Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200326-126-01-9A

Certificate holder:	**Shandong Sheng Ann Special Protection Products Co., Ltd.** No.1066, Huayang Street, Ningyang County (Huan Cheng Industrial Park), Taian City, Shandong Province, P. R. China
Product:	**Particle Filtering Half Mask** Detailed product description listed in the Annex
Model(s):	SAN950
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-07-03
Revision date:	2020-07-03
Expiry date:	2021-07-02

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425.
Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.
CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.
If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.
This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.

CE

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

ISO 17065 IVNAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

Approved by:

CCQS Ireland Certification

Owen Bian Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200326-126-01-9A

Applicable standards and specification:
EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Model reference	Product description
SAN950	Folding filtering half mask fitted with ear loops with head harness clip, no valves, external metal nose clip Classification: FFP2 NR Test report No.: 2020(D) - 0593

Certificate Revision	Revision date	Revision details
A	2020-07-03	Initial issue

CE

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie

TECHNICAL REPORT

EN 149:2001 + A1:2009 Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking

Report

Report reference No ……..…..:	PPE-20209018
Assessed by ……..:	Edward Davy ----------
Approved by ……:	John Ullson ----------
Date of issue ……:	2020-4-6
Number of pages (Report) ……..:	14

Assessing Party

Name.....:	SQS TECHNICAL SERVICE (UK) LIMITED.
Address .....:	SUTE 8525, 16-18 CIRCUS ROAD, ST.JOHN'S WOOD,LONDON, NW8 6PG ENGLAND.
Assess location .....:	Same as above

Applicant

Name ..... :	Shandong Sheng Ann Special Protection Products Co., Ltd.
Address ..... :	NO.1066, Huayang Street, Ningyang City (Huan cheng industrial park), Shandong Province,China.

Report specification

Standard.....:	EN 149:2001 + A1:2009
Assessing procedure .....:	/
Procedure deviation.....:	N.A.
Non-standard assess method .....:	/

Report form/blank report

Report form No ……:	SQS EN 149:2001 + A1:2009
Master TRF ……:	SQS TECHNICAL SERVICE (UK) LIMITED.
Copyright blank report …..…:	This report is based on a blank report prepared by SQS using information obtained from the TRF originator

Assessing item

Description ……..…..…..……:	Disposable respirator (air-purifying particle)
Trademark ……..:	Sheng an
Model and/or type reference……:	SAN950 Ear band
Classification :	FFP2 NR
Manufacturer……..:	Shandong Sheng Ann Special Protection Products Co., Ltd.

Assessing Date

Date of receipt of Files ……...:	2020-04-04
Date(s) of assessing ……..:	2020-04-04 to 2020-04-05

Assessing verdicts

Assess case does not apply to the object ..... :	N/A (Not Applicable)
Assess item does meet the requirement ..... :	P (Pass)
Assessitem does not meet the requirement ..... :	F (Fail)

General remarks

This report shall not be reproduced except in full without the written approval of the assessment party.

The results presented in this report relate only to the datas supplied by the applicant.

"(see remark #)" refers to a remark appended to the report.

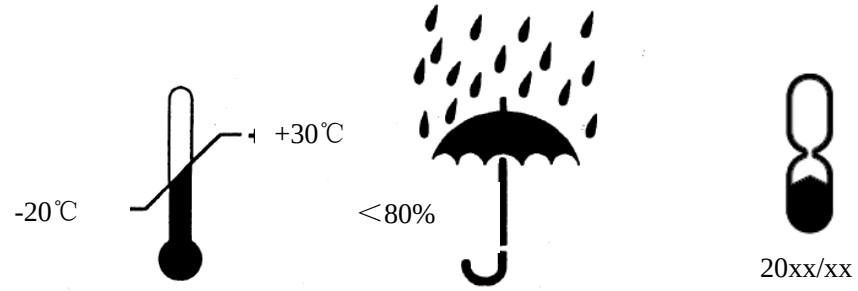
"(see appended table)" refers to a table appended to the report.

Throughout this report a comma is used as the decimal separator.

