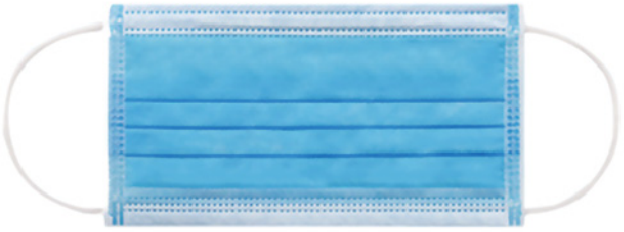
Guangzhou Haowei Technology Co., Ltd.

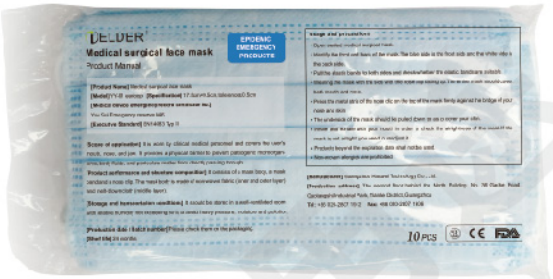
Guangzhou Haowei Technology Co., Ltd. is a professional manufacturer of masks in China. The factory is located in Sanrui Science and Technology Industrial Park, Tianhe District, Guangzhou. It is a modern factory with a complete, advanced and intelligent production line. The mainly products are medical masks and other anti-epidemic products. The factory has high standard purification workshop and related inspection and testing capabilities.The Production area is more than 1600square meters with 6 technicians and 2 senior engineers, daily output is 600,000pcs masks, annual output is 200 million masks, the products are exported to the United States, Canada, Australia, Europe, Japan, South Korea , Singapore, Malaysia, Hong Kong, Taiwan and more than 50 countries and regions.

The brand ELDER® is registered by the National Trademark Office of the People's Republic of China, and combine and apply national standards of different countries in the world to develop and produce masks adapted to different countries, regions and different face types. Company's existing certificate CE EN149: 2001 and US FDA certification standard.

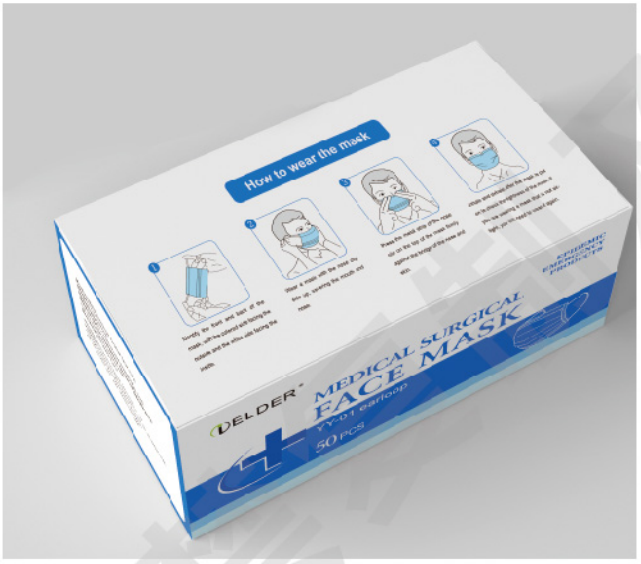
02 Picture&Specification



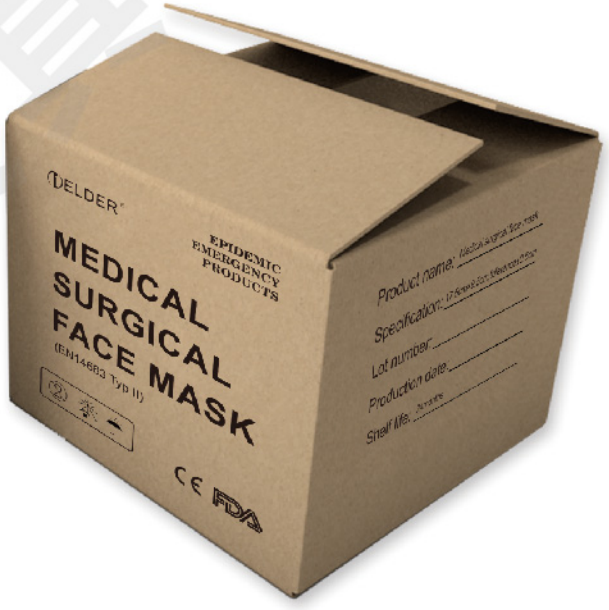
Single



10 pcs / bag



50 pcs / box



2000 pcs / carton

Bag Dimension: length 22.5cm, width 12cm, 10 pieces per bag

Box Dimension: length 19.5cm, width 10.5cm, height 9cm, 5 bags per box

Carton Dimension: length 44cm,width 41cm,height 47.5cm, 40 boxes per carton

编号：S0412018002640

统一社会信用代码

91440101MA5AYE1F8R

营业执照

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 广州皓威科技有限公司

类　　型 有限责任公司(自然人独资)

