

HYNAUT
海氏海诺®

青岛海诺生物工程有限公司

Qingdao Hainuo Biological Engineering Co., Ltd.

青岛海诺生物工程有限公司，是一家集研发、生产、销售为一体的生物科技企业，隶属于青岛海氏海诺集团，集团成立于2004年，拥有逾20多家子公司，总部位于青岛莱西市姜山工业园区，厂区占地1000余亩，毗邻姜山湖、青荣轻轨、高速公路、青岛国际机场、青岛港码头，距华山国际高尔夫球场一步之遥，地理位置优越，交通便利。



公司拥有符合国际化标准的现代化厂房、车间及物流仓储设施，配有国际先进的生产设备及高精尖检测仪器。有包括国家级“千人计划”专家3人，院士3人，医学类博士30人。





HYNAUT
海氏海诺®



生产线

检测设备



“千人计划”专家

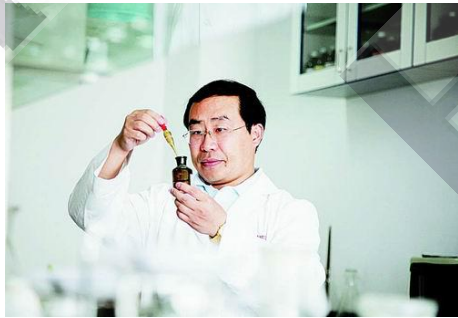


国家级千人专家**惠觅宙**教授专利产品，**B-HA**（活性透明质酸）牙膏及鼻咽喷雾，广谱抗菌消炎，目前已取得美国专利。

千人专家**宁新**教授现在的主要研究领域为非织造材料和装备，卫生及医用耗材，产业纺织品复合材料，高分子药物释放体系，环境工程功能纤维及材料。



千人专家**姜国辉**教授主持的利用核技术研究新型特效中草药有效成份药物课题，曾多次获得国家自然科学基金及国家重点学科项目基金资助，具有丰富的药理学、毒理学、分子生物学及新药研究开发经验。



陈璞 院士



加拿大工程院院士、加拿大纳米生物材料方向国家首席教授。陈璞院士牵头的小核酸类抗肿瘤新药研发项目, 在纳米生物医药技术领域处于国际领先水平。我们与陈院士合作成立的青岛泰诺德生物科技公司, 项目进展顺利, 拟在姜山设立工作站, 2020年将实现4000万销售收入。

希拉姆 院士



英国皇家工程院外籍院士、印度国家工程院院士、新加坡工程院院士。研究方向为高分子复合材料、生物复合材料、静电纺丝纳米纤维的加工和表面功能化，在多个科学领域进行了独创性的研究，在纳米科技领域做出了巨大贡献。

管华诗 院士

中国工程院院士，我国海洋医药方面的专家，中国“蓝色药库”的倡导者，一种以海洋生物治疗阿尔茨海默症的主要研发者。我们与青岛海大海洋医药生物研究院合作成立海生健康科技公司，联合开发海洋医药类产品。



海氏海诺集团先后多次被评为“中国创口贴行业三强企业”，年销售额超40亿，是全国第二大创口贴品牌，其中，卡通创口贴开创国内创口贴行业先河。公司主营产品有：一次性使用医用外科口罩、一次性使用医用口罩、KN95防护口罩、创口贴、医用输液贴、压敏胶带、医用消毒棉球、医用消毒棉片、创伤应急包、注射器、输液器、早早孕试纸、排卵试纸、防磨脚贴、暖贴、医用退热贴、纱布绷带、消毒液、牙线棒、玻尿酸牙膏、医用护理垫、冰垫、避孕套等百余品种。



海诺公司先后获得“青岛守合同重信用企业”、“青岛市优秀民营企业”、“山东省名优企业博览会优秀奖”、“中国医用敷料行业杰出品牌”、“中国优秀民营企业”等荣誉称号，董事长麻兆晖获得“青岛市企业家新锐奖”。2010年“HAINUO”商标被评为“山东省著名商标”，海诺牌创伤应急包被评为“山东名牌”。2012年公司被评为“莱西优秀福利企业”、“中国医疗器械行业最具创新活力竞争力前三强企业”、“青岛市高新技术企业”，2013年公司被中国社会福利协会评为“全国福利企业示范单位”、“青岛市医用敷料工程技术研究中心”，“海氏海诺”商标被评为“山东著名商标”，2015年“HAINUO”品牌被评为“中国驰名商标”，2016年公司被评为青岛市工业企业“隐形冠军”企业。2017年公司产品“无菌敷贴”被评为“青岛市专精特新产品”，公司被评为青岛市专精特新示范企业。



