

Test Report 3552840-R.


Hunan Zhenheyikang Medical
Instrument Co., Ltd.

Introduction.

This report has been prepared by Ali Askari and relates to the activity detailed below:

Job/Registration Details	Client Details
Job number: 3552840-R Job type: Testing Samples Submitted Start Date: 11/04/2022 Test type: Type Sample ID: 10202422 Registration: CE 758982 Scheme: Negative Pressure RPE Protocol: PP123 Scheme Manager: Nathan Shipley	Hunan Zhenheyikang Medical Instrument Co., Ltd. No.6 Building Jingxiang Energy No.55 Xiaguang East Road Gaoxin District Xiangtan Hunan China

The report has been approved for issue by Tim Wicksey – Subject Matter Expert

Approved For Issue	
	Issue Date: 6 May 2022

Objectives.

This is an independent Type Test evaluation to BS EN 149:2001 + A1:2009.

Product Scope.

Respiratory protective device - Filtering half masks to protect against particles.

Report Summary.

The samples were received on 4 March 2022 and the testing was started on 11 April 2022.

The samples submitted complied with the requirements of the test work conducted.

Test Samples.

Sample ID	ER Number	Description
1 to 60	10202422	Model: ZK-10305 FFP2

Description of Test Samples.

Sample Description
Model: ZK-10305 FFP2. Valveless filtering half mask with headstrap Batch number: 20220221

Test Requirements.

BS EN 149:2001 + A1:2009

Respiratory protective devices - Filtering half masks to protect against particles.

CLAUSE	REQUIREMENTS	ASSESSMENT
7	Requirements	-
7.1	General	-
7.2	Nominal values and tolerances	-
7.3	Visual Inspection	Pass - See Note 1
7.4	Packaging	N/T - See Note 1
7.5	Material	Manufacturer's declaration
7.6	Cleaning and disinfecting	N/A - See Note 2
7.7	Practical performance	Pass
7.8	Finish of parts	Pass
7.9	Leakage	-
7.9.1	Total inward leakage	Pass
7.9.2	Penetration of filter material	Pass
7.10	Compatibility with skin	Pass
7.11	Flammability	Pass
7.12	Carbon dioxide content of inhalation air	Pass
7.13	Head harness	Pass
7.14	Field of vision	Pass
7.15	Exhalation valves	N/A - See Note 3
7.16	Breathing resistance	Pass
7.17	Clogging	N/T - See Note 3
7.18	Demountable parts	N/A - See Note 3
9	Marking	N/T - See Note 1
10	Information to be supplied by the manufacturer	N/T - See Note 1
Appendix A - Test Panel Data		
Product Photographs		

Note 1: Packaging, Marking and Information were not tested, as requested by BSI Product Certification.

Note 2: Single use mask.

Note 3: Not a design feature of this product.

Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories

Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.

Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.

Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.

Fail: Non-compliance. Product does not meet the requirements of this clause.

Fail*: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.

N/T: Not Tested

N/A: Not Applicable

AR: As Received

TC: Temperature Conditioned

SW: Simulated Wear

FT: Flow Tested

MS: Mechanical strength

Conditions of Issue.

This Test Report is issued subject to the conditions stated in current issue of 'BSI Terms of Service'. The results contained herein apply only to the particular sample(s) tested and to the specific tests carried out, as detailed in this Test Report. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by BSI of any product. No extract, abridgement or abstraction from a Test Report may be published or used to advertise a product without the written consent of BSI, who reserve the absolute right to agree or reject all or any of the details of any items or publicity for which consent may be sought.

Should you wish to speak with BSI in relation to this report, please contact Customer Services on +44 (0)8450 80 9000.

BSI
Kitemark House
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4SQ



Opinions and Interpretations expressed herein are outside the scope of our UKAS accreditation.

Unless otherwise stated, any results not obtained from testing in a BSI laboratory are outside the scope of our UKAS accreditation.

Test Results.

BS EN 149:2001 + A1:2009

Respiratory protective devices - Filtering half masks to protect against particles.

