



# HENGSHUKANG

Product Name: Disposable Medical Mask

Executive Standard: YY/T 0969-2013

From: MK

E-Mail: [makaiyu0721gmail.com](mailto:makaiyu0721gmail.com)

Complete Qualifications

恒舒康®  
HENGSHUKANG  
永远守护你的健康



HENGSHUKANG

# Product Description

## Disposable Medical Mask



Product Name: Disposable Medical Mask

Executive Standard: YY/T 0969-2013

Product Structure: Non-sterile product, which is made by heat sealing and press of nonwoven cloth, melt-blown cloth, ear loops and nose bride band.

Specification Model: Ear-hook type 17.5cmX9.5cm

Storage Conditions: Tightly seal packages, and store the products in dry ventilation room without sunshine and etchant gas.

**【Scope of application】**Cover the mouth, nose and lower jaw of user; suitable for common medical environment or outdoor environment to prevent mouth cavity and the nasal cavity from exhaling or spouting pollutants

Use Period: Within two years



# Disposable Medical Mask

恒舒康<sup>®</sup>  
HENGSHUKANG

## 【Three layers of protection】

The first layer: non-woven fabric;  
The second layer: melt blown cloth, with strong bacterial filtration efficiency;  
The third layer: skin-friendly non-woven fabric

## 【Adjustable plastic nose strip】

Built-in double-core nose bridge, strong plasticity, strong protection, bends to a degree, fits the shape of the nose, and will not deform after long wear

