

# ISOLATION EYES COVER

隔离眼罩 & 隔离面罩



! <sup>40</sup> DJM

CE 166:2001



# ISOLATION FACE MASK



Shenzhen DJ Medical Equipment Co.,Ltd. 深圳德技医疗器械有限公司



# ABOUT US

## 关于我们

**深圳德技医疗器械有限公司**成立于2016年1月,公司主要从事医疗器械的研发生产。经营范围:医学美容项目仪器、美容设备、康复健身设备的研究、制造;医用卫生材料及敷料、普通诊察器械、中医器械、医用化验和基础设备器具、消毒和灭菌设备及器具的批发、零售业务。

公司于2017年9月ISO13485:2016认证,2018年获得深圳市高新技术企业,2019年10月获得ISO9001:2015认证,疫情之初被国务院列为“应对新型冠状病毒肺炎疫情联防联控重点生产企业”;同时我们是阿里巴巴直接采购供应商,直接面对全球采购。



5.1.2e

## ABOUT US

**Shenzhen DJ Medical Equipment Co., Ltd.** was established in January 2016. The company is mainly engaged in the research and development and production of medical devices. Scope of business: research and manufacturing of medical and beauty project equipment, beauty equipment, rehabilitation and fitness equipment; medical and sanitary materials and dressings, general diagnostic equipment, traditional Chinese medical equipment, medical laboratory and basic equipment and appliances, wholesale of disinfection and sterilization equipment and appliances, Retail business.

The company obtained ISO13485: 2016 certification in September 2017, obtained Shenzhen high-tech enterprises in 2018, and ISO9001: 2015 certification in October 2019. "At the beginning of the epidemic, it was listed by the State Council as "a key production enterprise for joint prevention and control of COVID-19 pneumonia epidemics". At the same time, we are a direct procurement supplier of Alibaba and face global procurement directly.

 **CE 166:2001** 

# ISOLATION EYES COVER

隔离眼罩

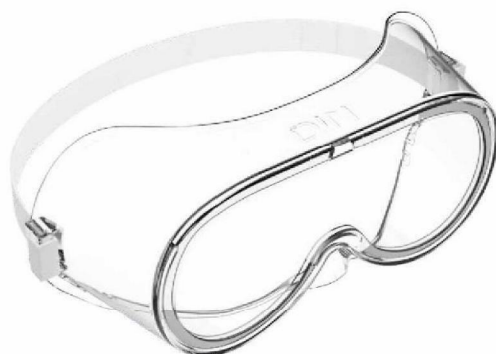
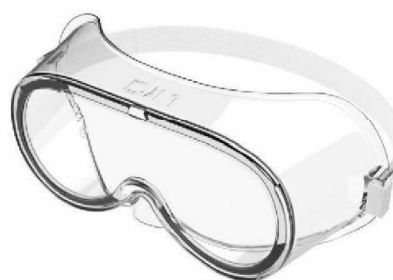


**【Model / Specification】 GLYZ1-1**  
【型号】 GLYZ1-1

## PRODUCT DESCRIPTION

产 品 描 述

It consists of a protective cover,  
Nonsterile,  
single-use.



由高分子材料制成的防护罩，  
非无菌提供，一次性使用。

ISOLATION EYES COVER  
隔离眼罩

PRODUCT DISPLAY  
产品细节展示



ISOLATION EYES COVER  
隔离眼罩

PRODUCT APPLICATION

产 品 用 途

For personal face protection.

