

KN95 Medical Mask

Overview & Quotation

Product - KN95

Classic & double rope
with CE / FDA certification

Regulated by the Chinese government, they are almost identical in performance to N95 masks.

BFE > 98%

(Bacterial Filtration Efficiency)

PFE > 90%

(Particle Filtration Efficiency)



Packaging



Secured, informative packaging box



Individually-wrapped masks (2 in a pack)

Certification - FDA


Fiscal Year 2020
CERTIFICATION OF FDA REGISTRATION

This certifies that:

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

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10064344



Device Listing:

Listing No	Code	Device Name	Proprietary Name
D37868	LYU	ACCESSORY, SURGICAL APPAREL	Disposable Face Mask

CCT 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. CCT 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. CCT 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 misbranding 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. CCT is not affiliated with the U.S. Food and Drug Administration.

Shenzhen CCT Testing Technology Co., Ltd.
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Chief Engineer
Issued: 03/25/2020
Expiration Date: 12/31/2020



Web: <http://www.fda.gov> Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: wc@mail@cc.td.gov

Certification & Testing Report - CE

CERTIFICATE ◆ CERTIFICATE ◆ CERTIFICATE

CIC

CERTIFICATE OF CONFORMITY

EU - Personal protective equipment (PPE)-
No. CIC200310028-ZJ-ZS

Applicant : Wenzhou Zhongjie Plastic Products Co., Ltd.
Address : Chuitang Road, Chuiyang Village, Aojiang Town, Pingyang County,
Wenzhou City, Zhejiang Province, China
Manufacturer : Wenzhou Zhongjie Plastic Products Co., Ltd.
Address : Chuitang Road, Chuiyang Village, Aojiang Town, Pingyang County,
Wenzhou City, Zhejiang Province, China
Product : MASK
Trade Name : /
Model(s) : KN95 (Without a nose clip)
Test Report No. : CIC200310028-ZJ
Test Standards : EN 149:2001+A1:2009

The tests that base on the above designated product Complies with the essential requirements of Regulation 2016/425/EU.
The test results apply only to the particular sample tested and to the specific tests carried out.
Specifically to the sample investigated in our test reference number only.
The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.
Other relevant Directives have to be observed.



CIC
Hale Zhao (Chief engineer)
March 05, 2020

Shenzhen CIC Testing Technology Co., Ltd.
Add: No.102, Floor 1, Building A, No. 26 of Xinh Road, Xinqiao Community, Xinqiao Street,
Baoan District, Shenzhen, Guangdong, China.
Web: <http://www.soncap-saso.com> Tel: 4008-707-283 Fax: +86-0755-23208027

CIC

TEST REPORT

MEASUREMENT AND TEST REPORT For

Wenzhou Zhongjie Plastic Products Co., Ltd.
Chuitang Road, Chuiyang Village, Aojiang Town, Pingyang County, Wenzhou City,
Zhejiang Province, China

Model: KN95 (Without a
nose clip)

March 11, 2020

This Report Concerns: <input checked="" type="checkbox"/> Original Report	Equipment Type: MASK
Test Engineer: <i>Dana Huang</i>	
Report Number: CIC200310028-ZJ	
Test Date: <i>March 11, 2020</i>	
Reviewed By: <i>Hale Zhao</i>	
Prepared By: Shenzhen CIC Testing Technology Co., Ltd. No.102, Floor 1, Building A, No. 26 of Xinh Road, Xinqiao Community, Xinqiao Street, Baoan District, Shenzhen, Guangdong, China. Tel: 4008-707-283 Fax: +86-0755-23208027 Web: http://www.soncap-saso.com	

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 CIC Testing Technology Co., Ltd.

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TEST REPORT EN 149

Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Report reference No. : CIC200310028-ZJ
Tested by (+signature) : Dana Huangsee cover page.....
Approved by (+ signature) : Hale Zhaosee cover page.....
Date of issue : March 11, 2020

Testing laboratory

Name : Shenzhen CIC Testing Technology Co., Ltd.
Address : No.102, Floor 1, Building A, No. 26 of Xinh Road, Xinqiao Community,
Xinqiao Street, Baoan District, Shenzhen, Guangdong, China.
Test location : (Same as above)

Client

Name : Wenzhou Zhongjie Plastic Products Co., Ltd.
Address : Chuitang Road, Chuiyang Village, Aojiang Town, Pingyang County,
Wenzhou City, Zhejiang Province, China

Test specification

Standard : EN 149: 2001+ A1: 2009
Test procedure : CE-PPE
Procedure deviation : N.A.
Non-standard test method : N.A.



