

**CERTIFICATE OF CONFORMANCE****Certificate No: 2163-PPE-1241/01**

Respiratory protective devices, filtering half masks to protect against particles manufactured by

**Shenzhen Zhishan Medical Co., Ltd.**2/F, Building B, Tongzhou Electronic Longgang Factory, No. 1 Road 5, Baolong Community,  
Baolong Street 5, Longgang District, Shenzhen, China

Continues to fulfil the requirements of

**EN 149:2001 + A1:2009 Respiratory Protective Devices -  
Filtering Half Masks to Protect Against Particles -  
Requirements, Testing, Marking**

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

**Product Definition**

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
zhishan / 10217	FFP2 NR	2163-PPE-1241	09.08.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **09/08/2020** and will be valid for one year, until **08/08/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.



Suat KAÇMAZ  
UNIVERSAL CERTIFICATION  
Director



**EU-KONFORMITÄTSERKLÄRUNG / EU DECLARATION OF CONFORMITY  
VERORDNUNG ÜBER PERSÖNLICHE SCHUTZAUSRÜSTUNG /  
PERSONAL PROTECTIVE EQUIPMENT REGULATION  
(EU) 2016/425**

Shenzhen Zhishan Medical Co., Ltd, No.1, Baolong 5th Road, , Baolong street, Longgang District, Shenzhen, China erklärt hiermit, dass die folgende persönliche Schutzausrüstung (PSA):  
*Shenzhen Zhishan Medical Co., Ltd, No.1, Baolong 5th Road, , Baolong street, Longgang District, Shenzhen, China being the manufacturer, hereby declare the following Personal Protective Equipment (PPE):*

Produkt / Product:	<b>Partikelfiltrierende Halbmaske / Particulate Filtrating Respirator</b>
Produktbezeichnung / Product Description:	<b>AIR PROTECT FFP2</b>
Modell / Model:	<b>10217</b>
EAN:	<b>4250284209545 / 4350284212729</b>

in Übereinstimmung mit den Bestimmungen der Verordnung (EU) 2016/425, einschließlich der Erfüllung der geltenden grundlegenden Sicherheits- und Gesundheitsanforderungen gemäß Anhang 11 der harmonisierten europäischen Norm:  
*is in conformity with the provision of Regulation (EU) 2016/425, including fulfilment of the applicable essential health and safety requirements set out in Annex 11 of the harmonized European Standard Number:*

**EN 149:2001+A1:2009 (Veröffentlichungsjahr / Release Year 2009)**

umgesetzt und identisch mit der PSA, die Gegenstand der EU-Baumusterprüfung (Modul B der Verordnung (EU) 2016/425 ist, auf die in dem Zertifikat 2163-PPE-1241 vom 09.08.2020 verwiesen wird, welches von der benannten Stelle UNIVERSAL, Necip Fazil Bulvan Keyap Sitesi E2 Blok No. 44/84, Yukan Dudullu Ümraniye / ISTANBUL /TÜRKIYE ausgestellt wurde und unterliegt dem Verfahren gemäß Modul B und C2 der Verordnung (EU)2016/425 unter der Aufsicht von UNIVERSAL (Benannte Stelle Nr. 2163).

*and is identical to the PPE which is the subject of EU type-examination (Module B and C2 of Regulation (EU) 2016/425) referenced on the certificate 2163-PPE-1241, issued on 09.08.2020 by the Notified Body UNIVERSAL, Necip Fazil Bulvan Keyap Sitesi E2 Blok No. 44/84, Yukan Dudullu Ümraniye / ISTANBUL /TÜRKIYE and is subject to the procedures set out in Module D of Regulation (EU) 2016/425 under the surveillance of UNIVERSAL (Notified Body 2163).*



23th of January 2021

**Test Report No.:** 244287526a 001

Page 1 of 7

**Client:** **MASTERDIS GMBH**  
 Maria-Merian-Str.12 85521 Ottobrunn, Germany  
**Contact Information:** Contact Person: Jan Priepke

**Sample Description As Declared :**

No. Of Sample	100pcs
Product Description	Filtering Half Mask FFP2
Material	Polypropylene
Colour	White
Model No.	10217
Lot No./Batch Code	2020ZS6006
Manufacture	Shenzhen Zhishan Medical Co., Ltd

