



Declaration of Conformity

Certificate No.: WUX202003030600SC

Applicant: ZHANGJIAGANG ZHENYUAN GARMENT CO., LTD

Address: qinfeng jincun village tangqiao town zhangjiagang city jiangsu province china

Manufacturer: ZHANGJIAGANG ZHENYUAN GARMENT CO., LTD

Address: qinfeng jincun village tangqiao town zhangjiagang city jiangsu province china

Product Name: disposable mask

Model No.: 172*90mm

Trade Mark: /

Type: FFP2 NR

Test Standard: EN 149:2001+A1:2009

Test Report Number(s): WUX202003030600SC

PPE directive (EU) 2016/425

Remarks:
The CE markings as shown below can be affixed on the product after preparation of necessary conformity documentation, as stipulated in article 10 of the Council Directive (EU) 2016/425.





Tony Bi
Technical Director



Shenzhen Huacetong Testing and Certification Co., Ltd.
 Building B, Xinbaosheng, No.233, Xixiang Street, Bao'an District, Shenzhen, China.
 Web: www.szcttlab.com Tel: 86-755-23592524 E-mail: ctt_lab@foxmail.com



Attestation of Conformity



No. ICR Polska/M83060920

Name and address of Registered Manufacturer:

Zhangjiagang City Zhenyuan Garment Co., Ltd
 Jincun Village, Tangqiao Town, Zhangjiagang City, Jiangsu Province, China

Product name:

Disposable Protective Mask

Product type/model:

172*90

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive: Medical Device Directive 93/42/EEC

Conformity assessment procedure: EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)

Classification: Class I according Rule 1 of Annex IX of Directive 93/42/EEC

Applied normative documents: EN 14683:2019

Applied Quality Management System: EN ISO 13485:2016

This Attestation of Conformity will remain valid only if Quality Management System Certificate remains valid and the surveillance audits are conducted.
 The assessment 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 Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

No. of test report: JAT-20(03)B073-MDD

Issue date: 18.03.2020

Expiration date: 17.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-8360.

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





Director: Rafał Kalinowski

Warsaw, 18. 03. 2020.



ICR Polska Co. Ltd.
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 www.icrpolska.com, e-mail: icrpolska@icrpqa.com



TEST REPORT	
EN 149	
Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking	
Report Number.....	WUX202003030600S
Test by (name+signature).....	Sally Liu
Compiled by (+signature).....	Lucy Ni
Approved by (+signature).....	Tony Bi
Date of issue.....	Mar. 21, 2020
Total number of pages.....	13 pages
Testing laboratory	Shenzhen Huacetong Testing and certification Co., Ltd.
Address	Building B, Xinbaosheng, No.233, Xixiang Street, Bao'an District, Shenzhen, China
Testing location	As above
Applicant's name.....	ZHANGJIAGANG ZHENYUAN GARMENT CO., LTD
Address.....	qinfeng jincun village tangqiao town zhangjiagang city jiangsu province china
Test specification:	
Standard.....	EN 149:2001+A1:2009
Test procedure.....	N/A
Non-standard test method.....	N/A
Test Report Form No.....	EN 149
Test Report Form(s) Originator.....	Huacetong
Master TRF.....	N/A
Test item description.....	disposable mask
/	
Manufacturer.....	ZHANGJIAGANG ZHENYUAN GARMENT CO., LTD
Address.....	qinfeng jincun village tangqiao town zhangjiagang city jiangsu province china
Model/Type reference.....	172*90mm

Summary of testing:	
Tests performed (name of test and test clause): - EN 149:2001+A1:2009 The submitted samples were found to comply with the requirements of above specification.	Testing location: Shenzhen Huacetong Testing and certification Co., Ltd. Building B, Xinbaosheng, No.233, Xixiang Street, Bao'an District, Shenzhen, China

