



mediroc

# Disposable Protective **Face Mask**

*KN95 NR*



# PROTECTIVE MASK KN95



## 5 LAYER PROTECTION

### Non-Woven Fabric

Blocking large particles or microorganisms.

### Hot Air Cotton Filter

Enhanced filtering fine particles.

### Melt-Blown Filter

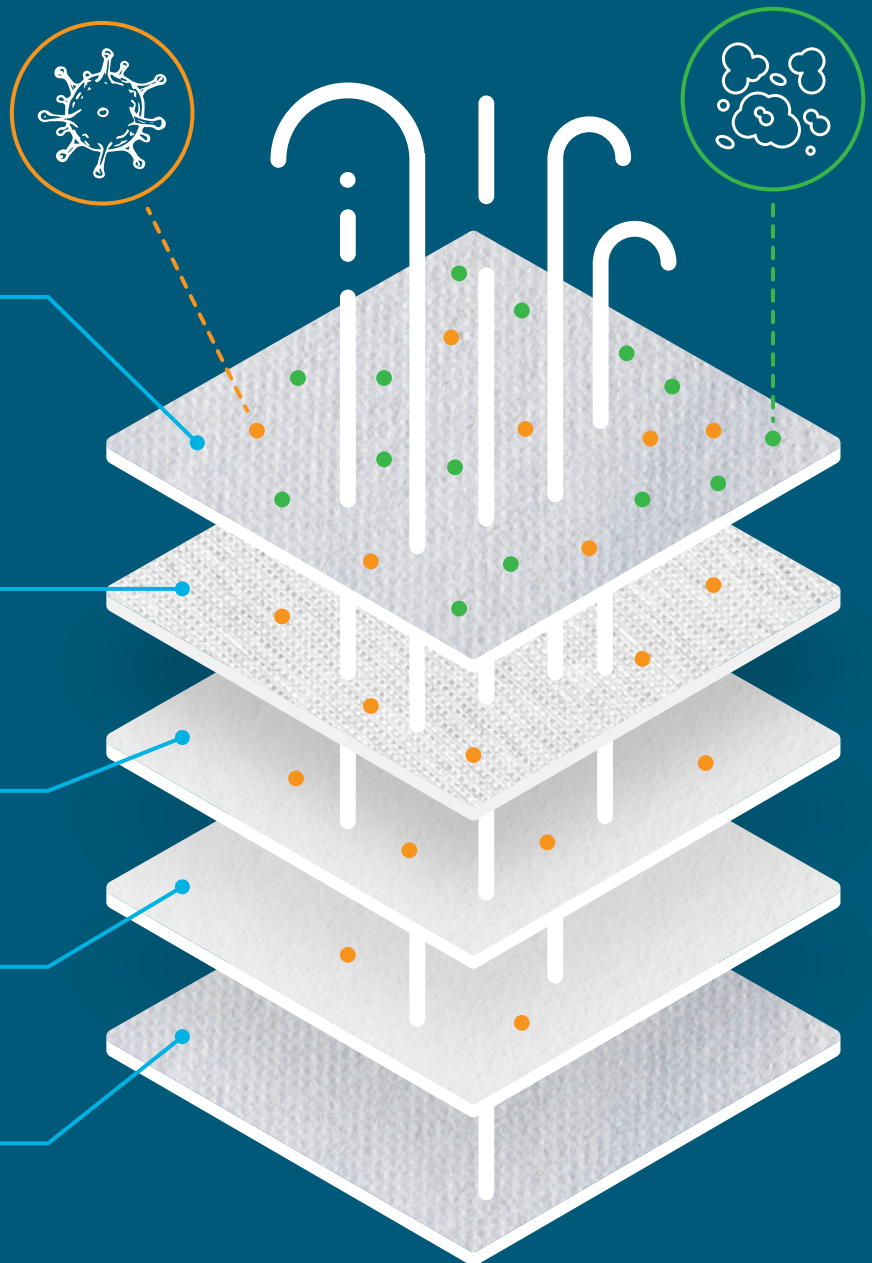
Polypropylene non-woven fabric.

