Medical Device Technical File Review Report

Report No.:	MDD GZES2003013559ME
Applicant:	Shenzhen Peninsula Medical Co., Ltd.
Address:	3F Block A, Building F2, Changfeng Industrial Park, Liuxian 3rd Road, 68# Xin'an Street, Bao'an District，Shenzhen, 518100, P.R.China.
Product(s) Name:	Disposable Surgical Mask
Type(s)/Model(s):	Flat-type
Classification:	Class I not sterile or measuring under Directive 93/42/EEC
Review Purpose:	Review the completeness of the Technical Documentation in accordance with the requirements of Annex VII of Directive 93/42/EEC as amended by 2007/47/EC
Review Result:	During the review of the Technical Documentation **(File No. BDCE-001, Version No. 1.0, date 2020-03-03)** provided for the above listed product(s), no non-compliance was detected according to the requirements of Annex VII of Directive 93/42/EEC
Date of Review:	2020-03-27 to 2020-05-14
Date of Expire:	2021-05-14

Jason Hoo

Laboratory Manager

SGS-CSTC Standards Technical Services Co., Ltd. E&E Lab Guangzhou

Disclaimer:

This report relates only to the product(s) as described in the Technical Documentation on the date and version shown. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the manufacture, quality control, safety and performance of the product(s).

Test Report

Report No.: GZES200301355802

Date: 2020-06-03

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

Applicant:	Shenzhen Peninsula Medical Co., Ltd 3F Block A，Building F2，Changfeng Industrial Park，Liuxian 3rd Road，68# Xin'an Street，Bao'an District，Shenzhen,518100, P.R.China.
Manufacturer:	The same as the applicant
Sample Name:	Disposable Surgical Mask
Lot No. :	202003001
Quantity:	70 PCS
Model/Type Reference:	Flat-type 175mm×95mm
Date of Sample Received:	2020-04-08
Date of Testing:	2020-04-08 to 2020-06-03
The Standards:	EN 14683:2019+AC:2019
Test Items:	Bacterial filtration efficiency, Differential pressure, Splash resistance pressure and Microbial cleanliness
Test Result:	-Please refer to next page(s)-
Remark:	1. The ISO 22609:2004 testing was performed by SGS-CSTC Standards Technical Services(Shanghai) Co., Ltd Testing Center(No.CNAS L0599). 2. The EN 14683:2019+AC:2019 Annex B, EN 14683:2019+AC:2019 Annex C and EN ISO 11737-1:2018 Tests were performed by Taiwan Textile Research Institute(No.TAF 0491).

Jova Lan

Jova Lan
Technical Manager
Medical Laboratory
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Summary of Test Results

Test Items		Result - Remarks	Test Methods	Requirements	Verdicts
Differential Pressure (Pa/cm^2)	1#	35.3	EN 14683:2019+AC:2019 Annex C	Type ⅡR <60	Pass
	2#	33.6			
	3#	35.0			
	4#	32.6			
	5#	34.0			
Splash Resistance Pressure:16.0 kPa	1#~32#	All pass	EN 14683:2019+AC:2019 ISO 22609:2004	Type ⅡR AQL: 4.0%	Pass
Bacterial Filtration Efficiency (BFE)(%)	1#	99.7	EN 14683:2019+AC:2019 Annex B	Type ⅡR ≥98	Pass
	2#	99.8			
	3#	99.7			
	4#	99.8			
	5#	99.8			
Microbial Cleanliness (cfu/g)	1#	2.0	EN 14683:2019+AC:2019 EN ISO 11737-1:2018	Type ⅡR ≤30	Pass
	2#	<2.0			
	3#	3.0			
	4#	<2.0			
	5#	2.0			

note: 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.

No.198 Kezhu Road, Scientech Park, Guangzhou Economic & Technology Development District, Guangzhou, China 510663 t (86-20) 82155555 f (86-20) 82075058 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075058 sgs.china@sgs.com

Differential Pressure

1. Test method
EN 14683:2019+AC:2019 Annex C

2. Test principle
The differential pressure is measured by a device. It is required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material.

