

ANEXO TÉCNICO TECHNICAL ANNEX

0370-4095-PPE/B

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

MARCA BRAND	YPHD
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) IDENTIFICATION OF THE PPE (TYPE NUMBER)	YD-003 Disposable mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP3 NR
INFORME DE ENSAYO TEST REPORT	S20061201301E-R4 issued by Shenzhen NTEK Testing Technology Co., Ltd.

CERTIFICADO DE EXAMEN UE DE TIPO EU-TYPE EXAMINATION CERTIFICATE



No. 0370-4095-PPE/B

ORGANISMO NOTIFICADO Nº NOTIFIED BODY NUMBER	0370 - LGAJ TECHNOLOGICAL CENTER (APPLUS)
SOLICITANTE APPLICANT	Guangdong YiDao Medical Technology Co., Ltd. Room 302, Building 2, No.1, Lane 1, Xiju Road Hengli, Dongguan City, Guangdong Province, P.R. CHINA
FABRICANTE MANUFACTURER	Guangdong YiDao Medical Technology Co., Ltd. Room 302, Building 2, No.1, Lane 1, Xiju Road Hengli, Dongguan City, Guangdong Province, P.R. CHINA
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD / APPLICABLE REGULATION TO GIVE CONFORMITY: REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD CONFORMITY ASSESSMENT PROCEDURE	Módulo // Module: B EXAMEN UE DE TIPO / EU TYPE EXAMINATION
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) IDENTIFICATION OF THE PPE (TYPE NUMBER)	YD-003 Disposable mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP3 NR
NORMAS ARMONIZADAS / HARMONISED STANDARDS	EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado. EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking
FECHA DE EMISIÓN / ISSUE DATE	24/07/2020
VALIDEZ HASTA / VALIDITY UNTIL	24/07/2025
El presente certificado se mantendrá vigente durante 5 años siempre que el producto descrito no sea modificado y cumpla los requisitos esenciales de salud y seguridad establecidos en el Reglamento (UE) 2016/425. Para asegurar dicho cumplimiento, este certificado deberá ir acompañado de la documentación correspondiente a la Evaluación de Conformidad con el tipo según módulo C2, D (realizada por un Organismo Notificado, según frecuencia establecida). This certificate will remain valid for 5 years as long as the indicated product is not modified and fulfills the essential requirements of health and safety established in (EU) Regulation 2016/425. To ensure such compliance, this certificate must be accompanied by the documentation corresponding to the Conformity Assessment to type according to C2, D (carried out by a Notified Body according, to the established frequency).	

LGAJ Technological Center, S.A.
Xavier Ruiz Peña
Managing Director, Product Conformity B.U.



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CE 检测报告

CE test report



Report No.: S20061201301E-R1

page 1 of 12

Test Report

Applicant: Guangdong YiDao Medical Technology Co., Ltd.
Address: Room 302, Building 2, No. 1, Alley 1, Xiju Road, Hengli Town, Dongguan City, Guangdong Province

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

Product name: Disposable mask FFP3
Model: YD-003
Trade mark: YPHD
Manufacturer: Guangdong YiDao Medical Technology Co., Ltd.
Address: Room 302, Building 2, No. 1, Alley 1, Xiju Road, Hengli Town, Dongguan City, Guangdong Province
Claim level: FFP3
Sample quantity: 150Pcs

Sample Received Date: Jun. 23, 2020
Testing Period: Jun. 23, 2020 - Jul. 09, 2020

Test Requirement:

According to the requirement of the client, the test item(s) of the sample is according to the standard EN149:2001+A1:2009.

Test Result(s): Please refer to the following page(s)

Test Method: Please refer to the following page(s)

Compiled by:  Reviewed by: 
 Approved by:  Date: 2020-07-10



Report No.: S20061201301E-R1

page 2 of 12

Summary of assessment*

Clause	Assessment
7.3 Visual inspection	NRq
7.4 Packaging	Pass
7.5 Material	Pass
7.6 Cleaning and disinfecting	N.A.
7.7 Practical performance	Pass
7.8 Finish of parts	Pass
7.9.1 Total inward leakage	Pass
7.9.2 Penetration of filter material	Pass
7.10 Compatibility with skin	Pass
7.11 Flammability	Pass
7.12 Carbon dioxide content of the inhalation air	Pass
7.13 Head harness	Pass
7.14 Field of vision	Pass
7.15 Exhalation valve(s)	N.A.
7.16 Breathing resistance	Pass
7.17 Clogging	N.A.
7.18 Demountable parts	Pass

Key

Pass	Requirement satisfied.
NRq	The clauses were not required.
Fail	Requirement not satisfied. Refer to the "Result details" section for more information.
N.A.	Assessment not carried out.

