8

María Dolores Luzuriaga Naranjo

De: c.rodriguez c.rodriguez <c.rodriguez@waetiquetas.com>
Enviado el: miércoles, 1 de julio de 2020 17:35
Para: Adquisiciones
Asunto: ADQUISICION DE 25.500 MASCARILLAS PARA LA EPMTPQ
Datos adjuntos: 1 2 9.pdf; 14 CE.pdf; DETALLE CERTIFICADO DE RECONOCIMIENTO INEN MASCARILLAS.pdf; IMG-20200612-WA0030.jpg; MASCARILLAS KN95 QUITO.jpg; PROFORMA EPMTPQ MASCARILLAS KN95 IMPORTADAS.jpg

Estimados Señores
EMPRESA PUBLICA METROLPOLITANA DE TRANSPORTE DE PASAJEROS QUITO
RUC 1768156710001
Av. 5 de Junio S/N y Av. Rodrigo de Chávez
Quito – Ecuador

Buenas tardes,

Adjunto a esta misiva, sírvase encontrar la OFERTA Y COTIZACION para la adquisición de 25.500 MASCARILLAS KN95 para la prevención de riesgos de contagio de COVID 19 para dotar a los trabajadores y servidores de la EPMTPQ que se encuentran expuestos en los diferentes puestos de trabajo.

En espera de participar y ser aprobados, anticipo mis agradecimientos.

Atentamente

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Enviado desde Correo para Windows 10

YANGYUE
扬越安防

KN95 GB2626-2006

Respirator Face Mask



1. Product Overviev

Filtering facepiece respirators(FFR), which are also called disposable respirators, are subject to vanous regulatory standards around the world (see examples below). Certain required physical properties and performance characteristics are specified in order for respirators to claim Compliance with particular standard N95/KN95/FFP2 respirators are commonly Recommended by health authorities during pandemic or emergency situations. They are not exactly the same, but respirators certified as meeting these standards can be expected to function very similar to on another.

- N95(United States NIOSH-42CFR84)
- KN95(China GB2626-2006)
- FFP2(Europe EN 149-2001)

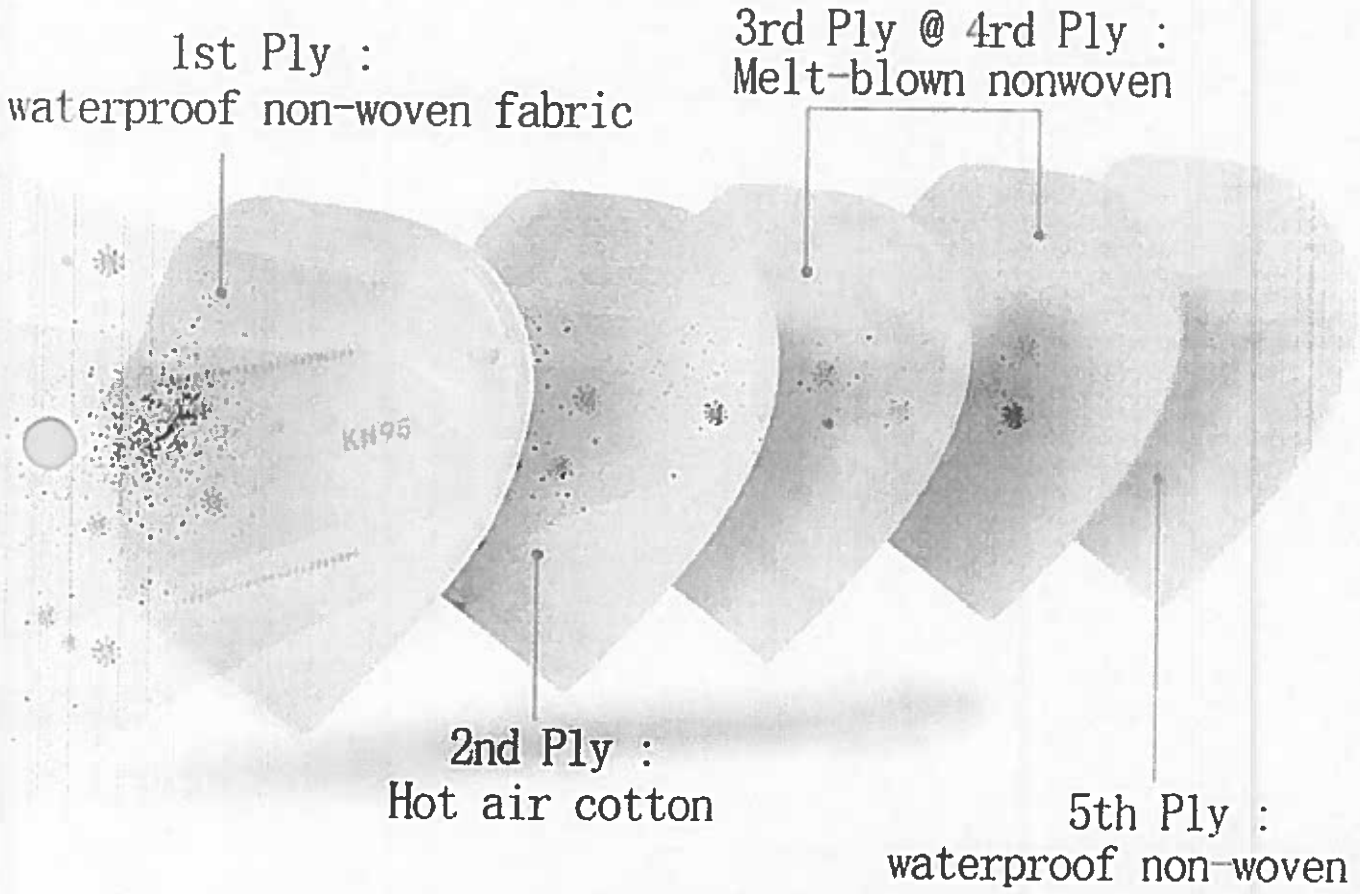
3M released a Technical Bulletin on January 2020 regarding Comparison of FFP2 KN95, and N95 and Other Filtering Facepiece respirators Classes. Based on this comparison, it is reasonable to consider China KN95, as"equivalent"to US NIOSH N95 and European FFP2 respirators for filtering non-oil-based particles such as those resulting from wildfires. PM 2.5 air pollution volcanic eruptions, or bioaerosols(e.g. viruses).

