

$12 \times 2 \times 12$

EU DECLARATION OF CONFORMITY

Manufacturer

Name: Shandong Daddy's Choice Health Science and Technology Co.,Ltd.

Address: Tiandingfeng road Garden street Economic Development Zone Linyi County Dezhou

City Shandong Province

declares that the new PPE described hereafter

Description of products	Protective face mask	
Product style/order No	Purism	
Double to the control of	White	
Product colour and type	Non-reusable, folded type	
Classification	FFP2 NR	

are in conformity with the Regulation (EU) 2016/425 and with harmonized standard EN 149:2001 + A1:2009

SGS Fimko Oy

Takomotie 8, FI-00380 Helsinki, Finland

Notified Body No. 0598

performed the EU type-examination (Module B) and issued the EU type-examination certificate FI 20/966301.

The PPE is subject to the conformity assessment procedure: EU type-examination (module B) set out in Annex V, and either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D) under surveillance of the notified body SGS Fimko Oy, Notified Body No. 0598.

Signed for on behalf of Company

Name: Zhang Wenkun

Position: Management representative

Signature:

Date: 2020.08.07



The 3rd Party Document of Medical Device Registration

Note:

This file is Not being issued by FDA. We, GTS, as the 3rd party, produce it, intended to facilitate customer display & transmit information. The following contents, FDA registered Facility/Owner/Operator&FDA listing Medical Device, are excerpted from database at www.fda.gov.

Establishment:

Shandong Daddy's Choice Health Science and Technology

<u>Co.,LTD</u>Tiandingfeng road Garden street Economic Development Zone Linyi County Dezhou City Shandong Province ,China251500

Registration Number / FEINumber*:3016615665

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Status: Active

Date of Registration Status: 2020

Owner/Operator

Shandong Daddy's Choice Health Science and Technology

Co.,LTDTiandingfeng road Garden street Economic Development Zone Linyi County

Dezhou City Shandong Province ,China251500

Owner/Operator Number: 10062911

Official Correspondent

Contact Name: Amie Yang Foreign Business Manager

Tiandingfeng road Garden street Economic Development Zone Linyi County Dezhou

City Shandong Province, China 251500

Tel:+86-534-8271567 E-mail: amieyang@daddychoice.com

U.S. Agent

Contact Name: XIAO JIN

Address: 19800 MACARTHUR BLVD STE 300, IRVINE CA 92612-2479 U.S.A

Phone:(310)3109983 E-mail:nateX@daddychoice.com

Devices Listing Information

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Disposable Face Mask	LYU	1	D37****	Manufacturer
KN95 FACE MASK	MSH	1	D37****	Manufacturer
Disposable Isolation Gown	HOY	1	D37****	Manufacturer
Disposable Protective Clothing	HOY	1	D37****	Manufacturer
Disposable Isolation Gown	OEA	1	D37****	Manufacturer
Disposable Protective Clothing	OEA	1	D37****	Manufacturer
Disposable protective coverall	OEA	1	D37****	Manufacturer

Please careful protect your <u>Listing Number</u>.

More details on the website: http://www.gts-lab.com Need help? Contact us, GTS, at +86(021) 33637866 & info@gts-lab.com

FDA CERTIFICATE NUM: GTS22151



Certificate CN20/42187

The management system of

Shandong Daddy's Choice Health Science and Technology Co., Ltd.

Tiandingfeng Road, Garden Street Economic Development Zone, Linyi County, Dezhou City, Shandong Province, 100024, 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 Daddy's Choice (logo) Purism white folded Particle
Filtering Half Mask.

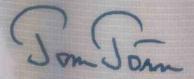
(Note: All products marked CE0598 must have a valid EU typeexamination certificate issued under Module B or a valid EC typeexamination certificate issued under Article 10 of Directive 89/686/EEC.)

This certificate is valid from 13 August 2020 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 13 August 2020

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

Authorised by



SGS FIMKO OY, Notified Body 0598

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SESSESSES

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Certificate FI20/966301

Shandong Daddy's Choice Health Science and Technology Co.,Ltd.

Tiandingfeng road Garden street, Economic Development Zone, Linyi County, Dezhou City, Shandong Province

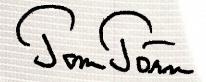
It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

Regulation (EU) 2016/425

Module B, EU type-examination

This certificate is valid from 05 August 2020 until 05 August 2025 1. Certified since 05 August 2020

Authorised by



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

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Certificate FI20/966301, continued

Shandong Daddy's Choice Health Science and Technology Co.,Ltd.

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

Daddy's Choice (logo) Purism white folded half mask, consisting of a white five layer (polypropylene/ polypropylene/ polypropylene /Polyethylene&Polyethylene terephthalate/ polypropylene) disposable particle filtering half mask, with polypropylene/iron wire nose clip, nylon/ polyurethane ear band, foam and polypropylene retaining clip.

