

Mascarillas FFP2 con certificado europeo CE (embolsadas individualmente - caja de 10 unidades)



Características técnicas:

- Cumplen con la normativa EN 149:2001+A1:2009
- Eficiencia de filtrado >95%
- Certificado europeo CE 2163. Las mascarillas cuentan con certificado CE para los productos de la categoría III. Las mascarillas han superado con éxito los tests que se han llevado a cabo y cumple con los requisitos establecidos en el Reglamento sobre equipos de protección personal (UE) 2016/425 y normas armonizadas, garantizadas por evaluaciones basadas en el anexo 7 (módulo C) o el anexo 8 (módulo d).
- Diseño de cinco capas: Agradable para la piel. El exterior está elaborado con tela no tejida, dos capas de tela fundida envuelta con capa de relleno
- Filtro medio de mayor eficiencia para la más alta protección contra partículas por encima de los requisitos estándar
- Aumenta efectivamente el tiempo de uso en un 30%.
- No irrita la piel, absorbe el agua, es cómoda y suave.
- Puente nasal interior de alta estabilidad.
- Testeada y probada su eficacia en laboratorios. Este certificado de cumplimiento se ha otorgado en función de los resultados de las pruebas realizadas por BEFTILAT Test Technology Shangay., Ltd. Acreditada por IAS (International Accreditation Service).
- Medios filtrantes de alto rendimiento con baja resistencia a la respiración.
- Excepcional comodidad y ajuste de la mascarilla para los usuarios.



NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE-730

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

Zhejiang Luyao Electronics Technology Co., Ltd.

Wei 1st Road Mechanical Park, Wanquan Light Industrial Base Pingyang, Wenzhou, Zhejiang, 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**Brand Name:** LUYAO **Model:** LY-N900-N909

Filtering half mask

Classification: FFP2 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 09 /06/2020 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 KACMAZ
UNIVERSAL CERTIFICATION
Director

CERTIFICATE OF CONFORMANCE

Certificate No: 2163 - PPE – 730/01

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

Zhejiang Luyao Electronics Technology Co., Ltd.

Wei 1st Road Mechanical Park, Wanquan Light Industrial Base Pingyang, Wenzhou, Zhejiang,
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
LUYAO / LY-N900-N909	FFP2 NR	2163-PPE -730	09.06.2020	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 09/06/2020 and will be valid for one year, until 08/06/2021 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 KACMAZ
UNIVERSAL CERTIFICATION
Director



ZHEJIANG LUYAO ELECTRONICS TECHNOLOGY CO.,LTD
WEI 1ST ROAD,MECHANICAL PARK,WANQUAN LIGHT INDUSTRIAL BASE,PINGYANG
COUNTY,WENZHOU CITY,ZHEJIANG PROVINCE,CHINA

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

Sample Description : (A)Filtering half mask

Sample Color : (A)white

Style No. : LY-N901

Manufacturer : ZHEJIANG LUYAO ELECTRONICS TECHNOLOGY CO.,LTD

Supplier : ZHEJIANG LUYAO ELECTRONICS TECHNOLOGY CO.,LTD

Retest : No

Proposed Care Instruction : /

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

Sample Receiving Date : Feb 08, 2021

Testing Period : Feb 08, 2021 - Mar 01, 2021

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

Sara Guo (Account Executive)

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Test Result

Personal Protective Equipment - 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 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 facepiece or straps.	Comply	
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.

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)

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
The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve 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.	4.50	4.44	4.19	4.56	3.10	4.16
Luo	2	A.R.	4.54	4.97	5.15	5.61	5.54	5.16
Lu	3	A.R.	4.60	4.02	4.24	4.50	4.28	4.33
Wang	4	A.R.	2.66	2.42	3.95	3.49	3.79	3.26
Bao	5	A.R.	5.96	5.21	4.28	5.56	5.91	5.38
Ding	6	T.C.	3.77	3.35	3.59	3.47	3.38	3.51
Li	7	T.C.	5.67	5.43	5.91	5.32	5.19	5.50
Chen	8	T.C.	3.89	3.46	3.28	3.94	3.53	3.62
Song	9	T.C.	4.54	4.22	4.65	5.10	4.33	4.57
Ye	10	T.C.	6.11	5.37	5.56	6.49	5.89	5.88

