

# DISPOSABLE SANITARY MASK & NON-CONTACT INFRARED THERMOMETER

CERTIFICATES - TESTS

# CE & FDA certificate

Form QAT\_10-M04, version 00, effective since March 4th, 2020

## Certificate of Compliance

No. 08200323M.SMN0120

Certificate's Holder:

Certification ECM Mark:

Product: Protective mask  
Model(s): MC-A010, MC-A011, MC-012, MC-013, MC-015, MC-016, MC-017, MC-A018, MC-019, MC-B016, MC-B018, MC-B019  
[Classification: 9001 FFP2 NR D]  
Standard: EN 149:2001+A1:2009

Verification to:

Related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products according to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

**CE** The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products, RG01\_ECM rev.3 available at: [www.entecerma.it](http://www.entecerma.it)

Issuance date: 23 March 2020  
Expiry date: 22 March 2025

Reviewer: Technical expert Amanda Payne  
Approver: ECM Service Director Luca Bordini

Ente Certificazione Macchine Srl  
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## Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

**Owner/Operator Number: 10064492**  
**Device Listing#: See annex**

*This ACIC 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. ACIC makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. ACIC assumes no liability to any person or entity in connection with the foregoing.*

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, ACICs not affiliated with the U.S. Food and Drug Administration.

**Andy Liu**  
Chief engineer  
Issued: March 27, 2020  
Expiration Date: December 31, 2020

Shenzhen A Commitment Inspection & Certificate Co., LTD.  
W: [www.acic-china.com](http://www.acic-china.com) E: [acic@acic-china.com](mailto:acic@acic-china.com)  
Web: <http://www.fda.gov> Tel: 1-888-INFO-FDA (1-888-463-6332) E-mail: [vcpr@fda.gov](mailto:vcpr@fda.gov)

## Fiscal Year 2020 CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10064125

Listing No.	Code	Device Name	Proprietary Names	Activities
D379217	LYU	ACCESSORY, SURGICAL APPAREL	Protective mask MC-A010, MC-A011, MC-012, MC-013, MC-015, MC-016, MC-017, MC-018, MC-019, MC-B016, MC-B018, MC-B019,	Manufacturer

**END OF THE ANNEX**

**Andy Liu**  
Chief engineer  
Issued: March 27, 2020  
Expiration Date: December 31, 2020

# KN95 CE TEST REPORT

## TEST REPORT

Customer: [REDACTED]

Report Number: ACIC20200317073RCF

Total Page: 8 Pages

Report on the submitted sample said to be:

Sample name: Protective mask

Model: MC-A010, MC-A011, MC-012, MC-013, MC-015, MC-016, MC-017, MC-018, MC-019, MC-B016,

MC-B018, MC-B019

Manufacturer: [REDACTED] Ltd

Sample received date: Mar. 10, 2020

Testing period: Mar. 10, 2020 - Mar. 17, 2020

Test (Issue) laboratory:

Test location: [REDACTED]

Test Conclusion:

Test Requested	Conclusion
EN 149: 2001 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking	PASS

\*\*\*\*\* FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S) \*\*\*\*\*

Signed for and on behalf of ACIC

Tested by: Sophie Lu

Approved by: Jack [Signature]



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## TEST REPORT

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### Test data sheet

The following tests were carried out according to The manufacturers technical requirements and refer to EN 149: 2001 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking  
Note: P means meet the requirement, N/A means not applicable, F means does not meet the requirement.