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: Protective face mask/ Purism, version 1, dated: 2020-07-01.

SGS Reference Number UK/CRS 241399.

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









Test Report SL22002253011901TX Date: Jun 04,2020 Page 1 of 10

SHANDONG DADDY'S CHOICE HEALTH SCIENCE AND TECHNOLOGY CO., LTD TIANDINGFENG ROAD GARDEN STREET ECONOMIC DEVELOPMENT ZONE LINYI COUNTY DEZHOU CITY SHANDONG PROVINCE CHINA,251500 CN

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

Sample Description : (A)mask(Protective face mask)

Sample color : White

Composition : Non-woven fabric melt-blown fabric

Manufacturer : SHANDONG DADDY'S CHOICE HEALTH SCIENCE AND TECHNOLOGY CO.,

LTD

Supplier : SHANDONG DADDY'S CHOICE HEALTH SCIENCE AND TECHNOLOGY CO.,

LTD

Style No : Purism

Sample Receiving Date : May 04, 2020

Testing Period : May 04, 2020 - Jun 04, 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).

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

Conclusion:

Sample No.	Recommendation level	
(A)	FFP2 NR	

Signed for and on behalf of

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

Angel Guo (Account Executive)



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Date: Jun 04,2020



Test Report

SL22002253011901TX

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Test Result

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

(EN 149:2001+A1:2009)

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	Comply	Pass
before use.		

Clause 7.5 Material*

(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 class.	Not applicable (Not designed to be re-usable)	N.A.



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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

Clause 7.8 Finish of Parts*

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

\Lit 110:2001-711:2000, Gladoo 0:2)		
Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no	No sharp edges	Pass
sharp edges or burrs.	or burrs	1 033

Clause 7.9.1 Total Inward Leakage*

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

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	Pass

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
1#	1	A.R.	6.6	7.2	7.1	7.2	6.7	7.0
2#	2	A.R.	6.3	6.7	7.1	7.0	6.4	6.7
3#	3	A.R.	6.6	7.1	7.3	7.3	6.6	7.0
4#	4	A.R.	7.0	7.8	7.8	8.0	7.4	7.6
5#	5	A.R.	6.4	7.1	7.2	7.2	6.6	6.9
6#	6	T.C.	6.5	7.3	7.4	7.4	6.7	7.1
7#	7	T.C.	6.4	7.2	7.6	7.2	6.8	7.0
8#	8	T.C.	6.6	7.3	7.2	7.2	6.7	7.0
9#	9	T.C.	7.2	8.0	7.9	8.1	7.5	7.7
10#	10	T.C.	7.1	7.6	8.1	7.8	7.3	7.6
50 out of	50 out of the 50 individual exercise results ≤ 11 %			Pass				
10 of the	10 of the 10 individual arithmetic means ≤ 8%							



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Facial Dimension

Subject	Face length(mm)	Face Width(mm)	Face Depth(mm)	Mouth Width(mm)
1#	120	130	109	59
2#	122	140	115	65
3#	119	160	139	55
4#	112	122	119	63
5#	110	130	118	60
6#	115	119	110	59
7#	112	123	113	55
8#	103	130	100	50
9#	118	139	130	63
10#	120	135	125	50



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Clause 7.9.2 Penetration of Filter Material*

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

Tes	t Requireme	nt	Results	Comment	
The	penetration	of the filter of the particle filte	е		
req	uirements of t	he following table.			
	Classifica	Maximum penetration	on of test aerosol		
	tion	Sodium chloride test 95	Paraffin oil test 95 l/min		
		l/min		Detellentente	
		%	%	Detail refer to Appendix 2	Pass
		max.	max.	Appendix 2	
	FFP1	20	20		
	FFP2	6	6		
	FFP3	1	1		

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
		11	0.1	
	As received	12	0.2	
Sodium chloride test		13	0.1	
		14	0.2	
	Simulated wearing treatment	15	0.1	
		16	0.1	
	Machanical atranath +Tomparatura	17	0.3	
	Mechanical strength +Temperature conditioned	18	0.2	
	conditioned	19	0.2	
		20	0.2	Pass
	As received	21	0.3	
		22	0.2	
		23	0.3	
Paraffin oil test	Simulated wearing treatment	24	0.2	
	-	25	0.2	
	Machanical atranath L Tamparatura	26	0.8	
	Mechanical strength +Temperature conditioned	27	0.7	
	Conditioned	28	0.9	
	Flow conditioning: Single filter: 95.0	L/min]



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Clause 7.10 Compatibility with Skin*

(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 When tested, the particle filtering half mask shall not burn or not to continue	Detail refer to Appendix 3	Pass
to burn for more than 5 s after removal from the flame.		

