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海氏海诺®

Qingdao Hainuo Biological Engineering Co., Ltd.

青岛海诺生物工程有限公司

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About US

Qingdao Hainuo Biological Engineering Co., Ltd. is a biotechnology enterprise integrating R & D, production and sales. It is affiliated to Qingdao Haishi Hainuo Group. The Group was founded in 2004 and now has more than 20 subsidiary corporations. Our headquarter is located in Jiangshan Industrial Park in Laixi Qingdao, with superior geographical location and convenient transportation, covering an area of 330,000 square meters, which is adjacent to Jiangshan Lake, Qingrong Light Rail, major highways, Qingdao International Airport and Qingdao Port, and It's one step away from Huashan International Golf Course.

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We have several modern workshops and logistics storage facilities that meet international standards, equipped with advanced production facilities and high-precision testing instruments. There are nearly 2,000 employees including experts, professors and licensed pharmacists from the Chinese Pharmaceutical Association. Technical support and collaboration are provided by many scientific research institutions and companies from USA, Germany and Taiwan, China.

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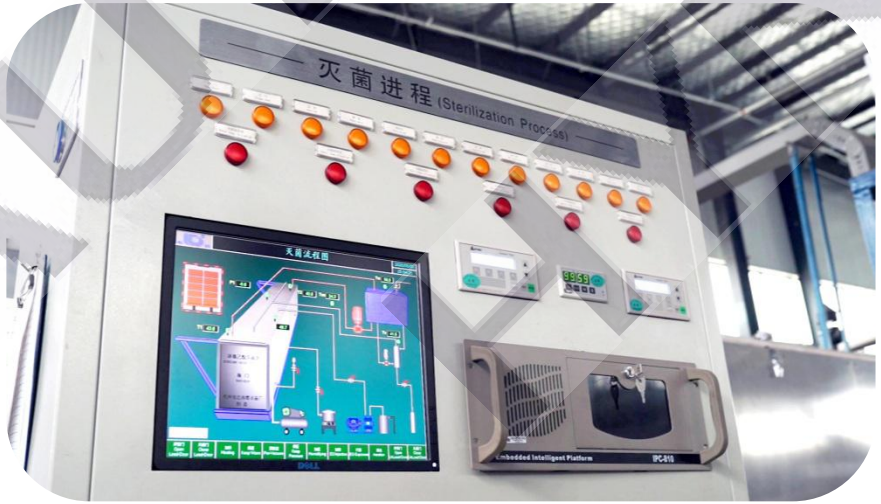
Clean Workshop



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Production Line

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Detecting instrument

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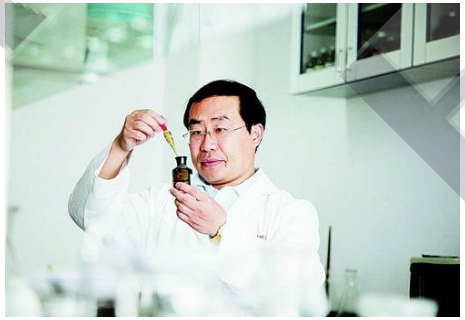
Experts of the Thousand Talents Plan

Professor Hui Miyu's patented products, B-HA (active hyaluronic acid) toothpaste and nasopharyngeal spray, broad-spectrum anti-bacterial anti-inflammatory, have been patented in the United States.

Professor Ning Xin's main research areas are nonwoven materials and equipment, hygiene and medical supplies, industrial textile composites, polymer drug release systems, environmental engineering functional fibers and materials.



Professor Jiang Guohui has presided over the topic of using nuclear technology to study new special effects of herbal active ingredients, which has received the support of the National Natural Science Foundation of China and the National Science Research Project Fund, and he has rich experience in pharmacology, toxicology, molecular biology and research and development of new drugs.

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Chen Pu academician

Academician of the Canadian Academy of Engineering and National Chief Professor of Nanobiomaterials in Canada. The small nucleic acid anti-tumor drug research and development project led by Academician Chen is at the international advanced level in the field of nano-biomedicine technology. We cooperated with Academician Chen to establish Qingdao TC-Norder Biotechnology Co., Ltd. The company's project is progressing smoothly. It is planned to set up a workstation in Jiangshan and will achieve 40 million sales revenue in 2020.

Seeram Ramakrishna academician

Foreign academician of the Royal Academy of Engineering, Indian National Academy of Engineering, Academician of the Singapore Academy of Engineering. His research direction is the processing and surface functionalization of polymer composite materials, biocomposite materials, and electrospinning nanofibers. He has conducted original research in many scientific fields and made great contributions in the field of nanotechnology.

Guan huashi academician

Academician of the Chinese Academy of Engineering, an expert in China's marine medicine, an advocate of China's "blue drug bank", and a major developer of treating Alzheimer's disease with marine organisms. We cooperated with Institute of Marine Medicine and Biology of Qingdao Ocean University to set up Haisheng Health Technology Co., Ltd to jointly develop marine medicine products.

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Haishi Hainuo Group has been repeatedly awarded as one of the "Top Three Enterprises in China's Band-Aid Industry", and cartoon Band-Aids pioneered the domestic band-aid industry. The company's main products are: face masks, wound stickers, medical infusion stickers, pressure-sensitive adhesive tape, medical disinfection cotton balls, medical disinfection cotton pads, trauma emergency kits, syringes, infusion sets, early pregnancy test paper, ovulation test paper, foot stickers, warm patch, medical antipyretic stickers, gauze bandages, disinfectant, dental floss sticks, hyaluronic acid toothpaste, medical care pads, ice pads, condoms, etc.

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The group has successively won the honorary titles of "Contract-keeping and Credit-honoring Enterprise of Qingdao", "Excellent Private Enterprise of Qingdao", "Excellent Award of Shandong Famous Enterprise Expo", "Outstanding Brand in Medical Dressing Industry of China", "Excellent Private Enterprise of China".

Chairman Mr. Ma Zhaohui won the "Trailblazing Entrepreneur Award of Qingdao".

In 2010, the "HAINUO" trademark was rated as "Famous Trademark of Shandong Province", and the HAINUO Trauma Emergency Kit was rated as "Famous product of Shandong Province".

In 2012, the company was rated as "Laixi Outstanding Welfare Enterprise", "Top Three Most Innovative and Competitive Enterprises in China's Medical Device Industry" and "Qingdao High-tech Enterprise".

In 2013, the company was rated as "National Welfare Enterprise Demonstration Unit" by the China Social Welfare Association and "Qingdao Medical Dressing Engineering Technology Research Center". “Hainuo Hainuo” trademark was rated as “Shandong Famous Trademark”, 2015 “HAINUO” brand was rated as “China Famous Brand”.

In 2016, the company was named "Invisible Champion" Enterprise of Qingdao Industrial Enterprise.

In 2017, the company's product "Sterile patches" was rated as "Qingdao Specialized New Product", and the company was rated as Qingdao Specialized Special New Model Enterprise.

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In 2008, the company reached a cooperation with American Warner Company, making the world-famous cat and mouse cartoon image become the endorsement of Hainuo products. In 2013, on the basis of "TOM and JERRY", the company successfully signed the "Superman" image to become the company's product image endorsement. Products of Hainuo have entered into thousands of households.

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Qingdao Hainuo Biological Engineering Co., Ltd is on the

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

CHINA CHAMBER OF COMMERCE FOR
IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS

http://www.cccmhpie.org.cn/

中国医药保健品进出口商会
服 务 产 业 链 | 助 力 国 际 化

English 登陆 | 注册

请输入关键词进行搜索

开具不可抗力相关事实性证明

取得国外认证和注册企业查询

首页 | 关于商会 | 新闻中心 | 行业服务 | 权威发布 | 商会会刊 | 企业风采 | 会员之家 | 加入商会

取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

青岛海诺 检索

企业名称（中文）	企业名称（英文）	产品类别	统一社会信用代码	国外注册认证情况
青岛海诺生物工程有限公司	Qingdao Hainuo Biological Engineering Co., Ltd	医用口罩	913702857180717488	欧盟CE

Medical Face Mask

EU CE

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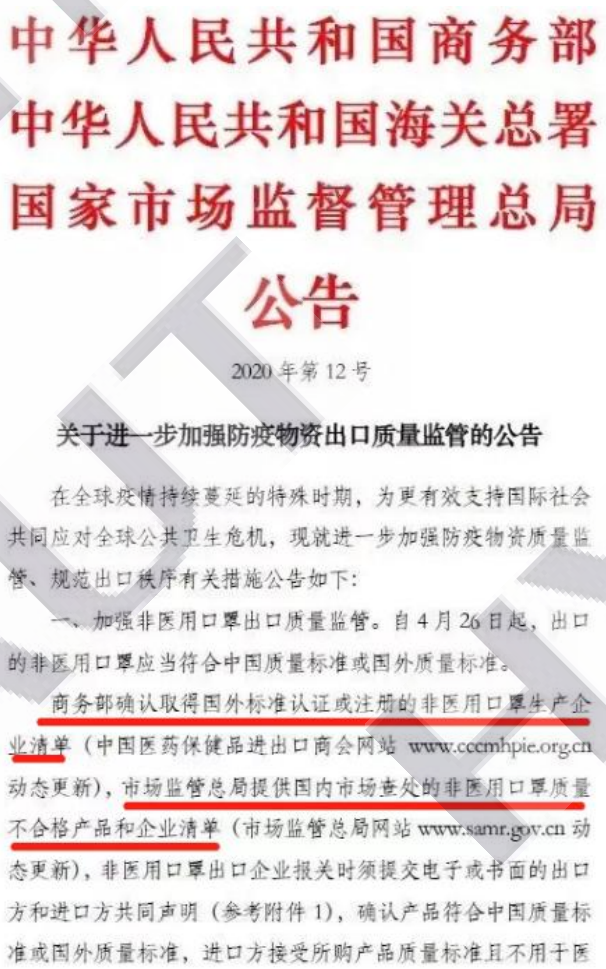
Qingdao Hainuo Biological Engineering Co., Ltd. under the group is a national white-listed enterprise for anti-epidemic materials, a special credit subsidy unit for financial credit granted by banks, and a white-listed enterprise for face mask approval by the State and Provincial Drug Administration.



