INSPEC

UKAS TESTING 0316

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Test Report

EN 149 : 2001 + A1 : 2009

Report no:	09.09.21
Client:	INSPEC Asia Pacific Room 515 Huawen Plazza No. 999, West Zhongshan Road Changning District Shanghai 200051 PR China
Client order:	TA09/0166
Order(s) received:	12 August 2009
Manufacturer:	Shanghai Zhongzhi Health Articles Co., Ltd
Model(s):	ZH3071 and ZH3071V
Date(s) of tests:	12 August to 9 September 2009

Conditions:

Opinions, comments and interpretations expressed herein are outside the scope of UKAS accreditation and shown in italics in this report. Any INSPEC interpretations are referenced in this report and copies are available upon request.

Tests marked ☒ are not included in the UKAS accreditation schedule for INSPEC.

Samples will be disposed of four weeks from the date of this report.

Signed: P. Threlfall

Peter Threlfall, Laboratory Supervisor

Issued: 14 September 2009

Summary of assessment*

Clause		Assessment	
	Model:	**ZH3071**	**ZH3071V**
7.4	Packaging	**Fail**	
7.5	Material	Ltd	Ltd
7.6	Cleaning and disinfecting		
7.7	Practical performance	Ltd	Ltd
7.8	Finish of parts	Ltd	**Fail**
7.9.1	Total inward leakage		Pass
7.9.2	Penetration of filter material: Sodium chloride		Pass
7.9.2	Penetration of filter material: Paraffin oil		Pass
7.10	Compatibility with skin	Ltd	Ltd
7.11	Flammability		Pass
7.12	Carbon dioxide content of the inhalation air	Pass	
7.13	Head harness	Ltd	Ltd
7.14	Field of vision	Ltd	Ltd
7.15	Exhalation valve(s)		Pass
7.16	Breathing resistance	Ltd	Pass
7.17	Clogging		
7.18	Demountable parts		NAp
9	Marking	**Fail**	**Fail**
10	Information to be supplied by the manufacturer	**Fail**	**Fail**

Key

	Highlighting shows the clauses requested for each model. Any other clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing was insufficient to completely verify compliance with clause. Refer to "Procedures / Result detail".
Fail	Requirement not satisfied. Refer to the "Result detail" section for more information.
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

* Assessment relates only to those items tested in this report.

Product characteristics

Property	Characteristic	
Model	ZH3071	ZH3071V
Classification claimed	FFP2 claimed	FFP2 claimed
Exhalation valve(s)	None	One
Usage designation	NR	NR

Sample details

Product	Quantity	Received	INSPEC no. (U690+)
ZH3071 filtering half mask	35	10 August 2009	111 to 160
ZH3071V filtering half mask	70		201 to 263

Procedures

Testing was performed in accordance with BS EN 149 : 2001 incorporating Corrigendum No. 1 (January 2003), and amendment A1 (2009) unless otherwise specified below.

Unless stated otherwise, samples were tested in the condition as received at INSPEC.

7.7 The client instructed that practical performance testing be carried out on one sample of each model.

Practical performance tests were conducted in simulation of the practical use of the apparatus under the conditions prevailing in the gallery area of the laboratory. The exercises undertaken and the equipment used were as specified in the standard.

7.9.2 Filter penetration testing by the paraffin oil method was carried out using a modified Phoenix SG-20 aerosol generator and a Phoenix model JM-6000 photometer or a TEC Services' model PH-3 photometer. These give similar performance to the instruments specified.

For the 120mg exposure test, the peak penetration during exposure is reported and in addition the penetration after three minutes for comparison purposes.

During the 120mg exposure test, the sodium chloride penetration showed continued decline and the test was terminated as the product was claimed NR.

7.16 Exhalation resistance was tested at a continuous flow of 160 l/min.

Result detail

7.4 Packaging

Model: ZH3071

The masks were not packaged as offered for sale. Manufacturer to certify regarding the final packaging to be used. **Fail**

The masks were packaged in clear plastic bags that gave some protection against mechanical damage or contamination before use. **Pass**

7.5 Material

Model: ZH3071

Samples 120 to 122 were conditioned in accordance with 8.3.1. **Pass**

Samples 117 to 119 were conditioned in accordance with 8.3.2. **Pass**

The effects of filter media release were not assessed. Manufacturer to certify. **NAs**

Model: ZH3071V

Samples 220 to 225 were conditioned in accordance with 8.3.1. **Pass**

Samples 206 to 210, 217 to 219, 226 to 231, 233, 239, 240, 246, 247, 256 to 259 and 261 to 263 were conditioned in accordance with 8.3.2. **Pass**

The effects of filter media release were not assessed. Manufacturer to certify. **NAs**

7.7 Practical performance

Model: ZH3071

Sample and subject details:

Sample	Subject	
148	PBU	**Pass**
149	-	**NAs**

No adverse comments were made following testing.

