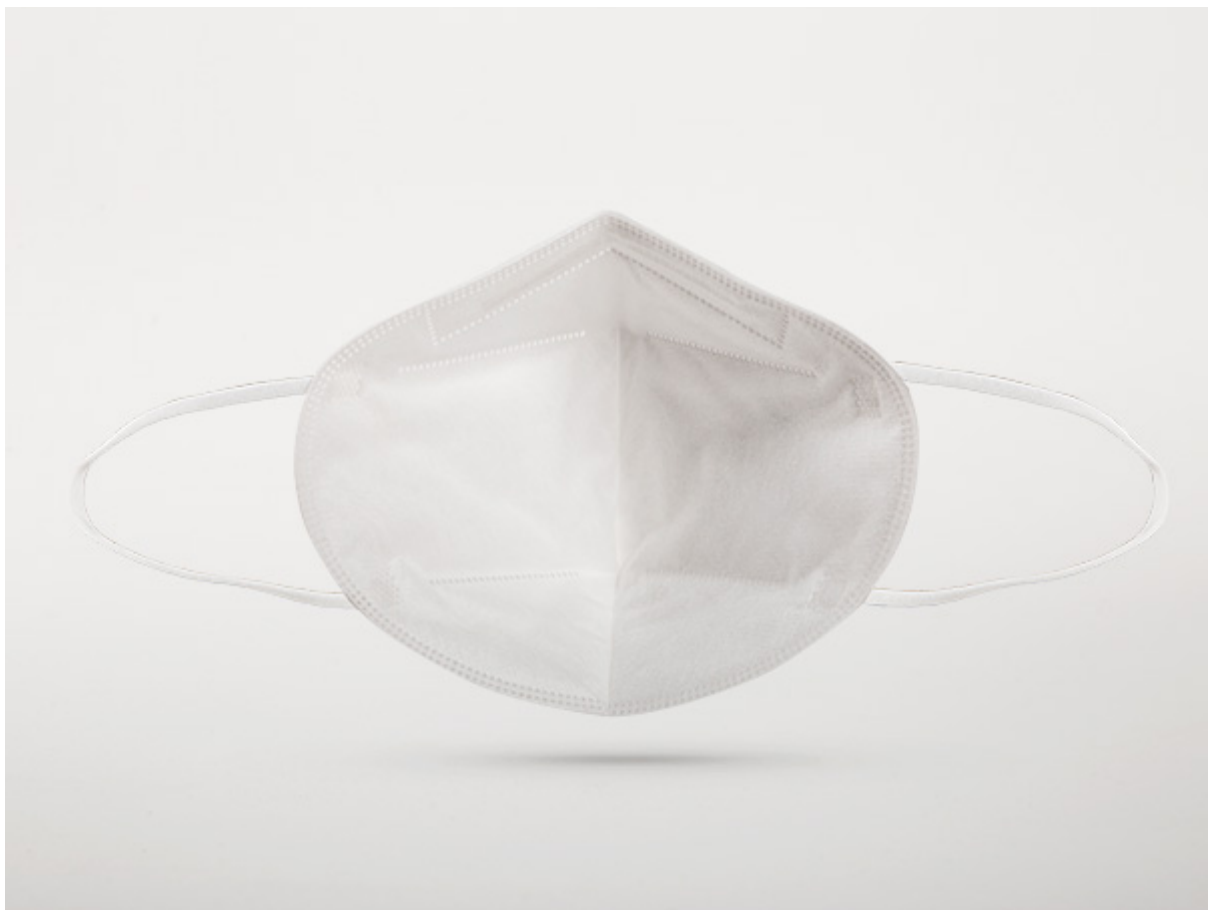


MedRhein FFP2 CE 0598 Ohrschlaufen





EU-Konformitätserklärung für eine PSA der Kategorie III

TongCheng Zhengheng Protective products Co.,Ltd
Jingsi Road,Tongcheng Economic and Technological Development Zone,Tongcheng
City, Anqing, Anhui, China.
Email: zhmask@163.com

Wir als Hersteller erklären hiermit, dass das nachstehend beschriebene Produkt
Artikel-Nr.: 9501A

Bezeichnung: Atemschutzmaske FFP2

mit den folgenden harmonisierten Normen übereinstimmt:

EN149:2001 +A1:2009

Dieses Produkt entspricht der PSA-Verordnung (EU) 2016 / 425 und ist mit der PSA
identisch, für die die

Prüfnummer: CN20/42532, FI20/967071

von der notifizierten Stelle:

SGS Fimko Oy

Takomotie 8, FI-00380 Helsinki, Finland.