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.	FFP2 NR0	P
6	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification	"D" clearly marked	P
7	Requirements		P
7.1	All test all test samples shall meet the requirements	Complied see below	P
7.2	Nominal values and tolerances Unless otherwise specified, the values stated in this European Standard are expenditure limits	Actual using value is clear	P
7.3	Visual inspection 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 Offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Distinct design and warning are made on packaging, see sample body	P
7.5	Material Materials suitable to withstand handling and wear over the period. Any material from the filter media released shall not constitute a hazard or nuisance for the wearer.	Comfortable wearing, when releasing no hazards is produced	P
7.6	Cleaning and disinfecting The materials used shall withstand the cleaning and disinfecting	Single-use equipment	N
7.7	Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see below test	P

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## REPORT

Date: Mar. 17, 2020 Page

Soft equipment

ve

t

Enough safe condition is provide

hall FFP2, not exceed 11%

Complied, see below test

Have no irritation or adverse effect to skin and health

Have no such hazard

er

r

n air <1.0%

of

The designing is considered

or 3 the

Clear field of vision when wearing

One valve provided

Clearly function

f or

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Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.

16 Breathing resistance

Exhalation resistances apply to valved and valveless and shall meet the requirements

17 Clogging

17.1 General

For single-use devices clogging test is an optional test.

Devices designed to be resistant to clogging, shown by a slow increase

The specified breathing resistances shall not be exceeded before the required dust load of 833 mg l/m<sup>3</sup>

17.2 Breathing resistance

17.2.1 Valved particle filtering half masks

17.2.2 Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed

1/4 FFP1: 3 mbar

1/4 FFP2: 4 mbar

1/4 FFP3: 5 mbar

at 95 l/min continuous flow.

17.3 Penetration of filter media

All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.

17.16 Demountable parts

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.

9 Marking

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

Complied, clearly marked

See user manual

Type-identifying marking

Complied, clearly marked

See user manual

Type-identifying marking

Complied, clearly marked

See user manual

Type-identifying marking

Complied, clearly marked

See user manual

Type-identifying marking

Complied, clearly marked

See user manual

Type-identifying marking

Complied, clearly marked

See user manual

Type-identifying marking

Complied, clearly marked

See user manual

Type-identifying marking

Complied, clearly marked

See user manual

Type-identifying marking

Complied, clearly marked

See user manual

Type-identifying marking

Complied, clearly marked

See user manual

# KN95 CE TEST REPORT

## TEST REPORT

Report No.: ACIC20200317073RCF Date: Mar.17, 2020

Classification: FFP1, FFP2, FFP3

9.1.3 The number and year of publication of this European Standard

9.1.5 At least the year of end of shelf life

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

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

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter 'D'

9.2 Particle filtering half masks

complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier

9.2.2 Type-identifying marking

9.2.3 The number and year of publication of this European Standard

9.2.4 The symbols FFP1, FFP2 or FFP3 according to class

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)

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified

10 Information to be supplied by the manufacturer

10.1 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination

10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on

1/4 application/limitations

1/4 the meaning of any colour coding

1/4 checks prior to use

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1/4 donning, fitting

1/4 use

1/4 maintenance (e.g. cleaning, disinfecting), if applicable

1/4 storage

1/4 the meaning of any symbols/pictograms used of the equipment

10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added

Warning shall be given against problems likely to be encountered, for example:

1/4 fit of particle filtering half mask (check prior to use)

1/4 it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal

1/4 air quality (contaminants, oxygen deficiency)

1/4 use of equipment in explosive atmosphere

10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded

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## TEST REPORT

Report No.: ACIC20200317073RCF Date: Mar.17, 2020

Attachments: test table

Table 8.5 Leakage test

Models Sample 1 Sample 2 Sample 3 Sample 4

Item

NaCl flow rate (L/min)

90 105 105 110

NaCl aerosol (µm)

0.3 0.3 0.3 0.3

Pumping flow rate (L/min)

30 30 30 30

NaCl concentration before mask (Mg/m<sup>3</sup>)

2 2 2 2

NaCl concentration after mask (Mg/m<sup>3</sup>)

0.17 0.16 0.16 0.17

Note: Test air volume is 2m<sup>3</sup>

Average Leakage ratio is 0.20%±1%

Calculation formula as below:

$$P(\%) = \frac{C_2}{C_1} \times \frac{100}{100 - \frac{Q}{V}} \times 100$$

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## TEST REPORT

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Table 8.9.1 Breathing resistance test

