0004723

统一社会信用代码

91317227574600 5XX

营业执照

(副 本) 1-1

扫描二维码登录'国家企业信用信息公示系统'了解更多登记、备案、许可、监管信息

名　　称　山东朱氏药业集团有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　朱坤福

经营范围　医药产品研制；I类、II类、III类医疗器械产品的生产、销售；I类、II类、III类消毒产品的生产、销售；一般液态单元（护发清洁类、护肤水类）、膏霜乳液单元（护肤清洁类、护发类）、粉单元（散粉类、块状粉类）、气雾剂及有机溶剂单元（有机溶剂类）、蜡基单元（蜡基类）、牙膏单元（牙膏类）；洗涤剂产品、日用品、家用电器的生产、销售；化学原料、化学试剂、生物试剂（不含危险化学品、易制毒品）的销售；从事生物科技产品的技术开发、技术咨询、技术转让；实验室耗材的批发零售；食品生产加工、销售；非织造布生产、销售；空气净化产品生产、销售。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

注册资本　壹亿元整

成立日期　2003 年 12 月 05 日

营业期限　2003 年 12 月 05 日至　年　月　日

住　　所　单县开发区樊楼路南

登记机关

2020 年 04 月 14 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告

国家市场监督管理总局监制

医疗器械生产许可证

许可证编号 鲁食药监械生产许 20140053 号

企业名称：山东朱氏药业集团有限公司

法定代表人：朱坤福

企业负责人：朱坤福

住　　所：单县经济技术开发区樊楼路南

生产地址：山东单县经济技术开发区和山东单县经济技术开发区食品药品产业园单德路 6 号

生产范围：

2002 年分类目录：II 类:6815 注射穿刺器械,6826-3-光谱辐射治疗仪器,6826-7-磁疗仪器,6841-4-血液化验设备和器具,6864-2-敷料、护创材料,6864-4-手术用品,6866-2-妇科检查器械,6866-4-导管、引流管,6866-6-肠道插管,6866-9-一般医疗用品,6820-1-体温计;
III 类：6815 注射穿刺器械，6866-1-输液、输血器具及管路
2017 年分类目录：II 类：01-03 高频/射频手术设备及附件，02-12 手术器械-穿刺导引器，03-05 神经和心血管手术器械-夹，06-16 内窥镜辅助用品，08-06 呼吸、麻醉用管路、面罩，09-02 温热（冷）治疗设备/器具，14-05 非血管内导（插）管，14-06 与非血管内导管配套用体外器械，14-13 手术室感染控制用品，18-01 妇产科手术器械，07-03 生理参数分析测量设备；14-14 医护人员防护用品；III 类：14-02 血管内输液器械

发证部门：山东省药品监督管理局

有效期限：至 2023 年 07 月 25 日

发证日期：2020 年 04 月 10 日

国家药品监督管理局制

中华人民共和国医疗器械注册证

注册证编号：鲁械注准 20192140064

注册人名称	山东朱氏药业集团有限公司
注册人住所	单县开发区樊楼路南
生产地址	山东单县经济技术开发区
代理人名称	（“进口医疗器械适用”）
代理人住所	（“进口医疗器械适用”）
产品名称	一次性使用医用外科口罩
型号、规格	17.5cm×9.5cm
结构及组成	由表层、中间层、底层、口罩带、鼻夹组成。表层材料为卫生级聚丙烯仿粘布、中间层材料为聚丙烯喷丝法制成的高效过滤熔喷布、底层材料为卫生级聚丙烯仿粘布、口罩带为涤纶线和少量氨纶线针织而成、鼻夹为可弯折可定型的聚丙烯制成。
适用范围	供临床医务人员在有创操作过程中佩带，覆盖住使用者的口、鼻及下颌，为防止病原体微生物、体液、颗粒物等的直接透过提供物理屏障。
附件	注册产品技术要求：鲁械注准 20192140064
其他内容	
备注	原《医疗器械分类目录》产品分类编码：II类：6864 医用卫生材料及敷料