2008年海诺携手美国华纳公司，让风靡世界的猫和老鼠卡通形象成为海诺产品的形象代言。2013年，公司与美国华纳合作在“TOM and JERRY”成为公司产品形象代言的基础上成功签约“超人”形象，海氏海诺产品走进万户千家。



《取得国外标准认证或注册的医疗物资生产企业清单》白名单企业

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

30
1988-2018



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

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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

* 医用口罩 欧盟CE认证

青岛海诺生物工程有限公司是国家防疫物资白名单企业、银行特殊授信财政贴息补贴单位、国家和省药监局口罩许可白名单企业。

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予于医

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 国际贸易 口罩

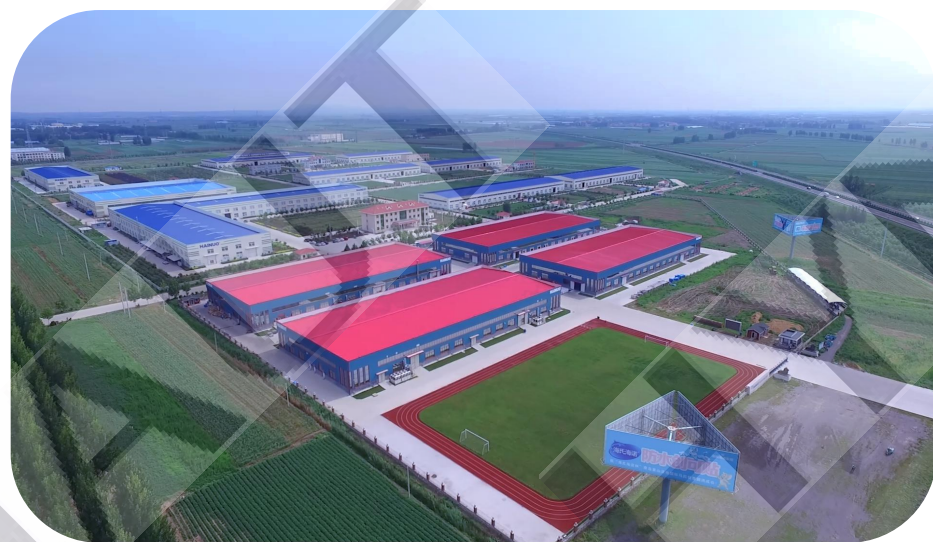
昨天（4月25日）傍晚，商务部、海关总署和国家市场监督管理总局紧急发布 2020年第12号公告，宣布进一步升级对包括非医用口罩在内防疫物资出口质量监管措施！

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！这基本可以看作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20162640455	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20162640872	医用口罩	山东华景医疗器械有限公司
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20162640383	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20162640682	医用外科口罩	青岛上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



集团在国内与逾20万家药店和多家连锁便利店达成长期战略合作，产品不仅在国内享有极高的知名度和声誉，同时远销海外，深受欧美等地区消费者青睐。近年来，随着集团规模的日益壮大，产品，产线，技术和研发团队都与日俱进。我们始终立于行业的前沿，致力于提供最尖端的产品与最完善的服务。

