N95 NIOSH / **V4200**

N95 NIOSH / **V4200**

Product Number: SDL-WC001

Certified Standard:	NIOSH N95
Equivalent Rating:	N95+
Registrations:	NIOSH, CDC
Testing Lab:	NIOSH
Certification Report Issue Date:	20 July, 2006

National Institute for Occupational Safety and Health NIOSH®

CDC Centers for Disease Control and Prevention

IS 9473 CM/L-0007143057 / CE 0121 EN 149:2001+A1:2009 / NIOSH

NIOSH Approved N95 respirators
- Filters >95% non oil based particles

Superior microfibre media
- Provides protection against sub-micron particles, fine dusts, water/oil based liquid mist and biological agents e.g. TB, SARS and pandemic influenza

Anti Clogging (NR D)
- Having passed dolomite test, they resist clogging even in very high dust environments

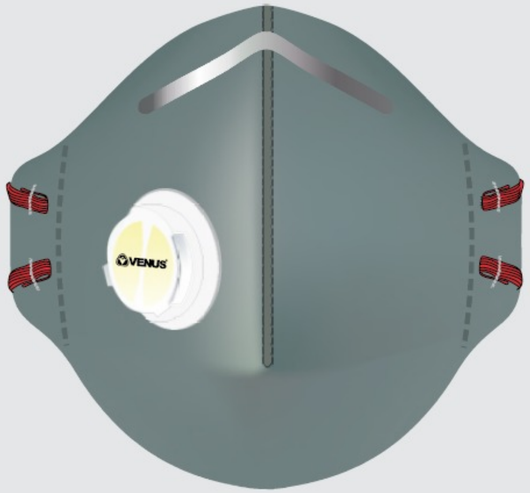
Color coded fittings
- Allows easy identification
- Denotes the level of protection

Flat Fold style
- Large pocket style design
- Easy and compact to store while not in use
- Enhanced protection & comfort

Embedded nose clip (V4200/V430)
- inside media

Choice of different colours
- To suit user conditions

Universal Fit
- Suits wide range of face contours



Stay cool butterfly vent valve
- Provides breathing comfort and promotes easy communication
- Effectively removes heat build-up

Activated carbon, (V414 & V425)
- For absorption of Nuisance level of obnoxious odour and vapour

Outer flame retardant layer (V425)
- Protects from welding sparks

Aluminum nose clip
- Leak-proof fit
- Disallows fogging of eyewear

Compatibility
- Compatible with Venus head protection and eye protection devices

Latex free textile elastic
- Long life
- Skin friendly
- Does not deform in high temperature

Elastic fitted outside filter media
- Leakproof
- Avoids puncture in filter area

Nose liner
- Prevents leakage
- Provides fit and comfort

Unique fit adjusters
- Provides optimum protection & comfort

Transparent Valve
- Transparent valve clearly demonstrates the performance of valve It also supports fit verification

KN95 / **FFP2**

Product Number: SDL-DZ001

Certified Standard:	GB 2626-2006 KN95 (Respiratory protective equipment -- non-powered air-purifying particle respirator) FFP2 EN 149-2001+A1:2009 EN 14683 TYPE II
Equivalent Rating:	N95 (United States NIOSH-42CFR84), FFP2 (EU EN 149-2001+A1:2009), P2 (AS/NZ 1716:2012)
Registrations:	CE, FDA
Testing Lab:	GTT www.gzgjjt.cn
Certification Report Issue Date:	25 Feb, 2020

Mask Construction:
- 4 layer
- Non-woven fabric
- Melt-blown fabric
- Adjustable nose molding strip
- Ultrasonically welded ear strap

Filter performance, which is the evaluation of the filter to measure the reduction in concentrations of specific aerosols in air that passes through the filter :
Test standard: BFE ≥ 95%. Actual test results BFE ≥ 99% (per test report)

PM2.5
Non-sterile
Disposable

KN95 / **FFP2**

Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

Cert. No.: 2020FDA02SPICACN083

This certifies that:

Establishment: DONGGUAN YISHION GROUP CO., LTD
Registered Address: No.3 Xinxia Road HuaiDe Industrial Zone, HuMen Town
DongGuan, Guangdong, 523900, CHINA
Registration Number: Not Yet Assigned

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration. such registration having been verified as currently effective on the date hereof by SPICA MEDTECH CORP:

Owner/Operator Number: 10064370 (Device Listing#: See annex)
U.S. Agent for FDA: SPICA MEDTECH CORP
Communications: 2255 EMRSON ST Denver,CO,80205,USA
Phone: 720 6176666 Ext .Email: spica_us@yahoo.com

SPICA MEDTECH CORP 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. SPICA MEDTECH CORP 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.. 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.

SPICA MEDTECH CORP (in USA)
SHANGHAI SPICA MANAGEMENT CONSULTING CO.,LTD (in China)
SPICA MEDTECH CERTIFICATION COMPANY LIMITED (in UK)
spica_us@yahoo.com. www.spicagloble.com

Spica Consulting
Regulation Service

For and on behalf of
SPICA MEDTECH CORP
Silverdew Mee
Authorized Signature(s)

SPICA CHINA Add: No.216 Building,No.500 Zhubai Road, Shanghai 200120, P.R.China

Cert. No.: 2020FDA02SPICACN082

Establishment: DONGGUAN YISHION GROUP CO., LTD
Registered Address: No.3 Xinxia Road HuaiDe Industrial Zone, HuMen Town
DongGuan, Guangdong, 523900, CHINA
Registration Number: Not Yet Assigned

Listing No	Code	Device Name
D378919	LYU	Disposable Medical Mask
D378920	OEA	Disposable Isolation Gown

END OF THE ANNEX

SPICA CHINA Add: No.216 Building,No.500 Zhubai Road, Shanghai 200120, P.R.China

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

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

CE Documentation Review

No. 0B200323M.DYG0100

Holder:	Dongguan Yishion Group Co., Ltd. No. 3 Xinxia Road HuaiDe Industrial Zone, HuMen Town, DongGuan City, GuangDong, PRC
Review goal:	Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII
Product:	Medical Protective Mask (Not Sterile)
Model(s):	KN95 mask YS-02-1, KN95 mask YS-02-2 (BFE ≥ 95%)
Classification:	Class I (Not Sterile) (accordingly to the Manufacturer's declaration)
Review output:	This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 23 March 2020
Approver
ECM Service Director
Luca Bedonni

Expiry date 22 March 2025
Technical Expert
Amanda Davino

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

FDA / **CE**

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00119Q34695R1L/4400

We hereby certify that

Dongguan Yishion Group Co.,Ltd.

Unified Social Credit Code: 91441900797739864H

No.3, Xinxia Road, Huaide Communtiy, Humen Town, Dongguan City,Guangdong Province, China

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

GB/T 19001-2016 / ISO 9001:2015

The Quality Management System Applies in the following area:

Design and Production of Brand "Yishion"Casual Attires

Certified since: July 13, 2016 Valid from: June 24, 2019 Valid until: July 12, 2022

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.
Please access www.cqc.com.cn for checking validity of the certificate.
This certificate and its relevant information can query in the website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

IAF CNAS 中国认可 国际互认 管理体系 MANAGEMENT SYSTEM CNAS C001-M Signed by: Lu Mei Partner of IQNet CHINA QUALITY CERTIFICATION CENTRE

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China
http://www.cqc.com.cn

A 0022779 2018年版

International Certification Registrar International Certification Registrar International Certification Registrar

Certificate

No. ICR Polska/P7700123 CE

Name and address of manufacturer:	DONGGUAN YISHION GROUP CO.,LTD. No.3 Xinxia Road HuaiDe Industrial Zone,HuMen Town, DongGuan City, GuangDong,PRC
Product name:	KN95 Protective Mask
Product types:	YS-02-1,YS-02-2
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 UAC Quality Technology Service（UK）Ltd

No. of test reports:	TCF-UAC-20200322103PPE
Certificate issue date:	25.03.2020
Expiration date:	24.03.2025

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

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

ICR REGISTERED FIRM

Director: Rafał Kalinowski

Warsaw, 25. 03. 2020

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

Shenzhen Tian Hai Test Technology Co.,Ltd.

CE Certificate of Conformity

Certification number: TH20CC-295S Report number: TH20CR-295S

Shenzhen Tian Hai Test Technology Co.,Ltd. hereby declares that testing has been completed and reports have been generated for:

Applicant:	**DONGGUAN YISHION GROUP CO.,LTD.**
Address:	No.3 Xinxia Road, HuaiDe Industrial Zone, HuMen Town, DongGuan City, GuangDong, PRC
Manufacturer:	**DONGGUAN YISHION GROUP CO.,LTD.**
Address:	No.3 Xinxia Road, HuaiDe Industrial Zone, HuMen Town, DongGuan City, GuangDong, PRC
Product:	**Protective face Mask**
Trade mark:	YISHION
Model:	KN95,YS-02-1, YS-02-2

And, in accordance with the following applicable directives:

(EU)2016/425 Personal Protective Equipment(PPE)

This product has been assessed against the following applicable standards;

Standard: EN 149:2001+A1:2009

Therefore, Shenzhen Tian Hai Test Technology Co.,Ltd. hereby acknowledges that the applicant may issue a DECLARATION of CONFORMITY and apply the CE marking in accordance with European Union Rules.

Attestation by:

Thomas Wong

Date of Issued: March 23, 2020

4F,A3 BLDG,The Silicon Valley Power intelligent terminal industrial park,Guan lan street,Longhua district,Shenzhen
Tel:+86-755-86615100 Fax:+86-755-86615105 http://www.tianhaitest.com

CQC / COC

检验检测报告 （电子版）

防伪查询网址：www.gttc.net.cn
防伪码：LFKR-9826-34

No:200010718

委托单位	东莞市以纯集团有限公司 地址：东莞市虎门镇怀德工业区矮岗村新下路				
客户认定信息	KN95防护口罩 30个 生产单位：东莞市以纯集团有限公司 ----------				
检验性质	委托检测	样品受理/测试开始日期	2020-02-20	报告签发日期	2020-02-25
判定依据	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》				
综合检验结论	---				

检验检测结果

检验检测项目	判定依据	判定
NaCl颗粒物过滤效率	GB 2626-2006	符合
吸气阻力	GB 2626-2006	符合
呼气阻力	GB 2626-2006	符合
可燃性	GB 2626-2006	符合
头带	GB 2626-2006	符合

备注

客户要求按KN95判定
本报告中检验检测项目均在相应标准规定的环境条件下进行（有注明的除外）。
复印件、副本未重新加盖报告书确认章无效。
本报告检验检测地址为广州市番禺区珠江路1号。

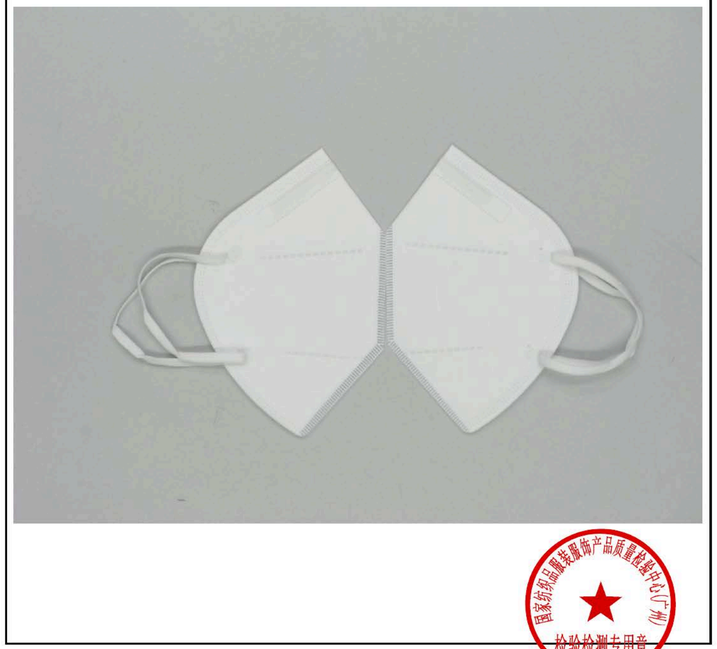
国家纺织品服装服饰产品质量检验中心（广州） 检验检测专用章

签发：马楠 工程师 马楠

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161

样品图片 （电子版）

No:200010718



国家纺织品服装服饰产品质量检验中心（广州） 检验检测专用章

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161

检验检测报告附页 （电子版）

No:200010718

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
●NaCl颗粒物过滤效率	GB 2626-2006 6.3 空气流量:85L/min 气溶胶颗粒:NaCl 气溶胶浓度:15mg/m^3 温度:23.0℃ 相对湿度:37.0%	过滤效率(%): ≥95.0 (KN95)	过滤效率(%): 未处理样品 1# 99.959 2# 99.953 3# 99.963 4# 99.951 5# 99.949 6# 99.946 7# 99.952 8# 99.959 9# 99.961 10# 99.958 温湿度预处理后样品 1# 99.891 2# 99.929 3# 99.768 4# 99.886 5# 99.915	符合	
●吸气阻力(Pa)	GB 2626-2006 6.5	≤350	未处理样品 1# 107.3 2# 123.5 温湿度预处理后样品 1# 98.1 2# 92.0	符合	
●呼气阻力(Pa)	GB 2626-2006 6.6	≤250	未处理样品 1# 111.0 2# 104.5 温湿度预处理后样品 1# 92.4 2# 91.0	符合	
●可燃性(s)	GB 2626-2006 6.15	续燃时间 ≤5	续燃时间 未处理样品 1# 0.0 2# 0.0 温湿度预处理后样品 3# 0.0 4# 0.0	符合	
●头带	GB 2626-2006 6.11	按标准5.9条要求	未处理样品 1# 符合要求 温湿度预处理后样品 1# 符合要求	符合	

备注 (本栏空白)

国家纺织品服装服饰产品质量检验中心（广州） 检验检测专用章

———本报告结束———

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161

GTT / TEST

Shenzhen Tian Hai Test Technology Co.,Ltd.