### Melt-Blown Filter

Polypropylene non-woven fabric.

### Non-Woven Fabric


Safe non-woven soft and skin-friendly.





# TEST REPORT

Respiratory Protective Devices  
Requirements, Testing, Marking

<b>TEST REPORT</b> <b>EN 149:2001+A1:2009</b> <b>Respiratory protective devices — Filtering half masks to protect against particles</b> <b>—Requirements, testing, marking</b>	
Report Reference No.....:	MNK20200320332R
Tested by (name + signature).....:	<i>Candy</i> 
Approved by (name + signature).....:	<i>Daisy</i>
Date of test.....:	Feb. 28, 2020 — Mar. 18, 2020
Date of issue.....:	Mar. 18, 2020
Testing Laboratory.....:	Shenzhen monlka Technology Co.,Ltd
Address .....	Building A、 B ,Baoshi Science & Technology Park, Baoshi Road, Shiyuan Street Bao'an District, Shenzhen, Guangdong, China
Applicant's name.....:	Quanzhou Fengye Electronics Co. Ltd
Address .....	Fengye Building Xinzhai Industrial Zone ,Changtai Street, Licheng Area, Quanzhou Fujian China.
Testing standard.....:	EN 149:2001+A1:2009
Test item description.....:	Disposable protective mask
Trade Mark .....	N/A
Manufacturer.....:	Quanzhou Fengye Electronics Co. Ltd
Address.....:	Fengye Building Xinzhai Industrial Zone ,Changtai Street, Licheng Area, Quanzhou Fujian China.
Model/Type reference .....	KN95, N95
Conclusions .....	<b>PASS</b>
This report shows that the product technically complies with the Council PPE Directive 2016/425/EU requirements.	
<b>Possible test case verdicts:</b>	
- 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)	
<b>General remarks:</b>	
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.	



EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
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	In all tests all test samples shall meet the requirements.		P
7.2	Nominal values and tolerances		
	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 $\pm 5\%$ .	the ambient temperature for testing shall be (16-32°C, and the temperature limits shall be subject to an accuracy of $\pm 1$ °C.	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	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		P
7.7	Practical performance		P



EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	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 wearer shall have no sharp edges or burrs.		P
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
	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		N
	11 % for FFP2	9.4%	P
	5 % for FFP3		N
	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		N
	8 % for FFP2	6.7%	P
	2 % for FFP3		N
7.9.2	Penetration of filter materia		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements.	Sodium chloride: AR--1.08%; TC--0.92%; SW--0.84%; MS--0.31%	P
		Paraffin oil: AR—1.7%; TC—1.2%; SW—1.4%; MS—1.4%	P
7.10	Compatibility with skin		P



EN 149:2001+A1:2009																									
Clause	Requirement – Test	Result - Remark	Verdict																						
	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.																								
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).	0.72%	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 The field of vision is acceptable if determined so in practical performance tests.		P																						
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 to comply with 7.9.		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 faceblank, 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 of Table 2	Inhalation(30 l/min): 0.65	P																						
		Inhalation(95 l/min): 2.2	P																						
		Exhalation(160 l/min): 2.8	P																						
	<table border="1"> <caption>Table 2 – Breathing resistance</caption> <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		
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																						
7.17	Clogging		P																						
7.17.1	General		P																						
	For single shift use devices, the clogging test is an optional test. For re-usable devices the test is Mandatory The specified breathing resistances shall not be exceeded before the required dust load of 833 mg • h/m <sup>3</sup> is reached		P																						





EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks		N
	After clogging the inhalation resistances shall not exceed		N
	---FFP1: 4 mbar		N
	---FFP2: 5 mbar		N
	---FFP3: 7 mbar		N
7.17.2.2	Valveless particle filtering half masks		P
	After clogging the inhalation and exhalation resistances shall not exceed		P
	– FFP1: 3 mbar		N
	– FFP2: 4 mbar	3.5mbar	P
	– FFP3: 5 mbar		N
7.17.3	Penetration of filter material		P
	All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.		P
7.18	Demountable parts		P
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		P
<b>8</b>	<b>Testing</b>		<b>P</b>
8.1	General		P
	If no special measuring devices and methods are specified, commonly used devices and methods shall be used.		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 by the following process.		P
8.3.2	Temperature conditioning		P
	Expose the particle filtering half masks to the following thermal cycle:		P
	a) for 24 h to a dry atmosphere of $(70 \pm 3) ^\circ \text{C}$ ; BS EN 149:2001+A1:2009		P
	b) for 24 h to a temperature of $(-30 \pm 3) ^\circ \text{C}$ ;		P
	and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.		P
8.3.3	Mechanical strength		P
	Conditioning shall be done in accordance with EN 143.		P
8.3.4	Flow conditioning A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2.		N
8.4	Practical performance		P



EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
8.4.1	General		P
	A total of 2 particle filtering half masks shall be tested: both as received. All tests shall be carried out by two test subjects at ambient temperature and the test temperature and humidity shall be recorded. Prior to the test there shall be an examination to assure that the particle filtering half mask is in good working condition and that it can be used without hazard.		P
	a) head harness comfort;		P
	b) security of fastenings;		P
	c) field of vision;		P
	d) any other comments reported by the wearer on request.		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.		P
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. The test shall be completed within a total working time of 20 min.	The test shall be completed within a total working time of 20min.	P
	a) walking on the level with headroom of $(1.3 \pm 0.2)$ m for 5 min;		P
	b) crawling on the level with headroom of $(0.70 \pm 0.05)$ m for 5min;		P
	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		P
	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
8.5.1	General test procedure		P
8.5.1.1	Total inward leakage		P



EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	<p>A total of 10 test specimens shall be tested: 5 as received and 5 after temperature conditioning .</p> <p>For the test, persons shall be selected who are familiar with using such or similar equipment.</p> <p>A panel of ten clean-shaven persons shall be selected covering the spectrum of facial characteristics of typical users</p> <p>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.</p>	The total inward leakage shall be tested using sodium chloride aerosol.	P
8.5.1.2	Test equipment		P
	The test atmosphere shall preferably enter the top of the enclosure through a flow distributor, and be directed downwards over the head of the test subject at a minimum flow rate of 0,12 m/s. The concentration of the test agent inside the effective working volume shall be checked to be homogeneous. The flow rate should be measured close to the subject's head	A level treadmill is required capable of working at 6 km/h.	P
8.5.1.3	Test procedure		P
	Ask the test subjects to read the manufacturer' s fitting information and if more than one size of particle filtering half mask is manufactured, ask the test subject to select the size deemed by him to be the most appropriate. If necessary the test supervisor shall show the test subjects how to fit the particle filtering half mask correctly in accordance with the fitting information. The test sequence shall be as follows:		P
	a) Ensure the test atmosphere is OFF.		P
	b) Place the test subject in the enclosure. Connect up the facepiece sampling probe. Have the test subject walk at 6 km/h for 2 min. Measure the test agent concentration inside the particle filtering half mask to establish the background level.		P
	c) Obtain a stable reading.		P
	d) Turn the test atmosphere ON.		P
	e) The subject shall continue to walk for a further 2 min or until the test atmosphere has stabilized.		P



EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	f) Whilst still walking the subject shall perform the following exercises: 1) walking for 2 min without head movement or talking; 2) turning head from side to side (approx. 15 times), as if inspecting the walls of a tunnel for 2 min; 3) moving the head up and down (approx. 15 times), as if inspecting the roof and floor for 2 min; 4) reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min; 5) walking for 2 min without head movement or talking.		P
	g) Record 1) enclosure concentration; 2) the leakage over each exercise period.		P
	h) Turn off the test atmosphere and when the test agent has cleared from the enclosure remove the subject.		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. Through this enclosure flows a constant concentration of NaCl aerosol. The air inside the particle filtering half mask is 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 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		P
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



EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	The mean NaCl concentration within the enclosure shall be $(8 \pm 4)$ mg/m <sup>3</sup> and the variation throughout the effective working volume shall be not more than 10 %. The particle size distribution shall be 0,02 mm to 2mm equivalent aerodynamic diameter with a mass mediandiameter 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/m <sup>3</sup> and 5 ng/m <sup>3</sup> ;		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 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:		N
	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. The sensor shall have an adjustable threshold and be capable of differential signalling when the threshold is crossed in either direction. The sensor shall work reliably when subjected to the accelerations produced by the head movements of the subject;		N
	c) An interfacing system to actuate the valve in response to a signal from the pressure sensor;		N



EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	d) timing device to record the proportion of the total respiratory cycle during which sampling took place.		N
8.5.2.2.5	Sampling 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.		
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. 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 connected to the pressure sensor.		P
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.		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 $(60 \pm 5)$ mm/s.		P
	The head is arranged to pass over a propane burner the position of which can be adjusted. By means of a suitable gauge, the distance between the top of the burner, and the lowest part of the facepiece (when positioned directly over the burner) shall be set to $(20 \pm 2)$ mm.		P



EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	With the head turned away from the area adjacent to the burner, the propane gas is turned on, the pressure adjusted to between 0,2 bar and 0,3 bar and the gas ignited. By means of a needle valve and fine adjustments to the supply pressure, the flame height shall be set to $(40 \pm 4)$ mm. This is measured with a suitable gauge. The temperature of the flame measured at a height of $(20 \pm 2)$ mm above the burner tip by means of a 1,5 mm diameter mineral insulated thermocouple probe, shall be $(800 \pm 50)$ °C.		P
	Failure to meet the temperature requirement indicates that a fault such as a partially blocked burner exists. This shall be rectified before testing.		P
	The head is set in motion and the effect of passing the facepiece once through the flame shall be noted. The test shall be repeated to enable an assessment to be made of all materials on the exterior of the device. Any one component shall be passed through the flame once only.		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 <sub>2</sub> flowmeter and a CO <sub>2</sub> analyser. The apparatus subjects the particlefiltering half mask to a respiration cycle by the breathing machine.		P
8.8	Strength of attachment of exhalation valve housing		P
	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 as shown in Figure 9. Apply an axial tensile force of 10 N to the valve (housing) for 10 s, and note the results.		P
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 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		P
8.9.1.2	Valved particle filtering half masks		P
8.9.2	Exhalation resistance		P



EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	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.		P
8.9.3	Inhalation resistance		P
	Test the inhalation resistance at 30l/min and 95 l/min continuous flow.		P
8.10	Clogging		P
8.10.1	Principle		P
	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		P
8.10.2	Test equipment		P
	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 2,0l/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 $(37 \pm 2) ^\circ\text{C}$ and 95 % R.H. minimum		P
8.10.3	Test conditions		P
	---Dust: DRB 4/15 dolomite The size distribution of dolomite dust is given.		P
8.10.4	Test procedure		P
	Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m <sup>3</sup> /h. Fit the sample particle filtering half mask in a leaktight manner to a dummy head or a suitable filter holder located in the dust chamber.		P
8.10.5	Assessment of clogging		P
	Following the exposure, measure the breathing resistance of the particle filtering half mask using clean air. Then measure the filter penetration in accordance with 8.11.		P
8.11	Filter penetration		P
	The device shall be mounted in a leaktight 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
<b>9</b>	<b>Marking</b>		<b>P</b>
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





EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
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.	FFP2	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 mas		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.	FFP2	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation		P
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		P
<b>10</b>	<b>Information to be supplied by the manufacturer</b>		<b>P</b>
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		P
	---application/limitations;		P
	---the meaning of any colour coding;		P
	---checks prior to use;		P
	---donning, fitting;		P
	---use;		P
	---maintenance (e.g. cleaning, disinfecting), if applicable;		P
---storage;		P	