2. Specifications

Product Name:	KN95 Respirator Face Mask
Aerosol Type:	Non-oil
Color:	White
Size:	Universal
Exhalation Valve:	NO
Strap Attachment:	Stapled
Adjustable Nose Clips:	Yes
Standards:	KN95 (China GB2626-2006)
Certification:	FDA & CE Certified

Note:

1. Not suitable for harmful gases and steam
2. Not suitable for hypoxic environments, underwater operations or fire fighting



- KN95 Anti-bacterial and dust respirator with earloop
- professional protective face masks BFE≥95%
- Resistance to penetration byeasy- penetrating liquids (paraffin oil,etc.) and by body liquids like blood
- Filtration of solid particles (smog, dust,pollen, etc.) and microorganisms(viruses, bacteria)
- Better comfort while using for longer time

20ZCTS0319010SP

TEST REPORT

EN 149

Respiratory protective devices. Filtering half masks to protect against particles.Requirements,testing,marking

Report Reference No	20ZCTS0319010SP
Checked by (printed name and signature)	Kevin Yang
Approved by (printed name and signature)	King Hu
Date of issue	Mar 20, 2020
Testing laboratory	Shenzhen ZCT Technology Co., Ltd
Address	3F,5th Building,Bao'an Road 4336, Bao'an Distrct,Shenzhen,China
Applicant's name	Guangzhou Yanhou Biotechnology Co., Ltd
Address	16 Datang Road, Dalang Village, Baiyun Street, Baiyun District, Guangdong Province
Manufacturer's name	Guangzhou Yanhou Biotechnology Co., Ltd
Address	16 Datang Road, Dalang Village, Baiyun Street, Baiyun District, Guangdong Province
Factory's name	Same as applicant
Address	
Test specification:	
Standard	☒ EN 149:2001+A1:2009
Test procedure	CE
Non-standard test method	N/A
Test Report Form No	20ZCTS0319010SP
TRF Originator	ZCT
Master TRF	Dated 2019-01
Test item description	Kn95 filter respirator
Trade Mark	+ yi yan hou
Model/Type reference	KN95
Ratings	–

Possible test case verdicts: - test case does not apply to the test object ..... N (Not apply) - test object does meet the requirement ..... P (Pass) - test object does not meet the requirement ..... F (Fail)
Testing ..... Date of receipt of test item ..... Mar 12, 2020 Date(s) of performance of tests ..... Mar 12, 2020 to Mar 20, 2020
General remarks: 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. "(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report.
General product information: N/A
Copy of marking plate: Kn95 filter respirator Model:KN95 Classification:FFP2 NR Standard: EN 149:2001+A1:2009 **Guangzhou Yanhou Biotechnology Co., Ltd** **Made in China**