TEST REPORT

EN 149:2001+A1:2009

Respiratory protective devices-filtering half masks to protect against particles-requirements,testing,marking

For

DONGGUAN YISHION GROUP CO.,LTD.

No.3 Xinxia Road, HuaiDe Industrial Zone, HuMen Town, DongGuan City, GuangDong, PRC

Model: KN95,YS-02-1, YS-02-2

March 23, 2020

This Report Concerns: ☒ Original Report	**Equipment Type:** Protective face Mask
Test Engineer:	Eric/
Report Number:	TH20CR-295S
Test Date:	March 18 - 23, 2020
Reviewed By:	Prince/
Approved By:	Prince/
Prepared By:	**Shenzhen Tian Hai Test Technology Co.,Ltd.** 4F, A3 BLDG, The Silicon Valley Power intelligent terminal industrial park, Guanlan street, Longhua district, Shenzhen Tel: +86-755-86615100 Fax:+86-755-86615105

Note: This test report is limited to the above client company and the product model only. It may not be duplicated without prior written consent of Shenzhen Tian Hai Test Technology Co.,Ltd.

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STHTT / TEST

TEST REPORT
EN 149:2001+A1:2009
respiratory protective devices-filtering half masks to protect against particles-requirements,testing,marking

Report		
Report reference No.	:	TH20CR-295S
Tested by (+signature)	:	Eric
Reviewed by (+signature)	:	Prince
Approved by (+signature)	:	Prince
Date of issue	:	March 23, 2020
Testing laboratory		
Name	:	**Shenzhen Tian Hai Test Technology Co.,Ltd.**
Address	:	4F, A3 BLDG, The Silicon Valley Power intelligent terminal industrial park, Guanlan street, Longhua district, Shenzhen.
Test location	:	Same as above
Client		
Name	:	**DONGGUAN YISHION GROUP CO.,LTD.**
Address	:	No.3 Xinxia Road, HuaiDe Industrial Zone, HuMen Town, DongGuan City, GuangDong, PRC
Test specification		
Standard	:	EN 149:2001+A1:2009
Non-standard test method	:	N/A
Test item		
Description	:	**Protective face Mask**
Model and or type reference	:	KN95,YS-02-1, YS-02-2
Trademark	:	YISHION
Manufacturer	:	**DONGGUAN YISHION GROUP CO.,LTD.**
Address	:	No.3 Xinxia Road, HuaiDe Industrial Zone, HuMen Town, DongGuan City, GuangDong, PRC
Note	:	--.

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Test case verdicts		
Test case does not apply to the test object	:	N/A (Not apply)
Test item does meet the requirement	:	P(Pass)
Test item does not meet the requirement	:	F(Fail)
General remarks:		

""See remark #)""refers to a remark appended to the report.
""See appended table)""refers to a table appended to the report.
Throughout this report a comma is used as the decimal separator.
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.

Attachement include:
Appendix for photo

Remarks:
Copy of the marking plate

Product: Protective face Mask
Model: YS-02-1 Classification: FFP2
CE
EN 149:2001+A1:2009
DONGGUAN YISHION GROUP CO.,LTD.
No.3 Xinxia Road, HuaiDe Industrial Zone, HuMen Town, DongGuan City, GuangDong, PRC

4F,A3 BLDG,The Silicon Valley Power intelligent terminal industrial park,Guan lan street,Longhua district,Shenzhen
Tel:+86-755-86615100 Fax:+86-755-86615105 http://www.tianhaitest.com

Clause	Requirement Test	Result	Verdict
4	**Description**		P
	A particle filtering half mask covers the nose and mouth and the chin		P
	These devices are designed to protect against both solid and liquid aerosols		P
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		P
	Particle filtering half mask EN149,year of publication, classification,option(where "D" is an option for a non re-useable particle filtering half mask and mandatory for re-useable particle filtering half mask		P
	Particle filtering half mask EN 149:2001+A1:2009 FFP1 NR D		N/A
7	**Requirements**		P
7.1	General		P
7.2	Nominal values and tolerances		P
	Except for temperature limits,values which are not stated as maxima or minima shall be subject to a tolerance of ± 5%.	All within ± 5%	P
	Unless other wise specified,the ambient temperature for testing shall be (6-32)°C,and the temperature limits shall be subject to an accuracy of±1°C	24.2°C	P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Complied	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.	Complied	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.	Complied	P
	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.		P
	Three particle filtering half masks shall be tested.	Complied	P
	When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.		P

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Clause	Requirement Test	Result	Verdict
	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.		P
	Testing shall be done in accordance with 8.2.		P
7.6	Cleaning and disinfecting		N/A
	If the particle filtering half mask is designed to be re-usable,the materials used shall with stand the cleaning and disinfecting agent sand procedures to be specified by the manufacturer	Not re-usable	N/A
	Testing shall be done in accordance with 8.4 and 8.5.		N/A
7.7	Practical performance		P
7.8	Finish of parts		P
	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs	No sharp edges or burrs	P
7.9	Leakage		P
7.9.1	Total in ward leakage		P
	The total in ward leakage consists of three components:face seal leakage,exhalation valve leakage and filter penetration		P
	For particle filtering half masks fitted in accordance with the manufacturer's information,at least 46 out of the 50 individual exercise results for total inward leakage shall be not greater than: 25% for FFP1,11% for FFP2,5% for FFP3.	8.9%	P
	and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22% for FFP1,8% for FFP2,2% for FFP3	6.1%	P
	Testing shall be done in accordance with 8.5.		P
7.9.2	Penetration of filter material		P
7.10	Compatibility with skin		P
	Materials shall not be known to be likely to cause irritation or any other adverse effect to health	Complied	P
	Testing shall be done in accordance with 8.4 and 8.5.		P
7.11	Flammability		P
	When test , the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame	Burn time:3.3s	P
7.12	Carbon dioxide content of the inhalation air		P
7.13	Head harness		P
7.14	Field of vision		P
7.15	Exhalation valve(s)		P
	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.		P
	Testing shall be done in accordance with 8.2 and 8.9.1.		P

4F,A3 BLDG,The Silicon Valley Power intelligent terminal industrial park,Guan lan street,Longhua district,Shenzhen
Tel:+86-755-86615100 Fax:+86-755-86615105 http://www.tianhaitest.com

Clause	Requirement Test	Result	Verdict
	If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	No exhalation valve	N/A
	Testing shall be done in accordance with 8.2.		N/A
	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		N/A
	Testing shall be done in accordance with 8.3.4.		N/A
	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.		N/A
	Testing shall be done in accordance with 8.6.		N/A
7.16	Breathing resistance		P
	Table 2 — Breathing resistance Classification / Maximum permitted resistance (mbar): inhalation (30 l/min, 95 l/min, 160 l/min); exhalation (160 l/min) FFP1: 0.6, 2.1, 3.0; 3.0 FFP2: 0.7, 2.4, 3.0; 3.0 FFP3: 1.0, 3.0, 3.0	Meet FFP2 requirements	P
	The breathing resistance shall meet the requirement s of table 2		
7.17	Clogging		P
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks		P
	After clogging the inhalation resistances shall not exceed--FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar	4.3mbar	P
	At 95l/min continuous flow		P
	The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.	1.6mbar	P
7.17.2.2	Valveless particle filtering half masks		N/A
	After clogging the inhalation resistances shall not exceed--FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar	3.0mbar	N/A
	At 95l/min continuous flow		N/A
7.17.3	Penetration of filter material		P
7.18	Demountable parts		P
8	**Testing**		P
9	**Marking**		P
9.1	Packaging		P
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied	P

4F,A3 BLDG,The Silicon Valley Power intelligent terminal industrial park,Guan lan street,Longhua district,Shenzhen
Tel:+86-755-86615100 Fax:+86-755-86615105 http://www.tianhaitest.com

Clause	Requirement Test	Result	Verdict
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.	DONGGUAN YISHION GROUP CO.,LTD.	P
9.1.2	Type-identifying marking.	KN95,YS-02-1, YS-02-2	P
9.1.3	Classification	FFP2	P
9.1.4	The number and year of publication of this European Standard.	EN 149:2001+A1:2009	P
9.1.5	At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.	2021/12	P
9.1.6	The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination; or by using the pictogram.		P
9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram		P
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".		N/A
	This letter shall follow the classification marking preceded by a single space.		P
9.2	Particle filtering half mask		P
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:		P
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.	DONGGUAN YISHION GROUP CO.,LTD.	P
9.2.2	Type-identifying marking.	KN95,YS-02-1, YS-02-2	P
9.2.3	The number and year of publication of this European Standard.	EN 149:2001+A1:2009	P
9.2.4	Classification	FFP2	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance.		N/A
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		P
10	**Information to be supplied by the manufacturer**		P
10.1	Information supplied by the manufacturer shall accompany every smallest commercial available package.		P
10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.		P
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on		P
	-- application/limitations;		P
	-- the meaning of any colour coding;		P
	-- checks prior to use;		P
	-- donning, fitting;		P

4F,A3 BLDG,The Silicon Valley Power intelligent terminal industrial park,Guan lan street,Longhua district,Shenzhen
Tel:+86-755-86615100 Fax:+86-755-86615105 http://www.tianhaitest.com

Clause	Requirement Test	Result	Verdict
	-- use;		P
	-- maintenance (e.g. cleaning, disinfecting), if applicable;		P
	-- storage;		P
	-- the meaning of any symbols/pictograms used of the equipment.		P
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Complied	P
10.5	Warning shall be given against problems likely to be encountered, for example:		P
	--fit of particle filtering half mask (check prior to use);		P
	--it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;		P
	--air quality (contaminants, oxygen deficiency);		P
	--use of equipment in explosive atmosphere.		P
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P
10.7	For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.		P

4F,A3 BLDG,The Silicon Valley Power intelligent terminal industrial park,Guan lan street,Longhua district,Shenzhen
Tel:+86-755-86615100 Fax:+86-755-86615105 http://www.tianhaitest.com

FACTORY/ **PRODUCTION**

KN95 **(GB 2626-2006)**

KN95 **(GB 2626-2006)**

Product Number: SDL-WH001

Certified Standard:	GB 2626-2006 KN95 (Respiratory protective equipment -- non-powered air-purifying particle respirator)
Equivalent Rating:	N95 (United States NIOSH-42CFR84), FFP2 (EU EN 149-2001+A1:2009), P2 (AS/NZ 1716:2012)
Registrations:	CE, FDA
Testing Lab:	FZTTJ - www.fzttj.com
Certification Report Issue Date:	13 March, 2020

Mask Construction:
- 4 layer
- Non-woven fabric
- Melt-blown fabric
- Adjustable nose molding strip
- Ultrasonically welded ear strap

Filter performance, which is the evaluation of the filter to measure the reduction in concentrations of specific aerosols in air that passes through the filter :
Test standard: BFE ≥ 95%. Actual test results BFE ≥ 98% (per test report)

PM2.5
Non-sterile
Disposable

The 3rd Party Certificate of
FDA Medical Device Registration

Note:

This file is Not being issued by FDA, We, SFT, as the 3rd party, produce it, intended to facilitate customer display & transmit information. All the following contents, FDA registered Facility/Owner/Operator&FDA listing Medical Device, are excerpted from database at www.fda.gov.