Environment ： Ambient temperature : 25.0℃ humidity:40%

MARKING

<table>
<tr><td colspan="4">Disposable respirator (air-purifying particle)</td><td rowspan="5">Sheng an

CE</td></tr>
<tr><td>Type:</td><td>SAN950 Ear band</td><td>Standard:</td><td>EN 149: 2001 + A1: 2009</td></tr>
<tr><td>Classification:</td><td>FFP2 NR</td><td>Package:</td><td>/ PCS</td></tr>
<tr><td colspan="4">Manufacturer: Shandong Sheng Ann Special Protection Products Co., Ltd.
Address: NO.1066, Huayang Street, Ningyang City (Huan cheng industrial park), Shandong Province,China.</td></tr>
<tr><td colspan="4"> 
</td></tr>
<tr><td colspan="4">  See information by the manufacturer</td></tr>
</table>

PHOTO

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict

EN 149:2001 + A1:2009			
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:FFP1,FFP2 and FFP3	FFP2	P
6	**Designation**		**P**
	Particle filtering half masks meeting the requirements of this European Standard shall be designated.		P
7	**Requirements**		**P**
7.1	General		P
	In all tests, all test samples shall meet the requirements.		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%.		P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.		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.		P
7.5	Material		P
	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.		P
7.6	Cleaning and disinfecting		P
	If the particle filtering half mask is designed for more than a single shift, the materials used shall withstand the cleaning and disinfecting agents recommended by the manufacturer.		P
7.7	Practical performance		P
	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.		P
7.8	Finish of parts		P
	Parts of the device likely to come into contact with the		P

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	wearer shall have no sharp edges or burrs.		
7.9	Leakage		P
7.9.1	Total inward leakage		P
	The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected.		P
	The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information.		P
	Total inward leakage shall be not greater than: 25% for FFP1 11% for FFP2 5% for FFP3	10.8%	P
7.9.2	Penetration of filter material	Sodium chloride: 1# 5.8% 2# 5.5% 3# 5.6% Paraffin oil: 1# 5.6% 2# 5.4% 3# 5.3%	P
	The penetration of the filter of the particle filtering half mask shall meet the requirements.		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.		P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.	During the test, the particle filtering half mask does not burn.	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).	The carbon dioxide: 0.62%	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.	The head harness is adjustable.	P
7.14	Field of vision		P
	The field of vision is acceptable if determined so in	The vision does not be	P

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	practical performance tests.	affected by the sample.	
7.15	Exhalation valve(s)		N
	A particle filtering half mask may have one or more exhalation valve(s), which 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 that may be necessary for the particle filtering half mask.		N
	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.		N
	When the exhalation valve housing is attached to the face-blank, it shall 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 particle filtering half masks and shall meet the requirements .	Inhalation: 0.7mbar at 30 l/min 2.4 mbar at 95 l/min Exhalation: 2.7 mbar at 160 l/min	P
7.17	Clogging		P
7.17.1	General		N
	For single-use devices only, the clogging test is an optional test.		N
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks		N
	After clogging the inhalation resistances shall not exceed: ——FFP1: 4mbar ——FFP2: 5mbar ——FFP3: 7mbar		N
7.17.2.2	Valveless particle filtering half masks		N
	After clogging the inhalation and exhalation resistances shall not exceed: ——FFP1: 3 mbar ——FFP2: 4 mbar ——FFP3: 5 mbar		N
7.17.3	Filter penetration		N
	All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the penetration requirements after the		N

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	treatment.		
7.18	Demountable parts		P
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		P
8	**Testing**		**P**
8.1	General		P
8.2	Visual inspection		P
	The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	Conditioning by simulated wearing treatment shall be carried out .		P
8.3.2	Temperature conditioning		P
	Expose the particle filtering half masks to the following thermal cycle: a) for 24 h to a dry atmosphere of (70±3) ℃; b) for 24 h to a temperature of (-30±3) ℃; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	After test, the sample is still in good condition.	P
8.3.3	Mechanical strength		P
	Conditioning shall be done in accordance with EN 143.		P
8.3.4	Flow conditioning		N
	A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned.		N
8.4	Practical performance		P
8.4.1	General		P
	A total of 2 particle filtering half masks shall be tested: both as received. a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.	All samples meet the test requirements.	P
8.4.2	Walking test		P
	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.	After this test, the subjects still feel comfortable.	P

