





中国认可 国际互认 检测 TESTING CNAS L0599

Test Report SL52025257468801TX Date:June 04,2020 Page 1 of 3

HUNAN LIANGGUO MEDICAL TECHNOLOGY CO., LTD.

NO. 40613, ZHONGCHUANG SPACE CARD BLOCK, 4TH FLOOR, COMPREHENSIVE BUILDING, HUNAN UNIVERSITY SCIENCE AND TECHNOLOGY INDUSTRIAL PARK, NO. 001, JINZHOU NORTH ROAD, NINGXIANG HIGH-TECH INDUSTRIAL PARK, CHANGSHA CITY, HUNAN PROVINCE

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

Sample Description : (A)Medical Surgical Face Mask: Flat form ear loop

Country of Destination: EU Member States

Composition : (A)Melt-blown fabric and spunbond non-woven fabric

Sample Color : (A)Blue/ white

Manufacturer : HUNAN LIANGGUO MEDICAL TECHNOLOGY CO., LTD.
Supplier : HUNAN LIANGGUO MEDICAL TECHNOLOGY CO., LTD.

Proposed Care Instruction: -

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

Sample Receiving Date : May 14, 2020

Testing Period : May 14, 2020 - Jun 04, 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).

Signed for and on behalf of

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu (Authorized Signatory)



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Test Result

### **Medical Face Masks-Requirements and Test Methods**

(EN 14683:2019)

# Clause 5.2.2 Bacterial filtration efficiency (BFE)\*

(EN 14683 :2019 Annex B)

1# 2# 3# 4# 5# (BFE), % >99.9 >99.9 >99.9 >99.9

Remark: Performance Requirement: Type I≥95%, Type II≥98%, Type IIR≥98%

## Clause 5.2.3 Breathability (Differential Pressure)

(EN 14683 :2019 Annex C, Flow rate 8 I/min)

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm²)	37	38	39	38	37

Remark: Performance Requirement: Type I<40 Pa/cm<sup>2</sup>, Type II<40 Pa/cm<sup>2</sup>, Type IIR<60 Pa/cm<sup>2</sup>

### Clause 5.2.4 Splash Resistance

(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface									
1#	2#	3#	4#	5#	6#	7#	8#		
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass		
9#	10#	11#	12#	13#	14#	15#	16#		
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass		
17#	18#	19#	20#	21#	22#	23#	24#		
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass		
25#	26#	27#	28#	29#	30#	31#	32#		
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass		
Number of Pass:		32							
Overall result:		Acceptable							

#### Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
- 3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
- 4) 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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<sup>\*</sup> This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CMA (China Metrology Accreditation).



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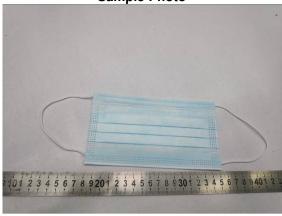
## **Clause 5.2.5 Microbial Cleanliness**

(EN ISO 11737-1:2018)

1# 2# 3# 4# 5# CFU/g 8 7 15 1 11

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g





The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

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



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