Establishment:

Chilong Industrial (JIAXING) Co. , Ltd.
No.258,xiuyuan road,shimen gaoyangji town,Jiaxing city,zhejiang province, China 314500
Registration Number / FEI Number*:
* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set
Status: **Active**
Date of Registration Status: **2020**

Owner/Operator

Chilong Industrial (JIAXING) Co. , Ltd.
No.258,xiuyuan road,shimen gaoyangji town,Jiaxing city,zhejiang province, China 314500
Owner/Operator Number: 10063026

Official Correspondent

Contact Name: ELISA ZHENG SALES MANAGER
No.258,xiuyuan road,shimen gaoyangji town,Jiaxing city,zhejiang province, China 314500
Tel: +86- 137-3819511-0 E-mail: ELISAZHENG1@163.COM

U.S. Agent

Contact Name: Grace Liu
Address: 839 FM 1489 Road, Brookshire, Texas 77423 U.S.A
Phone: (281) 600-8227 E-mail: grace.liu@ltlqa.com

Devices Listing Information

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
PROTECTION MASK	LYU	1	D37****	Manufacturer

⚠ Please careful protect your Listing Number.

Approved by: Reilly

Professional FDA Registration Services, by Shanghai Shifu Testing Service Co., Ltd.
More details on the website: http://www.sft-lab.com.
Need help? Contact us, SFT, at +86(021) 51300821&sales@sft-lab.com.cn
FDA CERTIFICATE NUM: SFT20MAR083C

Certificate – Сертификат – 證明書 – Certificat – □ □ □ – شهادة –

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

Certificate of Compliance

No. 0P200318T.CIJ0009
Technical Construction File no. TPMJ2003063578

Certificate's Holder: Chilong Industrial (JIAXING) Co., Ltd.
No.258, Xiuyuan Road, Shimen Gaoyangji Town, Jiaxing City, Zhejiang Province, China

Certification ECM Mark: Type Approved

Product: Protection Mask
Model(s): KN95 MASK- 001, KN95 MASK -002, 3PLY MASK-001, 3PLY MASK-002

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 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: 18 March 2020
Expiry date: 17 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

FDA / CE

180011112242 （2018）国认监认字（244）号

检 验 报 告

TEST REPORT

扫一扫关注我们　扫一扫查询真伪

报 告 编 号 REPORT NO. 国纺委字第 YJ202002670 号

产 品 名 称 NAME OF SAMPLE KN95 防护口罩

委 托 单 位 CUSTOMER 全隆实业(嘉兴)有限责任公司

检 验 类 别 TEST CATEGORY 委托检验

浙江省轻工业品质量检验研究院

（浙江省纺织测试研究院）

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心（浙江）

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心（浙江）

检验报告

国纺委字第 YJ202002670 号　　第 1 页 共 3 页

委托单位名称 Name of Customer	全隆实业(嘉兴)有限责任公司	地 址 Address	浙江省嘉兴市桐乡市石门镇羔羊集镇秀园路 258 号
生产单位 Manufacturer	---	地 址 Address	---
样品信息 Sample information	样品名称 Name of sample：KN95 防护口罩 样品特性 Characteristics：白色 商标 Trademark：--- 规格/号型 Specification/model：--- 等 级 Level：KN95 安全技术类别 Category of safety specification：--- 样品款号/货号 Art. No.：--- ----------		
以上为客供信息（Above-mentioned information by Customer-supplied）			
来样方式 The sent way of sample	快递	样品数量 Sample quantity	1 包
送检日期 Receiving Date of Sample	2020-03-12	检测类别 Test Category	委托检验
判定依据 RatingRequirements	GB 2626-2006		
检测结论/Test Summary： 实测结果详见附页。 （检验报告专用章/Test Seal） 批准日期/ Date of Approval：2020-03-13			
备 注 Remarks	样品未经预处理。		

签 发：Approved by

检验报告

国纺委字第 YJ202002670 号　　第 2 页 共 3 页

序号	检测项目		检测方法	单位	标准要求（KN95）	实测值	单项评价	结果备注
1	呼吸阻力	吸气阻力	GB 2626-2006 6.5 6.6	Pa	≤350	87.4	符合	---
		呼气阻力		Pa	≤250	66.6		
2	过滤效率		GB 2626-2006 6.3	%	≥95.0	98.0	符合	---

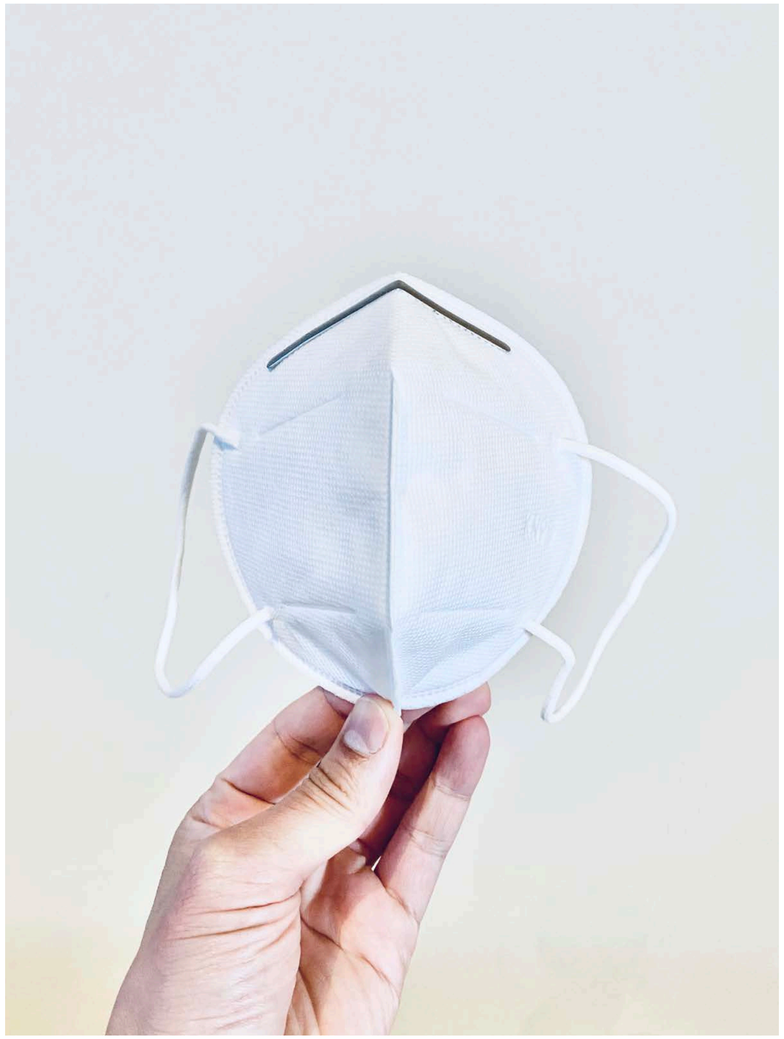
检验报告

国纺委字第 YJ202002670 号　　第 3 页 共 3 页

样品照片

—以下空白—

CNAS / TEST



KN95 **(GB 2626-2006)**

3-PLY **(GB 32610-2016)**

Product Number: SDL-WH002

Certified Standard:	GB 32610-2016
Equivalent Rating:	YY-0469-2011
Registrations:	CE, FDA
Testing Lab:	GTT - www.gttc.net.cn
Certification Report Issue Date:	25 March, 2020

Mask Construction:
- 3 layer
- Non-woven fabric
- Melt-blown fabric
- Adjustable nose molding strip

Filter performance, which is the evaluation of the filter to measure the reduction in concentrations of specific aerosols in air that passes through the filter :
Test standard: BFE ≥ 95%. Actual test results BFE ≥ 98% (per test report)

Non-sterile
Disposable

3-PLY **(GB 32610-2016)**

Fiscal Year 2020

FDA REGISTRATION CERTIFICATE

Certificate No.: JF-FDA-0325-0100

Certificate Holder:

V-JOY ENTERPRISE CO., LTD

1500 Lin Mei Street South, HuShi Town, XiuYu District

Putian, Fujian, 351146, CHINA

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

Registration Number: N

Owner/Operator Number: 10063458

Device Listing:

Device#	Product Codes	Device Name
D378739	LYU	ACCESSORY, SURGICAL APPAREL (Disposable Surgical Face Mask)

Registration Expiration Date: 2020-12-31

J&F TECHNOLOGY SERVICES LLC has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuit to the Code of Federal Regulation 21 CFR 207, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. J&F TECHNOLOGY SERVICES LLC assumes no liability to any person or entity in connection with the foregoing. J&F TECHNOLOGY SERVICES LLC is a private registration agent and is not affiliated with the US Food and Drug Administration.

J&F TECHNOLOGY SERVICES LLC.

2424 Morris Ave 818 Union

NEW JERSEY 07083

United States

FDA

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

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

CE Documentation Review

No. 4S200329B.VJE0066

Holder: V-Joy Enterprise Co.,Ltd
1500 Lin Mei Street South, HuShi Town, XiuYu District, Putian City, FuJian Province

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

Product: Disposable Surgical Face Mask (Not Sterile)

Model(s): KZ0110

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

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

Date of issue 29 March 2020
Approver
ECM Service Director
Luca Bedonni

Expiry date 28March 2025

Technical Expert
Amanda Rayne

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

FDA / CE

Inspection & Testing Report （电子版）

防伪查询网址：www.gttc.net.cn
防伪码：AOXD-6014-04

No:200046865 Total 3 pages Page1

Client	Company Name: 乐澄（中国）生活用品有限公司 Address：福建省莆田市秀屿区笏石镇岭美南街1500号				
Client Confirm Information	Face Mask 80pieces ----------				
Testing Nature	To Test	Sample received date	2020-03-20	Report Issue Date	2020-03-25
Report According to	T/CTCA 7-2019 《General Protective Mask》				
Final Test Outcome	---				

Test Results	Test Items	Test Methods	Results
	pH value	T/CTCA 7-2019	Pass
	Formaldehyde Content	T/CTCA 7-2019	Pass
	Bacteria Filtration Efficiency	T/CTCA 7-2019	Pass
	Breaking Strength between mask loop and mask body	T/CTCA 7-2019	Pass
	Particle Filtration Efficiency	T/CTCA 7-2019	Pass
	Resistance to ventilation	T/CTCA 7-2019	Pass

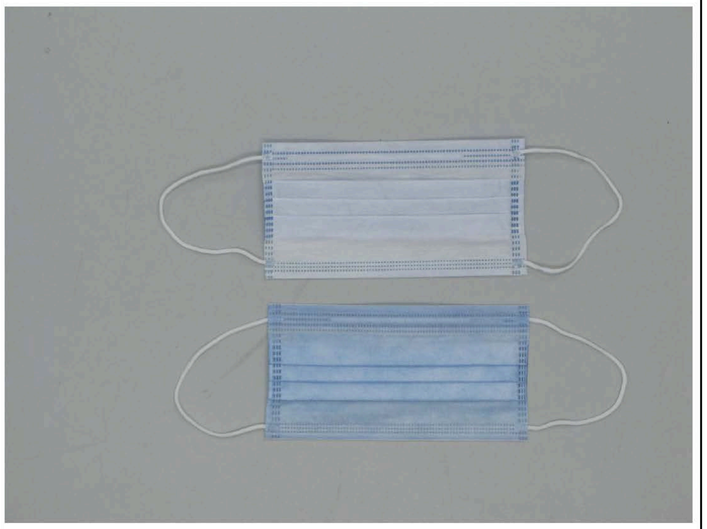
Remarks	The tests conducted in this report is done under specified conditions (unless otherwise stated) 。Copies and duplicates without official stamp are not valid.。 This report is done at 广州市番禺区珠江路1号。