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
8.4.3	Work simulation test		P
	The particle filtering half mask shall be tested under conditions which can be expected during normal use. During this test the following activities shall be carried out in simulation of the practical use of the particle filtering half mask. a) walking on the level with headroom of (1.3±0.2) m for 5 min; b) walking on the level with headroom of (1.3±0.2) m for 5 min; c) filling a small basket 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.	After this test, the subjects still feel comfortable.	P
8.5	Leakage		P
8.5.1	General test procedure		P
8.5.1.1	Total inward leakage		P
	A total of 10 test specimens shall be tested: 5 as received and 5 after temperature conditioning. For the test, persons shall be selected who are familiar with using such or similar equipment. A panel of ten clean-shaven persons shall be selected covering the spectrum of facial characteristics of typical users. It is to be expected that exceptionally some persons cannot be satisfactorily fitted with a particle filtering half mask. Such exceptional subjects shall not be used for testing particle filtering half masks.	Samples can fit subjects' faces well after this tests.	P
8.5.2	Method		P
8.5.2.1	Principle		P
	The subject wearing the particle filtering half mask under test walks on a treadmill over which is an enclosure. sampled and analysed during the inhalation phase of the respiratory cycle to determine the NaCl content. The sample is extracted by punching a hole in the particle filtering half mask and inserting a probe through which the sample is drawn. The pressure		P

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	variation inside the particle filtering half mask is used to actuate a change-over valve so that inhaled air only is sampled. A second probe is inserted for this purpose.		
8.5.2.2	Test equipment		P
8.5.2.2.1	Aerosol generator		P
	The NaCl aerosol shall be generated from a 2 % solution of reagent grade NaCl in distilled water.		P
	The type described should be used. This requires an air flow rate of 100 l/min at a pressure of 7 bar. The atomizer and its housing shall be fitted into a duct through which a constant flow of air is maintained. It may be necessary to heat or dehumidify the air in order to obtain complete drying of the aerosol particles.		P
8.5.2.2.2	Test agent		P
	The mean NaCl concentration within the enclosure shall be (8 ±4) mg/m3 and the variation throughout the effective working volume shall be not more than 10 %. The particle size distribution shall be 0,02 mm to 2 mm equivalent aerodynamic diameter with a mass median diameter of 0,6 mm.		P
8.5.2.2.3	Flame photometer		P
	A flame photometer shall be used to measure the concentration of NaCl inside the particle filtering half mask. Essential performance characteristics for a suitable instrument are:		P
	a) It should be a flame photometer specifically designed for the direct analysis of NaCl aerosol;		P
	b) It should be capable of measuring concentrations of NaCl aerosol between 15 mg/m3 and 5 ng/m3;		P
	c) The total aerosol sample required by the photometer should not be greater than 15 l/min;		P
	d) The response time of the photometer, excluding the sampling system, should not be greater than 500 ms;		P
	e) It is necessary to reduce the response to other elements, particularly carbon, the concentration of which will vary during the breathing cycle. This will be achieved by ensuring that the band pass width of the interference filter is no greater than 3 nm and that all necessary side-band filters are included.		P
8.5.2.2.4	Sample selector		N
	A system is required which will switch the sample to the		N

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	photometer only during the inhalation phase of the respiratory cycle. During the exhalation phase clean air shall be fed to the photometer. The essential elements of such a system are:		
	a) An electrically operated valve with a response time of the order of 100 ms. The valve should have the minimum possible dead space compatible with straight-through, unrestricted flow when open;		N
	b) A pressure sensor which is capable of detecting a minimum pressure change of approx. 0,05 mbar and which can be connected to a probe inserted in the cavity of the particle filtering half mask.		N
	c) An interfacing system to actuate the valve in response to a signal from the pressure sensor;		N
	d) timing device to record the proportion of the total respiratory cycle during which sampling took place.		N
8.5.2.2.5	Sample probe		P
	The probe shall be fitted securely in an airtight manner to the particle filtering half mask as near as possible to the centre line of the particle filtering half mask. A multiple hole sampling probe is strongly recommended. Measures shall be taken to prevent the influence of condensation in the sampling probe on the measurement.		P
8.5.2.2.6	Sample pump		P
	If no pump is incorporated into the photometer an adjustable flow pump is used to withdraw an air sample from the particle filtering half mask under test. This pump is so adjusted as to withdraw a constant flow of 1 l/min from the sample probe. Dependent on the type of photometer it may be necessary to dilute the sample with clean air.		P
8.5.2.2.7	Sampling of enclosure concentration		P
	The enclosure aerosol concentration is monitored during the tests using a separate sampling system, to avoid contamination of the particle filtering half mask sampling lines. It is preferable to use a separate flame photometer for this purpose.		P
	However, time will then be required to allow the photometer to return to a clean background.		P
8.5.2.2.8	Pressure detection probe		P
	A second probe is fitted near to the sample probe and is		P