CLAUSE	REQUIREMENTS	ASSESSMENT
7.1	General In all tests all samples shall meet the requirements.	-
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 $\pm 5\%$. Unless otherwise specified, the ambient temperature for testing shall be (16 – 32) °C, and the temperature limits shall be subject to an accuracy of $\pm 1^\circ\text{C}$.	-
7.3	Visual Inspection The visual inspection shall also include the marking and the information supplied by the manufacturer.	Pass See Note 1
7.5	Material 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. After undergoing the conditioning described in clause 8.3.1 of the standard none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. Three particle filtering half masks shall be tested. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. Testing shall be done in accordance with 8.2.	Pass Pass Pass Manufacturer's declaration
7.7	Practical performance 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. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. Testing shall be done in accordance with 8.4.	Pass See Table A

Table A: Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
JS2	1 AR	Good	Good	Good	Nose band uncomfortable on bridge of nose	Pass
JB1	2 AR	Good	Good	Good	None	Pass

7.8	Finish of parts Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. Testing shall be done in accordance with 8.2.	Pass
------------	--	------

Note 1: Marking and Information were not tested, as requested by BSI Product Certification.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
--------	--------------	------------

7.9 Leakage

7.9.1 Total inward leakage

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.

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, 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

Pass
See Table B

Testing shall be done in accordance with 8.5.

Table B: Clause 7.9.1 - Total inward leakage.

Test candidate	Sample	Pre-test condition	Inward leakage (%).					Average
			A	B	C	D	E	
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	
JS2	3	AR	0.0462	0.0918	0.1021	0.3336	0.1006	0.1346
SI1	4	AR	0.0192	0.0213	0.0165	0.0238	0.0162	0.0194
JB1	5	AR	0.9721	0.8810	1.3625	0.4813	0.5538	0.8501
CB1	6	AR	1.8181	1.4024	1.4509	0.9355	1.5807	1.4375
BD1	7	AR	0.3808	0.6343	0.4255	0.2893	0.2202	0.3900
JW1	8	TC	0.2080	0.2785	0.4304	0.1920	0.2615	0.2741
LM1	9	TC	0.1411	0.3861	0.3464	0.6567	0.3170	0.3695
EH1	10	TC	0.1890	1.4814	1.2014	2.2449	3.7138	1.7661
MN1	11	TC	11.9538	9.8071	11.2047	8.3381	9.8391	10.2286
PM1	12	TC	3.8961	4.2974	4.1271	3.3683	4.7593	4.0896

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.9.2	<p>Penetration of filter material</p> <p>The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1</p> <p>A total of 9 samples of particle filtering half masks shall be tested for each aerosol. Testing in accordance with 8.11 using the Penetration test according to EN 13274-7, shall be performed on:</p> <ul style="list-style-type: none"> 3 samples as received, 3 samples after the simulated wearing treatment described in 8.3.1. <p>Testing in accordance with 8.11 using the Exposure test with a specified mass of test aerosol of 120 mg, and for particle filtering devices claimed to be re-usable additionally the Storage test, according to EN 13274-7, shall be performed:</p> <p>for non-re-usable devices on:</p> <ul style="list-style-type: none"> 3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2. <p>for re-usable devices on:</p> <ul style="list-style-type: none"> 3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2 and followed by one cleaning and disinfecting cycle according to the manufacturer's instruction. 	<p>Pass See Tables C and D</p> <p>Pass See Table E and F</p> <p>N/A See Note 1</p>

Table C: Clause 8.11 - Sodium Chloride penetration test.

Sample	Pre-test condition	Continuous flow (l/min)	Penetration (%)	
			Limit	Measured
13	AR	95	6.0	0.0165
14	AR	95	6.0	0.0293
15	AR	95	6.0	0.0200
16	SW	95	6.0	0.0162
17	SW	95	6.0	0.0129
18	SW	95	6.0	0.0127

Table D: Clause 8.11 - Paraffin oil penetration test.

Sample	Pre-test condition	Continuous flow (l/min)	Penetration (%)	
			Limit	Measured
19	AR	95	6.0	0.0755
20	AR	95	6.0	0.0895
21	AR	95	6.0	0.1165
22	SW	95	6.0	0.1010
23	SW	95	6.0	0.0665
24	SW	95	6.0	0.1250

Note 1: Not a design feature of this product.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
--------	--------------	------------

7.9.2 Penetration of filter material (continued)

Table E: Clause 8.11. Exposure test Sodium Chloride.