审批部门：山东省食品药品监督管理局　　批准日期：2019 年 03 月 19 日

有效期至：2024 年 03 月 18 日

TMZC21103433D01T171122

第 21103433 号

商标注册证

东贝

核定使用商品/服务项目（国际分类：10）

第10类：医疗器械和仪器；护理器械；外科仪器和器械；健美按摩设备；按摩器械；医疗器械箱；兽医用器械和工具；医用身体康复仪；杀菌消毒器械；医用诊断设备（截止）

注 册 人 山东朱氏药业集团有限公司

注册人地址 山东省菏泽市单县开发区樊楼路南

注册日期 2017年10月28日 **有效期至** 2027年10月27日

局 长 刘俊臣 **发证机关** 中华人民共和国国家工商行政管理总局 商标局

MODEL : ZS-B

ZHUSHI

Disposable Surgical Face Mask

3ply with Earloop

CE ISO FDA NON STERILE

10PCS

Shandong Zhushi Pharmaceutical Group Co., Ltd

【Product Name】 Disposable Surgical Face Mask
【Specifications】 17.5cm × 9.5cm
【Structure And Composition】 This product is composed of three materials: non-woven fabric, nose strip and elastic band. The face mask is divided into inner, middle and outer layers, the inner layer is ordinary non-woven fabric, the middle layer is ultra-fine polypropylene fiber melt-blown fabric, and the outer layer is non-woven fabric or ultra-fine polypropylene melt-blown fabric. The ear strap is made of elastic band, which is made of non-woven fabric with elastic band inside; the material of the nose strip is a metal strip, which is covered with fine galvanized iron wire material.
【Application Scope】 It is suitable for the health care of the wearer in the general medical environment.
【Precautions and Warnings】
1. It is disposable for one use.
2. Keep away from liquid and flame before usage.
3. For disposable hygiene care under regular environment.
4. No usage if the package is broken.
【Contraindications】 Those who are allergic to this product are prohibited.
【Instructions】
1. Place the mask on the lower half of the face, and the ear hanging rope outward.
2. Press the bridge of the nose to ensure full fit, pull the lower end of the mask down to cover the lower jaw, and hook the ear rope to the back of the ear. Finally, make sure that the mask completely covers the lower half of the face and obtains the maximum area of protection.
【Storage Conditions】 Product transportation shall be carried out in accordance with the contract.The transportation should be covered to prevent rain and snow; The product should be stored at room temperature, dry,warehouse with good ventilation
【Expire Date】 2 Years
【Production Date】 See the seal

EC REP SUNGO Europe B.V. VAT: NL857821659B01
Add: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands Contact: SUNGO Secretary
Tel/Fax: +31 (0) 2021 11106 E-mail: ec.rep@sungogroup.com

Shandong Zhushi Pharmaceutical Group Co., Ltd
Add: No.6 Shande Road,Shan County, Heze City, Shandong, China 274300
STANDARD:YY 0469-2011
REGISTRATION NO:LUXIEZHUZHUN20192140064
PRODUCTION LICENSE NO:LUSHIYAOJIANXIESHENGCHANXU20140053HAO

6 935318 862702

Made In China

Test Report **SL52025245644701TX** **Date:May 08,2020**

SHANDONG ZHUSHI PHARMACEUTICAL GROUP CO., LTD.
NO.6 SHANDE ROAD, SHAN COUNTY, HEZE CITY, SHANDONG, CHINA

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

Sample Description	:	(A)Disposable surgical face mask: in blue (Disposable surgical face mask (non-sterile)) (Claimed Type IIR)
Style No.	:	ZS-B
Sample Color	:	(A)blue
Proposed Care Instruction	:	-
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 23, 2020
Testing Period	:	Apr 23, 2020 - May 08, 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).

Comment:

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

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

Sara Guo (Account Executive)

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.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

Test Result

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

Clause 5.2.2 Bacterial filtration efficiency (BFE)"

	1#	2#	3#	4#	5#
(BFE), %	99.6	99.8	99.8	99.9	99.7

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 △P (Pa/cm^2)	34	36	35	36	36

Remark: Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004, Pressure 16.0 kPa)

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: ≥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

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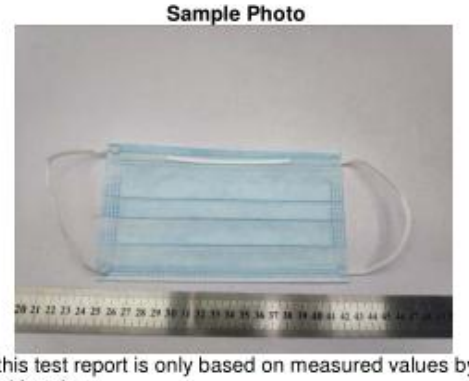
Clause 5.2.5 Microbial Cleanliness
(EN 14683: 2019 Annex D)

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

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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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

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Shandong Zhushi Pharmaceutical Group Co., Ltd.**
CLIENT ADDRESS	No.6 Shande Road,Shan County, Heze City, Shandong, China
TEST PERIOD	15-Apr-2020~29-Apr-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

