

**EU DECLARATION OF CONFORMITY****Manufacturer****Authorized Representative****Name: Zhejiang Lanhine Medical Products Ltd.****Name: Anteo Medical Supplies BV****Address: 1989 Cidong Road, Cidongbinhai District,  
315300 Cixi City, Zhejiang Province,  
People's Republic of China****Address: Mahatma Gandhistraat 52,  
3066VA Rotterdam  
The Netherlands**

**We, Zhejiang Lanhine Medical Products Ltd (the manufacturer), herewith declares that the product:**

**Disposable face mask Model L(17.5\*9.5cm) Type IIR with Product Codes:**

Type IIR 50pcs Box	Type IIR Multipacks	Type IIR Tie-On
FMSUR2RLAM1 FMSUR2RBLAM1 FMSUR2RGLAM1	FMCIV2R4PBLAM1 FMCIV2R5PGLAM1 FMCIV2R5PBLAM1 FMCIV2R10PBLAM1 FMCIV2R10PGLAM1 FMCHILD2RMBLAM1	FMSUR2RTOLAM1

**(A) Procedure Face Mask (SGS Reference No. NBHL2004005210MD)  
UMDNS-Code: 6971513689010**

**Meet the provisions of Directive 93/42/EEC which apply to them.**

**The medical device has been assigned to Class I according to Annex IX of the Directive 93/42/EEC. It bears the mark:**



**Following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC. Applicable standards: EN 14683+C1, EN ISO 13485:2016**

**This Declaration of Conformity covers all medical devices as specified in the products list belonging to this declaration.**

**Zhejiang Lanhine Medical Products Ltd. is exclusively responsible for declaration of conformity.**

**Place: Ninbo Zhejiang**

**Date: 2020-08-01**



**Gu Junfei/QA Manager  
On behalf of Zhejiang Lanhine Products Ltd.**

**Test Report**                      **SL52025257261801TX**                      **Date: May 27, 2020**                      **Page 1 of 3**  
ZHEJIANG LANHINE MEDICAL PRODUCTS LTD.  
1989 CIDONG ROAD, CIDONGBINHAI DISTRICT, 315300 CIXI CITY, ZHEJIANG PROVINCE, PEOPLE'S  
REPUBLIC OF CHINA

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

Sample Description                      :    (A)Procedure Face Mask

SGS Internal Ref.No.                    :    NBHL2004005210MD

Sample Color                            :    (A)Blue

Style No.                                 :    Model L

Manufacturer                            :    ZHEJIANG LANHINE MEDICAL PRODUCTS LTD.

Supplier                                  :    ZHEJIANG LANHINE MEDICAL PRODUCTS LTD.

Proposed Care Instruction            :    -

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

Sample Receiving Date                :    May 12, 2020

Testing Period                          :    May 12, 2020 - May 27, 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)



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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)

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Testing Center (Technical Services)    中国·上海·徐汇区宜山路889号3号楼 邮编: 200233    t (86-21) 61402666    f (86-21) 64958763    e [sgs.china@sgs.com](mailto:sgs.china@sgs.com)

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), %	99.4	99.3	99.9	99.5	>99.9

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

\* 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).

**Clause 5.2.3 Breathability (Differential Pressure)**

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

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm <sup>2</sup> )	26	35	27	35	27

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)

<b>Penetration on inside surface</b>							
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	Fail	Pass	Pass	Fail	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	Fail	Pass	Pass	Pass
Number of Pass:			29				
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

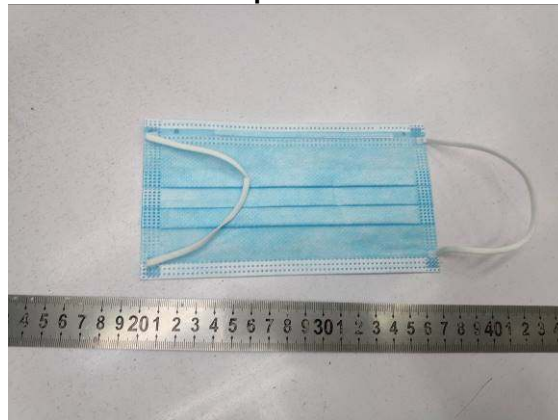


**Clause 5.2.5 Microbial Cleanliness**  
(EN 14683: 2019 Annex D)

	1#	2#	3#	4#	5#
CFU/g	<1	2	<1	3	1

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

**Sample Photo**



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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