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
5	Classification		–
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:		P
	- FFP1		N
	- FFP2	>95%	P
	- FFP3		N
6	Designation		–
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification, option	Particle filtering half mask EN 149:2001+A1:2009 FFP2 NR	P
7	**Requirements**		–
7.1	General		P
	All test all test samples shall meet the requirements.	Compled the requirement, see bellow	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified,the values stated in this European Standard are experature limits.		P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Clear marking is provided, see sample body	P
7.4	Packaging		P
	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.		P
7.5	Material		P
	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. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comfortable wearing, when releasing no hazards is produced.	P
7.6	Cleaning and disinfecting		N
	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.	It's is not re-usable.	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see append test.	P
7.8	Finish of parts		P
	come into contact with the wearer shall have no sharp edges or burrs		P
7.9	Leakage	See append table 8.5	P
7.9.1	Total inward leakage		P
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected.	Enough safe condition is Provide.	P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	Exercise results for total inward leakage shall be not greater than		P
	25 % for FFP1 11% for FFP2 5% for FFP3	FFP2, Not exceed 11%	P
	And, in addition, at least 8 out of the 10 individual wearer anthmetic means for the total inward leakage shall be not greater than.		P
	22 % for FFP1 8 % for FFP2 2 % for FFP3	FFP2, Not exceed 8%	P
7.9.2	Penetration of filter material		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	see append table 7.92	P
7.10	Compatibility with shin		P
	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.		P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
7.12	Carbon dioxide content of the inhalation air		P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume)	<1.0%	P
7.13	Head harness		P
	Head harness shall be designed can be donned and removed easily and adjustable or selfadjusting and sufficiently robust to hold the particle.	Head harness is donned and removed easily	P
7.14	Field of vision		P
	Field of vision is acceptable in practical performance tests.	Clear field of vsion when weanng	P
7.15	Exhalation valve(s)		N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.	One valve provided	N
	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.	Clearly function	N
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		N
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.		N
7.16	Breathing resistance		P
	Ereathing resistances apply to valved and valveless and shall meet the requirements.		P
7.17	Clogging		N
	General		N
	For single-use devices clogging test is an optional test.		N
	Devices designed to be resistant to clogging, shown by a slow increase		N

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m³		N
7.17.2	Breathing resistance		N
7.17.2.1	Valved particle filtering half masks		N
7.17.2.2	Valveless particle filtering half masks		N
7.17.3	Penetration of filter materia		N
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		N
7.18	Demountable parts		N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No such demountable part	N
8	Testing		–
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.		P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke.	25 cycles/min 2,0 l/stroke.	P
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head.	A saturator incorporated by breathing machine and the dummy head	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
8.3.2	Temperature conditioning		P
	Exposet masks to the following thermal cycle		P
	a) for 24 h to a dry atmosphere of (70 ± 3) °C;		P
	b) for 24 h to a temperature of (-30 ± 3) °C;		P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	4 h to paid for	P
8.3.4	Flow conditioning		P
	A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2.		P
9	Marking		–
9.1	Packaging		P
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied, clearly marked	P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.		P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2, FFP3.	FFP2 NR	P
9.1.4	The number and year of publication of this European Standard.		P
9.1.5	At least the year of end of shelf life.		P
9.1.6	The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.		P
9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.	See product manual	P
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall beadditionally marked with the letter "D".		N
9.2	Particle filtering half mask		P
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:		P
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.	Guangzhou Yanhou Biotechnology Co., Ltd	P
9.2.2	Type-identifying marking.		P
9.2.3	The number and year of publication of this European Standard.		P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2 NR	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).		N
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		N

Attachments: Test table

Table 7.9.2	Penetration of test aerosol test					P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Sodium chloride test 95 l/min	5.6	5.7	5.5	5.6	5.7	5.6
Paraffin oil test 95 l/min	5.4	5.6	5.7	5.7	5.6	5.5

Table 8.5	Leakage test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
NaCl flow rate (L/min)	90	100	120	110	120
NaCl aerosol (um)	0.3	0.3	0.3	0.3	0.3
0.3Pumping flow rate (L/min)	30	30	30	30	30
NaCl concentration before mask (Mg/m3)	2	2	2	2	2
NaCl concentration after mask (Mg/m3)	0.05	0.06	0.07	0.08	0.06

Note: Test ark volume is $2m^3$
Average Leakage ratio is 8%<11%
Calculation formula as below:

$$P(\%)=\frac{C_2}{C_1}\times\left(\frac{{}^{t}IN-{}^{t}EX}{{}^{t}IN}\right)\times 100$$

Table 8.9.2	Exhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	160	160	160	160	160
Maximum resistance (mbar)	2.45	2.47	2.45	2.46	2.46
Conclusion: Maximum permitted resistance < 3.0 mbar					