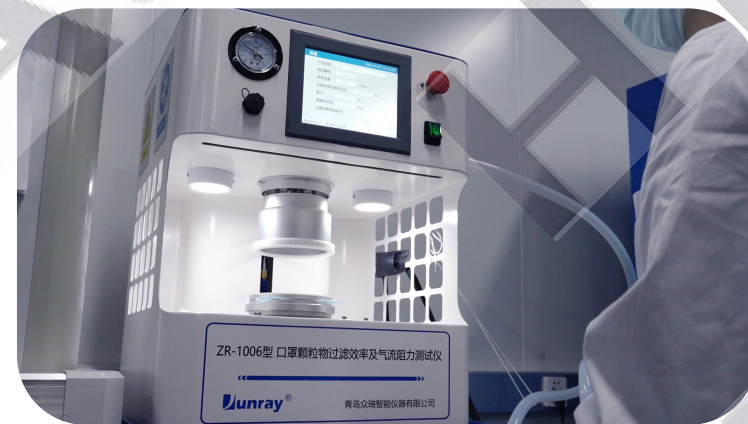


已合作的全国百强连锁药店



公司曾承办多届国际性马拉松及马术比赛，努力促进体育与文化、科技的融合与发展。



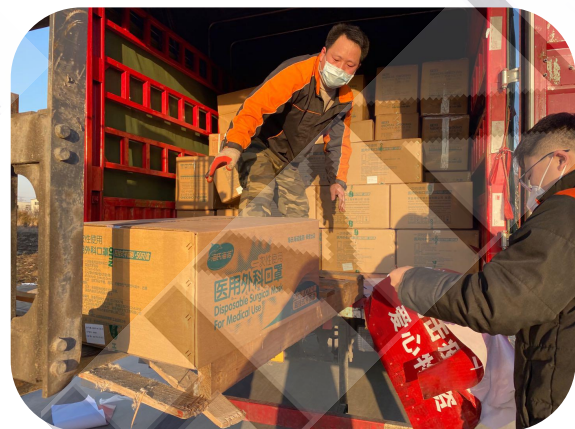


新冠肺炎疫情发生后，公司投资8000余万元，新上多条一次性医用口罩，KN95防护口罩，酒精、碘伏棉片，PE手套等生产线，目前口罩日产量达360万只。



央视、新华网、青岛新闻等相关报道





集团已累计向武汉、青岛医疗队、潘基文基金会等国内外抗疫一线捐赠包括防护用品、酒精消毒类产品和日用品，总价值达**1000**多万元。



口罩系列产品

- 海氏海诺HYNAUT品牌，工厂直销，品质保证，直签合同，交易安心。
- CE/FDA资质齐全，可提供各种产品检测报告。





一次性三层防护口罩 Disposable Face Mask

采用三层设计：无纺布+熔喷布+无纺布
non-woven + melt-blown + non-woven

- 一次性民用
- 一次性医用
- 一次性医用外科

欧盟标准 **EN14683 type I**
 欧盟标准 **EN14683 type IIR**

包装Packing	箱规 L*W*H	Gross Weight 毛重	Net Weight 净重	Volume 体积
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





KN95口罩(柳叶型) KN95 Protective Face Mask (Willow Leaf)

*采用四层设计：无纺布+熔喷布*2层+无纺布
non-woven + melt-blown x2 + non-woven

*每袋1片独立包装，每箱200袋。
1pc/bag, 200bags/ctn

*四层防护，多重过滤，过滤效率 $\geq 95\%$ 。
柳叶形剪裁，更贴合面部，佩戴舒适。



包装Packing	箱规 L*W*H	Gross Weight 毛重	Net Weight 净重	Volume 体积
1pcs/bag*200bags=200pcs/ctn	29.5*25.5*22.5	1.9	1.55	0.017





KN95口罩(立体型) KN95 Protective Face Mask (Folded)

*采用四层设计：无纺布+熔喷布*2层+无纺布
non-woven + melt-blown x2 + non-woven

*每袋1片独立包装，每箱200袋。
1pc/bag, 200bags/ctn

*四层防护，多重过滤，过滤效率 $\geq 95\%$ 。
立体设计，佩戴安心舒适。



包装Packing	箱规 L*W*H	Gross Weight 毛重	Net Weight 净重	Volume 体积
1pcs/bag*200bags=200pcs/ctn	34*20.5*22.5	1.9	1.55	0.016

HYNAUT

海氏海诺®

儿童用



公司资质

HYNAUT
海氏海诺®



营业执照

(副本) 1-1

统一社会信用代码
913702857180717488

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
等信息

名称	青岛海诺生物工程有限公司	注册资本	贰仟万元整
类型	有限责任公司(自然人投资或控股)	成立日期	2000年05月29日
法定代表人	麻兆晖	营业期限	2000年05月29日至 年 月 日
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)		
登记机关	莱西市行政审批服务局		
	2020年03月23日		