* Assessment relates only to those specimens which were tested and are the subject of this report.

CE 检测报告

CE test report



Report No.: S20061201301E-R1

page 3 of 12

Test Result

Respiratory Protective Devices — Filtering Half Masks to Protect against Particles — Requirements, Testing, Marking
(EN 149:2001+A1:2009)

Clause 7.3 Visual inspection

Test Requirement	Results	Comment
Marking and the information supplied by the manufacturer, requirements refer to clause 9 and clause 10.	The clauses were not required.	NRq

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

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	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.	Comply	Pass
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	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.	Comply	Pass



Report No.: S20061201301E-R1

page 4 of 12

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.	Assessment not carried out.	N.A.

Clause 7.7 Practical Performance

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

Test Requirement	Results	Comment
	Sample 11#-12#:	
General: a) head harness comfort b) security of fastenings c) field of vision d) any other comments reported by the wearer on request.	No imperfections	Pass
Walking Test: The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min.	No imperfections	
Work Simulation Test: a) walking on the level with headroom of (1.3±0.2)m for 5min b) crawling on the level with headroom of (0.7±0.05)m for 5min c) filling a small basket (see Figure 1, approximate volume = 8 l) with chippings or other suitable material from a hopper which stands 1.5 m high and has an opening at the bottom to allow the contents to be shovelled out and a further opening at the top where the basket full of chippings is returned.	No imperfections	

CE 检测报告

CE test report



Report No.: S20061201301E-R1

page 5 of 12

Clause 7.8 Finish of Parts

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

Test Requirement	Results	Comment
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

Clause 7.9.1 Total Inward Leakage

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

Test Requirement	Results	Comment
For particle filtering half masks fitted in accordance with the manufacturer's information, at least 48 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

Subject	Sample	Condition	Normal Breathing (%)	Head Side/Side (%)	Head Up/Down (%)	Speak Loudly (%)	Normal Breathing (%)	Mean (%)
Huang	1#	A.R.	1.6	1.7	1.7	1.8	1.5	1.7
Zhou	2#	A.R.	1.9	2.0	2.0	2.1	1.8	2.0
Ma	3#	A.R.	1.5	1.7	1.6	1.8	1.5	1.6
Wu	4#	A.R.	1.8	1.9	2.1	2.2	1.9	2.0
Li	5#	A.R.	1.7	1.9	1.9	1.9	1.6	1.8
Wu	6#	T.C.	1.4	1.6	1.8	1.7	1.5	1.6
Zhai	7#	T.C.	1.8	1.7	1.9	2.1	1.8	1.9
Zheng	8#	T.C.	1.6	1.5	1.8	1.9	1.6	1.7
Huang	9#	T.C.	1.4	1.8	1.8	1.9	1.5	1.7
Wu	10#	T.C.	1.9	2.2	2.1	2.4	2.0	2.1



Report No.: S20061201301E-R1

page 6 of 12

Facial Dimension:

Subject	Length of Face (mm)	Width of Face (mm)	Depth of Face (mm)	Width of Mouth (mm)
Huang	130	140	125	53
Zhou	100	148	125	55
Ma	120	158	110	50
Wu	120	154	128	54
Li	112	146	112	50
Wu	110	148	121	44
Zhai	135	165	125	53
Zheng	106	157	118	51
Huang	112	172	118	55
Wu	105	157	118	51

Clause 7.9.2 Penetration of Filter Material

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

Test Requirement	Results	Comment		
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 2	Pass		
Classification			Maximum penetration of test aerosol	
			Sodium chloride test 95 L/min % max.	Paraffin oil test 95 L/min % max.
FFP1			20	20
FFP2	6	6		
FFP3	1	1		

CE 检测报告

CE test report



Report No.: S20061201301E-R1

page 7 of 12

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			Average in 30s after 3 min	Max. during exposure	
Sodium chloride test	A.R.	13#	0.5	/	Pass
		14#	0.5	/	
		15#	0.6	/	
	S.W.	22#	0.5	/	
		23#	0.5	/	
		24#	0.6	/	
	M.S. + T.C.	25#	/	0.1	
		26#	/	0.1	
		27#	/	0.2	
28#		/	0.2		
Paraffin oil test	A.R.	16#	0.5	/	Pass
		17#	0.5	/	
		18#	0.5	/	
	S.W.	19#	0.5	/	
		20#	0.5	/	
		21#	0.6	/	
	M.S. + T.C.	29#	/	0.3	
		30#	/	0.1	
		31#	/	0.1	

