

**MZ22 Atemschutzmaske FFP2 NR CE 2797**





### **EU-Konformitätserklärung für eine PSA der Kategorie III**

Shanghai Zhongzhi Health Articles Co. Ltd.

No. 1068, Mingye Road, Sheshan Industrial Zone, Songjiang District, Shanghai  
China.

Email: Nina98@zhongzhimask.com

EU Autorisierte Vertretung: Lotus NL. B.V.

Köningen Juliansplein 10, 1e Verd 2595 AA, The Hague, Netherlands

Wir als Hersteller erklären hiermit, dass das nachstehend beschriebene Produkt

Artikel-Nr.: ZH 3161, ZH 3361

Bezeichnung: Atemschutzmaske FFP2, FFP3

mit den folgenden harmonisierten Normen übereinstimmt: EN149:2001 + A1:2009

Dieses Produkt entspricht der PSA-Verordnung (EU) 2016 / 425 und ist mit der  
PSA identisch, für die die

Prüfnummer: CE 714721, CE 720473

von der notifizierten Stelle: INSPEC Certification Services

56 Leslie Hough Way

Salford, Greater Manchester, M6 6AJ England

Notified Body 0086

ausgestellt wurde.

Dieses Produkt unterliegt dem Konformitätsbewertungsverfahren gemäß Modul

D unter Überwachung der notifizierten Stelle.

BSI Group the Netherlands B.V. (2797)

John M. Keynesplein 9

1066 EP Amsterdam

The Netherlands

上海众志卫生用品有限公司  
SHANGHAI ZHONGZHI HEALTH ARTICLES CO., LTD.





## Conformity to Type based on Quality Assurance of the Production Process

This is to certify that:

Shanghai Zhongzhi Health Articles  
Co., Ltd  
No. 1068, Mingye Road  
Sheshan Industrial Zone  
Songjiang District  
Shanghai  
201602  
China



Holds Certificate Number:

CE 720473

In respect of:

**The manufacture of PPE for respiratory protection to the standards specified on the continuation sheet.**

on the basis that BSI carried out the quality assurance assessment under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VIII (Module D)

For and on behalf of BSI, a Notified  
Body for the above Regulation  
(Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2020-04-24

Latest Issue: 2020-04-24

Drs. Dave Hagenaaers, Managing Director

Effective Date: 2020-04-24

Expiry Date: 2025-04-24

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BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands  
A member of BSI Group of Companies.

# Conformity to Type based on Quality Assurance of the Production Process

No. CE 720473

**Product manufactured by:**

Shanghai Zhongzhi Health Articles Co., Ltd  
No. 1068, Mingye Road  
Sheshan Industrial Zone  
Songjiang District  
Shanghai  
201602  
China



**Product Specifications:**

The products covered by the Module D scope of this Certificate conform to the following standards:

Standard	Product Type
EN 149:2001+A1:2009	Respiratory protective devices. Filtering half masks to protect against particles.

**Certificate Administration Details.**

**Certificate Amendment Record**

Issue date	Comments
April 2020	First Issue

**BSI Project Number**  
2797:20:3098463

**Certificate validity**

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes

The validity of the Certificate is also dependent on the maintenance of an ISO 9001 quality system certified by a recognized certification organisation

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## EU Type Examination Certificate

This is to certify that:

Shanghai Zhongzhi Health Articles  
Co., Ltd  
No. 1068, Mingye Road  
Sheshan Industrial Zone  
Songjiang District  
Shanghai  
201602  
China

Holds Certificate Number:

CE 714721

In respect of:

**Respiratory protective devices to EN 149:2001+A1:2009-  
Filtering half masks to protect against particles see continuation sheets for Models**

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified  
Body for the above Regulation  
(Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2020-08-06

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Drs. Dave Hagenaaers, Managing Director

Effective Date: 2020-08-06

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# EU Type Examination Certificate