Leo Liu

(Leo Liu)
Authorized Signatory

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
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Phone : +86 (21) 6037 6375
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Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

TEST REPORT

Sample Description	:	Disposable Surgical Face Mask
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	Lot20041002
Specification	:	/
Size	:	17.5cm×9.5cm
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Test Standard Type ⅡR	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 98	Pass
2	Differential Pressure Test (Pa/cm²)	EN 14683:2019+AC:2019(E) Annex C	< 60	Pass
3	Synthetic Blood Penetration Test (kPa)	ISO 22609:2004	≥ 16.0	Pass
4	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.6% Specimen 2#: 99.6% Specimen 3#: 99.6% Specimen 4#: 99.6% Specimen 5#: 99.6%
2	Differential Pressure Test	34.2 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~32#: None seen
4	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: 2 CFU/g Specimen 3#: <1 CFU/g Specimen 4#: <1 CFU/g Specimen 5#: 2 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Disposable Surgical Face Mask
Specification : /
Lot Number : Lot20041002
Sample Receiving Date : 2020-04-15

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T) / C \times 100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	23	56	0	0	0	0	0	0
2	52	150	0	0	0	0	0	0
3	134	198	0	0	0	0	0	0
4	230	308	0	0	0	0	0	0
5	1241	1314	0	7	6	5	6	5
6	670	606	0	2	5	5	5	4
Total (*T*), CFU	2350	2632	<1	9	11	10	11	9
Average (C), CFU	$2.5 \times 10^3 = (P_A+P_B) / 2$							
BFE ,%				99.6	99.6	99.6	99.6	99.6
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description : Disposable Surgical Face Mask
Specification : /
Lot Number : Lot20041002
Sample Receiving Date : 2020-04-15

3.Test Method

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

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5) °C and (85±5)% relative humidity.

6. Procedure

6.1 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.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm^2, test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm^2)	Average (Pa/cm^2)	Requirements	Judgement
1#	33.2	34.2	< 60	Pass
2#	34.5			
3#	32.1			
4#	34.9			
5#	36.3			

Synthetic Blood Penetration Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	Disposable Surgical Face Mask
Specification	:	/
Lot Number	:	Lot20041002
Sample Receiving Date	:	2020-04-15

3.Test Method

ISO 22609:2004

4.Apparatus and materials

4.1 Synthetic blood.
4.2 Tensiometer.
4.3 Synthetic blood penetration test apparatus;
4.4 Targeting plate.
4.5 Air pressure source.
4.6 Ruler.
4.7 Balance.
4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 32 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
6.2 Determine the density of the synthetic blood.
6.3 Fill the reservoir with new synthetic blood.
6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
6.5 Set the reservoir pressure to the approximate pressure.
6.6 Place the targeting plate approximately 1 cm away from the mask.
6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting

hole).

6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula: (p is the density of the test fluid.) $t = 0.5 + (2 \times p$ - g at 0.5 s) / (g at 1.5 s - g at 0.5 s).

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass
14#	None Seen		Pass
15#	None Seen		Pass
16#	None Seen		Pass
17#	None Seen		Pass
18#	None Seen		Pass
19#	None Seen		Pass
20#	None Seen		Pass
21#	None Seen		Pass
22#	None Seen		Pass
23#	None Seen		Pass
24#	None Seen		Pass
25#	None Seen		Pass
26#	None Seen		Pass
27#	None Seen		Pass
28#	None Seen		Pass
29#	None Seen		Pass
30#	None Seen		Pass
31#	None Seen		Pass
32#	None Seen		Pass

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
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Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description	:	Disposable Surgical Face Mask
Specification	:	/
Lot Number	:	Lot20041002
Sample Receiving Date	:	2020-04-15

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um 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 SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	0	0	<1	EN 14683:2019+AC:2019(E) Annex D EN ISO 11737-1:2018 ≤ 30 CFU/g	Pass
2#	0	2	2		
3#	0	0	<1		
4#	0	0	<1		
5#	0	2	2		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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Test Report **SL52025245444301TX** **Date:June 02,2020**

SHANDONG ZHUSHI PHARMACEUTICAL GROUP CO., LTD.
NO.6 SHANDE ROAD, SHAN COUNTY, HEZE CITY, SHANDONG, CHINA

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

Sample Description	:	(A) Disposable Surgical Face Mask (Claimed Level II)
Style No.	:	ZS-A
Sample Color	:	(A)blue
Proposed Care Instruction	:	-
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 21, 2020
Testing Period	:	Apr 21, 2020 - Jun 02, 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).