	Sample 28 MS TC	Sample 29 MS TC	Sample 30 MS TC
Flow through filter	95 l/min		
Elapsed time (minutes)	Measured penetration % (Maximum permitted penetration 6.0 %)		
5	0.079934	0.072369	0.096584
10	0.083082 See Note 1	0.076499 See Note 1	0.103714 See Note 1
15	0.078466	0.073415	0.102557
20	0.069134	0.065122	0.091994
25	0.056981	0.052440	0.073934
30	0.044800	0.043895	0.052335
35	0.034787	0.030366	0.034009
Result	Pass	Pass	Pass

Note 1: The reading at which 5 subsequent sampling intervals showed a declining filter penetration. The testing was terminated without the 120mg exposure limit being reached, as permitted by BS EN 13274-7.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
--------	--------------	------------

7.9.2 Penetration of filter material (continued)

Table F: Clause 8.11 Paraffin oil exposure test.

	Sample 25 MS TC	Sample 26 MS TC	Sample 27 MS TC
Flow through filter	95 l/min		
Elapsed time (minutes)	Measured penetration % (Maximum permitted penetration 6.0 %)		
3	0.7560	1.3100	0.6930
5	0.7885	1.4200	0.7330
10	0.8745	1.6120	0.8395
15	0.9550	1.8130	0.9050
20	1.0160	1.9530	0.9775
25	1.0910	2.2095	1.0335
30	1.1440	2.4295	1.1305
35	1.1865	2.6170	1.1615
40	1.2390	2.7700	1.2680
45	1.3045	2.9040	1.3460
50	1.3710	3.0335	1.4195
55	1.4830	3.2585	1.4950
60	1.5205	3.3810	1.5740
Note 1	1.5585	3.4830	1.6345
Result	Pass	Pass	Pass

Note 1: A loading of 120 mg was achieved after a period of 63 minutes, 10 seconds had elapsed.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT																
7.10	<p>Compatibility with skin</p> <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> <p>Testing shall be done in accordance with 8.4 and 8.5.</p>	Pass																
7.11	<p>Flammability</p> <p>The material used shall not present a danger for the wearer and shall not be of a highly flammable nature.</p> <p>When tested, the particle filtering half mask shall not burn or not continue to burn for more than 5 seconds after removal from the flame.</p> <p>The particle filtering half mask does not have to be usable after the test.</p> <p>Testing shall be done in accordance with 8.6.</p> <p>Table G: Clause 8.6 – Flammability.</p> <table border="1"> <thead> <tr> <th>Sample</th> <th>Area exposed</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td>34 AR</td> <td>Across Filter Material, Mid seam/Outer seam, Nose band</td> <td>Did not ignite</td> </tr> <tr> <td>35 AR</td> <td>Head strap/Head strap clip, Head strap join</td> <td>Did not ignite</td> </tr> <tr> <td>36 TC</td> <td>Across Filter Material, Mid seam/Outer seam, Nose band</td> <td>Did not ignite</td> </tr> <tr> <td>37 TC</td> <td>Head strap/Head strap clip, Head strap join</td> <td>Did not ignite</td> </tr> </tbody> </table>	Sample	Area exposed	Comments	34 AR	Across Filter Material, Mid seam/Outer seam, Nose band	Did not ignite	35 AR	Head strap/Head strap clip, Head strap join	Did not ignite	36 TC	Across Filter Material, Mid seam/Outer seam, Nose band	Did not ignite	37 TC	Head strap/Head strap clip, Head strap join	Did not ignite	Pass See Table G	
Sample	Area exposed	Comments																
34 AR	Across Filter Material, Mid seam/Outer seam, Nose band	Did not ignite																
35 AR	Head strap/Head strap clip, Head strap join	Did not ignite																
36 TC	Across Filter Material, Mid seam/Outer seam, Nose band	Did not ignite																
37 TC	Head strap/Head strap clip, Head strap join	Did not ignite																
7.12	<p>Carbon dioxide content of inhalation air</p> <p>The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume).</p> <p>Testing shall be done in accordance with 8.7.</p> <p>Table H: Clause 8.7 - Carbon Dioxide content of the inhalation air.</p> <table border="1"> <thead> <tr> <th>Sample</th> <th>Pre-test condition</th> <th>Limit (%)</th> <th>Measured (%)</th> </tr> </thead> <tbody> <tr> <td>38</td> <td>AR</td> <td>1.0</td> <td>0.43</td> </tr> <tr> <td>39</td> <td>AR</td> <td>1.0</td> <td>0.38</td> </tr> <tr> <td>40</td> <td>AR</td> <td>1.0</td> <td>0.38</td> </tr> </tbody> </table>	Sample	Pre-test condition	Limit (%)	Measured (%)	38	AR	1.0	0.43	39	AR	1.0	0.38	40	AR	1.0	0.38	Pass See Table H
Sample	Pre-test condition	Limit (%)	Measured (%)															
38	AR	1.0	0.43															
39	AR	1.0	0.38															
40	AR	1.0	0.38															
7.13	<p>Head harness</p> <p>The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.</p> <p>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.</p> <p>Testing shall be done in accordance with 8.4 and 8.5.</p>	Pass																
7.14	<p>Field of vision</p> <p>The field of vision is acceptable if determined so in practical performance tests.</p> <p>Testing shall be done in accordance with 8.4.</p>	Pass																