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ISOLATION EYES COVER  
隔离眼罩

PRODUCT DISPLAY

穿戴展示

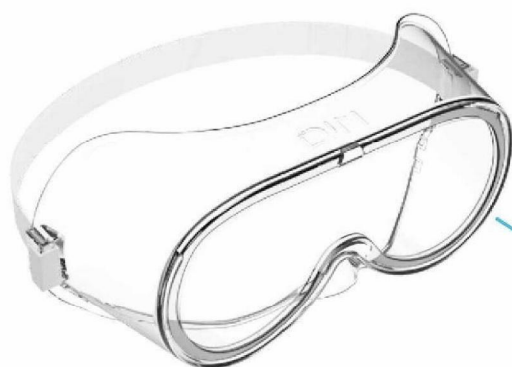
5.1.2e

# ISOLATION EYES COVER

## 隔离眼罩

### SPECIFICATIONS

### 产 品 规 格



**Original: China**

原产地:中国

**Terms of trade: TT**

贸易条款:TT

1pcs product size 单个产品尺寸	203.5*57.5*86mm
1pcs product weight 单个产品重量	51.5g
package 包装配置	The Chinese and English instructions are printed on the package 中英文说明书丝印在包装袋上
1 boxes quantity 内箱数量	5.1.1c
carton quantity 整箱数量	5.1.1c
N.W 整箱净重	10.3kg
G.W 整箱毛重	16.52kg
Meast 外箱尺寸	950*480*375mm
Certificate 资质	CE、CFDA



## ISOLATION EYES COVER 隔离眼罩

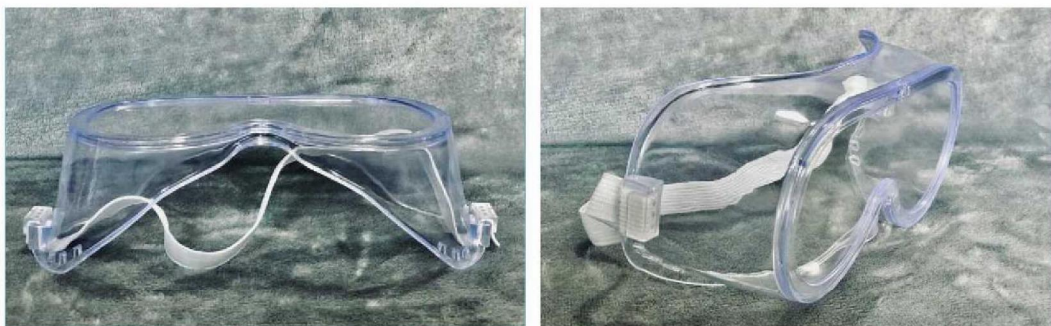
### INSTRUCTIONS

#### 使用 方 法

- 1、Unpack the inner packaging, remove the isolation mask product, and remove the protective film on both sides.
- 2、After the two ends of the foam strip (commonly known as elastic band) are fastened, wear it on the forehead to adjust it comfortably.

1、拆开内包装,取出隔离眼罩产品(无需安装)。

2、将泡沫条(俗称松紧带)套于额头上,根据各自适宜的舒适调节松紧带长度。



### ATTENTION

#### 注 意 事 项

- 1、Do not expose the isolation eyes cover to strong sunlight.
- 2、Handle carefully. The part of the isolation eyes cover must not touch sharp objects.

1、隔离眼罩切勿在强阳光下暴晒。

2、注意轻放,隔离眼罩部位不得接触尖锐物体。

ISOLATION EYES COVER  
隔离眼罩

**WARNING**

警告

**Do not use if the packaging damaged or time expires.**

包装破损或超过有效期禁止使用。

**STORAGE CONDITIONS**

储存条件

**It should be stored in a room with relative humidity not exceeding 80%, no corrosiveas, and well-ventilated.**

应贮存在相对湿度不超过80%,无腐蚀性气体,通风良好的室内。

**40 DJM CE 166:2001 FDA**

# ISOLATION FACE MASK

隔离面罩

【Model】GLMZ1-1

【型号】GLMZ1-1

5.1.2e

## PRODUCT DESCRIPTION

### 产 品 描 述

It consists of a protective cover,  
foam strip and fixing  
device made of  
polymer materials.  
Nonsterile,  
single-use.

由高分子材料制成的防护罩、  
泡沫条和固定装置组成。  
非无菌提供，一次性使用。



ISOLATION FACE MASK  
隔离面罩

PRODUCT DISPLAY  
产品细节展示



ISOLATION FACE MASK  
隔离面罩

PRODUCT DISPLAY

穿戴展示

5.1.2e

# ISOLATION FACE MASK

## 隔离面罩

### SPECIFICATIONS

### 产 品 规 格



**Original: China**

原产地: 中国

**Terms of trade: TT**

贸易条款: TT

1pcs product size 单个产品尺寸	350*240*30mm
1pcs product weight 单个产品重量	60.7g
package 包装配置	The Chinese and English instructions are printed on the package 中英文说明书丝印在包装袋上
1 boxes quantity 内箱数量	No inner box 无内箱
carton quantity 整箱数量	5.1.1c
N.W 整箱净重	12.14kg
G.W 整箱毛重	13.87kg
Meast 外箱尺寸	680*383*415mm
Certificate 资质	CE、CFDA



## ISOLATION FACE MASK 隔离面罩

### INSTRUCTIONS

#### 使用方法

- 1、Unpack the inner packaging, remove the isolation mask product, and remove the protective film on both sides.
- 2、After the two ends of the foam strip (commonly known as elastic band) are fastened, wear it on the forehead to adjust it comfortably.