Model: ZH3071V

Sample and subject details:

Sample	Subject	
248	-	**NAs**
249	CKN	**Pass**

The subject commented that the exhalation valve was rubbing on their nose. The irritation was not so severe that the subject could not complete the test.

7.8 Finish of parts

Model: ZH3071

None of the samples used in the limited laboratory testing undertaken showed evidence of sharp edges or burrs.

Model: ZH3071V

Sample 207 had a protruding piece of metal wire on the nose clip, which was reasonably sharp. This sample was not used for further testing. **Fail**

7.9.1 Total inward leakage (%)

Model: ZH3071V

Subject	Sample	Cond	Walk	Head side/ side	Head up/down	Talk	Walk	Mean
JD	**201**	**AR**	2.47	2.18	0.72	2.11	3.08	2.11
CKN	**202**	**AR**	6.85	9.85	7.40	7.07	4.31	7.10
RAF	**203**	**AR**	0.47	0.80	0.22	0.17	0.27	0.38
DC	**204**	**AR**	9.18	4.71	3.27	2.44	2.76	4.47
JR	**205**	**AR**	0.53	0.25	0.41	0.85	0.70	0.55
NL	**206**	**TC**	0.14	0.10	0.14	0.76	0.26	0.28
BH	**208**	**TC**	0.09	0.11	0.18	0.30	0.07	0.15
INH	**209**	**TC**	0.13	0.25	0.10	0.47	0.13	0.22
PBU	**210**	**TC**	0.17	0.17	0.35	0.31	0.13	0.23
KRB	**256**	**TC**	0.10	0.09	0.11	0.14	0.11	0.11
Maximum permitted			**11**					**8**

All 50 individual exercise results were less than 11% **Pass**

All 10 individual wearer arithmetic means were less than 8% **Pass**

Subjects CKN and DC commented that the exhalation valve was rubbing on their nose. The irritations were not so severe that the subjects could not complete the tests.

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
JD	115	152	114	57
CKN	112	145	114	54
RAF	120	137	116	55
DC	122	149	122	57
JR	120	133	105	53
NL	106	140	116	51
BH	120	139	108	54
INH	125	153	95	58
PBU	116	141	90	52
KRB	108	130	108	49

7.9.2 Penetration of filter material

Model: ZH3071V

Either Sodium chloride **Pass**

Sample	Condition	Penetration (%)	
		After 3 mins	Max during exposure
211	**A.R.**	0.15	
212		0.15	
213		0.15	
220	**S.W.**	0.15	
221		0.14	
222		0.13	
226	**M.S. + T.C.**	0.20	0.30
227		0.22	0.22
228		0.22	0.24
Maximum permitted		**6.0**	

Paraffin oil: **Pass**

Sample	Condition	Penetration (%)	
		After 3 mins	Max during exposure
214	A.R.	1.0	
215		0.95	
216		0.90	
223	S.W.	1.1	
224		1.0	
225		0.97	
229	M.S. + T.C.	1.6	1.9
230		1.4	1.7
231		1.4	1.8
Maximum permitted		**6.0**	

7.10 Compatibility with skin

Model: ZH3071

No problems were encountered during limited practical performance testing. Inward leakage testing was not carried out.

The likelihood of materials in contact with the skin causing irritation or other adverse effect on health was not assessed. Manufacturer to certify. **NAs**

Model: ZH3071V

No problems were encountered during total inward leakage or limited practical performance testing.

The likelihood of materials in contact with the skin causing irritation or other adverse effect on health was not assessed. Manufacturer to certify. **NAs**

7.11 Flammability

Model: ZH3071V

Samples 244 and 245 (A.R.) and 246 and 247 (T.C.) were tested. None of the samples ignited. **Pass**

7.12 Carbon dioxide content of the inhalation air

Model: ZH3071 **Pass**

Sample	CO_2 (%)
135	0.97
136	0.97
137	0.92
Maximum permitted	**1.0**

7.13 Head harness

Model: ZH3071

The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during limited practical performance.

The head harness was self-adjusting and there were no adverse comments regarding security following limited practical performance.

Inward leakage testing was not carried out. **NAs**

Model: ZH3071V

The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during limited practical performance and total inward leakage testing.

