

# EU DECLARATION OF CONFORMITY

NANTONG HUAXU MEDICAL EQUIPMENT CO.,LTD NO.889 ZHAOXIA ROAD, HIGH  
TECH INDUSTRY ZON, NANTONG CITY, JIANGSU PROVINCE, CHINA

declares that the new PPE described hereafter

## **PROTECTIVE MASK/ K-2020**

is in conformity with the provisions of Module B of the Regulation (EU) 2016/425 Personal  
Protective Equipment and with the national standard transposing harmonized standard  
(s)**EN149:2001+A1 :2009**

is identical to the PPE which is the subject of EU certification of conformity issued by  
SGS Fimko Oy,  
Takomotie 8,  
FI-00380 Helsinki,  
Finland.  
Notified Body No. 0598

the PPE is subject to the conformity assessment procedure conformity to type based on  
internal production control plus supervised product checks at random intervals (Module  
C2) under surveillance of the notified body

SGS Fimko Oy,  
Takomotie 8,  
FI-00380 Helsinki,  
Finland.  
Notified Body No. 0598

Done at Place , Date Nantong China 2020-09-14

Name .....  
On behalf of Company



Certificate FI20/967136

# Nantong Huaxu Medical Equipment Co, Ltd.

NO.889 Zhaoxia Road, High Tech Industry Zoon,  
Nantong City,  
Jiangsu Province,  
China

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 04 November 2020 until 04 November 2025  
1. Certified since 04 November 2020

Authorised by

*Tom Tom*

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

SGS FIMKO OY, Notified Body 0598

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# **NANTONG HUAXU MEDICAL EQUIPMENT CO.,LTD**

## **Regulation (EU) 2016/425**

**Module B, EU type-examination**

Issue 1

PPE Product

5C (logo) K-2020 particle filtering half mask, consisting of a five layer  
(Polypropylene/Ethylene) disposable face mask, with  
Polypropylene/Polyethylene nose bridge, and Polyamides/Polyurethanes  
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 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:

HUAXU CE001, Dated 01.09.2020

SGS Reference Number UK/CRS 242353

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

**Test Report** SL52035261493801TX **Date:** July 07, 2020 **Page 1 of 10**  
NANTONG HUAXU MEDICAL EQUIPMENT CO., LTD  
NO.889 ZHAOXIA ROAD, HIGH TECH INDUSTRY ZONE, NANTONG CITY, JIANGSU PROVINCE, CHINA

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

Sample Description : (A) PROTECTIVE MASK  
Claimed : FFP2 NR

SGS Internal Ref No. : GZHL2006033918CE  
Style No. : K-2020  
Sample Color : (A) WHITE

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

Sample Receiving Date : Jun 24, 2020  
Testing Period : Jun 24, 2020 - Jul 07, 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

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



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## 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
<p>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</p> <p>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</p>	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(%)
Zhou	1	A.R.	5.87	6.60	6.76	4.61	5.10	5.79
Luo	2	A.R.	7.33	6.82	7.60	6.88	6.99	7.12
Lu	3	A.R.	5.28	6.17	5.05	6.83	6.86	6.04
Wang	4	A.R.	5.43	5.91	4.36	5.00	6.31	5.40
Bao	5	A.R.	7.29	7.24	6.57	6.00	8.60	7.14
Ding	6	T.C.	5.92	6.29	4.85	4.88	6.37	5.66
Li	7	T.C.	6.42	8.16	7.61	8.61	7.13	7.59
Chen	8	T.C.	6.46	5.97	5.54	5.29	5.69	5.79
Song	9	T.C.	6.53	6.80	5.18	5.48	6.55	6.11
Ye	10	T.C.	8.44	8.61	7.84	5.94	6.75	7.52