中华人民共和国商务部
中华人民共和国海关总署
国家市场监督管理总局
公告

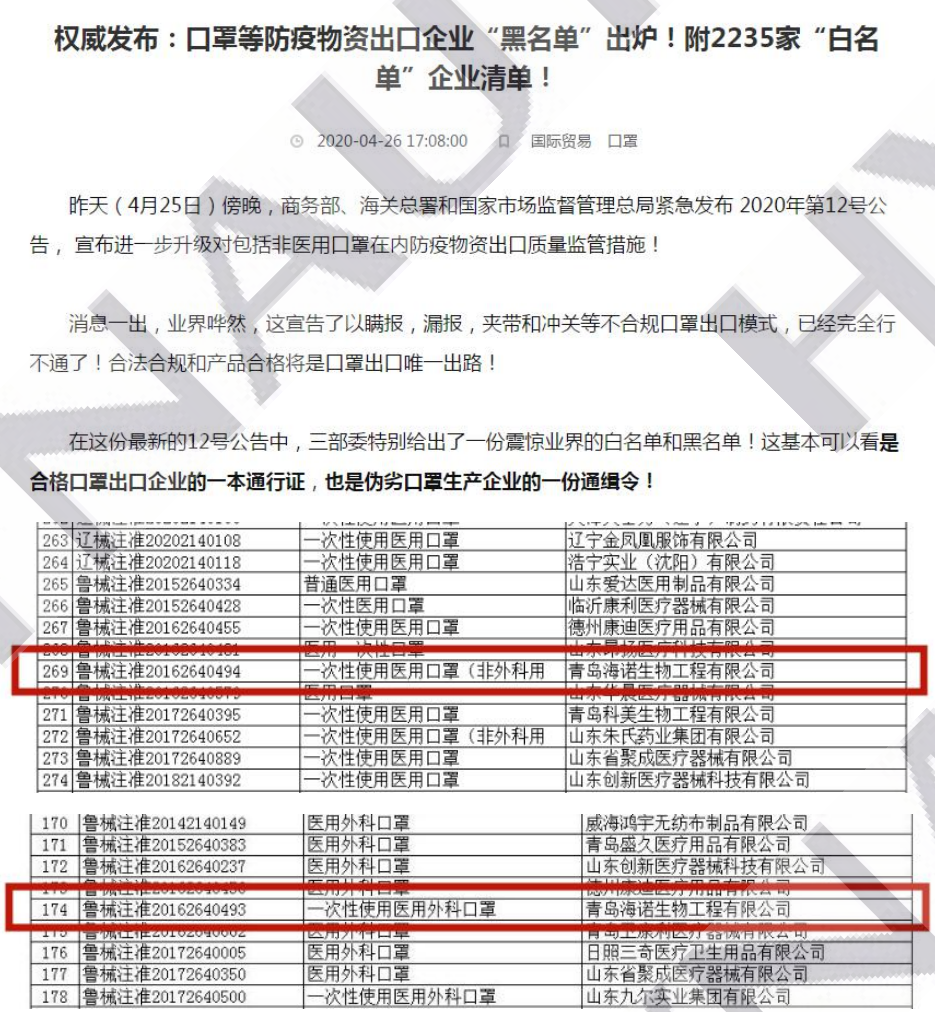
2020 年第 12 号

关于进一步加强防疫物资出口质量监管的公告

在全球疫情持续蔓延的特殊时期，为更有效支持国际社会共同应对全球公共卫生危机，现就进一步加强防疫物资质量监管、规范出口秩序有关措施公告如下：

一、加强非医用口罩出口质量监管。自 4 月 26 日起，出口的非医用口罩应当符合中国质量标准或国外质量标准。

商务部确认取得国外标准认证或注册的非医用口罩生产企业清单（中国医药保健品进出口商会网站 www.cccmhpie.org.cn 动态更新），市场监管总局提供国内市场查处的非医用口罩质量不合格产品和企业清单（市场监管总局网站 www.samr.gov.cn 动态更新），非医用口罩出口企业报关时须提交电子或书面的出口方和进口方共同声明（参考附件 1），确认产品符合中国质量标准或国外质量标准，进口方接受所购产品质量标准且不用于医



权威发布：口罩等防疫物资出口企业“黑名单”出炉！附2235家“白名单”企业清单！

2020-04-26 17:08:00 口 国际贸易 口罩

昨天（4月25日）傍晚，商务部、海关总署和国家市场监督管理总局紧急发布 2020年第12号公告，宣布进一步升级对包括非医用口罩在内防疫物资出口质量监管措施！

消息一出，业界哗然，这宣告了以瞒报，漏报，夹带和冲关等不合规口罩出口模式，已经完全行不通了！合法合规和产品合格将是口罩出口唯一出路！

在这份最新的12号公告中，三部委特别给出了一份震惊业界的白名单和黑名单！这基本可以看**是合格口罩出口企业的一本通行证，也是伪劣口罩生产企业的一份通缉令！**

263	辽械注准20202140108	一次性使用医用口罩	辽宁金凤凰服饰有限公司
264	辽械注准20202140118	一次性使用医用口罩	浩宁实业（沈阳）有限公司
265	鲁械注准20152640334	普通医用口罩	山东爱达医用制品有限公司
266	鲁械注准20152640428	一次性医用口罩	临沂康利医疗器械有限公司
267	鲁械注准20162640455	一次性使用医用口罩	德州康迪医疗用品有限公司
268	鲁械注准20162640481	医用一次性口罩	山东昂扬医疗科技有限公司
269	鲁械注准20162640494	一次性使用医用口罩（非外科用	青岛海诺生物工程有限公司
270	鲁械注准20162640497	医用口罩	山东华晨医疗器械有限公司
271	鲁械注准20172640395	一次性使用医用口罩	青岛科美生物工程有限公司
272	鲁械注准20172640652	一次性使用医用口罩（非外科用	山东朱氏药业集团有限公司
273	鲁械注准20172640889	一次性使用医用口罩	山东省聚成医疗器械有限公司
274	鲁械注准20182140392	一次性使用医用口罩	山东创新医疗器械科技有限公司

170	鲁械注准20142140149	医用外科口罩	威海鸿宇无纺布制品有限公司
171	鲁械注准20152640383	医用外科口罩	青岛盛久医疗用品有限公司
172	鲁械注准20162640237	医用外科口罩	山东创新医疗器械科技有限公司
173	鲁械注准20162640436	医用外科口罩	德州康迪医疗用品有限公司
174	鲁械注准20162640493	一次性使用医用外科口罩	青岛海诺生物工程有限公司
175	鲁械注准20162640662	医用外科口罩	青岛正康利医疗器械有限公司
176	鲁械注准20172640005	医用外科口罩	日照三奇医疗卫生用品有限公司
177	鲁械注准20172640350	医用外科口罩	山东省聚成医疗器械有限公司
178	鲁械注准20172640500	一次性使用医用外科口罩	山东九尔实业集团有限公司

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We have achieved long-term strategic cooperation with more than 200,000 pharmacies and a large number of chain convenience stores in China. Our products not only enjoy high popularity and reputation in domestic market, but also exported to overseas, favored by European, American and other customers all over the world. In recent years, as the Group grows in size, our products, production lines, research& development teams are all growing. We are always at the forefront of the industry, committed to providing the world's people with the most cutting-edge products and best service.

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海氏海诺®

Partners: China's top 100 chain pharmacies

SHUYU 漱玉平民

国药零售 国大药房 GuoDa Drugstore

海王星辰 NEP-STAR DRUG STORE

大参林dashenlin

一心堂 www.hxyxt.com

百草堂 BAICAOTANG

成大方圆医药连锁 CDFY PHARMACY CHAIN

好药师

老百姓大药房 LBX PHARMACY

高济医疗 Cowell Health

吉林大药房 THE GREAT JILIN MEDICINE STORE

健之佳®

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The company has undertaken many international marathons and equestrian competitions, and strives to promote the integration and development of sports, culture and technology.

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After the outbreak of the coronavirus COVID-19, the company invested more than 80 million yuan and added a number of new production lines for disposable medical face masks, KN95 protective masks, alcohol & iodine wipes and PE gloves production lines. Currently, the daily output of face masks reaches 3.6 million.

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Related Reports from CCTV, Xinhua Net, Qingdao News

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The Group has donated to Wuhan & Qingdao Medical Team, Ban Ki-moon Foundation and other domestic and foreign anti-epidemic first-line donations including protective supplies, alcohol disinfection products and daily necessities, with a total value of more than 10 million yuan.

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Face mask Series

- HYNAUT brand.
- Direct sales from the factory to ensure high quality.
- Direct contract signing to ensure safe transactions.
- CE / FDA / TGA and other qualifications are complete.

