Road
#02-08
Singapore 159555

Dear Low Huiyu

RE: STATUS OF SUPPLY OF MEDICAL DEVICES IN SINGAPORE

This letter serves to confirm that the following medical device product(s) have been issued Provisional Authorisation for supply in Singapore and may be exported from Singapore.

No.	Device Proprietary Name	Intended Use
1	ProTect™ COVID-19 RT-qPCR Kit (10024) (10027)	The ProTect™ Coronavirus Disease 2019 (COVID-19) RT-qPCR kit by JN Medsys provides all necessary reagents for the in vitro qualitative detection of SARS-CoV-2 from upper respiratory nasopharyngeal specimens. The test is targeting SARS-CoV-2 N1, N2 and N3 genes and the human RNase P control gene.

Product Owner: JN Medsys Pte Ltd
217 Henderson Road
#02-08
Singapore 159555

Manufacturing Site: JN Medsys Pte Ltd
217 Henderson Road
#02-08
Singapore 159555

Page 1 of 2

Health Products Regulation Group • Blood Services Group • Applied Sciences Group

2. The medical device product(s) may be supplied to the healthcare institutions, private hospitals, medical clinics or clinical laboratories licensed under the PHMC Act (Cap. 248) for use on their patients.

3. The medical device product(s) may be exported out of Singapore subject to the duties and obligations as stipulated in the Health Products Act and the Health Products (Medical Devices) Regulation 2010.