<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: I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

山东省食品药品监督管理局

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

国家食品药品监督管理总局制

中华人民共和国医疗器械注册证

注册证编号: 鲁械注准 20140101001

注册人名称	青岛海诺生物工程技术有限公司
注册人住所	青岛莱西市莱山镇工业园
生产地址	青岛莱西市莱山镇工业园
代理人名称	“进出口医疗器械进口”
代理人住所	“进口医疗器械进口”
产品名称	一次性使用医用口罩 (非外科用)
型号、规格	非挂式平面形 17.5cmX18.5cm, 18.5cmX18.5cm 带绳式平面形 17.5cmX18.5cm 非挂式平面形 18.5cmX18.5cm, 17.5cmX18.5cm
结构及组成	由口罩体、鼻夹和口带等组成,口罩体有正反面结构分为:内、外层与聚丙烯(PP)无纺布,中间层为聚丙烯(PP)无纺布,鼻夹为聚乙烯(PE)软质材料,口带为弹性或非弹性材料,弹性材料为聚酯,非弹性材料为聚丙烯(PP)无纺布。
适用范围	按照该类产品说明书中操作过程中佩戴,覆盖住使用者口鼻,避免飞沫、尘埃、细菌等传播,防止病毒等通过呼吸道传播。
附件	注册产品技术要求、合格证
其他内容	
备注	

青岛莱西市市场监督管理局

中华人民共和国医疗器械注册证

注册证编号: 鲁械注准 20140101001

注册人名称	青岛海诺生物工程技术有限公司
注册人住所	青岛莱西市莱山镇工业园
生产地址	青岛莱西市莱山镇工业园
代理人名称	“进出口医疗器械进口”
代理人住所	“进口医疗器械进口”
产品名称	一次性使用医用口罩 (非外科用)
型号、规格	非挂式平面形 17.5cmX18.5cm, 18.5cmX18.5cm 带绳式平面形 17.5cmX18.5cm 非挂式平面形 18.5cmX18.5cm, 17.5cmX18.5cm
结构及组成	由口罩体、鼻夹和口带等组成,口罩体有正反面结构分为:内、外层与聚丙烯(PP)无纺布,中间层为聚丙烯(PP)无纺布,鼻夹为聚乙烯(PE)软质材料,口带为弹性或非弹性材料,弹性材料为聚酯,非弹性材料为聚丙烯(PP)无纺布。
适用范围	按照该类产品说明书中操作过程中佩戴,覆盖住使用者口鼻,避免飞沫、尘埃、细菌等传播,防止病毒等通过呼吸道传播。
附件	注册产品技术要求、合格证
其他内容	
备注	

青岛莱西市市场监督管理局

对外贸易经营者备案登记表

备案登记表编号: 进出口企业代码:

经营者中文名称	青岛海诺生物工程技术有限公司		
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	青岛市莱西市莱山镇工业园		
经营场所(中文)	青岛市莱西市莱山镇工业园		
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	2010-5-29	工商登记注册号	37010120100000000000000000000000

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	麻兆晖	有效证件号	
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 个体工商户负责人姓名	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户负责人签字



2013 年 11 月 06 日

CERTIFICATE



PAGE 1 of 2

CERTIFICATE OF FDA REGISTRATION

Certification No.: 912146-2012313

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

Owner/Operator Number: 10040387
Registration Number: 3008808560



General Manager
CH REGISTRATION LLC
Email: ch@china-med.com
Web: <http://www.ch-med.com/>

Validity: Nov.7, 2019 - Dec.31, 2020

Conclusion:
This certificate makes no other representations or warranties, nor does it make any representations or warranties to any person or entity other than the named certificate holder. CMC assumes no liability in any person or entity in connection with the foregoing. 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. CMC is not affiliated with the U.S. Food and Drug Administration.

FDA QIR's Website: <https://www.fda.gov/>

FDA认证



PAGE 2 of 2

ANNEX TO CERTIFICATION

Qingdao Hainuo Biological Engineering Co., Ltd.