Signed: 马楠 Engineer 马楠

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161

Picture of Sample （电子版）

No:200046865
Total 3 Pages Page2



总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161

Test Report Appendix （电子版）

No:200046865
Total 3 pages Page3

Test Items (Units of Measurement) [Sample recognition]	Test Methods	Standard Value & Tolerances	Test Results	Outcome	Remarks
●pH value	GB/T 7573-2009 0.1mol/L KClsolution	4.0～7.5	6.3	Pass	*
● Formaldehyde Content (mg/kg)	GB/T 2912.1-2009 Water extraction method Test method limit:20mg/kg	≤20	Not detected	Pass	*
●Bacteria Filtration Efficiency (%)	YY 0469-2011 Appendix B Test Strains: Staphyloccocus Aureus ATCC 6538 Test area: 40cm Air flow speed: 28.3L/min Average particle diameter: 3.0μm 阳 Property Control Value : 1.9×10 CFU Negative quality control value: ＜1CFU	≥95	BFE 98.8 BFE 98.6 BFE 98.6	Pass	*
● Breaking Strength between mask loop and mask body	YY 0469-2011 5.4	≥10N	Meeting specs	Pass	*
●Particle Filtration Efficiency (%)	YY 0469-2011 5.6.2 Air flow speed: 30L/min Aerosol particle: NaCl Aerosol concentration: 15mg/m Temperature: 23.1℃ Relative humidity: 36.0%	≥80	Minimum 84.2	Pass	*
●Resistance to ventilation (Pa)	YY 0469-2011 5.6.2 Air flow speed: 30L/min Aerosol particle: NaCl Aerosol concentration: 15mg/m Temperature: 23.1℃ Relative humidity: 36.0%	≤80	Maximum 16.7	Pass	*

Remarks	*：Testing criteria is provided by client standards (T/CTCA 7-2019) 。Our unit was awarded with CMA and CAL recognized and authorized with the testing capabilities meeting the testing items of T/CTCA 7-2019。

----------End of Report ----------

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161

GTT / TEST

检 测 报 告

W20003390

防伪码：NM131106574

客户提供信息	委托方	乐澄（中国）生活用品有限公司 / 福建省莆田市秀屿区笏石镇岭美南街1500号		
	样 品	一次性防护口罩	商标	品度
	货/款/样号	KZ0110		
	规格号型	---	安全类别/等级	--- / ---
	生产单位	乐澄（中国）生活用品有限公司		
样品描述		30个蓝色无纺布口罩，状态正常		
样品接收/试验日期		2020-03-10/2020-03-10 ～ 2020-03-12	检验类别	委托检验（送样）
检测项目及方法		（见检测报告续页）		
判定依据		GB/T 32610-2016 日常防护型口罩技术规范		
检验结论		（见检测报告续页） 报告签发日期：2020年3月12日		
备注		---		

说明：1、检测地点：福州市照屿路17号
2、报告无“检验检测专用章”无效，无编制和审批签名无效，报告涂改无效。
3、未经本中心批准不得部分复制报告，复制报告未重新加盖“检验检测专用章”无效。
4、客户提供信息由委托方提供并确认，本中心不对其真实性及完整性负责。
5、本报告检测结果仅适用于所接收样品。
6、对报告的异议请于收到报告之日起十五日内提出。

审批：贾颖 高级工程师　　编制：邱建伟

检 测 报 告 续 页

W20003390

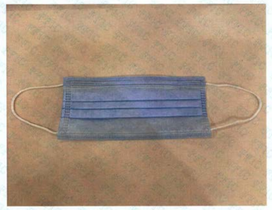
检测项目	测试方法	标准值及允差	检测结果	单项判定
耐干摩擦色牢度,级	GB/T 29865-2013	≥4	4-5	符合
可分解致癌芳香胺染料,mg/kg	GB/T 17592-2011	禁用	未检出（详见附表C）	符合
甲醛含量,mg/kg	GB/T 2912.1-2009（检出限20mg/kg）	≤20	未检出	符合
pH值	GB/T 7573-2009（萃取介质为氯化钾溶液）	4.0～8.5	6.6	符合

福 建 省 纤 维 检 验 中 心
Fujian Fiber Inspection Center
国家纺织服装产品质量监督检验中心(福建)
National Textile And Garment Quality Supervision Testing Center(Fujian)

检 测 报 告 附 件

W20003390

贴样/样品图片



报告正文结束

福州总部地址：福州市仓山区照屿路17号　电话：0591-83710801/87887663/87893952/83598339
晋江实验室地址：晋江市洪山路236号明丰大厦3楼　电话：0595-88123970/82682768

检 测 报 告 续 页

W20003390

附表C:可分解致癌芳香胺染料检测结果（气相色谱/质谱法）

序号	芳香胺名称	化学文摘编号	检测结果
1	4-氨基联苯	92-67-1	未检出
2	联苯胺	92-87-5	未检出
3	4-氯-邻甲苯胺	95-69-2	未检出
4	2-萘胺	91-59-8	未检出
5	邻氨基偶氮甲苯	97-56-3	未检出
6	5-硝基-邻甲苯胺	99-55-8	未检出
7	对氯苯胺	106-47-8	未检出
8	2,4-二氨基苯甲醚	615-05-4	未检出
9	4,4’-二氨基二苯甲烷	101-77-9	未检出
10	3,3’-二氯联苯胺	91-94-1	未检出
11	3,3’-二甲氧基联苯胺	119-90-4	未检出
12	3,3’-二甲基联苯胺	119-93-7	未检出
13	3,3’-二甲基-4,4’-二氨基二苯甲烷	838-88-0	未检出
14	2-甲氧基-5-甲基苯胺	120-71-8	未检出
15	4,4’-亚甲基-二-(2-氯苯胺)	101-14-4	未检出
16	4,4’-二氨基二苯醚	101-80-4	未检出
17	4,4’-二氨基二苯硫醚	139-65-1	未检出
18	邻甲苯胺	95-53-4	未检出
19	2,4-二氨基甲苯	95-80-7	未检出
20	2,4,5-三甲基苯胺	137-17-7	未检出
21	邻氨基苯甲醚	90-04-0	未检出
22	4-氨基偶氮苯	60-09-3	未检出
23	2,4-二甲基苯胺	95-68-1	未检出
24	2,6-二甲基苯胺	87-62-7	未检出

注：表中“未检出”表示检测结果低于测定低限，本方法的测定低限为5mg/kg。

福州总部地址：福州市仓山区照屿路17号　电话：0591-83710801/87887663/87893952/83598339
晋江实验室地址：晋江市洪山路236号明丰大厦3楼　电话：0595-88123970/82682768

FFIC / TEST

KN95 **(GB 2626-2006)**

3-PLY **(YY/T 0969-2013)**

Product Number: SDL-WH003

Certified Standard:	YY/T 0969-2013
Equivalent Rating:	YY Professional Standard - Pharmaceuticals
Registrations:	CE, FDA
Testing Lab:	HNMD - www.hnti.org.cn
Certification Report Issue Date:	25 Feb, 2020

Mask Construction:
- 3 layer
- Non-woven fabric
- Melt-blown fabric
- Adjustable nose molding strip

Filter performance, which is the evaluation of the filter to measure the reduction in concentrations of specific aerosols in air that passes through the filter :
Test standard: BFE ≥ 95%. Actual test results BFE ≥ 98% (per test report)

Non-sterile
Disposable

3-PLY **(YY/T 0969-2013)**

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

JIEBAO DAILY CHEMICAL (XIANGXI) CO., LTD

Floor 1, building a, Guangzhou Industrial Park Industrial Center, Xiangxi Economic Development Zone, Xiangxi, HUNAN, 416000, CHINA

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

HEALREG SERVICE INC

Owner/Operator Number: 10063397

Device Listing#: See annex

HEALREG 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. HEALREG 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. HEALREG 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, HEALREG SERVICE INC is not affiliated with the U.S. Food and Drug Administration.

FDA

Chief engineer
Issued: March 20, 2020
Expiration Date: December 31, 2020

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10063397

Listing No.	Code	Device Name	Proprietary Names	Activities
D376234	MSH	Respirator, surgical	Protective mask（Disposable mask） JBRH01	Manufacturer

END OF THE ANNEX

Chief engineer
Issued: March 20, 2020
Expiration Date: December 31, 2020

notice

CERTIFICATE

Certificate Number

AI-MDD-0011/03/2020

Manufacturer : Jiebao Daily Chemical (Xiangxi) Co., Ltd.

Address : 1 St Floor, Standard Workshop, Building A, Guangzhou Industrial Park Industrial Center, Xiangxi Economic Development Zone, Hunan Province

Product(s) : Disposable medical mask

Model(s) :

Standard sizes	Length (±5%)	Width (±5%)	Layers
17.5×9.5cm	17.5	9.5	3 layers

Product Classification : Class I

Related Directive : 93/42/EEC Medical Device Directive

Technical File Document Number : TCF-XXJB-001

First Issue Date and Place : 2020.03.24 & Istanbul

Revision Number and Date : 00 / --

Validity Date : 2024.05.26

This certificate has been issued according to the voluntary application of the manufacturer. NOTICE confirms that a technical file exists for the above mentioned product(s) and Declaration of Conformity prepared by the manufacturer is available. This certificate is valid only for the product(s) described in above mentioned tehcnical file. It is manufacturer's sole responsibility to fullfill all necessary conformity assessment activities according to 93/42/EEC Medical Devices Directive and related standards for the mentioned product(s) before placing them on the market. It is the manufacture's responsibility to compile a full Technical File according to Annex VII of 93/42/EEC in order to comply with the requirements of 93/42/EEC and to appoint a European Representative before placing the products on the European Market. Additionally, the manufacturer is responsible to take necessary actions, such as internal production controls to fullfill the essential requirements of the related Directive(s), before affixing CE mark on the product(s).

Özgür Vicdan
General Manager

NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.

Esentepe Mahallesi Milangaz Caddesi
No:75/A/92 Kartal / İstanbul / TÜRKİYE
www.notice.com.tr

AI-MDD-0011/03/2020

1 of 1

FDA / CE

CTE

Coffee-T Electronics Technology Co., Limited.

CE Declaration of Conformity

Declaration No.: CTE20BC-317N Report No.: CTE20BR-317N

Applicant	:	**Jiebao daily Chemical (Xiangxi) Co. , Ltd.** Floor 1, building a, Guangzhou Industrial Park Industrial Center, Xiangxi Economic Development Zone, Hunan
Manufacturer	:	**Jiebao daily Chemical (Xiangxi) Co. , Ltd.** Floor 1, building a, Guangzhou Industrial Park Industrial Center, Xiangxi Economic Development Zone, Hunan
Product	:	**Disposable protective mask**
Model	:	A（11.5cmx7cm），B（12.5cmx9cm），C（17cmx9.5cm），D（17.5cmx9.5cm），E（18cmx9cm），F（18cmx9.5cm），G（20cmx7cm）
Test Standards		**EN 149: 2001+A1:2009**
Classed	:	**FFP2**

The EUT described above has been tested by us with the listed standards and found in compliance with the council PPE Directive 89/686/EEC. It is possible to use CE marking to demonstrate the compliance with this PPE Directive.

The results in this report are applicable only to the equipment tested. This report shall not be re-produced except in full without the written approval of **Shenzhen Coffee-T Electronics Technology Co., LTD.**

Sunny Li

Date of Issued: March 7, 2020

4th Floor,Bldg A3,Digital Tech Park,7th GaoXin South Blvd,Tech Park,NanShan,ShenZhen,China

Tel:+86-755-86622903(50 Lines) Fax:+86-755-86622819

Http://www.szkht.com.cn

intertek

Total Quality. Assured.