No. CE 714721

## Product Specification:

<b>Product Type:</b>	ZH3001 Series of Filtering half masks to protect against particles.			
<b>Model(s):</b>	ZH3001 ZH3001V ZH4001 ZH4001V			
<b>Product description:</b>	The particulate respirators are designed to protect against dust particulate and/or non-volatile liquid particles. The masks are held on the face by a pair of elasticated straps. The models are single shift devices denoted by the classification symbol NR.			
<b>Technical specifications:</b>	EN 149:2001+A1:2009 – Respiratory Protective Devices. Filtering half masks to protect against particles.			
<b>EN 149 Classification</b>	<b>Model</b>	<b>Classification</b>	<b>Valve</b>	<b>Carbon</b>
	<b>ZH3001</b>	FFP1 NR	No	No
	<b>ZH3001V</b>	FFP1 NR	Yes	No
	<b>ZH4001</b>	FFP1 NR	No	Yes
	<b>ZH4001V</b>	FFP1 NR	Yes	Yes

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# EU Type Examination Certificate

No. CE 714721

## Product Specification Continued:

<b>Product Type:</b>	ZH3071 Series of Filtering half masks to protect against particles.		
<b>Model(s):</b>	ZH3071 ZH3071V		
<b>Product description:</b>	The particulate respirators are designed to protect against dust particulate and/or non-volatile liquid particles. The masks are held on the face by a pair of elasticated straps. The models are single shift devices denoted by the classification symbol NR.		
<b>Technical specifications:</b>	EN 149:2001+A1:2009 – Respiratory Protective Devices. Filtering half masks to protect against particles.		
<b>EN 149 Classification</b>	<b>Model</b>	<b>Classification</b>	<b>Valve</b>
	<b>ZH3071</b>	FFP1/FFP2 NR	No
	<b>ZH3071V</b>	FFP1/FFP2 NR	Yes
		<b>Carbon</b>	
			Yes

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# EU Type Examination Certificate

No. CE 714721

## Product Specification Continued:

<b>Product Type:</b>	ZH3310 Series of Filtering half masks to protect against particles.			
<b>Model(s):</b>	ZH3310 ZH3310V ZH4310 ZH4310V			
<b>Product description:</b>	The particulate respirators are designed to protect against dust particulate and/or non-volatile liquid particles. The masks are held on the face by a pair of elasticated straps. The models are single shift devices denoted by the classification symbol NR.			
<b>Technical specifications:</b>	EN 149:2001+A1:2009 – Respiratory Protective Devices. Filtering half masks to protect against particles.			
<b>EN 149 Classification</b>	<b>Model</b>	<b>Classification</b>	<b>Valve</b>	<b>Carbon</b>
	<b>ZH3310</b>	FFP1/FFP2 NR	No	No
	<b>ZH3310V</b>	FFP1/FFP2 NR	Yes	No
	<b>ZH4310</b>	FFP1/FFP2 NR	No	Yes
	<b>ZH4310V</b>	FFP1/FFP2 NR	Yes	Yes

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# EU Type Examination Certificate

No. CE 714721

## Product Specification Continued:

<b>Product Type:</b>	ZH3161 Series of Filtering half masks to protect against particles.			
<b>Model(s):</b>	ZH3161 ZH3161V			
<b>Product description:</b>	The particulate respirators are designed to protect against dust particulate and/or non-volatile liquid particles. The masks are held on the face by a pair of elasticated straps. The models are single shift devices denoted by the classification symbol NR.			
<b>Technical specifications:</b>	EN 149:2001+A1:2009 – Respiratory Protective Devices. Filtering half masks to protect against particles.			
<b>EN 149 Classification</b>	<b>Model</b>	<b>Classification</b>	<b>Valve</b>	<b>Carbon</b>
	<b>ZH3161</b>	FFP1/FFP2 NR	No	No
	<b>ZH3161V</b>	FFP1/FFP2 NR	Yes	No

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# EU Type Examination Certificate

No. CE 714721

## Product Specification Continued:

<b>Product Type:</b>	ZH4071 Series of Filtering half masks to protect against particles.			
<b>Model(s):</b>	ZH4071 ZH4071V			
<b>Product description:</b>	The particulate respirators are designed to protect against dust particulate and/or non-volatile liquid particles. The masks are held on the face by a pair of elasticated straps. The models are single shift devices denoted by the classification symbol NR.			
<b>Technical specifications:</b>	EN 149:2001+A1:2009 – Respiratory Protective Devices. Filtering half masks to protect against particles.			
<b>EN 149 Classification</b>	<b>Model</b>	<b>Classification</b>	<b>Valve</b>	<b>Carbon</b>
	<b>ZH4071</b>	FFP1/FFP2/FFP3 NR	No	Yes
	<b>ZH4071V</b>	FFP1/FFP2/FFP3 NR	Yes	Yes