EN 149:2001+A1:2009			
Clause	Requirement – Test	Result - Remark	Verdict
	---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:		P
	---fit of particle filtering half mask (check prior to use);		P
	---it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;		P
	---air quality (contaminants, oxygen deficiency);		P
	---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



Photos of sample



Fig 1



Fig 2

-----THE END OF REPORT-----



## Establishment Registration & Device Listing

FDA Home Medical Devices Databases



New Search Back To Search Results

**Establishment:**  
 QUANZHOU FENGYE ELECTRONICS CO., LTD  
 Fengye Building Xinzhai Industrial Zone  
 Changtai Street, Licheng Area  
 Quanzhou Fujian, CN 362000  
**Registration Number:** 3016449655  
**FEI Number\*:** 3016449655  
**Status:** Active  
**Date Of Registration Status:** 2020

**Owner/Operator:**  
[Quanzhou Fengye Electronics Co., Ltd](#)  
 Fengye Building Xinzhai Industrial Zone  
 Changtai Street, Licheng Area  
 Quanzhou, Fujian CN 362000  
**Owner/Operator Number:** [10054252](#)

**Official Correspondent:**  
 Lihui Su  
 Fengye Building Xinzhai Industrial Zone  
 Changtai Street, Licheng Area  
 Quanzhou, Fujian CN 362000  
**Phone:** 86-137-74827475

**US Agent:**  
 Yin Cheng  
 13611 38th Ave  
 Flushing, NY US 11354  
**Phone:** 484 3839031 Ext  
**Email:** [Usmethod@Yahoo.Com](mailto:Usmethod@Yahoo.Com)

\* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

## Establishment Registration & Device Listing

FDA Home Medical Devices Databases



1 result found for **Establishment Registration**  
 or **FEI Number** : 3016449655

New Search

Establishment Name		Registration Number	Current Registration Yr
<a href="#">QUANZHOU FENGYE ELECTRONICS CO., LTD</a>	CHINA	3016449655	2020
<a href="#">Respirator, Surgical - Disposable Protective Mask; Fengye; KN95, N95</a>			Manufacturer

Can't find what you're looking for? [Try a new search](#)

Page Last Updated: 05/11/2020

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية





**CE CERTIFICATE  
CERTIFICATE OF CONFORMITY  
BARCODE**



STL Teknoloji Ltd. Sti.  
Alemdag, Çatalmese Mah. Resadiye Cad, 186. Sk. No:18 4794  
Çekmeköy  
İstanbul  
Turkey  
Att. Sükrü Aybar

Brøndby, 20 May 2020

Task no. 120-27170  
Product Testing and Chemical Analysis  
RAFB/MKRA

### Reg. Confirmation on reception

I hereby confirm that we have received your masks for test on the 8<sup>th</sup>. of May 2020.

Testing is according to the temporary test scheme PPE-R/02.075. Application for conformity assessment according to "Commission Recommendation (EU) 2020/403 of 13 March 2020"  
Company name: QUANZHOU FENGYE ELECTRONICS CO., LTD

Pre-payment regarding this matter has also been received.

Your samples are now in queue for testing in our laboratory, and you are allowed to sell your product after the test has been passed and as soon as the certification process is started.

Kind regards  
FORCE Technology

Malene Kaae Rasmussen  
Secretary



QUANZHOU FENGYE  
ELECTRONICS CO., LTD

Fengye Building Xinzhai Industrial Zone  
Changtai Street, Licheng Area  
Quanzhou Fujian, China

## EU Declaration of Conformity

### Mediroc KN95 Face Mask

Declaration Number : 2020051295

Description : KN95 Face Mask

Brand :  mediroc

Model : KN95

Manufacturer : QUANZHOU FENGYE ELECTRONICS CO., LTD  
Fengye Building Xinzhai Industrial Zone Changtai Street, Licheng Area Quanzhou  
Fujian, China

### Regulation (EU) 2016/425

EU Standard : EN 149:2001+A1:2009

Description : Respiratory protective devices - filtering half masks to protect against particles

Reference of EU Commission Recommendation : (EU) 2020/403

We, hereby declare that the product identified above meets the requirements of the above EU Directives.