认 证 证 书

兹证明，以下组织：

洁宝日化（湘西）有限责任公司

生产地址：中国湖南省湘西土家族苗族自治州吉首市湘西经济开发区广州工业园产业中心A栋标准厂房一楼、二楼

的质量管理体系，符合以下要求：

美国食品和药品管理局颁布的《化妆品良好操作规范指南》(2008)

认证范围：

生产一般液态单元，包括护肤水类

生产湿巾

首次年度评审 二次年度评审

初次审核及每次年度评审合格后，证书上会附有Intertek激光标志，以证明证书有效。

GMPC

Intertek

证书编号：
SZ1904A7

首次审核日期：
2019 年 3 月 4-6 日

发证日期：
2019 年 4 月 4 日

有效日期：
2022 年 4 月 3 日

Certification Administration Centre
Intertek Testing Services

Helen Xue
General Manager
Chemicals & Pharmaceuticals Division

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

营业执照

（副本）

副本编号：1 - 1

统一社会信用代码

91433100599403286E

名 称 洁宝日化（湘西）有限责任公司

类 型 有限责任公司(自然人投资或控股)

法定代表人 周学平

经营范围 无纺布、无纺布制品、洗涤用品、美容面膜、化妆品、逗巾日用品研发生产及销售，植物提取技术研发及生产销售，自营和代理各类商品及技术的进出口(但国家限定公司经营或禁止进出口的商品和技术除外)，房屋租赁服务，二类医疗器械、消毒产品生产及销售。(依法须经批准的项目，经相关部门批准后方可开展经营活动)

注册资本 伍仟壹佰伍拾万元整

成立日期 2012年07月03日

营业期限 2012年07月03日 至 2032年07月02日

住 所 湖南省湘西经济开发区广州工业园产业中心A栋标准厂房一楼

登记机关

2020 年 2 月 12 日

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

COC / QA

检 验 报 告

报告编号：YQ202030191

委托单位　洁宝日化（湘西）有限责任公司

样品名称　一次性使用医用口罩(非无菌型)

型　　号　PM-G-D

检验类别　注册检验

湖南省医疗器械检验检测所

说　　明

一、报告无本检测机构“检验报告专用章”或本机构公章无效。

二、本所无CMA标志的报告，仅供使用方内部参考，不具有对社会的证明作用。

三、报告未经本检测机构书面批准不得复制（全文复制除外）。

四、本报告涂改、增删、或未加盖检测单位印章的复印件均无效。

五、检验报告上的检验结果和检验单位名称，未经同意不得用于广告、评优及商业宣传。

六、对本报告若有异议，应于收到报告之日起七个工作日内以书面方式向检验单位提出，逾期不予受理。

七、报告仅对来样负责。

地址：长沙市雨花区体院路510号
邮编：410014
电话：0731-84285035
传真：0731-84285035
网址：www.hnti.org.cn
邮箱：ywk@hnti.org.cn

湖南省医疗器械检验检测所

检　验　报　告　首　页

报告编号：YQ202030191

样品名称	一次性使用医用口罩(非无菌型)	样品编号	YQ202030191
型号规格	PM-G-D	商　标	/
委托单位	洁宝日化（湘西）有限责任公司	检验类别	注册检验
委托单位地址	湖南省湘西经济开发区广州工业园产业中心A栋标准厂房一楼	产品编号/批号	YYKZ20200201
生产单位	洁宝日化（湘西）有限责任公司	抽样单/协议编号	QX202000356
受检单位	洁宝日化（湘西）有限责任公司	生产日期	2020.02.20
抽样单位	/	样品数量	50 个
抽样地点	/	抽样基数	/
抽样日期	/	检验地点	长沙市八一路60号
收样日期	2020-02-25	检验日期	2020-02-26 ～ 2020-03-03
检验项目	单项检验		
检验依据	洁宝日化（湘西）有限责任公司一次性使用医用口罩（非无菌型）产品技术要求		
检验结论	被检样品受检项目符合洁宝日化（湘西）有限责任公司一次性使用医用口罩（非无菌型）产品技术要求。 （检验报告专用章或检验单位公章） 签发日期 2020-03-04		
备注	1）报告中的“——”表示此项不适用，报告中“/”表示此项空白。 2）应急注册检验，本品为非无菌产品。 3）细菌过滤效率（BFE）系委托湖南省药品检验研究院（湖南药用辅料检验检测中心）检验（证书编号：15180014017）。		

批准：　　审核：　　检验：

职务：副所长

HNMD / TEST

湖南省医疗器械检验检测所

检 验 报 告

报告编号:YQ202030191　　第2页共2页

序号	检验项目	标准条款	标准要求	检验结果	单项结论	备注
1	细菌过滤效率（BFE）	2.5	口罩的细菌过滤效率应不小于95%	99.5%	符合	/

以下空白

湖南省一次性使用医用口罩应急备案凭证

备案号：湘州械应急备 2020002 号

企业名称	洁宝日化（湘西）有限责任公司
统一社会信用代码	91433100599403286E
企业法人	周学平
企业住所	湖南省湘西经济开发区广州工业园产业中心 A 栋标准厂房一楼
企业生产地址	湖南省湘西经济开发区广州工业园产业中心 A 栋标准厂房一楼
产品名称	一次性使用医用口罩(非无菌型)
产品型号/规格	平面形耳挂式 175*95mm 50 个/盒
执行标准	YY/T0969-2013 一次性使用医用口罩
结构组成	本产品由口罩布、鼻夹、口罩带组成。罩布内外层由无纺布，中间层由熔喷布制成，口罩带由非织造布或松紧带制成，鼻夹由可弯折的聚丙烯鼻夹材料制成。该产品非无菌供应。
适用范围	本应急备案产品仅限在非医疗环境下使用
备案单位、日期	湘西自治州市场监督管理局 备案日期：2020 年 03 月 06 日
备注	本应急备案凭证仅在疫情防控应急期间使用，有效期至二级应急响应结束。本应急备案产品仅限在非医疗环境下使用。

扫描全能王 创建

对外贸易经营者备案登记表

统一社会信用代码：91433100599403286E

备案登记表编号：04742024　　进出口企业代码：----------

经营者中文名称	洁宝日化（湘西）有限责任公司		
经营者英文名称	Jiebao Daily Chemical（xiangxi）Co.,Ltd		
组织机构代码	---------	经营者类型（由备案登记机关填写）	有限责任公司
住　所	湖南省湘西经济开发区广州工业园产业中心A栋标准厂房一楼		
经营场所（中文）	湖南省湘西经济开发区广州工业园产业中心A栋标准厂房一楼		
经营场所（英文）	1st Floor,Standard Workshop,Building A,Guangzhou Industrial Park Industrial Center,Xiangxi Economic Development Zone,Hunan Province		
联系电话	0743-8532755	联系传真	0743-8523619
邮政编码	416000	电子邮箱	675446007@qq.com
工商登记注册日期	2012-7-3	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	周学平	有效证件号	430426198106292737
注册资金	伍仟壹佰伍拾万元		（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

2020 年 03 月 05 日

扫描全能王 创建

HNMD / TEST

3-PLY **(YY/T 0969-2013)**

PROTECTIVE GOWN **(GB 19082-2009)**

Product Number: SDL-DZ002

Certified Standard:	GB 19082-2009 (Technical requirements for single-use protective clothing for medical use)
Equivalent Rating:	EN 14126:2003+AC:2004, EN ISO 13982-1:2004+A1:2010
Registrations:	CE, FDA
Testing Lab:	CEPREI (http://www.ceprei.org)
Certification Report Issue Date:	15 March, 2020

Garment Style	Coveralls
Garment Type	General Purpose
Material	PP Non Woven Fabric w/ PE FIlm
Size	S, M, L, XL
Color	White
ISO Class	NonCleanroom
Cuff Style	Elastic w/Thumb-loop
Ankle Style	Elastic
Closure Type	Zipper
Hazardous Protection Level	NonHazardous
Seam Style	Taped
Additional Features	Hood; Storm Flap; Self-Adhesive Chin Flap; Elastic Waist

PROTECTIVE GOWN **(GB 19082-2009)**

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Dandong Devote Garment Co., Ltd.

No.83 Tongxing Road,Tongxing Town,Zhen'an District,Dandong, Liaoning, 118000, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through Shenzhen Huide Medical Device Certification Service Co., Ltd.

Owner/Operator Number: 10063478

Listing Number:	Product Code:	Device Name:
D376548	OEA	Disposable Isolation Gown
D376549	LYU	Disposable Protective Coverall

Shenzhen Huide Medical Device Certification Service Co., Ltd. will confirm that such registration remains effective upon request and presentation of this certificate until end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. Shenzhen Huide Medical Device Certification Service Co., Ltd. makes no other representations or warranties, nor does this certificate make any representation or warranties to any person or entity other than the named certificate holder, for those 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. Shenzhen Huide Medical Device Certification Service Co., Ltd. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registratio n 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, Shenzhen Huide Medical Device Certification Service Co., Ltd. is not affiliated with the U.S. Food and Drug Administration.

Shenzhen Huide Medical Device
Certification Service Co., Ltd.
16C, Building 1, Sunshine Green,

Issue Date: March 20, 2020
Expiration Date: 31 December, 2020

OCT
OUCHENG TESTING

Certificate of Conformity

Certification No: OCT20200318118P
Applicant: Dandong Devote Garment Co., Ltd.
Address: No. 83 Tongxing Road, Tongxing Town, Zhen' an District, Dandong
Manufacturer: Dandong Devote Garment Co., Ltd.
Address: No. 83 Tongxing Road, Tongxing Town, Zhen' an District, Dandong
Certification Marking: CE-PPE
Product Description: Medical Disposable Protective Suit
Model: 170/175/180/185

Sufficient samples of the product have been tested and found to be in conformity with

Test Standards	:	EN 14126:2003+AC:2004, EN ISO 13982-1:2004+A1:2010

When tested as specified, the submitted sample complies with Personal Protective Equipment (PPE) – Regulation (EU) 2016/425

OCT OUCHENG TESTING

The certificate is based on a single evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test laboratory logo.

CE

Authorized Signer:
Manager
March 17, 2020

Oct Technology Testing Co., Ltd.
637,No. 56, zhongyun Road,Panyu District,Guangzhou,Guangdong Province,China
TEL:020-89015652,888@oucetesting.com,www.oucetesting.com

Declaration of Conformity

Dandong Devote Garment Co., Ltd.
No. 83 Tongxing Road, Tongxing Town, Zhen' an District, Dandong
We declare that the following product :

Medical Disposable Protective Suit

Models No: 170/175/180/185

Described above is in conformity with the following directive (s) :
Personal Protective Equipment 2016/425

Relevant standard (s):

EN 14126:2003+AC:2004, EN ISO 13982-1:2004+A1:2010

The reference of the File identified with the No:
MESTTCF-PPE

And we are aware about the contents and information included in the ModCOM04.06 Regulation that is considered totally accepted.

CE

Date of issue
2020.03.17

Stamp and Signature of authorized personnel

FDA / **CE + COC**

PPE TEST REPORT

For

Dandong Devote Garment Co., Ltd.

Medical disposable protective suit

Model: 170

Prepared For : **Dandong Devote Garment Co., Ltd.**
No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong

Prepared By : **China Ceprei (Sichuan) Laboratory**
No.45 Wenming Dong Road Longquanyi District, Chengdu, Sichuan

Report Number: **PCTCF0315-PPE**
Date of Test: **Mar.15, 2020**
Date of Report: **Mar.15, 2020**

CEPREI / TEST

PCTCF0315-PPE

TEST REPORT DECLARATION

Applicant	:	Dandong Devote Garment Co., Ltd.
Address	:	No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong
Manufacturer	:	Dandong Devote Garment Co., Ltd.
Address	:	No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong
EUT Description	:	Medical disposable protective suit
Model No.	:	170
Remark	:	N/A

Test Procedure Used:
EN 14126:2003+AC:2004, EN ISO 13982-1:2004+A1:2010

The test results of this report relate only to the tested sample identified in this report.

