



FFP3产品介绍

God Bless Well (神保佑)

99%的细菌过滤率 / 99%的氯化钠过滤率 / 99%的油性过滤率

广东腾盛药业科技有限公司



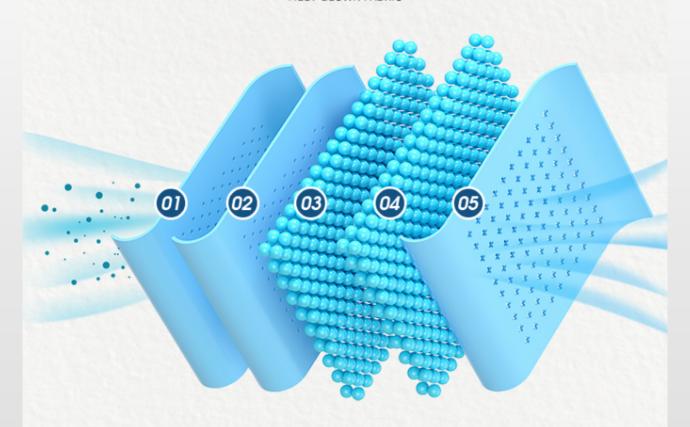




5重过滤 安心净化

多层过滤更高效,过滤效率达到99%

MELT-BLOWN FABRIC



01.

加软无纺布

阻隔灰尘异味 和有害颗粒

02.

热风棉

加强过滤 细微颗粒 03.

熔喷布过滤层

有效过滤≤0.5微米 有效过滤≥95% 颗粒物

04.

熔喷布过滤层

05.

亲肤无纺布

防潮透气过滤 遗漏灰尘



熔喷布 关键滤材

FFP3过滤效率达到99%,有效保护呼吸健康

EFFECTIVELY PROTECT RESPIRATORY HEALTH.



呼吸阻力

FFP3.滤效

<80_{pa} | 99_%



人体工程学设计

3D立体剪裁,根据人体脸部曲线设计,贴合性强

THREE-DIMENSIONAL JOINT



360° ^{面部贴合}

5层 防护保护



耳挂式FFP3折叠型产品图片





产品包装



单个独立包装

单个口罩使用OPP袋,没有二次污染,干净卫生

A SINGLE INDEPENDENT PACKING



便携 卫生





耳挂式FFPE产品500个包装



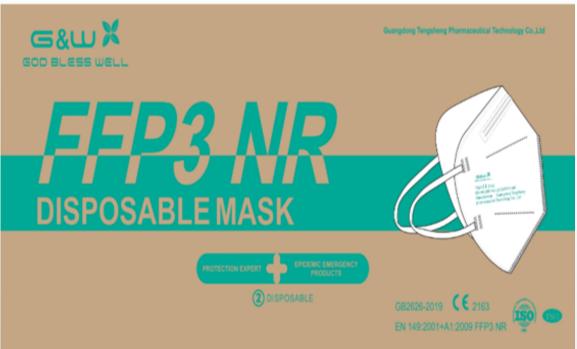






耳挂式FFPE产品500个包装







包装方式1:包装规格:1个单包,10个一盒,500个一箱。

外箱尺寸: 73.5X42.5X32.5CM **毛重:** 7.44KG 净重: 6.14KG



耳挂式FFPE产品800个包装

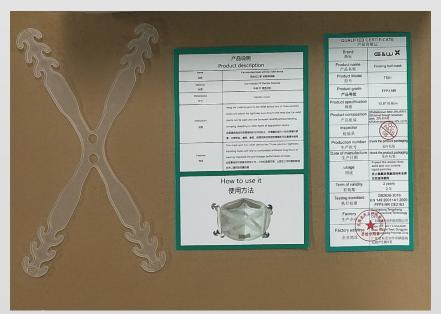




内包膜单个包

彩盒10个装





调节扣,合格证, 说明书



耳挂式FFPE产品800个包装





包装方式1:包装规格:1个单包,800个/箱(配彩盒,合格

证,说明书,调节扣80套)。

外箱尺寸: 73.5X42.5X32.5CM **毛重:** 11.12KG 净重: 9.82KG



耳挂式CE检测报告







TEST REPORT

Report Number...... TSGK-2020-0656-T-XG2

SERVICES Trade Co.