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result	Assessment
An received	29	Burn for 0.1s	
As received	30	Burn for 0.1s	Pass
Temperature	31	Burn for 0.1s	Fa55
conditioned	32	Burn for 0.1s	

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	Detail refer to	Pass
exceed an average of 1,0 % (by volume)	Appendix 4	F455

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Resu	Assessment	
	33	0.7125%		
As received	34	0.7135%	Mean value :0.71%	Pass
	35	0.7145%		



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Clause 7.13 Head Harness*

(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 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 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 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 exhalation valve	



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Clause 7.16 Breathing Resistance*

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

penetration of the filter of the particle filtering half mask shall mee irements of the following table. Assification			Results	Comment
he following tal	ble		t the	
	•	, ,	Detail refer to	Pass
11111	aiation	Extralation		
30 l/min	95 l/min	160 l/min	Appendix 5	
0.6	2.1	3.0		
0.7	2.4	3.0		
1.0	3.0	3.0		
(of the filter of the following ta Maximu Inh 30 I/min 0.6 0.7	of the filter of the particle filterin the following table. Maximum permitted resis Inhalation 30 l/min 95 l/min 0.6 2.1 0.7 2.4	of the filter of the particle filtering half mask shall meet the following table. Maximum permitted resistance (mbar) Inhalation So I/min 95 I/min 160 I/min 0.6 2.1 3.0 0.7 2.4 3.0	of the filter of the particle filtering half mask shall meet the he following table. Maximum permitted resistance (mbar) Inhalation Exhalation Detail refer to Appendix 5

Appendix 5: Summarization of Test Data

	resistance	

Breatning resista	ance (mbar <u>)</u>																
As received	Flow r	ate	5	Speci	men	No.3	6	S	Specii	men	No.3	7	S	Speci	men	No.3	8
			Α	В	С	D	Е	Α	В	С	D	Е	Α	В	С	D	Е
	Inhalation	30 l/min	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.2	0.3
		95 l/min	1.1	1.2	1.1	1.1	1.2	1.2	1.2	1.1	1.1	1.1	1.1	1.2	1.1	1.1	1.1
	Exhalation	160 l/min	1.5	1.6	1.6	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.5	1.6	1.6	1.6
Simulated	Flow r	ate	5	Speci	men	No.3	9	S	Specii	men	No.4	0	Specimen No.41				
wearing treatment			Α	В	С	D	Е	Α	В	С	D	Е	Α	В	С	D	Ε
	Inhalation	30 l/min	0.3	0.3	0.2	0.3	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.2	0.2	0.2
		95 l/min	1.1	1.2	1.2	1.1	1.1	1.1	1.2	1.2	1.1	1.1	1.1	1.2	1.1	1.2	1.1
	Exhalation	160 l/min	1.6	1.6	1.5	1.6	1.6	1.6	1.6	1.7	1.6	1.7	1.7	1.7	1.6	1.7	1.7
Temperature	Flow r	ate	5	Speci	men	No.4	2	S	Specii	men	No.4	3	S	Specimen No.44			
conditioned			Α	В	С	D	Е	Α	В	С	D	Е	Α	В	С	D	Е
	Inhalation	30 l/min	0.3	0.3	0.3	0.2	0.2	0.2	0.2	0.3	0.2	0.2	0.2	0.3	0.2	0.2	0.3
		95 l/min	1.1	1.2	1.2	1.2	1.1	1.1	1.2	1.2	1.1	1.1	1.1	1.2	1.1	1.1	1.1
	Exhalation	160 l/min	1.7	1.5	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8
Assessment							Pass	;									

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
Clause 7.17.2 Breathing resistance Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow.			Optional for single shift device only	N.A
After clogging the	<u>filtering half masks:</u> inhalation and exhalation resist FP2: 4 mbar, FFP3: 5 mbar at 95			
Clause 7.17.3 Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.				
Classificatio	Maximum penetration of test aerosol			
n	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min	Optional for single	N.A
	%	%	shift device only	
	max.	max.		
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		

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	Not applicable	N.A

^{*} Test items were carried out by (Jiangsu Guojian Testing Technology Co., Ltd) (CNAS L10118) assessed as competent, were not included in the CNAS Accredited Schedule for our laboratory.

pH Value

Test Method: According to ISO 3071:2020; 0.1mol/l KCL extraction

pH value	6.28	4.0 - 7.5	PASS

Note: pH value of extraction medium 5.80

Temperature of the extraction

solution



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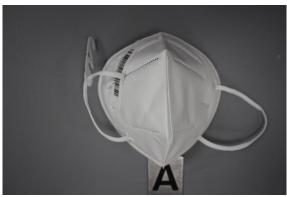




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Test	Uncertainty
Total inward leakage	2.98%
Penetration of filter material	1.00%
Flammability	1.00%
Carbon dioxide content of the inhalation air	0.93%
Breathing resistance	1.90%
pH Value	3.98%

Sample photo





The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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