The head harness was self-adjusting and there were no adverse comments regarding security following limited practical performance and total inward leakage testing.

The product satisfied the total inward leakage requirements. See 7.9.1 for results. **Pass**

7.14 Field of vision

Model: ZH3071

There were no adverse comments following limited practical performance tests.

Model: ZH3071V

There were no adverse comments following limited practical performance tests.

7.15 Exhalation valve

Model: ZH3071V

There were no observed problems during testing of function in all orientations. See 7.16 for results. **Pass**

The valve was protected against dirt and mechanical damage by a shroud. **Pass**

The product satisfied leakage requirements. See 7.9 for results. **Pass**

There were no observed problems when assessing operation after high exhalation flow. See 7.16 for results. **Pass**

The valve housing withstood 10N applied for 10s. Samples 232 (A.R.), 233 (T.C.) and 234 (M.S.) were tested. **Pass**

7.16 Breathing resistance

Model: ZH3071

Sample	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)
		At 30 l/min	At 95 l/min	At 160 l/min
111	A.R.	Not requested	Not requested	1.49
112				1.42
113				1.38
117	T.C.	Not requested	Not requested	1.31
118				1.41
119				1.40
120	S.W.	Not requested	Not requested	1.52
121				1.54
122				1.51
Maximum permitted				3.0

Model: ZH3071V

Pass

Sample	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)
		At 30 l/min	At 95 l/min	At 160 l/min
211	A.R.	0.29	0.98	1.01
212		0.27	0.93	0.99
213		0.28	0.97	1.17
217	T.C.	0.27	0.92	1.07
218		0.28	0.91	1.03
219		0.29	0.93	1.01
220	S.W.	0.26	0.87	0.95
221		0.28	0.86	0.94
222		0.30	0.96	1.00
238	A.R. + F.C.	0.29	0.91	0.91
239	T.C. + F.C.	0.27	0.89	1.04
240		0.29	0.92	0.95
Maximum permitted		0.7	2.4	3.0

7.18 Demountable parts

Model: ZH3071V

No demountable parts were used. **NAp**

9	**Marking**	
	Both models	
9.1	**Packaging**	
	The samples were submitted in plastic bags with printed self-adhesive labels.	
	The marking on the packaging was clear and durable.	**Pass**
	The markings required by the Standard were assessed as follows.	
9.1.1	The manufacturer's identification was not present.	**Fail**
9.1.2	Type identification was marked.	**Pass**
9.1.3	The classification given did not include 'R' or 'NR'.	**Fail**
9.1.4	The number and year of the standard were not given.	**Fail**
9.1.5	The end of shelf life was not given.	**Fail**
9.1.6	Neither the required statement nor pictogram relating to manufacturer's information were present.	**Fail**
9.1.7	The recommended storage requirements were not given.	**Fail**
9.1.8	The letter "D" was neither appropriate nor marked.	**NAp**
9.2	**Particle filtering half mask**	
	The particle filtering half mask was not marked.	**Fail**
	The markings required by the Standard were assessed as follows.	
9.2.1	The manufacturer's identification was not present.	**Fail**
9.2.2	Type identification was not marked.	**Fail**
9.2.3	The number and year of the standard were not given.	**Fail**
9.2.4	No classification was marked.	**Fail**
9.2.4	The classification marked was incorrect.	**Fail**
9.2.5	Resistance to clogging was not claimed, and the letter "D" was not marked.	**NAp**
9.2.6	There were no sub-assemblies or components to mark for identification.	**NAp**

10 Information to be supplied by the manufacturer

INSPEC Testing Services has not assessed these instructions with respect to claims made by the manufacturer outside of the requirements of the Standard, and therefore accepts no responsibility for the legitimacy of any such claims.

The information specified by the Standard was assessed as follows.

Model: ZH3071 / Both models

10.1	The information did not accompany smallest package, an example copy was sent.	**Fail**
10.2	Were in the official language (English).	**Pass**
10.3	Contained all necessary information for trained and qualified persons apart from;-	**Pass**
	- colour codes were neither used or explained;	**NAp**
	- maintenance information was not given, the mask was designated single use;	**NAp**
	- there were no symbols or pictograms used.	**NAp**
10.4	Were clear and comprehensible.	**Pass**
10.5	Required warnings were given against various problems likely to be encountered.	**Pass**
10.6	Discard information was provided.	**Pass**
10.7	The product was not marked with R or NR, manufacturer to certify regarding reuse of the device. However, the required warning on single shift use was given.	

ANNEX

This Annex comprises two sections.