3. Test apparatus and materials
3.1 Differential pressure measurement system
3.2 5 masks which conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h.

4. Test procedure
4.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 l/min.
4.2 The holder is opened and the test specimen is placed across the 25 mm diameter orifice (total area 4.9 cm^2) between the top and bottom parts of the holder. Then it is clamped in place using a mechanical clamp with sufficient pressure to avoid air leaks.
4.3 The differential pressure is read directly.
4.4 The procedure described in steps 4.1 to 4.3 is carried out on 5 (or appropriate number) different areas of the mask and the readings averaged.

5. Test results

Test specimens	Result (Pa/cm^2)	Test Methods	Requirements	Verdicts
1#	35.3	EN 14683:2019+AC:2019 Annex C	Type Ⅱ R <60	Pass
2#	33.6			
3#	35.0			
4#	32.6			
5#	34.0			

SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch Electronic Technology Service EEC Laboratory
No.198 Kezhu Road, Scientech Park, Guangzhou Economic & Technology Development District, Guangzhou, China 510663 t (86-20) 82155555 f (86-20) 82075058 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075058 sgs.china@sgs.com

Splash Resistance Pressure

1. Test method
ISO 22609:2004

2. Test principle
A specimen medical face mask is supported on an apparatus. A volume of synthetic blood is sprayed horizontally at the specimen mask to simulate the scenario of a mask being splashed by a punctured blood vessel.

3. Test apparatus and materials
3.1 Synthetic blood penetration testing equipment, air-pressure source, graduated cylinder, balance, temperature/humidity recorder, controlled temperature and humidity chamber or space, targeting plate.
3.2 Synthetic blood, isopropanol.
3.3 32 masks for testing, which conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h.

4. Test procedure
4.1 Conduct all testing in an environment having a temperature of (21 ± 5) °C and a relative humidity of (85 ± 10) %.
4.2 Install a clean 12.7 mm long canula with an inside diameter of 0.84 mm on the front of the pneumatic-controlled valve.
4.3 Fill the reservoir with new synthetic blood (approximately 1 l).
4.4 Set the valve time corresponding to the blood pressure being assessed in accordance with Table below.

Valve times for standard test pressures

Pressure (kPa)	Velocity (cm/s)	Valve time for standard apparatus and fluid (s)
16.0	550	0.66

4.5 The volume of synthetic blood can be measured by determining the mass using a balance. For the standard fluid, with a specific gravity of 1.005, the 2 ml of fluid would weigh (2.010 ± 0.040) g.
4.6 Place a small droplet (approximately 0.1 ml) of the synthetic blood on the normal inside surface of an extra medical face mask.
4.7 Remove a specimen from the conditioning chamber. Mount the specimen on the specimen-holding fixture and position the specimen for impact of the synthetic blood to occur in the target area. Position the end of the pneumatic-controlled valve at a distance of (300 ± 10) mm from the target area from the specimen.
4.8 Squirt the synthetic blood onto the specimen medical face mask. Ensure that the synthetic blood hits the target area of the medical face mask. Conduct the test within 60 s after removal from conditioning chamber.
4.9 Inspect the viewing side of the specimen for synthetic blood (10 ± 1) s after squirting the synthetic blood against the target area. Note whether any synthetic blood or other evidence of wetness, or both, appears on the viewing side of the specimen using suitable lighting.
4.10 Test the remaining specimens.

SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch Testing Service EEC Laboratory
No.198 Kezhu Road, Scientech Park, Guangzhou Economic & Technology Development District, Guangzhou, China 510663 t (86-20) 82155555 f (86-20) 82075058 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075058 sgs.china@sgs.com

5. Test results

Test specimens	Results	Test specimens	Results	Test Methods	Requirements	Verdicts
1#	Pass	17#	Pass	EN 14683:2019+AC:2019 ISO 22609:2004	Type IIR AQL: 4.0%	Pass
2#	Pass	18#	Pass			
3#	Pass	19#	Pass			
4#	Pass	20#	Pass			
5#	Pass	21#	Pass			
6#	Pass	22#	Pass			
7#	Pass	23#	Pass			
8#	Pass	24#	Pass			
9#	Pass	25#	Pass			
10#	Pass	26#	Pass			
11#	Pass	27#	Pass			
12#	Pass	28#	Pass			
13#	Pass	29#	Pass			
14#	Pass	30#	Pass			
15#	Pass	31#	Pass			
16#	Pass	32#	Pass			

note: 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.

SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch (SGS-CSTC Standards Technical Services Co., Ltd. EEC Laboratory)
No.198 Kezhu Road, Scientech Park, Guangzhou Economic & Technology Development District, Guangzhou, China 510663 t (86-20) 82155555 f (86-20) 82075058 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075058 sgs.china@sgs.com

Bacterial Filtration Efficiency (BFE)

1. Test method
EN 14683:2019+AC:2019 Annex B

2. Test principle
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

3. Test apparatus and materials
3.1 BFE test apparatus including six stage cascade impactor, nebulizer, aerosol chamber, flow meters, pressure gauge, erlenmeyer flasks, peristaltic or syringe pump, vacuum pump.
3.2 Tryptic soy agar, Tryptic soy broth, Peptone water, Culture of Staphylococcus aureus ATCC 6538.
3.3 5 masks which conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h.

4. Test procedure
4.1 Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.
4.2 Perform a positive control run without a test specimen. Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28.3 l/min.Deliver the bacterial challenge for 1 min. Maintain the airflow through the cascade impactor one additional minute (total test time is 2 min). Then remove the plates from the cascade impactor. Ensure that each plate is numbered to indicate its position in the cascade impactor.
4.3 Place fresh plates in the cascade impactor, clamp the test specimen in place between the first stage of the cascade impactor and the inlet cone.The outside of the mask is facing towards the challenge aerosol. Repeat the procedure described in 4.2, The test area is 39.5m^2.
4.4 Repeat this procedure for each test specimen.
4.5 After the last test specimen has been tested, perform a further positive control run.
4.6 Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.
4.7 Incubate all the plates at (37 ± 2) °C for (20 to 52) h.
4.8 For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of CFU collected by the cascade impactor. Use the “positive hole” conversion table in accordance with the instructions of the cascade impactor manufacturer for stages 3 to 6. For the two positive control runs, take the mean of the two totals. From the positive control plates calculate the mean particle size (MPS) of bacterial challenge aerosol using the formula given in B.6 of EN 14683:2019+AC:2019 Annex B.
MPS=3.2 μm.
4.9 Calculation of bacterial filtration efficiency (BFE)
For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:
$B = (C - T) / C \times 100$
where
C is the mean of the total plate counts for the two positive control runs;
T is the total plate count for the test specimen.

5. Test results

SGS-CSTC Standards Technical Services Co.,Ltd. Guangzhou Branch Testing Center EEC Laboratory.
No.198 Kezhu Road, Scientech Park, Guangzhou Economic & Technology Development District, Guangzhou, China 510663 t (86–20) 82155555 f (86–20) 82075058 www.sgsgroup.com.cn
中国・广州・经济技术开发区科学城科珠路198号 邮编: 510663 t (86–20) 82155555 f (86–20) 82075058 sgs.china@sgs.com

Test specimens	Results(%)	Test Methods	Requirements	Verdicts
1#	99.7	EN 14683:2019+AC:2019 Annex B	Type ⅡR ≥98	Pass
2#	99.8			
3#	99.7			
4#	99.8			
5#	99.8			

SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch Electrical Technical Services EEC Laboratory
No.198 Kezhu Road, Scientech Park, Guangzhou Economic & Technology Development District, Guangzhou, China 510663 t (86-20) 82155555 f (86-20) 82075058 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075058 sgs.china@sgs.com

Microbial Cleanliness

1. Test method
EN ISO 11737-1:2018 and EN 14683:2019+AC:2019 Annex D

2. Test principle
The bacteria and fungi on the product were collected by the instrument, and then cultured in a petri dish at the appropriate temperature to count.