4. The confirmation above is subject to the manufacturer's activities conforming to the ISO 13485 quality system.

Yours sincerely,

DR LAKSHMIDEVI BALAKRISHNAN
SENIOR REGULATORY SPECIALIST
For GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

Page 2 of 2

INFRARED **THERMOMETER**

carestar.com.sg

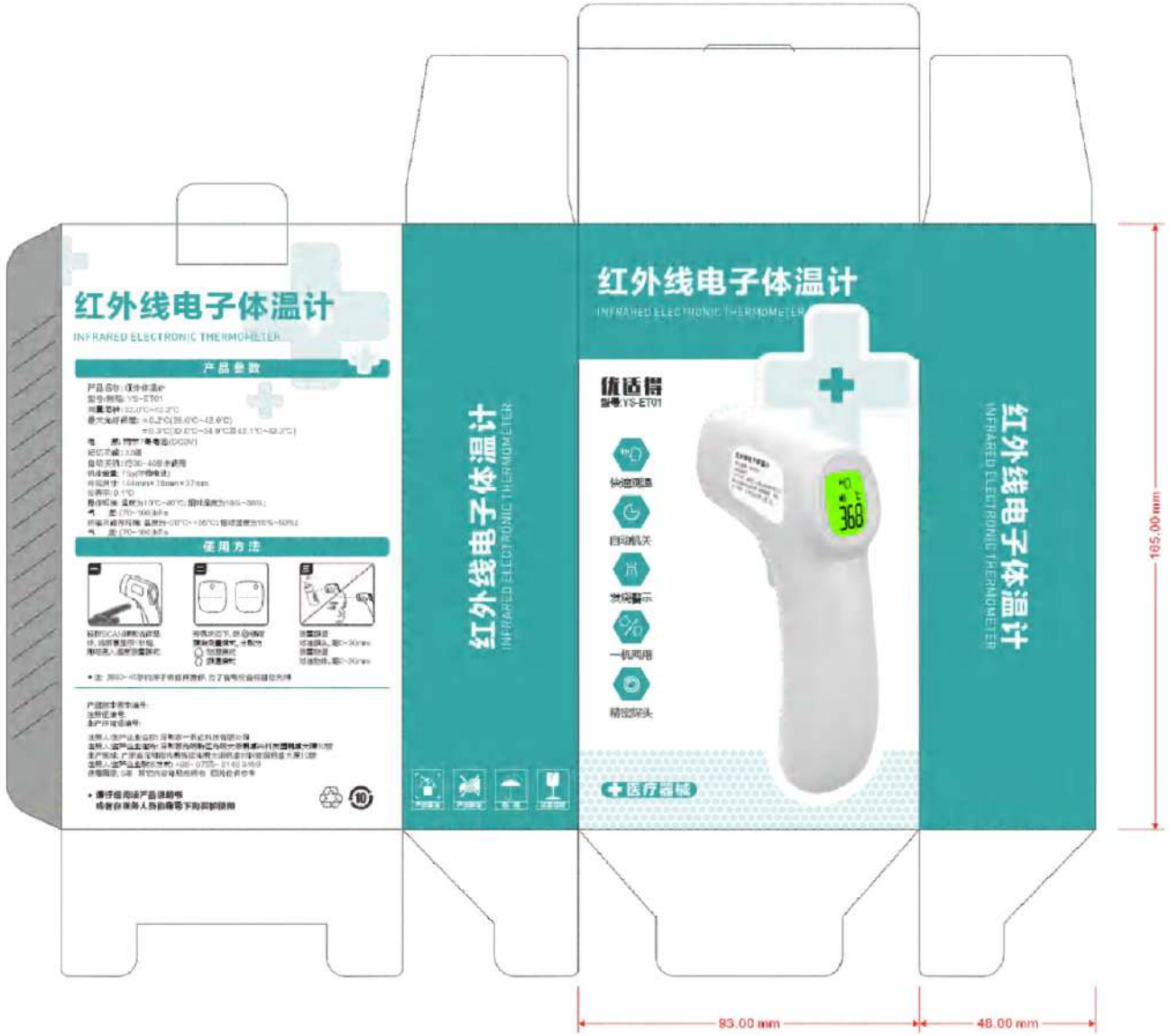
COVID-19 ESSENTIALS

INFRARED THERMOMETER

FOREHEAD SCANNING

INFRARED THERMOMETER

BOX DIMENSION



INFRARED THERMOMETER

CE CERTIFIED

Certificate of Conformity

Registration No.: A2003100-C01-R01

Applicant : Shenzhen Yostand Technology Co., Ltd.

Address : East Factory, 10th Floor, Mingzhuo Building, Mingzhuo Xingye Science and Technology Park, Gongming Street, Gongming Street, Guangming New District, Shenzhen, China

Product : Infrared Thermometer

Model No. : YS-ET03

Trademark : 优适得 yostand

The submitted products have been tested by us with the listed standards and found in compliance with the following European Directives:

The EMC Directive 2014/30/EU

EN 61000-6-3:2007 + A1:2011
EN 61000-6-1:2007

The tests were performed in normal operation mode, the test results apply only to the particular sample tested and to the specific tests carried out. This certificate applies specifically to the sample investigated in our test reference number only.

The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.

Other relevant Directives have to be observed.

CE

Certified by:

March 13, 2020

SHENZHEN ALPHA PRODUCT TESTING CO., LTD. ALPHA TESTING

Shenzhen Alpha Product Testing Co., Ltd.
Building i, No.2, Lixin Road, Fuyong Street, Bao'an District,
518103, Shenzhen City, Guangdong Province, P.R. China
Website:http://www.a-lab.cn Email:service@a-lab.cn