Date of Test : Mar.15, 2020

Prepared by : (Jack)

Checked by : (Gina)

Approved by : (Johnson)

PCTCF0315-PPE

EN 14126:2003+AC:2004			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
1	Scope		P
	This European Standard specifies requirements and test methods for re-usable and limited use protective clothing providing protection against infective agents. Clothing worn by surgical teams or drapes laid on patients to prevent cross-contamination during surgical interventions are not covered by the scope of this standard.		P
2	Normative references		P
	This European standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).		P
3	Terms and definitions		P
	For the purposes of this European Standard, the terms and definitions of prCEN ISO/TR 11610:2003 and the following terms and definitions apply.		P
4	Requirements		P
4.1	Materials requirements		P
	4.1.1 General If the care instructions indicate that the clothing can be cleaned and reprocessed at least five times, protective clothing materials shall be submitted to five cleaning and reprocessing cycles according to the manufacturer's care instructions before testing. If the care instructions specify a lower number of cleaning/reprocessing cycles, then materials shall be submitted to the number of cleaning/reprocessing cycles indicated. Unless otherwise stated in the relevant test procedure, the specimens shall be conditioned for at least 24 h in an atmosphere of (20 ±2) °C and (65 ±5) % relative humidity before testing. Tests shall be carried out in the same atmosphere or within 5 min of removing the sample from the conditioning atmosphere.		P
	4.1.2 Mechanical and flammability requirements The materials shall be tested and classified in		P

EN 14126:2003+AC:2004			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.		
	4.1.3 Chemical requirements If protection against chemicals is claimed, the materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.		P
	4.1.4 Performance requirements against penetration by infective agents 4.1.4.1 Resistance to penetration by contaminated liquids under hydrostatic pressure When tested in accordance with ISO/FDIS 16603 and ISO/FDIS 16604 the material shall be classified according to the levels of performance given in Table 1, as obtained in the bacteriophage test (ISO/FDIS 16604).		P
	Table 1 — Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (ISO/FDIS 16604) Class | Hydrostatic pressure at which the material passes the test 6 | 20 kPa 5 | 14 kPa 4 | 7 kPa 3 | 3,5 kPa 2 | 1,75 kPa 1 | 0 kPa [a] [a] this means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell		
	4.1.4.2 Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids. When tested in accordance with Annex A the material shall be classified according to the levels of performance given in Table 2.		P
	Table 2 — Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids Class | Breakthrough time, t min 6 | $t > 75$ 5 | $60 < t \leq 75$ 4 | $45 < t \leq 60$ 3 | $30 < t \leq 45$ 2 | $15 < t \leq 30$ 1 | ≤ 15 min		
	4.1.4.3 Resistance to penetration by contaminated		P

EN 14126:2003+AC:2004			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	liquid aerosols When tested in accordance with ISO/DIS 22611 the material shall be classified according to the levels of performance given in Table 3.		
	Table 3 — Classification of resistance to penetration by contaminated liquid aerosols Class | Penetration ratio (log) 3 | log > 5 2 | 3 < log ≤ 5 1 | 1 < log ≤ 3		
	4.1.4.4 Resistance to penetration by contaminated solid particles. When tested in accordance with ISO/DIS 22612 the material shall be classified according to the levels of performance given in Table 4.		P
	Table 4 — Classification of resistance to penetration by contaminated solid particles Class | Penetration (log cfu) 3 | ≤ 1 2 | 1 < log cfu ≤ 2 1 | 2 < log cfu ≤ 3		
4.2	Performance requirements for seams, joins and assemblages		P
	Seams, joins and assemblages of protective clothing against infective agents shall fulfil the requirements specified in the relevant clauses of prEN 14325 Seam strength shall be classified according to 5.5 of prEN 14325:2001.		P
4.3	Whole suit requirements		P
	Protective clothing against infective agents shall fulfil the relevant requirements of EN 340 and the whole suit requirements specified in the relevant standard for chemical protective clothing (see Table 5). The materials and design used shall not cause skin irritation nor have any adverse effect to health.		P

EN 14126:2003+AC:2004			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	Table 5 — Types of protective clothing against infective agents Type of clothing | Relevant standard type 1a, 1b, 1c, 2 | EN 943-1 (EN 943-2 for ET suits) type 3 | EN 466 type 4 | EN 465 type 5 | DIN ISO 13982-1 type 6 | prEN 13854 partial body protection | EN 467		P
5	Marking		P
	The clothing shall be marked in accordance with the applicable requirements of the relevant standard for chemical protective clothing. The marking of protective clothing against infective agents shall contain the following additional information: a) the number of this European Standard; b) the type of protective clothing, as specified in Table 5, with the suffix "-IR", e.g. type 3-IR; c) the pictogram "protection against biological hazard"		P
6	Information supplied by the manufacturer		P
	The information for the user shall be worded clearly and unambiguously and be understandable by a trained person. The information for the user of protective clothing against infective agents shall contain all the information required by EN 340 and by the relevant standard for that specific type of chemical protective clothing. In addition it shall contain the following information: a) the number of this European Standard; b) the type designation, e.g. type 3-IR; c) the biological agents against which the protective clothing has been tested. This information shall be expressed as performance levels, as specified in 4.1.4.1 to 4.1.4.4 for the relevant types of biological challenge; d) all other relevant information on performance levels, preferably as a Table; e) the information necessary for trained persons about: application and limitations of use (temperature range, etc.); if relevant, checks to be carried out by the wearer before use; fitting and adjustments, and any accessories needed to provide the claimed level of protection; use; maintenance, cleaning and disinfection; storage; if relevant, a warning against problems likely to be encountered;		P

EN 14126:2003+AC:2004			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	if relevant, illustrations, part numbers and marking of spare parts, etc. disposal after use.		

	accordance with Equation (7) and reported: $\bar{L}_{ij} = \frac{1}{j}\sum_{j} L_{ij,j} = \frac{1}{i}\sum_{i} L_{i,ij} = \frac{1}{m}\sum_{m} L_{ij,m} = \frac{1}{n}\sum_{n} L_{ij,n}$		
8	Test report		--
	The test report shall contain the following information: a) reference to this International Standard (i.e., ISO 13982-2:2004); b) identity of the manufacturer of the suit; c) size of the suits tested and the body measurements of the test subjects, in accordance with the provisions of EN 340; d) description of the underwear worn by test subjects; e) description of any pre-treatment and/or preconditioning of the suits tested, e.g. mechanical pre-stressing of suits for determining the durability of barrier efficiency; f) description of any additional protective equipment or any accessories worn during the test and if and how the accessories were taped to the suit; g) temperature and relative humidity inside the test chamber prior to the testing of each suit and at the end of all test exercises for each suit; h) concentration of test agent inside the suit at all three sampling positions for each suit prior to testing, concentration of test agent inside the test chamber after stabilizing the test agent concentration and at the end of all test exercises; i) all inward leakage results, presented in the form of data tables: – tables giving the percentage inward leakage values $L_{ij,mn}$ and averages per test subject and test suit (i.e., at least 10 tables modelled on Table 2), – table giving total inward leakage values for all test subjects and test suits (modelled on Table 3), – table giving total inward leakage values per test subject (modelled on Table 4); j) any comments considered appropriate by the person who has carried out the tests.		P

Table 1 — Sampling sequence for probes inside the suit during the period when the test subject is present in the chamber and during the sequence of activity

Measuring sequence Number	Activity	Timing [1] min	Sampling through probe at position:	Feeding of clean air through probe at position:	Exercise
1	measuring the background inside suit (before donning of the aerosol)	3	knee	chest	standing still
		3	waist back	knee	
		3	chest	waist back	
2	waiting for stabilization and measuring the test agent concentration inside chamber	—	—	—	
3	measuring the test agent concentration inside suit	3	knee	chest	standing still
		3	waist back	knee	
		3	chest	waist back	
		3	knee	chest	walking
		3	waist back	knee	
		3	chest	waist back	
4	stabilization between walking and squatting	1	knee	chest	standing still
		1	waist back	knee	
		1	chest	waist back	
5	measuring the test agent concentration inside suit	3	knee	chest	squatting
		3	waist back	knee	
		3	chest	waist back	
6	measuring the test agent concentration inside chamber	—	—	—	standing still

Table 2 — Model for reporting inward leakage values, expressed in percent, of suit / worn by test subject /

Exercise	Sampling position/Feeding-in position Knee/Chest	Waist back/Knee	Chest/Waist back	Average per exercise %
standing still	$L_{i,j,1,1}$	$L_{i,j,1,2}$	$L_{i,j,1,3}$	$L_{E1,j}$
walking	$L_{i,j,2,1}$	$L_{i,j,2,2}$	$L_{i,j,2,3}$	$L_{E2,j}$
squatting	$L_{i,j,3,1}$	$L_{i,j,3,2}$	$L_{i,j,3,3}$	$L_{E3,j}$
average per sampling position	$L_{IP1,j}$	$L_{IP2,j}$	$L_{IP3,j}$	L_{Sj}

Table 3 — Model for reporting total inward leakage values, expressed in percent, per sampling position and per exercise (averaged over all suits)

Exercise	Sampling position/Feeding-in position Knee/Chest	Waist back/Knee	Chest/Waist back	Average per exercise %
standing still	$L_{IP1,1}$	$L_{IP1,2}$	$L_{IP1,3}$	L_{E1}
walking	$L_{IP2,1}$	$L_{IP2,2}$	$L_{IP2,3}$	L_{E2}
squatting	$L_{IP3,1}$	$L_{IP3,2}$	$L_{IP3,3}$	L_{E3}
average per sampling position	L_{IP1}	L_{IP2}	L_{IP3}	$\bar{L}$

Table 4 — Model for reporting total inward leakage values, expressed in percent, per test subject

Test subject	Total inward leakage per suit, L_{Sj}	Total inward leakage per human test subject, L_{Hk}
1	L_{S1}; L_{S2}	L_{H1}
2	L_{S3}; L_{S4}	L_{H2}
...	L_{Sj-1}; L_{Sj}	...
average	$\bar{L}$	$\bar{L}$

- End of Review Report -

Annex: Technical Information

(1) Product Photos

A.1

Registration Certificate of Medical Apparatus and Instruments of the People's Republic of China

Serial No. of Registration Certificate: L. X. Z. Z. 20202140026

Registrant Name	Dandong Devota Garment Co., Ltd.
Registrant Address	No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong.
Production Address	No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong.
Agent Name	Not applicable
Agent Address	Not applicable
Product Name	Medical disposable protective clothing
Model and Specifications	One-piece: 160, 165, 170, 175, 180, 185
Structure and Composition	The product uses the polypropylene non-woven fabric with polyethylene film as its materials. The sealing rubber strip is made of rubber-lined non-woven fabric. It consists of a hooded jacket and pants, and there are elastic closing up designs on the cuffs and foot openings. The elastic closing up design is applied in the hoodie face and waist. The product is in the type of one-piece, and uses cobalt-60 radiation sterilization.
Scope of Application	It is suitable for playing a role of barrier and protection for clinical medical staff who may be in contact with the blood, body fluids, secretions, etc. of potentially infectious patients during the work as well as the particles in air.
Annex	Technical Requirements of Product
Other Contents	N/A
Remarks	This product is an emergency product with temporary approval during the COVID-19 outbreak, and the registration certificate is valid for 30 days.

Approval Authority: Liaoning Provincial Medical Products Administration

Approval date: February 21, 2020
Valid until: March 21, 2020
Special Seal for Filing of Medical Apparatus and Instruments of Dandong Municipal Administration for Market Regulation (Seal)

PROTECTIVE GOWN **(GB 19082-2009)**

ISOLATION PROTECTIVE SHIELD **(EN 166-2001)**

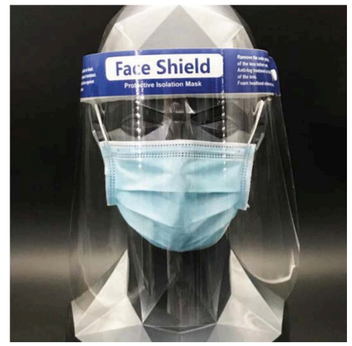
Product Number: SDL-DZ003

Certified Standard:	EN 166-2001 (Personal Eye-Protection)
Equivalent Rating:	EN STANDARD
Registrations:	CE
Testing Lab:	TMC - www.tmc-lab.com
Certification Report Issue Date:	25 March, 2020

Face shields provide a lightweight splash and anti-fog barrier for applications where exposure to fluids is possible. They are constructed from a single PE optical shield with a removable film for protection in shipping and handling. The headband is constructed from a foam brow that provides comforting cushioning and ventilation for extreme environments. The elastic headband is self tensioning for a customized fit to a variety of head shapes. Face shields are compatible for use over goggles or optical glasses and eyewear. Available in 3/4 length (7.5”) and full length (9”)

Product Features:

- Anti-fog and anti-glare PE film shield with minimal optical distortion and full peripheral vision
- Adjustable elastic band for any head size
- Vented foam headband for airflow and comfort fit
- Free of natural rubber latex
- Single use



ISO PROTECTIVE SHIELD **(EN 166-2001)**

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

TMC
Access to global market

Certificate of Compliance

Certificate No.:	TMC200324119-S
Applicant/ Address:	**SHENZHEN SNK PRINTING PRODUCTS CO.,LTD** No.2 Ceng, building 15, no.6, Xingye 1st Road, Fenghuang community, Fuyong street, Bao'an District, Shenzhen
Manufacturer/ Address:	**SHENZHEN SNK PRINTING PRODUCTS CO.,LTD** No.2 Ceng, building 15, no.6, Xingye 1st Road, Fenghuang community, Fuyong street, Bao'an District, Shenzhen
Product Name:	**Isolation protective mask**
Trade Name:	N/A
Model/Item Number :	M1
Rated:	--
Classification:	Class I
Date and Number of Test Report:	March 25,2020 TMC200324119-S
EC-directive:	PPE Directive (EU) 2016/425
Test Standard:	EN166:2001

Conclusion

This Declaration of PPE Compliance has been granted to applicant based on the results of tests, performed by Laboratory of TMC Testing Services (Shenzhen) Co., Ltd. on sample of the above-mentioned product in accordance with the provisions of the relevant specific standards and the PPE Directive (EU) 2016/425. It is possible to use CE marking to demonstrate the compliance with this Directive.

