#### **Produktinformationsblatt**



Agentur Pflichtfeld Varnbülerstr. 4 70191 Stuttgart

## FFP3 Atemschutzmaske ZH3361

Klassenkennzeichnung	FFP3 Atemschutzmaske ohne Ausatemventil
Typenkennzeichnung (Modell)	ZH3361
CE 2797	BSI (CE 714721 Zertifikat-Nummer)
Zertifizierung	EN 149:2001+A1:2009
	Konformitätskennzeichen entsprechend der PSA-VO
	(EU) 2016/425.
Hersteller	Shanghai Zhongzhi Health Articles Co.,Ltd.
	1068 <sup>th</sup> , Migye Road, Sheshan Industrial Zone
	Songjiang District, Shanghai.
Zugelassener Vertreter der EU	Lotus NL B.V.
	Koningin Julianaplein 10, 1e Verd, 2595AA, Den
	Haag, Niederlande.
Haltbarkeit	3 Jahre bei Lagerung in feuchtigkeitsbeständigem,
	regenfreiem und belüftetem Raum.
Verpackung	30 Masken im Polybag in einer Box
	20 Boxen im Karton
Maße	Box (16cm*13,5cm*14cm)
	Karton (69cm*28,5cm*43cm)
Produktspezifikationen	4-Lagig
	Kopfschlaufen
	Material: 29% Polypropylen Vlies, 40% Meltblown
	Polypropylen, 31% Polyesterfaser
	Farbe: weiß
	Einmalgebrauch
Produktabmessungen	15,5cm*24cm



**CE 2797** 







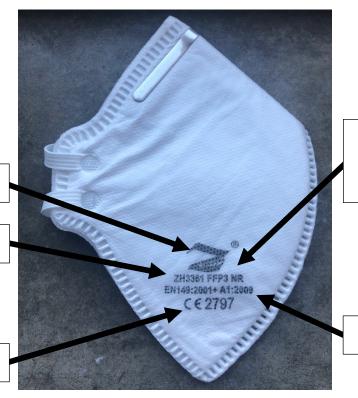
#### Kennzeichnung der Ware





**Agentur Pflichtfeld** Varnbülerstr. 4 70191 Stuttgart

#### FFP3 Atemschutzmaske **ZH3361**



"filtering face piece" Atemschutzmaske der Schutzklasse 3 NR=Einmalgebrauch

Zertifizierung

CE / NB Nummer

Bildmarke Hersteller

Typkennzeichnung / Modell

**CE 2797** 







#### **EU-KONFORMITÄTSERKLÄRUNG (DE)**

Die vorliegende Konformitätserklärung, die unter der alleinigen Verantwortung des Herstellers

Shanghai Zhongzhi Health Articles Co.,Ltd Nr. 1068, Mingye Road, Sheshan Industrial Zone, Songjiang District, Shanghai, China

#### Zugelassener Vertreter der EU:

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, Den Haag, Niederlande.

ausgestellt wurde, bezieht sich auf die folgende persönliche Schutzausrüstung (PSA)

#### Produktmodelle:

ZH3161, ZH3161V, ZH3310, ZH3310V, ZH3361, ZH3361V, ZH3081, ZH3081V, ZH3071, ZH4071V, ZH4071V, ZH4361V, ZH4361V, ZH4310V, ZH4310V, ZH4081V, ZH4081V, ZH3291V

Produktbeschreibung: Partikelfiltrierende Halbmaske

stimmt mit den Bestimmungen der folgenden europäischen Verordnungen und/oder Richtlinien überein

#### Verordnung über persönliche Schutzausrüstungen (PSA)

Das Modell entspricht den Bestimmungen der Verordnung (EU) 2016/425, einschließlich der Erfüllung der geltenden grundlegenden Gesundheits- und Sicherheitsanforderungen gemäß Anhang II, und der nationalen Norm zur Umsetzung der harmonisierten europäischen Standardnorm(en):

#### EN 149:2001+A1:2009

und ist identisch mit der PSA, die Gegenstand der EU-Baumusterprüfung (Modul B der Verordnung [EU] 2016/425) ist, auf die in der Zertifikatsnummer verwiesen wird:

上海众志卫生用品有限公司

CE 714721 (EU Baumusterprüfungs Zertifikat )

**CE 720473 (Module D)** 

Ausgestellt von

BSI Group The Netherlands B.V. (2797) John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands, Nummer der benannten Stelle. 2797

und unterliegt den Verfahren des Moduls D der Verordnung (EU) 2016/425 unter der Aufsicht von BSI Group The Netherlands B.V. (2797) John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands, Nummer der benannten Stelle 2797







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

This is to certify that: Shanghai Zhongzhi

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 Hagenaars, Managing Director

Effective Date: 2020-04-24 Expiry Date: 2025-04-24

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

No. CE 720473

Product manufactured by:
Shanghai Zhongzhi Health Arioes
No. 1068, Mingye Road
Sheshan Industrial Zone
Songjiang District
Shanghai
201602



#### **Product Specifications:**

China

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 BSI Project Number

April 2020 First Issue 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

First Issued: 2020-04-24 Effective Date: 2020-04-24 Latest Issue: 2020-04-24 Expiry Date: 2025-04-24

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This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.

To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated online.







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 Latest Issue: 2020-08-06 Drs. Dave Hagenaars, Managing Director

Effective Date: 2020-08-06 Expiry Date: 2025-08-06

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#### **Product Specification:**

13	O				
EU Type Examina	ntion Certific	ate			
EU Type Examination Certificate  No. CE 714721					
Product Specification:					
Product Type:	ZH3001 Series of Fi	ltering half masks to p	protect against particle	S.	
Model(s):	ZH3001 ZH3001V ZH4001 ZH4001V				
Product description:	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.				
Technical specifications:	EN 149:2001+A1:20 protect against part		ective Devices. Filterin	g half masks to	
	Model	Classification	Valve	Carbon	
1	ZH3001	FFP1 NR	No	No	
EN 149 Classification	ZH3001V	FFP1 NR	Yes	No	
10,0	ZH4001	FFP1 NR	No	Yes	
<b>70</b> ),	ZH4001V	FFP1 NR	Yes	Yes	

First Issued: 2020-08-06 Effective Date: 2020-08-06 Latest Issue: 2020-08-06 Expiry Date: 2025-08-06

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#### **Product Specification Continued:**

	011			<b>\</b>		
EU Type Examir	nation Certif	icate		170		
No. CE 714721				60.110		
Product Specification Co	ontinued:		105			
Product Type:	ZH3071 Series of	Filtering half masks to p	rotect against partic	les.		
Model(s):	ZH3071 ZH3071V					
Product description:	and/or non-volati	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.				
Technical specifications:	EN 149:2001+A1 protect against p	:2009 – Respiratory Proto articles.	ective Devices. Filter	ing half masks to		
	Model	Classification	Valve	Carbon		
EN 149 Classification	ZH3071	FFP1/FFP2 NR	No	Yes		
	ZH3071V	FFP1/FFP2 NR	Yes	Yes		
Shandhai		65	-0.710			

ealth First Issued: 2020-08-06 Effective Date: 2020-08-06 Latest Issue: 2020-08-06 Expiry Date: 2025-08-06

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#### **Product Specification Continued:**

1	00,			۵.,	
EU Type Examin	ation Certifi	cate		0.710	
No. CE 714721				0.7	
Product Specification Co	ntinued:		5		
Product Type:	ZH3310 Series of	Filtering half masks to pr	otect against particles.		
Model(s):	ZH3310 ZH3310V ZH4310 ZH4310V	ZH3310V ZH4310			
Product description:	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.				
Technical specifications:	EN 149:2001+A1 protect against pa	:2009 – Respiratory Prote articles.	ective Devices. Filtering	half masks to	
	Model	Classification	Valve	Carbon	
EN 140 Classification	ZH3310	FFP1/FFP2 NR	No	No	
EN 149 Classification	ZH3310V	FFP1/FFP2 NR	Yes	No	
	ZH4310	FFP1/FFP2 NR	No	Yes	
Mo	ZH4310V	FFP1/FFP2 NR	Yes	Yes	
Shandha		5			

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#### **Product Specification Continued:**