Facial Dimension

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
Ding	134	150	110	52

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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			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	Meet FFP1, Meet FFP2, Meet FFP3
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		

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	1	0.212
		2	0.211
		3	0.236
	Simulated wearing treatment	4	0.241
		5	0.225
		6	0.218
	Mechanical strength +Temperature conditioned	7	0.475
		8	0.397
		9	0.453
Paraffin oil test	As received	10	0.324
		11	0.379
		12	0.331
	Simulated wearing treatment	13	0.351
		14	0.362
		15	0.373
	Mechanical strength +Temperature conditioned	16	0.791
		17	0.885
		18	0.864
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 to 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
As received	1	NIL
	2	NIL
Temperature conditioned	3	NIL
	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.	Result
As received	1	0.5824
	2	0.5811
	3	0.5819
		Mean value:0.58



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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	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 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	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.	Not applicable due to No exhalation valve	
(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 Requirement				Results	Comment
The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of the following table.				Detail refer to Appendix 5	Meet FFP1, Meet FFP2, Meet FFP3
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

Breathing resistance (mbar)

	Flow rate(l/min)	1					2					3					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
As received	Inhalation	30	0.4	0.3	0.4	0.4	0.4	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.3	0.3	0.4
		95	1.4	1.4	1.3	1.3	1.4	1.4	1.3	1.4	1.3	1.3	1.4	1.4	1.4	1.4	1.3
	Exhalation	160	2.3	2.3	2.3	2.3	2.2	2.2	2.3	2.3	2.3	2.2	2.3	2.2	2.3	2.3	2.3
Simulated wearing treatment	Inhalation	30	0.4	0.4	0.3	0.3	0.4	0.3	0.4	0.4	0.4	0.4	0.3	0.4	0.3	0.4	0.4
		95	1.3	1.4	1.4	1.4	1.3	1.3	1.4	1.3	1.4	1.4	1.4	1.3	1.4	1.3	1.3
	Exhalation	160	2.3	2.3	2.2	2.2	2.3	2.3	2.2	2.2	2.3	2.2	2.3	2.3	2.2	2.3	2.3
Temperature conditioned	Inhalation	30	0.3	0.4	0.3	0.3	0.3	0.3	0.4	0.3	0.4	0.4	0.3	0.3	0.4	0.3	0.3
		95	1.3	1.3	1.4	1.4	1.4	1.3	1.4	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.4
	Exhalation	160	2.2	2.3	2.2	2.2	2.2	2.3	2.2	2.3	2.3	2.3	2.3	2.3	2.2	2.2	2.2

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																			
<p><u>Clause 7.17.2 Breathing resistance</u> <u>Valved particle filtering half masks:</u> 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><u>Valveless particle filtering half masks:</u> 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>	Optional for single shift device only	N.A.																			
<p><u>Clause 7.17.3 Penetration of filter material</u> 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	Optional for single shift device only	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	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%