Address...... Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı

Dudullu Ümraniye/İSTANBUL – TURKEY

Manufacturer name.....: Guangdong Tengsheng pharmaceutical Technology Co.,

Ltd.

Address...... Room 301, No. 7, Linhai North Road, Shatian Town,

Dongguan City, Guangdong Province, China

Trade mark.....:

Product name.....: Filtering half mask

Receiving date of sample...... Jun. 8, 2020

Test conclusion.....: The sample upon testing, the test clauses meet the

requirements of the EN 149:2001 + A1:2009 standard. The

details of test results refer to the following.



陈便串

Tester

罗晓腾

2020.07.3

2020.07.3

COOV



耳挂式CE检测报告 ■

TSGK-2020-0656-T-XG2

Serial	Test item	Technical requ	uirements	Result	- Rema	ark			CIF		Verdic	:t
1	Visual inspection	The visual insinclude the mainformation sumanufacturer.	arking and applied by the	Meet re	equiren	nent					Р	
2	Packaging	Particle filtering shall be offere packaged in statement of they are protecting mechanical data contamination.	d for sale uch a way that cted against amage and	Meet re	equiren	nent			15 Cit		Р	2
3	Material	and wear over which the part	d shall be hstand handling r the period for icle filtering half ned to be used.	Meet re	equiren	nent			- CIT		Р	
4	Cleaning and disinfecting	If the particle f mask is design usable, the mashall withstand and disinfecting procedures to the manufacture.	ned to be re- aterials used d the cleaning ng agents and be specified by	Not Ap	plicable	е			4		N/A	
	42 City	Head harness comfort	should be	Meet requirement								<
5	Practical performance	Fastenings are reliable	e safe and	Meet requirement							Р	
		Field of vision	is acceptable	Meet re	equiren	nent						
6	Finish of parts	Parts of the de come into con wearer shall h edges or burrs	tact with the ave no sharp	Meet re	equiren	nent			Par		Р	5
				Exerc	E1	E2	E3	E4	E5	TIL		
	V	At least 46 out individual exer		ises	(%)	(%)	(%)	(%)	(%)	(%)		
		shall be not gr			0.2	0.1	0.1	0.2	0.2	0.2		
	4	25 % for F			0.2	0.2	0.2	0.2	0.2	0.2		
	420	■ 11 % 101 F		A.R.	0.2	0.2	0.2	0.3	0.2	0.2		
	<u>6</u> 1	And in addition	n, a least 8 out		0.2	0.2	0.2	0.3	0.2	0.2	Р	
7	Total inward	of the 10 indiv	idual wearer ans for the total		0.2	0.3	0.3	0.5	0.3	0.3		
•	leakage	inward leakag		4	0.1	0.2	0.2	0.3	0.2	0.2		
	□ 22 % □ 8 %	greater than 22 % for F	FP1:		0.3	0.3	0.5	0.8	0.4	0.5		
		22 % for FFP1; T.C.			0.2	0.3	0.2	0.3	0.3	0.5		
		2 % for FF				7		2742.341				1
				0.2	0.1	0.2	0.2	0.2	0.2			
		Subject	Face Length (mm)	Face (m			ce Dep (mm)	th	Mouth \ mn)			



