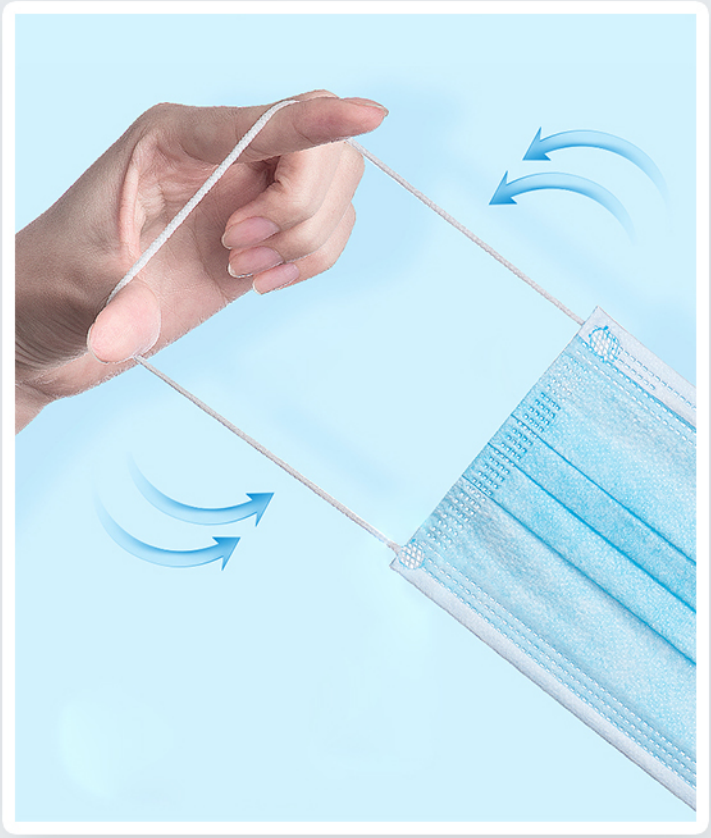
D I S P O S A B L E  M E D I C A L  F A C E  M A S K

# MEDICAL FACE MASK

## 医用一次性口罩

**安徽富美医疗科技有限公司**

**3A MEDICAL PRODUCTS CO., LTD**



# 安徽富美医疗科技有限公司
# 3A MEDICAL PRODUCTS CO., LTD

世界对平面口罩的性能标准主要有两个：欧标（EN14683）和美标（ASTM）。
Commonly recognized standards of medical face masks are EN14683 (EU) and ASTM (USA).

## 欧标 European Union

欧标的标护性从弱到强：Type I , Type II , Type IIR。
protection penformance levels of EN14683 , from low to high are Type I , Type II ,Type IIR .

富美平面口罩性能符合 Type IIR
3A medical face mask meets requirements of Type IIR

**欧标主要性能参数与富美平面口罩实验数据的对比**
**EN14683 Key Parameters vs 3A Medical Face Mask Test Readings**

| 实验项目<br>Test | **富美平面口罩实验数据<br>Test reading of<br>3A Medical Face Mask** | EN14683<br>TYPE I | EN14683<br>TYPE II | EN14683<br>TYPE IIR |
|---|---|---|---|---|
| 微生物过滤效率<br>BFE（Bacterial Filtration Efficiency） | **≥98%** | ≥95% | ≥98% | ≥98% |
| 口罩内外压差<br>Differential Pressure<br>(Pa/CM$^2$) | **≤49** | ≤29.4 | ≤29.4 | ≤49 |
| 合成血液穿透<br>Synthetic Blood Resistance<br>(mmHg) | **120mmHg** | 无需求<br>Not Required | 无需求<br>Not Required | 120mmHg |
| 微生物净度<br>Microbial Cleanliness | **≤30%** | ≤30% | ≤30% | ≤30% |

美标USA美标的防护性从弱到强：ASTM Leve1，Leve2，Level3。
Protection performance levels of ASTM, from low to high are Level 1, Level 2, Level 3.

