

SHANDONG SHENGQUAN NEW MATERIALS CO., LTD  
DIAOZHEN INDUSTRIAL DEVELOPMENT ZONE, ZHANGQIU, JINAN, CHINA

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

Sample Description : (A) Face mask (Disposable Medical Face Mask)

Style No. : SMDP20605

Sample Color : (A) blue and grey

Lot No./Batch No. : Not provided

Proposed Care Instruction : -

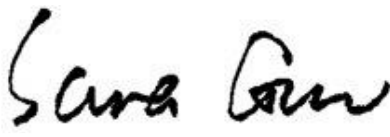
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Apr 07, 2020

Testing Period : Apr 07, 2020 - Jul 14, 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)



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)

3<sup>rd</sup> Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233  
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  
t (86-21) 61402666 f (86-21) 64958763

[www.sgsgroup.com.cn](http://www.sgsgroup.com.cn)  
e [sgs.china@sgs.com](mailto:sgs.china@sgs.com)

Test Result

**EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**

**Clause 5.2 Performance Requirement**

**Clause 5.2.6 Biocompatibility**

(ISO 10993-1)

**Tests for in vitro cytotoxicity (test on extracts)\***

(ISO 10993-5:2009)

**Cell line**

Mouse fibroblast cells L929 was purchased from cell bank of Chinese Academy of Sciences, Shanghai.

**Cell culture medium**

1640 medium, supplemented with L-glutamine and 10% FBS.

**Sample preparation**

The test article was sterilized at 121 °C for 30 min and was extracted with 1640 Medium in ratio of 3 cm<sup>2</sup>/mL in 37 °C for 24h. Positive control: Polyurethane film containing 0.1% zinc diethyl-dithiocarbamate (ZDEC).

**Test procedures**

L929 cells were cultured in RPMI 1640 medium with 10% FBS and Penicillin-Streptomycin, and placed in cells incubator of 37 °C and 5.0% CO<sub>2</sub>.

L929 cells were seeded in 96-well plates and each well was added 100 µl cell solution in a density of 1×10<sup>5</sup>/ml. Cells were treated with the extract of the test sample and 6 replicate wells were used.

After 24h treatment, 50 µl MTT solution were added to each well. After incubation, washing and Isopropanol extraction, the absorbance of each well was detected at 570 nm with a spectrophotometer and cell viability were calculated.

**Test results**

**Cytotoxicity tests results of face mask**

Group	Cell viability
Solution control	100%
Test article	93.86%
Positive control	0.63%

**Conclusions**

Under the conditions of this study, the negative controls and the positive controls in the test performed as anticipated, the cytotoxicity of the sample was grade 0, which is non-cytotoxic

**Remark:**

\* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L1009.



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-Document.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)

3<sup>rd</sup> Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233  
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  
t (86-21) 61402666 f (86-21) 64958763

[www.sgs.com](http://www.sgs.com)  
[sgs.china@sgs.com](mailto:sgs.china@sgs.com)

**Animal Skin Irritant Test\***  
(ISO 10993.10-2010)

**Test animal**

Four healthy conventional New Zealand White Rabbits, female, 2.0-3.0 kg each, supplied by Shanghai KeShuo Experiment Animal Co., LTD, Certificate No. SCXK(Hu)2017-0013). The animal feed were supplied by Huzhou Eastern Hope Animal Nutrition Food Co., LTD, license No. Zhe Feed Approval(2019)05022.

**Test environment**

Rabbit room of conventional condition. Certificate No. SYXK(Hu)2019-0033, room temperature 18-23°C, relative humidity 45-65%

**Test Results**

Tab.1

Rabbit Number	response	Observation time					
		24 h		48 h		72 h	
		Sample S	Contrast C	Sample S	Contrast C	Sample S	Contrast C
5013#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
5014#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
5015#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0

The Primary Irritation Score of the sample was 0.

Tab.2 Primary irritation index categories in a rabbit

Mean score	Response category
0~0.4	Negligible
0.5~1.9	Slight
2~4.9	Moderate
5~8	Severe

**Conclusions**

According to Primary irritation index categories in a rabbit, the sample was found to be a negligible irritant to rabbits' skin

**Remark:**

\* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L1009.



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)  
 3<sup>rd</sup> Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgs.com.cn  
 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)

**Skin Sensitisation test\***  
(ISO 10993-10:2010)

**Test environment**

Animal room of conventional condition. Certificate No. SYXK(Hu) 2019-0033, room temperature 20-22°C, relative humidity 45-65%.

**Experimental animals**

Guinea pigs, female, 300-500g, supplied by Shanghai KeShuo Experiment Animal Co., LTD, Certificate No. SCXK(Hu)2017-0013). The animal feed were supplied by Jiangsu Xietong Medical bio-engineering Co. LTD. License No: Su Feed Approval(2014) 01008

**Test results**

Delayed hypersensitivity tests results of face mask

Group	Time(h)	Skin response				Sensitization rate %
		0	1	2	3	
Normal saline	24	5	0	0	0	0
	48	5	0	0	0	0
The test article	24	10	0	0	0	0
	48	10	0	0	0	0

**Magnusson and Kligman scale Patch test reaction Grading scale**

Patch test reaction	Scoring
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

**Conclusions**

Under the conditions of the study, the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig

**Remark:**

\* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L1009.

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-CTC (Shanghai) Technical Service Co., Ltd. 3<sup>rd</sup> Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn  
Testing Center for Technical Services (Shanghai) Co., Ltd. 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)