耳挂式CE检测报告



TSGK-2020-0656-T-XG2

Serial	Test item	Technical requ	then 124 135 110 49						Verdict		
	45	Luo	128	1	49	11	6	54	<		
		Chen	124	1	35	11	0	49			
		Liang	119	1	47	11	5	58			
		Chen	115	1	39	11	119				
	e c	Yuan	107	1.	25	11	0	52	(
		Lai	118	1	35	11	7	55			
		Yang 115		1	27	12	4	53			
		Jiang	119	1	26	11	6	59			
	-	Feng	120	1-	45	11	9	54			
	1201	Zeng	109	1	23	11	5	52	6		
		Sodium chlorid	le:	A.F	٦.	0.1%	0.2%	0.1%			
		FFP1: ≤ 20		S.V	٧.	0.2%	0.4%	0.1%			
Penetration of		 FFP2: ≤ 6 %; FFP3: ≤ 1 %.			M.S.+T.C.		0.2%	.2% 0.5%			
8	filter material	Paraffin oil:	a COT	A.F	₹.	0.1%	0.2%	0.2%	P		
	1	FFP1: ≤ 20	S.V	٧.	0.3%	0.3%	0.2%				
		FFP2: ≤ 6 FFP3: ≤ 1	M.S.+	T.C.	0.5%	0.6%	0.3%				
9	Compatibility	Materials that r	e wearer's skin	A.R. 5 pieces all don't caus			't cause irri	tation.	P		
9	with skin	shall not be kno to cause irritation adverse effect	on or any other	T.C. 5 pie		5 pieces all don't cause irritation.					
		When tested, the		A.R.	Burn	for 0s					
10	Flammability		ontinue to burn			for 0s			Р		
		for more than 5 from the flame	s after removal	T.C.		for 0s			-		
	0-4	The carbon dio	xide content of		0.41	- 41		-CH			
11	Carbon dioxide content of the	the inhalation a	ir (dead space) d an average of		0.43	%	Mean val	ue: 0.42 %	Р		
	inhalation air	1,0 % (by volur			0.439	%					
		The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.			Mee	t requireme	equirement				
12	Head harness	The head harn adjustable or so and shall be su to hold the part mask firmly in p	T.C. Meet requirement					P			
13	Field of vision	The field of visi	on is	Meet r	equire	ment			Р		



耳挂式CE检测报告 🗪

TSGK-2020-0656-T-XG2

Serial	Test item	Technical requirements	Resul	t - Remar	k		-3	7	Verdict		
	43	acceptable if determined so in practical performance tests.			,2		P		7		
		Exhalation valve(s) shall function correctly in all orientations	Not A	oplicable							
14	Exhalation valve(s)	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 A	oplicable	SCH.		-5G	N/A			
	, SCIL	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		oplicable	SCI.		EST	~c			
		When the exhalation valve housing is attached to the	A.R.	Not Ap	plicable						
		faceblank, it shall withstand	M.S.	Not Ap	plicable						
		axially a tensile force of 10 N applied for 10 s	T.C.	T.C. Not Applicable							
	CH	in the contract of	Pos.	Α	В	С	D	E			
	43	45		0.4	0.4	0.4	0.3	0.4			
			A.R	0.4	0.5	0.4	0.5	0.5			
		Inhalation: 30 L/min		0.5	0.5	0.5	0.4	0.5			
		FFP1: ≤ 0.6 mbar;		0.4	0.4	0.4	0.4	0.4			
		FFP2: ≤ 0.7 mbar;	S.W.	0.4	0.5	0.5	0.4	0.5			
	"COL	FFP3: ≤ 1.0 mbar;	1	0.5 0.9	0.5	0.4	0.5	0.4			
	1,7	,,,		0.5	0.6	0.5	0.6	0.6			
			T.C.	0.5	0.5	0.5	0.4	0.4			
				0.4	0.5	0.4	0.4	0.4	1		
4-	Breathing	Breathing	Breathing		1.8	1.9	1.8	1.8	1.8	1 _	
15	resistance	A STATE OF THE STA	A.R.	1.9	1.9	1.8	1.8	1.8	P		
	620,	15° 15°	7	1.9	2.0	1.8	1.8	1.9			
		Inhalation: 95 L/min		1.9	1.9	1.8	1.8	1.7			
		FFP1: ≤ 2.1 mbar;	s.w.	1.8	1.7	1.6	1.7	1.7	1		
		FFP2: ≤ 2.4 mbar; FFP3: ≤ 3.0 mbar;		1.9	2.0	1.9	1.8	1.8			
		111 0. = 0.0 mbar,		1.9	1.9	1.8	1.8	1.9	1		
	COL	- Cit Ci	T.C.	2.0	2.1	1.9	2.0	1.9			
	43	45		1.9	1.9	1.8	1.8	1.8			
		Exhalation: 160 L/min		2.3	2.4	2.3	2.5	2.3	1		
		FFP1: ≤ 3.0 mbar;	A.R.	2.4	2.3	2.3	2.2	2.4	1		
		FFP2: ≤ 3.0 mbar;		2.4	2.5	2.3	2.3	2.4			

