



TEST REPORT

Hunan Nun Medical Supplies Co., Ltd.
#404 #504, Building No.3, Xingsha International Enterprise Center, No.68 Luositang Road, National
Ecological and Technical Development Zone, Chuangshui, Hunan, China.

Lot No. / Batch Code:	20201029
Sample Description:	Medical surgical mask (Non-sterile)
Quantity Submitted:	200pcs
Manufacturer / Supplier:	Hunan Nun Medical Supplies Co., Ltd.
Manufactured Date:	2020-10-29
Sample Receiving Condition:	In unopened plastic bag under ambient condition
Country of Origin:	China
Sample Receiving Date:	November 2, 2020
Testing Period:	November 2, 2020 –November 13, 2020

Test Requested :Please refer to the result summary.

Test Method &Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods	Pass

Signed for and on behalf of Shenzhen Academy of Metrology & Quality Inspection:

周子楠 陈国忠
Tester

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Checker

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EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

Clause Test Items/requirement

Test Result Summary

5 Requirements

5.2 Performance requirements

5.2.2 Bacterial filtration efficiency (BFE)	> 98%
5.2.3 Breathability (Differential Pressure)	< 40Pa/cm ²
5.2.4 Microbial cleanliness (Bioburden)	<30 cfu/g
5.2.5 Summary of performance requirements	See Table 1

Table 1 Performance requirements for medical face masks

Characteristics	Type I ^a	Type II	Type IIR
Bacterial filtration efficiency (BFE), %	≥ 95	≥ 98	≥ 98
Differential pressure, Pa/cm ²	< 40	< 40	< 60
Splash resistance (kPa) [#]	Not Required	Not Required	≥16.0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

^a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

[#] - An acceptable quality limit of 4,0 % is met for a single sampling plan when 29 or more of the 32 tested specimens show

pass results



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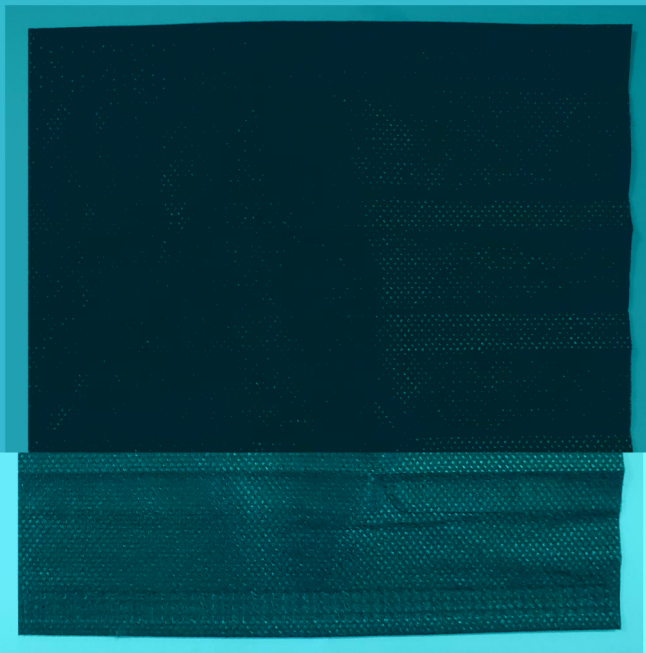
Test Results:

TABLE: Breathability(Differential pressure)		
Test Specimen number-test area number	Differential pressure for each test area (Pa/cm ²)	The averaged differential pressure for each test specimen(Pa/cm ²)
1-1	26.3	27.0
1-2	29.5	
1-3	27.0	
1-4	25.7	
1-5	26.4	
2-1	26.8	27.0
2-2	26.6	
2-3	27.7	
2-4	28.9	
2-5	25.1	
3-1	25.5	27.7
3-2	30.5	
3-3	26.6	
3-4	26.7	
3-5	29.0	
4-1	29.9	28.7
4-2	28.8	
4-3	28.9	
4-4	28.2	
4-5	27.5	
5-1	25.3	27.1
5-2	29.1	
5-3	28.6	
5-4	29.1	
5-5	23.3	



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Photo of test location:



Result 3 Microbial cleanliness (Bioburden) (EN 14683:2019+AC:2019 Annex D)

Test Methods

Bioburden

The analyses were performed according to EN 14683:2019+AC:2019 Annex D and ISO 11737-1:2018

Test Results

Article Number	Mask Weight/g	Total Bioburden, cfu/mask	Total Bioburden, cfu/g
1	3.0	31.8	10.6
2	3.0	32.7	10.9
3	3.1	44.4	14.3
4	3.0	39.6	13.2
5	3.0	22.8	7.6

Standard requirement[#]: ≤30 cfu/g

Note:

1. cfu = Colony Forming Units
2. Extraction method:by stomacher at 250rpm for 5 minutes
3. [#] EN 14683:2019+AC:2019 -Medical face masks - Requirements and test methods - Performance requirements for medical face masks - Microbial cleanliness



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Photo Appendix



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