Flow conditioning: 95.0 L/min

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

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Complaint Tel: +86-755-36995510 | Complaint E-mail: complaint@ntek.org.cn



Report No.: S20061201301E-R1

page 8 of 12

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 on burn for more than 5 s after removal from the flame.	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result	Assessment
A.R.	31#	Nonflammable	Pass
	32#	Nonflammable	
T.C.	33#	Nonflammable	
	34#	Nonflammable	

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.	Result	Assessment
A.R.	35#	0.31%	Pass
	36#	0.36%	
	37#	0.35%	
		Mean value	
		0.34%	

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CE 检测报告

CE test report



Report No.: S20061201301E-R1

page 9 of 12

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	Pass
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	

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	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.	Assessment not carried out.	N.A.
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.	Assessment not carried out.	
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.	Assessment not carried out.	
(d) When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10 s.	Assessment not carried out.	



Report No.: S20061201301E-R1

page 10 of 12

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

Test Requirement				Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.				Detail refer to Appendix 5	Pass
Classification	Maximum permitted resistance (mbar)				
	Inhalation		Exhalation		
	30 L/min	95 L/min	160 L/min		
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

Specimen	Condition	Inhalation		Exhalation resistance(mbar)				
		At 30 L/min	At 95 L/min	At 160 L/min				
				A	B	C	D	E
38#	A.R.	0.5	2.1	2.8	2.8	2.7	2.8	2.8
39#		0.5	2.1	2.8	2.8	2.8	2.7	2.8
40#		0.5	2.1	2.7	2.8	2.8	2.8	2.7
41#	S.W.	0.6	2.2	2.8	2.9	2.8	2.9	2.9
42#		0.6	2.2	2.8	2.9	2.9	2.9	2.9
43#		0.6	2.2	2.9	2.9	2.9	2.9	2.9
44#	T.C.	0.5	2.1	2.7	2.7	2.7	2.7	2.7
45#		0.5	2.1	2.7	2.7	2.7	2.7	2.7
46#		0.5	2.1	2.7	2.7	2.7	2.7	2.7
/	F.C.	/	/	/	/	/	/	/
/		/	/	/	/	/	/	/
/		/	/	/	/	/	/	/

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

CE 检测报告

CE test report

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Report No.: S20061201301E-R1

page 11 of 12

Clause 7.17 Clogging

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

Test Requirement	Results	Comment																			
<p>Clause 7.17.2 Breathing resistance</p> <p>Valved particle filtering half masks:</p> <p>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.</p> <p>Valveless particle filtering half masks:</p> <p>After clogging the inhalation and exhalation resistances shall not exceed: FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow</p>	Assessment not carried out	N.A.																			
<p>Clause 7.17.3 Penetration of filter material</p> <p>All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.</p> <table border="1"> <thead> <tr> <th rowspan="3">Classification</th> <th colspan="2">Maximum penetration of test aerosol</th> </tr> <tr> <th>Sodium chloride test 95 L/min</th> <th>Paraffin oil test 95 L/min</th> </tr> <tr> <th>%</th> <th>%</th> </tr> </thead> <tbody> <tr> <td></td> <td>max.</td> <td>max.</td> </tr> <tr> <td>FFP1</td> <td>20</td> <td>20</td> </tr> <tr> <td>FFP2</td> <td>6</td> <td>6</td> </tr> <tr> <td>FFP3</td> <td>1</td> <td>1</td> </tr> </tbody> </table>	Classification	Maximum penetration of test aerosol		Sodium chloride test 95 L/min	Paraffin oil test 95 L/min	%	%		max.	max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	Assessment not carried out	N.A.
Classification		Maximum penetration of test aerosol																			
		Sodium chloride test 95 L/min	Paraffin oil test 95 L/min																		
	%	%																			
	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	Comply	Pass

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Report No.: S20061201301E-R1

page 12 of 12

Sample photo(s):



Fig.1



Fig.2

This test report displaces the original report No. S20061201301E, and the original one was invalid since the date of this test report No. S20061201301E released.

****End of Report****

The test report is effective only with both signature and specialized stamp, the result(s) shown in this report refer only to the sample(s) tested. Without written approval of NTEK, this report can't be reproduced except in full.

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