Notified Body 0598

ausgestellt wurde.

Dieses Produkt unterliegt dem Konformitätsbewertungsverfahren gemäß Modul C2
unter Überwachung der notifizierten Stelle.

SGS Fimko Oy

Takomotie 8, FI-00380 Helsinki, Finland.

Notified Body 0598

Unterzeichnet im Namen des Unternehmens

Name: Lu Jindun

Position: Manager



Unterschrift: 

Datum: 2020.11.15



Certificate CN20/42532

The management system of

TongCheng Zhengheng Protective Products Co, Ltd.

Jingsi Road, Tongcheng Economic and Technological Development Zone,
Tongcheng City,
Anqing, Anhui,
China.

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425 Module C2

For the following activities

Manufacture of XINZHENGHENG (logo) 9501A particle filtering half mask.

(Note: All products marked CE0598 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of Directive 89/686/EEC.)

This certificate is valid from 14 November 2020
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 14 November 2020

Authorised by

SGS FIMKO OY, Notified Body 0598

Takomatie 8, FI-00380 Helsinki, Finland
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FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)



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Certificate FI20/967071

TongCheng Zhengheng Protective Products Co, Ltd.

Jingsi Road, Tongcheng Economic and Technological Development Zone,
Tongcheng City,
Anqing, Anhui,
China.

It is certified that the manufacturer's technical file and the PPE product detailed on
page 2 have been assessed and found to be in accordance with

Regulation (EU) 2016/425 Module B, EU type-examination

This certificate is valid from 28 October 2020 until 28 October 2025
1. Certified since 28 October 2020

Authorised by



SGS FIMKO OY, Notified Body 0598

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**TongCheng Zhengheng
Protective Products Co, Ltd.**

Regulation (EU) 2016/425
Module B, EU type-examination

Issue 1

PPE Product

XINZHENGHENG (logo) 9501A particle filtering half mask, consisting of a five layer (Polypropylene/Hot air cotton) disposable face mask, with Polyolefins covered galvanized iron wire nose piece and Polyester/Spandex Ear straps.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149: 2001 +A1:2009 (Respiratory protective devices- filtering half masks to protect against particles) device classification: FFP2 NR.



This certificate is issued on strict condition that appropriate checks on manufactured PPE, as detailed in Article 19(c) of the regulation are implemented and maintained while the model is in production.

Certification is based on technical file reference:
Filtering half mask(non medical) 9501A, Dated 07.09.2020

SGS Reference Number UK/CRS 241922

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request



中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report

SL52035272492501TX

Date: July 09,2020

Page 1 of 10

TONGCHENG ZHENGHENG PROTECTIVE PRODUCTS CO.,LTD
JINGSI ROAD, TONGCHENG ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, TONGCHENG
CITY, ANQING, ANHUI, CHINA

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

Sample Description : (A) Filtering half mask (non-medical)
Sample color : White
Style No : 9501A
Country of Origin : CHINA
Country of Destination : EU

Sample Receiving Date : May 23, 2020
Testing Period : May 23, 2020 - Jul 09, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the
sample(s) tested, for further details, please refer to the following page(s).

Test Performed : Selected test(s) as requested by applicant

Conclusion:

Sample No.	Recommendation Level
(A)	FFP2 NR

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)



SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Testing Center-Head Office

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Test Result

Respiratory Protective Devices — Filtering Half Masks to Protect against Particles — Requirements,

Testing, Marking

(EN 149:2001+A1:2009)

Clause 7.4 Packaging

(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
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.	Comply	Pass

Clause 7.5 Material*

(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
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.	Comply	Pass
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.	Comply	
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	

Clause 7.6 Cleaning and Disinfecting*

(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
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. 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.	Not applicable (Not designed to be re-usable)	N.A.