Summary of testing:				
Tests performed (name of test and test clause):				Testing location:
EN 149				
7.2	Nominal values and tolerances	Applicable	Pass	1)
7.3	Visual inspection	Applicable	Pass	1)
7.4	Packaging	Applicable	Pass	1)
7.5	Material	Applicable	Pass	1)
7.6	Cleaning and disinfecting	Non-Applicable	N/A	1)
7.7	Practical performance	Applicable	Pass	1)
7.8	Finish of parts	Applicable	Pass	1)
7.9	Leakage	Applicable	Pass	1)
7.10	Compatibility with skin	Applicable	Pass	1)
7.11	Flammability	Applicable	Pass	1)
7.12	Carbon dioxide content of the inhalation air	Applicable	Pass	1)
7.13	Head harness	Applicable	Pass	1)
7.14	Field of vision	Applicable	Pass	1)
7.15	Exhalation valve(s)	Applicable	Pass	1)
7.16	Breathing resistance	Applicable	Pass	1)
7.17	Clogging	Non-Applicable	N/A	1)
7.18	Demountable parts	Non-Applicable	N/A	1)

Shenzhen Huacetong Testing and certification Co., Ltd.

Test item particulars.....:	
Temperature.....:	20°C
Relative humidity.....:	40-50%
Atmospheric pressure.....:	(9.0±0.2)kPa
Mass of the equipment (kg).....:	See instruction
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement.....:	P (Pass)
- test object does not meet the requirement.....:	F (Fail)
Testing.....:	
Date of receipt of test item.....:	Mar. 03, 2020
Date (s) of performance of tests.....:	Mar. 03, 2020 to Mar. 21, 2020

<p>General remarks:</p> <p>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.</p> <p>Throughout this report a <input checked="" type="checkbox"/> comma / <input type="checkbox"/> point is used as the decimal separator.</p> <p>Clause numbers between brackets refer to clauses in report</p> <p>Attachment No. 1: 1 pages of photo.</p> <p>General product information: The product is disposable mask, without valve, Non-reusable.</p>

EN149			
Clause(s)	Test(s)	Test Remarks	Result
4	Description		P
	A particle filtering half mask covers the nose and mouth and the chin and may have inhalation and/or exhalation valve.	Without valve	P
5	Classification		P
	FFP1, FFP2 and FFP3	FFP2	P
6	Designation		P
7	Requirements		N/A
7.1	General		P
	In all tests all test samples shall meet the requirements.		P
7.2	Nominal values and tolerances	25°C	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.	Closed plastic bag	P
7.5	Material	See 8.3.1, 8.3.2, 8.2	P
7.6	Cleaning and disinfecting		N/A
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.		P
7.8	Finish of parts	No sharp edges or burrs on mask	P
7.9	Leakage		P
	the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected.		P
	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		P


	25 % for FFP1 11 % for FFP2 5 % for FFP3	9.1%	P														
	at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than		P														
	22 % for FFP1 8 % for FFP2 2 % for FFP3	7.3%	P														
7.9.2	Penetration of filter material		P														
	Sodium chloride test, 95 l/min	5.5%, Test 9 samples	P														
	Paraffin oil test 95 l/min	5.1%, Test 9 samples	P														
	<table><tr><td rowspan="2">Classification</td><td colspan="2">C) Maximum penetration of test aerosol (%)</td></tr><tr><td>Sodium chloride test 95 l/min % max.</td><td>Paraffin oil test 95 l/min % 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	C) 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		
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FFP1	20	20															
FFP2	6	6															
FFP3	1	1															
7.10	Compatibility with skin		P														
	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.		P														
7.11	Flammability		P														
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.	<4.0s	P														
7.12	Carbon dioxide content of the inhalation air		P														
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	<0.69%	P														
7.13	Head harness		P														
	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Removed easily and donned, self-adjusting. Elastic rope fixing	P														
7.14	Field of vision		P														
	The field of vision is acceptable if determined so in practical performance tests.	Does not affect line of sight	P														
7.15	Exhalation valve(s)		N/A														
	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	No exhalation valve	N/A														