  Various product test reports are available.

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Disposable Face Mask

non-woven + melt-blown + non-woven

- *Personal Protective*
- *Medical EN14683 type I*
- *Medical EN14683 type IIR*

Packing	Carton L*W*H	Gross Weight	Net Weight	Volume
1pcs/bag*200bags=200pcs/ctn	73.5*47*31	8.5	7.2	0.107
50pcs/box*40boxes=2000pcs/ctn	52*39*42.5	9.05	8	0.086

HYNAUT
海氏海诺®

KN95 Protective Face Mask
(Willow Leaf)

- 4-ply design
- non-woven + melt-blown x2 + non-woven
- Four layers of protection, multiple filtration, filtration efficiency ≥95%.
  Willow-leaf cut, fits the face more comfortably.

Packing	Carton L*W*H	Gross Weight	Net Weight	Volume
1pcs/bag*200bags=200pcs/ctn	29.5*25.5*22.5	1.9	1.55	0.017

HYNAUT
海氏海诺®

KN95 Protective Face Mask (Folded)

- 4-ply design
- non-woven + melt-blown x2 + non-woven
- Four layers of protection, multiple filtration, filtration efficiency ≥95%.
  Three-dimensional design, very comfortable to wear.

Packing	Carton L*W*H	Gross Weight	Net Weight	Volume
1pcs/bag*200bags=200pcs/ctn	34*20.5*22.5	1.9	1.55	0.016

HYNAUT
海氏海诺®

KN95 Protective Face Mask
(For kids)

- 4-ply design
- non-woven + melt-blown x2 + non-woven
- Four layers of protection, multiple filtration, filtration efficiency ≥95%.

Packing	Carton L*W*H	Gross Weight	Net Weight	Volume
1pcs/bag*200bags=200pcs/ctn	31.5*19.0*21.5	1.6	1.35	0.013

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Qualification

统一社会信用代码
91370285718071748 8

营业执照

（副 本） 1-1

名 称 青岛海诺生物工程有限公司

类 型 有限责任公司(自然人投资或控股)

法定代表人 麻兆晖

经营范围 普通货物运输，专用货物运输（集装箱）（以上项目不含危险品及违禁品，并依据道路运输管理局颁发的许可证从事经营活动），I 类、II 类、III类医疗器械的生产、销售；化妆品、消毒用品的生产、销售（危险品除外）；劳保用品的生产、销售；日用百货销售；口罩、清洁用品、驱蚊用品、口腔用品、晕车贴、皮肤清洁用品、热敷贴、药盒、呼吸贴的生产、销售；生物技术研究、开发；以上货物、技术进出口。（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 贰仟万元整

成立日期 2000 年 05 月 29 日

营业期限 2000 年 05 月 29 日至 年 月 日

住 所 青岛市莱西市姜山镇工业园

登记机关 莱西市行政审批服务局

2020 年 03 月 23 日

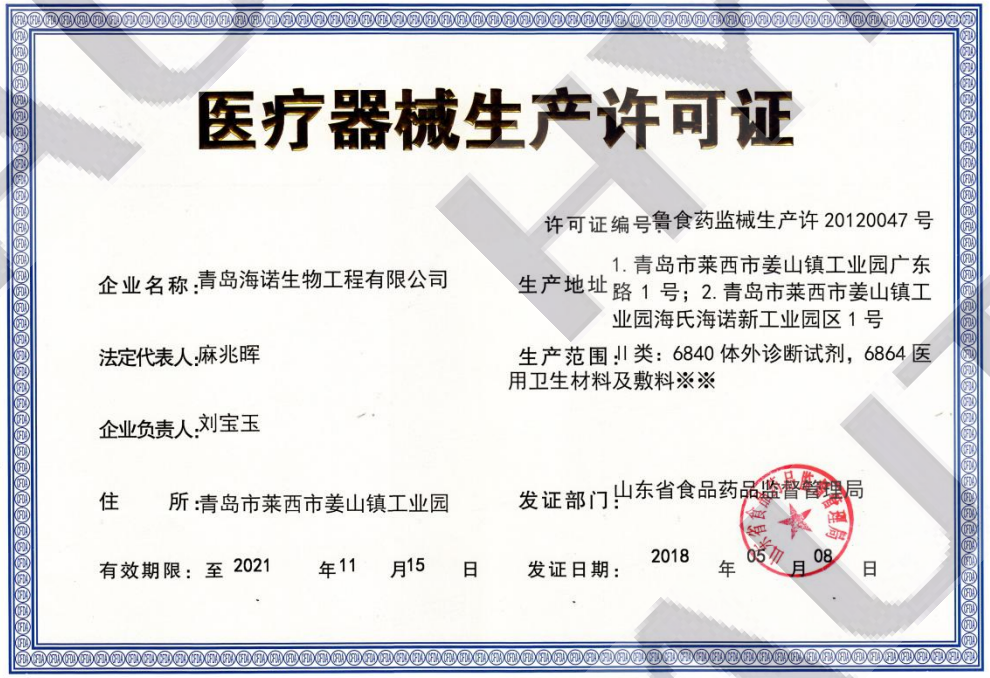
扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息

http://www.gsxt.gov.cn

国家企业信用信息公示系统网址：

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 鲁食药监械生产许 20120047 号

企业名称：青岛海诺生物工程有限公司

生产地址：1. 青岛市莱西市姜山镇工业园广东路 1 号；2. 青岛市莱西市姜山镇工业园海氏海诺新工业园区 1 号

法定代表人：麻兆晖

生产范围：II 类：6840 体外诊断试剂，6864 医用卫生材料及敷料※※

企业负责人：刘宝玉

住 所：青岛市莱西市姜山镇工业园

发证部门：山东省食品药品监督管理局

有效期限：至 2021 年 11 月 15 日

发证日期：2018 年 05 月 08 日

国家食品药品监督管理总局制

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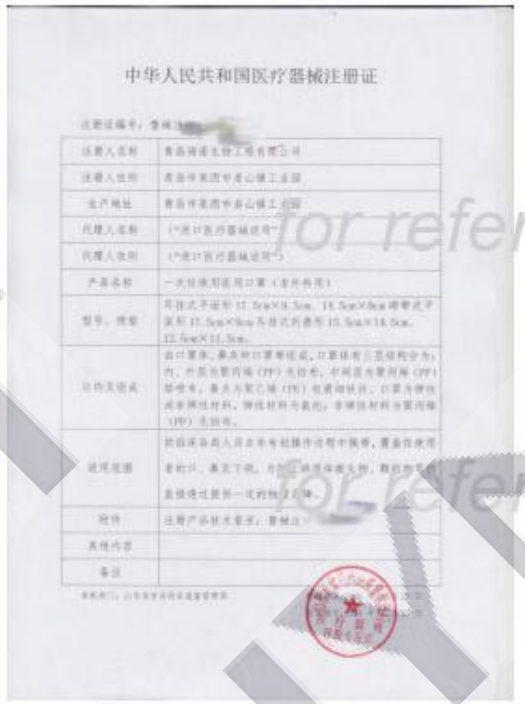
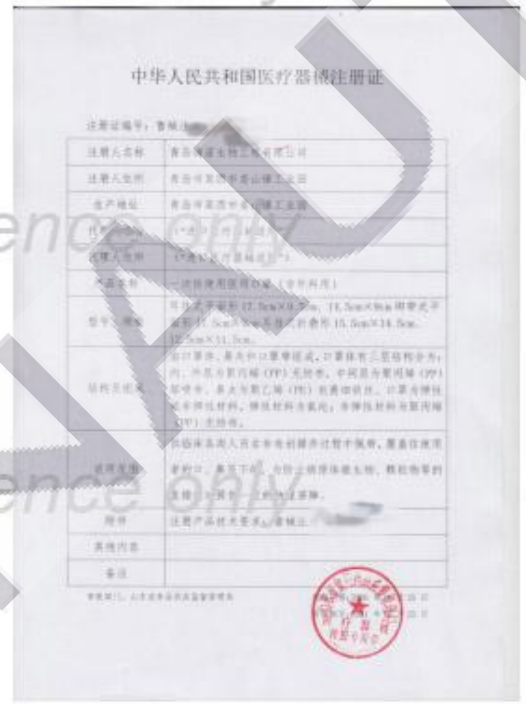

中华人民共和国医疗器械注册证


中华人民共和国医疗器械注册证

对外贸易经营者备案登记表

备案登记表编号：[redacted]　　进出口企业代码：[redacted]

经营者中文名称	青岛海诺生物工程有限公司		
经营者英文名称	QINGDAO HAINUO BIOLOGICAL ENGINEERING CO.,LTD		
组织机构代码	718071748	经营者类型（由备案登记机关填写）	有限责任公司
住　所	青岛市莱西市姜山镇工业园		
经营场所（中文）	青岛市莱西市姜山镇工业园		
经营场所（英文）	Jiangshan International Industrial Area of Laixi Qingdao		
联系电话	053286463333	联系传真	053286460000
邮政编码	266603	电子邮箱	hn@hainuocn.com
工商登记注册日期	2000-5-29	工商登记注册号	[redacted]

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	麻兆晔	有效证件号	[redacted]
注册资金	贰仟万元	（折美元）	

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人 个体工商负责人姓名		有效证件号	
企业资产/个人财产		（折美元）	