1. Estimates of the uncertainty of measurement. (1 page)

2. Photographs of the products tested. (2 pages)

EN 149 : 2001 + (A1 : 2009)

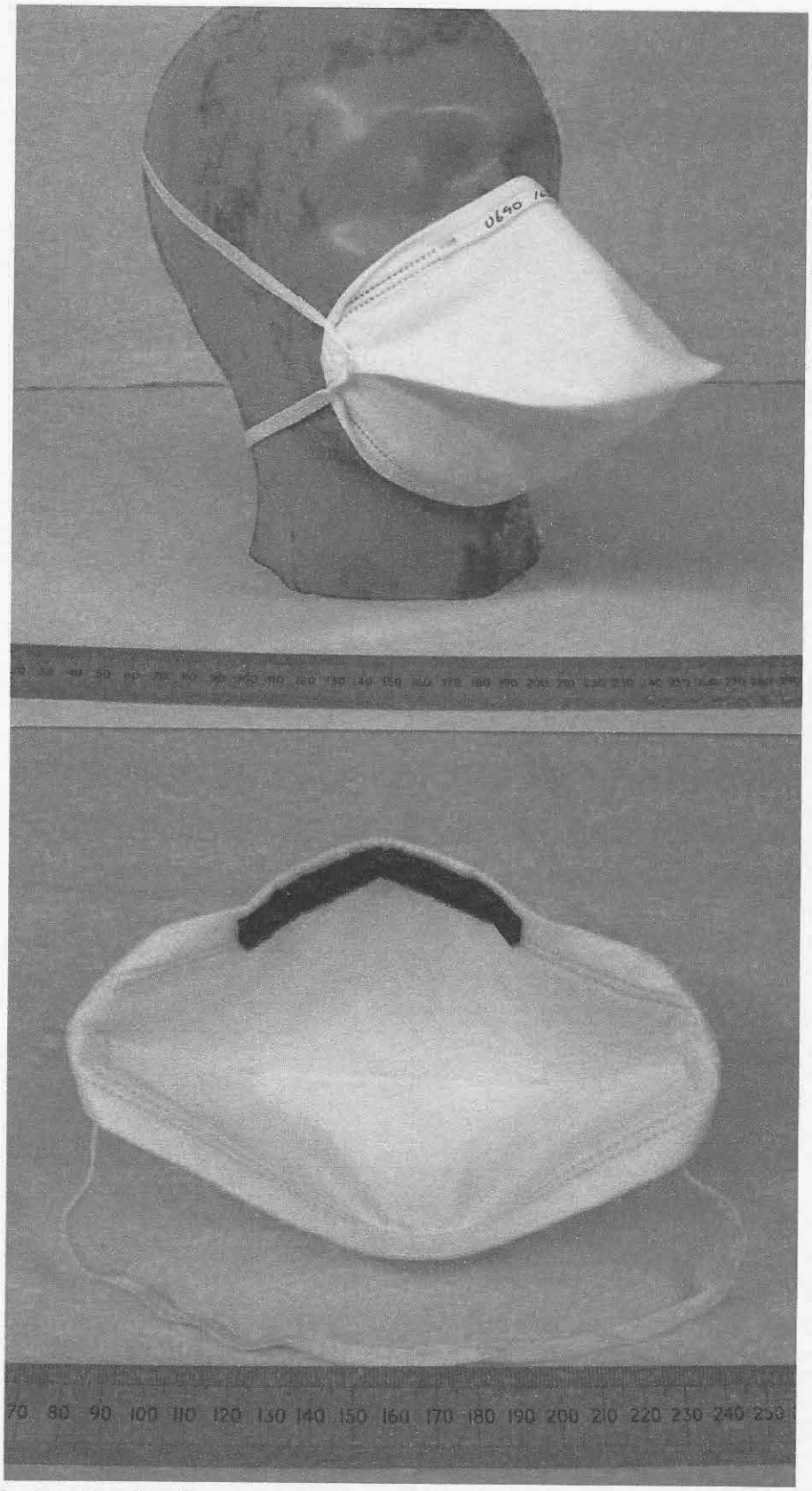
Estimates of the uncertainty of measurement

Clause	Test	Uncertainty
7.9.1	Total inward leakage	4.7%
7.9.2	Penetration of filter material - Sodium chloride	4.7%
7.9.2	Penetration of filter material - Paraffin oil	5.0%
7.12	CO_2 content of the inhalation air	4.0%
7.16	Breathing resistance	1.8%
7.17.2	Breathing resistance after clogging	3.5%
7.17.3	Filter penetration after clogging - Sodium chloride	4.7%
7.17.3	Filter penetration after clogging - Paraffin oil	5.0%

Values expressed as a percentage (%) are relative.

