(3) mediroc

Disposable Protective Face Mask







TEST REPORT

Respiratory Protective Devices Requirements, Testing, Marking

.....see cover page.....

TEST REPORT EN 149

Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Report reference No......: A20032470SR-01

Tested by (+signature).....: Steven

Approved by (+ signature)... : Liuze

Date of issue.....: Mar.,24, 2020

ture)... : Liuzesee cover page......

Testing laboratory

Name.....: United Testing Technology (Hong Kong) Limited

Address.....: Unit 04,7/F,Bright Way Tower,No.33 Mong Kok Road, Kowloon, HK.

Test location.....: (Same as above)

Client

Name...... YIWU BAIBIAN ELECTRONIC TECHNOLOGICAL CO., LTD.

Address...... : NO.76 JINGJU WEST ROAD, XIHE INDUSTRIAL ZONE, HOUZHAI, YIWU

CITY, ZHEJIANG PROVINCE, CHINA

Test specification

Standard.....: EN 149: 2001+ A1: 2009

Test procedure.....: CE-PPE

Procedure deviation......: N.A.

Non-standard test method.: N.A.

Test Report Form No......: EN_149

Test item

Description.....: Disposable mask

Model No. : 17.5*9.5

Trade Mark.....: N.A.

Manufacturer.....: YIWU BAIBIAN ELECTRONIC TECHNOLOGICAL CO., LTD.

CITY, ZHEJIANG PROVINCE, CHINA

Classification.....: FFP2



Test case verdicts

Test case does not apply to the test object.....: N(.A.)

Test item does meet the requirement.....: P(ass)

Test item does not meet the requirement...... F(ail)

Testing

Date of receipt of test item Feb., 15, 2020

Date(s) of performance of test Feb., 15, 2020 - Mar., 23, 2020

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.

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

"(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.

Remark:

The EUT complies with the standard EN 149 requirement.

Copy of marking plate:

Disposable mask

Model: 17.5*9.5 Classification: FFP2

EN 149: 2001+ A1: 2009





YIWU BAIBIAN ELECTRONIC TECHNOLOGICAL CO.,

Made In China



	EN 149				
Clause	Requirement + Test	Result - Remark	Verdict		
5	Classification				
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:	Complied with standard, see appended.	Р		
	- FFP1		N		
	- FFP2		Р		
	- FFP3		N		

6	Designation		
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification	Р	

7	Requirements			
7.1	In all tests all test samples shall meet the requirements	Complied see bellow	Р	
7.2	Nomial values and tolerances		Р	
	Unless otherwise specified,the values stated in this European Standard are expressed as normal values.	Actual using value is clear	Р	
7.3	Visual inspection		Р	
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Clear marking is provided, see sample body	Р	
7.4	Packaging		Р	
	Masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Distinct design and warning are made on packaging, see sample body	Р	
7.5	Material		Р	
	Materials used shall be suitable to withstand handling and wear over the period. Any material from the filter media released shall not constitute a hazard or nuisance for the wearer.	Comfortable wearing, when releasing no hazards is produced	Р	
7.6	Cleaning and disinfecting		N	
	The materials used shall withstand the cleaning and disinfecting	Single-use equipment	N	
7.7	Practical performance		Р	
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see bellow test	Р	



	EN 149				
Clause	Requirement + Test	Result - Remark	Verdict		
7.8	Finish of parts	Soft equipment	N		
	Parts likeyl to come into contact with the wearer shall have no sharp edges or burrs		N		
7.9	Leakage		Р		
7.9.1	Total inward leakage				
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected.	Enough safe condition is provide	Р		
	Exercise results for total inward leakage shall be not greater than	FFP2, See below test table	Р		
	25% for FFP1				
	11% for FFP2				
7.9.2	5% for FFP3 Penetration of filter material		P		
1.9.2					
	Meet the requirements of Table 1	FFP2 Sodium chloride test: 9.2% Paraffin oil test: 9.7%	P		
7.10	Compatibility with skin		Р		
	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.	Have no irritation or adverse effect to skin and health	Р		
7.11	Flammability	Have no such hazard	Р		
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		Р		
7.12	Carbon dioxide content of the inhalation air		N		
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	<1.0%	Р		
7.13	Head harness				
	Head harness shall be designed so that mask can be doned and removed easily.	The design is considered	Р		
	Head harness shall be adjustable or self- adjusting and sufficiently robust to hold the mask firmly in position .	The design is considered	Р		
7.14	Field of vision		Р		
	The field of vision is acceptable if determined so in practical performance tests.	Clear field of vision when wearing	Р		
7.15	Exhalation valve(s)		N		
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.		N		