Table 8.9.3	Inhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	30	30	30	30	30
Maximum resistance (mbar)	0.42	0.44	0.44	0.45	0.43
Conclusion: Maximum Inhalation resistance < 0.7 mbar					

Table 8.9.3.2	Inhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation (L/min)	95	95	95	95	95
Maximum resistance (mbar)	2.12	2.14	2.16	2.15	2.14
Conclusion: Maximum Inhalation resistance < 2.4mbar					

Details of: Kn95 filter respirator, model : KN95

Details of: Kn95 filter respirator, model : KN95

View:

[X] general

[ ] front

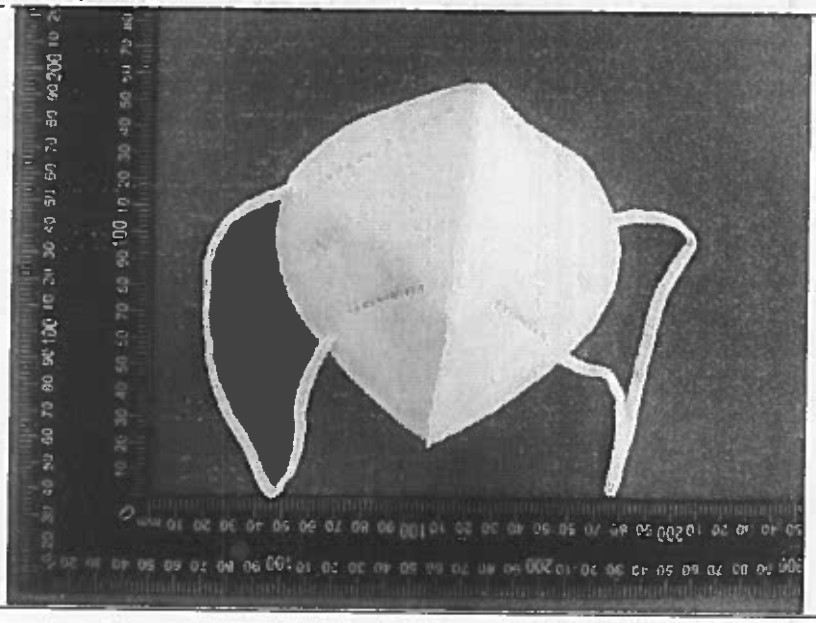
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Details of: Kn95 filter respirator, model : KN95

View:

[X] general

[ ] front

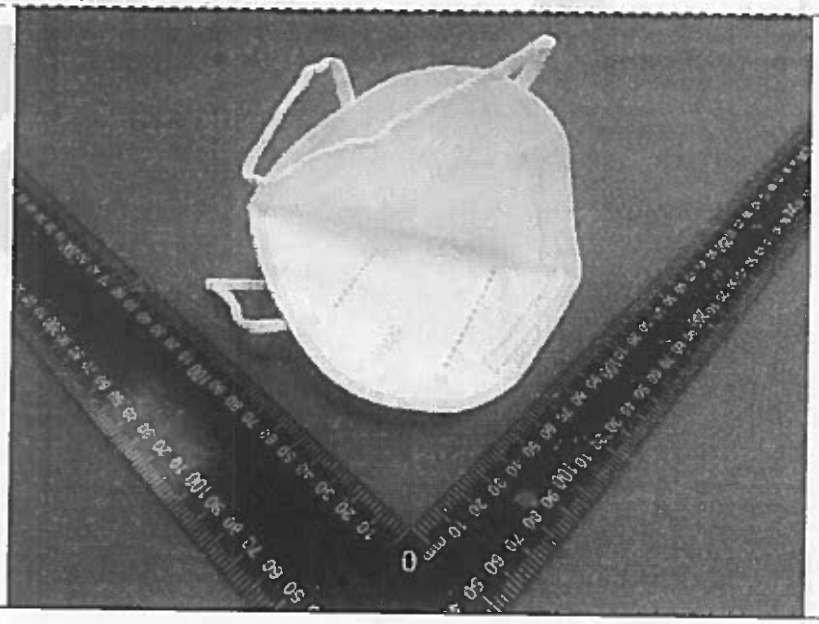
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- End of Test Report -

20ZCTS0319010SP

TEST REPORT

EN 149

Respiratory protective devices. Filtering half masks to protect against particles.Requirements,testing,marking