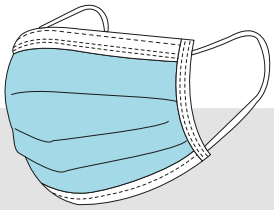
## 富美平面口罩性能符合 ASTM Level1
## 3A medical face mask meets requirements of AsTM level 1

**美标主要性能参数与富美平面口罩实验数据的对比**
**ASTM Key Parameters vs 3A Medical Face Mask Test Readings**

| 实验项目<br>Test | **富美平面口罩实验数据<br>Test reading of<br>3A Medical Face Mask** | EN14683<br>TYPE I | EN14683<br>TYPE II | EN14683<br>TYPE IIR |
|---|---|---|---|---|
| 微生物过滤效率<br>BFE (Bacterial Filtration Efficiency) | **≥98%** | ≥95% | ≥98% | ≥98% |
| 口罩内外压差<br>Differential Pressure ($mmH2O/CM^2$) | **≤4.0** | ≤4.0 | ≤4.0 | ≤5.0 |
| 合成血液穿透<br>Synthetic Blood Resistance (mmHg) | **120mmHg** | 80 | 120 | 160 |
| 阻燃<br>Flame Spread | **一级<br>Class1** | 一级<br>Class1 | 一级<br>Class1 | 一级<br>Class1 |

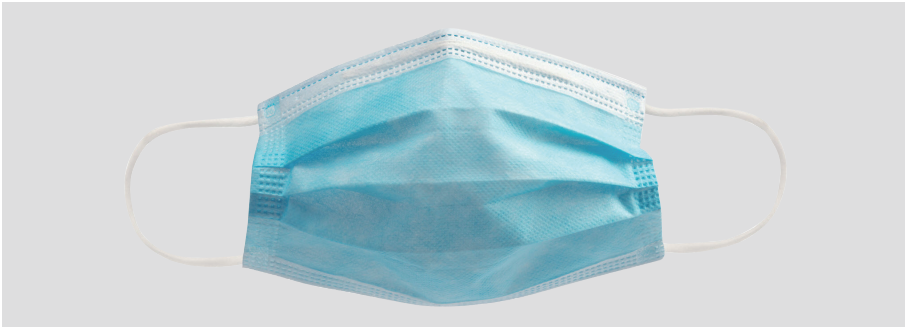
## 包装信息 Packing Details

| | |
|---|---|
| **2，000个口罩一箱** | 2，000 masks per shipper carton |
| **50个口罩一盒 40盒一箱** | 50 masks per box；40 boxes per shipper carton |
| **卡盒尺寸：18x10x9.5 厘米**<br>**外箱尺寸：53x37x40 厘米** | Inner box: 18 x 10 x 9.5 cm<br>Shipper Carton: 53 x 37 x40 cm |
| **毛重：9.5 KG** | GW: 9.5 KG |

