Harbin Haoweiweiye Technology Development Co., Ltd.

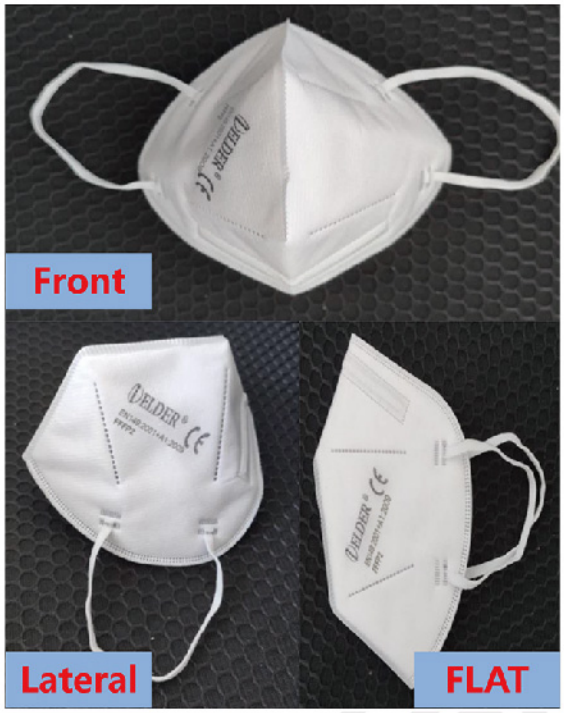
Harbin Haoweiweiye Technology Development Co., Ltd. is a professional manufacturer of masks in China. The factory is located in the Science and Technology Park of Harbin Medical University, Limin Development Zone, Harbin. It is a modern factory with a complete and advanced intelligent manufacturing line. The mainly produces are Medical masks and other anti-epidemic products. Possess high standard purification workshop and related inspection and testing capabilities. Production area are more than 800 square meters, 4 technicians, 2 senior engineers, daily output is 180,000pcs N95(FFFP2) 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® are 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.

