

GUANGZHOU KING YON MEDICAL TECH CO., LTD

Co.Registration No & VAT No.:914401110701730113

Blv San Yuan Li, Bai Yuan District, Guang dong,guang zhou Post Code:510403

Attn:Sam Deng(Mr) Mobile: +86-15089203268

www.King-Yon.com Mail Address: sales@King-Yon.com

Our face mask manufacture sector has 38 sets automatic mask producing machine: 2 sets High-Speed FFP2/KN95 face mask machine, 20sets surgical face mask machine, which enable us to supply with the FFP2 NR 1,000,000 pieces per day. We use the qualified non-woven fabric which is compliant to CE & FDA. All the products are tested strictly during the producing. Products qualified to the the standard: EN149:2001+A1:2009 and CE0598

FFP2 NR Particle Filtering Half Mask with CE

Model Number	OKV001 (5 layers Protection)	Product Info
CE Notified Body	0598 (Based on EN 149:2001+A1:2001)	
Regulation	(EU) 2016/425	OKV°
	Module B, EU type-examination Module C	Particle Filtering Half Mask
Testing Report	By SGS	FFP2 NK EN149-2001+A1-2009 Art OKY001
Main Material	Non-woven Fabric, Melt-blown Fabric,	CCERT
	Melt-Cloth Fabric	10 Sheet below the control of the co
Filter Principle	Electrostatic Adsorption	These description of the property of the prope
Filter Efficiency	≥96.3	paras .
Protection Effect	Disposable	NOSE CLIP 80MM 4 MASK STRAPS ±55MM/ LENGTH:190MM
Breathing Resistance	160L/min: Uncertainty:4.3%	70MM ±5MM
Size	Adults Size	E5MM
Quantity in a Box	5pcs/Pack, 6 Packs in a box, 30pcs/Box	GPF III
Carton Dimension	L55xW36xH40cm, 36boxes in a case	160MM 25MM 25MM
Lead Time	10,000pcs>:1days 100,000pcs>2days	55MM MASK BODY
	100,000pcs< To be Negotiated	TOMM
M.O.Q	10000 Pcs	1 100MM ±5MM
Container Loading	HQ40":756 cases, 816480pcs	LEDZ NE
Quantity	40"GP: 630 Cases, 680400pcs	OKV'
	20": 300 cases, 324000pcs	FFP2 NR WARRING TO THE
Payment	T/T, Western Union,	



CE Notified Body:0598 Regulation (EU) 2016/425 Module B, EU type-examination





SGS

Certificate FI20/966225, continued

Zhongshan Jiashengfeng Clothing Co., Ltd

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

OKV® OKV001 white folded half mask, consisting of a white five layer (polypropylene/ polypropylene & electret master batch/ polypropylene & electret master batch / polypropylene / polypropylene) disposable particle filtering half mask, with polyethylene/

Polypropylene/cored wire nose clip and chinlon/spandex ear band.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001+A1:2009 (Respiratory protective devices - filtering half masks to protect against particles) device classification: FFP2 NR.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

Certification is based on technical file reference:

OKV001, dated: 2020/6/28

SGS Reference Number UK/CRS 241351

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request





CE Notified Body:0598 Regulation (EU) 2016/425 Module C



Certificate CN20/42167

The management system of

ZHONGSHAN JIASHENGFENG CLOTHING CO., LTD.

FLOOR1, BUILDING A, NO. 6, LONGXING SOUTH ROAD, SHAXI TOWN, ZHONGSHAN CITY, GUANGDONG PROVINCE, P.R. China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module C2

For the following activities

Manufacture of OKV® OKV001 white folded Particle Filtering Half

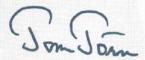
Note: All products marked CE0598 must have a valid EU typeexamination certificate issued under Module B or a valid EC typeexamination certificate issued under Article 10 of Directive 89/686/EEC.

This certificate is valid from 3 August 2020 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 3 August 2020

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by



SGS FIMKO OY, Notified Body 0598
Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com