Guangdong Tsaint Hi-tech Co., Ltd.



耳挂式CE检测报告



TSGK-2020-0656-T-XG2

Serial	Test item	Technical requirements	Result	- Rema	rk		6		Verdict
	43	FFP3: ≤ 3.0 mbar		2.3	2.4	2.2	2.3	2.3	
			S.W.	2.5	2.5	2.3	2.4	2.4	
			2.4 2.5 2.3	2.3	2.3	2.3			
	EGH EGH		2.6	2.5	2.5	2.3	2.4		
		T.C.	2.3 2.3	2.4	2.4	2.3			
C SOL	SCIA		2.5	2.5	2.3	2.4	2.3		
			B: facir C: facir D: lying	ng verticang verticang on the	ly ahead ally upwa ally dow left side; right side	ards; nwards;			
16	Demountable parts	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand		equirem	Silv	7	r GCS		. <

Note:

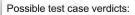
The test results presented in this report relate only to the object tested.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

Throughout this report a point is used as the decimal separator.

The test items practical performance, total inward leakage; penetration of filter material, compatibility with skin and field of vision are not within CNAS recognized scope.

This report is the substitute of the report No.TSGK-2020-0656-T-XG1, which is invalidated as this one issued.



Test case does not apply to the test object: N/A (Not applicable)

Test object does meet the requirement: P (Pass)

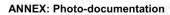
Test object does not meet the requirement: F (Fail)





耳挂式CE检测报告 📑

TSGK-2020-0656-T-XG2





----- End of test report -----



耳挂式CE证书B证





EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1118

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

Guangdong Tengsheng pharmaceutical Technology Co., Ltd. Room 301, No. 7, Linhai North Road, Shatian Town, Dongguan City, Guangdong Province, China

are tested and evaluated according to

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

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Model: TS01 Filtering half mask Classification: FFP3 NR

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.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on Annex 7 (Module C2) or Annex 8 (Module D) of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on 21/07/2020 and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



耳挂式CE证书C2证



CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1118/01

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

Guangdong Tengsheng Pharmaceutical Technology Co., Ltd

Room 301, No.7, Linhai North Road, Shatian Town, Dongguan City, Guangdong
Province, 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

	Cl	EU Type Examination Certifica							
Model	Class	Serial No	Date	Issuing NB No					
TS01	FFP3 NR	2163-PPE-1118	21.07.2020	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 14/08/2020 and will be valid for one year, until 13/08/2021 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



头戴式FFP3折叠型产品图片









产品包装



单个独立包装

单个口罩使用OPP袋,没有二次污染,干净卫生

A SINGLE INDEPENDENT PACKING







头戴式FFP3产品500个包装









头戴式FFP3产品500个包装







包装方式1:包装规格:1个单包,10个一盒,500个一箱。

外箱尺寸: 73.5X42.5X32.5CM **毛重:** 7.84KG 净重: 6.5KG



头戴式FFP3产品800个包装

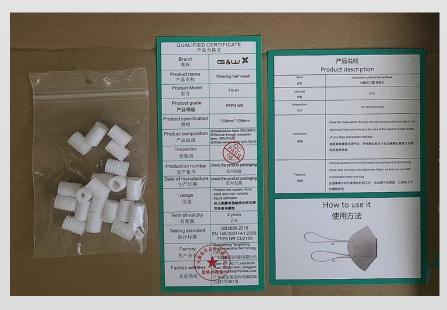




内包膜单个包

彩盒10个装





调节扣,合格证, 说明书



头戴式FFP3产品800个包装







包装方式2:包装规格:1个单包,800个/箱(配彩盒,合格证,说明

书,调节扣80套)