Manufacture Address	2/F, Building B, Tongzhou Electronic Longgang Factory, no 1 Road 5, Baolong community, baolong street5, longgang district, Shenzhen.
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Contry Of Origin	China
Test Type	Partial test
Product Type	Single shift use only
Claimed Classification	FFP2

**Sample obtaining method:** Sending by customer

**Sample Receiving date:** 2020-12-21

**Delivery condition:** *Apparent good, Samples tested as received*
**Test Period:** 2020-12-21 to 2021-01-13

**Test Specification:**

 EN 149:2001 + A1:2009 Respiratory Protective Devices – Filtering Half Masks  
 to Protect against particles- Requirements, testing, marking

**Test Result**
*Please refer to next page*
**For and on behalf of**
**TÜV Rheinland (Shanghai) Co., Ltd.**


2021-01-14 Joyce Zhou/Assistant Technical Manager

Date

Name/Position

*Test result is drawn according to the kind and extent of tests performed.*
*This test report relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.*

**Summary of test results**

Clause	Item	M001
7.3	Visual inspection	N/R
7.4	Package	M
7.5	Material	M
7.6	Cleaning and disinfection	N/A
7.7	Practical performance	M
7.8	Finish of parts	M
7.9.1	Leakage	M
7.9.2	Penetration of filter material	M
7.10	Compatibility with skin	M
7.11	Flammability	M
7.12	Carbon dioxide content of the inhalation air	M
7.13	Head harness	M
7.14	Field of vision	M
7.15	Exhalation valve(s)	N/A
7.16	Breathing Resistance	M
7.17	Clogging	N/A
7.18	Demountable parts	M
9	Marking	N/R
10	Information to be supplied by the manufacturer	N/R

Note : M = Meet Performance Standard  
 N/R = Not Request  
 N/A = Not Applicable

F = Below Performance Standard  
 \* = No Submitted Information  
 # = Refer to result page

**Material list**

Material No.	Material	Color/Pattern	Location
M001	Whole Product	White	Filtering Half Mask FFP2

## 1. Visual inspection

Test method : EN 149:2001+A1:2009 Clause 8.2

Clause	Item	M001
7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer.	N/R
7.4	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Pass
7.5	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.	Pass
	After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the face piece or straps.	Pass
	When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass
	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Pass
7.8	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs	Pass
7.18	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Pass

Remark:

N/A: Due to no relevant information/material

N/R: Due to not request

## 2. Practical performance

Test method : EN 149:2001+A1:2009 Clause 8.4 &amp; 8.5

Clause	Item	M001
7.7	Wearing	Pass
7.7	Walking test	Pass
7.7	Work simulation test	Pass
7.10	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	Pass
7.13	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. 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	Pass
7.14	The field of vision is acceptable if determined so in practical performance tests	Pass

Remark:

N/A: Due to no relevant information/material

N/R: Due to not request

### 3. Leakage

Test method : EN 149:2001+A1:2009 Clause 8.5  
 Requirement : FFP2 :  
 At least 46 out of the 50 individual exercise results for total inward leakage  $\leq 11\%$   
 At least 8 out of the 10 individual wearer arithmetic means for the total inward leakage  $\leq 8\%$

M001									
Subject	Condition	Specimen No.	Leakage (%)					Walk	Mean
			Walk	Head Side/side	Head Up/down	Talk			
BM	As received	1	4.348	3.792	4.062	3.240	8.175	4.723	
ACH		2	5.167	5.732	6.114	7.243	5.286	5.908	
ML		3	4.968	4.734	5.926	6.148	5.305	5.416	
LLC		4	5.267	5.246	6.849	7.665	6.842	6.374	
DG		5	6.623	6.743	5.923	7.863	7.442	6.919	
SG	After conditioning	6	4.993	4.691	3.622	5.565	6.301	5.034	
YL		7	6.367	6.724	6.783	7.867	5.840	6.716	
KQ		8	5.721	6.006	7.123	7.802	5.446	6.420	
KXH		9	5.963	6.326	6.847	7.065	7.123	6.665	
YY		10	6.389	6.927	5.993	8.126	6.144	6.716	
Conclusion		Pass							

Facial Dimension Of Subject (mm)										
Subject	BM	ACH	ML	LLC	DG	SG	YL	KQ	KXH	YY
Face length	135	127	120	120	130	135	115	120	130	130
Face width	160	159	133	140	145	155	135	135	155	165
Face Depth	130	122	115	115	132	132	118	115	120	143
Mouth Width	52	55	52	50	50	55	48	50	52	50