	0					
EU Type Examir	nation Certif	icate		16		
No. CE 714721				-0.1		
Product Specification Co	ntinued:			Co		
Product Type:	ZH3161 Series of	f Filtering half masks to p	rotect against particl	es.		
Model(s):	ZH3161 ZH3161V		Nic.			
Product description:	and/or non-volat elasticated straps	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.				
Technical specifications:	EN 149:2001+A1 protect against p	1:2009 – Respiratory Prote particles.	ective Devices. Filter	ing half masks to		
	Model	Classification	Valve	Carbon		
EN 149 Classification	ZH3161	FFP1/FFP2 NR	No	No		
	ZH3161V	FFP1/FFP2 NR	Yes	No		
Shandhai		5	CO.,,,,,			

First Issued: 2020-08-06 Effective Date: 2020-08-06 Latest Issue: 2020-08-06 Expiry Date: 2025-08-06

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#### **Product Specification Continued:**

	011			
EU Type Examin	ation Certifi	icate		10
No. CE 714721				C.O.,
Product Specification Con	ntinued:			Co
Product Type:	ZH4071 Series of	Filtering half masks to prote	ct against particle	es.
Model(s):	ZH4071 ZH4071V		VIC.	
Product description:	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.			
Technical specifications:	EN 149:2001+A1 protect against pa	:2009 – Respiratory Protectivarticles.	ve Devices. Filterir	ng half masks to
	Model	Classification	Valve	Carbon
EN 149 Classification	ZH4071	FFP1/FFP2/FFP3 NR	No	Yes
	ZH4071V	FFP1/FFP2/FFP3 NR	Yes	Yes
Shanohai		65	,,,,,	

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#### **Product Specification Continued:**

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EU Type Examina	ation Certii	ficate		0.1
No. CE 714721			C	
Product Specification Con	tinued:		5	
riodact Specification con			. 6	
Product Type:	ZH3361 Series o	of Filtering half masks to prote	ct against particles.	'
Model(s):	ZH3361 ZH3361V ZH4361 ZH4361V			
Product description:	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.			
Technical specifications:	EN 149:2001+A protect against	1:2009 – Respiratory Protectiv particles.	e Devices. Filtering	half masks to
	Model	Classification	Valve	Carbon
	ZH3361	FFP1/FFP2/FFP3 NR	No	No
EN 149 Classification	ZH3361V	FFP1/FFP2/FFP3 NR	Yes	No
	ZH4361	FFP1/FFP2/FFP3 NR	No	Yes
	ZH4361V	FFP1/FFP2/FFP3 NR	Yes	Yes
Sho				
<b>.</b>	170			
First Issued: 2020-08-06 Latest Issue: 2020-08-06		E E	Effective Date: 202 Expiry Date: 2025-0	
			_	

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#### **Product Specification Continued:**

	Colus				
A V				0.110	
EU Type Examin	ation Certif	icate		0.7	
No. CE 714721			C	,	
Product Specification Con	ntinued:		105		
Product Type:	ZH3081 Series of	f Filtering half masks to prote	ct against particles.		
Model(s):	ZH3081 ZH3081V ZH4081 ZH4081V				
Product description:	and/or non-volat elasticated straps	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.			
Technical specifications:	EN 149:2001+A1 protect against p	:2009 – Respiratory Protectiverticles.	ve Devices. Filtering	half masks to	
	Model	Classification	Valve	Carbon	
EN 149 Classification	ZH3081	FFP1/FFP2/FFP3 NR	No	No	
EN 143 Classification	ZH3081V	FFP1/FFP2/FFP3 NR	Yes	No	
	ZH4081	FFP1/FFP2/FFP3 NR	No	Yes	
700	ZH4081V	FFP1/FFP2/FFP3 NR	Yes	Yes	
Shar		ntiicle's	0.,		
First Issued: 2020-08-06 Latest Issue: 2020-08-06	Healt		Effective Date: 2020 Expiry Date: 2025-0		
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# Mongkii **EU Type Examination Certificate**

#### **Product Specification continued:**

Product Specification co			65	
Product Type:  Model(s):		Filtering half masks to prote th exhalation valve)	ect against partic	cies.
Product description:	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.			
Technical specifications:	EN 149:2001+A1:2 protect against par		e Devices. Filteri	ng half masks to
	NA - J - I	Classification	Valve	Carbon
EN 149 Classification	Model ZH3291V	FFP1/FFP2/FFP3 NR	Yes	No

tt-First Issued: 2020-08-06 Effective Date: 2020-08-06 Latest Issue: 2020-08-06 Expiry Date: 2025-08-06

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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.

