Medical Mask

(Class I sterile)

1、富美企业营业执照

营业执照

（副本）

统一社会信用代码
91341500MA2MYEKA31(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　安徽富美医疗科技有限公司

类　　型　有限责任公司（非自然人投资或控股的法人独资）

法定代表人　吴运颖

经营范围　生物科技专业领域内的技术开发、技术咨询、技术服务、技术转让、仪表仪器、包装材料、记标机软硬件及配件的销售、医疗器械、一次性无纺医疗用品及无纺布制品的生产、销售；智能设备制造、研发及销售；以上产品及货物的进出口业务（涉及国家前置登记和国家明令禁止的商品和技术除外）。（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　壹仟万圆整

成立日期　2016年08月01日

营业期限　/长期

住　　所　六安市裕安区城南工业园区

登记机关　六安市裕安区市场监督管理局

2020 年 03 月 18 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

国家市场监督管理总局监制

2、富美医疗器械生产许可证

医疗器械生产许可证

许可证编号 皖食药监械生产许20180032号

企业名称：安徽富美医疗科技有限公司

生产地址：六安市裕安区城南工业园区工业路1号

法定代表人：戴文韬

生产范围：Ⅱ类:6864 医用卫生材料及敷料
Ⅱ类:14-10 创面敷料

企业负责人：蒋军

住　　所：六安市裕安区城南工业园区工业路1号

发证部门：安徽省药品监督管理局

有效期限：至　2023 年08 月30 日

发证日期：　2019 年 05 月16 日

国家药品监督管理局制

3、卫生许可

消毒产品生产企业卫生许可证

皖卫消证字[2018]第 N0006 号

单 位 名 称：安徽富美医疗科技有限公司

法定代表人： 戴 文 韬

注 册 地 址：六安市裕安区城南工业园区（润南路）

生 产 地 址：六安市裕安区城南工业园区

生 产 方 式：生 产

生 产 项 目：消毒器械类

生 产 类 别：用于压力蒸汽灭菌且带有灭菌标识的包装物，用于环氧乙烷灭菌且带有灭菌标识的包装物

注：本许可证只对许可批准时的生产条件负责，不是对企业所生产产品的许可，不代表对企业生产产品卫生质量的认可。应在卫生许可证有效期届满前 30 个工作日之前提出延续申请。

发 证 机 关

二〇一八年三月七日

有效期限：2018 年 03 月 07 日至 2022 年 03 月 06 日

4、富美企业 ISO 质量认证书

TUV 证书即是欧盟认证

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 096662 0003 Rev. 01

Holder of Certificate: **3A Medical Products Co., Ltd.**
Yu An Industrial Park
230001 Liu An
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): 3A Medical Products Co., Ltd.
Yu An Industrial Park, 230001 Liu An, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Surgical Gown, Surgical Drape, Surgical Pack, Coverall, and Isolation Gown**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19111104

Valid from: 2019-10-17
Valid until: 2022-10-16

Date, 2019-08-30

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

5、产品 CE 认证证书

TUV 证书即是欧盟认证

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 16 08 96662 002

Manufacturer: **3A Medical Products Co., Ltd.**
Yu An Industrial Park
230001 Liu An
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Surgical Gown, Surgical Drape, Surgical Pack**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH16111101

Valid from: 2016-10-17
Valid until: 2021-10-16

Date, 2016-10-17

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

A1 / 04.11

Declaration of Conformity(face mask)

1. Declaration of Conformity

Manufacturer: 3A Medical Products Co..Ltd..

Product name: medical mask

Type:16.5*11 cm

Classification: Class I Sterile

Rule: According to Rule I

We herewith declare that above mentioned products meet the requirement of the MDD 93/42/EEC Medical device directive and the following harmonized standards:

ENISO14971:2012

EN14683:2014

ENISO15223-1:2016

ENISO1041:2008A1:2013

ENISO10993-1:2009/AC:2010

ENISO10993-5:2009

ENISO10993-10:2013

Date CE mark was affixed:2020-04-06

Signature :

Name: JiangJun

Position:General Manager

Date: 2020-04-06

Add: YuAn Industrial Park Lu An City, Anhui Province, China 237100
Tel: 86-564-3611700 Fax:86-564-3611700

3A Medical Products Co. Ltd, Yu An Industrial Park, 230001 Liu An. PR China

Your notice of	Your reference	Date
17-03-2020		03-04-2020

Analysis Report

Required tests :

