

Test Result

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

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial filtration efficiency (BFE)*

(EN 14683:2019 Annex B)

Sample: A

	1#	2#	3#	4#	5#
(BFE), %	99.4	99.7	99.6	99.4	99.2

Remark: Performance Requirement: Type I $\geq 95\%$, Type II $\geq 98\%$, Type IIR $\geq 98\%$

* 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

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test number and location : 5 random areas for each specimen (face mask)
 Conditioning Parameters : Minimum of 4 hours at $21 \pm 5^\circ\text{C}$ and $85 \pm 5\%$ R.H.
 Test Area : 4.9 cm^2
 Flow Rate : 8 l/min

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm ²)	38	37	37	37	37

Remark: Performance Requirement: Type I $< 40 \text{ Pa/cm}^2$, Type II $< 40 \text{ Pa/cm}^2$, Type IIR $< 60 \text{ Pa/cm}^2$



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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	Fail	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:			31				
Overall result:			Acceptable				

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: $\geq 16.0\text{kPa}$
- 2) Distance of the medical face mask target area surface to the tip of cannula is $300\pm 10\text{mm}$.
- 3) Condition and Test temperature $(21\pm 5)^{\circ}\text{C}$, relative humidity $(85\pm 10)\%$
- 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+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

	1#	2#	3#	4#	5#
CFU/g	15	18	12	1	<1

Remark: Performance Requirement: Type I $\leq 30\text{CFU/g}$, Type II $\leq 30\text{CFU/g}$, Type IIR $\leq 30\text{CFU/g}$



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Sample Photo



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

Sample Description : (A)Medical Face Mask

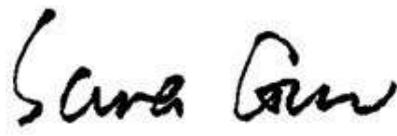
Style No. : REF code 05MSK339CRVNE
 Sample Color : (A)Blue/White
 Manufacturer : BENEFIS S.R.L
 Lot No./Batch No. : Not provided

Sample Receiving Date : May 28, 2020
 Testing Period : May 28, 2020 - Aug 28, 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).

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

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods	(A)
Clause 5.2 Performance Requirement	
Clause 5.2.2 Bacterial filtration efficiency (BFE)	EXCLUDED
Clause 5.2.3 Breathability	EXCLUDED
Clause 5.2.4 Splash Resistance	EXCLUDED
Clause 5.2.5 Microbial Cleanliness	EXCLUDED
Clause 5.2.6 Biocompatibility	Vitro cytotoxicity: non-cytotoxic Animal Skin Irritant Test: negligible irritant Skin Sensitisation test: no evidence of causing delayed dermal contact sensitization

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


 Sara Guo (Account Executive)



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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 cm²/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% CO₂.

L929 cells were seeded in 96-well plates and each well was added 100 µl cell solution in a density of 1 × 10⁵/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 add to each wells. 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	102.70%
Positive control	1.18%

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.



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
6336#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
6337#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
6338#	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:

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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

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Sample Photo



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