	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	>300 l/min Tensile force 10N, 10s No damaged, Function no change.	N/A																						
7.16	Breathing resistance		P																						
	The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements		P																						
	inhalation		P																						
	30 l/min	0.64	P																						
	95 l/min	1.77	P																						
	exhalation		P																						
	160 l/min	2.46	P																						
	<table border="1"> <thead> <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> </thead> <tbody> <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> </tbody> </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		--
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FFP2	0.7	2.4	3.0																						
FFP3	1.0	3.0	3.0																						
7.17	Clogging		N/A																						
7.17.1	General		N/A																						
	For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory		N/A																						
	Devices designed to be resistant to clogging, shown by a slow increase of breathing resistance when loaded with dust		N/A																						
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg · h/m ² is reached.		N/A																						
7.17.2	Breathing resistance		N/A																						
7.17.2.1	Valved particle filtering half masks		N/A																						
	FFP1: 4 mbar		N/A																						
	FFP2: 5 mbar		N/A																						
	FFP3: 7 mbar		N/A																						
	at 95 l/min continuous flow		N/A																						
	The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.		N/A																						
7.17.2.2	Valveless particle filtering half masks		N/A																						
	After clogging the inhalation and exhalation resistances shall not exceed		N/A																						

	FFP1: 3 mbar		N/A
	FFP2: 4 mbar		N/A
	FFP3: 5 mbar		N/A
	at 95 l/min continuous flow.		N/A
7.17.3	Penetration of filter material		N/A
	All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement		N/A
7.18	Demountable parts	No demountable parts	N/A
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		N/A
8	Testing		P
8.1	General		P
8.2	Visual inspection		P
8.3.1	Simulated wearing treatment	Saturated at (37 ± 2) °C	P
8.3.2	Temperature conditioning		P
	Expose the particle filtering half masks to the following thermal cycle:		P
	for 24 h to a dry atmosphere of (70 ± 3) °C;	70°C 24h	P
	for 24 h to a temperature of (-30 ± 3) ° C;	-30°C 3h	P
8.3.3	Mechanical strength		P
8.3.4	Flow conditioning		P
8.4	Practical performance	Test 2 samples	P
	head harness comfort	Good	P
	security of fastenings	Good	P
	field of vision	Does not affect line of sight	P
	any other comments reported by the wearer on request.	No other comments	P
8.4.2	Walking test	6km/h, 10 min	P
8.4.3	Work simulation test		P

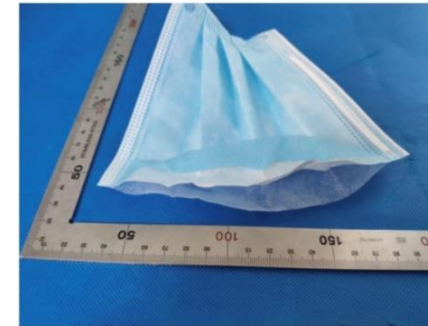
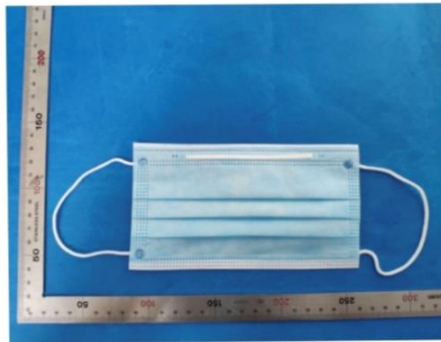
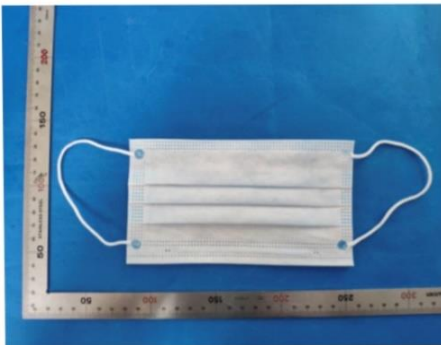
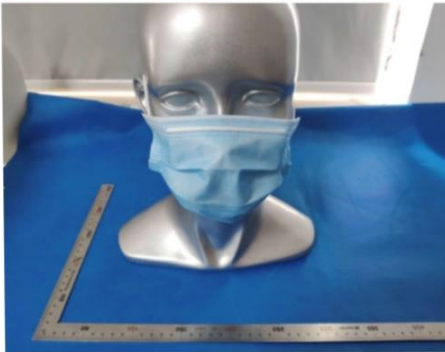
	walking on the level with headroom of (1,3 ± 0,2) m for 5 min; crawling on the level with headroom of (0,70 ± 0,05) m for 5 min; c) filling a small basket (see Figure 1, approximate volume = 8 l) with chippings or other suitable material from a hopper which stands 1,5 m high and has an opening at the 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.		P
8.5	Leakage		P
	General test procedure	total of 10 test specimens	P
	The total inward leakage shall be tested using sodium chloride aerosol.		P
	ten clean-shaven persons (without beards or sideburns)	6km/h	P
	Test procedure		P
	Method		P
8.6	Flammability	800°C flame height: 40mm	P
8.7	Carbon dioxide content of the inhalation air	Test 3 samples	P
	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.		P
	The total dead space of the gas path (excluding the breathing machine) of the test installation should not exceed 2000 ml.		P
	The air flow from the front shall be 0,5 m/s.		P
8.8	Strength of attachment of exhalation valve housing	10N, 10s Test 3 samples	N/A
8.9	Breathing Resistance	Test 12pcs samples	P