Report Reference No	20ZCTS0319010SP
Checked by (printed name and signature)	Kevin Yang
Approved by (printed name and signature)	King Hu
Date of issue	Mar 20, 2020
Testing laboratory	Shenzhen ZCT Technology Co., Ltd.
Address	3F,5th Building,Bao'an Road 4336, Bao'an Distrct,Shenzhen,China
Applicant's name	Guangzhou Yanhou Biotechnology Co., Ltd
Address	16 Datang Road, Dalang Village, Baiyun Street, Baiyun District, Guangdong Province
Manufacturer's name	Guangzhou Yanhou Biotechnology Co., Ltd
Address	16 Datang Road, Dalang Village, Baiyun Street, Baiyun District, Guangdong Province
Factory's name	Same as applicant
Address	
Test specification:	
Standard	☒ EN 149:2001+A1:2009
Test procedure	CE
Non-standard test method	N/A
Test Report Form No	20ZCTS0319010SP
TRF Originator	ZCT
Master TRF	Dated 2019-01
Test item description	Kn95 filter respirator
Trade Mark	+ yi yan hou
Model/Type reference	KN95
Ratings	-

Possible test case verdicts: - test case does not apply to the test object ... N (Not apply) - test object does meet the requirement.....P (Pass) - test object does not meet the requirement.....F (Fail)
Testing ..... Date of receipt of test item ..... Mar 12, 2020 Date(s) of performance of tests ..... Mar 12, 2020 to Mar 20, 2020
General remarks: 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. "(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report.
General product information: N/A
Copy of marking plate: Kn95 filter respirator Model:KN95 Classification:FFP2 NR Standard: EN 149:2001+A1:2009 **Guangzhou Yanhou Biotechnology Co., Ltd** **Made in China**

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
5	Classification		–
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:		P
	- FFP1		N
	- FFP2	>95%	P
	- FFP3		N
6	Designation		–
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification, option	Particle filtering half mask EN 149:2001+A1:2009 FFP2 NR	P
7	Requirements		–
7.1	General		P
	All test all test samples shall meet the requirements.	Compled the requirement, see bellow	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified,the values stated in this European Standard are experature limits.		P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer	Clear marking is provided, see sample body	P
7.4	Packaging		P
	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.		P
7.5	Material		P
	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. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comfortable wearing, when releasing no hazards is produced.	P
7.6	Cleaning and disinfecting		N
	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.	It's is not re-usable.	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see append test	P
7.8	Finish of parts		P
	come into contact with the wearer shall have no sharp edges or burrs		P
7.9	Leakage	See append table 8.5	P
7.9.1	Total inward leakage		P
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected	Enough safe condition is Provide	P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	Exercise results for total inward leakage shall be not greater than		P
	25 % for FFP1 11% for FFP2 5 % for FFP3	FFP2, Not exceed 11%	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.		P
	22 % for FFP1 8 % for FFP2 2 % for FFP3	FFP2, Not exceed 8%	P
7.9.2	Penetration of filter material		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	see append table 7.92	P
7.10	Compatibility with skin		P
	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.		P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
7.12	Carbon dioxide content of the inhalation air		P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume).	<1.0%	P
7.13	Head harness		P
	Head harness shall be designed can be donned and removed easily and adjustable or selfadjusting and sufficiently robust to hold the particle.	Head harness is donned and removed easily	P
7.14	Field of vision		P
	Field of vision is acceptable in practical performance tests.	Clear field of vsion when wearing	P
7.15	Exhalation valve(s)		N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.	One valve provided	N
	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.	Clearly function	N
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		N
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s		N
7.16	Breathing resistance		P
	Ereathing resistances apply to valved and valveless and shall meet the requirements.		P
7.17	Clogging		N
	General		N
	For single-use devices clogging test is an optional test.		N
	Devices designed to be resistant to clogging, shown by a [illegible]		N

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg h/m³.		N
7.17.2	Breathing resistance		N
7.17.2.1	Valved particle filtering half masks		N
7.17.2.2	Valveless particle filtering half masks		N
7.17.3	Penetration of filter materia		N
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		N
7.18	Demountable parts		N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No such demountable part	N
8	Testing		--
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.		P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke.	25 cycles/min 2,0 l/stroke.	P
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head.	A saturator incorporated by breathing machine and the dummy head.	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
8.3.2	Temperature conditioning		P
	Exposet masks to the following thermal cycle:		P
	a) for 24 h to a dry atmosphere of (70 ± 3) °C;		P
	b) for 24 h to a temperature of (-30 ± 3) °C;		P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	4 h to paid for	P
8.3.4	Flow conditioning		P
	A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2.		P
9	Marking		--
9.1	Packaging		P
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied, clearly marked	P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.		P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2, FFP3	FFP2 NR	P
9.1.4	The number and year of publication of this European Standard.		P
9.1.5	At least the year of end of shelf life.		P
9.1.6	The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.		P
9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.	See product manual	P
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall beadditionally marked with the letter "D".		N
9.2	Particle filtering half mask		P
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:		P
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.	Guangzhou Yanhou Biotechnology Co., Ltd	P
9.2.2	Type-identifying marking.		P
9.2.3	The number and year of publication of this European Standard.		P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2 NR	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).		N
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		N