- 1、拆开内包装,取出隔离面罩产品,撕去两面的保护膜。
- 2、将泡沫条(俗称松紧带)两端扣合后,戴于额头上调至舒适即可。



### ATTENTION

#### 注意事项

- 1、Do not expose the isolation face mask to strong sunlight.
- 2、Handle with care. The part of the isolation face mask must not touch sharp objects.

- 1、隔离面罩切勿在强阳光下暴晒。
- 2、注意轻放,隔离面罩部位不得接触尖锐物体。

# ISOLATION FACE MASK

## 隔离面罩

### WARNING

警告

**Do not use if the packaging damaged or time expires.**

包装破损或超过有效期禁止使用。

### STORAGE CONDITIONS

储存条件

**It should be stored in a room with relative humidity not exceeding 80%, no corrosive gases, and well-ventilated.**

应贮存在相对湿度不超过80%，无腐蚀性气体，通风良好的室内。

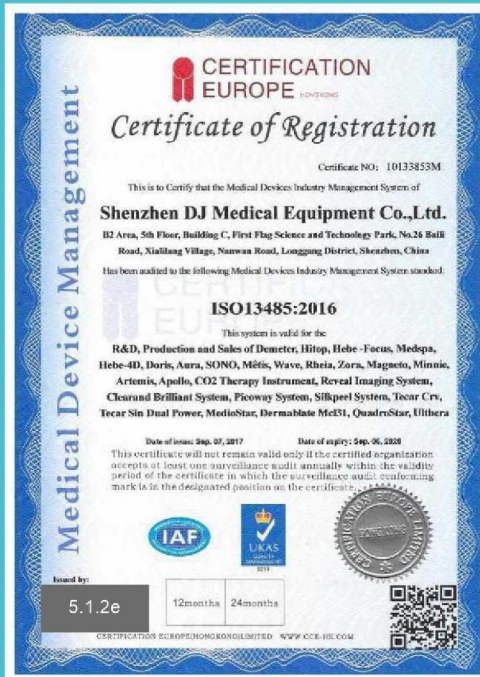


## Certificate of SHENZHEN DJ MEDICAL CO.,LTD —— 深圳德技医疗器械公司证件 ——





Certificate of SHENZHEN DJ MEDICAL CO.,LTD  
 深圳德技医疗器械公司证件



## isolation eyes cover certificate of China

### 隔离眼罩国内资质证件

#### 第一类医疗器械备案信息表

备案号：粤深械备 20200034 号

备案人名称	深圳德技医疗器械有限公司
统一社会信用代码	91440300359751629F
备案人注册地址	深圳市龙岗区南湾街道下李朗白李路 26 号康丰数字科技园 C 栋 5 楼 B2 区
生产地址	深圳市龙岗区南湾街道下李朗白李路 26 号康丰数字科技园 C 栋 5 楼 B2 区
产品名称	医用隔离眼罩
型号/规格	GLVZ1-1
产品描述	通常由高分子材料制成的防护罩。泡沫条和固定装置组成。非无菌提供，一次性使用。
预期用途	用于医疗机构中检查治疗时起防护作用，阻隔体液、血液飞溅或喷洒。
备注	
备案单位和日期	<p>深圳市市场监督管理局</p>  <p>备案日期：2020 年 2 月 6 日</p>
变更情况	

#### 第一类医疗器械备案凭证



深圳德技医疗器械有限公司：

根据相关法规要求，对你单位第一类医疗器械：医用隔离眼罩予以备案，备案号：粤深械备 20200034 号。





## isolation eyes cover certificate of FDA

隔离眼罩FDA资质证件

### DJM隔离眼罩 FDA 查询方式:

isolation eyes cover certificate of FDA inquiry way

FDA 官网 → Medical Devices → Databases  
→ Owner/Operator Number → 10067324 → Search

