95+ ™

9511
Face Mask

KN95/FFP2 *NON-MEDICAL FACE MASK*

PM 0.3 ***FILTER EFFICIENCY ≥ 99%***

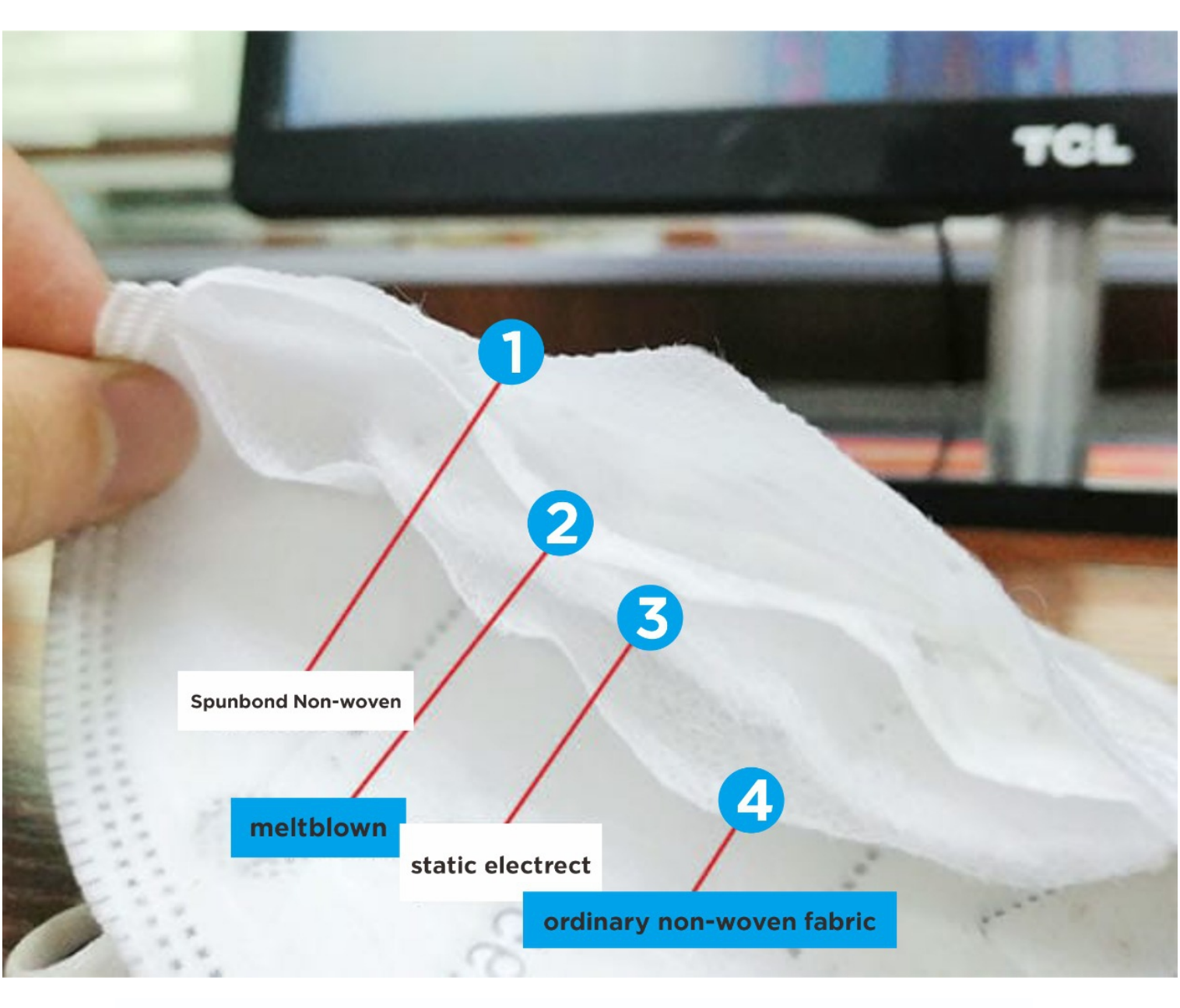
CERTIFICATE **FDA/CE**

LAB TEST REPORT : **KN95/FFP2/N95**

MANUFACTURE : **95 PLUS SG (SINGAPORE)**

FACTORY : **CHINA, VIETNAM, MALAYSIA, HONGKONG**

Product Preview



Product Picture

Model

Plastic Bag & Mask

Color Box

Carton Size :
10bags/1000pcs, 40box
66cmx42cmx52cm
15kg

Certificate

Certificate – Сертификат – 證明書 – 증명서 – شهادة

Certificate of Compliance

No. 3P200326G.PSP0U31

ENTE CERTIFICAZIONE MACCHINE – ECM – let's be your partner

Certificate's Holder:	95 Plus SG Pte. Ltd #14-06, 101 Cecil Street, Tong Eng Building, Singapore 069533
Certification ECM Mark:	European Conformity – Type Approved ®
Product:	Air Pollution Mask
Model(s):	9511
Verification to:	Standard: EN 149:2001+A1: 2009 related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

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

Additional information and clarification about the Marking

CE

The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 26 March 2020

Expiry date: 25 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

FDA Registration Certificate
FDA
Fiscal Year 2020

95 PLUS SG PTE. LTD.
#14-06, 101 CECIL STREET,TONG ENG BUILDING SINGAPORE,
CENTRAL SINGAPORE, 069533

Registration No: 3016678041

Owner/Operator No: 10062951

Device Listing:

Listing No.	Code No.	Device Name	Proprietary Name	Model
D374950	LYU	ACCESSORY SURGICAL APPAREL	Air Pollution Mask	9511

Issue Date: Mar 14, 2020.
Expire Date: Dec 31, 2020

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

Test Report

国检检测 CHINA COMPONENTS TEST

Test Report

(2020) WSZ FHL NO. 2125

Product Name: Civil protective mask

Applicant: 95 PLUS SG PTE. LTD

Manufacturer: —

Test Type: Entrusted inspection

Jiangsu Guojian Testing Technology Co.,Ltd