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关
签（章）

2013 年 11 月 06 日

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CONFIRMATION OF FDA REGISTRATION

Registration No.:3008808560

Dear Official Correspondent:
This document provides notification of the registration number assigned to your establishment:

Establishment: QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD.
Address: JIANGSHAN INDUSTRIAL AREA OF JIANGSHAN TOWN, LAIXI, QINGDAO, SHANDONG, 266603, CHINA
Listing Number See Appendix

General Manager
Email: ctc-086@hotmail.com
Web: www.ctc-086.com

Validity: Dec.31,2020

Conclusion:

FDA Official Website:

CONFIRMATION OF FDA REGISTRATION

Registration No.:3008808560

Appendix:

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Proprietary Name
D333004	Enforcement Discretion	LKB	Pad, alcohol, device disinfectant	ALCOHOL WIPES, ALCOHOL PREP PAD
D303241	Exempt	KXP	APPLICATOR, ABSORBENT TIPPED, NON-STERILE	COTTON SWAB
D305240	Exempt	NAC	Dressing, wound, hydrophilic	WOUND DRESSING,I.V. ADHESIVE DRESSING
D333093	Exempt	NAB	Gauze /sponge,nonresorbable for external use	GAUZE PAD, UNDERPAD, COTTON BALLS
D361412	Exempt	LRI	Disinfectant, medical devices	IODINE SWAB
D145666	Exempt	KGX	Tape and bandage, adhesive	MEDICAL TAPE, ADHESIVE BANDAGE, WOUND PLASTER
D361413	Exempt	JKS	FLOSS, DENTAL	FLOSS PICK
D389702	Enforcement Discretion	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per HE guidance	DISPOSABLE PROTECTIVE FACE MASK
D333095	Enforcement Discretion	OHR	Mouthguard, over-the-counter	FACE MASK
D361541	Enforcement Discretion	OHO	First aid kit without drug	FIRST AID KIT
D145667	Exempt	FQM	BANDAGE, ELASTIC	ELASTIC BANDAGE,GAUZE BANDAGE
D145668	Exempt	IMD	PACK, HOT OR COLD, DISPOSABLE	WARM PATCH, COLD PACK, COOL PATCH, FEVER RELIEF PATCH, COOL GEL, FREEZE GEL
D391705	Exempt	KHA	MASK, SCAVENGING	

Conclusion:

FDA Official Website:

EU Declaration of Conformity

Manufacturer: QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD
NO.1 GUANGDONG ROAD,JIANGSHAN INDUSTRIAL ZONE LAIXI CITY, QINGDAO, CHINA
Tel: +86-532-86463333/86464444

SRN: /

European Representative: CMC Medical Devices & Drugs S.L.
Horacio Lengo Nº 18, CP 29006 ,Málaga ,Spain

Product Name: Disposable Medical Face Mask
Product Type: EN14683:2019 TYPE I
Product Code: QOQ
Specification: 17.5cmx9.5cm
GMDN Code: 12-458

Classification (MDD, Annex IX): Class I, Rule 1.

Conformity Assessment Route: Annex IX of MDD 93/42/EEC.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Applied standards, common specification, guidance:
EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, MDCG 2019-15.

Signature:
Name: Gong Baoning
Position: General Manager
Place/date: Qingdao/ 5 Apr 2020
File No.: HN/CE01-01, ver.A/0

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/03042020.5

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. is the European Authorized Representative of

QINGDAO HAINUO BIOLOGICAL ENGINEERING CO LTD
NO 1 GUANGDONG ROAD, JIANGSHAN INDUSTRIAL ZONE LAIXI CITY QINGDAO

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/433/2020**

Issued on: 03/04/2020

Valid until: 02/04/2021

Authorised signatory
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com

EC REP CERTIFICATE

ANNEX I Medical Device Products

Disposable Medical Face Mask

www.cmcmedicaldevices.com

USA FDA

EU CE

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Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	334843	Australia and New Zealand Health Products Limited - Mask, surgical, single use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Australia and New Zealand Health Products Limited	
Postal Address	Suite 802 Level 8 167 - 169 Queen Street, Melbourne, VIC, 3000 Australia	
ARTG Start Date	22/04/2020	
Product category	Medical Device Class 1	
Status	Active	
Approval area	Medical Devices	

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.

Manufacturers

Name	Address
Qingdao Hainuo Biological Engineering Co Ltd	Jiashan Industrial Area of Jingshan Town Laixi Qingdao, Shandong, 266600 China

Products

1. Mask, surgical, single use

Product Type	Single Device Product	**Effective date**	22/04/2020
GMDN	35177 Mask, surgical, single use		
Intended purpose	This mask is to assist in the reduction of the spreading of germs and bacteria.		
Specific Conditions			

This is not an ARTG Certificate document.

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
Visit www.tga.gov.au for contact information

Australia TGA

KCL

시험성적서

성적서번호 : MY18-00275

○ 시험결과

시험·검사항목		단 위	기 준			시험·검사 결과	항목판정
성상		-	육안관찰			이상없음	적합
형상		mm	본체	가로	마스크의 장변을 가로로 정의함	130	적합
				세로	가로의 수직방향을 세로로 정의함	157	
			머리끈	길이	머리끈의 장변을 길이로 정의함	좌 : 167 우 : 158	
				폭	길이의 수직방향을 폭으로 정의함	5.2	
순도	색소	-	관찰하여 색을 나타내지 않음			색 나타내지 않음	적합
	산 또는 알칼리	-	홍색을 나타내지 않음(메놀프탈레인 시액) 적색을 나타내지 않음(메틸오렌지 시액)			홍색, 적색 나타내지 않음	적합
	형광	-	자외선(350~370 nm)에서 형광을 나타내지 않음			형광 없음	적합
			전이성 형광증백제 시험에서 형광 유 무				
	포름알데히드	-	검액의 색이 비교액의 색보다 진하지 않음			진하지 않음	적합
인장강도		N	절단하중(N) 평균(3회)이 10 N 이상			평균값 39.2	적합
안면부흡기저항		Pa	6개 각각의 결과가 70 Pa (KF94) 이하			본품 40.9 42.0 41.4 전처리 51.1 44.4 45.2	적합
포집효율(NaCl)		%	본품 3개, 전처리 3개 결과가 94 % (KF94) 이상			본품 99.1 99.1 99.2 전처리 98.8 99.1 99.0	적합
포집효율(파라핀오일)		%	본품 3개, 전처리 3개 결과가 94 % (KF94) 이상			본품 97.2 98.2 98.1 전처리 98.1 98.1 98.3	적합

Korea KF94

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CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

All A-Z Topics

Search NIOSH

The National Personal Protective Technology Laboratory (NPPTL)

NIOSH > NPPTL > Respirator Assessments to Support COVID-19 Response

NPPTL

- What's New on the NPPTL Website +
- A to Z Index
- For Respirator Users +

Promoting productive workplaces through safety and health research NIOSH

NPPTL Respirator Assessments to Support the COVID-19 Response

Updated May 8, 2020

International Assessment Results – Not NIOSH-approved

NPPTL has completed International Assessments for the products listed below.

NPPTL makes no representation as to the authenticity of the samples received and assessed. As part of its standard respirator approval process for NIOSH-approved respirators, NPPTL conducts a comprehensive quality assurance review of the quality process and manufacturing site. None of these reviews were conducted during this limited assessment. Further, no certificates of approval were provided with the samples. Therefore, validation of the claims that the product meets a particular international standard cannot be made.

For each model listed, ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. Only particulate filter efficiency was assessed. The results of these tests are for the sample tested and may or may not be representative of a larger lot or population of similar respirators. The results of any filter penetration test can only be used to provide a check of the product's filter efficiency. No conclusions can be made regarding equivalency to N95 products that are NIOSH approved.

No certificates of approval were provided with the samples received. Therefore, the authenticity of the claims, that the product meets a particular international standard, cannot be validated.

These assessments are not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process.

Purvigor	KN95 Antibacterial Mask	GB2626	[illegible]	69.80	2020-33.1
Qingdao Hainuo Bioengineering Co., Ltd.	Hynaut KN95 Protective Face Mask	GB2626	98.37	97.98	2020-96.1

CDC official website announced that our KN95 protective mask passed NPPTL's test

These assessments were developed as an assessment of the filter efficiency for those respirators represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers and other workers due to the respirator shortage associated with COVID-19.

Most of these products have an ear loop design. NIOSH-approved N95s typically have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

These results are not to be used by manufacturers, distributors, suppliers, and importers to make claims about their products and/or to influence purchasers.

Manufacturer	Model Number/Product Line	International Standard	Filtration Efficiency (%) Maximum	Minimum	Test Report
Anhui Baishidun Protective Equipment Co., Ltd.	Baishidun FFP2	EN149, GB2626	53.00	46.10	2020-51.1
Anhui Changli Environmental Protection Technology Co., Ltd	KN95 Protective Mask	EN149	95.74	94.73	2020-50.1
Purvigor	KN95 Antibacterial Mask	GB2626	74.20	69.80	2020-33.1
Qingdao Hainuo Bioengineering Co., Ltd.	Hynaut KN95 Protective Face Mask	GB2626	98.37	97.98	2020-96.1
Qingdao Maysheng Medical Devices Co., Ltd	KN95 Protective Mask (Self Suction Filter Respirator FFP2)	GB2626	99.59	99.30	2020-45.1
Rizhao Sanqi Medical & Health Articles Co., Ltd.	3Q 9505	GB2626	99.39	96.95	2020-29.1
San Jiao	JS95-01	EN149	89.00	82.40	2020-104.1

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NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Qingdao Hainuo Bioengineering Co., Ltd.
Model Tested: Hynaut KN95 Protective Face Mask
Date Tested: April 30, 2020

These findings pertain to the respirator Qingdao Hainuo Bioengineering Co., Ltd., Hynaut KN95 Protective Face Mask. The packaging for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found here.