3. Test apparatus and materials
3.1 Orbital shaker, balance, biochemical incubator, vertical pressure steam sterilizer, 0.45 μm filter.
3.2 TSA plate, SDA with chloramphenicol, extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l polysorbate surfactant 20).
3.3 When 5 samples are selected take the top, bottom and 3 randomly chosen masks.

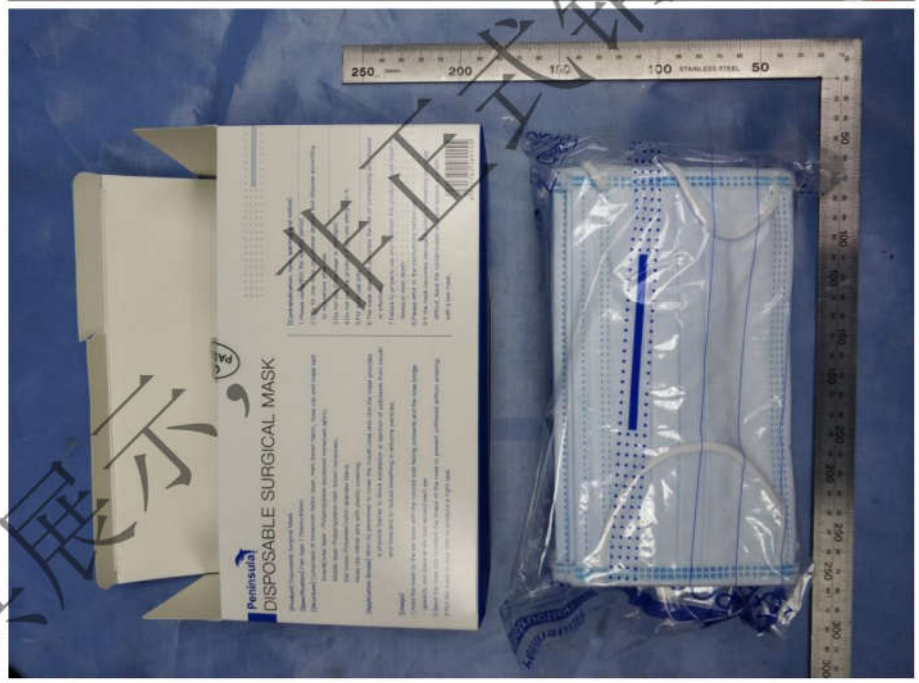
4. Test procedure
4.1 Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid.
4.2 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 μm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 to 25) °C for TSA and SDA plates respectively.

5. Test results

Test specimens	Result (cfu/g)	Test Methods	Requirements	Verdicts
1#	2.0	EN 14683:2019+AC:2019 EN ISO 11737-1:2018	Type IIR ≤30	Pass
2#	<2.0			
3#	3.0			
4#	<2.0			
5#	2.0			

No.198 Kezhu Road, Scientech Park, Guangzhou Economic & Technology Development District, Guangzhou, China 510663 t (86-20) 82155555 f (86-20) 82075058 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075058 sgs.china@sgs.com

Photo documentation:



Sample description
Disposable Surgical Mask

-- End of this report--

SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch (Guangzhou EEC Laboratory)
No.198 Kezhu Road, Scientech Park, Guangzhou Economic & Technology Development District, Guangzhou, China 510663 t (86-20) 82155555 f (86-20) 82075058 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075058 sgs.china@sgs.com
Member of the SGS Group (SGS SA)