外箱尺寸: 73.5X42.5X32.5CM **毛重:** 11.76KG 净重: 10.46KG





Report NO: TSGK-2020-1560-T





TEST REPORT

This report cannot be partially copied without permission.



Sample name: Filtering half mask

Sample model: TS-01

Applicant: Guangdong Tengsheng Pharmaceutical Technology

Co., Ltd

Inspection type: Entrusted testing





头戴式CE检测报告 ■

Report NO: TSGK-2020-1560-T Page 1 of 9

Test report

Applicant: Guangdong Tengsheng Pharmaceutical Technology Co., Ltd

Applicant Add.: Room 301, No.7 Linhai North Road, Shatian Town, Dongguan City, Guangdong Province, China

Manufacturer: Same as applicant

Manufacturer Add.: Same as applicant

Sample name: Filtering half mask

Sample model: TS-01

Trade mark: /

Sample classification: FFP3

Sample quantity: 120 pcs

Sample source: Provide by applicant **Receiving date of sample:** 2020.08.26

Date(s) of tests: 2020.08.26-2020.09.12

According to the standard:

EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—requirements, testing, marking

Test results: See the continued page.

Chief Tester:

陈健强

Date: 2020.09.12

Reviewer:

際便串

Date: 2020.09.12

Approver:



Date: 2020.09.12



Note:

1.Possible abbreviations: Pass=Meet Requirement, Fail=Below Requirement, N/A= Not Applicable, N/T = Not tested, A.R.=As received, M.S.=Mechanical strength, T.C. = Temperature conditioned, S.W.=Simulated wearing treatment, F.C. = Flow conditioned, C.D.= Cleaning and Disinfecting.

2. Sample description: Single shift use only.





Test results and conclusions

	A		A	
Clause	Test Items	Technical requirements	Result	Conclusion
7.3	Visual inspection	The visual inspection shall also include the marking and the information supplied by the manufacturer.	As requested by the client, marking and information supplied by the manufacturer was not inspected.	N/T
7.4	Packaging	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.	Meet the requirements.	Pass
7.5	Material	See attached Table 1 for details	s.	Pass
7.6	Cleaning and disinfecting	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 class.	Single shift use only and this item is not applicable.	N/A
7.7	Practical performance	See attached Table 2 for details	s. Active contraction	Pass
7.8	Finish of parts	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs.	Pass
7.9.1	Total inward leakage	See attached Table 3 for details	S.	Pass
7.9.2	Penetration of filter material	See attached Table 4 for details	S.	Pass
7.10	Compatibility with skin	See attached Table 5 for details	s. cit cit	Pass
7.11	Flammability	See attached Table 6 for details	s.	Pass
7.12	Carbon dioxide content of the inhalation air	See attached Table 7 for details	S.	Pass
7.13	Head harness	See attached Table 8 for details	s.	Pass
7.14	Field of vision	The field of vision is acceptable if determined so in practical performance tests.	Field of vision is acceptable, see the test results of practical performance.	Pass
7.15	Exhalation valve(s)	Not Applicable.	7	N/A
7.16	Breathing resistance	See attached Table 9 for details	S.	Pass
7.17	Clogging	For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory.	Single shift use only and this item is not tested.	N/T
7.18	Demountable parts	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Meet the requirements	Pass







Report NO: TSGK-2020-1560-T Page 3 of 9

Table 1 Material

Technical requirements:

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. After undergoing the conditioning described in 8.3.1 (simulated wearing treatment) none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. When conditioned in accordance with 8.3.1(simulated wearing treatment) and 8.3.2(temperature conditioning) the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Result:		
	01#	No mechanical failure or collapse after conditioning.
S.W.	02#	No mechanical failure or collapse after conditioning.
	03#	No mechanical failure or collapse after conditioning.
	17#	No mechanical failure or collapse after conditioning.
T.C.	18#	No mechanical failure or collapse after conditioning.
	19#	No mechanical failure or collapse after conditioning.
Verd	lict	Pass

Table 2 Practical performance

Technical requirements:

Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections.