江苏国健检测技术有限公司 检验专用章

Test Report

[2020] WSZ FHL NO.2125 Page 1 of 2

Product name	Civil protective mask	Specification	9511
		Brand	—
Applicant/Add/Tel	95 PLUS SG PTE.LTD/101 CECIL STREET #14-06 TONG ENG BUILDING SINGAPORE (069533) /18621799048		
Manufacturer/Add/Tel	—/—/—		
Sample grade	N95	Sample number	GW 2125-2020
Sample quantity	30 pcs	Receiving date of sample	14/03/2020
Test type	Entrusted test	Batch number/Article number	—
Test date	14/03/2020~15/03/2020	Test site	Testing room
Sample state	Comply with standard requirements		
Test standard(s)	NIOSH 42 CFR Part 84 Subpart K Non-Powered Air-Purifying Particulate Respirators		
Test items	Filter efficiency		
Test conclusion	The test item complies with NIOSH 42 CFR Part 84 Subpart K requirements. The detailed test results are shown on page 2. Issue date: 2020.3.23		
Note	Sample information is provided by the applicant; The test report of this certification is responsible only for the sample provided by the applicant.		

Approver: 苏 [signature] Reviewer: [signature] Tester: [signature]

Test Result

[2020] WSZ FHL NO.2125 Page 2 of 2

Number	Test item	Unit	Technical requirement	Test result	Single Item decision
1	Filter efficiency	—	N95: ≥95% (The test samples was preconditioned with 38℃, 85%RH for 25 hours.)	99.6%	Qualified
				99.8%	
				99.6%	
				99.7%	
				99.6%	
				99.5%	
				99.6%	
				99.7%	
				99.7%	
				99.6%	
				99.7%	
				99.7%	
				99.6%	
				99.6%	
				99.7%	
				99.6%	
				99.8%	
				99.8%	
				99.8%	
				99.7%	
Note					

The End

Technical Construction File

File No：3P200326G.PSP0U31

Type of Equipment:	95 Plus SG Pte. Ltd
Product Name:	Air Pollution Mask
Model No.:	9511
Issued Date:	March 26, 2020
Brand Name/Trade mark	/
Directive(S)	Equipment Regulation (EU) 2016/425
Harmonized Standards:	EN 149: 2001+A1:2009

CE

Prepared for:

95 Plus SG Pte. Ltd
#14-06, 101 Cecil Street, Tong Eng Building, Singapore 069533

Content

Part I: General

1. Declaration of Conformity

Manufacturer: 95 Plus SG Pte. Ltd
#14-06, 101 Cecil Street, Tong Eng Building, Singapore 069533
European Representative:
Product Name: Air Pollution Mask

Model Number: 9511

RISK CATEGORIES: Category I

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

DIRECTIVES

General applicable directives:
Personal Protective Equipment Regulation (EU) 2016/425

Standard Applied:

EN 149: 2001+A1:2009

2.0 General description

2.1 Overview our product

See Manual

2.**2 Classification**
RISK CATEGORIES: Category I

Regulations

- Personal Protective Equipment Regulation: (EU) 2016/425

2.3 Device Labeling

Product name: Air Pollution Mask
Model: 9511
EN 149:2001+A1:2009 FFP2 NR D
95 Plus SG Pte. Ltd
#14-06, 101 Cecil Street, Tong Eng Building, Singapore 069533
Manufactured date: March. 2020 MADE IN CHINA
CE

Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

Symbol for "CE"

Symbol for "KEEP DRY"

Symbol for "KEEP AWAY FROM SUNLIGHT"

Please see detailed mark on the product and package.
Label sample and instruction manual in English

3.0 Quality control system

In order to ensure the conformity of the series production, Our company has taken the related procedures mentioned below:

(1)The complete technical construction file（TCF）have been established before applying for the CE marking certificate.

（2） Carry out the inspection for parts and components according to the TCF
Before the assemblies of the series production, the QC engineers has to check and inspect the technical specifications and intended functions of parts and components to ensure the correct use of them according to the contents of TCF and principle described in the related technical information.

（3） Carry out the inspection ＆ testing for the products before packing
Before packing the products, the QC engineers have to do the necessary inspection and testing to ensure the conformity of related requirements. In particular, they should do the testing and inspection of electrical characteristics and outer feature.

（4） Carry out the inspection for the package.
After finishing the necessary inspection and testing for the products, an inspection for the packing has to be done to ensure the necessary elements being included in this packing before shipment.

（5） Provision for the change of design
Any change of the products described in this TCF must be checked in detail and written down again in the TCF by the designer if the change may effects the related characteristics of product.

4.0 List of applicable regulations and standards

No.	File No.	Version	File Title
1	EN 149	2001	Respiratory protective devices — Filtering half masks to protect against particles —Requirements, testing, marking

EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
5	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	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner: Particle filtering half mask EN 149, year of publication, 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
7.2	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of ± 5 %. Unless otherwise specified, the ambient temperature for testing shall be (16 - 32) °C, and the temperature limits shall be subject to an accuracy of ± 1 °C		P
7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance test		P
7.4	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests		P

EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
7.5	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask is mounted on a Sheffield dummy head. For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head. The air shall be saturated at (37±2) °C at the mouth of the dummy head. In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be inclined so that the water runs away from the mouth and is collected in a trap. Expose the particle filtering half masks to the following thermal cycle: a) for 24 h to a dry atmosphere of (70±3) °C; b) for 24 h to a temperature of (-30±3)°C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning shall be carried out in a manner which ensures that no thermal shock occurs.	Melt blown filter	P
7.6	If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. Testing shall be done in accordance with 8.11		P

EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
7.7	Walking test The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min. Work simulation test The individual activities shall be arranged so that sufficient time is left for the comments prescribed. a) walking on the level with headroom of (1,3 ± 0,2) m for 5 min; b) crawling on the level with headroom of (0,70 ± 0,05) m for 5 min; c) filling a small basket (see Figure 1, approximate volume = 8 l) with chippings or other suitable material from a hopper which stands 1,5 m high and has an opening at the bottom to allow the contents to be shovelled out and a further opening at the top where the basket full of chippings is returned The subject shall stoop or kneel as he wishes and fill the basket with chippings. He shall then lift the basket and empty the contents back into the hopper. This shall be done 20 times in 10 min	The particle filtering half mask could undergo practical performance tests under realistic conditions	P
7.8	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. Testing shall be done in accordance with 8.2.	No sharp edges and burrs	P

EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
7.9.1	1) walking for 2 min without head movement or talking; 2) turning head from side to side (approx. 15 times), as if inspecting the walls of a tunnel for 2 min; 3) moving the head up and down (approx. 15 times), as if inspecting the roof and floor for 2 min; 4) reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min; 5) walking for 2 min without head movement or talking. The leakage P shall be calculated from measurements made over the last 100s of each of the exercise periods to avoid carry over of results from one exercise to the other. $P(\%)=\frac{C_2}{C_1}\times\left(\frac{t_{IN}+t_{EX}}{t_{IN}}\right)\times 100$ where C 1 is the challenge concentration C 2 is the measured mean concentration in the breathing zone of the test subject tIN is the total duration of inhalation t EX is the total duration of exhalation	Total inward leakage is 9%	
7.9.2	The device shall be mounted in a leaktight manner on a suitable adaptor and subjected to the test(s) ensuring that components of the device that could affect filter penetration values such as valves and harness attachment points are exposed to the challenge aerosol. Testing of penetration, exposure and storage shall be done in accordance with EN13274-7. The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	The penetration of paraffin oil test is 4 % The penetration of sodium chloride test is 3.3%	P

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

Clause	Requirement – Test	Result - Remark	Verdict
7.10	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Inner and out layer : Nonwoven pet fabric	P

EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
7.11	The facepiece is put on a metallic dummy head which is motorized such that it describes a horizontal circle with a linear speed, measured at the tip of the nose, of (60 ± 5) mm/s The head is arranged to pass over a propane burner the position of which can be adjusted. By means of a suitable gauge, the distance between the top of the burner, and the lowest part of the facepiece (when positioned directly over the burner) shall be set to (20 ± 2) mm. With the head turned away from the area adjacent to the burner, the propane gas is turned on, the pressure adjusted to between 0,2 bar and 0,3 bar and the gas ignited. By means of a needle valve and fine adjustments to the supply pressure, the flame heigt shall be set to (40 ± 4) mm. This is measured with a suitable gauge. The temperature of the flame measured at a height of (20 ± 2) mm above the burner tip by means of a 1,5 mm diameter mineral insulated thermocouple probe, shall be (800 ± 50) °C The head is set in motion and the effect of passing the facepiece once through the flame shall be noted. The test shall be repeated to enable an assessment to be made of all materials on the exterior of the device. Any one component shall be passed through the flame once only	The particle filtering half mask does not to continue to burn for more than 5 s after removal from the flame.	P

EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
7.12	For this test the particle filtering half mask shall be fitted securely in a leak-tight manner but without deformation to a Sheffield dummy head (see Figure 6) Air shall be supplied to it from a breathing machine adjusted to 25 cycles/min and 2,0 l/stroke and the exhaled air shall have a carbon dioxide content of 5 % by volume The CO_2 is fed into the breathing machine via a control valve, a flowmeter, a compensating bag and two-non-return valves. Immediately before the solenoid valve a small quantity of exhaled air is preferably continuously withdrawn through a sampling line and then fed into the exhaled air via a CO_2 analyser. To measure the CO 2 content of the inhaled air, 5 % of the stroke volume of the inhalation phase of the breathing machine is drawn off at the marked place by an auxiliary lung and fed to a CO 2 analyser. The total dead space of the gas path (excluding the breathing machine) of the test installation should not exceed 2000 ml Measure the carbon dioxide content of the inhaled air and record continuously.	The carbon dioxide content of the inhalation air (dead space).does not exceed an average of 1,0%	P
7.13	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device		P
7.14	The field of vision is acceptable if determined so in practical performance tests		N/A
7.15	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations 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 When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s		P

EN 149:2001+A1:2009

Clause	Requirement – Test	Result - Remark	Verdict
7.16	Seal the particle filtering half mask on the Sheffield dummy head. Measure the exhalation resistance at the opening for mouth of the dummy head using the adapter shown in Figure 6 and a breathing machine adjusted to 25 cycles/min and 2.0 l/stroke or a continous flow 160 l/min. Use a suitable pressure transducer. Measure the exhalation resistance with the dummy head successively placed in 5 defined positions: - facing directly ahead - facing vertically upwards - facing vertically downwards - lying on the left side - lying on the right side Test the inhalation resistance at 30 l/min and 95 l/min continuous flow The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.	Inhalation resistance at 30 1/min:<0.7mbar.Inhalation resistance at 95 min:<2.4mbar. Exhalation resistance at 160 1/min: <3.0mbar.	P