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# EU Type Examination Certificate

No. CE 714721

## Product Specification Continued:

<b>Product Type:</b>	ZH3361 Series of Filtering half masks to protect against particles.			
<b>Model(s):</b>	ZH3361 ZH3361V ZH4361 ZH4361V			
<b>Product description:</b>	The particulate respirators are designed to protect against dust particulate and/or non-volatile liquid particles. The masks are held on the face by a pair of elasticated straps. The models are single shift devices denoted by the classification symbol NR.			
<b>Technical specifications:</b>	EN 149:2001+A1:2009 – Respiratory Protective Devices. Filtering half masks to protect against particles.			
<b>EN 149 Classification</b>	<b>Model</b>	<b>Classification</b>	<b>Valve</b>	<b>Carbon</b>
	<b>ZH3361</b>	FFP1/FFP2/FFP3 NR	No	No
	<b>ZH3361V</b>	FFP1/FFP2/FFP3 NR	Yes	No
	<b>ZH4361</b>	FFP1/FFP2/FFP3 NR	No	Yes
	<b>ZH4361V</b>	FFP1/FFP2/FFP3 NR	Yes	Yes

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# EU Type Examination Certificate

No. CE 714721

## Product Specification Continued:

<b>Product Type:</b>	ZH3081 Series of Filtering half masks to protect against particles.			
<b>Model(s):</b>	ZH3081 ZH3081V ZH4081 ZH4081V			
<b>Product description:</b>	The particulate respirators are designed to protect against dust particulate and/or non-volatile liquid particles. The masks are held on the face by a pair of elasticated straps. The models are single shift devices denoted by the classification symbol NR.			
<b>Technical specifications:</b>	EN 149:2001+A1:2009 – Respiratory Protective Devices. Filtering half masks to protect against particles.			
<b>EN 149 Classification</b>	<b>Model</b>	<b>Classification</b>	<b>Valve</b>	<b>Carbon</b>
	<b>ZH3081</b>	FFP1/FFP2/FFP3 NR	No	No
	<b>ZH3081V</b>	FFP1/FFP2/FFP3 NR	Yes	No
	<b>ZH4081</b>	FFP1/FFP2/FFP3 NR	No	Yes
	<b>ZH4081V</b>	FFP1/FFP2/FFP3 NR	Yes	Yes

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# EU Type Examination Certificate

No. CE 714721

## Product Specification continued:

<b>Product Type:</b>	ZH3291V Series of Filtering half masks to protect against particles.			
<b>Model(s):</b>	ZH3291V (mask with exhalation valve)			
<b>Product description:</b>	The particulate respirators are designed to protect against solid and non-volatile liquid particles. They include a valve, with no carbon. The masks are held on the face by a pair of elasticated straps. The models are single shift devices denoted by the classification symbol NR.			
<b>Technical specifications:</b>	EN 149:2001+A1:2009 – Respiratory Protective Devices. Filtering half masks to protect against particles.			
<b>EN 149 Classification</b>	<b>Model</b>	<b>Classification</b>	<b>Valve</b>	<b>Carbon</b>
	<b>ZH3291V</b>	FFP1/FFP2/FFP3 NR	Yes	No

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# EU Type Examination Certificate

No. CE 714721

## Certificate Administration Details

Technical File reference: ZH3001/ZH3291V/ZH3071/ZH3081/ZH3161/ZH3310/ZH3361 and ZH4071

## Certificate Amendment Record:

Issue date	Comments	BSI Review Number
August 2020	First issue under PPE Regulation (EU) 2016/425.	2797:20:3044784

## Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 720473.