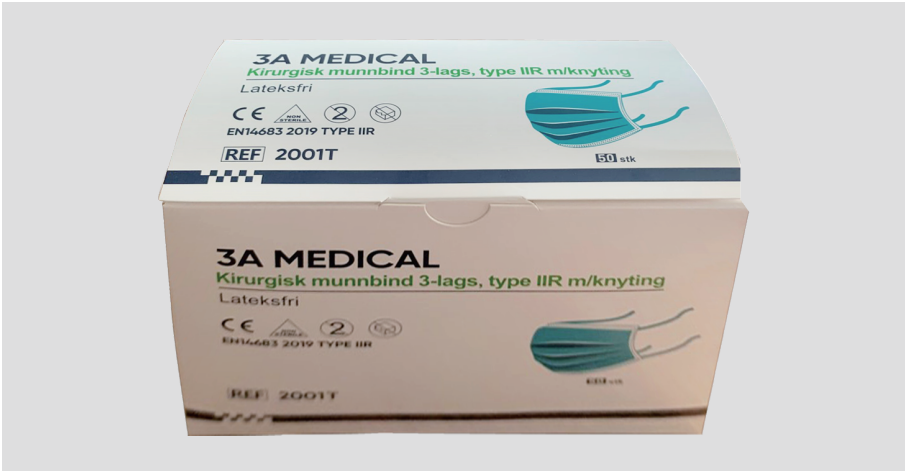


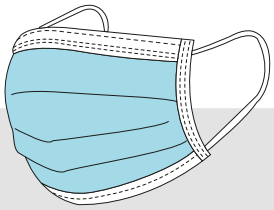
# Medical face mask

**平面口罩**
**Medical Face Mask**



**中盒**
**Inner box**



# Medical face mask


**纸箱**
**Shipper Carton**

# 中华人民共和国医疗器械注册证

注册证编号：皖械注准 20202140040

| | |
|---|---|
| 注册人名称 | 安徽富美医疗科技有限公司 |
| 注册人住所 | 六安市裕安区城南工业园区 |
| 生产地址 | 六安市裕安区城南工业园区工业路 1 号 |
| 产品名称 | 一次性使用医用口罩 |
| 型号、规格 | 平面 A 型 17.5cm× 9.5cm、平面 B 型 17.5cm× 9.5cm |
| 结构及组成 | 产品由罩体（内外层为无纺布、中间过滤层为熔喷布）含鼻夹（可塑性材料）和耳带（耳挂式为橡筋材质，系带式为无纺布材质）组成。 |
| 适用范围 | 用于佩戴者在不存在体液和喷溅风险的普通医疗环境下的卫生护理。 |
| 附　件 | /。 |
| 其他内容 | / |
| 备　注 | 1. 本产品为新型冠状肺炎应急防护用品，注册证有效期一年。<br>2. 注册人需在发证之日起一年内按照补正通知要求完善生物相容性研究和产品有效期研究资料。<br>3. 加强产品原材料供应商审计和产品质量管理。 |

审批部门：安徽省药品监督管理局

批准日期：2020 年 02 月 20 日

有效期至：2021 年 02 月 19 日

# 检 验 报 告

报 告 编 号：AH2020-QZC-00104

检 品 名 称：医用口罩

检 验 目 的：注册检验

安徽省食品药品检验研究院

检验报告专用章

ZLJL-165-04

# 安徽省食品药品检验研究院
# 检 验 报 告 首 页

**报告编号：** AH2020-QZC-00104　　共 3 页 第 1 页

| | | | |
|---|---|---|---|
| 样品名称 | 医用口罩<br>送样（√） 抽样（ ） | 样品编号 | AH2020-QZC-00104 |
| 商　　标 | / | 型号规格 | 平面形A型 |
| 委托方 | 安徽富美医疗科技有限公司 | 检验类别 | 注册检验 |
| 委托方地址 | 六安市裕安区城南工业园区 | 产品编号/批号 | 20200202 |
| 生产单位 | 安徽富美医疗科技有限公司 | 抽样单编号 | / |
| 受检单位 | 安徽富美医疗科技有限公司 | 生产日期 | 2020年2月13日 |
| 抽样单位 | / | 样品数量 | 100只 |
| 抽样地点 | / | 抽样基数 | / |
| 抽样日期 | / | 检验地点 | 安徽省食品药品检验研究院 |
| 收样日期 | 2020/02/17 | 检验日期 | 2020/02/17～2020/02/28 |
| 检验项目 | 2.1-2.7 | | |
| 检验依据 | 安徽富美医疗科技有限公司《医用口罩》产品技术要求 | | |
| 检验结论 | 被检样品符合安徽富美医疗科技有限公司《医用口罩》产品技术要求的要求。<br>（检验报告专用章或检验单位公章）<br>签发日期：2020/2/28 | | |
| 备注 | 报告中“--”表示不适用项，“/”表示空白项。 | | |