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Clause	Requirement – Test	Result - Remark	Verdict
7.17	Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m^3 /h. Fit the sample particle filtering half mask in a leaktight manner to a dummy head or a suitable filter holder located in the dust chamber. Connect the breathing machine and humidifier to the sample and operate for the specified testing time The concentration of dust in the test chamber may be measured by drawing air at 2 l/min through a sampling probe equipped with a pre-weighed, high efficiency filter (open face, diameter 37 mm) located near the test sample, as shown in Figure 10 Calculate the dust concentration from the weight of dust collected, the flow rate through the filter and the time of collection		N/A

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File No：3P200326G.PSP0U31

EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
7.18	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand		N/A
9.1	9.1 Packaging The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent. 9.1.1 The name, trademark or other means of identification of the manufacturer or supplier. 9.1.2 Type-identifying marking. 9.1.3 Classification The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. 9.1.4 The number and year of publication of this European Standard 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 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. 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. 9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". ! This letter shall follow the classification marking preceded by a single space.	FFP2 NR D	P

95 Plus SG Pte. Ltd
Address: #14-06, 101 Cecil Street, Tong Eng Building, Singapore 069533

File No：3P200326G.PSP0U31

Production Photos

EC DECLARATION OF CONFORMITY

MANUFACTURER	95 Plus SG Pte. Ltd #14-06, 101 Cecil Street, Tong Eng Building, Singapore 069533
The undersigned Company certifies under its sole responsibility that the item of equipment specified below satisfies the requirements of the 2016/425/EU which is apply to it. The item of equipment identified below has been subject to internal manufacturing checks with monitoring of the final assessment by 95 Plus SG Pte. Ltd	
PRODUCT	Air Pollution Mask
MODEL / TYPE	9511
DIRECTIVES 2016/425/EU	
Regulations Applied acc. to HARMONIZE STANDARDS EN 149:2001+A1:2009	
Place and date of issue	: Singapore 2020/04/02
Name and position of authorized person	: Yu Jingjia Director
Singanature of authorized person	: [signature]

171021110579

中国认可
国际互认
检测
TESTING
CNAS L7901

STFWT20202728

Product Name Civil protective mask

Trust Unit 95 PLUS SG PTE LTD.

Test Category Entrusted sample inspection

Test Report

STFWT20202728

防伪查询
共 2 页 第 1 页
Page 1 of 2

Product Name	Civil protective mask	Specification Type	9511
		Trademark	95+
Trust Unit	95 PLUS SG PTE.LED.	Tel	18621799048
Manufacturer	/	Sample Grade	KN95
Sample Quantity	30	Sample Receiving Date	2020-03-03
Test Category	Entrusted sample inspection	Serial Number	——
Samples Conditions	Compliance with test requirements		
Document and Decide Accordance	GB 2626-2006 [Respiratory protective equipment--Non-powered air-purifying particle respirator]		
Test Conclusion	The samples have been tested and the items inspected meet the KN95 requirements of GB 2626-2006. Date of issue: 2020-03-06		
Remarks	The client requires the sample to be filtered without pretreatment. The inspection conclusions of this report are only drawn for the inspected items, and do not mean that the untested items or functions meet the requirements. This report is only responsible for incoming samples。		

批 准：Approver [signature] 审 核：Examiner [signature] 主 检：Majortester [signature]

Testing Results

STFWT20202728

Page 2 of 2

Serial	Test Items	Unit	Requirement	Results				Individual Judgment
				试样编号		实测值		
1	Filtration efficiency /%(NaCl particulate matter)	——	KN95：≥95.0	Without pretreatment	1#	Initial	99.9	合 格
						Loading	99.2	
					2#	Initial	99.8	
						Loading	99.1	
					3#	Initial	99.8	
						Loading	99.2	
					4#	Initial	99.7	
						Loading	99.0	
					5#	Initial	99.7	
						Loading	99.1	
					6#	Initial	99.8	
						Loading	99.2	
					7#	Initial	99.8	
						Loading	99.0	
					8#	Initial	99.8	
						Loading	99.1	
					9#	Initial	99.8	
						Loading	99.0	
					10#	Initial	99.8	
						Loading	99.1	