### 4. Flammability

Test method : EN 149:2001+A1:2009 Clause 8.6  
 Requirement :  $\leq 5s$

M001				
Item	Condition	Specimen No	Test results	Conclusion
Afterflame time (s)	As received	1	1.0	Pass
		2	1.0	
	After conditioning	3	1.2	
		4	1.1	

### 5. Carbon Dioxide Content Of The Inhalation Air

Test method : EN 149:2001+A1:2009 Clause 8.7  
 Requirement :  $\leq 1\%$

M001.						
Item	Condition	Test results				Conclusion
Content (%)	As received	Specimen 1	Specimen 2	Specimen 3	Mean	Pass
		0.60	0.61	0.62	0.61	

## 6. Breathing Resistance

Test method	:	EN 149:2001+A1:2009 Clause 8.9
	:	FFP2:
Requirement		Inhalation: 30l/min: ≤0.7mbar
		Inhalation: 95l/min: ≤2.4mbar
		Exhalation: 160l/min: ≤3.0mbar

M001																
Flow rate (l/min)		Resistance (mbar)														
As received		Specimen 1					Specimen 2					Specimen 3				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	95	1.3	1.3	1.3	1.3	1.3	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3
Exhalation	160	2.2	2.2	2.2	2.2	2.2	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1
Simulated wearing treatment		Specimen 4					Specimen 5					Specimen 6				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	95	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3
Exhalation	160	2.1	2.1	2.1	2.1	2.1	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1
Temperature conditioned		Specimen 7					Specimen 8					Specimen 9				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Inhalation	30	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	95	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3
Exhalation	160	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0
Conclusion		Pass														

Remark: A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

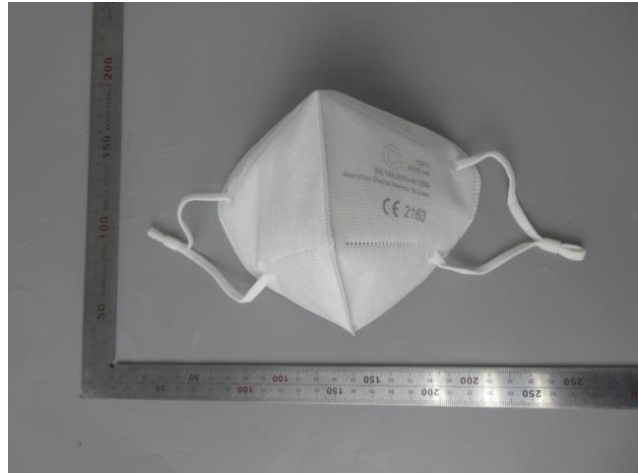
**7. Penetration Of Filter Material**

Test method : EN 149:2001+A1:2009 Clause 8.11

Requirement : FFP2:≤6%

M001			
Aerosol	Condition	Specimen No.	Penetration (%)
Sodium chloride Penetration	As received	1	0.036
		2	0.049
		3	0.087
	Simulated wearing treatment	4	0.023
		5	0.028
		6	0.057
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	7	0.052
		8	0.068
		9	0.079
Paraffin oil Penetration	As received	10	0.139
		11	0.122
		12	0.131
	Simulated wearing treatment	13	0.146
		14	0.120
		15	0.124
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	16	0.326
		17	0.928
		18	0.153
Conclusion	Pass		

**Photo:**



- END -



Dermatest<sup>®</sup> GmbH Engelstr. 37 48143 Münster

masterdis gmbh  
maria-merian-str. 12  
85521 ottobrunn

Münster, 30.10.2020

# Zertifikat

über das Produkt

## FFP2 10217

### (Innenvlies)

## Dermatologische Prüfungen am Menschen 2020

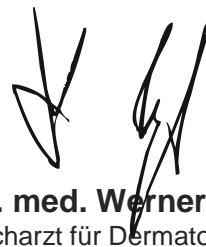
Die von mir unter fachärztlicher Kontrolle durchgeführten dermatologischen Prüfungen Ihres o. g. Produktes bestand das Produkt mit

**„sehr gut“**

Bei dem genannten Präparat traten im Epikutantest nach internationalen Richtlinien keine toxisch-irritativen Unverträglichkeitsreaktionen auf. Das Präparat kann deshalb mit dermatologisch getestet deklariert werden.