Comment:

Standard Specification for Performance of Materials Used in Medical Face Masks(ASTM F2100-2019)	(A)
Clause 6.1 Bacterial filtration efficiency	M
Clause 6.1 Differential pressure	M
Clause 6.1 Sub-micron particulate filtration efficiency	M
Clause 6.1 Resistance to penetration by synthetic blood	M
Clause 6.2 Flammability	M

Remark: M=Meet ASTM F2100-2019 Level II requirement

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

Standard Specification for Performance of Materials Used in Medical Face Masks
(ASTM F2100-2019)

Section 6.1 Bacterial filtration efficiency (BFE)*
(ASTM F2101)

	1#	2#	3#	4#	5#
(BFE), %	99.7	99.7	99.9	99.5	99.5

Remark: Performance Requirement: Level 1≥95%, Level 2≥98%, Level 3≥98%

* Tests denoted with an * in this test report have been subcontracted to another ISO 17025 Accredited Laboratory.

Section 6.1 Differential Pressure
(EN 14683 :2019 Annex C, Flow rate 8 l/min)

	1#	2#	3#	4#	5#
Differential pressure △ P (mm H_2O/cm^2)	3.8	3.6	3.6	3.5	3.5

Remark: Performance Level: Level 1 Barrier: <5.0mm H_2O/cm^2, Level 2 Barrier: <6.0 mm H_2O/cm^2, Level 3 Barrier: <6.0 mm H_2O/cm^2

Section 6.1 Sub-micron particulate filtration efficiency(PFE)*
(ASTM F2299)

	1#	2#	3#	4#	5#
(PFE), %	99.86	99.78	99.78	99.81	99.900

Remark: Performance Requirement: Level 1≥95%, Level 2≥98%, Level 3≥98%

* Tests denoted with an * in this test report have been subcontracted to another ISO 17025 Accredited Laboratory.

Section 6.1 Resistance to Penetration by Synthetic Blood
(ASTM F1862/F1862M-2017)

Pressure 120mmHg

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				

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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

对外贸易经营者备案登记表

备案登记表编号：02413085　　统一社会信用代码：91371722757460005XX　　进出口企业代码：

经营者中文名称	山东朱氏药业集团有限公司		
经营者英文名称	Shandong zhushi pharmaceutical group co., LTD		
组织机构代码	---------	经营者类型（由备案登记机关填写）	有限责任公司
住　所	单县开发区樊楼路南		
经营场所（中文）	单县开发区樊楼路南		
经营场所（英文）	south of Fanlou Road of Development Zone of Shan County		
联系电话	15853016677	联系传真	05304266111
邮政编码	274300	电子邮箱	sushanshan096@126.com
工商登记注册日期	2003-12-5	工商登记注册号	----------

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	朱坤福	有效证件号	372925197002215517
注册资金	壹亿元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人/个体工商负责人姓名		有效证件号	
企业资产/个人财产			（折美元）

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关

签　章

2015　年12　月23　日

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：鲁菏食药监械出 20200019 号
Certificate NO.: 鲁菏食药监械出 20200019 号

产品名称：见附件
Product(s): See Attachment

规格型号：见附件
Model: See Attachment

产品注册或备案凭证号：见附件
Registration certificate(s): See Attachment

生产企业：山东朱氏药业集团有限公司
Manufacturer: Shandong Zhushi Pharmaceutical Group Co. Ltd

生产企业住所：单县开发区樊楼路南
Address of manufacturer: South Fanlou Road,Development Zone,Shan County

生产许可或备案凭证号：鲁食药监械生产许 20140053 号
Manufacturing License(s): 鲁食药监械生产许 20140053 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2022 年 4 月 9 日
This certification valid until: April 9, 2022

备注：/
Remark: /

2020 年 4 月 10 日

证书编号：鲁药食药监械出 20200019 号　　附件
Certificate NO.：鲁药食药监械出 20200019 号　　Attachment

序号	产品名称		规格型号	产品备案凭证号
1	中文	一次性使用医用口罩(非外科用)	12.0cm×7.0cm、14.5cm×9.5cm、17.5cm×9.5cm	鲁械注准 20172640652
	英文	disposable medical mask (non-surgical)	12.0cm×7.0cm、14.5cm×9.5cm、17.5cm×9.5cm	
2	中文	一次性使用医用外科口罩	17.5cm×9.5cm	鲁械注准 20192140064
	英文	disposable medical surgical mask	17.5cm×9.5cm	
3	中文	医用一次性防护服	连体式 160、165、170、175、180、185	鲁械注准 20202140108
	英文	medical disposable protective clothing	Siamese 160、165、170、175、180、185	
4	中文	额温枪	ZST-A	鲁械注准 20202070112
	英文	forehead temperature gun	ZST-A	

以下空白。

REGISTRATION NO. 04720Q10122R0M

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Shandong Zhushi Pharmaceutical Group Co. Ltd.