批　　准：　　审　　核：　　主　　检：

职　　务：　授权签字人

ZLJL-165-04

# 安徽省食品药品检验研究院
# 检 验 报 告 首 页

报告编号：AH2020-QZC-00104　　共 3 页　第 2 页

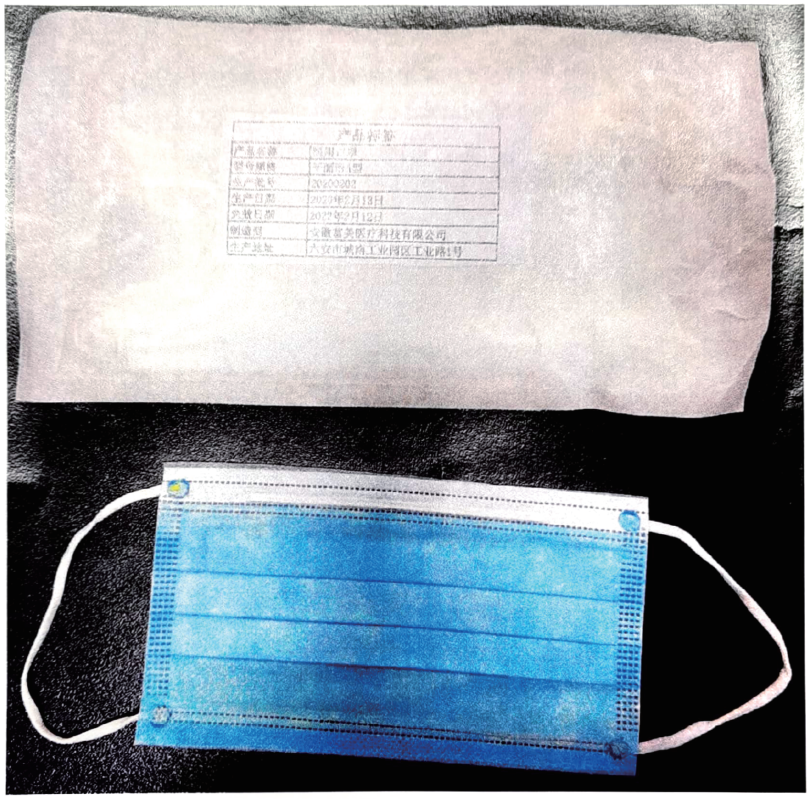
| 序号 | 检验项目 | 标准条款 | 标准要求 | 检验结果 | 单项结论 |
|---|---|---|---|---|---|
| 1 | 外观 | 2.1 | 口罩外观应整洁、形状完好，表面不得有破洞、污渍 | 符合要求 | 符合 |
| 2 | 结构与尺寸 | 2.2 | 口罩佩戴好后，应能罩住佩戴者的鼻、口至下颌 | 符合要求 | 符合 |
| | | | 长度：17.5cm±5% | 17.1～17.2cm | |
| | | | 宽度：9.5cm±5% | 9.4cm | |
| | | | 口罩带：10～20cm | 15～16cm | |
| 3 | 鼻夹 | 2.3.1 | 口罩上必须配有鼻夹，鼻夹由可塑性材料制成 | 符合要求 | 符合 |
| | | 2.3.2 | 鼻夹的长度应不小于 8.0cm | 10.1～10.3cm | 符合 |
| 4 | 口罩带 | 2.4.1 | 口罩带应取戴方便 | 符合要求 | 符合 |
| | | 2.4.2 | 每根口罩带与口罩体连接点处的断裂强力应不小于 10N | 符合要求 | 符合 |
| 5 | 细菌过滤效率（BFE） | 2.5 | 口罩的细菌过滤效率应不小于 95%。 | 100% | 符合 |
| 6 | 通气阻力 | 2.6 | 口罩两侧面进行气体交换的通气阻力应不大于 49Pa/cm$^2$ | 33～39 Pa/cm$^2$ | 符合 |
| 7 | 微生物指标 | 2.7 | 细菌菌落总数：应≤100cfu/g | ＜20 cfu/g | 符合 |
| | | | 大肠菌群:不得检出 | 未检出 | |
| | | | 绿脓杆菌：不得检出 | 未检出 | |
| | | | 金黄色葡萄球菌：不得检出 | 未检出 | |
| | | | 溶血性链球菌：不得检出 | 未检出 | |
| | | | 真菌：不得检出 | 未检出 | |