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.16	<p>Breathing resistance</p> <p>The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.</p> <p>Testing shall be done in accordance with 8.9.</p> <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> <p>Testing shall be done in accordance with 8.9.</p> <p>A total of 12 valved particle filtering half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2, 3 after the test for simulated wearing in accordance with 8.3.1, and 3 after the flow conditioning in accordance with 8.3.4.</p> <p>Testing shall be done in accordance with 8.9.</p>	<p>Pass See Tables I, J and K</p> <p>N/A See Note 1</p>

Table I: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow.

Sample	Pre-test condition	Flow (l/min)	Limit (mbar)	Measured (mbar)
13	AR	30	0.7	0.39
14	AR	30	0.7	0.39
15	AR	30	0.7	0.39
16	SW	30	0.7	0.38
17	SW	30	0.7	0.39
18	SW	30	0.7	0.38
31	TC	30	0.7	0.33
32	TC	30	0.7	0.39
33	TC	30	0.7	0.37

Note 1: Not a design feature of this product.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
--------	--------------	------------

7.16 Breathing resistance (continued)

Table J: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow.

Sample	Pre-test condition	Flow (l/min)	Limit (mbar)	Measured (mbar)
13	AR	95	2.4	1.35
14	AR	95	2.4	1.31
15	AR	95	2.4	1.31
16	SW	95	2.4	1.29
17	SW	95	2.4	1.27
18	SW	95	2.4	1.27
31	TC	95	2.4	1.09
32	TC	95	2.4	1.32
33	TC	95	2.4	1.31

Table K: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the highest value recorded.

Sample	Pre-test condition	Flow (l/min)	Limit (mbar)	Measured (mbar)
13	AR	160	3.0	2.08
14	AR	160	3.0	2.06
15	AR	160	3.0	2.06
16	SW	160	3.0	1.97
17	SW	160	3.0	1.87
18	SW	160	3.0	1.91
31	TC	160	3.0	1.74
32	TC	160	3.0	2.03
33	TC	160	3.0	1.99

Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Gender
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
JS2	126	142	125	57	575	Male
SI1	121	135	142	48	575	Male
JB1	114	144	108	59	574	Male
CB1	117	147	130	57	566	Male
BD1	133	151	117	53	570	Male
JW1	116	126	122	48	570	Male
LM1	114	127	117	46	570	Female
EH1	115	131	111	49	577	Male
MN1	115	137	142	60	585	Male
PM1	122	154	130	54	615	Male

Note: All candidates were clean shaven.

Product photographs.



Front view



Side view



Inside view

*** End of Report ***