EN 149				
Clause	Requirement + Test	Result - Remark	Verdict	
	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		N	
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		N	
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.		N	
7.16	Breathing resistance		Р	
	The breathing resistances apply to valved and valveless and shall meet the requirements	Complied, see below test table	Р	
7.17	Clogging		Р	
7.17.1	General	Single-use device	Р	
	For single-use devices clogging test is an optional test.		Р	
	Devices designed to be resistant to clogging, shown by a slow increase		Р	
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m3.		Р	
7.17.2	Breathing resistance		Р	
7.17.2.1	Valved particle filtering half masks		N	
7.17.2.2	Valveless particle filtering half masks		Р	
	After clogging the inhalation and exhalation resistances shall not exceed - FFP1: 3 mbar - FFP2: 4 mbar - FFP3: 5 mbar	FFP2: <4 mbar	Р	
	at 95 l/min continuous flow.		Р	
7.17.3	Penetration of filter materia		Р	
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		Р	
7.18	Demountable parts	No any such part	N	
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.			

8	Testing	Р
8.1	General	Р



EN 149				
Clause	Requirement + Test	Result - Remark	Verdict	
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.	Common methods	Р	
8.2	Visual inspection		Р	
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests.	Considered	Р	
8.3	Conditioning		Р	
8.3.1	Simulated wearing treatment		Р	
	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke.	25 cycles/min 2,0 l/stroke.	Р	
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head,	a saturator incorporated by breathing machine and the dummy head	Р	
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	Р	
8.3.2	Temperature conditioning		Р	
	Exposet masks to the following thermal cycle:	Complied	Р	
	a) for 24 h to a dry atmosphere of (70 \pm 3) $^{\circ}$ C;		Р	
	b) for 24 h to a temperature of (-30 ± 3) °C;		Р	
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	5h	Р	

9	Marking		
9.1	Packaging		Р
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied, clearly marked	Р
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.	See user manual	Р
9.1.2	Type-identifying marking.		Р
9.1.3	Classification: FFP1, FFP2, FFP3.	FFP2	Р
9.1.4	The number and year of publication of this European Standard.	See above	Р
9.1.5	At least the year of end of shelf life.	3 years	Р
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.	English used	



	EN 149		
Clause	Requirement + Test	Result - Remark	Verdict
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.	See user manual	Р
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".		Р
9.2	Particle filtering half mask		Р
	Particle filtering half masks		Р
	Complying with this European Standard shall be clearly and durably marked with the following:		Р
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.		Р
9.2.2	Type-identifying marking.		Р
9.2.3	The number and year of publication of this European Standard.	See above	Р
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2	Р
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).		N
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		N

10	Information to be supplied by the manufacturer		
10.1	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.	English	Р
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; - donning, fitting; - use; - maintenance (e.g. cleaning, disinfecting), if applicable; - storage; - the meaning of any symbols/pictograms used of the equipment.	See user manual See user manual	Р
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Clearly considered	Р



EN 149				
Clause	Requirement + Test	Result - Remark	Verdict	
10.5	Warning shall be given against problems likely to be encountered, for example:	See user manual	Р	
	 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.			
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		Р	



Attachments: test table

Table 8.5	Leakage t	est	st				
Mode	els	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	
Test subject wal	k (km/h)	5	5	5	5	5	
Particle siz		0.08~1.6	0.08~1.6	0.08~1.6	0.08~1.6	0.08~1.6	
NaCl flow r (L/min)	ate	99~104	99~104	99~104	99~104	99~104	
NaCl concentration mask (mg/m3)		7.9~8.3	7.9~8.3	7.9~8.3	7.9~8.3	7.9~8.3	
NaCl concentration after mask (mg/m3)		0.48	0.8	0.47	0.51	0.53	
	Note: Test ark volume is 2m³ Test result total inward Leakage is 6.2%<11%						

Table 8.9-1	Inhalation breathing resistance test at 30 L/min			Р		
Models Item		Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)		30	30	30	30	30
Maximum resistance (mbar)		0.63	0.62	0.62	0.62	0.64
Note: Maximum permitted resistance <1.0 mbar						

Table 8.9-2	Inhalation breathing resistance test at 95 L/min				Р	
Models Item		Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)		95	95	95	95	95
Maximum resistance (mbar)		3.46	3.33	3.44	3.36	3.28
Note: Maximum permitted resistance < 4.0 mbar						