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Email: [testing@inspec-international.com](mailto:testing@inspec-international.com) Website: [www.inspec-international.com](http://www.inspec-international.com)  
Tel: +44 (0)16 1737 0699 Fax: +44 (0)16 1736 0101

# Test Report

## EN 149 : 2001 + A1 : 2009

**Report no:** 1.13.05.01

**Client:** INSPEC Certification Services  
56 Leslie Hough Way  
Salford  
Greater Manchester  
M6 6AJ

**(on behalf of):** Shanghai Zhongzhi Health Articles Co., Ltd

**Client order:** TA13/0022

**Order(s) received:** 26 March 2013

**Model(s):** ZH3161 and ZH3161V

**Date(s) of tests:** 27 March to 1 May 2013

**Signed:** 

Peter Threlfall, Laboratory Supervisor

**Issued:** 2 May 2013

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**Conditions**

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Opinions, comments and interpretations expressed herein are outside the scope of UKAS accreditation and are 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.

Specimens will be disposed of four weeks from the date of this report, unless otherwise instructed.

This report has been provided in accordance with our standard Terms of Business, which can be viewed at, and printed from:

<http://inspec-international.com/ToB.pdf>

If you have difficulty accessing the Terms of Business, you may contact us for a copy.

**Summary of assessment\***

Clause	Requirement	Assessment (See Key)	
		Model:	
		<b>ZH3161</b>	<b>ZH3161V</b>
7.4	Packaging	Ltd	
7.5	Material	Ltd	Ltd
7.6	Cleaning and disinfecting		
7.7	Practical performance	Ltd	Ltd
7.8	Finish of parts	Ltd	Ltd
7.9.1	Total inward leakage		Pass (FFP2)
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**

	Shading shows the clauses requested. Any other clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "Result details" section for more information.
Fail	Requirement not satisfied. Refer to the "Result details" 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 specimens which were tested and are the subject of this report.



**Product characteristics**

Property	Characteristic	
Model	ZH3161	ZH3161V
Classification claimed	Unspecified	Unspecified
Exhalation valve(s)	None	Single
Usage designation	NR	NR

**Submission details**

Product	Quantity	Date received	INSPEC specimen no. (1A0157 +)
ZH3161 filtering half mask	30	22 March 2013	111 to 160
ZH3161V filtering half mask	65		201 to 260

**Procedures**

Specimens were selected at random from the submission(s) detailed above.

Testing was performed in accordance with BS EN 149 : 2001 incorporating Corrigendum No. 1 (January 2003), and amendment A1 (2009) unless otherwise specified below. Reference should be made to the standard when reading this report.

Unless stated otherwise, specimens were tested in the condition as received by INSPEC.

- 7.7** The client instructed that practical performance testing be carried out on one specimen 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 marked NR.

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

**Result details****7.4 Packaging****Model ZH3161**

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

**NAs**

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

**Pass****7.5 Material****Model ZH3161**

Specimens 121, 122 and 151 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.

**Pass**

Specimens 117 to 119 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse.

**Pass**

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

**NAs****Model ZH3161V**

Specimens 220 to 225 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.

**Pass**

Specimens 206 to 210, 217 to 219, 226 to 231, 233, 239, 240, 246 and 247 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse.

**Pass**

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

**NAs****7.7 Practical performance****Model ZH3161****Specimen and subject details:**

Specimen	Subject
148	AH
149	-

**Pass****NAs**

*No adverse comments were made following testing.*

**Model ZH3161V****Specimen and subject details:**

Specimen	Subject
248	ED
249	-

**Pass****NAs**

*No adverse comments were made following testing.*

**7.8 Finish of parts****Model ZH3161**

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

**Ltd****Model ZH3161V**

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

**Ltd****7.9.1 Total inward leakage (%)****Model ZH3161V**

Subject	Specimen	Cond	Walk	Head side/ side	Head up/down	Talk	Walk	Mean
KDS	201	AR	5.78	5.91	5.16	5.36	5.28	5.50
WA	202	AR	3.06	3.04	5.42	1.07	1.43	2.80
AH	203	AR	3.70	4.38	5.14	2.15	2.25	3.53
JDU	204	AR	8.05	7.42	7.65	9.08	6.74	7.79
ED	205	AR	3.92	1.02	2.65	0.40	0.96	1.79
VE	206	TC	8.20	10.47	7.12	2.09	5.02	6.58
BH	207	TC	4.75	4.46	5.89	1.86	1.79	3.75
SMT	208	TC	2.11	2.55	2.09	2.32	2.36	2.29
SR	209	TC	10.43	3.84	2.15	2.17	2.69	4.26
INH	210	TC	1.11	3.01	1.38	2.85	1.53	1.98
Maximum permitted (FFP1)			25					22
Maximum permitted (FFP2)			11					8
Maximum permitted (FFP3)			5					2

**Pass****Pass****Fail**

All 50 individual exercise results were not greater than 25% (FFP1).