Result:			\$5. \Q
		Head harness	Comfortable
	24#	Fastenings	Safe and reliable
	34#	Field of vision	Acceptable
A.B.		Others	
A.R.		Head harness	Comfortable
	25"	Fastenings	Safe and reliable
	35#	Field of vision	Acceptable
		Others	/
Verdic	t		Pass

Report NO: TSGK-2020-1560-T Page 4 of 9

Table 3 Total inward leakage

Technical requirements: 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. Result: Face Mouth Face Face E2 TIL E1 E3 E4 E5 Width Exercises Subject Length Width Depth (%) (%) (%) (%) (%) (%) (mm) (mm) (mm) (mm) 1.2 1.1 1.0 1.8 1.5 128 149 116 54 Luo 37# 1.3 1.4 1.2 1.5 0.9 1.3 124 135 110 49 Chen A.R. 1.6 1.2 1.7 119 147 115 58 38# 1.5 1.8 1.6 Liang 39# 1.2 1.3 1.2 1.8 1.5 1.4 Chen 115 139 55 40# 0.8 0.9 107 52 1.1 1.3 1.3 1.1 Yuan 125 110 55 20# 1.4 1.3 1.6 1.5 1.3 1.4 Lai 118 135 117 0.8 1.9 1.9 1.7 1.3 1.5 127 53 21# Yang 115 124 T.C. 0.7 0.9 119 22# 0.8 1.6 1.8 1.2 Jiang 126 116 59 1.2 1.2 1.6 1.2 1.3 120 145 23# 1.1 Feng 119 54 24# 1.8 0.9 1.7 1.2 1.4 109 123 115 52 1.6 Zeng Verdict Pass

Table 4 Penetration of filter material

Technical red	quirements: 🔲	FFP1: \$	≤ 20 %;	F	FP2: ≤	6 %; ∑	FFP3	: ≤ 1%			
			A.R.	CC3		S.W.	31-	M.S.+T.C.			
	Sodium chloride	41#	42#	43#	04#	05#	06#	11#	12#	13#	
Result		0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.2	0.1	
(%)	Paraffin oil		A.R.		S.W.			M.S.+T.C.			
		44#	45#	46#	07#	08#	09#	14#	15#	16#	
č	30	0.1	0.4	0.4	0.2	0.3	0.3	0.4	0.2	0.3	
Verdict					Pass						

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Table 5 Compatibility with skin

Technical requirements: 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. Result: 36# No irritation or any other adverse effect to health. No irritation or any other adverse effect to health. A.R. 38# No irritation or any other adverse effect to health. 39# No irritation or any other adverse effect to health. 40# No irritation or any other adverse effect to health. 20# No irritation or any other adverse effect to health. 21# No irritation or any other adverse effect to health. T.C. 22# No irritation or any other adverse effect to health. 23# No irritation or any other adverse effect to health. 24# No irritation or any other adverse effect to health. Verdict **Pass**

Table 6 Flammability

 Technical requirements: 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.

 Result:

 A.R.
 47#
 Burn for 0s

 Burn for 0s
 Burn for 0s

 T.C.
 Burn for 0s

 Verdict
 Pass

Table 7 Carbon dioxide content of the inhalation air

Technical requirements: 1,0 % (by volume).	The carbon dioxide content of t	he inhalation air (dead space) sl	nall not exceed an average of
Result(%):			
A.R.49#	A.R.50#	A.R.51#	Average value:
0.28	0.25	0.27	0.27
Verdict		Pass	334



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Table 8 Head harness

Technical requirements: 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.