## 【3D three-dimensional folds】

Multiple folds better cover the cheeks

## 【Ultrasonic welding technology】

Wearing firmly, resistant to pulling, not easy to fall off

## 【Elastic ear rope】

Elastic earbands, strong elasticity, comfortable to wear, long-term non-leaving



## Three layers of protection and filtration

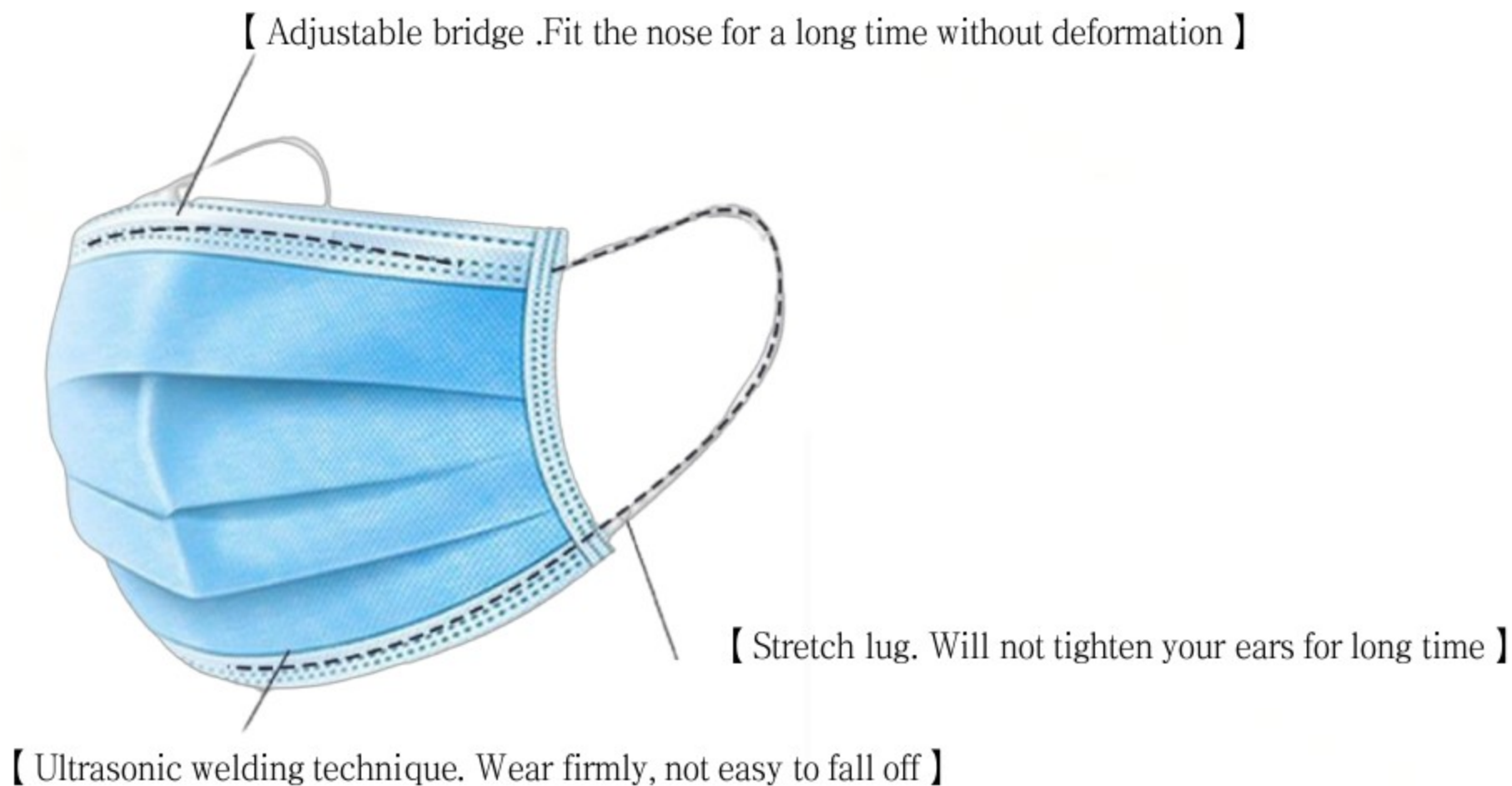


【 Outer non woven protective layer  
Filtering large particulate matter and dust pollutants 】

【 High quality molten spray filter layer  
Good adsorbability, good filtration 】

【 Inner soft non-woven fabric  
Breathable, high comfort, soft and skin-friendly 】

3d stereo cutting Multi -fold pleats better cover the face, suitable for fat and thin



# Disposable Medical Mask

恒舒康®  
HENGSHUKANG



Individual package



Box

【Specification】: 215\*103\*105mm  
【Product Quantity】: 50 pieces/box  
【Gross Weight】: 0.245kg/box



Carton

【Size】: 54\*44.5\*44cm  
【Quantity】: 50 pcs/box, 40 boxes/box, 2000 pcs  
【Gross Weight】: 11kg/carton

## CERTIFICATION

Product name: Disposable Medical Mask  
Execution standard: YY/T 0969-2013  
Specifications: Ear-hook type 17.5cm\*9.5cm  
Main material: 66% Non-woven 34%Melt Blown  
Production date/Batch number: See jet code  
Quality inspector: Inspector 06  
Use Period: 2 years  
Manufacturer: Zhongshan Juyi Electronics Co., Ltd  
Factory address: Floor 2, and left side of building 1 no.27 jinyi south road, Dongfeng Town, Zhongshan city guangdong province, China  
Quality standard, this product after the experience of provisions, granted the factory.