Attachments: Test table

Table 7.9.2	Penetration of test aerosol test					P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Sodium chlonde test 95 l/min	5.6	5.7	5.5	5.6	5.7	5.6
Paraffin oil test 95 l/min	5.4	5.6	5.7	5.7	5.6	5.5

Table 8.5	Leakage test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
NaCl flow rate (L/min)	90	100	120	110	120
NaCl aerosol (um)	0.3	0.3	0.3	0.3	0.3
0.3Pumping flow rate (L/min)	30	30	30	30	30
NaCl concentration before mask (Mg/m3)	2	2	2	2	2
NaCl concentration after mask (Mg/m3)	0.05	0.06	0.07	0.08	0.06

Note: Test ark volume is $2m^3$
Average Leakage ratio is 8%<11%
Calculation formula as below:

$$P(\%)=\frac{C_2}{C_1}\times\left(\frac{t_{IN}-t_{EX}}{t_{IN}}\right)\times 100$$

Table 8.9.2	Exhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	160	160	160	160	160
Maximum resistance (mbar)	2.45	2.47	2.45	2.46	2.46
Conclusion: Maximum permitted resistance < 3.0 mbar					

Table 8.9.3	Inhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	30	30	30	30	30
Maximum resistance (mbar)	0.42	0.44	0.44	0.45	0.43
Conclusion: Maximum Inhalation resistance < 0.7 mbar					

Table 8.9.3.2	Inhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation (L/min)	95	95	95	95	95
Maximum resistance (mbar)	2.12	2.14	2.16	2.15	2.14
Conclusion: Maximum Inhalation resistance < 2.4mbar					

Details of: Kn95 filter respirator, model : KN95

Details of: Kn95 filter respirator, model : KN95

View:

[X] general

[ ] front

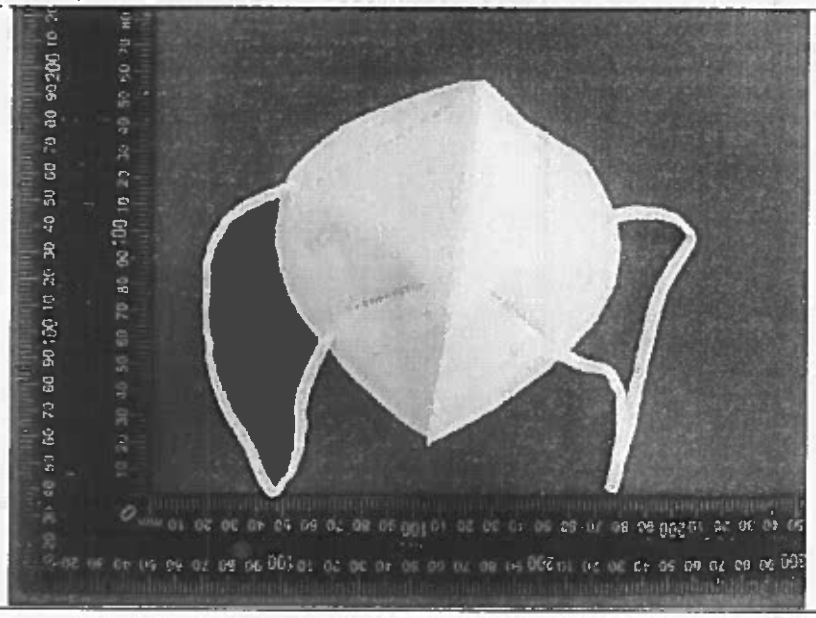
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Details of: Kn95 filter respirator, model : KN95

View:

[X] general

[ ] front

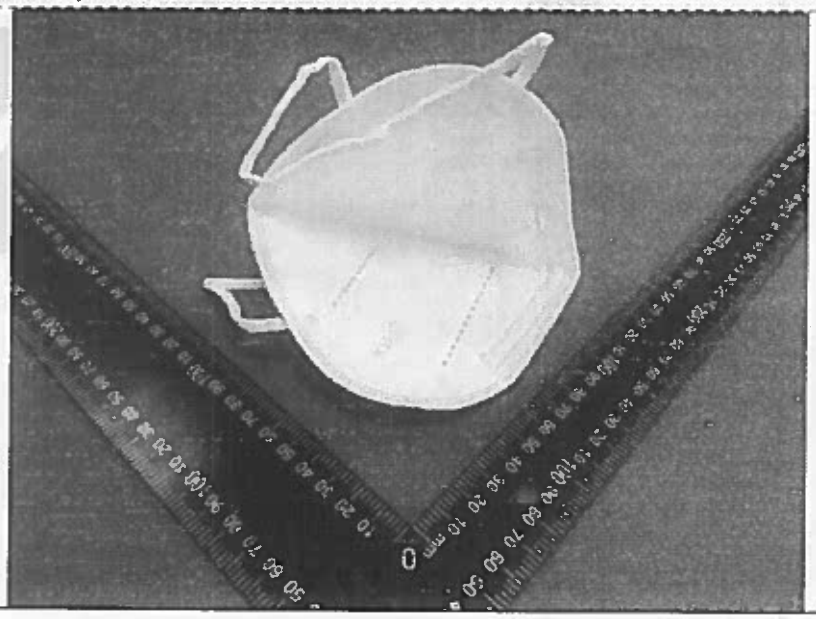
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- End of Test Report -

Ventanilla Única Ecuatoriana

1791309839001 WAEL ALAM ETIQUETAS INTERNACIONALES CIA. LTDA. Cerrar Sesión

ECUAPASS

Elaboración de Solicitud | Proceso de Solicitud | Soporte al Usuario

Consulta de Estado Actual de Procesamiento

Certificado de Reconocimiento - INEN

Datos de Básicos

Número de Solicitud	169289202020000000014P	Fecha de Solicitud	15/05/2020
Número de Certificado de INEN	169289202020000000014P		
Fecha de Emisión	09/06/2020	Fecha de Vencimiento	08/06/2021

Datos de Solicitante

Clasificación	(•) Persona Jurídica ( ) Persona Natural	Número de Identificación de la Empresa Solicitante (RUC)	RUC 1791309839001
Nombre o Razón Social de Solicitante	WAEL ALAM ETIQUETAS INTERNACIONALES CIA. LTDA.		
Provincia de la Empresa Solicitante	PICHINCHA	Cantón/Ciudad de la Empresa Solicitante	QUITO
Parroquia de la Empresa Solicitante	CARCELEN		
Dirección de la Empresa Solicitante	JUAN DE SELIS 76-78 Y MANUEL NAJAS		
Nombre de Solicitante	EL ALAM KHAMIS WAEL YACOUB		
Telefono de Solicitante	022482334	Fax de Solicitante	

Nombre de Producto	EQUIPOS DE PROTECCION RESPIRATORIA		
No. Solicitud		No. Registro Sanitario/ NSO(ARCSA)	
No. Emisión de Certificado		Fecha de Vencimiento	
Marca Comercial	GUANGZHOU YANGYUE SAFETY EQUIPMENT		
Nombre de Fabricante	GUANGZHOU YANHOU BIOTECHNOLOGY CO LTD		
País de origen	CHINA	Puerto de Embarque	
Distribuidor	GUANGZHOU YANGYUE SAFETY EQUIPMENT		
No. de Factura o Nota de Pedido			
Observaciones			
NTE INEN Nº	402881c730f3341e0130f33fe82eb174	RTE INEN Nº	402881c730f3341e0130f33fe82eb1
Partida Arancelaria	630790300000000000 MASCARILLAS DE PROTECCION		
Cantidad de Producto	100,000	Unidad de Cantidad	PZA
Descripción de Producto	MASCARILLAS DE PROTECCION KN95 FILTER RESPIRATOR		
Tipo	MASCARILLAS DE PROTECCION MODELO KN95-1		

FDA

Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that

GUANGZHOU YANHOU BIOTECHNOLOGY CO., LTD
16 Datang Road, Datang Village, Baiyun Street, Baiyun District Guangzhou, Guangdong, 510430, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

Owner/Operator Number: 10064606

Listing No.	Product Code:	Device Name:
D380091	MSH	Respirator, surgical KN95 filter face mask

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. makes no other representations or warranties, and states this certificate may not be represented to any person or entity other than the named certificate holder for whose sole benefit it is issued. This certificate does not constitute endorsement or approval of the particular person's device or establishment by the U.S. Food and Drug Administration. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the issuance.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