**Pass**

All 10 individual wearer arithmetic means were not greater than 22% (FFP1).

**Pass**

All 50 individual exercise results were not greater than 11% (FFP2).

**Pass**

All 10 individual wearer arithmetic means were not greater than 8% (FFP2).

**Pass**

32 out of 50 individual exercise results were not greater than 5% (FFP3).

**Fail**

2 out of 10 individual wearer arithmetic means were not greater than 2% (FFP3).

**Fail**

**Subject facial dimensions:**

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
KDS	102	128	98	49
WA	121	138	120	56
AH	119	113	115	50
JDU	123	156	132	49
ED	114	138	100	47
VE	116	132	115	45
BH	120	139	108	54
SMT	117	131	115	40
SR	126	137	138	52
INH	125	153	95	58

**7.9.2 Penetration of filter material****Model ZH3161V****Sodium chloride**

Specimen	Condition	Penetration (%)		
		After 3 minutes	Max. during exposure	
211	A.R.	0.02		
212		0.02		
213		0.02		
220	S.W.	0.15		
221		0.05		
222		0.03		
226	M.S. + T.C.	0.04	0.04	
227		0.08	0.08	
228		0.07	0.07	
Maximum permitted (FFP1)		20		Pass
Maximum permitted (FFP2)		6.0		Pass
Maximum permitted (FFP3)		1.0		Pass

**Paraffin oil:**

Specimen	Condition	Penetration (%)		
		After 3 minutes	Max. during exposure	
214	A.R.	0.10		
215		0.08		
216		0.08		
223	S.W.	0.12		
224		0.16		
225		0.28		
229	M.S. + T.C.	0.22	0.32	
230		0.16	0.19	
231		0.27	0.33	
Maximum permitted (FFP1)		20		Pass
Maximum permitted (FFP2)		6.0		Pass
Maximum permitted (FFP3)		1.0		Pass

**7.10 Compatibility with skin****Model ZH3161**

*No problems were encountered during limited practical performance testing.*

**Ltd**

*Total inward leakage testing was not carried out.*

**NAs**

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 ZH3161V**

*No problems were encountered during limited practical performance testing.*

**Ltd**

*No problems were encountered during total inward leakage testing.*

**Pass**

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 ZH3161V**

Specimens 244 and 245 (A.R.) and 246 and 247 (T.C.) were tested. None of the specimens ignited.

**Pass**



**7.12 Carbon dioxide content of the inhalation air****Model ZH3161****Pass**

Specimen	CO <sub>2</sub> (%)
135	0.64
136	0.74
137	0.75
Maximum permitted	1.0

**7.13 Head harness****Model ZH3161**

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

**Ltd**

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

**Ltd**

Inward leakage testing was not carried out.

**NAs****Model ZH3161V**

*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.*

**Ltd**

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

**Ltd**

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

**Pass****7.14 Field of vision****Model ZH3161**

*There were no adverse comments following limited practical performance tests.*

**Ltd****Model ZH3161V**

*There were no adverse comments following limited practical performance tests.*

**Ltd****7.15 Exhalation valve****Model ZH3161V**

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 as FFP2. 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. Specimens 232 (A.R.), 233 (T.C.) and 234 (M.S.) were tested.