It should be noted that the above values have not been taken into account when making assessment to the pass/fail criteria

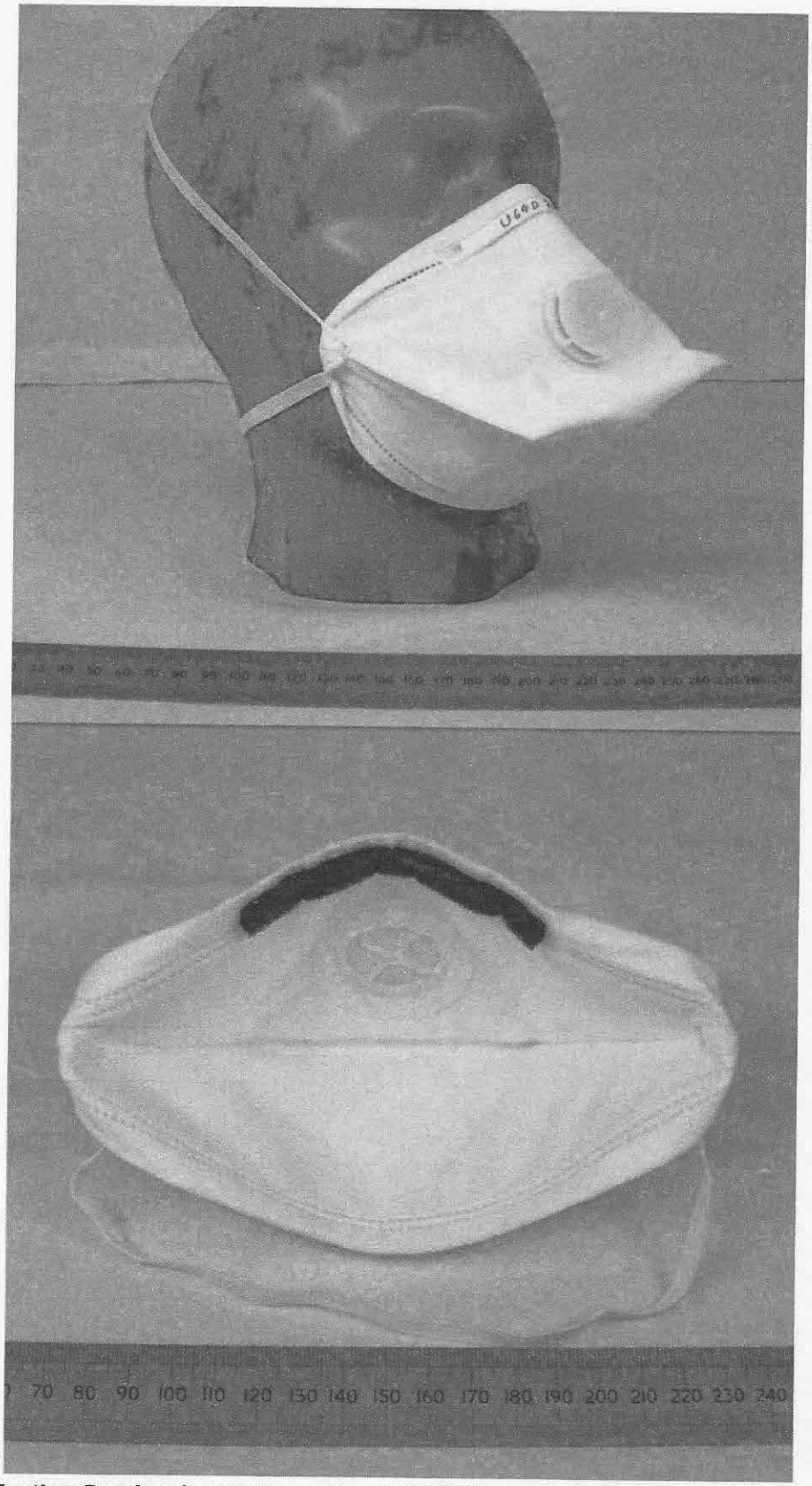
Shanghai Zhongzhi Health Articles Co., Ltd's model ZH3071 Filtering Half Mask



INSPEC Testing Services' sample number U690160

18 August 2009

Shanghai Zhongzhi Health Articles Co., Ltd's model ZH3071V Filtering Half Mask



INSPEC Testing Services' sample number U690260

18 August 2009