Certification

【Specification】: 50\*70mm

## 医疗器械生产许可证

许可证编号：粤食药监械生产许 20203901 号

企业名称：中山市路路通电子有限公司

生产地址：中山市东凤镇金怡南路 27 号 1 幢左侧一层、二  
层、五层

法定代表人：黎扬勇

生产范围：见医疗器械生产产品登记表

企业负责人：郭顺利

住 所：中山市东凤镇金怡南路 27 号 1 幢左侧二层、五层 发证部门：广东省药品监督管理局

有效期限：至 2025 年 08 月 12 日 发证日期：2020 年 10 月 12 日

国家食品药品监督管理总局制

## 医疗器械生产产品登记表

| 企业名称  | 中山市路路通电子有限公司   |                     |                  |    |
|---|--|---------------------|------------------|----|
| 许可证编号                                       | 粤食药监械生产许 20203901 号  |                     |                  |    |
| 许可证有效期限                                     | 至 2025 年 08 月 12 日   |                     |                  |    |
| 生产范围  | II 类 14 注输、护理和防护器械-13 手术室感染控制用品，<br>II 类 14 注输、护理和防护器械-14 医护人员防护用品 |                     |                  |    |
| <b>生产产品列表</b>                               |  |                     |                  |    |
| 序号  | 产品名称   | 注册号                 | 登载日期             | 备注 |
| 1   | 一次性使用医用口罩  | 粤械注准<br>20202141177 | 2020 年 08 月 13 日 |    |
| 2   | 医用外科口罩   | 粤械注准<br>20202141553 | 2020 年 10 月 12 日 |    |
| 发证部门（公章）：<br>广东省药品监督管理局<br>2020 年 10 月 12 日 |  |                     |                  |    |



## 中华人民共和国医疗器械注册证

注册证编号：粤械注准 20202141177

|       |  |
|-------|--|
| 注册人名称 | 中山市路路通电子有限公司   |
| 注册人住所 | 中山市东凤镇金怡南路 27 号 1 幢左侧二层、五层                                     |
| 生产地址  | 中山市东凤镇金怡南路 27 号 1 幢左侧一层、二层、五层                                  |
| 产品名称  | 一次性使用医用口罩  |
| 型号、规格 | 型号：耳挂式<br>规格：17.5cm×9.5cm                                      |
| 结构及组成 | 由无纺布、熔喷布、口罩带、鼻梁条经机压热合制成，为非灭菌产品，一次性使用。                          |
| 适用范围  | 供临床各类人员在非有创操作过程中佩戴，覆盖住使用者的口、鼻及下颌，为防止病原体微生物、颗粒物等的直接透过提供一定的物理屏障。 |
| 附件    | 产品技术要求。  |
| 其他内容  | 无  |
| 备注    |  |

审批部门：广东省药品监督管理局

批准日期：2020 年 08 月 07 日  
有效期至：2025 年 08 月 06 日



## 第二类医疗器械经营备案凭证

备案编号：粤中食药监械经营备 20201130 号

|       |   |
|-------|---|
| 企业名称  | 中山市路路通电子有限公司  |
| 法定代表人 | 黎扬勇   |
| 企业负责人 | 郭顺利   |
| 经营方式  | 批发  |
| 住所    | 中山市东凤镇金怡南路 27 号 1 幢左侧二层、五层（住所申报）  |
| 经营场所  | 中山市东凤镇金怡南路 27 号 1 幢左侧二层   |
| 库房地址  | 中山市东凤镇金怡南路 27 号 1 幢左侧一层   |
| 经营范围  | 2002 年分类目录<br>6801, 6802, 6803, 6804, 6805, 6806, 6807, 6808, 6809,<br>6810, 6812, 6813, 6815, 6816, 6820, 6821, 6822, 6823,<br>6824, 6825, 6826, 6827, 6828, 6830, 6831, 6832, 6833,<br>6834, 6841, 6845, 6854, 6855, 6856, 6857, 6858, 6863,<br>6864, 6865, 6866, 6870<br>2017 年分类目录<br>01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 14, 15, 16,<br>17, 18, 19, 20, 21, 22** |

备案部门：中山市市场监督管理局

备案日期：2020 年 8 月 5 日



# Complete Qualifications



**EC Declaration of Conformity**

**CE**

**Manufacturers Name:** ZHONGSHAN LULUTONG ELECTRONIC CO., LTD

**Manufacturers Address:** Floor 2, left side, building 1, No. 27, Jinyi South Road, Dongfeng Town, Zhongshan City, 528425, Guangdong Province, China

**Authorized Representative Name (if applicable):** Wellkang Ltd

**Authorized Representative Address (if applicable):** 16 Castle St, Dover, Kent, CT16 1PW, England, UK

**Name of the Device (s):** Disposable Earloop Medical Face Mask


**Model/Specification:** HSK- PM001 / 17.5cm \* 9.5cm

**Standards:** See Annex I attached

**Classification:** Class I, Rule 1

**Conformity assessment route:** ZHONGSHAN LULUTONG ELECTRONIC CO., LTD uses the following procedures for the CE-labeling of their products according to the MDD 93/42/EEC:  
Class I: EC conformity declaration according to annex VII