**U.S. FOOD & DRUG ADMINISTRATION**

Follow FDA | En Español

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

### Establishment Registration & Device Listing

FDA Home | Medical Devices | Databases

New Search | Back To Search Results

Proprietary Name: Isolation eyes cover, model GLYZ1-1, GLYZ1-2, GLYZ1-3;  
Isolation Face Mask, model GLMZ1-1

Classification Name: ACCESSORY, SURGICAL APPAREL

Product Code: LYU

Device Class: 1

Regulation Number: 378.4040

Medical Specialty: General & Plastic Surgery

Registered Establishment Name: SHENZHEN DJ MEDICAL EQUIPMENT CO.,LTD

Owner/Operator: Shenzhen DJ Medical Equipment Co.,Ltd

Owner/Operator Number: 10067324

Establishment Operations: Manufacturer

Page Last Updated: 03/30/2020  
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

### Establishment Registration & Device Listing

1 result found for Owner/Operator Number: 10067324

Establishment Name	Registration Number	Current Registration Yr
SHENZHEN DJ MEDICAL EQUIPMENT CO.,LTD CHINA	No number listed	2020

Accessory, Surgical Appare - Isolation Eyes Cover, Model GLYZ1-1, GLYZ1-2, GLYZ1-3;  
Isolation Face Mask, Model GLMZ1-1

Manufacturer

Can't find what you're looking for? Try a new search

登记号没有出来  
FDA系统没有刷新, 预计1周出来  
已经能在官网查询列名和产品信息

\*因FDA系统原因需一周后可查询注册证件号

Due to the FDA system, the registration certificate number can be checked after one week.

isolation eyes cover certificate of CE

隔离眼罩CE资质证件

产品类别：欧盟分类class 1

欧盟指令PPE:个人防护用品

Product category,EU Classification Class 1 personal protective equipment

TEST REPORT Form with fields for Client, Applicant, Test Method, and Results.

Technical specifications and test results section of the report.

Table with columns: Clause, Requirement, Test, Result, Verdict. Includes sub-tables for High Visibility and High Velocity Impact.

Table with columns: Clause, Requirement, Test, Result, Verdict. Includes sub-tables for Penetration, Optical Density, and Flammability.

Table with columns: Clause, Requirement, Test, Result, Verdict. Includes sub-tables for Flammability, Tear Resistance, and Disassembly.



End of Report




## isolation eyes cover certificate of CE

### 隔离眼罩CE资质证件

产品类别: 欧盟分类class 1  
 欧盟指令PPE: 个人防护用品

Product category, EU Classification Class 1  
 personal protective equipment

International Certification Registrar - International Certification Registrar



# Certificate

No. ICR Polska/PG301828 **CE**

**Name and address of certificate owner:** Shenzhen DJ Medical Equipment Co., Ltd.  
 82 Area, 10th Floor, Building C, FirstFlag Science and Technology Park, No.26 Ball Road, Gullery Village, Nanshan Road, Longgang District, Shenzhen, China

**Name and address of manufacturer:** Shenzhen DJ Medical Equipment Co., Ltd.  
 82 Area, 10th Floor, Building C, FirstFlag Science and Technology Park, No.26 Ball Road, Gullery Village, Nanshan Road, Longgang District, Shenzhen, China

**Product name:** Isolation eyes cover

**Product types:** GY21-1, GY21-2, GY21-3

**Product trademark:** N/A

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425  
 = EN 166:2001

The certification process has been carried out in accordance with the program PC-9-31-02. Evaluation has been carried out in accordance with test reports made by East Notice Certification Services Co., Ltd.

**No. of test reports:** ENC2003041C225E1


**Certificate issue date:** 27.03.2020

**Expiration date:** 26.03.2025


The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3109.

This certificate applies to products having the same attributes (guaranteed), intended use, that have been evaluated and meet the requirements of the applicable zone standard.