We declare that our products have reached to the Notified Body listed below for testing and the testing process has begun.

Notified Body : FORCE Certification A/S

Notified Body Number : 0200

Service Number : 120-27170

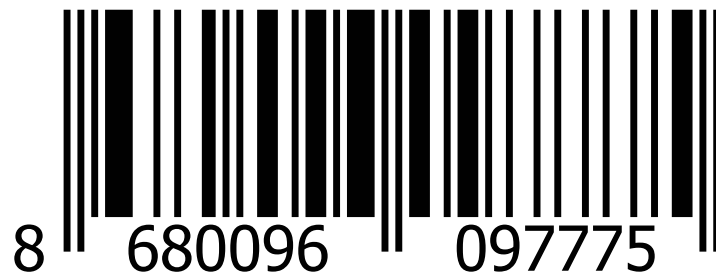
Applicant : QUANZHOU FENGYE ELECTRONICS CO., LTD

#### Manufacturer

QUANZHOU FENGYE ELECTRONICS  
CO., LTD



MADE IN CHINA



**Test Report Ref:** MNK20200320332R

**Test Standard:** EN 149:2001+A1:2009







# PRODUCT CERTIFICATION

Label

# 合格证

Product certification



公司 Company name	Quanzhou Fengye Electronics Co. Ltd	
品名 Product name	Personal Protective Face Mask	
材质 Main raw material	Melt Blown, Non Woven Cloth, Filter Cotton	
执行标准 Executive standard	GB2626-2006	
品牌 Brand	Mediroc	
规格 Specification	Large	
检验员 Inspector	08	
生产日期 Production date	2020-4-2	有效期 Shelf life: 2 Years (Unopened)
产地 Country of origin	中国 MADE IN CHINA	
Test Report Ref: MNK20200320332R Notified Body Lab Test No: 120-27170 Test Standart: EN 149:2001+A1:2009		MADE IN CHINA  8 680096 097775





# PACKAGING





GM700: 515x375x320mm

<p>民用防护面罩 <b>非医用</b></p> <p> mediroc</p> <p>Zhongshan Dongfeng Huangshang Electronic Factory</p> <p>PRODUCT NAME: PROTECTIVE FACE MASK MODEL: KN95 CLASSIFICATION: FFP2 NR</p> <p>MODEL NO: GM700 QTY: 800 PCS MADE IN P.R.C</p>	<p>民用防护面罩 <b>非医用</b></p> <p> mediroc</p> <p>Zhongshan Dongfeng Huangshang Electronic Factory</p> <p>PRODUCT NAME: PROTECTIVE FACE MASK MODEL: KN95 CLASSIFICATION: FFP2 NR</p> <p>MODEL NO: GM700 QTY: 800 PCS MADE IN P.R.C</p> <p></p>	<p>民用防护面罩 <b>非医用</b></p> <p> mediroc</p> <p>Zhongshan Dongfeng Huangshang Electronic Factory</p> <p>PRODUCT NAME: PROTECTIVE FACE MASK MODEL: KN95 CLASSIFICATION: FFP2 NR</p> <p>MODEL NO: GM700 QTY: 800 PCS MADE IN P.R.C</p>	<p>民用防护面罩 <b>非医用</b></p> <p> mediroc</p> <p>Zhongshan Dongfeng Huangshang Electronic Factory</p> <p>PRODUCT NAME: PROTECTIVE FACE MASK MODEL: KN95 CLASSIFICATION: FFP2 NR</p> <p>MODEL NO: GM700 QTY: 800 PCS MADE IN P.R.C</p> <p></p>
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THANK YOU!