法定代表人 黄艺晓

经营范围 科技推广和应用服务业（具体经营项目请登录广州市商事主体信息公示平台查询，网址：http://cri.gz.gov.cn/。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 壹佰万元（人民币）

成立日期 2018年06月29日

营业期限 2018年06月29日 至 长期

住　　所 广州市越秀区中山五路33号9层C单元(不可作厂房使用)

登记机关 广州市越秀区市场监督管理局

2020 年 02 月 12 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

国家市场监督管理总局监制

医疗器械经营许可证

许可证编号：粤穗食药监械经营许20181152号

企业名称：广州皓威科技有限公司　　法定代表人：黄艺晓

经营方式：批零兼营　　企业负责人：吴振洁

住　　所：广州市越秀区中山五路33号9层C单元　　经营范围：2002年分类目录：6821**
2017年分类目录：**

经营场所：广州市越秀区中山五路33号9层C单元

库房地址：广州市越秀区中山五路33号9层C单元　　发证部门：广州市食品药品监督管理局 行政许可专用章

有效期限：至 2023 年 11 月 20 日　　发证日期：2018 年 12 月 06 日

国家食品药品监督管理总局制

广州市防控急需用医疗器械备案凭证

备案号：[illegible]

备案人名称	广州皓威科技有限公司
统一社会信用代码	91440101MA5AYE1F8R
备案人注册地址	广州市越秀区中山五路33号9层C单元
生产地址	广州市天河区高塘石工业园区高科路36号北楼后二楼
产品名称	医用外科口罩（疫情应急产品 非无菌）
型号/规格	YY-01挂耳式
产品描述	由口罩体、口罩带和鼻夹组成。口罩体由非织造布（内外层）、熔喷布（中间层）加工制成。
预期用途	供临床医务人员佩带，覆盖住使用者的口、鼻及下颌，为阻止病原体微生物、体液、颗粒物等直接透过提供物理屏障。
备案单位和日期	广州市市场监督管理局 备案日期：2020年02月28日
备注	仅在防控新冠肺炎疫情期间有效

广州市市场监督管理局 备案专用章 (01)

TEST REPORT

VERIFICATION WEBSITE: www.gttc.net.cn
VERIFICATION CODE: BVYP-3742-54

No:200048002 ISSUE DATE:2020-03-20

APPLICANT: GUANGZHOU HAOWEI TECHNOLOGY CO., LTD.
ADDRESS: 2F, NORTH BUILDING, NO. 36 GAOKE ROAD, GAOTANGSHI INDUSTRIAL PARK, TIANHE DISTRICT, GUANGZHOU

APPLICANT PROVIDED SAMPLE DESCRIPTION:
THIRTY(30) PIECES OF MEDICAL SURGICAL MASK
SIZE: EAR HANGING 17.5cm×9.5cm TOLERENCE±10%

DATE RECEIVED/DATE TEST STARTED: 2020-03-20

CONCLUSION:

RESIDUAL ETHYLENE OXIDE	M
APPEARANCE	M
STRUCTURE AND SIZE	M
NOSE CLIP	M
MASK STRING	M
RESISTANCE AGAINST PENETRATION BY SYNTHETIC BLOOD	M
PARTICLE FILTRATION EFFICIENCY	M
FLAME RETARDANT PERFORMANCE	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"---" -NO COMMENT

REMARK:
THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200006155.
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R.CHINA.

国家纺织品服装质量监督检验中心(广州) 检验检测专用章

APPROVED BY: 郭子山
ZiShan Guo SENIOR ENGINEER

总部:广州市番禺区珠江路1号 电话:020-61994598/61994599

Attestation of Conformity

No. ICR Polska/M6101920

CE

Name and address of Registered Manufacturer:	Guangzhou Haowei Technology Co.,Ltd Unit C, 9 / f, no.33, Zhongshan fifth road, Yuexiu District, guangzhou city, Guangdong province, P.R.C
Product name:	Surgical Mask
Product type/model:	Type II R

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/43/EEC.

Relevant EC Directive:	Medical Device Directive 93/42/ECC
Conformity assessment procedure:	EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)
Classification:	Class I according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents:	EN 14683:2005
Applied Quality Management System	EN ISO 13485:2016

This Attestation of Conformity will remain valid only if Quality Management System Certificate remains valid and the surveillance audits are conducted.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test reports made by EUROPE CERTIFICATION UNION CO., LTD laboratory.