5.1.2e



Warsaw, 27.03.2020



ICR Polska Co. Ltd.  
 ul. Piłsudskiego 6, 01-644 Warszawa  
[www.icrpol.com](http://www.icrpol.com), e-mail: [info@icrpol.com](mailto:info@icrpol.com)

## ANSI Z87.1 TEST REPORT


For  
**Medical Isolation eyes cover**

**Model: GY21-1, GY21-2, GY21-3**

**Brand Name: N/A**

**Report No.: SCC2003041C225E1**

**Date of Issue: Mar., 16, 2020**

Prepared by  
  
**Shenzhen DJ Medical Equipment Co., Ltd.**  
 82 Area, 10th Floor, Building C, FirstFlag Science and Technology Park, No.26  
 Ball Road, Xialiang Village, Nanshan Road, Longgang District, Shenzhen,  
 China

Prepared By  
**CHINA CEPREI (SICHUAN) LABORATORY**  
 No.46 Wenming Dong Road, Longquanyi Chengdu 610100 P. R. China



isolation face mask certificate of FDA

医用隔离面罩FDA资质证件

DJM隔离面罩 FDA 查询方式:

isolation face mask certificate of FDA inquiry way

FDA 官网 → Medical Devices → Databases  
→ Owner/Operator Number → 10067324 → Search

**Establishment Registration & Device Listing**

Proprietary Name: Isolation eyes cover, model GLYZ1-1, GLYZ1-2, GLYZ1-3;  
Isolation Face Mask, model GLMZ1-1

Classification Name: ACCESSORY, SURGICAL APPAREL

Product Code: LYU

Device Class: 1

Regulation Number: 378.4040

Medical Specialty: General & Plastic Surgery

Registered Establishment Name: SHENZHEN DJ MEDICAL EQUIPMENT CO.,LTD

Owner/Operator: Shenzhen DJ Medical Equipment Co.,Ltd

Owner/Operator Number: 10067324

Establishment Operations: Manufacturer

**Establishment Registration & Device Listing**

1 result found for Owner/Operator Number: 10067324

Establishment Name	Registration Number	Current Registration Yr
SHENZHEN DJ MEDICAL EQUIPMENT CO.,LTD CHINA	No number listed	2020

Accessory, Surgical Appare - Isolation Eyes Cover, Model GLYZ1-1, GLYZ1-2, GLYZ1-3;  
Isolation Face Mask, Model GLMZ1-1

Manufacturer

登记号没有出来  
FDA系统没有刷新, 预计1周出来  
已经能在官网查询列名和产品信息

\*因FDA系统原因需一周后可查询注册证件号

Due to the FDA system, the registration certificate number can be checked after one week.



## isolation face mask certificate — 医用隔离面罩国外资质证件 —

佛山市质量计量监督检测中心  
检验报告

No. Q20-WY0001

报告号: QRC300204AYD2-0 共 6 页 第 1 页

产品名称 型号、规格 商标、等级	医用隔离面罩 GMZ-1	生产日期 批次号	2020年12月28日
委托单位	深圳德技医疗器械有限公司	检验类别	委托检验
委托单位地址	深圳市福田区南湾街道下李朗白李路26号康丰数字科技园C栋5楼B2区	检验依据 检验方式	YY 0469 1件送样
生产单位 (委托方提供)	深圳德技医疗器械有限公司	报检日期	2020年02月03日
生产单位地址 (委托方提供)	深圳市福田区南湾街道下李朗白李路26号康丰数字科技园C栋5楼B2区	报检人	叶嘉豪
样品特征 及状态	拆袋未用	检验日期	2020年02月03日
检验依据	GB 32166-2016《个体防护用品 医用防护口罩技术要求》第1部分: 普通型		
备注	送检时, 拆封项目符合GB 32166-2016标准的要求。		
说明	1. 本报告只对来样负责; 2. 报告“—”表示“不适用”; 3. 环境温度: 15℃~24℃, 相对湿度: 50%~75%。		

检测员: 梁嘉豪 梁嘉豪 梁嘉豪  
 检测地点: 广东省佛山市南海区桂城街道南湾路2号

### 第一类医疗器械备案信息表

备案号: 粤深械备 20200046 号

备案人名称	深圳德技医疗器械有限公司
统一社会信用代码	9144030359751625P
备案人注册地址	深圳市福田区南湾街道下李朗白李路26号康丰数字科技园C栋5楼B2区
生产地址	深圳市福田区南湾街道下李朗白李路26号康丰数字科技园C栋5楼B2区
产品名称	医用隔离面罩
型号/规格	GMZ-1
产品描述	由柔山高分子材料制成的防护罩, 泡沫条和固定装置组成, 非灭菌提供, 一次性使用。
预期用途	用于医疗机构中检查室行时起防护作用, 阻隔体液、血液飞溅或飞溅。
备注	
备案单位 和日期	深圳市场监督管理局 备案日期: 2020年2月12日
变更情况	