0010175

INFRARED THERMOMETER

CERTIFICATION FROM MEDICAL & HEALTH AUTHORITY

医疗器械生产许可证

许可证编号：粤食药监械生产许20010144号

企业名称：深圳市一讯达科技有限公司

生产地址：深圳市光明新区公明街道楼村社区第一工业区明卓兴业科技园明卓大厦十楼东厂房

法定代表人：姜红军

生产范围：Ⅱ类6826物理治疗及康复设备

企业负责人：姜红军

住　　所：深圳市光明新区公明街道楼村社区第一工业区明卓兴业科技园明卓大厦十楼东厂房

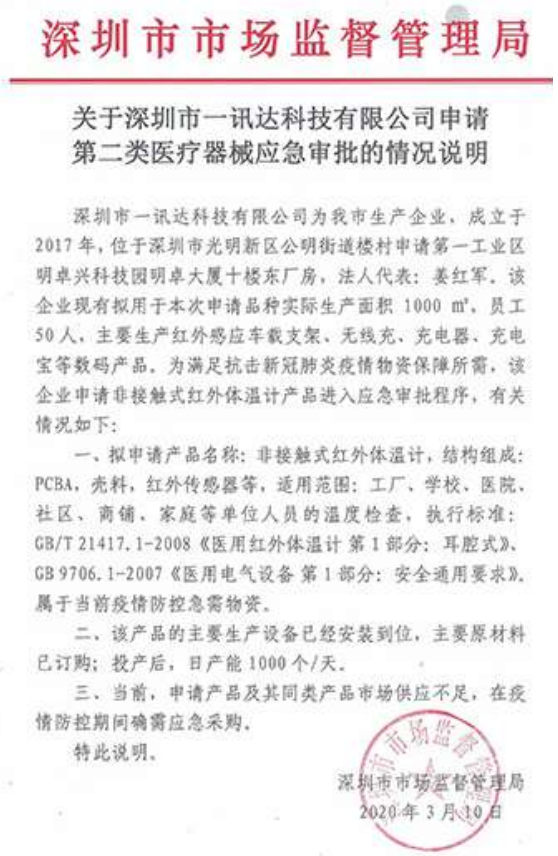
发证部门：广东省食品药品监督管理局

有效期限：至 2025 年 03 月 09 日

发证日期：2020 年 03 月 10 日

INFRARED THERMOMETER

APPROVAL FROM AUTHORITY ON MEDICAL GRADE PRODUCTS



深圳市市场监督管理局

关于深圳市一讯达科技有限公司申请第二类医疗器械应急审批的情况说明

深圳市一讯达科技有限公司为我市生产企业，成立于2017年，位于深圳市光明新区公明街道楼村申请第一工业区明卓兴科技园明卓大厦十楼东厂房，法人代表：姜红军。该企业现有拟用于本次申请品种实际生产面积1000㎡，员工50人，主要生产红外感应车载支架、无线充、充电器、充电宝等数码产品。为满足抗击新冠肺炎疫情物资保障所需，该企业申请非接触式红外体温计产品进入应急审批程序，有关情况如下：

一、拟申请产品名称：非接触式红外体温计，结构组成：PCBA，壳料，红外传感器等，适用范围：工厂、学校、医院、社区、商铺、家庭等单位人员的温度检查，执行标准：GB/T 21417.1-2008《医用红外体温计 第1部分：耳腔式》、GB 9706.1-2007《医用电气设备 第1部分：安全通用要求》。属于当前疫情防控急需物资。

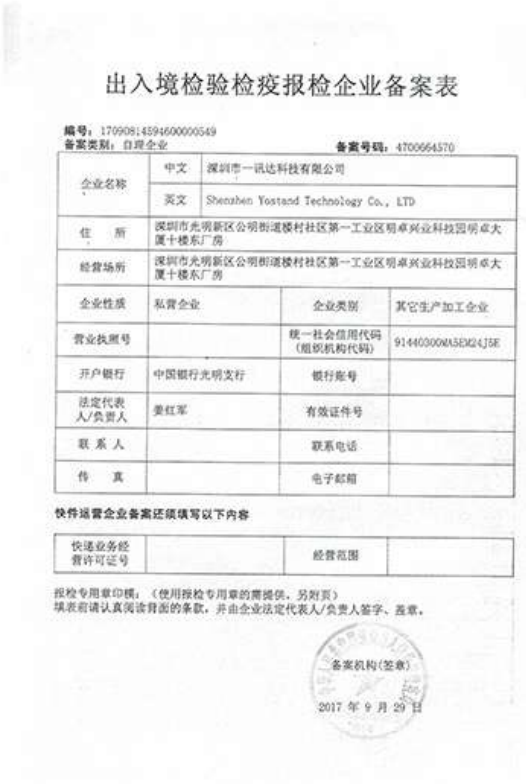
二、该产品的主要生产设备已经安装到位，主要原材料已订购；投产后，日产能1000个/天。