Health First Issued: 2020-08-06 Effective Date: 2020-08-06 Latest Issue: 2020-08-06 Expiry Date: 2025-08-06

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56 LESLIE HOUGH WAY · SALFORD · GREATER MANCHESTER · M6 6AJ · UNITED KINGDOM

Email: testing@inspec-international.com

Website: www.inspec-international.com

Tel: +44 (0)16 1737 0699

Report no:

Fax: +44 (0)16 1736 0101

## **Test Report**

EN 149: 2001 + A1: 2009

#### Particle filtering half masks

Client: **INSPEC Certification Services** 56 Leste Hough Wav Salford Greater Manche

Urme Kingdom

1.13.09.58

(on behalf of): Shanghai Zhong ₩øalth Articles Co., Ltd

Client order: TA13/0081

Order(s) received: 15 August 2013

Model(s): ZH3361, ZH3361V, ZH4361 and ZH4361V

Date(s) of tests: 15 August to 19 September 2013

P. Infall. Signed: Issued: 20 September 2013

Peter Threlfall, Laboratory Supervisor

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Conditions

This report may be reproduced and distributed to your clients, provided that it is reproduced and distributed in full.

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.

#### V.SPEC Test Repor No: 1.13.09.58

#### Summary of assessment\*

Ciause	e (t) Assessment				
	Model:	ZH3361	ZH3361V	ZH4361	ZH4361V
7.4	rackaging	Ltd			Ltd
7.5	Material	Ltd	Ltd	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	Ltd			Pass (FFP2)
7.9.2	Penetration of filter material: Sodium chloride		Pass		
7.9.2	Penetration of filter material: Paraffin oil		Pass		Ltd
7.10	Compatibility with skin				
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 (FFP2)
7.17	Clogging				
7.18	Demountable parts				NAp
9	Marking	Fail	Fail	Fail	Fail
10	Information to be supplied by the manufacturer		Fail		Fail

#### <u>Key</u>

	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.

<sup>\*</sup> Assessment relates only to those specimens which were tested and are the subject of this report.

#### Product characteristics

Property	Characteristic				
Model	ZH3361 ZH3361V ZH4361 ZH4361V				
Classification claimed	Not specified NR Not specified NR Not specified NR Not specifie				
Exhalation valve(s)	None	Single	None	Single	

#### **Submission details**

Product	Quantity	Date received	INSPEC specimen no. (1A0505 +)
ZH3361 filtering half mask	25		104 to 160
ZH3361V filtering half mask	45	14 August	211 to 260
ZH4361 filtering half mask	25	2013	311 to 360
ZH4361V filtering half mask	45		401 to 460

#### **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 only of models ZH3161 and ZH4361V.
  - 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.

VSPEC Test Report No: 1.13.09.58

Pesult details

Packaging

Model ZH 3361 and ZH4361V.

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 cardboard boxes that gave some protection against mechanical damage or contamination before use.

Pass

#### 7.5 Material

#### Model ZH3361

The materials used were able to withstand handling and wear during the limited laboratory testing carried out.

Ltd

The effect on materials from "in-use" environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors.

NAs

Specimens 120 to 122 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.

**Pass** 

Specimens 106 to 108 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 ZH3361V

The materials used were able to withstand handling and wear during the limited laboratory testing carried out.

Ltd

The effect on materials from "in-use" environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors.

NAs

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

**Pass** 

Specimens 226 to 231 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 ZH4361

The materials used were able to withstand handling and wear during the limited laboratory testing carried out.

Ltd

The effect on materials from "in-use" environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors.

NAs

Specimens 320 to 322 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.

Pass

Specimens 317 to 319 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 ZH4361

The material were able to withstand handling and wear during the limited aboratory testing carried out.

Ltd

The effect an materials from "in-use" environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors.

NAs

Specimens 423 to 425 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.

**Pass** 

Specimens 406 to 410, 417 to 419, 429 to 431, 433, 439, 440, 446 and 447 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse.