	<p>Exhalation resistance</p> <p>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 continuous flow 160 l/min. Use a suitable pressure transducer.</p> <p>Measure the exhalation resistance with the dummy head successively placed in 5 defined positions:</p> <ul style="list-style-type: none"> - facing directly ahead - facing vertically upwards - facing vertically downwards - lying on the left side - lying on the right side <p>8.9.3 Inhalation resistance</p> <p>Test the inhalation resistance at 30 l/min and 95 l/min continuous flow.</p>		P																																																
8.10	Clogging	Test 3 samples dolomite dust	N/A																																																
	<p>The working area of the test chamber has a suggested square section of 650 mm × 650 mm.</p> <p>The breathing machine has a displacement of 2,0 l/stroke. The exhaled air shall pass a humidifier in the exhaled air circuit, such that the exhaled air temperature, measured at the position of the sample particle filtering half mask is (37 ± 2) °C and 95 % R.H. minimum.</p>		N/A																																																
	<table border="1"> <thead> <tr> <th colspan="2">Coulter counter</th> <th colspan="2">Sedimentation analysis</th> </tr> <tr> <th>Size (equivalent spherical diameter)</th> <th>% Number particles oversize</th> <th>Size (Stokes diameter)</th> <th>% weight oversize</th> </tr> <tr> <th>µm</th> <th></th> <th>µm</th> <th></th> </tr> </thead> <tbody> <tr> <td>0.7</td> <td>100</td> <td>1</td> <td>99.5</td> </tr> <tr> <td>1</td> <td>80</td> <td>2</td> <td>97.5</td> </tr> <tr> <td>2</td> <td>30</td> <td>3</td> <td>95</td> </tr> <tr> <td>3</td> <td>17</td> <td>5</td> <td>85</td> </tr> <tr> <td>5</td> <td>7</td> <td>8</td> <td>70</td> </tr> <tr> <td></td> <td></td> <td>10</td> <td>50</td> </tr> <tr> <td>9</td> <td>2</td> <td>12</td> <td>26</td> </tr> <tr> <td></td> <td></td> <td>14</td> <td>10</td> </tr> <tr> <td>12</td> <td>1</td> <td>18</td> <td>1</td> </tr> </tbody> </table>	Coulter counter		Sedimentation analysis		Size (equivalent spherical diameter)	% Number particles oversize	Size (Stokes diameter)	% weight oversize	µm		µm		0.7	100	1	99.5	1	80	2	97.5	2	30	3	95	3	17	5	85	5	7	8	70			10	50	9	2	12	26			14	10	12	1	18	1		N/A
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8.11	Penetration of filter material		N/A																																																
9	Marking		P																																																

9.1	Packaging		P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.		P
9.1.2	Type-identifying marking.		P
9.1.3	Classification		P
9.1.3	FFP1, FFP2 or FFP3 "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. Example: FFP2 R D."	FFP2 NR	P
9.1.4	The number and year of publication of this European Standard		P
9.1.5	the year of end of shelf life.		P
9.1.6	<p>'see information supplied by the manufacturer'</p> 		P
9.1.7	The manufacturer's recommended conditions of storage		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
9.2	Particle filtering half mask		P

P

Photos



*****End of Test Report*****

■商品画像