This declaration of conformity is issued under the sole responsibility of ZHONGSHAN LULUTONG ELECTRONIC CO., LTD. We hereby declare that the medical device(s) specified above meet the provision of the MDD 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

**Signature:**  **Place and date (dd.mm.yyyy) of issue:** JUNE 08, 2020 Zhongshan, China

**NAME:** Yang Yong **FUNCTION:** CEO

  
**Medicines & Healthcare products Regulatory Agency**

Medicines & Healthcare products Regulatory Agency  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom  
+44 (0) 20 3060 6000  
gov.uk/mhra

**Wellkang Ltd**  
16 Castle St  
DOVER  
CT16 1PW  
United Kingdom

**21 September 2020**

Dear **Edward Wang**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **21 September 2020** has been reviewed:

Application reference: **2020092101185188**

Manufacturer organisation: **Zhongsan LULUTONG Electronic Co., Ltd.**  
Address: **Floor 2, left side, building 1, No. 27, Jinyi South Road, Dongfeng Town, Zhongshan City, Guangdong Province, 528425 China**

Manufacturer registration status: **Registered**

Device(s):

| GMDN term                                      | Status     | MHRA comment |
|--|------------|--------------|
| 35177 - Surgical/medical face mask, single-use | Registered |              |

**Please note** this letter **does not** represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:


- company/organisation information e.g. name and address
- additional devices (GMDN code or term)

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturers and authorised representatives and their devices that have been registered will be published on our [Public Access Registration Database \(PAR\)](#). This applies to non-in vitro diagnostic devices only.

The account number for your company/organisation is **0000010601**.

Yours sincerely,




**Ngozi Onyekwu**  
Device registrations service  
Devices division  
MHRA

Complete Qualifications



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医疗器械网络销售信息表

| 医疗器械网络销售类型*          | □自建类 纳入社类  |   |                     |             |               |                  |
|----------------------|--|---|---------------------|-------------|---------------|------------------|
| 联系人*                 | 姓名   | 身份证件类型  | 证件号                 | 电话          | 传真            | 电子邮件             |
|                      | 戴蒙   | 身份证   | 4432522199406121397 | 18682120258 | 0760-23803086 | 756619732@qq.com |
| 主体信息                 | 企业名称*  | 中山市路路通电子有限公司  |                     |             |               |                  |
|                      | 住所*  | 中山市东凤镇金怡南路27号1幢左侧二层、五层(住所申报)  |                     |             |               |                  |
|                      | 社会信用代码*  | 914420005883354098  |                     |             |               |                  |
|                      | 经营场所或生产场所*   | 中山市东凤镇金怡南路27号1幢左侧一层、二层、五层   |                     |             |               |                  |
|                      | 联系地址*  | 中山市东凤镇金怡南路27号1幢左侧一层   |                     |             |               |                  |
|                      | 主体业态(可多选)*   | <input checked="" type="checkbox"/> 医疗器械生产 <input checked="" type="checkbox"/> 医疗器械批发<br><input type="checkbox"/> 医疗器械零售 <input type="checkbox"/> 医疗器械批零兼营  |                     |             |               |                  |
|                      | 医疗器械生产(经营)许可证或备案凭证编号*  | 粤食药监械生产许20203901号、粤中食药监械经营备20201130号  |                     |             |               |                  |
|                      | 互联网药品信息服务资格证书编号(自建类必填)   | /   |                     |             |               |                  |
|                      | 经营范围*  | 仅限本厂生产医疗器械; 第二类医疗器械批发; 2020年分类目录: 6801, 6802, 6803, 6804, 6805, 6806, 6807, 6808, 6809, 6810, 6812, 6813, 6815, 6816, 6820, 6821, 6822, 6823, 6824, 6825, 6826, 6827, 6828, 6830, 6831, 6832, 6833, 6834, 6841, 6845, 6854, 6855, 6856, 6857, 6858, 6863, 6864, 6865, 6866, 6870***; 2017年分类目录: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 14, 15, 16, 17, 18, 19, 20, 21, 22*** |                     |             |               |                  |
|                      | 法定代表人*   | 黎扬勇   |                     |             |               |                  |
| 企业负责人*               | 郭顺利  |   |                     |             |               |                  |
| 入驻医疗器械网络交易服务第三方平台名称* | 医疗器械网络交易服务第三方平台备案凭证编号*   |   |                     |             |               |                  |
|                      | 上海寻梦信息技术有限公司(拼多多商城)  | (沪)网械平台备字[2018]第00003号  |                     |             |               |                  |
|                      | 杭州阿里巴巴广告有限公司(阿里巴巴)   | (浙)网械平台备字[2018]第00001号  |                     |             |               |                  |
| 备案意见                 | 以上信息已备案。<br>备案部门盖章: <br>2020年8月26日<br>备案编号: 粤中网械销售备字(2020)第00158号 |   |                     |             |               |                  |