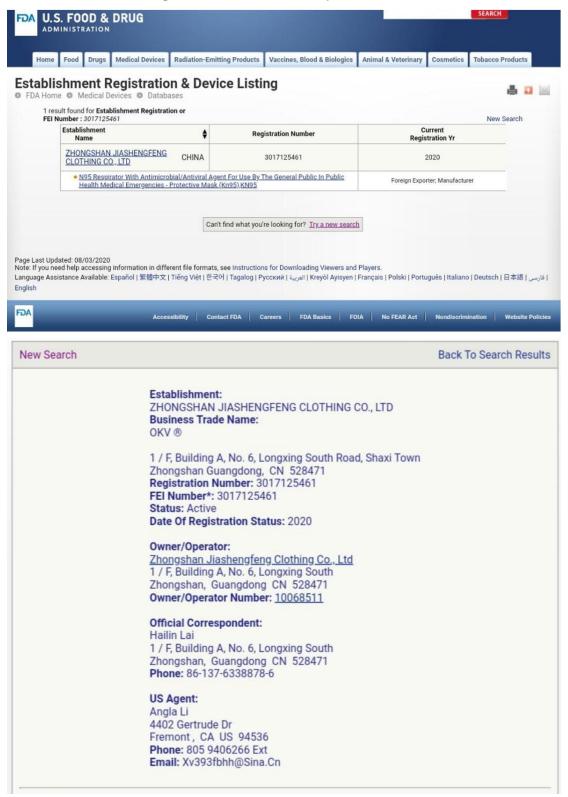




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FDA Registration No.: 3017125461 Operator No.: 10068511





Product Details







Mask Manufacture Machine





SGS Testing Report Based on EN 149:2001+A1:2001







中国认可 国际互认 TESTING **CNAS L0599**

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ZHONGSHAN JIASHENGFENG CLOTHING CO., LTD Date:June 15,2020 Page 1 of 10

FLOOR 1, BUILDING A, NO.6, LONGXING SOUTH ROAD, SHAXI TOWN, ZHONGSHAN CITY, GUANGDONG PROVINCE

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)Particle filtering half mask

Style No. OKV001 Sample Color (A)White

Manufacturer : ZHONGSHAN JIASHENGFENG CLOTHING CO., LTD

Country of Destination : European Union

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date May 29, 2020

Testing Period May 29, 2020 - Jun 15, 2020

Test Result(s) Unless otherwise stated the results shown in this test report refer only to the

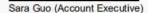
sample(s) tested, for further details, please refer to the following page(s).

Conclusion:

Sample No.	Recommendation Level	
(A)	FFP2 NR	

Signed for and on behalf of

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center









Test Report Test Result

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Personal Protective Equipment - Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking

Clause 7.4 Packaging

(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
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.	Comply	Pass

<u>Clause 7.5 Material</u> (EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
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.	Comply	
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Comply	Pass
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	

Clause 7.6 Cleaning and Disinfecting

(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant	Not applicable (Not designed to be re-usable)	N.A.

Clause 7.7 Practical Performance

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass



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Test Report S Clause 7.8 Finish of Parts SL52025259037201TX Date:June 15,2020

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Test Requirement Results Comment Parts of the device likely to come into contact with the wearer shall have no Comply Pass sharp edges or burrs.

<u>Clause 7.9.1 Total Inward Leakage</u> (EN 149:2001+A1:2009, Clause 8.5)

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3	Detail refer to Appendix 1	Meet FFP1, Meet FFP2

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	5.30	4.99	6.32	5.06	4.47	5.23
Luo	2	A.R.	6.27	5.59	6.71	5.37	6.70	6.13
Lu	3	A.R.	4.45	5.28	5.94	6.58	5.01	5.45
Wang	4	A.R.	5.04	3.96	4.29	4.31	3.84	4.29
Bao	5	A.R.	4.72	6.95	6.76	6.24	6.80	6.29
Ding	6	T.C.	3.75	4.48	4.64	4.53	5.08	4.50
Li	7	T.C.	6.48	6.26	7.59	4.97	6.43	6.35
Chen	8	T.C.	4.09	4.71	5.03	4.29	3.01	4.23
Song	9	T.C.	6.37	6.21	5.61	5.62	3.94	5.55
Ye	10	T.C.	6.50	6.21	7.09	6.44	7.34	6.72

Facial Dimension(mm)

Subject	Face length	Face Width	Face Depth	Mouth Width
Chen	125	150	120	58
Lu	115	132	107	48
Zhou	115	135	106	52
Li	125	130	107	46
Luo	125	136	100	43
Zheng	128	140	112	55
Wang	120	147	103	48
Song	120	140	100	50
Bao	130	134	104	50







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Ding	134	150	110	52
Liu	120	135	117	50
Ye	126	137	105	52

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

	Test Requirement	l .	Results	Comment
	of the filter of the particle filter the following table.	ering half mask shall meet the	31	
Classifica	Maximum penetrati	ion of test aerosol		
tion	Sodium chloride test 95 I/min %	Paraffin oil test 95 I/min %	Detail refer to Appendix 2	Meet FFP1, Meet FFP2
	max.	max.	1950	
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		2

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
ĺ		1	0.053
	As received	2	0.060
	A000000000000000	3	0.089
		4	0.075
Sodium chloride test	Simulated wearing treatment	5	0.055
		6	0.083
	Mechanical strength +Temperature	7	0.375
		8	0.398
	conditioned	9	0.339
i i		10	0.076
	As received	11	0.094
	3	12	0.075
		13	0.086
Paraffin oil test	Simulated wearing treatment	14	0.094
		15	0.086
		16	1.683
	Mechanical strength +Temperature	17	1.749
	conditioned	18	1.724