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency observed was 98.37% and 97.98%, respectively. All ten respirators measured more than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment was developed as an assessment of the filter efficiency for those respirator's represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for Crisis Capacity Strategies (during known shortages).

NPPTL COVID-19 Response: International Respirator Assessment

Evaluation of International Respirators

NPPTL
National Personal Protective Technology Laboratory

Test: Modified TEB-APR-STP-0059

Date Tested: April 30, 2020

Report Prepared: May 3, 2020

Manufacturer: Qingdao Hainuo Bioengineering Co., Ltd.

Item Tested: Hynaut KN95 Protective Face Mask

Country of Certification: China (GB2626-2006)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	12.0	1.64	1.64	98.36
2	85	12.7	1.99	1.99	98.01
3	85	12.4	1.63	1.63	98.37
4	85	12.7	1.72	1.72	98.28
5	85	12.5	1.78	1.78	98.22
6	85	12.9	2.02	2.02	97.98
7	85	12.7	1.66	1.66	98.34
8	85	12.7	1.87	1.87	98.13
9	85	13.5	1.68	1.68	98.32
10	85	12.5	1.87	1.87	98.13
Minimum Filter Efficiency: 97.98			Maximum Filter Efficiency: 98.37		

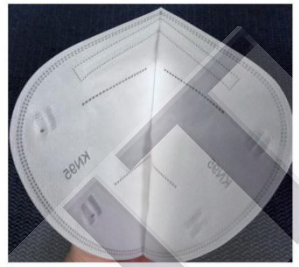
- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no contro over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.

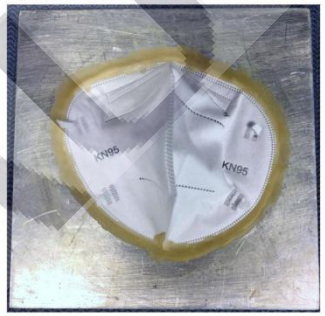
NPPTL COVID-19 Response: International Respirator Assessment

NPPTL COVID-19 Response: International Respirator Assessment

NPPTL COVID-19 Response: International Respirator Assessment

NPPTL COVID-19 Response: International Respirator Assessment





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Test Reports

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告
TEST REPORT

报告编号：WT204025604　　第 1 页，共 6 页

委 托 单 位 ： 青岛海诺生物工程有限公司QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD.

委托单位地址 ： 青岛市莱西市姜山镇工业园广东路1号NO.1 GUANGDONG ROAD, JIANGSHAN INDUSTUIAL ZONE LAIXI CITY, QINGDAO, CHINA

样 品 名 称 ： 防护口罩 KN95 Protective Face Mask

型号/规格/等级： C004

检 验 类 别 ： 送样检验

检 验 地 点 ： 龙华实验基地Longhua Experimental Base

深圳市计量质量检测研究院
（检验检测专用章）

批准人： 何行月

签发日期：2020年04月27日　　签名 ： 何行月

重 要 声 明
Important statement

1. 本院是深圳市人民政府依法设置的产品质量监督检验机构，系社会公益型非营利性技术机构，为各级政府执法部门进行监督管理提供技术支持和接受社会各界的委托检验。
SMQ is a legal non-profit technical institute established by Shenzhen Municipal Government to undertake the quality supervision and inspection of products, and to provide technical support to relevant supervision and administration and also conduct commission test from the society.

2. 本院保证检验的科学性、公正性和准确性，对检验的数据负责，并对委托单位所提供的样品和技术资料保密。
SMQ is committed to assuring the scientificness, impartiality and accuracy of all tests carried out, responsibility for test data gained, and keeping confidential of all test samples and technical documents provided.

3. 抽样按照本院程序文件CX11-01《抽样程序》和相应产品的检验细则的规定执行。
The sampling should be carried out according to the "sampling procedure" defined in the Procedure Document CX11-01 and relevant testing specifications.

4. 报告无主检、审核、批准人签字，或涂改，或未盖本院“检验检测专用章”及骑缝章无效。未经本院许可，不得部分复印、擅用或篡改本证书/报告内容。
Any report having not been signed by relevant responsible engineer, reviewer or authorized approver, or having been altered without authorization, or having not been stamped by both the "Dedicated Testing/Inspection Stamp" and the sealing stamp is deemed to be invalid. Copying or excerpting portion of, or altering the content of the report/certificate is not permitted without the written authorization of SMQ.

5. 送样委托检验结果仅对来样有效；委托检验的样品信息及委托方信息均由委托方填写，本院不对其真实性及准确性负责。
The test results presented in the report apply only to the tested sample. The product information and the applicant information are provided by the customer and SMQ assumes no responsibility for their validity and accuracy.

6. 未经检验机构同意，样品委托人不得擅自使用检验结果进行不当宣传。
Any use of SMQ test result for advertisement of the tested material or product must be approved in writing by SMQ.

7. 无 CMA 标志的报告，仅供使用方内部参考，不具有对社会的证明作用。含等字编号的 CAL 标志仅适用于产品标准和判定标准。
The non-CMA report issued by SMQ is only permitted to be used by the client as internal reference use and shall not be used for public demonstration purpose. CAL logo with symbol "Yue" is only relevant to product standards and reference of standards.

8. 对农产品监督抽查检验结果有异议的，可以自收到检验报告之日起五日内，向组织实施农产品质量安全监督抽查的农业行政主管部门或者其上级农业行政主管部门申请复检。对食品监督检验报告有异议的，可以自收到检验报告之日起七个工作日内向实施抽样检验的食品药品监督管理部门或者其上一级食品药品监督管理部门提出复检申请。对其它检验报告有异议的，应于报告发出之日起十五日内向本院提出。
Any objections to the testing results of supervision sampling of agricultural products should apply for retest within 5 days upon receiving the test report to the administrative department of agriculture who organizes and implements agricultural products' supervision sampling or its superior department. Any objections to the testing results of supervision sampling of food should apply for retest within 7 days upon receiving the test report to the administrative department of food and drug who organizes and implements supervision sampling for food or its superior department. Any objections to other inspection report issued by SMQ should be submitted to SMQ within 15 days after the issuance of the test report.

9. 电子版证书/报告更改后将不被追回，委托方有义务将更改后的报告/证书提供给使用原报告/证书的相关方。
SMQ is not responsible for recalling the electronic version of the original report/certificate when any revision is made to them. The applicant assumes the responsibility of providing the revised version to any interested party who uses them.

投诉电话 Complaint hotline： 0755- 86928949

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

报告编号：WT204025604　　第 2 页，共 6 页

样品信息：
样品名称： 防护口罩KN95 Protective Face Mask
商标： HYNAUT 海氏海诺
型号/规格/等级： C004
样品编/批号： 200401
生产日期： 2020-04-09
生产单位： 青岛海诺生物工程有限公司
生产单位地址： 青岛市莱西市姜山镇工业园 海诺大厦
样品数量： 50只　　抽样基数： ——————
抽样地点： ——————
抽样人员： ——————
检前样品描述： 正常。Normal.

客户信息：
委托单位： 青岛海诺生物工程有限公司QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD.
委托单位地址： 青岛市莱西市姜山镇工业园广东路1号NO.1 GUANGDONG ROAD, JIANGSHAN INDUSTUIAL ZONE LAIXI CITY, QINGDAO, CHINA
委托单位电话： 17561677800
邮政编码： ——————
受检单位： ——————

检验信息：
委托日期： 2020年04月20日　　委托单号： 8249572
检验类别： 送样检验　　获样方式： 送样
检验日期： 2020年04月20日 至 2020年04月27日
检验环境条件： （18～25）℃ （30～70）%RH
判定依据： GB 2626-2006
检测依据： GB 2626-2006

检验结论：
检验结果见附页。
Test result refer to next page.