Test Report Form No. : EN_149

Test item

Description : MASK
Model No. : KN95 (Without a nose clip)
Trade Mark : /
Manufacturer : Wenzhou Zhongjie Plastic Products Co., Ltd.
Address : Chuitang Road, Chuiyang Village, Aojiang Town, Pingyang County,
Wenzhou City, Zhejiang Province, China
Classification : FFP2 NR D

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Test case verdicts	
Test case does not apply to the test object.....	N(A)
Test item does meet the requirement.....	P(ass)
Test item does not meet the requirement.....	F(ail)
Testing	
Date of receipt of test item	March 03, 2020
Date(s) of performance of test	March 03-06, 2020
General remarks	
This test report shall not be reproduced except in full without the written approval of the testing laboratory.	
The test results presented in this report relate only to the item tested.	
(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.	
Remark :	
The EUT complies with the standard EN 149 requirement.	
Copy of marking plate:	
<div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>MASK</p> <p>Model: KN95(Without a nose clip)</p> <p>Classification: FFP2 NR D</p> <p>EN 149: 2001+A1: 2009</p> <p> </p> <p>Wenzhou Zhongjie Plastic Products Co., Ltd.</p> <p>Made in China</p> </div>	

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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:	Complied with standard, see appended.	P
	- FFP1		N
	- FFP2		P
	- FFP3		N
6	Designation		P
	Particle filtering half masks meeting the requirements of this European Standard.		P
	Year of publication, classification		
7	Requirements		P
7.1	In all tests all test samples shall meet the requirements	Complied see below	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified, the values stated in this European Standard are expressed as normal values.	Actual using value is clear	P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Clear marking is provided, see sample body	P
7.4	Packaging		P
	Masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Distinct design and warning are made on packaging, see sample body	P
7.5	Material		P
	Materials used shall be suitable to withstand handling and wear over the period. Any material from the filter media released shall not constitute a hazard or nuisance for the wearer.	Comfortable wearing, when releasing no hazards is produced	P
7.6	Cleaning and disinfecting		N
	The materials used shall withstand the cleaning and disinfecting	Single-use equipment	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see below test	P
7.8	Finish of parts		N
	Parts likely to come into contact with the wearer shall have no sharp edges or burrs	Soft equipment	N

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7.9	Leakage		P
7.9.1	Total inward leakage		P
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected.	Enough safe condition is provide	P
	Exercise results for total inward leakage shall be not greater than 25% for FFP1 11% for FFP2 5% for FFP3	FFP2, See below test table	P
7.9.2	Penetration of filter material		P
	Meet the requirements of Table 1	FFP2 Sodium chloride test: 2.8% Paraffin oil test: 3.1%	P
7.10	Compatibility with skin		P
	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Have no irritation or adverse effect to skin and health	P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.	Have no such hazard	P
7.12	Carbon dioxide content of the inhalation air		N
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).	<1.0%	P
7.13	Head harness		P
	Head harness shall be designed so that mask can be donned and removed easily.	The design is considered	P
	Head harness shall be adjustable or self-adjusting and sufficiently robust to hold the mask firmly in position.	The design is considered	P
7.14	Field of vision		P
	The field of vision is acceptable if determined so in practical performance tests.	Clear field of vision when wearing	P
7.15	Exhalation valve(s)		N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.		N
	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		N
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		N

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	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.		N
7.16	Breathing resistance		P
	The breathing resistances apply to valved and valveless and shall meet the requirements	Complied, see below test table	P
7.17	Clogging		P
7.17.1	General	Single-use device	P
	For single-use devices clogging test is an optional test.		P
	Devices designed to be resistant to clogging, shown by a slow increase		P
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg/h/m ³ .		P
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks.		N
7.17.2.2	Valveless particle filtering half masks		P
	After clogging the inhalation and exhalation resistances shall not exceed - FFP1: 3 mbar - FFP2: 4 mbar - FFP3: 5 mbar	FFP2: <4 mbar	P
	at 95 l/min continuous flow.		P
7.17.3	Penetration of filter media		P
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		P
7.18	Demountable parts	No any such part	N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		

8	Testing		P
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.	Common methods	P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests.	Considered	P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min	25 cycles/min	P