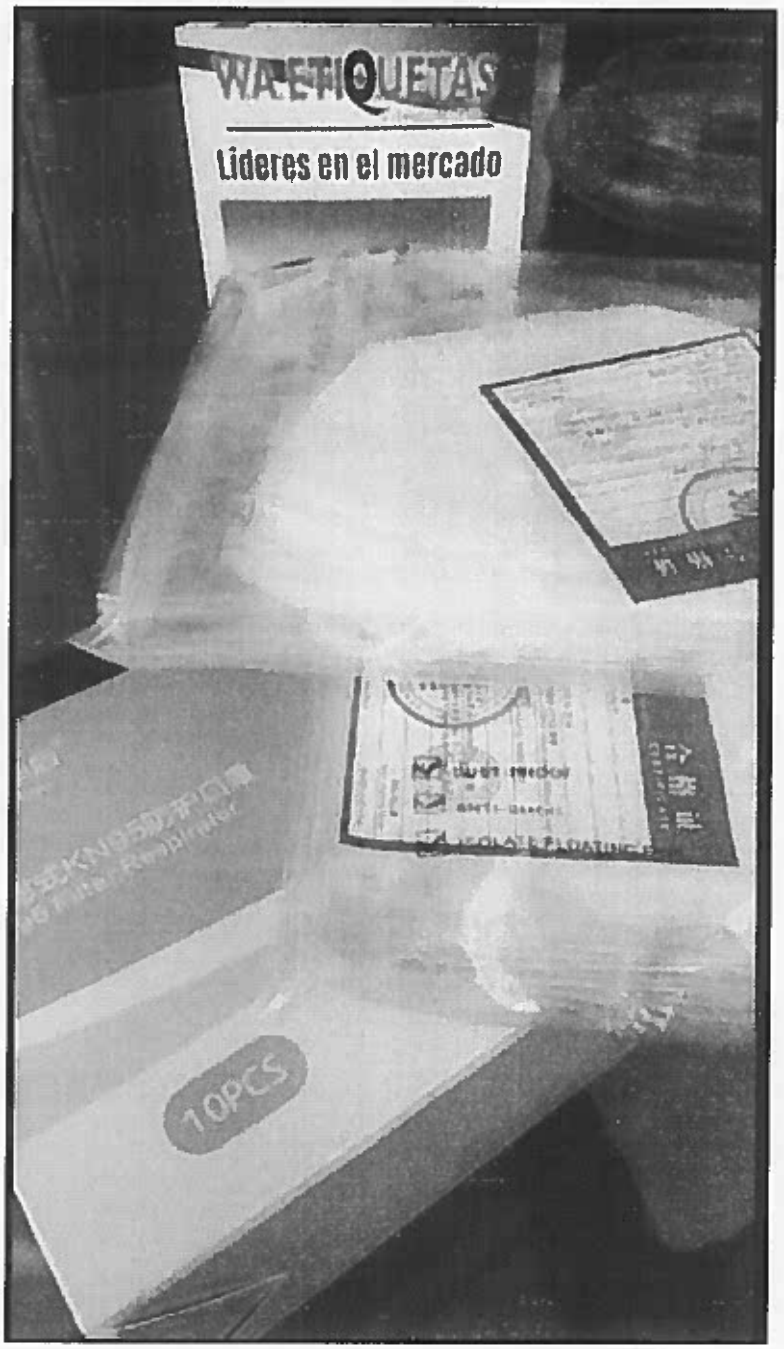
The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.

UCL

UCL-REG SERVICE INC.
102 ROCKWOOD ROAD WILMINGTON
NEW CASTLE DE 19803 USA

UCL-REG SERVICE INC.

Cert. No.: M00791
Issued Date: 27 March 2020
Expiration Date: 31 December 2020


WA ETIQUETAS
Líderes en el mercado
10PCS

W.A. ETIQUETAS

impresión color calidad flexográfica

Quito DM, 01 de julio del 2020

Señores
EMPRESA PÚBLICA METROPOLITANA DE TRANSPORTE DE PASAJEROS QUITO
RUC 1768156710001
Av. 5 de Junio S/N y Av. Rodrigo de Chávez
Quito – Ecuador

Buenas tardes,

PROFORMA

INFORMACION

RAZON SOCIAL:	WAEL ALAM ETIQUETAS INTERNACIONES CIA. LTDA.
RUC:	1791300839001
DIRECCION:	Panamericana Norte Km 7 ½, Av. Juan de Selis N76-78 Y Manuel Najas
CORREO:	[redacted]
TIEMPO DE ENTEGA:	Inmediato
DESCRIPCION DEL BIEN OFERTADO:	Todo lo solicitado y 5 capas. VER ANEXO

VALOR UNITARIO:	$ 1,70 MÁS IVA
MONTO TOTAL:	$ 43.350 MAS IVA
MONTO TOTAL INCLUIDO IVA:	$ 48.552 DOLARES AMERICANOS

OFERTA VALIDA POR 20 DIAS
GARANIA TECNICA: 6 MESES

Atentamente

W.A. ETIQUETAS INTERNACIONALES CIA. LTDA.
FIRMA AUTORIZADA

[redacted]