主检： 谢丹菊　　审核： 陈开江

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

报告编号：WT204025604　　第 3 页，共 6 页

检验项目 Test Item	标准要求 Requirement	实测结果 Test Result	单项结论 Conclusion
1.外观检查 Appearance		(GB 2626-2006)	符合 Conformity
(GB 2626-2006)	5.2条规定 5.2Item Requirement	1#～2#符合 Conformity	
2.过滤效率(%) Filtration efficiency (GB 2626-2006)	用氯化钠颗粒物检测： NaCl Non-oil aerosols KN95≥95.0	(GB 2626-2006) 未预处理样品Unpretreated sample: 1#：96.98 2#：96.53 3#：96.54 4#：96.60 5#：96.87 6#：96.72 7#：96.36 8#：96.77 9#：96.52 10#：96.50 预处理样品Pretreated sample: 1#：96.33 2#：96.60 3#：96.57 4#：96.19 5#：96.47 KN类 KN-Series 温度Temperature：22.3℃ 相对湿度Relative humidity：34.5% 颗粒物Aerosol chamber：NaCl 颗粒物浓度Concentration of aerosol chamber：15mg/m^3 (检测流量Flow meter rate: 85L/min)	符合 Conformity

检 验 报 告

检 验 项 目 Test Item	标 准 要 求 Requirement	实 测 结 果 Test Result	单项结论 Conclusion
3.呼吸阻力(Pa) Resistance of inhalation and exhalation (GB 2626-2006)	总吸气阻力Total inhalation Resistance ≤350	(GB 2626-2006) 吸气阻力Inhalation resistance: 未预处理样品Unpretreated sample: 1# 2# 76.1 70.4 预处理样品Pretreated sample: 1# 2# 111.6 128.1	符合 Conformity
	总呼气阻力Total exhalation Resistance ≤250	呼气阻力Exhalation resistance: 未预处理样品Unpretreated sample: 1# 2# 81.4 76.2 预处理样品Pretreated sample: 1# 2# 82.9 87.8 （通气量：85L/min） (Flow: 85L/min)	
4.死腔(%) Dead space (GB 2626-2006)	≤1	(GB 2626-2006) 随弃式面罩Disposable facepiece: 0.59 (温度Temperature：23.8℃)	符合 Conformity
5.头带Head harness (GB 2626-2006)	随弃式面罩Disposable facepiece: 10N，持续10s 10N, continuous 10s 不应出现滑脱、断裂 Noslippage、breakage	(GB 2626-2006) 未预处理样品Unpretreated sample: 1#～2#：符合Pass 预处理样品Pretreatedsample: 1#～2#：符合Pass	符合 Conformity

检 验 报 告

检 验 项 目 Test Item	标 准 要 求 Requirement	实 测 结 果 Test Result	单项结论 Conclusion
6.可燃性 Flammability (GB 2626-2006) 续燃时间(s) Afterflame time	≤5	(GB 2626-2006) 随弃式面罩Disposable facepiece: 未预处理样品Unpretreated sample: 1# 2# 0.0 0.0 预处理样品Pretreated sample: 1# 2# 0.0 0.0 头模鼻尖位移速度：60mm/s Displacement speed of Head mold nose tip: 60mm/s 距离燃烧器顶端20mm处的火焰温度：815℃ Flame temperature at 20mm from the top of the burner: 815℃	符合 Conformity

附注：

1.此报告以中文为准，英文仅作参考。The Chinese version of this test report is the standard one, the English version is only for reference.

2.温度湿度预处理，顺序按下述条件处理：

The sequence of temperature and humidity pretreatment is as follows:

a）在(38±2.5)℃和(85±5)%相对湿度环境放置（24±1）h

Place at (38 ± 2.5) ℃ and (85 ± 5)% relative humidity for (24 ± 1) hours;

b）在(70±3)℃ 干燥环境处理（24±1）h

Treatment in dry environment at (70 ± 3) ℃ for (24 ± 1) hours;

c）(-30±3)℃环境放置（24±1）h

Place at (-30 ± 3) ℃ for (24 ± 1) hours;

样品温度经恢复至室温后5h，再进行检测

After the sample temperature is restored to room temperature for 5 hours, the test shall be carried out again.

检 验 报 告

3.样品图片Photo(s) of the sample(s)：

以下空白 END OF REPORT

HYNAUT
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SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0599

QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD
JIANGSHAN INDUSTRIAL PARK, LAIXI, QINGDAO, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Disposable Medical Face Mask
Style No.	:	C010
Composition	:	(A)PP Non-woven, Melt-blown fabric
Sample Color	:	(A)Blue
Manufacturer	:	QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD
Country of Destination	:	EUR
Supplier	:	QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD
Proposed Care Instruction	:	-
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	May 06, 2020
Testing Period	:	May 09, 2020 - May 21, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

SGS

Test Result

Medical Face Masks-Requirements and Test Methods
(EN 14683:2019)

Clause 5.2.2 Bacterial filtration efficiency (BFE)*
(EN 14683 :2019 Annex B)

	1#	2#	3#	4#	5#
(BFE), %	>99.9	99.9	>99.9	99.9	99.9

Remark: Performance Requirement: Type I≥95%, Type II≥98%, Type IIR≥98%
* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CMA (China Metrology Accreditation).

Clause 5.2.3 Breathability (Differential Pressure)
(EN 14683 :2019 Annex C, Flow rate 8 l/min)

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm^2)	34	34	35	36	35

Remark: Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Fail	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			31				
Overall result:			Acceptable				

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

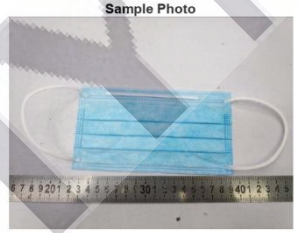
SGS

Clause 5.2.5 Microbial Cleanliness
(EN 14683: 2019 Annex D)

	1#	2#	3#	4#	5#
CFU/g	<1	<1	<1	<1	<1

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

TEST REPORT

报告编号：WT204032177 (替代WT204025656报告)

委 托 单 位 ： 青岛海诺生物工程有限公司QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD.

委托单位地址 ： 青岛市莱西市姜山镇工业园广东路1号NO.1 GUANGDONG ROAD,JIANGSHAN INDUSTUIAL ZONE LAIXI CITY, QINGDAO, CHINA

样 品 名 称 ： 见附页 Refer To Next Pages

型号/规格/等级： 非无菌 耳挂式平面型17.5cm*9.5cm

检 验 类 别 ： 送样检验

检 验 地 点 ： 龙华实验基地Longhua Experimental Base

深圳市计量质量检测研究院
（检验检测专用章）

批准人： 何行月

签发日期：2020年04月20日 签名 ： 何行月

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

报告编号：WT204032177

检验项目 Test Item	标准要求 Requirement	实测结果 Test Result	单项结论 Conclusion
2.外观 Appearance (YY/T 0969-2013)	4.1条 4.1Requirement	(YY/T 0969-2013) 1#~3#符合Conformity	符合 Conformity
2.结构与尺寸 Structure and size (YY/T 0969-2013)		(YY/T 0969-2013)	符合 Conformity
1).结构Structure	4.2条 4.2Requirement	1#~3#符合Conformity	
2).尺寸Size	4.2条 4.2Requirement	偏差Deviation rate (%) 1# 2# 3# 长度length: -0.6 -0.6 -0.6 宽度width: -1.1 -1.1 -1.1	
3.鼻夹Nose clip (YY/T 0969-2013)		(YY/T 0969-2013)	符合 Conformity
	4.3.1条 4.3.1Requirement 4.3.2条 4.3.2Requirement	1#~3#符合 Conformity 长度length (cm): 1# 2# 3# 10.2 10.3 10.2	
4.口罩带Mask string (YY/T 0969-2013)		(YY/T 0969-2013)	符合 Conformity
	4.4.1条 4.4.1Requirement 4.4.2条 4.4.2Requirement	符合Conformity 1#~3#:符合Conformity (定负荷Fixed load: 10N, 持续continuous: 5s)	

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

报告编号：WT204032177

检验项目 Test Item	标准要求 Requirement	实测结果 Test Result	单项结论 Conclusion
5.细菌过滤效率（%） Bacterial filtration efficiency (BFE) (YY/T 0969-2013)	≥95	(YY 0469-2011) 1# 2# 3# 100 100 100	符合 Conformity
6.通气阻力(Pa/cm²) Ventilation resistance (YY/T 0969-2013)	≤49	(YY/T 0969-2013) 1# 2# 3# 39.3 42.7 39.1 (气体流量Gas flow: 8L/min)	符合 Conformity
7.微生物 Microorganisms (YY/T 0969-2013)		(GB 15979-2002)	符合 Conformity
细菌菌落总数 (CFU/g) Total amount of bacterial colony	≤100	<4	
大肠菌群 Coliform group	不得检出No detected	未检出Not detected	
绿脓杆菌 Pseudomonas aeruginosa	不得检出No detected	未检出Not detected	
金黄色葡萄球菌 Staphylococcus aureus	不得检出No detected	未检出Not detected	
溶血性链球菌 Streptococcus hemolyticus	不得检出No detected	未检出Not detected	
真菌Fungal colony	不得检出No detected	未检出Not detected	

Messrs *QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD.*
NO.1 GUANGDONG ROAD,
JIANGSHAN INDUSTUIAL ZONE LAIXI CITY, QINGDAO, CHINA

Sample Identification: XIANS001 - DISPOSABLE SURGICAL MASK DATE OF MANUFACTURE 2020/03/17 - EXPIRATION DATE 2023/03/17 - 200317 - MANUFACTURER HAINUO
Sampling: Customer
Sampling site: Customer Site

Transport : External Representate - Room Temperature
Storage : Room Temperature

Recording Date : 20/04/2020
Beginning Test Date : 20/04/2020
End Test Date : 05/05/2020

MEDICAL FACE MASKS. REQUIREMENTS AND TEST METHODS

Scope — Evaluation of performance requirements of the medical face mask according to UNI EN 14683:2019

LABORATORIO ANALISI TECNAL
Errata Corrige n° 3434 of 08/05/2020 to this Report which deletes and replaces the previous
Test Report 361223 Date 06/05/2020 Sample n° 697240

Performance requirements for medical face masks (UNI EN 14683:2019, § 5.2.7):

Table 1

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

Summary of the test results:

Table 2

Test	Result	Compliance by type		
		Type I	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	99,6	Passed	Passed	Passed
Differential pressure (Pa/cm^2)	33	Passed	Passed	Passed
Splash resistance pressure (kPa)	Not performed			
Microbial cleanliness (cfu/g)	4	Passed	Passed	Passed