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	and 2.0 l/stroke.	2.0 l/stroke.	
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head.	a saturator incorporated by breathing machine and the dummy head	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
8.3.2	Temperature conditioning		P
	Exposet masks to the following thermal cycle:	Complied	P
	a) for 24 h to a dry atmosphere of (70 ± 3) °C;		P
	b) for 24 h to a temperature of (-30 ± 3) °C;		P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	5h	P

9	Marking		-
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, clearly marked	P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.	See user manual	P
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2, FFP3.	FFP2	P
9.1.4	The number and year of publication of this European Standard.	See above	P
9.1.5	At least the year of end of shelf life.	3 years	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 as shown in Figure 12b.	English used	
9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.	See user manual	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'.		P
9.2	Particle filtering half mask		P
	Particle filtering half masks		P
	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.		P
9.2.2	Type-identifying marking.		P

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9.2.3	The number and year of publication of this European Standard.	See above	P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).		N
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		N

10	Information to be supplied by the manufacturer		P
10.1	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.	English	P
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on - application/limitations; - the meaning of any colour coding; - checks prior to use; - donning, fitting; - use; - maintenance (e.g. cleaning, disinfecting), if applicable; - storage; - the meaning of any symbols/pictograms used of the equipment.	See user manual See user manual	P
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Clearly considered	P
10.5	Warning shall be given against problems likely to be encountered, for example: - fit of particle filtering half mask (check prior to use); - It is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; - air quality (contaminants, oxygen deficiency); - use of equipment in explosive atmosphere.	See user manual	P
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P

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Attachments: test table

Table 8.5 Leakage test					P
Models Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Test subject walk (km/h)	5	5	5	5	5
Particle size distribution(um)	0.08-1.6	0.08-1.6	0.08-1.6	0.08-1.6	0.08-1.6
NaCl flow rate (L/min)	99-104	99-104	99-104	99-104	99-104
NaCl concentration before mask (mg/m3)	7.9-8.3	7.9-8.3	7.9-8.3	7.9-8.3	7.9-8.3
NaCl concentration after mask (mg/m3)	0.47	0.49	0.50	0.50	0.50

Note: Test ark volume is 2m³
Test result total inward Leakage is 6.2%<11%

Table 8.9-1 Inhalation breathing resistance test at 30 L/min					P
Models Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	30	30	30	30	30
Maximum resistance (mbar)	0.60	0.63	0.61	0.62	0.62

Note: Maximum permitted resistance <1.0 mbar

Table 8.9-2 Inhalation breathing resistance test at 95 L/min					P
Models Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	95	95	95	95	95
Maximum resistance (mbar)	1.90	1.94	1.92	1.92	1.91

Note: Maximum permitted resistance < 3.0 mbar

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Table 8.9-3 Exhalation breathing resistance test at 160 L/min					P
Models Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Exhalation (L/min)	160	160	160	160	160
Maximum resistance (mbar)	2.19	2.18	2.20	2.11	2.14

Note: Maximum permitted resistance < 3.0 mbar

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Appendix Photo documentation

Photo 1

View:

- [√] front
- [] rear
- [] right side
- [] left side
- [] top
- [] bottom
- [] internal

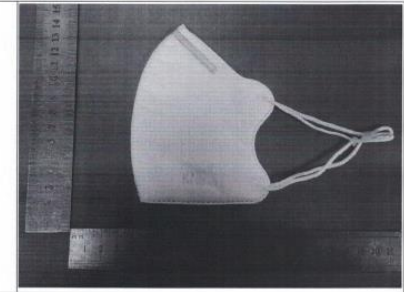
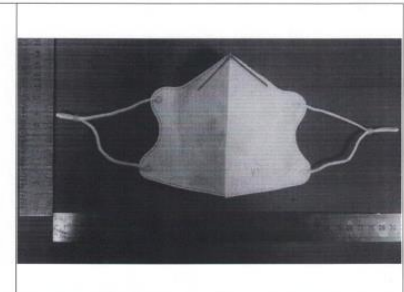


Photo 2

View:

- [] front
- [√] rear
- [] right side
- [] left side
- [] top
- [] bottom
- [] internal



***** End of this report *****

Factory License

医疗器械生产许可证	
许可证编号: [REDACTED]	
企业名称: [REDACTED]	生产地址: [REDACTED]
法定代表人: [REDACTED]	生产范围: 见医疗器械生产产品登记表
企业负责人: [REDACTED]	
住 所: [REDACTED]	发证部门: 江苏省食品药品监督管理局
有效期限: 至 2022 年 09 月 03 日	发证日期: 2017 年 09 月 04 日

国家食品药品监督管理总局制

Production Environment