### 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
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 &amp; 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
Classifica tion	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	0.843
		2	0.796
		3	0.857
	Simulated wearing treatment	4	0.855
		5	0.896
		6	0.812
	Mechanical strength +Temperature conditioned	7	0.821
		8	0.856
		9	0.878
Paraffin oil test	As received	10	0.888
		11	0.840
		12	0.846
	Simulated wearing treatment	13	0.875
		14	0.975
		15	0.936
	Mechanical strength +Temperature conditioned	16	0.986
		17	0.974
		18	0.990
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	0.4823
	2	0.4817
	3	0.4816
		Mean value: 0.48



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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 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

### Breathing resistance (mbar)

As received	Flow rate(l/min)		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30	0.4	0.5	0.4	0.5	0.5	0.4	0.4	0.5	0.4	0.5	0.5	0.4	0.5	0.4	0.5
Simulated wearing treatment	Inhalation	95	1.6	1.8	1.7	1.6	1.6	1.7	1.7	1.8	1.8	1.7	1.6	1.6	1.7	1.8	1.8
		160	2.6	2.7	2.5	2.7	2.6	2.6	2.6	2.7	2.6	2.7	2.5	2.5	2.6	2.7	2.5
	Exhalation	160	2.6	2.7	2.5	2.7	2.6	2.6	2.6	2.7	2.6	2.7	2.5	2.5	2.6	2.7	2.5
Temperature conditioned	Flow rate(l/min)		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30	0.5	0.4	0.5	0.5	0.5	0.4	0.5	0.5	0.5	0.5	0.5	0.4	0.5	0.5	0.4
	Inhalation	95	1.8	1.7	1.8	1.7	1.6	1.8	1.8	1.7	1.7	1.8	1.7	1.6	1.7	1.8	1.6
		160	2.6	2.7	2.7	2.6	2.7	2.6	2.6	2.7	2.5	2.7	2.7	2.6	2.6	2.7	2.5
Temperature conditioned	Flow rate(l/min)		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30	0.4	0.4	0.3	0.4	0.4	0.4	0.3	0.4	0.4	0.4	0.3	0.3	0.4	0.4	0.4
	Inhalation	95	1.5	1.7	1.6	1.7	1.5	1.6	1.7	1.5	1.6	1.7	1.6	1.7	1.7	1.6	1.5
		160	2.5	2.4	2.6	2.4	2.5	2.6	2.4	2.5	2.5	2.6	2.5	2.6	2.6	2.5	2.5