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	connected to the pressure sensor.		
8.5.2.3	Expression of results		P
	The leakage P shall be calculated from measurements made over the last 100 s of each of the exercise periods to avoid carry over of results from one exercise to the other.		P
8.6	Flammability		P
	A total of four particle filtering half masks shall be tested: two in the state as received and two after temperature conditioning in accordance with 8.3.2. The single burner test is carried out according to the following procedure.	During the test, the four sample do not burn.	P
	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.		P
8.7	Carbon dioxide content of the inhalation air		P
	A total of 3 particle filtering half masks shall be tested: all 3 as received. The apparatus consists essentially of a breathing machine with solenoid valves controlled by the breathing machine, a connector, a CO_2 flowmeter and a CO_2 analyst. The apparatus subjects the particle filtering half mask to a respiration cycle by the breathing machine.	The carbon dioxide: 0.062%	P
8.8	Strength of attachment of exhalation valve housing		N
	A total of three particle filtering half masks shall be tested: one as received, one temperature conditioned in accordance with 8.3.2 and one after the test described for mechanical strength in EN 143. Mount the particle filtering half mask securely to a fixture. Apply an axial tensile force of 10 N to the valve for 10 s, and note the results.		N
8.9	Breathing Resistance		P
8.9.1	Test samples and fixture		P
8.9.1.1	Valveless particle filtering half masks		P
	A total of 9 valveless particle filtering half masks shall be		P

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	tested:3 as received, 3 after temperature conditioning in accordance with 8.3.2 and 3 after the test for simulated wearing in accordance with 8.3.1.		
8.9.1.2	Valved particle filtering half masks		N
8.9.2	Exhalation resistance		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 and a breathing machine adjusted to 25 cycles/min and 2.0 l/stroke or a continuous flow 160 l/min.	2.7 mbar at 160 l/min	P
8.9.3	Inhalation resistance		P
	Test the inhalation resistance at 30 l/min and 95 l/min continuous flow.	0.7 mbar at 30 l/min 2.4 mbar at 95 l/min	P
8.10	Clogging		N
8.10.1	Principle		N
	The test aerosol shall be dolomite. A total of 3 particle filtering half masks shall be tested: 1 as received and 2 after temperature conditioning in accordance with 8.3.2. The test consists of subjecting the particle filtering half mask to a sinusoidal breathing simulation.		N
8.10.2	Test equipment		N
	A scheme of a typical apparatus is given. The working area of the test chamber has a suggested square section of 650 mm. 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) ℃ and 95 % R.H. minimum.		N
8.10.3	Test conditions		N
	---Dust: DRB 4/15 dolomite The size distribution of dolomite dust is given.		N
8.10.4	Test procedure		N
	Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m3/h. Fit the sample particle filtering half mask in a leak tight manner to a dummy head or a suitable filter holder located in the dust chamber.		N
8.10.5	Assessment of clogging		N
	Following the exposure, measure the breathing resistance of the particle filtering half mask using clean air. Then measure the filter penetration in accordance		N

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	with 8.11.		
8.11	Filter penetration		P
	The device shall be mounted in a leak tight manner on a suitable former and subjected to the filter penetration test, 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 shall be done in accordance with EN 143.		P
9	**Marking**		**P**
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.		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: FFP1, FFP2, FFP3.		P
9.1.4	The number and year of publication of this European Standard.		P
9.1.5	At least the year of end of shelf life. The end of shelf life may be informed by a pictogram, where yyyy/mm indicates the year and month.		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.		P
9.1.7	The manufacturer’s recommended conditions of storage or equivalent pictogram.		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 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
9.2.3	The number and year of publication of this European Standard.		P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.		P
9.2.5	If appropriate the letter D (dolomite) in accordance with		P