### 第一类医疗器械备案凭证

深圳德技医疗器械有限公司:

根据相关法规要求, 对你单位第一类医疗器械: 医用隔离面罩予以备案, 备案号: 粤深械备 20200046 号。

深圳市场监督管理局  
(盖章)  
2020年2月12日



## isolation face mask certificate — 医用隔离面罩国外资质证件 —

产品类别：欧盟分类class 1  
欧盟指令PPE:个人防护用品

Product category, EU Classification Class 1  
personal protective equipment

**ICR**  
International Certification Registrar

### Certificate

No. ICR Polska/P6301827 **CE**

**Name and address of certificate owner:** Shenzhen DJ Medical Equipment Co., Ltd.  
82 Area, 5th Floor, Building C, FirstFlag Science and Technology Park, No.26 Baik Road, Baik Road, Xialiang Village, Nanwan Road, Longgang District, Shenzhen City, China

**Name and address of manufacturer:** Shenzhen DJ Medical Equipment Co., Ltd.  
82 Area, 5th Floor, Building C, FirstFlag Science and Technology Park, No.26 Baik Road, Baik Road, Xialiang Village, Nanwan Road, Longgang District, Shenzhen City, China

**Product name:** Isolation face mask

**Product type:** GDM1-1

**Product trademark:** n/a

**This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425**  
EN 1713:2006

The certification process has been carried out in accordance with the program FC-P-ET-07. Evaluation has been carried out in accordance with test reports made by East Notice Certification Service Co., Ltd.

**No. of test reports:** [ENC2003041GZ31E1]  
**Certificate issue date:** 22.03.2020  
**Expiration date:** 24.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR-POL-NA-0009-1789.

This certificate applies to products having the same attributes (parameters), intended use that have been evaluated and meet the requirements of the aforementioned standards.

**5.1.2e**

Warsaw, 25. 03. 2020

**ICR Polska Co. Ltd.**  
ul. Tłocznik 25 k. 01-244 Warszawa  
www.icrpoland.com, email: icr@icrpoland.com

**ENG**

### CE TEST REPORT

074 166 2001

For  
**Medical Isolation face mask**

**Model:** GDM1-1  
**Brand Name:** N/A

**Report No.:** ENC2003041GZ31E1  
**Date of Issue:** Mar. 13, 2020

Prepared For  
**Shenzhen DJ Medical Equipment Co., Ltd.**  
B2 Area, 5th Floor, Building C, FirstFlag Science and Technology Park, No.26 Baik Road, Xialiang Village, Nanwan Road, Longgang District, Shenzhen, China

Prepared By  
**East Notice Certification Service Co., Ltd.**  
1/F, Haxhui Commercial Building, Zhujl Street, Dongpu Town, Tianhe District, Guangzhou City, China  
TEL: +86-20-2331-4234  
FAX: +86-20-8330-8828