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TECNAL s.r.l. - Via Castelfranco, 17/D - Loc. Bazzano 40053 VALSAMOGGIA (BO) – Tel 051 832915 - Fax 051 830802 www.tecnal.it – laboratorio@tecnal.it P.I. 00579881202 - C.F.02460570373 - R.E.A. n° 290231 - Ca. Soc. 26.000,00 i.v. - Registro Laboratori Autocontrollo Emilia Romagna N° 008/BO/005
Doc.01 Modello 13S Rev.01 Del 17/02/2020 Pagina 2 di 9

LABORATORIO ANALISI TECNAL
Errata Corrige n° 3434 of 08/05/2020 to this Report which deletes and replaces the previous
Test Report 361223 Date 06/05/2020 Sample n° 697240

Bacterial filtration efficiency (BFE)

Principle and Normative References

Scope	Evaluation of efficiency of the medical face mask material(s) as a barrier to bacterial penetration
Normative References	UNI EN 14683:2019

Experimental conditions

N° of medical face masks tested	5
Dimensions of the test specimens	100 mm x 100 mm
Size of the area tested	49 cm^2
Side of the test specimen facing the aerosol	Inside
Flow rate during testing	28,3 L/min
Test strain	*Staphylococcus aureus* ATCC 6538
Specimen conditioning	21 ± 5 °C and 85 ± 5 % HR for 4h
Incubation conditions	37 ± 2 °C for 20-52 h

Procedure:

Following procedures are performed for each of the five tested masks.
A representative test specimen of at least 100 mm x 100 mm is obtained from each mask. The specimen is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* ATCC 6538 is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (B) of each test specimen is calculated, as percentage using the following formula:

$B = (C - T) / C \times 100$

Where:
C is the mean of the total plate counts for the two positive control runs;
T is the total plate count for the test specimen.

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TECNAL s.r.l. - Via Castelfranco, 17/D - Loc. Bazzano 40053 VALSAMOGGIA (BO) – Tel 051 832915 - Fax 051 830802 www.tecnal.it – laboratorio@tecnal.it P.I. 00579881202 - C.F.02460570373 - R.E.A. n° 290231 - Ca. Soc. 26.000,00 i.v. - Registro Laboratori Autocontrollo Emilia Romagna N° 008/BO/005
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Results

Table 3 summarizes results obtained with the Bacterial filtration efficiency (BFE) test.

Table 3

Parameter *Test Method*	U.M.	Results
Positive controls	cfu	1700-3000
Negative control	cfu	0
Bacterial filtration efficiency BFE, Sample 1 *UNI EN 14683:2019 (Annex B)*	%	99,5
Bacterial filtration efficiency BFE, Sample 2 *UNI EN 14683:2019 (Annex B)*	%	99,7
Bacterial filtration efficiency BFE, Sample 3 *UNI EN 14683:2019 (Annex B)*	%	99,5
Bacterial filtration efficiency BFE, Sample 4 *UNI EN 14683:2019 (Annex B)*	%	99,6
Bacterial filtration efficiency BFE, Sample 5 *UNI EN 14683:2019 (Annex B)*	%	99,8
Bacterial filtration efficiency BFE, Mean *UNI EN 14683:2019 (Annex B)*	%	99,6

cfu: colony forming units; Positive control: test run without test specimen; Negative control: test run without bacterial suspension.

Breathability

Principle and Normative References

Scope	Evaluation of efficiency of the air permeability of the mask.
Normative References	UNI EN 14683:2019

Experimental conditions

N° of medical face masks tested	5
General location of the areas tested	Front
Size of the area tested	4,9 cm^2
Side of the test specimen facing the airflow	Inside
Air flow rate during testing	8 L/min
Specimen conditioning	21 ± 5 °C and 85 ± 5 % HR for 4h

Procedure:

Following procedures are performed for each of the five tested masks.
A device, which measures the differential pressure required to draw air through a specimen surface area of 4,9 cm^2 at a constant air flow rate of 8 L/min, is used to measure the air exchange pressure of the medical face mask material. A differential manometer is used to measure the differential pressure required to move air through the specimen surface area.

Results

Table 4 summarizes results obtained with the differential pressure test.

Table 4

Parameter *Test Method*	U.M.	Results
Differential pressure, Sample 1 *UNI EN 14683:2019 (Annex C)*	Pa/cm^2	34,2
Differential pressure, Sample 2 *UNI EN 14683:2019 (Annex C)*	Pa/cm^2	34,3
Differential pressure, Sample 3 *UNI EN 14683:2019 (Annex C)*	Pa/cm^2	30,6
Differential pressure, Sample 4 *UNI EN 14683:2019 (Annex C)*	Pa/cm^2	32,8
Differential pressure, Sample 5 *UNI EN 14683:2019 (Annex C)*	Pa/cm^2	32,6
Differential pressure, Mean *UNI EN 14683:2019 (Annex C)*	Pa/cm^2	33

Microbial cleanliness (Bioburden)

Principle and Normative References

Scope	Evaluation of microbial cleanliness performance requirements in medical face mask.
Normative References	UNI EN 14683:2019

Experimental conditions

N° of medical face masks tested	5
Culture media:	
Extraction liquid (used volume)	1g/L Peptone, 5g/L NaCl, 2g/L Polysorbate 20 (300 mL)
Total viable aerobic microbial count	TSA (Tryptic Soy Agar)
Total yeasts and moulds count	SDCA (Sabouraud Dextrose Agar with Chloramphenicol)
Extraction method	Orbital shaker for 5 min at 250 rpm
Analytical method	Membrane filtration (pore size 0,45 µm)
Incubation conditions:	
Total viable aerobic microbial count	30 ± 1 °C for 3 days
Total yeasts and moulds count	25 ± 1 °C for 7 days
Correction factor determined by the bioburden recovery efficiency	1,24

Procedure:

Following procedures are performed for each of the five tested masks.
Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid. The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDCA for yeasts and moulds enumeration. The plates are incubated for 3 days at 30 °C and 7 days at 25 °C for TSA and SDCA plates respectively.
The total bioburden is expressed by addition of the TSA and SDCA counts adjusted by a correction factor calculated from the bioburden recovery efficiency.

LABORATORIO ANALISI TECNAL
Errata Corrige n° 3434 of 08/05/2020 to this Report which deletes and replaces the previous
Test Report 361223 Date 06/05/2020 Sample n° 697240

Results

Table 5 summarizes results obtained with the microbial cleanliness (bioburden) tests.

Table 5

Parameter *Test Method*	U.M.	Results
Microbial cleanliness (Bioburden), Sample 1 *ISO 11737-1:2018*	cfu/mask[#]	11
Microbial cleanliness (Bioburden), Sample 2 *ISO 11737-1:2018*	cfu/mask[#]	< 7
Microbial cleanliness (Bioburden), Sample 3 *ISO 11737-1:2018*	cfu/mask[#]	< 7
Microbial cleanliness (Bioburden), Sample 4 *ISO 11737-1:2018*	cfu/mask[#]	22
Microbial cleanliness (Bioburden), Sample 5 *ISO 11737-1:2018*	cfu/mask[#]	11
Microbial cleanliness (Bioburden), Total *ISO 11737-1:2018*	cfu/g	4

[#] **Values adjusted by the bioburden correction factor.**

LABORATORIO ANALISI TECNAL
Errata Corrige n° 3434 of 08/05/2020 to this Report which deletes and replaces the previous
Test Report 361223 Date 06/05/2020 Sample n° 697240

Test Notes

MP: Laboratory-developed method
U.M.: Measurement Unit
Parameter Note: parameter information

N.R.: Not Detectable
The "Limits" column shows: the limits of quantification or detectability indicated with "(LDQ or LDR", the legal limits and / or guide values agreed with the client (The value indicated, if expressed in round brackets (), is to be considered "Guide Value" - Otherwise it is to be considered "Law Limit").
Errata Corrige/Supplemento: the change made to this test report are indicated in underlined and italic font
The result of the quantitative evidence on surfaces is obtained by recalculation performed on the basis of the measure declared by the person who performed the sampling.

Quantitative microbiological tests:
Quantitative microbiological tests are performed in single replication in accordance with ISO 7218: 2007 / Amd1: 2013. Expression of the result by matrix Food / Surfaces in accordance with ISO7218: 2007 / Amd1: 2013:
Present <4 or Present <40 or Present <400: means "microorganisms present but less than 4 or 40 or 400 cfu / g or cfu / ml" which means that the number of colonies grown in the plate at the first useful dilution is between 1ufc and 3 ufc.
Estimates: the estimated expression means that the number of colonies grown in the plate at the first useful dilution is between 4 cfu and 9 cfu. Expression of the result by Water matrix in compliance with ISO 8199:2018:
Present <3 or Present <300: means "Microorganisms present in the volume taken into consideration but less than 3 or 300 cfu / Volume" which means that the number of colonies grown in the plate at the first useful dilution is between 1 or 2 cfu.
Estimates: the estimated expression means that the number of colonies grown in the plate at the first useful dilution is between 3 cfu and 9 cfu

Uncertainty of measurement (I.D.M.):
For microbiological parameters the extended uncertainty of measurement is expressed as confidence interval (lower limit - upper limit) with coverage factor K = 2 and with confidence level of 95%. Quantitative tests are performed in a single replica in accordance with ISO 7218: 2007 / Amd 1: 2013.