三、当前，申请产品及其同类产品市场供应不足，在疫情防控期间确需应急采购。

特此说明。

深圳市市场监督管理局

2020年3月10日



出入境检验检疫报检企业备案表

编号：170908145946000000549　　备案号码：4700664570

企业名称	中文	深圳市一讯达科技有限公司	
	英文	Shenzhen Yostand Technology Co., LTD	
住　所	深圳市光明新区公明街道楼村社区第一工业区明卓兴业科技园明卓大厦十楼东厂房		
经营场所	深圳市光明新区公明街道楼村社区第一工业区明卓兴业科技园明卓大厦十楼东厂房		
企业性质	私营企业	企业类别	其它生产加工企业
营业执照号		统一社会信用代码（组织机构代码）	91440300MA5EM24J5E
开户银行	中国银行光明支行	银行账号	
法定代表人/负责人	姜红军	有效证件号	
联 系 人		联系电话	
传　真		电子邮箱	

快件运营企业备案还须填写以下内容

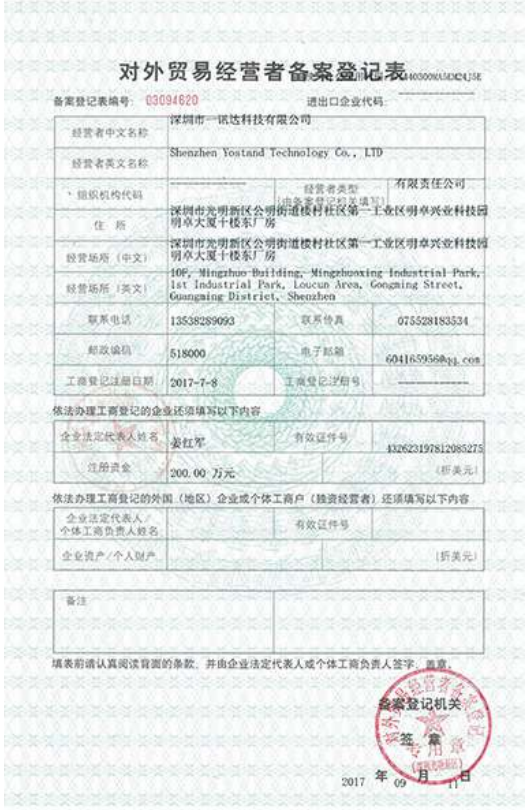
快递业务经营许可证号		经营范围	

报检专用章印模：（使用报检专用章的需提供，另附页）

填表前请认真阅读背面的条款，并由企业法定代表人/负责人签字、盖章。

备案机构（签章）

2017年9月29日



对外贸易经营者备案登记表

备案登记表编号：03094620　　进出口企业代码：

经营者中文名称	深圳市一讯达科技有限公司
经营者英文名称	Shenzhen Yostand Technology Co., LTD
组织机构代码	经营者类型：有限责任公司（备案登记机关填写）
住　所	深圳市光明新区公明街道楼村社区第一工业区明卓兴业科技园明卓大厦十楼东厂房
经营场所（中文）	深圳市光明新区公明街道楼村社区第一工业区明卓兴业科技园明卓大厦十楼东厂房
经营场所（英文）	10F, Mingzhuo Building, Minghuoxing Industrial Park, 1st Industrial Park, Loucun Area, Gongming Street, Guangming District, Shenzhen
联系电话	13538289093　　联系传真：075528183534
邮政编码	518000　　电子邮箱：6041659568@qq.com
工商登记注册日期	2017-7-8　　工商登记注册号：