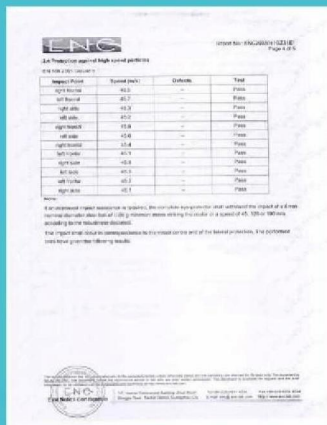
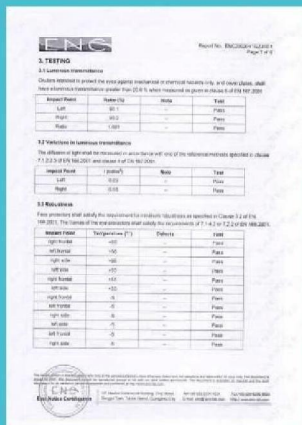
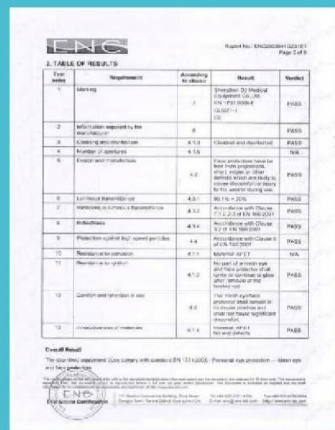
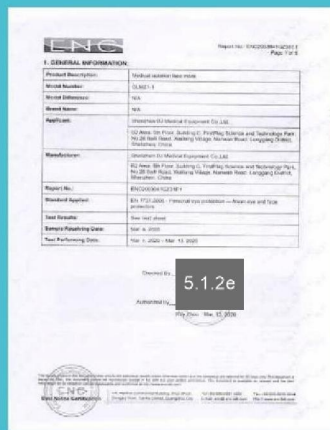
The certificate holder is responsible for the test reports issued. The certificate holder is responsible for the test reports issued. The certificate holder is responsible for the test reports issued. The certificate holder is responsible for the test reports issued.

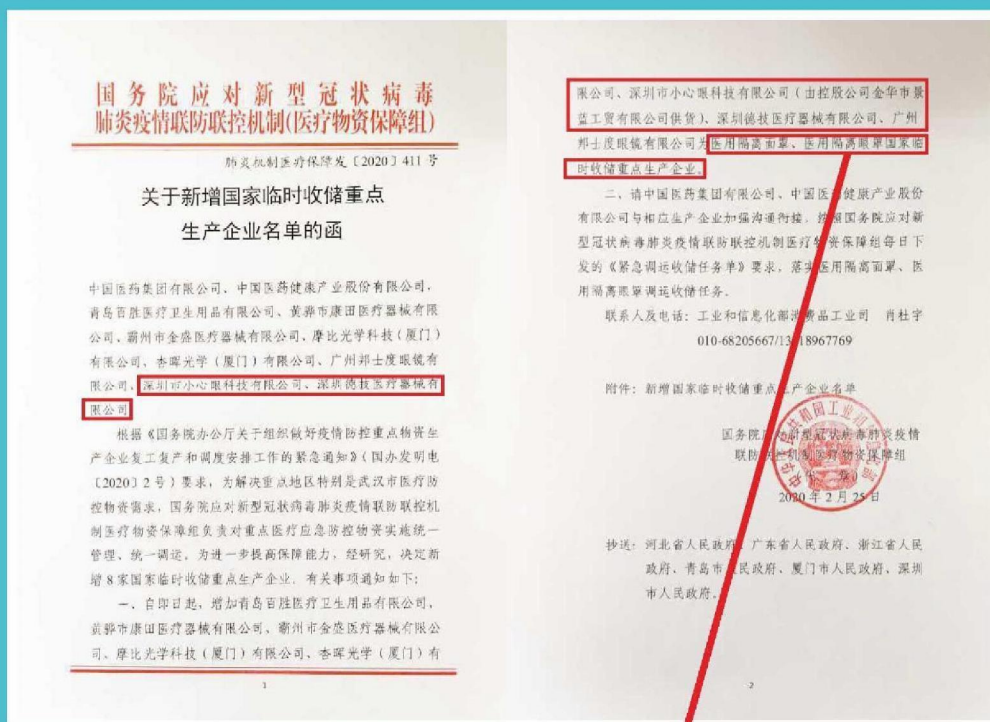
**ENG**  
East Notice Certification  
1/F, Haxhui Commercial Building, Zhujl Street, Dongpu Town, Tianhe District, Guangzhou City  
TEL: +86-20-2331-4234 FAX: +86-20-8330-8828  
E-mail: en@en.com.cn

# isolation face mask certificate — 医用隔离面罩国外资质证件 —

产品类别：欧盟分类class 1  
欧盟指令PPE：个人防护用品

Product category, EU Classification Class 1  
personal protective equipment





The Medical Material Support  
Group of the State Council of China,  
isolation eyes cover & isolation face mask  
The state key production enterprises of  
temporary collection and storage

**国务院医疗物资保障组**  
**医用隔离面罩、医用隔离眼罩**  
**国家临时收储重点生产企业**