Result	t:			
	36#			Meet the requirements
	37#	G/P	-cCit-	Meet the requirements
A.R.	38#	·	7-	Meet the requirements
	39#			Meet the requirements
	40#			Meet the requirements
	20#			Meet the requirements
	21#	C/F	-Cit	Meet the requirements
T.C.	22#		43	Meet the requirements
	23#			Meet the requirements
	24#			Meet the requirements
Ver	dict			Pass

Table 9 Breathing resistance

Techni	ical requireme	ents:															
			4			Ma	aximu	ım pei	mitte	d resis	stance	(mba	ır)				
	Classification		Inhalation									Exhalation					
		54	30 L/min						95 L	min				160) L/mi	in	
	FFP1		CO.	0.6		•	Cole.		2.	اے 1	3/2			200	3.0		
	FFP2			0.7					2.	4					3.0		
	FFP3			1.0		1			3.	0					3.0		
Result	(mbar):																
	Planata				53#					54#					55#		
	Flov	Flow rate		В	С	D	E	Α	В	C	D	Е	A	В	C	D	Е
A.R.	Inhalation	30 L/min	0.4	0.4	0.4	0.3	0.4	0.4	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.3	0.3
	Innatation	95 L/min	1.6	1.6	1.5	1.5	1.5	1.6	1.6	1.5	1.6	1.6	1.6	1.5	1.6	1.6	1.5
	Exhalation	160 L/min	1.9	1.9	1.9	1.8	1.8	1.9	1.8	1.8	1.8	1.8	2.1	2.0	2.0	2.1	2.0
	El				01#					02#			03#				
	Flov	v rate	Α	В	С	D	E	A	В	С	D	Е	A	В	C	D	Е
S.W.	75	30 L/min	0.4	0.4	0.3	0.3	0.3	0.4	0.4	0.3	0.3	0.3	0.5	0.4	0.4	0.5	0.4
	Inhalation	95 L/min	1.8	1.8	1.6	1.7	1.8	1.7	1.7	1.6	1.6	1.6	1.7	1.6	1.7	1.6	1.6
	Exhalation	160 L/min	2.0	2.0	1.9	1.9	2.0	1.9	1.9	1.8	1.8	1.8	2.0	2.0	1.9	1.8	1.8



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	Flow rate		30#					31#					32#				
T.C.			A	В	С	D	E	A	В	C	D	Е	A	В	C	D	Е
	Inhalation	30 L/min	0.2	0.2	0.2	0.3	0.2	0.2	0.2	0.2	0.1	0.2	0.2	0.2	0.2	0.2	0.1
		95 L/min	1.1	1.1	1.1	1.0	1.0	1.2	1.2	1.2	1.1	1.2	1.2	1.2	1.3	1.3	1.3
	Exhalation	160 L/min	1.4	1.4	1.4	1.4	1.3	1.4	1.5	1.5	1.5	1.4	1.4	1.3	1.3	1.4	1.4
Verdict		Pass															

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头戴式CE证书B证





EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1586

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

Guangdong Tengsheng Pharmaceutical Technology Co., Ltd.
Room 301, No.7 Linhai North Road, Shatian Town, Dongguan City, Guangdong Province,
China

are tested and evaluated according to

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

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Model: TS-01 Filtering half mask Classification: FFP3 NR

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.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on Annex 7 (Module C2) or Annex 8 (Module D) of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on 19/10/2020 and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



IS09001证书





此为证书 CN20/31090 译本

下述组织

广东腾盛药业科技有限公司

注册地址:中国广东省东莞市沙田镇临海北路7号301室经营地址:中国广东省东莞市沙田镇临海北路7号301室

统一社会信用代码 91441900MA54BKX98B

的管理体系已经过审核,并被证明符合下述要求

ISO 9001:2015

所涉及的活动范围覆盖

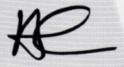
民用(非医用)口罩的生产

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