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	姜红军	有效证件号	432623197812085275
注册资金	200.00 万元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

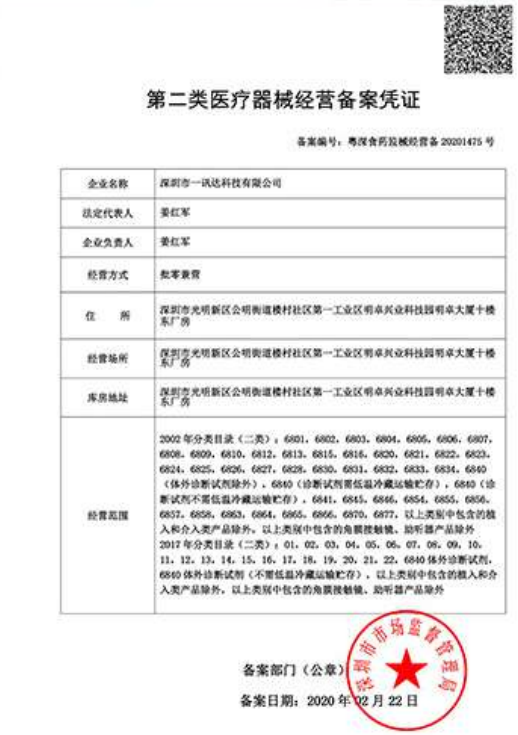
企业法定代表人/个体工商负责人姓名		有效证件号	
企业资产/个人财产			（折美元）

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关（签章）

2017年09月11日



第二类医疗器械经营备案凭证

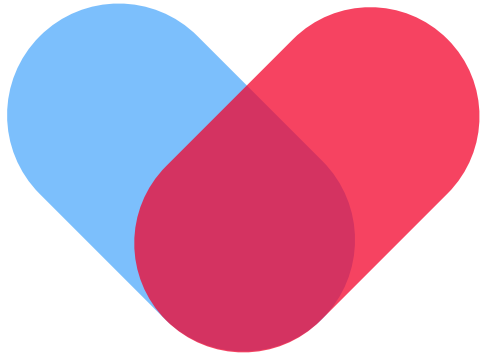
备案编号：粤深食药监械经营备20201475号

企业名称	深圳市一讯达科技有限公司
法定代表人	姜红军
企业负责人	姜红军
经营方式	批零兼营
住　所	深圳市光明新区公明街道楼村社区第一工业区明卓兴业科技园明卓大厦十楼东厂房
经营场所	深圳市光明新区公明街道楼村社区第一工业区明卓兴业科技园明卓大厦十楼东厂房
库房地址	深圳市光明新区公明街道楼村社区第一工业区明卓兴业科技园明卓大厦十楼东厂房
经营范围	2002年分类目录（二类）：6801，6802，6803，6804，6805，6806，6807，6808，6809，6810，6812，6813，6815，6816，6820，6821，6822，6823，6824，6825，6826，6827，6828，6830，6831，6832，6833，6834，6840（体外诊断试剂除外），6840（诊断试剂需低温冷藏运输贮存），6840（诊断试剂不需低温冷藏运输贮存），6841，6845，6846，6854，6855，6856，6857，6858，6863，6864，6865，6866，6870，6877。以上类别中包含的植入和介入类产品除外。以上类别中包含的角膜接触镜、助听器产品除外 2017年分类目录（二类）：01，02，03，04，05，06，07，08，09，10，11，12，13，14，15，16，17，18，19，20，21，22，6840体外诊断试剂，6840体外诊断试剂（不需低温冷藏运输贮存），以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外

备案部门（公章）

备案日期：2020年02月22日

COVID-19 ESSENTIALS



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COVID-19 ESSENTIALS