



HUACETONG

Declaration of Conformity

Certificate No.: WUX202003180545SC
Applicant: SHANDONG CIRS GARMENTS CO.,LTD
Address: MISHUI INDUSTRIAL PARK,NO.2XINGFU ROAD,GAOMI CITY,SHANDONG CHINA
Manufacturer: SHANDONG CIRS GARMENTS CO.,LTD
Address: MISHUI INDUSTRIAL PARK,NO.2XINGFU ROAD,GAOMI CITY,SHANDONG CHINA
Product Name: MASK
Model No.: KN95
Trade Mark: LEISHIDE
Type: FFP2 NR
Test Standard: EN 149:2001+A1:2009
Test Report Number(s): WUX202003180545S

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




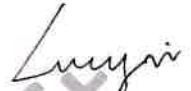
HUACETONG


**TEST REPORT
EN 149**

**Respiratory protective devices - Filtering half masks to protect
against particles - Requirements, testing, marking**

Report Number : WUX202003180545S

Test by (name+signature) : Sally Liu 

Compiled by (+signature) : Lucy Ni 

Approved by (+signature) : Tony Bi 

Date of issue : Mar. 18, 2020

Total number of pages : 12 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 : SHANDONG CIRS GARMENTS CO.,LTD

Address : MISHUI INDUSTRIAL PARK,NO.2XINGFU ROAD,GAOMI CITY,SHANDONG 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 : MASK

Trade Mark : LEISHIDE

Manufacturer : SHANDONG CIRS GARMENTS CO.,LTD

Model/Type reference : KN95

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)

Test item particulars.....:	
Temperature	23°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. 18, 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:</p> <p>The product is MASK, without valve.</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	8%	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	6%	P																	
7.9.2	Penetration of filter material		P																	
	Sodium chloride test, 95 l/min	4.6%, Test 9 samples	P																	
	Paraffin oil test 95 l/min	3.5%, Test 9 samples	P																	
	<table border="1"> <thead> <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> </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		
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	% max.	% max.																		
FFP1	20	20																		
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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.	<4s	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).	<0.80%	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.	Without 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	0,60	P																						
	95 l/min	1.88	P																						
	exhalation		P																						
	160 l/min	2.35	P																						
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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 ³ 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

	<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>		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" style="width: 100%; border-collapse: collapse;"> <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>86</td> </tr> <tr> <td>3</td> <td>17</td> <td>5</td> <td>86</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	86	3	17	5	86	5	7	8	70			10	50	9	2	12	26			14	10	12	1	18	1		N/A
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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	'see information supplied by the manufacturer' 		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****

draft draft draft



Manufacturer's name: **Shandong C.I.R.S Garments Co., Ltd.**
Address: **Mishui Industrial Park, Xingfu Road, Gaomi City, Shandong Province, P. R. China**
Date: **29.03.2020**
CCQS Project Reference: **CE-PC-200316-056**

Confirmation Letter

To whom it may concern:

This is to confirm that **Shandong C.I.R.S Garments Co., Ltd.**, Address: **Mishui Industrial Park, Xingfu Road, Gaomi City, Shandong Province, P. R. China** has entered into the service agreement **CE-PC-200316-056** with CCQS Certification Services Limited, with regards to the application of Module B EU Type Examination Certification and Module D Production Monitoring for **Particle filtering half mask, Model: LSD-007** within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III.

If in any doubt about the integrity of this letter, please contact CCQS by email to verify.

Yours Faithfully.



CCQS Certification Services Limited
Block1, Blanchardstown Corporate Park, Ballycoolin Rd.,
Blanchardstown, Dublin 15, D15 AKK1 Ireland
Tel: +353 (0) 1 588 6920
Email info@ccqs.co.ie
Registered in Ireland as a Limited Company No.623897

Approved by
Ireland Government
as a Notified Body for
CE Marking No.2834



Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

SHANDONG CIRS GARMENTS CO.,LTD.

MISHUI INDUSTRIAL PARK,XINGFU ROAD GAOMI, SHANDONG 261500 CHINA

Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuant to the Code of Federal Regulations 21 CFR 807, by Shenzhen Huacetong Testing and Certification Co., Ltd

Owner/Operator Number: 10064430
Device Listing#: See annex
Expiration Date: December. 31, 2020

Shenzhen Huacetong Testing and Certification Co., Ltd. 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. Shenzhen Huacetong Testing and Certification Co., Ltd 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. Shenzhen Huacetong Testing and Certification Co., Ltd 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, Shenzhen Huacetong Testing and Certification Co., Ltd is not affiliated with the U.S. Food and Drug Administration.

A handwritten signature in black ink, appearing to read "Tony B.", written over a horizontal line.

Executive Director

Issued: Mar.27, 2020

Expiration Date: Dec.31, 2020





Fiscal Year 2020

CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10064430

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
<i>MASK</i>	<i>LYU</i>	<i>1</i>	<i>D379044</i>	<i>Manufacturer Repackager/Relabeler</i>
<i>PROTECTIVE GARMENTS</i>	<i>LYU</i>	<i>1</i>	<i>D379045</i>	<i>Manufacturer Repackager/Relabeler</i>

A handwritten signature in black ink, appearing to read "Tony B.", written over a horizontal line.

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END OF THE ANNEX