EN 149:2001 + A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	clogging performance. This letter shall follow the class designation		
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		P
10	**Information to be supplied by the manufacture**		**P**
10.1	Information supplied by the manufacturer shall accompany every smallest commercial available package.		P
10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.		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; ——checks prior to use; ——use; ——maintenance (e.g. cleaning, disinfecting), if applicable; ——storage; ——the meaning of any symbols/pictograms used of the equipment.		P
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.		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.		P
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P

**********The End**********

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National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing)
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TEST REPORT

Particulate respirator-half facepiece

EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

Product: Particle filtering half mask

Report No: 2020 (D) - 0593

Client: CCQS Certification Services Limited

Model (s): SAN950

Date(s) of tests: 2020.05.05-2020.06.03

DESCRIPTION OF SAMPLES

General Information	**Classification**	**Main Components**
	FFP2 NR	White folding mask
Manufacturer	Shandong Sheng Ann Special Protection Products Co., Ltd.	
Manufacturer Address	No. 1066, Huayang Street, Ningyang County (Huan Cheng Industrial Park), Taian City, Shandong Province, P. R. China	

Signed:

陈倬为 Chen Zhuowei
Authorized Signatory, Lab Director

Issued: 2020.6.4

Conditions:

The test results presented in this report relate to the samples tested only.

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The authenticity of this test report and its contents can be verified by contacting the laboratory.

Test Results

7.3 Visual inspection **Not tested[1]**

The visual inspection shall include the marking and information supplied by the manufacturer.

Note1: As requested by the client, marking and information supplied by the manufacturer was not inspected.

7.4 Package **Pass[2]**

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.

Note2: In accordance with the requirement.

7.5 Material **Pass[3]**

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.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

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.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Note3: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

7.6 Cleaning and disinfecting **N/A[4]**

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.

Note4: Single shift use only.

7.7 Practical performance **Pass[5]**

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note5: No imperfections.

7.8 Finish of parts **Pass[6]**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note6: No sharp edges or burrs.

7.9.1 Total inward leakage **Pass[7]**

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

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

Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

7.9.2 Penetration of filter material **Pass[8]**

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%

FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

7.10 Compatibility with skin **Pass[9]**

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.

Note9: No irritation or any other adverse effect to health.

7.11 Flammability **Pass[10]**

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.

Note10: Test results are shown in Annex A Table 7.11.

7.12 Carbon dioxide content of the inhalation air **Pass[11]**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

Note11: Test results are shown in Annex A Table 7.12.

7.13 Head harness **Pass[12]**

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.

Note12: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.

7.14 Field of vision **Pass[13]**

The field of vision is acceptable if determined so in practical performance tests.

Note13: Pass the practical performance tests.

7.15 Exhalation valve **N/A[14]**

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

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.

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.

Note14: No exhalation valve.

7.16 Breathing resistance **Pass[15]**

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

Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.

7.17 Clogging **N/A[16]**

7.17.2 Breathing resistance

Valved particle filtering half masks:
After clogging the inhalation resistances shall not exceed:
FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow
The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks
After clogging the inhalation and exhalation resistances shall not exceed:
FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note16: Single shift use only.

7.18 Demountable parts **Pass[17]**

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand
Note17: In accordance with the requirement.

9 Marking **Not tested**

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. Example: FFP2 R D.
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.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 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. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

End of Test Results

Annex A: Summarization of Test Data

Table 7.9.1-A Inward leakage test data

Test specification: EN 149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	6.89	6.90	7.17	7.00	7.11	7.0
Gong	2	A.R.	7.04	7.26	7.08	7.15	7.46	7.2
Yu	3	A.R.	7.05	7.08	7.39	7.29	7.19	7.2
Hu	4	A.R.	9.59	10.17	9.79	9.83	9.60	9.8
Xu	5	A.R.	6.12	6.19	6.61	6.54	6.14	6.3
Deng	6	T.C.	7.91	8.04	8.13	8.17	8.22	8.1
Zhang	7	T.C.	6.62	6.98	6.92	6.83	6.69	6.8
Zhi	8	T.C.	5.64	6.09	5.95	5.81	5.87	5.9
Fang	9	T.C.	5.43	5.76	5.92	5.69	5.47	5.7
Lv	10	T.C.	6.97	7.29	7.42	7.01	7.20	7.2
All 50 individual exercise results were not greater than 11 % 8 out of 10 individual wearer arithmetic means were not greater than 8 %							Pass	