No. of test report:	ESC-GZHT-202003-MDD
Issue date:	11.03.2020
Expiration date:	10.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-1019.

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

Director: Rafał Kalinowski

Warsaw, 10. 03. 2020.

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

FDA

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Name: Haerbin Haowei Weiye Technology Development Co.,Ltd

Add: East, Ha fifth road, Industrial Park, Pingfang District, Haerbin Cty, Heilongjiang Province, P.R.C

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through

The Owner/ Operator Number for this Registration is : 10063143

Listing No	Code	Device Name
D375511	MSH	Respirator, Surgical, Health Care Particulate Respirator and Surgical Mask
D375512	KHA	Mask, Face Mask, Nonwoven Face Mask, Medical Disposable face Mask
D375514	OEA	Disposable protective clothing

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed 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.

ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification:Mar. 18, 2020

Date of expiration:Dec. 31, 2020

SH OFFICE

TEL:0086-21-50313932 Boyle Wang Phone:0086-18930777676 info@truthful.com.cn

ABMED SERVICE INC.

36 Scyth 18th Avenue, Suite A Brighton,CO USA 80601

TEL:213-375-3998 FAX:213-375-3998 info@abmed.com.cn

1.About FDA

FDA is the abbreviation of Food and Drug Administration. The FDA also sometimes represents the US Food and Drug Administration. Authorized by the U.S. Congress, the federal government, the FDA is the highest executive agency specializing in food and drug management.It is also a team of doctors, lawyers, microbiologists, chemists, and statisticians who are committed to protecting, promoting, and improving National health monitoring agency for government health control. Many other countries seek and receive help from the FDA to promote and monitor the safety of their products.

2.About CE

In the EU market, the "CE" mark is a compulsory certification mark. Whether it is a product produced by an enterprise within the EU or a product produced in another country, the product must meet the basic requirements of the EU's New Technical Coordination and Standardization Directive. A legal requirement on a product.

The countries that enforce CE certification standards are as follows:

① 28 EU countries: UK, France, Germany, Italy, Netherlands, Belgium, Luxembourg, single purchase, Ireland, Greece, Spain, Portugal, Austria, Finland, Sweden, Poland, Jack, Hungary, Slovakia, Slovenia, Cyprus, Malaysia and others , Latvia, Lithuania, Estonia, Bulgaria, Romania, Croatia.

②Association member states: Norway, Switzerland, Iceland, Liechtenstein

In addition to the above countries that must enforce CE certification, many countries around the world also recognize CE certification

100,000 level High clean dust-free Production

There are three types of medical devices, and masks belong to the second type of medical devices.

According to the Chinese Mandatory requirement, the production environment of medical masks must be 100,000 level clean, dust-free and sterile.

The cleanliness level of the dust-free workshop: 100 level> 1000 level> 10,000 level> 100,000 level> 300,000 level. The smaller the cleanliness value, the higher the purification level and the higher the relative cost. Aseptic masks are generally produced in no less than 100,000 clean Production.

100,000 level clean Standard:

The maximum allowable number of dust particles is no more than 3,500,000 particles, and the number of particles bigger than or equal to 5 microns must not exceed 20,000. The diameter of a hairstrand is about 70 to 100 microns, and the size of bacteria is about 1 to 2 microns. By purifying the air system, the number of particles greater than or equal to 5 microns must not exceed 20,000. The degree is very high.

Pressure Differential, The pressure difference between clean rooms of the same cleanliness level is the same. For different cleanliness, the pressure difference between adjacent clean rooms is ≥5Pa, and between clean rooms and non-clean rooms is ≥10Pa. This is mainly to ensure that the air flows from the clean area to the non-clean area, and to avoid the backflow of airflow.

The maximum allowable number of microorganisms, the number of planktonic bacteria shall not exceed 500 per cubic meter; the number of sedimentary bacteria shall not exceed 10 per culture dish. Microorganisms include bacteria, viruses, single-celled organisms, etc. The purification plant project focuses on examining two indicators of planktonic bacteria and sedimentary bacteria. When doing sedimentary bacteria detection, there must be a special petri dish. Based on bacteria growing in the nutrient, the numbers of sedimenting bacteria in the air can be calculated.

Temperature and humidity, the temperature is generally controlled at 20 ~ 22 ℃ in winter; 24 ~ 26 ℃ in summer; Allowable fluctuation range ± 2 ℃.

The humidity of clean room in winter is controlled at 30-50%, and the humidity of clean room in summer is controlled at 50-70%.

When there are no special requirements for temperature and humidity, it is advisable to wear clean work clothes without producing a comfortable feeling.