Models Sample 1 Sample 2 Sample 3 Sample 4 Sample 5

Item

Inhalation gas velocity (L/min)

30 30 30 30 30

Maximum resistance (mbar)

0.32 0.31 0.32 0.30 0.34

Note: Maximum permitted resistance < 0.6 mbar

Table 8.9.2 Exhalation resistance test

Models Sample 1 Sample 2 Sample 3 Sample 4 Sample 5

Item

Inhalation gas velocity (L/min)

95 95 95 95 95

Maximum resistance (mbar)

2.03 2.05 2.01 2.02 2.01

Note: Maximum permitted resistance < 2.1 mbar

Table 8.9.3 Breathing resistance test

Models Sample 1 Sample 2 Sample 3 Sample 4 Sample 5

Item

Exhalation (L/min)

160 160 160 160 160

Maximum resistance (mbar)

2.52 2.54 2.55 2.54 2.52

Note: Maximum permitted resistance < 3.0 mbar

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Attachments: one of real photos test samples

Photo 1

View:

[ ] front

[ ] rear

[ ] left side

[ ] right side

[ ] top

[ ] bottom

[ ] internal



\*\*\* THE END OF REPORT \*\*\*

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# TEST REPORT

## TEST REPORT

Customer: \_\_\_\_\_

Report Number: ACIC20200317072RCD

Total Page: 8 Pages

Report on the submitted sample said to be:

Sample name: Protective mask

Model: MC-A010,MC-A011,MC-012,MC-013,MC-015,MC-016,MC-018,MC-B019

Manufacturer: \_\_\_\_\_

Sample received date: Mar. 10, 2020

Testing period: Mar. 10, 2020 - Mar. 17, 2020

Test (issue) laboratory: Shenzhen A Commitment Inspection & C

Test location: No. 164-165, Pengda Road, Longgang Street, Longg

Test Conclusion:

Test Requested

EN 149: 2001 Respiratory Protective Devices - Filtering Half Mas  
Protect Against Particles - Requirements, Testing, Marking

\*\*\*\*\* FOR FURTHER DETAILS, PLEASE REFER TO THE

Signed for and on behalf of ACIC

Tested by: Sophie Lee Approved

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## TEST REPORT

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Test data sheet

The following tests were carried out according to The manufacturers technical requirements and refer to  
EN 149: 2001 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles -  
Requirements, Testing, Marking  
Note: P means meet the requirement, N/A means not applicable, F means does not meet the  
requirement.

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.	FFP2 NRD	P
6	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification	"D" clearly marked	P
7	Requirements		P
7.1	All test all test samples shall meet the requirements	Complied see below	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified, the values stated in this European Standard are exposure limits	Actual using value is clear	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
	offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Distinct design and warning are made on packaging, see sample body	P
7.5	Material		P
	Materials suitable to withstand handling and wear over the period. Any material from the filter media released 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
	The materials used shall withstand the cleaning and disinfecting	Single-use equipment	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see below test	P

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## TEST REPORT

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Finish of parts	Soft equipment	N
Time into contact with the wearer shall have no sharp edges or burrs		N
Sealing		P
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 provided	P
Exercise results for total inward leakage shall be not greater than	FFP2, not exceed 11%	P
5% for FFP1		
1% for FFP2		
1% for FFP3		
penetration of filter material		P
meet the requirements of Table 2.	Complied, see below test	P
compatibility with skin		P
the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Have no irritation or adverse effect to skin and health	P
flammability		P
the material used shall not present a danger to the wearer and shall not be of highly flammable nature.	Have no such hazard	P
carbon dioxide content of the inhalation air		N
the carbon dioxide content of the inhalation air (head space) shall not exceed an average of 10% (by volume).	<1.0%	P
head harness		
head harness shall be designed, can be donned and removed easily and adjustable or self-adjusting and sufficiently robust to hold the article	The designing is considered	P
field of vision		P
field of vision is acceptable in practical performance tests.	Clear field of vision when wearing	P
exhalation valve(s)		P
particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.	One valve provided	P
exhalation valve is provided it shall be rotected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device	Clearly function	P