Table 7.9.1-B Facial dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Yi	120	130	109	59
Gong	122	140	115	65
Yu	119	160	139	55
Hu	112	122	119	63
Xu	110	130	118	60
Deng	115	119	110	59
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63
Fang	115	129	120	50
Chen	116	150	132	56
Lv	110	121	110	53

Table -7.9.2 Penetration of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.201	Pass
		12	0.214	
		13	0.167	
	Simulated wearing treatment	14	0.122	
		15	0.285	
		16	0.294	
	Mechanical strength+ Temperature conditioned	17	0.379	
		18	0.348	
		19	0.412	
Paraffin oil test	As received	20	3.47	
		21	3.51	
		22	3.26	
	Simulated wearing treatment	23	3.31	
		24	4.12	
		25	4.25	
	Mechanical strength+ Temperature conditioned	26	4.26	
		27	4.31	
		28	4.47	
Flow conditioning： Single filter: 95.0 L/min				

Table 7.11 Flammability

Test specification: EN 149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	Burn for 1 s	Pass
	30	Burn for 1 s	
Temperature conditioned	31	Burn for 1 s	
	32	Burn for 1 s	

Table 7.12 Carbon dioxide content of the inhalation air

Test specification: EN 149-2001 Clause 8.7

Condition	Sample No.	Result		Assessment
As received	33	0.42%	Mean value 0.4%	Pass
	34	0.41%		
	35	0.41%		

Table 7.16 Breathing resistance (mbar)

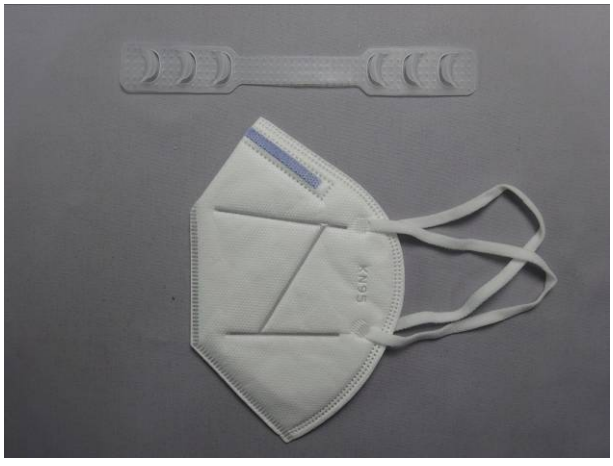
Test specification: EN 149-2001 Clause 8.9

	Flow rate		36					37					38				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30 l/min	0.4	0.5	0.6	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.4	0.4	0.6	0.5	0.6
		95 l/min	1.5	1.6	1.5	1.6	1.7	1.6	1.6	1.5	1.5	1.7	1.6	1.6	1.6	1.6	1.5
	Exhalation	160 l/min	1.9	2.0	2.0	2.0	2.0	1.9	2.0	2.1	1.9	2.1	2.0	1.9	2.0	2.1	2.1
	Flow rate		39					40					41				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Simulated wearing treatment	Inhalation	30 l/min	0.6	0.5	0.5	0.5	0.5	0.6	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.4	0.4
		95 l/min	1.7	1.6	1.6	1.6	1.6	1.6	1.5	1.5	1.7	1.5	1.5	1.5	1.5	1.6	1.6
	Exhalation	160 l/min	1.9	2.0	2.1	2.0	2.1	1.9	1.9	1.9	1.9	2.1	2.1	2.0	2.1	1.9	2.0
	Flow rate		42					43					44				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Temperature conditioned	Inhalation	30 l/min	0.5	0.5	0.5	0.5	0.5	0.6	0.5	0.4	0.5	0.4	0.4	0.4	0.5	0.5	0.6
		95 l/min	1.7	1.6	1.5	1.5	1.6	1.5	1.7	1.6	1.5	1.5	1.5	1.7	1.7	1.6	1.6
	Exhalation	160 l/min	1.9	2.1	2.0	1.9	2.0	2.0	2.1	2.0	2.0	1.9	2.1	2.0	2.0	1.9	2.0
Assessment	Pass																

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

End of Annex A

ANNEX B PHOTOS OF SAMPLES



End of Annex B