\_

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

Pass NAs

#### 7.7 Practical performance

#### Model ZH3361

#### Specimen and subject details:

Specimen	Subject
148	АН
149	-

Pass NAs

No adverse comments were made following testing.

#### Model ZH4361V

#### Specimen and subject details:

Specimen	Subject	
448	ED	Pa
449	-	N

Pass NAs

No adverse comments were made following testing.

#### 7.8 Finish of parts

#### Model ZH3361V

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

Ltd

#### Model ZH4361V

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

Ltd

#### INSTEC Rest Report No: 1.13.09.58

#### Total inward leakage (%)

Model ZH3361

Subject	Specimen	Cond	Walk	Head side/ side	Head up/down	Talk	Walk	Mean
ВН	104	AR	3.02	2.96	2.59	3.34	3.39	3.06
MLT	105	AR	0.79	4.71	4.77	3.32	4.35	3.59
INH	106	TC	0.40	0.87	1.03	0.74	1.12	0.83
VW	107	TC	0.39	1.80	0.58	0.52	0.58	0.78
NRA	108	TC	1.57	1.46	2.27	1.65	2.43	1.88
Maximum permitted (FFP1)			25				22	
Maximum permitted (FFP2)			11				8	
Maximum permitted (FFP3)			5				2	

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

Ltd

All 25 individual exercise results were not greater than 11%. (FFP2)

Ltd

All 25 individual exercise results were not greater than 5%. (FFP3)

Ltd

All 5 individual wearer arithmetic means were not greater than 22%. (FFP1)

Ltd

All 5 individual wearer arithmetic means were not greater than 8%. (FFP2)

Ltd

3 out of 5 individual wearer arithmetic means were not greater than 2%. (FFP3)

#### Model ZH4361V

Subject	Specimen	Cond	Walk	Head side/ side	Head up/down	Talk	Walk	Mean
ВН	401	AR	3.04	2.31	2.80	1.13	2.57	2.37
INH	403	AR	0.27	0.27	0.31	0.16	0.25	0.25
PBU	404	AR	0.06	0.19	0.20	0.12	0.09	0.13
vw	405	AR	1.64	3.20	0.94	1.03	2.48	1.86
MLT	414	AR	0.84	4.77	5.20	4.33	5.85	4.20
GW	406	TC	1.26	0.75	0.59	3,24	0.63	1,29
VE	407	TC	1.62	2.96	1.83	1.12	2.14	1.93
AH	408	TC	0.68	0.21	0.34	0.36	0.21	0.36
SR	409	TC	3.33	4.01	4.25	2.43	6.20	4.05
JAD	410	TC	1.12	1.36	1.56	0.98	0.76	1.15
Maximum permitted (FFP1)		25					22	
Maximur	Maximum permitted (FFP2)		11				8	
Maximur	m permitted (	ermitted (FFP3) 5					2	

Pass Pass Fail

All 50 individual exercise results were not greater than 25%. (FFP1)	Pass
50 indiviginal exercise results were not greater than 11%. (FFP2)	Pass
47 out of individual exercise results were not greater than 5%. (FFP3)	Pass
All 10 individual wearer arithmetic means were not greater than 22%.(FFP1)	Pass
All 10 individual wearer arithmetic means were not greater than 8%.(FFP2)	Pass
7 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)
ВН	120	139	108	54
MLT	109	136	103	41
INH	125	153	95	58
vw	110	139	103	43
NRA	114	138	116	50
PBU	116	141	90	52
GW	117	133	120	53
VE	116	132	115	45
АН	119	113	115	50
SR	126	137	138	52
JAD	113	136	120	54

#### 7.9 2 Renetration filter material

Model ZH3

Sodium Chland

(II)		Penetrat	ion (%)
Specimen	Condition	After 3 minutes	Max. during exposure
211		0.03	
212	A.R.	0.04	
213		0.03	
220		0.02	
221	S.W.	0.11	
222		0.09	
226		0.03	0.03
227	M.S. + T.C.	0.04	0.04
228		0.03	0.03
Maximum permitted (FFP1)		20	)
Maximum permitted (FFP2)		6.0	
Maximum pe	ermitted (FFP3)	1.0	