The product picture

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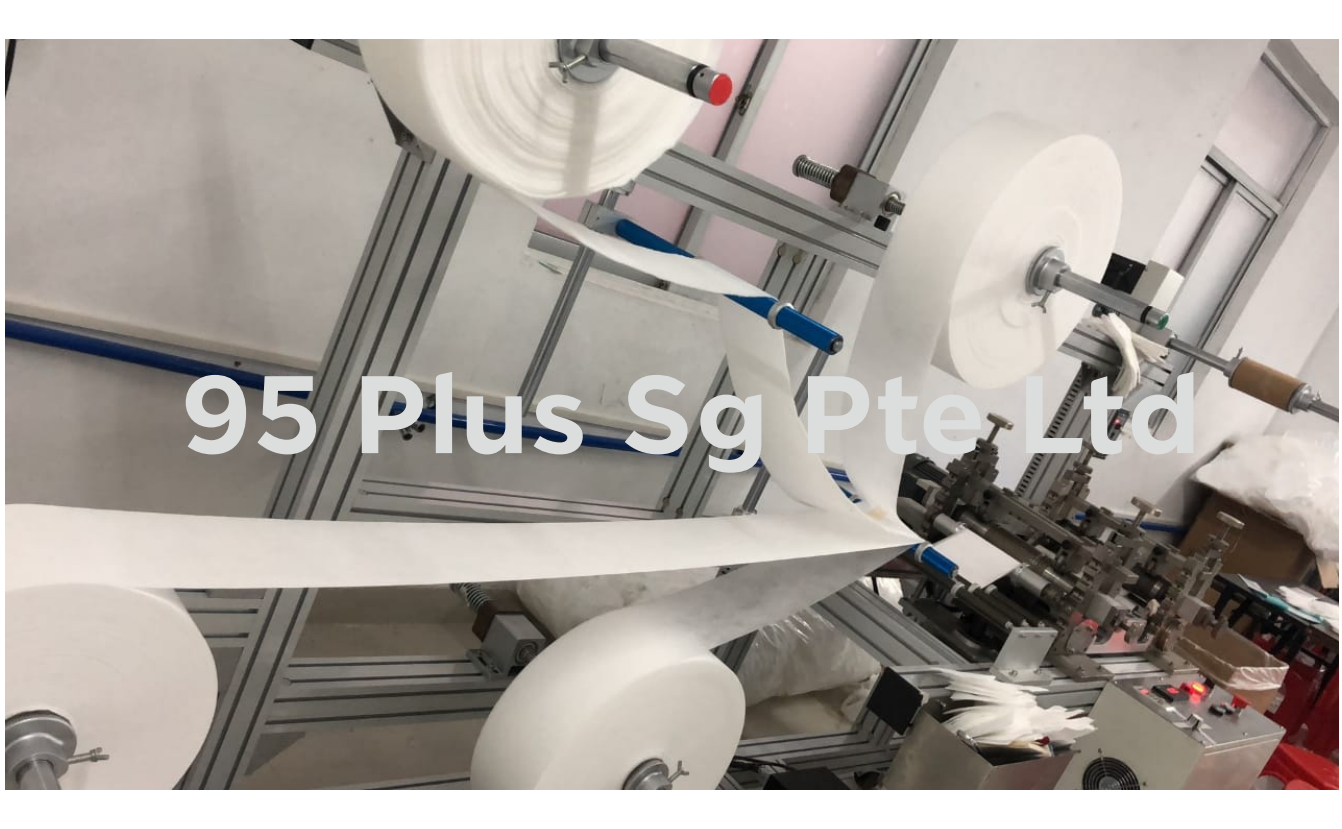
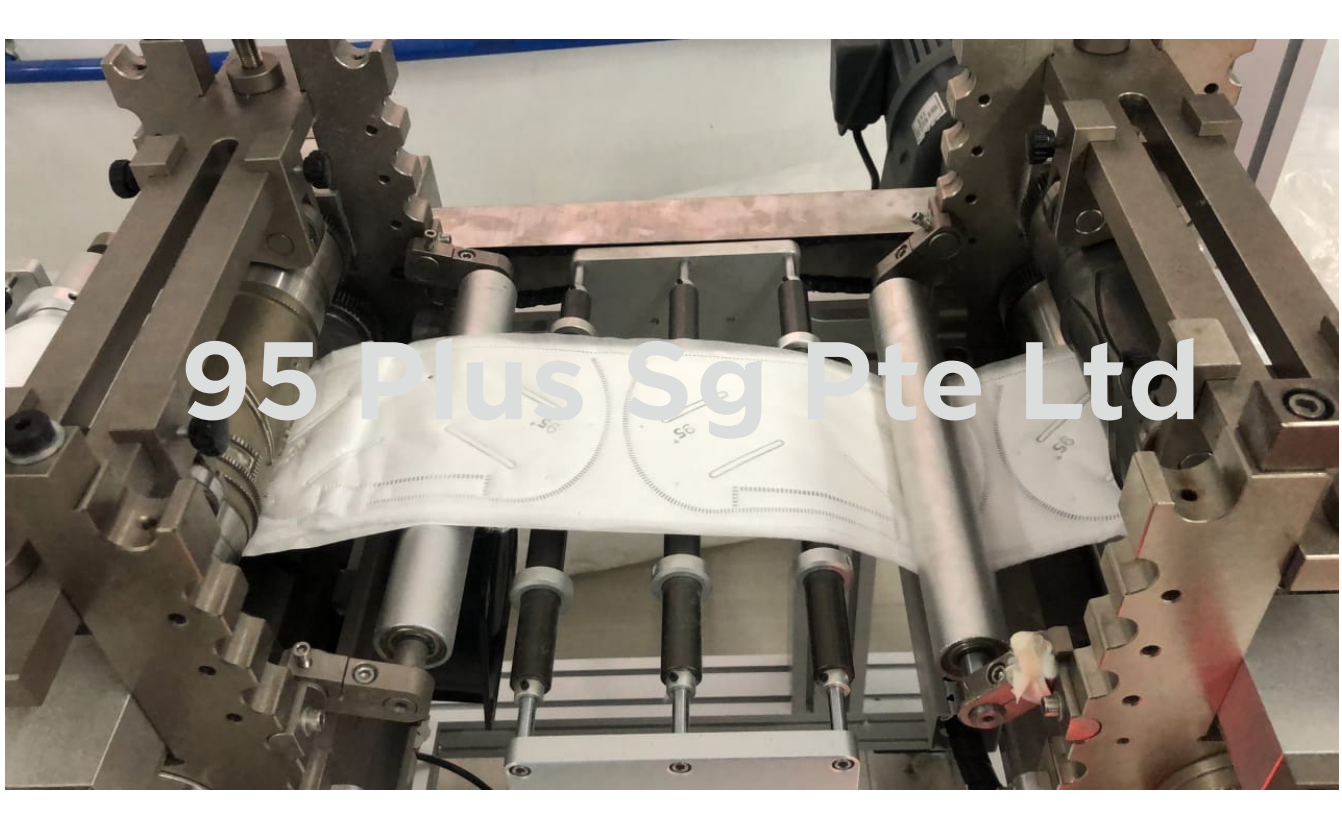
Factory Gallery





Global Stock

Holland

France

Italy

USA

Q & A

Are 95PLUS 9511 masks suitable for COVID-19 defenses :

- *Suitable, 95PLUS 9511 masks have passed China's Kn95 test, passed the European Union's En149 test, meet the FFP2 filter standard, and also passed the N95 filter standard test. PM0.3 has a filtration efficiency of >95%, which is completely suitable for COVID-19 for epidemic prevention.*

Can 95PLUS 9511 masks be used in hospitals?

- *Can be used in a non-operating room environment, but not suitable for use in an operating room.*
- *According to the KN95 and N95 test report data of 95PLUS 9511 masks, the PM0.3 filtration efficiency of this model is ≥99%, which has reached the levels of KN100 and FFP3. It has a particularly suitable for follow-up Use in groups with deep patient contact, such as nurses, consultation doctors, logistic staff, etc.*
- *However, because the 9511 mask is not sterilized, and it is not spray-proof, it is not suitable for use in the operating room of a hospital*