Test Report SL 520252 Clause 7.10 Compatibility with Skin SL52025259037201TX

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(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
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.	No irritation or any other adverse effect to health	Pass

Clause 7.11 Flammability

(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature	Detail refer to	Dave
When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.	Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result	
As received	1	NIL	
As received	2	NIL	
-	3	NIL	
emperature conditioned	4	NIL	

Clause 7.12 Carbon Dioxide Content of The Inhalation Air (EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Re	esult(%)
	1	0.5862	11 11 11 11 11 11 11 11 11 11 11 11 11
As received	2	0.5854	Mean value:0.59
	3	0.5851	







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<u>Clause 7.13 Head Harness</u> (EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	
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.	Comply	Pass

Clause 7.14 Field of Vision

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

Clause 7.15 Exhalation Valve(s)

(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
(a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Not applicable due to No exhalation valve	
(b) If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	Not applicable due to No exhalation valve	N.A.
(c) Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	Not applicable due to No exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to No exhalation valve	



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Clause 7.16 Breathing Resistance (EN 149:2001+A1:2009, Clause 8.9)

	Test	Results	Comment		
he penetration of the penetratio		he particle filterin ble.			
Classification	Maximu	m permitted resis	tance (mbar)	5.00	Meet FFP1, Meet FFP2, Meet FFP3
	Inha	alation	Exhalation	Detail refer to	
	30 I/min	95 I/min	160 I/min	Appendix 5	
FFP1	0.6	2.1	3.0		
FFP2	0.7	2.4	3.0		
FFP3	1.0	3.0	3.0		

Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

	E1	Land X		ZONIUS ET	1				ANIBRE	2					3	Keri Alberta	V
	Flow rate(I	/min)	Α	В	C	D	E	Α	В	C	D	Е	Α	В	C	D	E
As received Inhalation	30	0.4	0.5	0.5	0.4	0.4	0.5	0.5	0.4	0.4	0.4	0.5	0.5	0.5	0.4	0.5	
Jaine I Telhadan mene	innalauon	95	1.5	1.7	1.6	1.6	1.7	1.5	1.5	1.7	1.7	1.6	1.6	1.5	1.7	1.6	1.7
	Exhalation	160	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8
					4			e a reconstruction		5					6		
Simulated	Flow rate(I	/min)	Α	В	C	D	E	Α	В	C	D	E	Α	В	С	D	Е
wearing	oring	30	0.5	0.5	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4	0.5	0.4	0.4
treatment	Inhalation	95	1.7	1.6	1.7	1.7	1.6	1.5	1.7	1.7	1.5	1.6	1.6	1.7	1.7	1.6	1.6
	Exhalation	160	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8
					7	*	***		*	8	*	300			9		12. 1.4
	Flow rate(I	/min)	Α	В	C	D	E	Α	В	C	D	E	Α	В	C	D	Е
Temperature	Inhalation	30	0.3	0.4	0.4	0.3	0.4	0.3	0.3	0.4	0.4	0.3	0.3	0.4	0.4	0.3	0.3
conditioned	onditioned Innalation	95	1.5	1.7	1.6	1.7	1.6	1.6	1.5	1.5	1.6	1.6	1.5	1.6	1.7	1.6	1.7
	Exhalation	160	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8

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



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Clause 7.17 Clogging (EN 149:2001+A1:2009, Clause 8.9 & 8.10)

	Test Requirement	Results	Comment	
Valved particle fill After clogging the FFP1: 4 mbar, Fi The exhalation re low. Valveless particle After clogging the	eathing resistance tering half masks: e inhalation resistances shall not FP2: 5 mbar, FFP3: 7 mbar at 98 esistance shall not exceed 3 mb e filtering half masks: e inhalation and exhalation resis FP2: 4 mbar, FFP3: 5 mbar at 98	5L/min continuous flow par at 160 L/min continuous tances shall not exceed:	Optional for single shift device only	N.A.
All types (valved	enetration of filter material I and valveless) of particle filte g requirement shall also meet th			
Classificatio	Maximum penetration	n of test aerosol		
n	Sodium chloride test 95 I/min	Paraffin oil test 95 I/min	Optional for single	N.A.
	%	%	shift device only	
	max.	max.	1.51	
FFP1	20	20		
FFP2	6	6		

Clause 7.18 Demountable Parts (EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	No demountable parts	N.A.

Test	Uncertainty
Total inward leakage	3.4%
Penetration of filter material	4.8%
Carbon dioxide content of the inhalation air	3.9%
Breathing resistance (30L/min)	5.9%
Breathing resistance (95L/min)	4.9%
Breathing resistance (160L/min)	4.3%







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Sample Photo





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