Pass Pass Pass

#### Paraffin oil:

		Penetration (%)		
Specimen	Condition	After 3 minutes	Max. during exposure	
214		0.09		
215	A.R.	0.11		
216		0.11		
223		0.14		
224	S.W.	0.11		
225		0.18		
229		0.19	0.23	
230	M.S. + T.C.	0.25	0.34	
231		0.23	0.27	
Maximum permitted (FFP1)		20	)	
Maximum permitted (FFP2)		6.0	0	
Maximum permitted (FFP3)		1.0	0	

Pass Pass Pass

#### INSPECTO 1:13.09.58

Model ZH4361V Paraffin oil

THE WAS		Penetra	tion (%)
Specimen	Condition	After 3 minutes	Max. during exposure
414			
415	A.R.	Not requested	
416			
423		0.26	
424	S.W.	0.14	
425		0.41	
429		0.28	0.36
430	M.S. + T.C.	0.44	0.47
431		0.85	1.12
Maximum permitted (FFP1)		20	
Maximum permitted (FFP2)		6.0	
Maximum pe	Maximum permitted (FFP3)		.0

Ltd Ltd Fail

#### 7.11 Flammability

#### Model ZH4361V

Specimens 444 and 445 (A.R.) and 446 and 447 (T.C.) were tested.

Specimen 44 ignited on the mask body but self extinguished within 5 seconds. None of the other specimens ignited.

Pass

#### 7.12 Carbon dioxide content of the inhalation air

Model ZH4361 Pass

Specimen	CO <sub>2</sub> (%)
335	0.89
336	0.92
337	0.87
Maximum permitted	1.0



Head harnes

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

Ltd

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

Ltd

The product satisfied the total inward leakage requirements for the limited testing carried out. See 7.9.1 for results.

Ltd

#### Model ZH4361V

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 ZH3361

There were no adverse comments following limited practical performance tests.

Ltd

#### Model ZH4361V

There were no adverse comments following limited practical performance tests.

Ltd

#### 7.15 Exhalation valve

#### Model ZH4361V

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. Specimens 432 (A.R.), 433 (T.C.) and 434 (M.S.) were tested.

**Pass** 

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# Breathing resistance

Model Z

Specimen	Condition		resistance bar)	Exhalation resistance (mbar)
		At 30 l/min	At 95 l/min	At 160 l/min
311				1.92
312	A.R.	Not red	quested	1.98
313				2.03
317				1.93
318	T.C.	Not red	Not requested 1.99	1.99
319				1.95
320				2.58
321	S.W.	Not red	quested	2.37
322				2.16
	3.0			
	3.0			
	3.0			

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Ltd Ltd Ltd

# Model ZH4361V Pass Inhalation resistance Exhalation resistance (mbar)

Specimen	Condition	(mbar)		resistance (mbar)
		At 30 I/min	At 95 I/min	At 160 I/min
411	A.R.	0.52	1.76	2.00
412		0.46	1.59	1.54
413		0.49	1.71	1.73
417	T.C.	0.52	1.76	1.68
418		0.51	1.79	1.87
419		0.52	1.73	1.87
423	S.W.	0.59	2.11	1.96
424		0.42	1.56	1.40
425		0.49	1.69	1.60
438	A.R. + F.C.	0.54	1.89	1.54
439	T.C. + F.C.	0.38	1.40	1.52
440		0.53	1.75	1.63
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

Fail Pass Pass



#### Demound be parts

Mode ZMASS1V

No demonstrable parts were used. NAp

9 Marking

All models

9.1 Packaging

The packaging was not marked.

Fail

#### 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.

#### Models ZH3361V and ZH4361V

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.	NAs



#### similar of the uncertainty of measurement

viause	Testo	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	± 4.7%
7.9.2	Penetration of filter material - Sodium chloride	± 4.8%
7.9.2	Penetration of filter material - Paraffin oil	± 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	± 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	± 2.1%
7.17.2	Breathing resistance after clogging	± 3.9%
7.17.3	Filter penetration after clogging - Sodium chloride	± 4.7%
7.17.3	Filter penetration after clogging - Paraffin oil	± 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 comprises on section.

1. Photographs of the proceed ested.

(4 pages)