



# DECLARATION OF CONFORMITY

Regarding Medical Device Directive(93/42/EEC)  
including Directive 2007/47/EC

**Manufacturer:** Fujian Topcom Garment City Corp.,Ltd  
**Address:** NO.756 Qian Road,Gaishan Town,Cangshan District,Fuzhou  
city, Fujian province, China

**EC Representative:** SUNGO Europe B.V.  
**Address:** Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product Name:** Disposable Medical Mask  
**Specification:** 17\*9.5cm、CM1010

**Classification:** Class I (MDD, Annex IX)

## Conformity Assessment

**Procedure:** Annex VII of Medical Device Directive(93/42/EEC)

We herewith declare that the above-mentioned products meet the requirements of  
Medical Device Directive (93/42/EEC) and the following harmonized standards.


EN ISO 14971:2012 EN ISO 15223-1:2016

EN 1041:2013 EN ISO 10993-1:2018

EN ISO 10993-5:2009 EN ISO 10993-10:2013

EN ISO 14683:2019

*On behalf of SUNGO Europe office, I confirmed we are  
EU REP of the company who issue this document.*

**Signature:**   
**Name/ Position:** Dicky Lin/Compliance Director

**Date:** 21th April,2020

**Place:** NO.756 Qian Road,Gaishan Town,Cangshan District,Fuzhou city, Fujian province, China



Authorized Signature (S)

**Test Report**                      **SL52025233818701TX**                      **Date: April 21, 2020**                      **Page 1 of 3**  
FUJIAN TOPCOM GARMENT CITY CORP.,LTD  
NO.756 QIAN ROAD, GAISHAN TOWN, CANGSHAN DISTRICT, FUZHOU

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

Sample Description : (A) Disposable Medical Mask (non-sterilized) (Claimed Type IIR)  
Style No. : CM1010  
Composition : (A) Melt-blown fabric/Non-woven fabric  
Sample Color : (A) White  
End Use : (A) Medical protective  
Order No. : 20031501  
Manufacturer : Fujian Topcom Garment City Corp.,Ltd  
Country of Destination : Europe/America  
Country of Origin : China  
Supplier : Fuzhou Spring Investment Corp.,Ltd  
Proposed Care Instruction : -  
Test Performed : Selected test(s) as requested by applicant  
Sample Receiving Date : Mar 31,2020  
Testing Period : Mar 31,2020 - Apr 21,2020  
Test Result(s) : For further details, please refer to the following page(s).

**Comment:**

<b>Medical Face Masks-Requirements and Test Methods(EN 14683:2019)</b>	<b>(A)</b>
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	M
Clause 5.2.5 Microbial Cleanliness	M

Remark: M=Meet EN 14683:2019 Type IIR requirement  
F=Below EN 14683:2019 Type IIR requirement

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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)



Test Result

**Medical Face Masks-Requirements and Test Methods**  
(EN 14683:2019)

**Clause 5.2.2 Bacterial filtration efficiency (BFE)\*\*@**

(BFE), %	1#	2#	3#	4#	5#
	99.8	99.9	99.8	99.9	99.9

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

\*\* : The test was carried out by external laboratory assessed as competent

@ : This test method is not in CNAS accredited scope

**Clause 5.2.3 Breathability**

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

Sample: A

Differential pressure ΔP (Pa/cm <sup>2</sup> )	1#	2#	3#	4#	5#
	33.8	41.0	39.2	38.1	27.6

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)

Sample: A

**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

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.  
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



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

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

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\*\*\*



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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)

SGS-CSL Technical Services (Shanghai) Co., Ltd. 3<sup>rd</sup> Building, No. 889, Yishan Road, Xuhui District, Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958783 www.sgs.com.cn  
 Testing Center No. 889, Yishan Road, Xuhui District, Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958783 e [sgs.china@sgs.com](mailto:sgs.china@sgs.com)