EN 14683 (2019) + AC (2019)	**EN 14683 - annex B (2019) + AC (2019)**	**Bacterial filtration efficiency**
EN 14683 (2019) + AC (2019)	**ISO 22609 (2004)**	**Medical face masks - Splash Test**
EN 14683 (2019) + AC (2019)	**EN 14683 - annex C (2019) + AC (2019)**	**Medical face masks - Breathability (differential pressure)**
EN 14683 (2019) + AC (2019)	**EN 14683 - §5.2.5 (2019) AC (2019)**	**Microbial cleanliness on masks**

Identification number	Information given by the client	Date of receipt
T2006059	Cup mask code 2002 Lot 202001202	17-03-2020

Sylvie Niessen
Order responsible

ISO 17025 BELAC 056-TEST

CENTEXBEL • textile competence centre • www.centexbel.be • www.vkc.be
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KORTRIJK • Etienne Sabbelaan 49 • BE-8500 Kortrijk, Belgium • phone +32 56 29 27 00 • fax +32 56 29 27 01 • info@vkc.be
VAT BE 0459.218.289 • IBAN BE44 2100 4729 6545 • BIC GEBABEBB

Reference: T2006059 - Cup mask code 2002 Lot 202001202

Bacterial filtration efficiency

Date of ending the test	25-03-2020
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks :	5
BFE Area tested :	± 49 cm²
Masks conditioning :	21 ± 5°C and 85 ± 5% RH
Side of the mask in contact with the bacterial challenge :	Inner side
Challenge bacterial strain used :	*Staphylococcus aureus* ATCC6538
Bacterial challenge per test :	1700 - 3000 CFU
Total test time :	1 min. delivering challenge + 1 min. without challenge (air flow continuing)
Flow rate :	28.3 l/min.
Positive control	Tests performed with no filter material in the air stream
Negative control	Test performed without challenge

Results

B = Bacterial filtration efficiency (%)

$$B = \frac{(C - T)}{C} \; X \; 100$$

With C = mean of the total plate counts for the positive control runs T = total count for the tested mask

# Mask	B (%)
1	> 99.9*
2	> 99.9*
3	> 99.9*
4	> 99.9*
5	> 99.9*

* no detected colonie on any of the Andersen sampler plates

Mean particle size of the bacterial challenge aerosol : 2.9 µm

Controls

Mean positive controls 2636 CFU
Negative control < 1 CFU

Reference: **T2006059 - Cup mask code 2002 Lot 202001202**

Medical face masks - Splash Test

Date of ending the test	26-03-2020
Standard used	ISO 22609 (2004)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks :	32
Blood surface tension	42 ± 2 dynes/cm
Volume of the delivered blood	2 ml
Distance "canula-mask"	30 ± 1 cm
Side of the mask "impacted"	Outer side
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Results

Blood pressure tested **16.0 kPa**

Controls

Blood visualisation on the mask	OK
Calibration procedure	OK
Control of the blood volume delivered (2 ml)	
- before the test :	OK
- after 16 masks :	OK
- after 32 masks :	OK

Results obtained on the set of masks

# Mask	Results : pass / fail
1	Pass
2	Pass
3	Pass
4	Pass
5	Pass
6	Pass
7	Pass
8	Pass
9	Pass
10	Pass
11	Pass
12	Pass
13	Pass
14	Pass
15	Pass
16	Pass
17	Pass
18	Pass
19	Pass
20	Pass
21	Pass
22	Pass
23	Pass
24	Pass
25	Pass
26	Pass
27	Pass
28	Pass
29	Pass
30	Pass
31	Pass
32	Pass

Summary P = 16.0 kPa

Number of "Pass" masks	Number of "Fail" masks
32	0

Pass = no blood detected on the observed side
Fail = blood detected on the observed side

In agreement with the customer the number of tested mask has been determined based on a single sampling plan providing an AQL of 4 % (acceptable quality limit).