**Dr. med. Gerrit Schlippe**  
Facharzt für Dermatologie,  
Venerologie



**Dr. med. Werner Voss**  
Facharzt für Dermatologie,  
Venerologie, Allergologie,  
Phlebologie und Umweltmedizin



## DE AUFSETZANLEITUNG



Maske mit Nasenclipseite nach oben zuerst am Kinn aufsetzen.



Gummibänder hinter die Ohren legen, Maske ausrichten bis sie bequem sitzt.



Nasenclip mit den Fingern an die Nase drücken.



Korrekten Sitz und enges Anliegen der Maske überprüfen.

## EN USING INSTRUCTION

Face the mask with nose bridge upside against the chin first.

Pull the earband back to the ears and align the mask until it fits comfortable

Press the fingers inwardly according to the shape of the nose bridge to conform to the shape of the nose.

Check the correct and tight fit of the mask.

## FR INSTRUCTION POUR METTRE LE MASQUE

Placez le masque sur le menton en premier, avec le pince-nez vers le haut.

Placez les élastiques derrière les oreilles, alignez le masque jusqu'à ce qu'il soit confortablement installé.

Pressez le pince-nez sur le nez avec vos doigts.

Vérifiez le bon ajustement et l'étanchéité du masque.

## IT IGUIDA DI INSTALLAZIONE

Posizionare la maschera sul mento con la clip per il naso rivolta verso l'alto.

Posizionare gli elastici dietro le orecchie, allineare la maschera fino a quando non si adatta comodamente.

Premere la clip per il naso sul naso con le dita.

Controllare la corretta calzatura e la tenuta della maschera.

## DE SCHUTZ

Schutz gegen verschiedene Arten von Staub und nichtöligen Nebel, bis zum zehnfachen Arbeitsplatzgrenzwert, der bei der Verarbeitung von Kohle, Eisenerz und quarzhaltigem Mineral oder durch Maschinen bei der Verarbeitung von Baumwolle, Mehl und anderen Materialien auftritt.

Schutzklasse FFP2 gemäß Verordnung (EU) 2016/425, EN 149:2001+A1:2009 (Veröffentlichungsjahr 2009).

## EN PROTECTION

It is suitable for steam odor reduction. Odor refers to the concentration not over the level of occupational exposure limit. Protection against various kinds of dust and non-oily mist of 10 times than the occupational exposure limit which occurs during processing of coal, iron ore and contain quartz mineral or by machinery during processing of cotton, flour and other materials.

PPE Class FFP2 according to regulation (EU) 2016/425, EN 149:2001+A1:2009 (Release year 2009).

## FR PROTECTION

Protection contre divers types de poussières et de brouillards non huileux, jusqu'à dix fois la limite d'exposition professionnelle, provenant du traitement du charbon, du minerai de fer et des minéraux contenant du quartz ou des machines utilisées dans le traitement du coton, de la farine et d'autres matériaux.

Classe de protection FFP2 selon le règlement (UE) 2016/425, EN 149:2001+A1:2009 (année de publication 2009).

## IT PROTEZIONE

Protezione contro vari tipi di polvere e nebbie non oleose, fino a dieci volte il limite di esposizione professionale, derivanti dalla lavorazione del carbone, del minerale di ferro e del minerale contenente quarzo o da macchinari utilizzati nella lavorazione del cotone, della farina e di altri materiali.

Classe di protezione FFP2 secondo il regolamento (UE) 2016/425, EN 149:2001+A1:2009 (anno di pubblicazione 2009).

## DE AUSNAHMEN

Nicht geeignet für die Umgebung, in der die von Maschinen erzeugte Staub- oder Nebelkonzentration das Zehnfache des Arbeitsplatzgrenzwertes überschreitet, wie z.B. bei Lackier- und Sandstralarbeiten. Nicht geeignet für die Umgebung, in der die Konzentration von Ölparkeln oder Dampf über dem Grenzwert für die berufliche Exposition liegt. Nicht verwendbar gegen Partikel radioaktiver Stoffe, luftgetragene biologische Arbeitsstoffe der Risikogruppe 3 und Enzyme.

## EN RESTRICTIONS

Not suitable for the environment in which the dust or mist concentration produced by machinery is 10 times over the occupational exposure limit, such as painting and sand blasting operations. It can't be used for the environment in which oily particles or steam concentration are over the occupational exposure limit. Not useable against particles of radioactive substances, airborne biological agents of risk group 3 and enzymes.