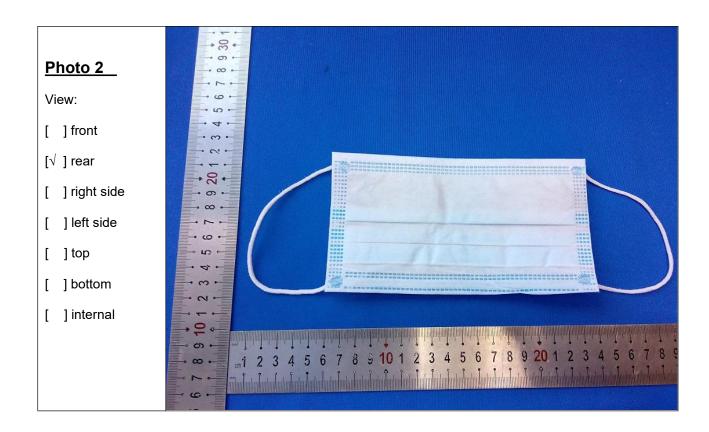
Table 8.9-3 Ext	Exhalation breathing resistance test at 160 L/min				Р	
Models Item		Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Exhalation (L/min)		160	160	160	160	160
Maximum resistance (mbar)		3.42	3.47	3.52	3.48	3.51

Note: Maximum permitted resistance < 4.0 mbar



Appendix Photo documentation









CE CERTIFICATE CERTIFICATE OF CONFORMITY BARCODE



Certificate

No. ICR Polska/P6301749



Name and address of

YIWU BAIBIAN ELECTRONIC TECHNOLOGICAL CO., LTD.

certificate owner:

NO.76 JINGJU WEST ROAD, XIHE INDUSTRIAL ZONE, HOUZHAI, YIWU CITY, ZHEJIAN(

PROVINCE.CHINA

Name and address of manufacturer:

YIWU BAIBIAN ELECTRONIC TECHNOLOGICAL CO., LTD.

NO.76 JINGJU WEST ROAD, XIHE INDUSTRIAL ZONE, HOUZHAI, YIWU CITY, ZHEJIAN(PROVINCE, CHINA

Product name:

Disposable mask

Product types:

17.5*9.5

Product trademark:

n/a

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC-P-07-07. Evaluation has been carried out in accordance with test reports made by United Testing Technology (Hong Kong) Limited

No. of test reports: A20032470SR-01

Certificate issue date: 24.03.2020 **Expiration date:** 23.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3109.

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





Director: Rafał Kalinowski

Warsaw, 24. 03. 2020



MADE IN CHINA

0 000090 097043

Test Report Ref: A20032470SR-01

CE Certificate No: P6301749

Test Standart: EN 149:2001+A1:2009



PRODUCT CERTIFICATION

Label

_			
	合格证 Product certification		
公司	义乌市百变电子科技有限公司		
Company name	Yiwu Baibian Electronic Technology CO.,LTD		
品名	一次性民用防护口罩(非医用口罩)		
Product name	Disposable face mask		
材质	内/外层:无纺布 中间层:熔喷布		
Main raw material	Outer/inner layer: non-woven fabric, middle layer: melt blown fabric		
执行标准 Executive standard	GB/T32610-2016		
品 牌 Brand	Mediroc		
规格	大号		
Specification	Large		
检验员 Inspector	08		
生产日期	16-4-2020 有效期:3年		
Production date	Shelf life: 3 years		
产 地	中国		
Country of origin	MADE IN CHINA		

Test Report Ref: A20032470SR-01 CE Certificate NO: P6301749

Test Standart: EN 149:2001+A1:2009

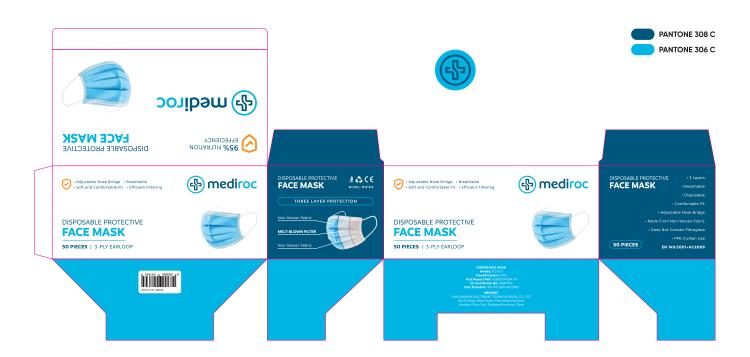
MADE IN CHINA





PACKAGING







THANK YOU!