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	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	Complied, see below	P
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.	Enough strong	P
7.16	Breathing resistance		P
	Breathing resistances apply to valved and valveless and shall meet the requirements	Complied, see below test	P
7.17	Clogging		N
7.17.1	General	single-use device	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
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg h/m <sup>3</sup>		N
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks		P
7.17.2.2	Valveless particle filtering half masks		P
	After clogging the inhalation and exhalation resistances shall not exceed	1/2 FFP2, not exceed 4 mbar	P
	1/2 FFP1: 3 mbar		
	1/2 FFP2: 4 mbar		
	1/2 FFP3: 5 mbar		
7.17.3	Penetration of filter material		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	No any such part	N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand		
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.	See user manual	P
9.1.2	Type-identifying marking.		P

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9.1.3	Classification: FFP1, FFP2, FFP3	FFP2 H
9.1.4	The number and year of publication of this European Standard.	See ab
9.1.5	At least the year of end of shelf life.	18 Mar
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.	English
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 us
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".	
9.2	Particle filtering half mask	
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:	
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.	Shenzh Century
9.2.2	Type-identifying marking.	
9.2.3	The number and year of publication of this European Standard.	See ab
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2 H
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).	
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.	
10	Information to be supplied by the manufacturer	
10.1	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.	English
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on: % application/imitations; % the meaning of any colour coding;	See us

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	% checks prior to use; % donning, fitting; % use; % maintenance (e.g. cleaning, disinfecting), if applicable; % storage; % the meaning of any symbols/pictograms used on the equipment).	See user
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Clearly co
10.5	Warning shall be given against problems likely to be encountered, for example: % fit of particle filtering half mask (check prior to use); % it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; % air quality (contaminants, oxygen deficiency); % use of equipment in explosive atmosphere.	See user
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.	

10	Information to be supplied by the manufacturer	
10.1	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.	English
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on: % application/imitations; % the meaning of any colour coding;	See us

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Attachments: test table

Table 8.5 Leakage test					
Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Item					
NaCl flow rate (L/min)	90	105	105	110	
NaCl aerosol (µm)	0.3	0.3	0.3	0.3	
Pumping flow rate (L/min)	30	30	30	30	
NaCl concentration before mask (µg/m <sup>3</sup> )	2	2	2	2	
NaCl concentration after mask (µg/m <sup>3</sup> )	0.17	0.15	0.15	0.17	

Note: Test air volume is 2m<sup>3</sup>  
Average Leakage ratio is 6.20%±11%  
Calculation formula as below:  
$$P(\%) = \frac{C_2}{C_1} \left( \frac{Q_1 - Q_2}{Q_1} \right) \times 100$$

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Table 8.6.1 Breathing resistance test						
Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	P
Item						
Inhalation gas velocity (L/min)	30	30	30	30	30	
Maximum resistance (mbar)	0.35	0.33	0.34	0.52	0.44	
Note: Maximum permitted resistance < 0.6 mbar						

Table 8.6.2 Exhalation resistance test						
Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	P
Item						
Inhalation gas velocity (L/min)	95	95	95	95	95	
Maximum resistance (mbar)	2.04	2.06	2.02	2.01	2.01	
Note: Maximum permitted resistance < 2.1 mbar						

Table 8.6.3 Breathing resistance test						
Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	P
Item						
Exhalation (L/min)	160	160	160	160	160	
Maximum resistance (mbar)	2.55	2.55	2.57	2.54	2.53	

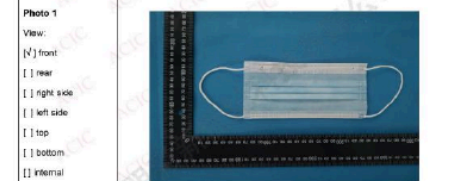
Note: Maximum permitted resistance < 3.0 mbar

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Attachments: one of real photos test samples



\*\*\* THE END OF REPORT \*\*\*

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