For chemical parameters the extended uncertainty values refer to a 95% confidence interval and a coverage factor K = 2

Documentation traceability:

The description of Laboratory-developed methods (MP), test procedures (PP) methods normed and Operating Procedures (P.O.) are at your disposal in the laboratory.

In laboratory are available all the documentation to trace the technicians who carried out the tests, as well as the sampling and transport.

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深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告
TEST REPORT

报告编号：WT204025664

委 托 单 位 ： 青岛海诺生物工程有限公司 QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD

委托单位地址 ： 青岛市莱西市姜山镇工业园广东路1号NO.1 GUANGDONG ROAD, JIANGSHAN INDUSTUIAL ZONE LAIXI CITY, QINGDAO, CHINA

样 品 名 称 ： 防护口罩Protective Face Mask

型号/规格/等级： 无纺布平面型C001, C006

检 验 类 别 ： 送样检验

检 验 地 点 ： 龙华实验基地Longhua Experimental Base

深圳市计量质量检测研究院
（检验检测专用章）

批准人： 何行月 陈晶

签发日期：2020年05月08日 签名 ：

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

样品信息：
样品名称： 防护口罩Protective Face Mask
商标： HYNAUT海氏海诺
型号/规格/等级： 无纺布平面型C001, C006
样品编/批号： 200331
生产日期： 2020-03-31
生产单位： 青岛海诺生物工程有限公司
生产单位地址： 青岛市莱西市姜山镇工业园
样品数量： 50只 抽样基数： ----------
抽样地点： ----------
抽样人员： ----------
检前样品描述： 正常，Normal.

客户信息：
委托单位： 青岛海诺生物工程有限公司 QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD
委托单位地址： 青岛市莱西市姜山镇工业园广东路1号NO.1 GUANGDONG ROAD, JIANGSHAN INDUSTUIAL ZONE LAIXI CITY, QINGDAO, CHINA
委托单位电话： 17561677800
邮政编码： ----------
受检单位： ----------

检验信息：
委托日期： 2020年04月20日 委托单号： 8249571
检验类别： 送样检验 获样方式： 送样
检验日期： 2020年04月20日 至 2020年05月08日
检验环境条件： （18～25）℃ （30～70）%RH
判定依据： T/CTCA 7-2019
检测依据： 见附页 refer to next pages

检验结论：
检验结果见附页
Test result refer to next pages.

主检： 谢丹菊 郭正祥 审核： 陈开江 黄建飞

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

检验项目 Test Item	标准要求 Requirement	实测结果 Test Result	单项结论 Conclusion
1.通气阻力（Pa） Ventilation resistance （T/CTCA 7-2019）	≤80	（YY 0469-2011） 1# 2# 3# 34.4 33.7 37.8 空气流量Flow：30L/min	符合 Conformity
2.颗粒物过滤效率 Particle filtration efficiency （%） （T/CTCA 7-2019）	≥80	（YY 0469-2011） 1# 2# 3# 94.23 93.98 94.66 气溶胶颗粒Aerosol chamber：NaCl 气溶胶浓度concentration of Aerosol chamber：15mg/m³ 温度Temperature：24.7℃ 相对湿度Relative humidity：34.7%	符合 Conformity
3.口罩带及口罩带与口罩体的连接处断裂强力 Tensile Strength of mask string and connect part between mask string and mask （N） （T/CTCA 7-2019）	≥10	（YY 0469-2011） 1#～3#符合 Conformity （定负荷：10N，持续5s） （fixed load:10N, lasting for 5s）	符合 Conformity

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

检验项目 Test Item	标准要求 Requirement	实测结果 Test Result	单项结论 Conclusion
4.细菌过滤效率(%) Bacterial filtration efficiency (BFE) （T/CTCA 7-2019）	≥95	（YY 0469-2011） 1# 2# 3# 100 100 100	符合 Conformity

附注Note：
1.此报告以中文为准，英文仅作参考。The Chinese version of this test report is the standard one, the English version is only for reference.
2.我院获CNAS认可能力范围未涉及T/CTCA 7-2019；
Testing scopes of CNAS do not involve T/CTCA 7-2019.

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深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

TEST REPORT

（替代WT204029174报告）

报告编号：WT204032179

委 托 单 位 ： 青岛海诺生物工程有限公司 QINGDAO HAINUO BIOLOGICAL ENGINEERING CO. LTD.

委托单位地址 ： 见附页 Refer To Next Pages

样 品 名 称 ： 防护口罩 KN95 Protective Face Mask

型号/规格/等级： C005

检 验 类 别 ： 送样检验

检 验 地 点 ： 龙华实验基地Longhua Experimental Base

深圳市计量质量检测研究院
（检验检测专用章）

批准人： 何行月

签发日期： 2020年04月20日

签名 ： 何行月

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

检 验 项 目 Test Item	标 准 要 求 Requirement	实 测 结 果 Test Result	单项结论 Conclusion
死腔(%) Dead space (GB 2626-2006)	≤1	(GB 2626-2006) 随弃式面罩Disposable facepiece: 0.56 (温度Temperature：23.8℃)	符合 Conformity

附注：

1.此报告以中文为准，英文仅作参考.The Chinese version of this test report is the standard one, the English version is only for reference.

2.温度湿度预处理，顺序按下述条件处理：

The sequence of temperature and humidity pretreatment is as follows:

a）在(38±2.5)℃和(85±5)%相对湿度环境放置（24±1）h

Place at (38 ± 2.5) ℃ and (85 ± 5)% relative humidity for (24 ± 1) hours;

b）在(70±3)℃ 干燥环境处理（24±1）h

Treatment in dry environment at (70 ± 3) ℃ for (24 ± 1) hours;

c）(-30±3)℃环境放置（24±1）h

Place at (-30 ± 3) ℃ for (24 ± 1) hours;

样品温度经恢复至室温后5h，再进行检测

After the sample temperature is restored to room temperature for 5 hours, the test shall be carried out again.

3.生产单位地址Manufacturer Address，委托单位地址 Applicant Address：

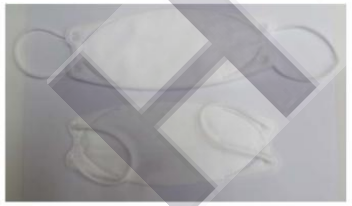
青岛市莱西市姜山镇工业园广东路1号

NO.1 GUANGDONG ROAD, JIANGSHAN INDUSTUIAL ZONE LAIXI CITY, QINGDAO, CHINA.

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

4.样品图片Photo(s) of the sample(s)：



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161019130764

国检检测 CHINA COMPONENTS TEST

检验检测报告
Test Report

（2020）WSZ FHL 第1381号

产品名称 Product Name：防霾防护口罩

委托单位 Applicant：青岛海诺生物工程有限公司

生产单位 Manufacturer：青岛海诺生物工程有限公司

检验检测类别 Test Type：委托检验

江苏国健检测技术有限公司
Jiangsu Guojian Testing Technology Co.,Ltd

检验专用章

检验检测报告
Test Report

[2020] WSZ FHL 第 1381 号　　共 2 页 第 1 页

产品名称 Product name	防霾防护口罩	规格型号 Specification	柳叶型 L
		商　标 Brand	HYNAUT 海氏海诺
委托单位/地址/联系电话 Applicant/Add/Tel	青岛海诺生物工程有限公司/青岛市莱西市姜山镇工业园/0532-86463333		
生产单位/地址/联系电话 Manufacturer/Add/Tel	青岛海诺生物工程有限公司/青岛市莱西市姜山镇工业园/0532-86463333		
样品等级 Sample grade	KN95	样品编号 Sample number	GW 1381-2020
样品数量 Sample quantity	26 只	样品接收日期 Receiving date of sample	2020 年 02 月 28 日
检验检测类别 Test type	委托检验	货号/批号/款号 Article number/Batch number/Style number	批号：200203
检验检测日期 Test date	2020/02/28~2020/03/02	检验检测地点 Test site	本公司检验室
样品状态 Sample state	符合检验检测要求		
检验检测依据 Test standard(s)	GB 2626-2006《呼吸防护用品 自吸过滤式防颗粒物呼吸器》		
检验检测项目 Test items	过滤效率、呼吸阻力		
检验检测结论 Test conclusion	样品经检验，所检项目符合 Q/0285HNS 039 标准规定的要求，具体检验结果详见第 2 页。 签发日期 2020 年 3 月 5 日		
备　注 Note	委托方要求所检项目按照 Q/0285HNS 039《防护口罩》进行判定 样品信息由委托方提供，本报告仅对来样负责 报告有效期为 1 年		

批准：　　审核：万恒　　主检：杨莹

检验检测结果
Test Result

[2020] WSZ FHL 第 1381 号　　共 2 页 第 2 页

序号 Number	检验检测项目 Test item		单位 Unit	技术要求 Technical requirement	检验检测结果 Test result		单项评价 Single item decision
1	呼吸阻力	吸气阻力	Pa	≤175	未预处理	103.2	合格
						98.7	
					预处理	99.6	
						97.3	
		呼气阻力		≤145	未预处理	83.1	合格
						80.2	
					预处理	81.2	
						80.7	
2	过滤效率		—	≥95%	未预处理	98.9%	合格
						98.8%	
						99.1%	
						99.0%	
						99.1%	
						99.2%	
						98.7%	
						98.9%	
						98.9%	
						99.2%	
					预处理	99.0%	
						98.7%	
						98.8%	
						99.1%	
						99.3%	
备注							

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