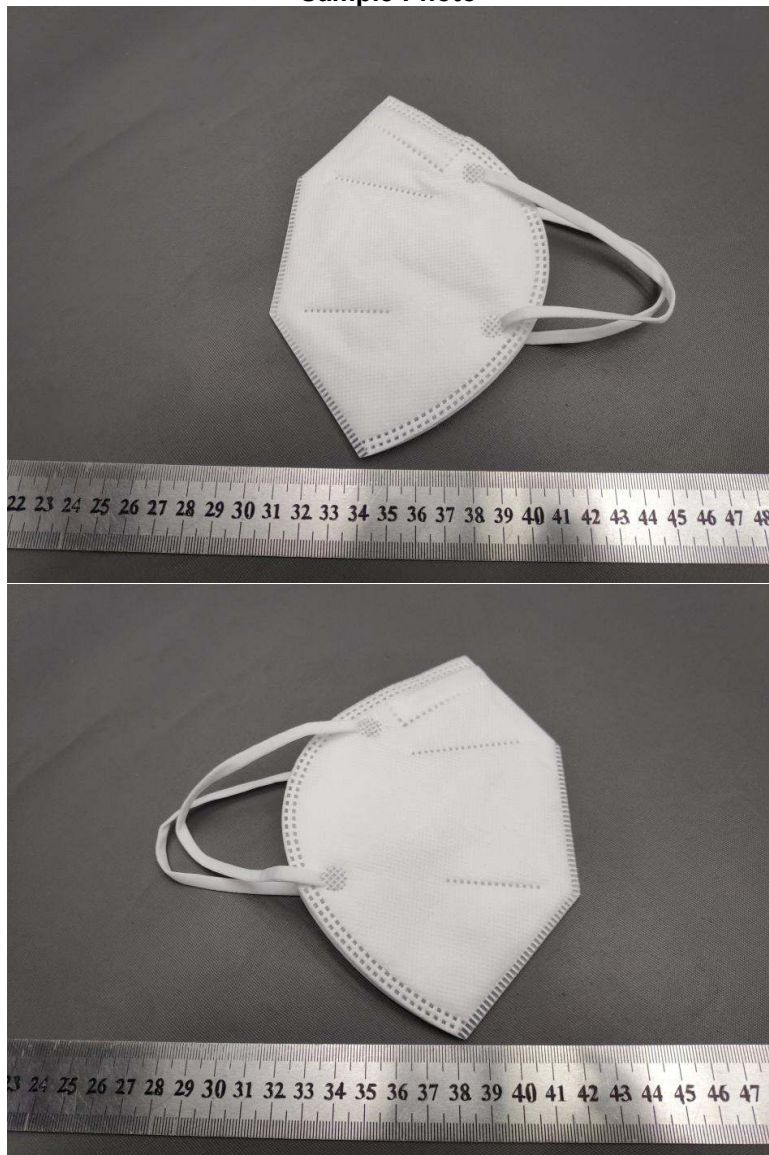


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Sample Photo

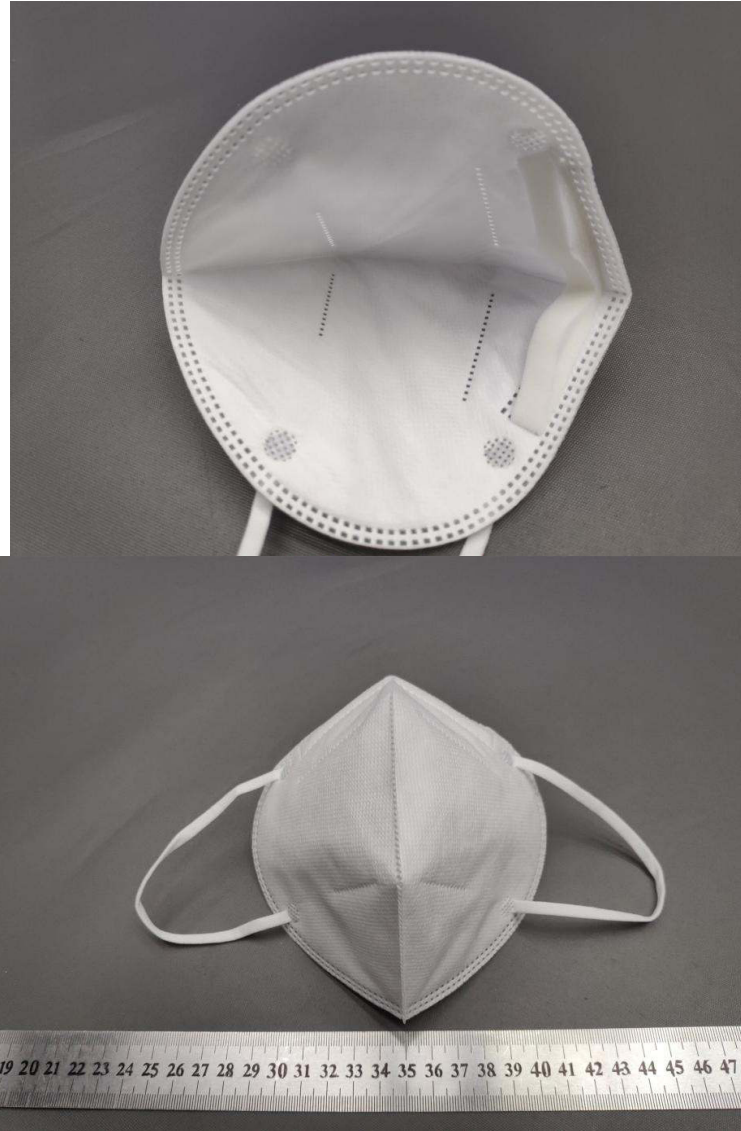


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