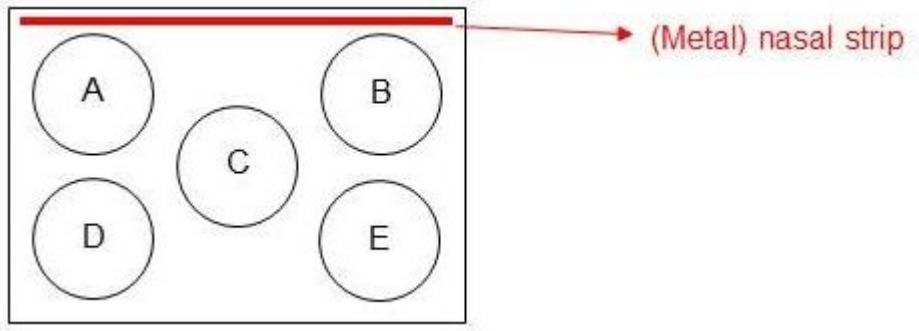
If 29 masks or more over 32 obtain a "Pass" result the 4% AQL is reached.

Reference: **T2006059 - Cup mask code 2002 Lot 202001202**

Medical face masks - Breathability (differential pressure)

Date of ending the test	25-03-2020
Standard used	EN 14683 - annex C (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Number of tested masks :	5
Number of areas per mask	5 (see figure)
Dimension of the areas :	Disc whose diameter is 2.5 cm
Surface areas :	4.9 cm²
Flow rate :	8 l/min.
Direction of the air flow :	From the inside of the mask to the outside
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Figure : Distribution of the areas in the mask



Results **Δ P**

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	122.6	122.0	139.3	123.0	120.4
Area B	126.5	134.0	145.7	131.4	129.0
Area C	168.7	180.3	119.8	172.5	162.6
Area D	131.4	134.5	125.1	153.2	147.3
Area E	144.6	167.5	157.7	156.9	139.1
Average ΔP (Pa/cm²)	**138.8**	**147.7**	**137.5**	**147.4**	**139.7**

Reference: **T2006059 - Cup mask code 2002 Lot 202001202**

Microbial cleanliness on masks

Date of ending the test	30-03-2020
Standard used	EN 14683 - §5.2.5 (2019) AC (2019)
Product standard	EN 14683 (2019) + AC (2019)

Number of tested masks	5
Extraction liquid	Peptone 1g/l, NaCl 5g/l & Tween 20 2g/l
Extraction volume	300 ml
Extraction time	5 min.
Counting technique	Membrane filtration
Filtration volume	100 ml
Culture media	TSA (Tryptic Soy Agar) SDA (Sabouraud Dextrose Agar with chloramphenicol)
Incubation conditions	3 days at 30°C (TSA) 7 days at 20-25°C (SDA)
Remark(s) :	For the fungi count of the mask #1 the result put in the table corresponds to the reading after 3 days. After 7 days the reading was impossible due to an overgrowing fungus.

Results

# Mask	Mask weight (g)	CFU*/mask		Microbial cleanliness	
		Aerobic microbial count (bacteria)	*Fungi count (SDA)*	*Σ CFU/mask*	*Σ CFU/g*
1	6.43	53	5	58	10
2	6.48	114	308	422	66
3	6.27	61	37	98	16
4	6.37	65	33	98	16
5	6.48	49	<3	< 52	< 9

7、富美公司关于以上 9 页测试报告的声明（富美是 Medical Mask 的生产商）

3A Medical Product Co., Ltd

DECLARATION

To whom this may concern,

We 3A medical hereby confirm that the tested product REF:2001, LOT NO :202001202 correspond to the actual code REF291011 that are producing for Medicalwear, S.A.

Add: YuAn Industrial Park Lu An City, Anhui Province, China 237100
Tel: 86-564-3611700 Fax: 86-564-3611700

8、包装盒


3A MEDICAL
HEALTH CARE
PARTICULATE RESPIRATOR
EN14683 TYPE IIR
SINGLE USE
20PCS
3A MEDICAL
HEALTH CARE
PARTICULATE RESPIRATOR
EN14683 TYPE IIR
• High filtration efficiency
• Low respiratory resistance
• More comfortable to wear
BFE 99%
20PCS
3A MEDICAL
HEALTH CARE
PARTICULATE RESPIRATOR
EN14683 TYPE IIR
BFE 99%
20PCS


20PCS
3A MEDICAL
HEALTH CARE
PARTICULATE RESPIRATOR
LOT 200503
2022-05
20PCS

9、实物图片

10. BOX Picture

Size	Qty	Weight
53cm x 38cm x 40 cm	1000 pcs	9.5kg

10. Offerte

	Name	Unit	Qty.	Price ($)	Reamrk
1	Medical Mask	PCS	10,000,000	1.38$	FOB ShangHai. China
			30,000,000	1.28$	
			50,000,000	1.18$	