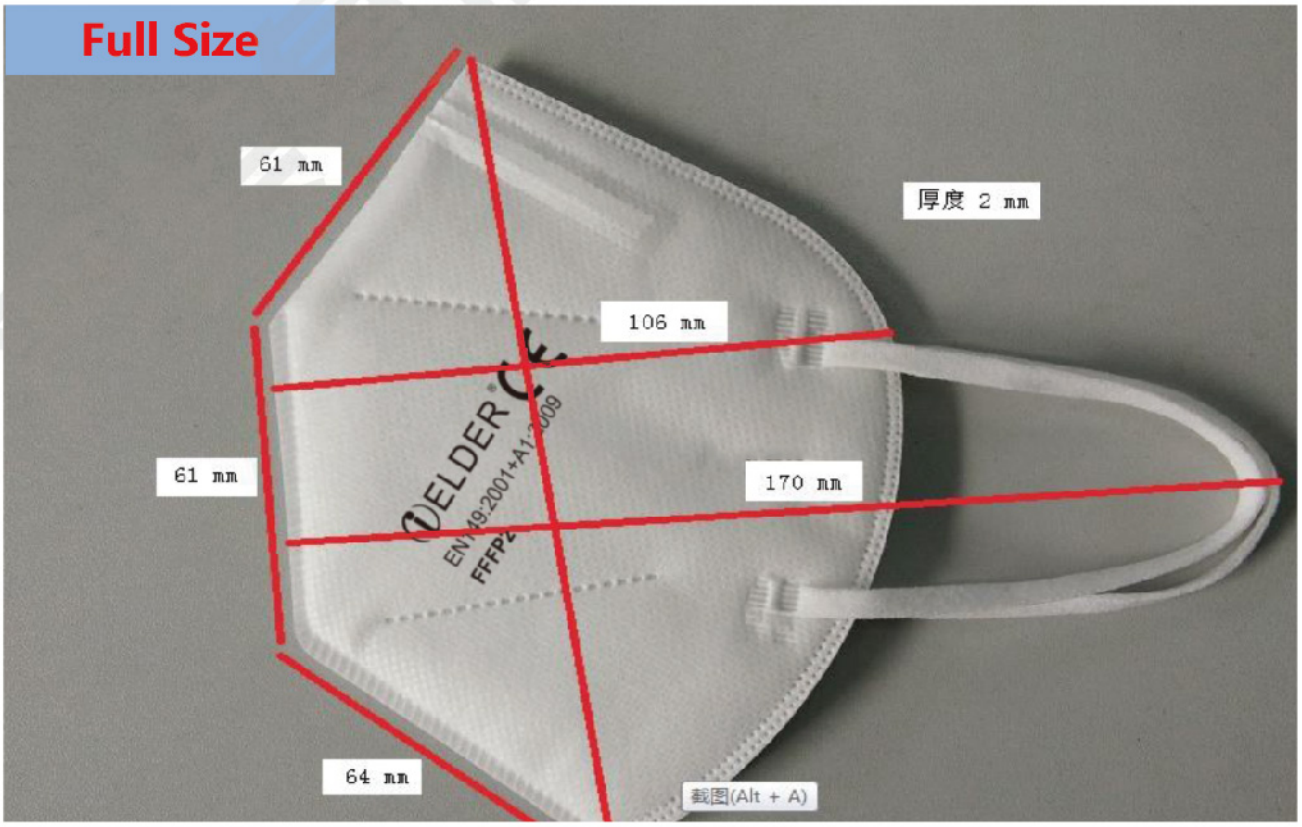
02 Product and place of origin

Bag Dimension: length 11cm, width 19cm, 5 pcs per bag
Box Dimension: length 29cm, width 16.5cm, height 13cm, 10 bags per box
Carton Dimension: length 60cm,width 51cm,height 41.5cm, 18 boxes per carton

Medical Protective Face Mask Introduction （Be Equal to FFP2）



Category	Directions
Product Name	Medical protective face mask
Type/Model	A(GB 19083-2010)/FFP2(EN 149 & EN 14683)
Size	18*15cm
Material	Non-woven+Medical Melt-blown fabric+Skin Friendly Non-woven
Color	White
Weight	5.5g
Nasal Clip	10cm*3mm
Ear Line	17cm
1 bag	5 pieces
1 box	50 pieces



统一社会信用代码

91230103552610181M

(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　哈尔滨皓威伟业科技发展有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　徐小宁

经营范围　水处理设备、净水设备、空气净化器、厨具的研发及生产；餐具、家用厨房电器、保健器材、清洁用品、化妆品及卫生用品、口腔清洁用品、服装的批发兼零售；食品生产经营；商品信息咨询服务；进出口业务；机械设备、液压传动设备的销售及维修；医疗器械的生产及销售；劳保用品的生产及销售。（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　捌仟零玖拾陆万圆整

成立日期　2010年04月14日

营业期限　长期

住　　所　哈尔滨市平房区工业园区哈五路东侧

登记机关　哈尔滨市平房区市场监督管理局

2020 年 02 月 23 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年度报告。

国家市场监督管理总局监制

医疗器械生产许可证

许可证编号：黑药监械生产许（临）20200015号

企业名称：哈尔滨皓威伟业科技发展有限公司

生产地址：哈尔滨利民开发区沈阳大街哈尔滨医科大学科技园

法定代表人：徐小宁

生产范围：

原《分类目录》

企业负责人：王宏

新《分类目录》Ⅱ类 14-14 注输、护理和防护器械-医护人员防护用品（限疫情防控期间生产）

住　　所：哈尔滨市平房区工业园区哈五路东侧

发证部门：黑龙江省药品监督管理局

有效期限：至 2020 年 08 月 25 日

发证日期：2020 年 03 月 12 日

国家药品监督管理局制

中华人民共和国医疗器械注册证（临）

注册证编号：黑械临注 [redacted]

注册人名称	哈尔滨皓威伟业科技发展有限公司
注册人住所	哈尔滨市平房区工业园区哈五路东侧
生产地址	哈尔滨利民开发区沈阳大街哈尔滨医科大学科技园
代理人名称	不适用
代理人住所	不适用
产品名称	医用防护口罩
型号、规格	A 型、B 型、C 型
结构及组成	由口罩体、口罩带和鼻夹组成。
适用范围	供医疗工作环境下，过滤空气中的颗粒物、阻隔飞沫、血液、体液、分泌物等用。产品应无菌。
附件	
其他内容	——
备注	一、仅限于在新型冠状病毒疫情期间生产使用，并需优先保障政府调配。 二、产品应符合标准 GB 19083-2010。

审批部门：黑龙江省药品监督管理局

批准日期：2020 年 3 月 10 日

有效期至：2020 年 8 月 25 日

CMA

1708001

检 验 报 告

TEST REPORT

No:

样品名称：医用防护口罩
Sample Name

委托单位：哈尔滨皓威伟业科技发展有限公司
Applicant

受检单位：——
Unit being tested

检验类别：委托检验
Test Purpose

黑龙江省质量监督检测研究院
The Academy of Quality Supervision and Inspection in Heilongjiang Province

黑龙江省质量监督检测研究院
The Academy of Quality Supervision and Inspection in Heilongjiang Province
检 验 报 告
Test Report