**CERTIFICATE OF MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM**

Certificate No. 15920QY0064R0M

This is to certify that the quality management system of  
**Zhongshan LULUTONG Electronic Co., Ltd.**  
(Unified Social Credit Code: 914420005883354098)

Registered Address: Second Floor And Fifth Floor, Left Side, Building 1, No. 27, Jinyi South Road, Dongfeng Town, Zhongshan City, Guangdong Province, P. R. China

is in conformity with  
**YY/T0287-2017/ISO13485:2016**

The quality management system is applicable to:

Certification Address: First floor, Second Floor And Fifth Floor, Left Side, Building 1, No. 27, Jinyi South Road, Dongfeng Town, Zhongshan City, Guangdong Province, P. R. China (Post Code: 528425)

Certification Scope: Quality management activities related to designing, manufacturing and selling products of disposable medical face masks. (Not applicable clause: 7.5.3/ 7.5.5/ 7.5.7/ 7.5.9.2)

The certification organization shall obtain the medical device registration certificate and medical device production license for the product within the certification within the validity period of this certificate and submit it to the certification body before it can renew the certification certificate for the normal cycle.

Issuer: 

Certification Body (Seal)  


Issue Date: July 10, 2020    Expiry Date: January 9, 2021    Initial Issue Date: July 10, 2020

The information of the certificate can be verified through the CNCA's website (www.cnca.gov.cn).  
The information and validity of the certificate can be verified through the CVC's website (www.cvc.org.cn).  
The validity of the certificate depends on the result of the regular supervision by the CVC in the period of validity. This certificate continues to be valid only if the certified organization would accept and pass the regular supervision.

**VKAN CERTIFICATION & TESTING CO., LTD.**  
No.3, Tiantaiyi Road, High-tech Industrial Development Zone, Guangzhou, P. R. China

# Complete Qualifications





## Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:  
**Zhongshan LULUTONG Electronic Co., Ltd**  
**Floor 2 and 5, left side, building 1, No. 27, Jinyi South Road, Dongfeng Town,**  
**Zhongshan City, Guangdong Province**  
 has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through  
**Shenzhen CHW Testing Technology Co., Ltd.**

**Owner/Operator Number: 10064650**

**Device Listing#:**

| Listing No | Code | Device Name | Proprietary Name  |
|------------|------|-------------|---|
| D379592    | LYU  | MASK        | Disposable medical mask 418<br>Four layer protective mask<br>Earloop 175mm*95mm |



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

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, CHW is not affiliated with the U.S. Food and Drug Administration.*



**Andy Liu**  
Chief Engineer  
Issued: March 26, 2020  
Expiration Date: December 31, 2020

Web: <http://www.fda.gov> Tel: 1-888-INFO-FDA (1-888-463-6332) E-mail: [vcpr@fda.gov](mailto:vcpr@fda.gov)



Total Quality Assured.