Registered Address: No. 6 Shande Road, Shan County, Heze City, Shandong Province, China. 274300

Manufacturing Address: No.6 Shande Road, Economic & technological development zone and shandong shan county economic and technological development zone food and drug industrial park, Heze City, Shandong Province, China 274300

Has been assessed and conformed to the following standard(s)
GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

Design, Development, Production and Service of Cold Compress Gel, Liquid Dressing, Spray Dressing, Wound Care Ointment, Medical Ultrasonic Coupling Agent, Medical Catheter Clip, Medical Antipyretic Paste, Medical Cold Compress, Far-infrared Physiotherapy Stickers, Hot Packs, Gynecological Heating Patch, Magnetic Hyperthermia, Acupoint Application Treatment Stickers, Aseptic Application, Disposable Medical Hydrogel Eye Patch, Scar Patches, Disposable Gastric Tubes, Disposable Medical Masks (non-surgical), Disposable Uterine Cavity Suction Tube Set, Disposable Sterile Urinary Catheter, Disposable Nasal Gastrointestinal Tube, Disposable Precision Filter Infusion Set, Disposable Protective Suit, Disposable Medical Surgical Face Mask, Infrared Thermometer, Isolation Gown.

Date of issue: April 07,2020
Date of expiry: April 06,2023

General Manager:

BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CNAS 中国认可 国际互认 管理体系 MANAGEMENT SYSTEM CNAS C047-M

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing.100011, P.R. China Telephone: 010-62351993

REGISTRATION NO. 04720Q10000145

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Shandong Zhushi Pharmaceutical Group Co. Ltd.

Registered Address: No. 6 Shande Road, Shan County, Heze City, Shandong Province, China. 274300

Manufacturing Address: No.6 Shande Road, Economic & technological development zone and shandong shan county economic and technological development zone food and drug industrial park, Heze City, Shandong Province, China 274300

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

Design, Development, Production and Service of Disposable Medical Masks (non-surgical), Disposable Protective Suit, Disposable Medical Surgical Face Mask, Infrared Thermometer,Is olation Gown.

Date of issue: April 07,2020

Date of expiry: April 06,2023

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

File No: CE-TCF-004

EC Declaration of Conformity

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

Applicant

Name: Shandong Zhushi Pharmaceutical Group Co., Ltd

Address: No.6 Shande Road,Shan County, Heze City, Shandong, China

EC Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable Surgical Face Mask (non-sterile)

Type: Length: 7cm ~ 24cm, Width:4cm ~ 20cm, or customized

Classification

Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)

SRN: -

UDI: -

医用外科口罩

Conformity Assessment Route

Annex VII

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards:

EN ISO 13485: 2016
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041: 2013
EN ISO 10993-1: 2009/AC: 2010
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14683:2019

Signature:

Date: 2020/04/20

Position:

FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the **Fiscal Year 2020** of

Shandong Zhushi Pharmaceutical Group Co., Ltd
South Fanlou Road, Shan County Development Zone, Heze, Shandong, China 274300

The facility registration and device listing information:

Registration Number: 3013496867		
Device Listing No.	Product Code	Product Name(s)
D273335	LYG	Acupoint Therapy Patch / Detox Foot Patch / Foot Pad
D273336	IMD	Heat Pads; Cooling Gel Patch
D324618	MDA	Silicone Gel For Scar; Silicone Scar Patch
D334868	ITG	Fiberglass Casting Tape
D334869	NOC	Medical Polymer Splint
D366904	IME	Pain Relief Cream; Pain Relief Patch
D366905	HHE	Menstrual Cup
D366906	HED	Vaginal Scrubber
D374392	KHA	Face Mask
D374393	OEA	Isolation Gown; Protective Suit
D374394	PXH	Theometer
D383124	FXO	Face Mask
D383125	QKR	Face Mask
D383126	LYU	Protective Suit

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. ***This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration.*** *SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.*

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and constitutes misbranding." ***The U.S. Food and Drug Administration does not issue a attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.***

Reference Number: 2006US666558
Issue date: Apr.26, 2020

For and on behalf of
SUNGO Technical Service Inc.

Authorized Signature
Only used for the US Agent Signature

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