ZLJL-165-04

# 安徽省食品药品检验研究院
# 检验报告

**报告编号：** AH2020-QZC-00104　　共 3 页　第 3 页

照片和说明




样品描述

/

型号规格或其它说明

型号规格：　平面形 A 型

Australian Government

Department of Health
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

## Lohas Holding Pty Ltd

for approval to supply

## Lohas Holding Pty Ltd - Mask, surgical, single use

| | |
|---|---|
| **ARTG Identifier** | 333796 |
| **ARTG Start date** | 9/04/2020 |
| **Product Category** | Medical Device Included Class 1 |
| **GMDN** | 35177 |
| **GMDN Term** | Mask, surgical, single use |
| **Intended Purpose** | To be worn over nose & mouth during medical/surgical procedures to prevent bi-directional flow of micro-organisms. . |

| Manufacturer Details | Address | Certificate number(s) |
|---|---|---|
| 3A Medical Products Co Ltd | Yu An Industrial Park<br>, Liu An, 230001<br>China | |

### ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

· - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Products Covered by This Entry

**1. Mask, surgical, single use**

### Product Specific Conditions

No specific conditions have been recorded against this entry.

**Anlage 1**
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00304117

# Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
# General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

## Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
## Form for Medical Devices except In Vitro Diagnostic Medical Devices

| **Zuständige Behörde / Competent authority** | | | |
|---|---|---|---|
| | Code<br>**DE/CA05** | | |
| | Bezeichnung / Name<br>**Behörde für Gesundheit und Verbraucherschutz, Referat V43** | | |
| | Staat / State<br>**Deutschland** | | Land / Federal state<br>**Hamburg** |
| | Ort / City<br>**Hamburg** | | Postleitzahl / Postal code<br>**20539** |
| | Straße, Haus-Nr. / Street, house no.<br>**Billstraße 80** | | |
| | Telefon / Phone<br>**+49-40-428280** | | Telefax / Fax<br>**+49-40-427310017** |
| | E-Mail / E-mail<br>**medizinprodukte@bgv.hamburg.de** | | |

| **Anzeige / Notification** | | | |
|---|---|---|---|
| | Registrierdatum bei der zuständigen Behörde<br>Registration date at competent authority<br>**03.06.2020** | | Registriernummer / Registration number<br>**DE/CA05/MP-238321-2778-00** |
| | Typ der Anzeige / Notification type<br>☒ Erstanzeige / Initial notification<br>☐ Änderungsanzeige / Notification of change<br>☐ Widerrufsanzeige / Notification of withdrawal | | |
| | Frühere Registriernummer bei Änderungs- und Widerrufsanzeige<br>Previous registration number if notification has been changed or withdrawn | | |
| | Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG<br>☐ Hersteller / Manufacturer<br>☒ Bevollmächtigter / Authorised Representative<br>☐ Einführer / Importer<br>☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG<br>☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV<br>Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV<br>☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG<br>Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG | | |

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| | Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG<br>☐ Hersteller / Manufacturer<br>☒ Bevollmächtigter / Authorised Representative<br>☐ Einführer / Importer<br>☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG<br>☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV<br>Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV<br>☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG<br>Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG | | |

**Anlage 1**
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00304117

# Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
# General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

## Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
## Form for Medical Devices except In Vitro Diagnostic Medical Devices

| **Zuständige Behörde / Competent authority** | | | |
|---|---|---|---|
| | Code<br>**DE/CA05** | | |
| | Bezeichnung / Name<br>**Behörde für Gesundheit und Verbraucherschutz, Referat V43** | | |
| | Staat / State<br>**Deutschland** | | Land / Federal state<br>**Hamburg** |
| | Ort / City<br>**Hamburg** | | Postleitzahl / Postal code<br>**20539** |
| | Straße, Haus-Nr. / Street, house no.<br>**Billstraße 80** | | |
| | Telefon / Phone<br>**+49-40-428280** | | Telefax / Fax<br>**+49-40-427310017** |
| | E-Mail / E-mail<br>**medizinprodukte@bgv.hamburg.de** | | |

| **Anzeige / Notification** | | | |
|---|---|---|---|
| | Registrierdatum bei der zuständigen Behörde<br>Registration date at competent authority<br>**03.06.2020** | | Registriernummer / Registration number<br>**DE/CA05/MP-238321-2778-00** |
| | Typ der Anzeige / Notification type<br>☒ Erstanzeige / Initial notification<br>☐ Änderungsanzeige / Notification of change<br>☐ Widerrufsanzeige / Notification of withdrawal | | |
| | Frühere Registriernummer bei Änderungs- und Widerrufsanzeige<br>Previous registration number if notification has been changed or withdrawn | | |
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**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 20.01605.03

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 |
|---|---|---|
| T2006058 | REF 2001<br>Lot 202001202 | 17-03-2020 |

Sylvie Niessen
Order responsible


The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.
In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.

ISO 17025 BELAC 056-TEST

**CENTEXBEL • textile competence centre • www.centexbel.be • www.vkc.be**
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GRÂCE-HOLLOGNE • Rue du Travail 5 • BE-4460 Grâce-Hollogne, Belgium • phone +32 4 296 82 00 • g-h@centexbel.be
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

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

| Your notice of | Your reference | Date |
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# 动态更新：取得国外标准认证或注册的医疗物资生产企业清单

2020年06月10日 中国医药保健品进出口商会 分享

6月10日，取得国外标准认证或注册的医疗物资生产企业清单继续更新，其中，医用口罩清单新增62家企业，医用防护服清单新增3家企业，红外体温计清单新增3家企业，新型冠状病毒检测试剂清单新增20家企业。

取得国外标准认证或注册的医疗物资生产企业清单
动态更新 日期：2020年6月10日下载

Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

| 序号 | 生产企业 | 统一社会信用代码 | 国外注册认证情况 |
|---|---|---|---|
| 一、医用口罩 Medical Face Masks | | | |
| 466 | 安徽创孚医疗科技有限公司<br>Anhui Triumph Medical Science And Technology Co., Ltd. | 91340800MA2NT3YB4T | 欧盟CE |
| 467 | 安徽富美医疗科技有限公司<br>3A Medical Products Co., Ltd. | 91341500MA2MYEKA31 | 欧盟CE |
| 468 | 安徽奥迪斯工贸有限公司<br>Medivish Co., Ltd | 91340100567543292A | 欧盟CE |
| 469 | 安徽省锦瑞汽车部件有限公司<br>Anhui Jinrui Auto Parts Co.,ltd | 91340123695726000X | 欧盟CE |
| 470 | 安徽长信安昌健康医疗大数据科技有限公司<br>Anhui Changxin Anchang Health & Medical Big Data Technology Co., Ltd | 91340700MA2UGUWW2J | 欧盟CE |

推荐阅读

- 动态更新：取得国外标准认证或注册的医疗物资生产...
- 动态更新：取得国外标准认证或注册的非医用口罩生...
- 关于新型冠状病毒肺炎的有关表述
- 我会党委书记孟冬平受邀参加“抗击疫情经验国际视...
- 医保商会党委书记孟冬平一行赴防疫物资生产企业北...
- 医保商会成功举办防疫物资海外资质审核交流视频会
- 党旗飘扬夺取双胜利 | 医保商会党组织负责人接受央视...
- 孟冬平副会长就防疫物资出口问题接受环球时报采访
- 关于12号公告有关热点关注的问与答（之二）
- 孟冬平副会长接受央视、凤凰卫视等媒体采访，就12...

统一社会信用代码

91341500MA2MYEKA31(1-1)

# 营业执照

（副 本）

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　戴文韬

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 341503017269

2020 年 03 月 12 日

# 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：戴文娟
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

# 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

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