No: X8 . . . . . 共 2 页 第 1 页 Page 1 of 2

样品名称 Sample Name	医用防护口罩			商标 Trademark	——
委托单位 Applicant	哈尔滨皓威伟业科技发展有限公司				
受检单位 Unit being Tested	——				
生产单位 Manufacturer	——				
抽样单位 sample unit	——				
规格型号 Specifications	A	样品等级/类型 Grade/Type	——	样品状态 Sample Description	完好
生产日期/批号 Producing Date/ Batch No.	200201	送样人员 Sending	王宏	送样日期 Samples arrival date	2020-2-29
抽样基数 Sample Batch	——	抽样人员 Sampling staff	——	抽样日期 Sampling date	——
样品数量 Sample Quantity	10个	抽样地点 sample address	——	检验类别 Test Purpose	委托检验
检验依据 Test Standard(s)	GB 19083-2010《医用防护口罩技术要求》				
检验项目 Test Item	过滤效率				
检验结论 Test Conclusion	检验结果详见本报告检验结果汇总表。 签发日期: Signature Date 2020年3月3日				
备注 Note	——				

黑龙江省质量监督检测研究院 085 检验报告专用章

批准: Approver 吴 审核: Verifier 主检: Inspector 张桂霞

黑龙江省质量监督检测研究院

The Academy of Quality Supervision and Inspection in Heilongjiang Province

检 验 报 告

Test Report

检验结果汇总表

No: X……)

序号 No.	检验项目 Inspection project	单位 Unit	技术要求 Standard grade	检验结果 Inspection Result	单项结论 Result
1	过滤效率	%	——	98	——

以下空白

检 验 报 告

报告编号：\

委 托 方　哈尔滨皓威生物科技发展有限公司

样品名称　医用防护口罩

型号/规格　A型

检验类别　委托检验

黑龙江省药品检验研究中心

黑龙江省药品检验研究中心
检验报告首页

报告书编号：[redacted]　　第1页/共2页

样品名称	医用防护口罩	样品编号	WJHLJ20200069
来样方式	送样	检验类别	委托检验
商　　标	/	型号/规格	A型
委托方	哈尔滨皓威伟业科技发展有限公司	批号	200201
委托方地址	哈尔滨市平房开发区	出厂编号	-
受检单位	哈尔滨皓威伟业科技发展有限公司	生产日期	2020-02-24
生产单位	哈尔滨皓威伟业科技发展有限公司	生产单位地址	哈尔滨市利民开发区医药产业园哈尔滨医大药业股份有限公司
抽样基数	--	样品数量	8袋×2只/袋
抽样单位	--	抽样单编号	--
抽样地点	哈尔滨市平房开发区	抽样日期	--
收样日期	2020年2月29日	检验地点	本中心实验室
检验项目	口罩基本要求、口罩带、气流阻力、合成血液穿透、表面抗湿性、无菌	检验日期	2020年2月29日～2020年3月14日
检验依据	《医用防护口罩技术要求》GB19083-2010		
检验结论	见检测数据，数据见下页。 签发日期：2020年3月14日		
备注：	1）“/”表示此项空白，“--”表示此项不适用。		

批准人：　　审核人：　　主检人：陈晨

黑龙江省药品检验研究中心

检 验 报 告

报告书编号：[redacted]　　第 2 页　共 2 页

序号	检验项目	标准条款	标准要求	样品编号	检验结果	单项结论	备注
1	口罩基本要求	4.1	口罩应覆盖佩戴者的口鼻部，应有良好的面部密合性，表面不得有破洞、污渍，不应有呼吸阀。	1	符合		
				2	符合		
				3	符合		
2	口罩带	4.3	口罩带应调节方便	1	符合		
				2	符合		
			应有足够强度固定口罩位置。每根口罩带与口罩体连接点处的断裂强度应不小于10N。	1	最小断裂强度为 12N		
				2	最小断裂强度为 13N		
3	气流阻力	4.5	经过温度预处理口罩的呼气阻力不得超过343.2Pa	1	141.1Pa		
				2	187.9Pa		
				3	162.8Pa		
			未经过温度预处理口罩的呼气阻力不得超过343.2Pa	1	172.3Pa		
				2	217.9Pa		
				3	186.1Pa		
4	合成血液穿透	4.6	口罩内侧不应出现渗透	1	无渗透		
				2	无渗透		
				3	无渗透		
				4	无渗透		
				5	无渗透		
5	表面抗湿性	4.7	口罩外表面沾水等级应不低于3级	1	4 级		
				2	4 级		
				3	4 级		
6	无菌	4.8.2	应无菌		无菌		

Certificate

No. ICR Polska/M8802420

CE

Name and address of certificate owner:	Harbin haowei weiye technology development Co., LTD east, ha fifth road, Industrial park, pingfang district, haerbin city, heilongjiang province, P.R.C
Name and address of manufacturer:	Harbin haowei weiye technology development Co., LTD east, ha fifth road, Industrial park, pingfang district, haerbin city, heilongjiang province, P.R.C
Product name:	Respiratory protective devices
Product types:	FFP2

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 149:2001+A1:2009

The certification 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 reports:	ESC-HBHT-202010-PPE
Certificate issue date:	16.03.2020
Expiration date:	15.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-8824.

This certificate 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, 16. 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 hair strand 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 the number of bacteria growing in the nutrient, the number 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.