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%

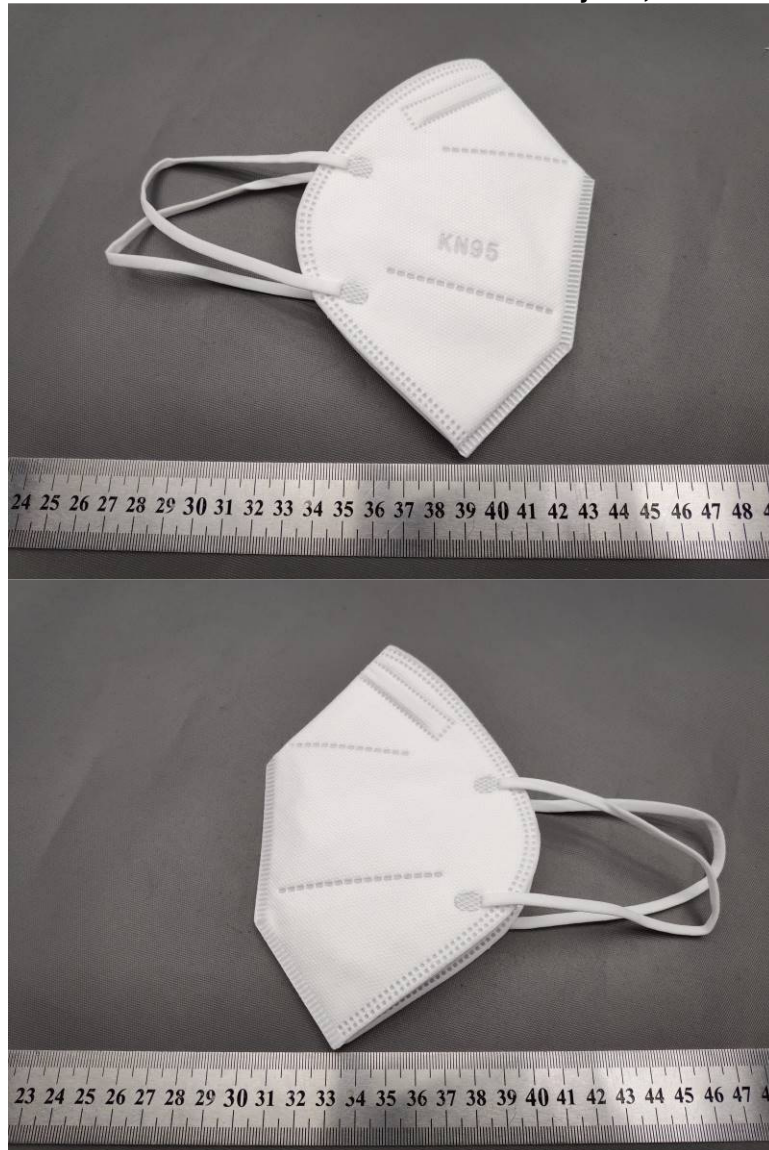


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## Sample Photo





\*\*\*End of Report\*\*\*

Certificate CN20/42726

The management system of

## Nantong Huaxu Medical Equipment Co., Ltd.

NO.889 Zhaoxia Road, High Tech Industry Zoon,  
Nantong City, Jiangsu Province, China

has been assessed and certified as meeting the requirements of

## Regulation (EU) 2016/425 Module C2

For the following activities

**Manufacture of 5C (logo) K-2020 particle filtering half mask.**  
(Note: All products marked CE0598 must have a valid EU type-  
examination certificate issued under Module B or a valid EC type-  
examination certificate issued under Article 10 of Directive  
89/686/EEC.)

This certificate is valid from 23 December 2020  
and remains valid subject to satisfactory surveillance audits.  
Issue 1. Certified since 23 December 2020

Authorised by



**SGS FIMKO OY, Notified Body 0598**

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Certificate CN21/42428

The management system of

# NANTONG HUAXU MEDICAL EQUIPMENT CO., LTD.

No. 889, Zhaoxia Road, High-tech Industry Zone,  
Nantong City, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

## Regulation (EU) 2016/425 Module D

For the following activities

**Manufacture of FFP2 Protective Respirators**

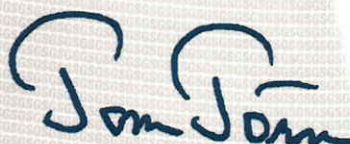
(Note: all products marked CE0598 must have a valid EU Type  
Examination Certificates issued under Module B or a valid EC type-  
examination certificate issued under Article 10 of the PPE Directive  
89/686/EEC.)

This certificate is valid from 8 June 2021 until 7 June 2024  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 24 April 2024

Issue 1. Certified since 8 June 2021

Authorised by



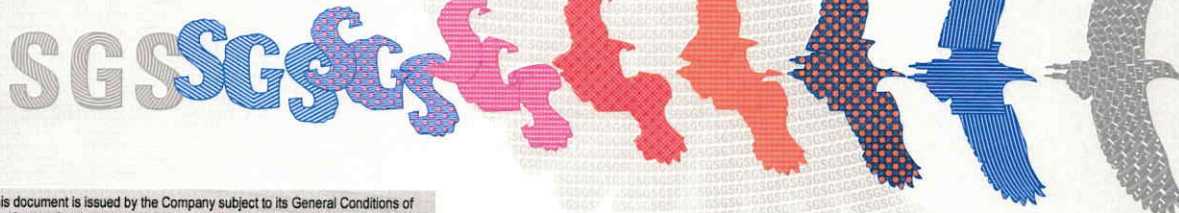
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