Place and date of issue: Shenzhen, March 25,2020

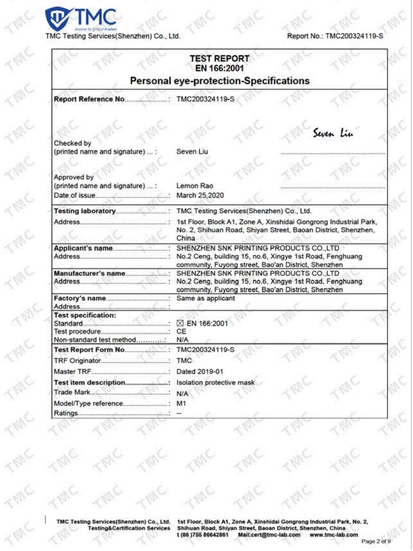
TMC Testing Services (Shenzhen) Co., Ltd.
1st Floor, Block A1, Zone A, Xinshidai Gongrong Industrial Park, No. 2,
Shihuan Road, Shiyan Street, Baoan District, Shenzhen, China
Tel: +86-755- 86642861
Email:cert@tmc-lab.com
Http://www.tmc-lab.com

Lab Director
Lemon Rao

CE

TMC

TMC / TEST + COC


TMC Testing Services(Shenzhen) Co., Ltd. Report No.: TMC200324119-S

TEST REPORT
EN 166:2001
Personal eye-protection-Specifications

Report Reference No.	TMC200324119-S
Checked by (printed name and signature)	Seven Liu
Approved by (printed name and signature)	Lemon Rao
Date of issue	March 25,2020
Testing laboratory	TMC Testing Services(Shenzhen) Co., Ltd.
Address	1st Floor, Block A1, Zone A, Xinshidai Gongrong Industrial Park, No. 2, Shihuan Road, Shiyan Street, Baoan District, Shenzhen, China
Applicant's name	SHENZHEN SNK PRINTING PRODUCTS CO.,LTD
Address	No.2 Ceng, building 15, no.6, Xingye 1st Road, Fenghuang community, Fuyong street, Bao'an District, Shenzhen
Manufacturer's name	SHENZHEN SNK PRINTING PRODUCTS CO.,LTD
Address	No.2 Ceng, building 15, no.6, Xingye 1st Road, Fenghuang community, Fuyong street, Bao'an District, Shenzhen
Factory's name	Same as applicant
Address	--
Test specification:	
Standard	EN 166:2001
Test procedure	CE
Non-standard test method	N/A
Test Report Form No.	TMC200324119-S
TRF Originator	TMC
Master TRF	Dated 2019-01
Test item description	Isolation protective mask
Trade Mark	N/A
Model/Type reference	M1
Ratings	--


TMC Testing Services(Shenzhen) Co., Ltd. Report No.: TMC200324119-S

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

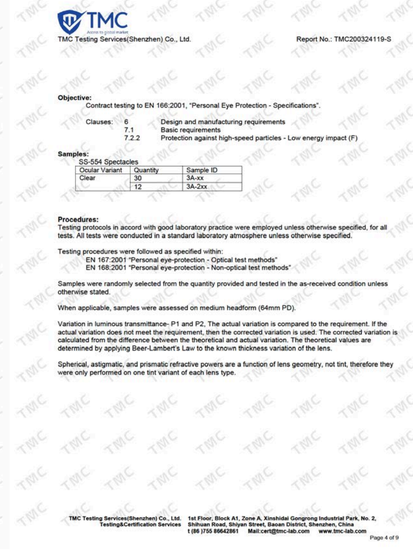
Testing
Date of receipt of test item ..... March 15, 2020
Date(s) of performance of tests ..... March 15, 2020 to March 25,2020

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.

General product information:
N/A

Copy of marking plate:

Isolation protective mask
Model:M1
Standard: EN 166:2001
CE
SHENZHEN SNK PRINTING PRODUCTS CO.,LTD
Made in China


TMC Testing Services(Shenzhen) Co., Ltd. Report No.: TMC200324119-S

Objective:
Contract testing to EN 166:2001, "Personal Eye Protection - Specifications".

Clauses: 6 Design and manufacturing requirements
7.1 Basic requirements
7.2.2 Protection against high-speed particles - Low energy impact (F)

Samples:
SS-554 Spectacles

Ocular Variant	Quantity	Sample ID
Clear	30	3A-xx
	12	3A-2xx

Procedures:
Testing protocols in accord with good laboratory practice were employed unless otherwise specified, for all tests. All tests were conducted in a standard laboratory atmosphere unless otherwise specified.

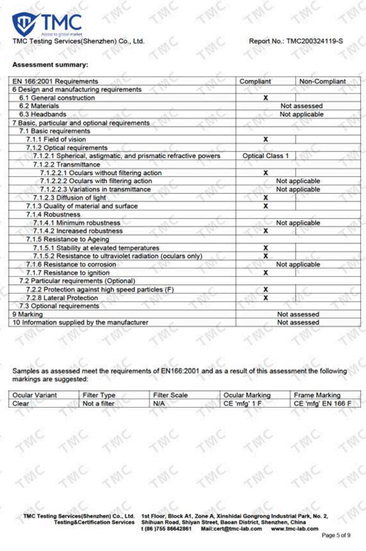
Testing procedures were followed as specified within:
EN 167:2001 "Personal eye-protection - Optical test methods"
EN 168:2001 "Personal eye-protection - Non-optical test methods"

Samples were randomly selected from the quantity provided and tested in the as-received condition unless otherwise stated.

When applicable, samples were assessed on medium headform (64mm PD).

Variation in luminous transmittance- P1 and P2. The actual variation is compared to the requirement. If the actual variation does not meet the requirement, then the corrected variation is used. The corrected variation is calculated from the difference between the theoretical and actual variation. The theoretical values are determined by applying Beer-Lambert's Law to the known thickness variation of the lens.

Spherical, astigmatic, and prismatic refractive powers are a function of lens geometry, not tint, therefore they were only performed on one tint variant of each lens type.

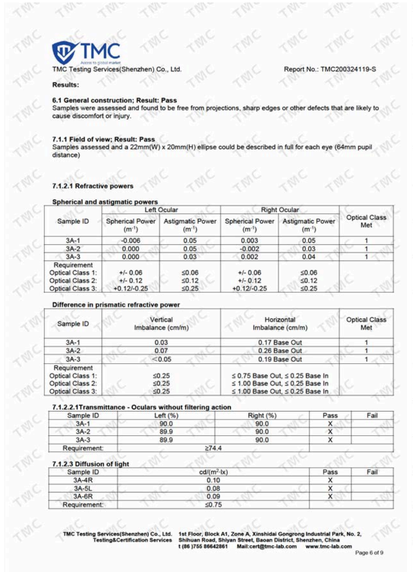

TMC Testing Services(Shenzhen) Co., Ltd. Report No.: TMC200324119-S

Assessment summary:

EN 166:2001 Requirements	Compliant	Non-Compliant
6 Design and manufacturing requirements		
6.1 General construction	X	
6.2 Materials		Not assessed
6.3 Headbands		Not applicable
7 Basic, particular and optional requirements		
7.1 Basic requirements		
7.1.1 Field of vision	X	
7.1.2 Optical requirements		
7.1.2.1 Spherical, astigmatic, and prismatic refractive powers	Optical Class 1	
7.1.2.2 Transmittance		
7.1.2.2.1 Oculars without filtering action	X	
7.1.2.2.2 Oculars with filtering action		Not applicable
7.1.2.2.3 Variations in transmittance		Not applicable
7.1.2.3 Diffusion of light	X	
7.1.3 Quality of material and surface	X	
7.1.4 Robustness		
7.1.4.1 Minimum robustness		Not applicable
7.1.4.2 Increased robustness	X	
7.1.5 Resistance to Ageing		
7.1.5.1 Stability at elevated temperatures	X	
7.1.5.2 Resistance to ultraviolet radiation (oculars only)	X	
7.1.6 Resistance to corrosion		Not applicable
7.1.7 Resistance to ignition	X	
7.2 Particular requirements (Optional)		
7.2.2 Protection against high speed particles (F)	X	
7.2.8 Lateral Protection	X	
7.3 Optional requirements		
9 Marking		Not assessed
10 Information supplied by the manufacturer		Not assessed

Samples as assessed meet the requirements of EN166:2001 and as a result of this assessment the following markings are suggested:

Ocular Variant	Filter Type	Filter Scale	Ocular Marking	Frame Marking
Clear	Not a filter	N/A	CE mfg' 1 F	CE mfg' EN 166 F


TMC Testing Services(Shenzhen) Co., Ltd. Report No.: TMC200324119-S

Results:

6.1 General construction; Result: Pass
Samples were assessed and found to be free from projections, sharp edges or other defects that are likely to cause discomfort or injury.

7.1.1 Field of view; Result: Pass
Samples assessed and a 22mm(W) x 20mm(H) ellipse could be described in full for each eye (64mm pupil distance)

7.1.2.1 Refractive powers

Spherical and astigmatic powers

Sample ID	Left Ocular		Right Ocular		Optical Class Met
	Spherical Power (m^{-1})	Astigmatic Power (m^{-1})	Spherical Power (m^{-1})	Astigmatic Power (m^{-1})	
3A-1	-0.006	0.05	0.003	0.05	1
3A-2	0.000	0.05	-0.002	0.03	1
3A-3	0.000	0.03	0.002	0.04	1
Requirement					
Optical Class 1:	+/- 0.06	≤0.06	+/- 0.06	≤0.06	
Optical Class 2:	+/- 0.12	≤0.12	+/- 0.12	≤0.12	
Optical Class 3:	+0.12/-0.25	≤0.25	+0.12/-0.25	≤0.25	

Difference in prismatic refractive power

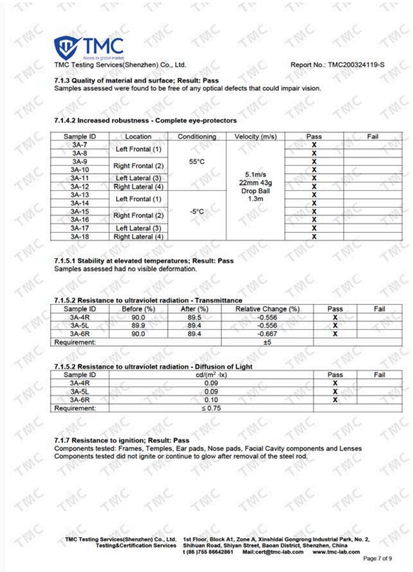
Sample ID	Vertical Imbalance (cm/m)	Horizontal Imbalance (cm/m)	Optical Class Met
3A-1	0.03	0.17 Base Out	1
3A-2	0.07	0.26 Base Out	1
3A-3	<0.05	0.19 Base Out	1
Requirement			
Optical Class 1:	≤0.25	≤ 0.75 Base Out, ≤ 0.25 Base In	
Optical Class 2:	≤0.25	≤ 1.00 Base Out, ≤ 0.25 Base In	
Optical Class 3:	≤0.25	≤ 1.00 Base Out, ≤ 0.25 Base In	

7.1.2.2.1Transmittance - Oculars without filtering action

Sample ID	Left (%)	Right (%)	Pass	Fail
3A-1	90.0	90.0	X	
3A-2	89.9	90.0	X	
3A-3	89.9	90.0	X	
Requirement:	≥74.4			

7.1.2.3 Diffusion of light

Sample ID	cd/(m^2·lx)	Pass	Fail
3A-4R	0.10	X	
3A-5L	0.08	X	
3A-6R	0.09	X	
Requirement:	≤0.75		


TMC Testing Services(Shenzhen) Co., Ltd. Report No.: TMC200324119-S

7.1.3 Quality of material and surface; Result: Pass
Samples assessed were found to be free of any optical defects that could impair vision.