Clause 7.7 Practical Performance*

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass

Clause 7.8 Finish of Parts

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass



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Clause 7.9.1 Total Inward Leakage*

(EN 149:2001+A1:2009, Clause 8.5)

Test Requirement	Results	Comment
<p>The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3</p> <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</p>	Detail refer to Appendix 1	Meet FFP1 Meet FFP2

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
1#	1	A.R.	6.0	6.3	5.0	6.7	6.9	6.2
2#	2	A.R.	5.3	6.4	4.8	6.1	6.6	5.8
3#	3	A.R.	6.2	6.8	5.6	7.1	7.3	6.6
4#	4	A.R.	4.9	6.3	4.7	6.4	7.5	6.0
5#	5	A.R.	5.9	5.2	5.2	6.5	7.0	6.0
6#	6	T.C.	5.8	6.2	5.0	6.9	6.6	6.1
7#	7	T.C.	5.6	5.9	4.8	6.4	6.7	5.9
8#	8	T.C.	6.1	6.3	5.2	6.6	6.9	6.2
9#	9	T.C.	5.4	5.9	4.8	6.2	6.5	5.8
10#	10	T.C.	6.4	6.7	5.5	7.1	7.5	6.6

Facial Dimension

Subject	Face length(mm)	Face Width(mm)	Face Depth(mm)	Mouth Width(mm)
1#	120	130	109	59
2#	122	140	115	65
3#	119	160	139	55
4#	112	122	119	63
5#	110	130	118	60
6#	115	119	110	59
7#	112	123	113	55
8#	103	130	100	50
9#	118	139	130	63
10#	120	135	125	50



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Clause 7.9.2 Penetration of Filter Material*

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

Test Requirement	Results	Comment																	
<p>The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.</p> <table border="1"> <tr> <th rowspan="2">Classification</th><th colspan="2">Maximum penetration of test aerosol</th></tr> <tr> <th>Sodium chloride test 95 l/min</th><th>Paraffin oil test 95 l/min</th></tr> <tr> <td></td><td>% max.</td><td>% max.</td></tr> <tr> <td>FFP1</td><td>20</td><td>20</td></tr> <tr> <td>FFP2</td><td>6</td><td>6</td></tr> <tr> <td>FFP3</td><td>1</td><td>1</td></tr> </table>	Classification	Maximum penetration of test aerosol		Sodium chloride test 95 l/min	Paraffin oil test 95 l/min		% max.	% max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	Detail refer to Appendix 2	Meet FFP1 Meet FFP2
Classification		Maximum penetration of test aerosol																	
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min																	
	% max.	% max.																	
FFP1	20	20																	
FFP2	6	6																	
FFP3	1	1																	

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	1	0.5
		2	0.6
		3	0.5
	Simulated wearing treatment	4	0.6
		5	0.5
		6	0.7
	Mechanical strength +Temperature conditioned	7	1.6
		8	1.7
		9	1.7
Paraffin oil test	As received	10	1.2
		11	1.1
		12	1.2
	Simulated wearing treatment	13	1.1
		14	1.2
		15	1.3
	Mechanical strength +Temperature conditioned	16	2.7
		17	2.5
		18	2.7

Flow conditioning : Single filter: 95.0 L/min


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Clause 7.10 Compatibility with Skin*

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
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.	No irritation or any other adverse effect to health	Pass

Clause 7.11 Flammability*

(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result
As received	1	Burn for 0.1s
	2	Burn for 0.1s
Temperature conditioned	3	Burn for 0.1s
	4	Burn for 0.1s

Clause 7.12 Carbon Dioxide Content of The Inhalation Air*

(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result
As received	1	0.7124%
	2	0.7130%
	3	0.7121%
		Mean value :0.71%



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Clause 7.13 Head Harness*

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	Pass
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.	Comply	

Clause 7.14 Field of Vision *

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

Clause 7.15 Exhalation Valve(s)*

(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
(a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Not applicable due to exhalation valve	N.A
(b) 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.	Not applicable due to exhalation valve	
(c) 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.	Not applicable due to exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to exhalation valve	


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Clause 7.16 Breathing Resistance*

(EN 149:2001+A1:2009, Clause 8.9)

Test Requirement	Results	Comment																						
<p>The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.</p> <table><tr><th rowspan="3">Classification</th><th colspan="3">Maximum permitted resistance (mbar)</th></tr><tr><th colspan="2">Inhalation</th><th>Exhalation</th></tr><tr><th>30 l/min</th><th>95 l/min</th><th>160 l/min</th></tr><tr><td>FFP1</td><td>0.6</td><td>2.1</td><td>3.0</td></tr><tr><td>FFP2</td><td>0.7</td><td>2.4</td><td>3.0</td></tr><tr><td>FFP3</td><td>1.0</td><td>3.0</td><td>3.0</td></tr></table>	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	<p>Detail refer to Appendix 5</p>	<p>Meet FFP1 Meet FFP2 Meet FFP3</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																					

Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

As received	Flow rate		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.2	0.3	0.2	0.2	0.3	0.2	0.2	0.3	0.2	0.2	0.3	0.2	0.2	0.3	0.2
		95 l/min	0.7	0.7	0.8	0.7	0.8	0.7	0.8	0.7	0.7	0.7	0.8	0.7	0.7	0.8	0.7
	Exhalation	160 l/min	1.4	1.4	1.3	1.4	1.4	1.4	1.3	1.4	1.4	1.3	1.3	1.4	1.4	1.3	1.4
Simulated wearing treatment	Flow rate		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.3	0.2	0.2	0.2	0.3	0.2	0.2	0.3	0.2	0.2	0.2	0.3	0.2	0.3	0.2
		95 l/min	0.7	0.8	0.7	0.7	0.8	0.8	0.7	0.7	0.8	0.7	0.7	0.7	0.8	0.7	0.7
	Exhalation	160 l/min	1.4	1.3	1.4	1.4	1.3	1.3	1.4	1.4	1.3	1.4	1.4	1.4	1.3	1.4	1.4
Temperature conditioned	Flow rate		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.2	0.2	0.3	0.2	0.2	0.3	0.3	0.2	0.2	0.3	0.2	0.2	0.2	0.3	0.2
		95 l/min	0.7	0.7	0.8	0.7	0.7	0.8	0.8	0.7	0.7	0.8	0.7	0.7	0.7	0.8	0.7
	Exhalation	160 l/min	1.3	1.4	1.4	1.3	1.4	1.4	1.4	1.3	1.4	1.4	1.4	1.3	1.4	1.4	1.3

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side



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Clause 7.17 Clogging*

(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

Test Requirement	Results	Comment																			
<p>Clause 7.17.2 Breathing resistance</p> <p>Valved particle filtering half masks:</p> <p>After clogging the inhalation resistances shall not exceed: FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow</p> <p>The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow.</p> <p>Valveless particle filtering half masks:</p> <p>After clogging the inhalation and exhalation resistances shall not exceed: FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow</p>	Optional for single shift device only	N.A																			
<p>Clause 7.17.3 Penetration of filter material</p> <p>All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.</p> <table border="1"> <thead> <tr> <th rowspan="3">Classification</th><th colspan="2">Maximum penetration of test aerosol</th></tr> <tr> <th>Sodium chloride test 95 l/min</th><th>Paraffin oil test 95 l/min</th></tr> <tr> <th>%</th><th>%</th></tr> </thead> <tbody> <tr> <td></td><td>max.</td><td>max.</td></tr> <tr> <td>FFP1</td><td>20</td><td>20</td></tr> <tr> <td>FFP2</td><td>6</td><td>6</td></tr> <tr> <td>FFP3</td><td>1</td><td>1</td></tr> </tbody> </table>	Classification	Maximum penetration of test aerosol		Sodium chloride test 95 l/min	Paraffin oil test 95 l/min	%	%		max.	max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	Optional for single shift device only	N.A
Classification		Maximum penetration of test aerosol																			
		Sodium chloride test 95 l/min	Paraffin oil test 95 l/min																		
	%	%																			
	max.	max.																			
FFP1	20	20																			
FFP2	6	6																			
FFP3	1	1																			

Clause 7.18 Demountable Parts

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	No demountable parts	N.A.

Test	Uncertainty
Total inward leakage	2.98%
Penetration of filter material	1.00%
Flammability	1.00%
Carbon dioxide content of the inhalation air	0.93%
Breathing resistance	1.90%

*: This test standard is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L10118.



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Sample Photo



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End of Report



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EU DECLARATION OF CONFORMITY

Manufacturer

Name: TongCheng Zhengheng Protective products Co.,Ltd

Address:Jingsi Road,Tongcheng Economic and Technological Development Zone,Tongcheng

City,Anqing,Anhui,China.

declares that the new PPE described hereafter

Description of products	Filtering half mask (Non-Medical)
Products Colour	White
Product style/order No	9501A
Product Type	Non-reusable, folded, particle filtering half mask

are in conformity with the Regulation (EU) 2016/425 and with harmonized standard EN 149:2001 + A1:2009

SGS Fimko Oy

Takomotie 8, FI-00380 Helsinki, Finland

Notified Body No. 0598

performed the EU type-examination (Module B) and issued the EU type-examination certificate

FI20/967071

The PPE is subject to the conformity assessment procedure either conformity to type based on

internal production, control plus supervised product checks at random intervals (Module C2)

under surveillance of the notified body SGS Fimko Oy, Notified Body No. 0598.

Signed for on behalf of Company

Name: Lu Jindun

Position: Manager

Signature:

Date: 2020.11.15