**Pass**

## 7.16 Breathing resistance

## Model ZH3161

Ltd

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)
		At 30 l/min	At 95 l/min	At 160 l/min
111	A.R.	Not requested		2.30
112				2.33
113				2.19
117	T.C.	Not requested		2.28
118				2.26
119				2.11
121	S.W.	Not requested		2.08
122				2.30
151				2.24
Maximum permitted				3.0

## Model ZH3161V

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)
		At 30 l/min	At 95 l/min	At 160 l/min
211	A.R.	0.59	1.91	1.88
212		0.53	1.74	1.80
213		0.51	1.76	1.86
217	T.C.	0.47	1.60	1.57
218		0.52	1.73	1.74
219		0.51	1.70	1.72
220	S.W.	0.49	1.61	1.71
221		0.50	1.70	1.48
222		0.49	1.71	1.69
238	A.R. + F.C.	0.54	1.81	1.88
239	T.C. + F.C.	0.54	1.73	1.79
240		0.56	1.89	2.06
Maximum permitted (FFP1)		0.6	2.1	3.0
Maximum permitted (FFP2)		0.7	2.4	3.0
Maximum permitted (FFP3)		1.0	3.0	3.0

Pass

Pass

Pass

**7.18 Demountable parts****Model ZH3161V**

No demountable parts were used.

**NAp**

**9 Marking****Both models****9.1 Packaging**

The specimens were submitted in plastic bags inside a large cardboard box.

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 was not given.

**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 was 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**

**10 Information to be supplied by the manufacturer**

The instructions to users have been assessed as detailed below, with reference only to the relevant requirements of the Standard.

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.

**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**

**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.

**NAs**

**Estimates of the uncertainty of measurement**

Clause	Test	Uncertainty
7.4	Packaging	Not Applicable
7.5	Material	See Note 1
7.6	Cleaning and disinfecting	Not Applicable
7.7	Practical performance	See Note 1
7.8	Finish of parts	Not Applicable
7.9.1	Total inward leakage	$\pm 4.7\%$
7.9.2	Penetration of filter material - Sodium chloride	$\pm 4.8\%$
7.9.2	Penetration of filter material - Paraffin oil	$\pm 4.2\%$
7.10	Compatibility with skin	Not Applicable
7.11	Flammability	See Note 1
7.12	CO <sub>2</sub> content of the inhalation air	$\pm 4.0\%$
7.13	Head harness	Not Applicable
7.14	Field of vision	See Note 1
7.15	Exhalation valve(s)	See Note 1
7.16	Breathing resistance	$\pm 2.1\%$
7.17.2	Breathing resistance after clogging	$\pm 3.9\%$
7.17.3	Filter penetration after clogging - Sodium chloride	$\pm 4.7\%$
7.17.3	Filter penetration after clogging - Paraffin oil	$\pm 4.1\%$
7.18	Demountable parts	Not Applicable

Note 1 The acceptance criterion for this test is a straightforward "Pass/Fail", rather than a numerical value. Consequently, as there is no value to be reported, uncertainty has not been reported either.

Note 2 The uncertainty value is based on a standard uncertainty multiplied by a coverage factor  $k = 2$ , which provides for a confidence level of approximately 95%. 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.



This Annex comprises one section.

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





## DECLARATION OF CONFORMITY

**PRODUCT TYPE:** Particulate Respirators  
**Model Name:** ZH3161  
**Classification:** FFP2 NR



The manufacturer or his nominated representative established in the community:

**Manufacturer:**

**Shanghai Zhongzhi Health Articles Co., Ltd**

**No. 1068, Mingye Road, Sheshan Industrial Zone, Songjiang District, Shanghai, China**

**Email:** [nina98@zhongzhimask.com](mailto:nina98@zhongzhimask.com)

**EU Authorized Representative:**

**Lotus NL B.V.**

**Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.**

Declares that the P.P.E described above in conformity with the provisions of Council **Regulation (EU) 2016/425** and where in such case the national standard transposing harmonized standard numbers:  
**EN 149:2001+A1:2009**

Is identical to the P.P.E which is subject of Certificate number:

**CE 714721 (EU TYPE-EXAMINATION CERTIFICATE )**

**CE 720473 (Module D)**

**EC TYPE-EXAMINATION CERTIFICATE**

Issued by:

**BSI Group The Netherlands B.V.**

**(2797) John M. Keynesplein 9, 1066**

**EP Amsterdam, The Netherlands**

上海众志卫生用品有限公司  
SHANGHAI ZHONGZHI HEALTH ARTICLES CO., LTD.

2/6/2020