7.1.4.2 Increased robustness - Complete eye-protectors

Sample ID	Location	Conditioning	Velocity (m/s)	Pass	Fail
3A-7	Left Frontal (1)	55°C	5.1m/s 22mm 43g Drop Ball 1.3m	X	
3A-8				X	
3A-9	Right Frontal (2)			X	
3A-10				X	
3A-11	Left Lateral (3)			X	
3A-12	Right Lateral (4)			X	
3A-13	Left Frontal (1)	-5°C		X	
3A-14				X	
3A-15	Right Frontal (2)			X	
3A-16				X	
3A-17	Left Lateral (3)			X	
3A-18	Right Lateral (4)			X	

7.1.5.1 Stability at elevated temperatures; Result: Pass
Samples assessed had no visible deformation.

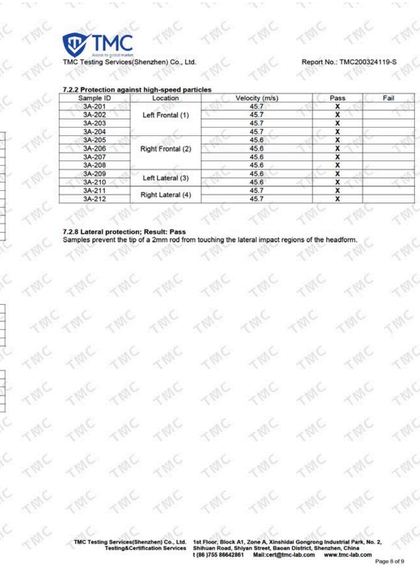
7.1.5.2 Resistance to ultraviolet radiation - Transmittance

Sample ID	Before (%)	After (%)	Relative Change (%)	Pass	Fail
3A-4R	90.0	89.5	-0.556	X	
3A-5L	89.9	89.4	-0.556	X	
3A-6R	90.0	89.4	-0.667	X	
Requirement:			≤5		

7.1.5.2 Resistance to ultraviolet radiation - Diffusion of Light

Sample ID	cd/(m^2·lx)	Pass	Fail
3A-4R	0.09	X	
3A-5L	0.09	X	
3A-6R	0.10	X	
Requirement:	≤ 0.75		

7.1.7 Resistance to ignition; Result: Pass
Components tested: Frames, Temples, Ear pads, Nose pads, Facial Cavity components and Lenses
Components tested did not ignite or continue to glow after removal of the steel rod.


TMC Testing Services(Shenzhen) Co., Ltd. Report No.: TMC200324119-S

7.2.2 Protection against high-speed particles

Sample ID	Location	Velocity (m/s)	Pass	Fail
3A-201	Left Frontal (1)	45.7	X	
3A-202		45.7	X	
3A-203		45.7	X	
3A-204	Right Frontal (2)	45.7	X	
3A-205		45.6	X	
3A-206		45.6	X	
3A-207		45.6	X	
3A-208		45.6	X	
3A-209	Left Lateral (3)	45.6	X	
3A-210		45.6	X	
3A-211	Right Lateral (4)	45.7	X	
3A-212		45.7	X	

7.2.8 Lateral protection; Result: Pass
Samples prevent the tip of a 2mm rod from touching the lateral impact regions of the headform.


TMC Testing Services(Shenzhen) Co., Ltd. Report No.: TMC200324119-S

Attachment No.1

Photo Documentation

Photo 1

Photo 2

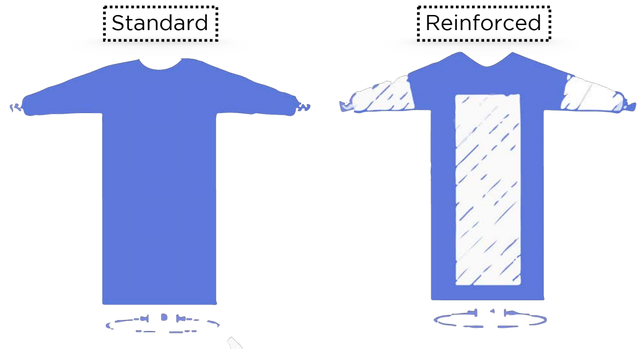
End of Test Report

SURGICAL GOWN **(EN 13795 ISO 13485)**

Product Number: SDL-WH005

Certified Standard:	EN 13795 ISO 13485
Equivalent Rating:	AAMI LEVEL 3
Registrations:	CE, FDA, ISO, EN
Testing Lab:	ICAS (www.icasiso.com)
Certification Report Issue Date:	28 October, 2016

Garment Style	One Piece Disposable Surgical Gown
Garment Type	Protective Clothing
Material	SMMS Non Woven
Weight	35gsm or 45 gsm
SMMS Performance	Fluid Proof and Anti Static and/or (AS & AR)
ISO Class	ISO 13484
Cuff Style	Sleeve w/ White Cuff
Size	S,M,L,XL,XXL,XXXL
Workmanship Details	Ultrasonic Technology in arm and sleeve
-	Four Belts w/ Belt Card
-	Comfortable Collar w/ soft white spunlace
-	Tear & Flame Resistant



SURGICAL GOWN SIZE (cm)							
Size	S	M	L	XL	XXL	XXXL	T
A	110	115	127	135	140	145	+-2
B	140	145	150	150	155	160	+-2

SURGICAL GOWN **(EN 13795 ISO 13485)**

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

HENAN JOINKONA MEDICAL PRODUCTS STOCK CO.,LTD

Xinxing Road, The South of Industry District, Lushan County, Pingdingshan, HENAN, 467300, CHINA

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

Shenzhen CTB Testing Technology Co., Ltd.

Owner/Operator Number: 10062713

Device Listing#: See annex

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

CTB FDA

Chief engineer

Issued: March 4, 2020

Expiration Date: December 31, 2020

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

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

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

NOT END OF THE ANNEX

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

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

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

END OF THE ANNEX

Chief engineer

Issued: March 4, 2020

Expiration Date: December 31, 2020

FDA / COR

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

Product Service

EC Certificate

Production Quality Assurance System

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

No. G2S 18 01 83528 008

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

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

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

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

Report No.: SH18783EXT01

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

Date, 2018-02-15

Stefan Preiß

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

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

TÜV®

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q8 083528 0011 Rev. 00

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

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

Certification Mark:

Scope of Certificate: **ETO Sterilization for Medical Device**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1978307

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-04-01

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Product Service

Supplement to Quality System Certificate

No. SUP 083528 0012 Rev. 00

This supplement is only valid in conjunction with the main certificate: **Q8 083528 0011 Rev. 00**

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

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

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

EN ISO 11135:2014 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)"

Audit Report: SH1978307

Dated: 2019-02-20

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization

Valid from: 2019-04-01

Stefan Preiß

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TUV / PQAS

ICAS 英格尔检测认证集团 ICAS Testing & Certification Group

TEST REPORT

Report No.: SHT16110079-01E Date: 2016-12-05 Page 1of 2

The following information of testing sample

Sample Name	Disposable Surgical Gown	Sample No.	T16110079-01
Sample Type	/	Sample Qty.	4pcs
Applicant	Henan Joinkona Medical Products Stock Co.,Ltd		
Address	Xinxing Road, The South of Industry District, LuShan County, PingDingShan City, Henan Province, China		
Sample Received Date	2016-10-28	Testing period	2016-10-28 to 2016-12-01
Test Items	Water resistance, Hydrostatic pressure test		
Test Method	AATCC 42-2013 AATCC 127-2013		
Test Results	Please refer to next page(s)		

******For more detailed information, please refer to next page(s)******

Redacted by: 王玉芳 (Yufang Wang) Reviewed by: 吴涛 (Tao Wu) Approved by: (Authorized signatory: Fei Xia)

英格尔检测技术服务（上海）有限公司 ICAS TESTING TECHNOLOGY SERVICES (SHANGHAI) CO.,LTD B 0200361

ICAS 英格尔检测认证集团 ICAS Testing & Certification Group

TEST REPORT

Report No.: SHT16110079-01E Date: 2016-12-05 Page 2of 2

Test Result(s):

1.Water resistance

Test Method: AATCC 42-2013

Determinate Standard: According to applicant's requirement

Test Item	Unit	Test Result	Limited Value	Determination
Water resistance	g	0.4	≤1.0	Pass

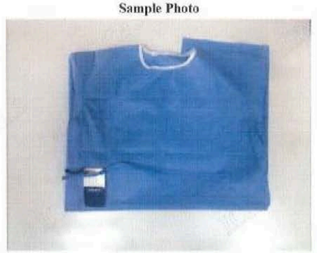
2.Hydrostatic pressure test

Test Method: AATCC 127-2013

Determinate Standard: According to applicant's requirement

Test Item	Unit	Test Result	Limited Value	Determination
Hydrostatic pressure test	cmH_2O	65.2	≥50	Pass

Sample Photo



The End

Remark: The samples provided by the customer, the report test results are only responsible for samples.
The test data is only used for reference, not as a social justice data.

英格尔检测技术服务（上海）有限公司 ICAS TESTING TECHNOLOGY SERVICES (SHANGHAI) CO.,LTD B 0200362

医疗器械生产产品登记表

企业名称	河南洁利康医疗用品有限公司
许可证编号	豫食药监械生产许20150081号
许可证有效期限	2019年09月18日 至 2023年01月26日
生产范围	原分类目录：II类：6864医用卫生材料及敷料。※
生产范围(新分类目录)	

生产产品列表

序号	产品名称	注册号	登载日期	备注
1	医用一次性防护服	豫械注准20172640921	2018-01-27	
2	手术洞巾	豫械注准20172640920	2018-01-27	
3	一次性使用手术衣	豫械注准20172640918	2018-01-27	
4	手术单	豫械注准20172640919	2018-01-27	
5	手术单组合包	豫械注准20172640922	2018-01-27	
6	一次性使用白内障眼科手术包	豫械注准20162640627	2018-01-27	
7	一次性使用无菌敷料包	豫械注准20172640864	2018-01-27	
8	一次性使用介入包	豫械注准20172640850	2018-01-27	
9	一次性使用剖腹产包	豫械注准20172640974	2018-01-27	
10	一次性使用无菌手术包	豫械注准20182640205	2019-09-18	

发证部门（公章）：2019年09月18日

第1页/共2页 第2页/共2页

中华人民共和国医疗器械注册变更文件

注册证编号：豫械注准20172640918

产品名称	一次性使用手术衣
变更内容	注册人名称由“河南洁利康医疗用品股份有限公司”变更为“河南洁利康医疗用品有限公司”。
备 注	本文件与“一次性使用手术衣（注册证编号：豫械注准20172640918）”注册证共同使用。

审批部门：河南省食品药品监督管理局 批准日期：二〇一七年十二月二十四日

中华人民共和国医疗器械注册证

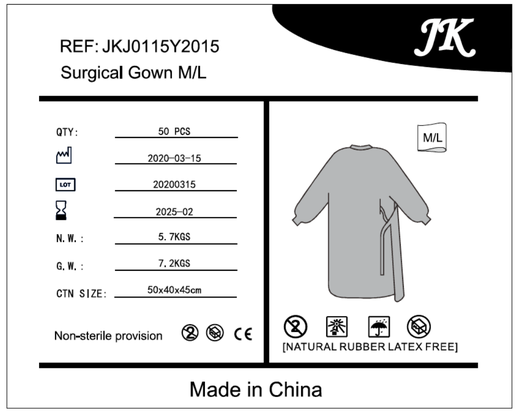
注册证编号：豫械注准20172640918

注册人名称	河南洁利康医疗用品股份有限公司
注册人住所	鲁山县产业集聚区南区新兴路
生产地址	鲁山县产业集聚区南区新兴路
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用手术衣
型号、规格	型号：普通型、加强型；规格：M-S、M、L、XL、XXL；（特殊规格按客户要求）
结构及组成	本产品普通型由非织造布制作而成，加强型在胸前及双袖袖加采用淋膜无纺布制作而成。
适用范围	适用于医疗单位手术时使用。
附 件	产品技术要求
其他内容	无
备 注	无

审批部门：河南省食品药品监督管理局 批准日期：二〇一七年十二月二十四日 有效期至：二〇二二年十二月二十三日

ICAS / **AATCC 42 & 127 TEST**

外箱标15*12cm



2020-03-15
LOT 20200315 生产日期，失效期，LOT号销售确认后印刷
2025-02

N.W. :净重
G.W. :毛重

SURGICAL GOWN **(EN 13795 ISO 13485)**