## FR EXCEPTIONS

Ne convient pas à l'environnement où la concentration de poussière ou de brouillard généré par les machines dépasse dix fois la valeur limite d'exposition professionnelle, comme dans les opérations de peinture et de sablage. Ne convient pas à l'environnement où la concentration de particules ou de vapeur d'huile dépasse la valeur limite d'exposition professionnelle. Ne convient pas à une utilisation contre les particules de substances radioactives, les agents biologiques en suspension dans l'air du groupe de risque 3 et les enzymes.

## IT ECCEZIONI

Non adatto all'ambiente in cui la concentrazione di polvere o nebbia generata dai macchinari supera dieci volte il valore limite di esposizione professionale, come nelle operazioni di verniciatura e sabbatura. Non adatto all'ambiente in cui la concentrazione di particelle di olio o di vapore supera il valore limite per l'esposizione professionale. Non adatto per l'uso contro particelle di sostanze radioattive, agenti biologici aerodispersi del gruppo di rischio 3 ed enzimi.

## DE ACHTUNG

- Verschmutzungsbereich sofort verlassen, wenn Atembeschwerden, Schwindel oder andere Beschwerden wahrgenommen werden.
- Maske sofort wechseln, wenn sie beschädigt ist oder verstärkter Atemwiderstand verspürt wird.
- Vor dem Gebrauch, die Maske auf ihren Zustand prüfen.
- Es ist unwahrscheinlich, dass die Anforderungen an die Leckage erfüllt werden, wenn Barthaare unter der Dichtlinie am Gesicht sind.
- Die Maske sollte nicht länger als vier Stunden getragen und danach entsorgt werden.
- Sie darf nicht für mehr als eine Schicht benutzt werden.

## EN ATTENTION

- Leave the pollution area immediately when you feel difficulty in breathing, dizziness or other discomforts.
- Replace the mask when it is damaged or by feeling more breathing resistance.
- Check the mask to ensure it is in good condition before using.
- It is unlikely that the leakage requirements will be met if whiskers are on the face below the seal line.
- The mask should not be worn for more than four hours and then disposed of.
- It should not be used for more than one shift.

## FR ATTENTION

- Quittez immédiatement la zone contaminée si vous remarquez des difficultés respiratoires, des vertiges ou d'autres maux.
- Changez immédiatement le masque si vous sentez qu'il est endommagé ou que la résistance respiratoire est accrue.
- Avant l'utilisation, vérifiez l'état du masque.
- Il est peu probable que les exigences en matière de fuite soient respectées s'il y a des moustaches sous la ligne d'étanchéité sur le visage.
- Le masque ne doit pas être porté pendant plus de quatre heures, puis être jeté.
- Il ne doit pas être utilisé pour plus d'un quart de travail.

## IT ATTENZIONE

- Lasciare immediatamente la zona contaminata se si notano difficoltà respiratorie, vertigini o altri disturbi.
- Cambiare immediatamente la maschera se è danneggiata o se si avverte una maggiore resistenza respiratoria.
- Prima dell'uso, controllare le condizioni della maschera.
- È improbabile che i requisiti di tenuta siano soddisfatti se ci sono baffi sotto la linea di tenuta sulla faccia.
- La maschera non deve essere indossata per più di quattro ore e poi scartata.
- Non deve essere utilizzato per più di un turno.



DE Nicht zur Wiederverwendung  
EN Not for reuse  
FR Pas de réutilisation  
IT Non per il riutilizzo



DE Temperaturbegrenzung  
EN Temperature limit  
FR Limite de température  
IT Limite di temperatura



DE Vor Nässe schützen  
EN Protect from moisture  
FR Protéger de l'humidité  
IT Proteggere dall'umidità



DE Vor Sonnenlicht schützen  
EN Protect from sunlight  
FR Protéger de la lumière solaire  
IT Proteggere dalla luce del sole



DE Gebrauchsanweisung beachten  
EN Follow the instruction  
FR Suivre le mode d'emploi  
IT Seguire le istruzioni per l'uso



DE CE-Zeichen mit Nummer der benannten Stelle  
EN CE sign with Notified Body Number  
FR Marquage CE avec le numéro de l'organisme notifié  
IT Marchio CE con numero di organismo notificato