### Test Report

Number: GZHT02328035

|                       |              |                                  |
|-----------------------|--------------|----------------------------------|
| <b>Report Ref:</b>    | GZHT02328035 |                                  |
| <b>Date Received:</b> | Aug 17, 2020 | <b>Date Issued:</b> Aug 25, 2020 |

|                      |  |
|----------------------|--|
| <b>Company Name:</b> | ZHONGSHAN LULUTONG ELECTRONIC CO., LTD   |
| <b>Address:</b>      | FLOOR 2 AND 5, LEFT SIDE, BUILDING 1<br>NO. 27, JINYI SOUTH ROAD, DONGFENG<br>TOWN, ZHONGSHAN CITY, GUANGDONG<br>PROVINCE, CHINA |
| <b>Contact Name:</b> | 侯家   |

|   |   |
|---|---|
| The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As: |   |
| End Uses  | Medical Face Mask                           |
| Ratings   | Level 3                                     |
| Sample Name   | Disposable Medical Face Mask                |
| No. Of Sample   | One(75 pieces)                              |
| Size  | 17.5cm*9.5cm                                |
| Colour  | Blue  |
| Standard  | ASTM F2100-19 <sup>11</sup>                 |
| Brand Name  | HENGSHUKANG                                 |
| Manufacturer  | ZHONGSHAN LULUTONG ELECTRONIC CO., LTD      |
| Date received/ Test Started   | Aug 17, 2020                                |
| Ref   | Type No.: HSK-PM001<br>Lot No.: 20200803001 |

Test was conducted on specific items, at our client's request.

---

Prepared And Checked By:  
 For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch



Lin Lin  
General Manager



Page 1 Of 7

**Intertek Testing Services Shenzhen Ltd. Guangzhou Branch**  
 深圳天祥质量技术服务有限公司广州分公司

Room 02, 1-8F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, Hengyun Building, 235 Kafa Ave., Guangzhou  
 No.7-2, Caim Road, Guangzhou Science City, GETDD, Guangzhou, China. Economic & Technological Development District, Guangzhou, China  
 中国广州经济技术开发区科学城彩虹路7号之二第1-8层02室 01室 广州经济技术开发区开泰大道235号恒运大厦3楼  
 101.  
 E201, E301, E401, E501, E601, E701, E801 +86 20 8396 6968 Fax: +86 20 8222 8108 Postcode: 510730  
 Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663



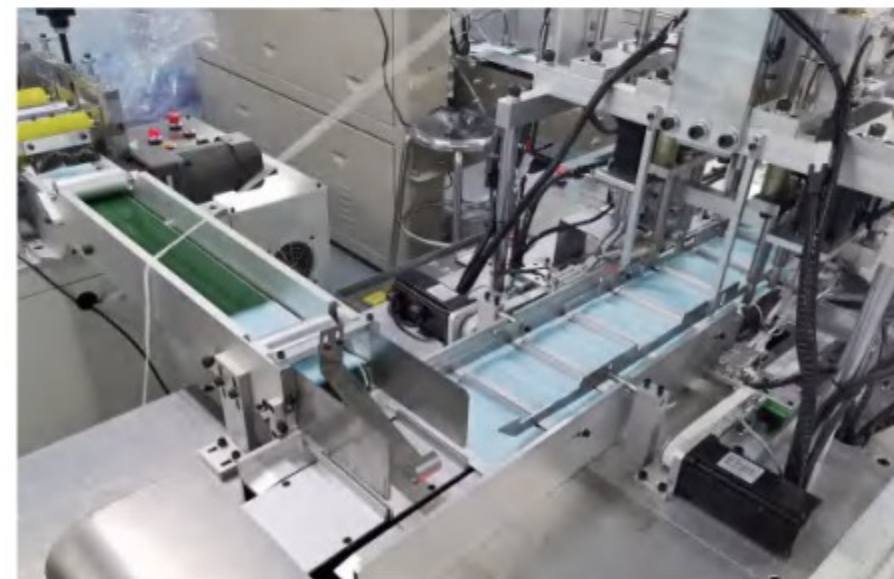
# Class 100000 Cleanroom

恒舒康®  
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永远守护你的健康



# Class 100000 Cleanroom

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永远守护你的健康





Mask particle filtration efficiency and airflow resistance tester



Mask bacteria filtration efficiency detector



Ethylene oxide sterilizer



Electric heating blast drying oven



Filter efficiency of mask particles



Water filtration



Balance/Microscope



Mold incubator



Electric pressure steam sterilizer



THANKS