Listing Number	Product Submission Number	Product Code(s)	Device Name(s) / Proprietary Name	Activities
0348142	Exempt	LRY	Disinfectant, medical device / Antiseptic	Manufacturer
0148960	Exempt	XGX	Tape and bandage, adhesive / Medical Tape, Adhesive Bandage, Wound Healer	Manufacturer
0348143	Exempt	JES	FLUOUS DEVELOC / Face Mask	Manufacturer
0343009	Enforcement Decision	QSR	Semi-conduct, over-the-counter / Face Mask	Manufacturer
0147609	Exempt	FQM	STERILE, ELECTRIC / Elastic Bandage, Gaster Bandage	Manufacturer
			FACE MASK COVER	
0145680	Exempt	FMD	Warm Blank, Cold Blank, Cool Blank, Fever Relief Blank, Cool gel, Fever gel	Manufacturer
0133094	Enforcement Decision	EXR	Full absorbent device, disinfectant / Alcohol Wipes, Alcohol prep pad	Manufacturer
0300241	Exempt	XTY	APPLICATOR, ASSURERENT / THERMAL NON-STERILE / Cotton Dress	Manufacturer
0300240	Exempt	XRC	Creasing wound, hydrophilic / Wound Dressing, T.V., Adhesive Dressing	Manufacturer
0318309	Exempt	XRB	Crease / sponge non-sterile for external use / Gaster Pad, Underpad, Cotton Ball	Manufacturer
0348141	Enforcement Decision	QND	Face and lip without drug / Face and lip	Manufacturer

THIS ANNEX IS ONLY VALID IF ATTACHED TO THE CERTIFICATION MENTIONED ABOVE.

EU Declaration of Conformity

Manufacturer: QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD
NO. 1 GUANGDONG ROAD, JIANGSHAN INDUSTRIAL ZONE, LAIXI CITY, QINGDAO, CHINA
Tel: +86-532-8946333/8946444

SRN: /

European Representative: CMC Medical Devices & Drugs S.L.
Paseo Lengo N° 18, CP 29008, Málaga, Spain

Product Name: Disposable Medical Face Mask
Product Type: EN14683:2019 TYPE I
Product Code: C207
Specification: 17.5cmx5cm
GMDN Code: 12-458

Classification (MDD, Annex IX), Class I, Risk 1
Conformity Assessment Route: Annex IX of MDD, 0342/EEC

We herewith declare that the above mentioned products meet the transposition provisions of the provisions of the following EU Regulation and Standards:
All supporting documentations are retained under the provision 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 8 September 2007

Applied standards, common specification, guidance:
EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 14879:2012, EN 62366-1:2018+AC:2019, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, MDCC 2019-15

CE

Signature: _____
Name: General Manager
Position: General Manager
Place/Date: Qingdao 6 June 2020
File No.: HNCED01-01, ver A10

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 regulation requirements, the manufacturer shall affix relevant CE marking to all affix 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 1 was registered in Spanish MOH with number RPS/433/2020

CE

Issued on: 03/04/2020 Valid until: 02/04/2021

Authorized Representative
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com

CE认证

EC REP CERTIFICATE

ANNEX 1 Medical Device Products

Disposable Medical Face Mask

QINGDAO HAINUO BIOLOGICAL ENGINEERING CO LTD

www.cmcmedicaldevices.com

CE


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 Haihuo Biological Engineering Co Ltd Jiaohan Industrial Area of Jinjishan Town Lixi
 Qingdao, Shandong, 266603
 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 The mask is to assist in the reduction of the spreading of germs and bacteria.

Specific Conditions

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澳大利亚TGA

KGL

시험성적서

성적서번호 : MY18-00275

○ 시험결과

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

韩国KF94

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.

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 (%)		Test Report
			Maximum	Minimum	
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

美国疾病预防控制中心（CDC）官网发布的针对 105家中国企业产口罩的“检测报告”！

青岛海诺生物工程有限公司KN95口罩通过检测！

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)	GB2626	99.59	99.30	2020-45.1



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

Pictures have been added to the end of this report.

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)

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	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 control 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



产品质检



检验报告

TEST REPORT

第 1 页, 共 6 页



报告编号: WT204025604

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 INDUSTRIAL 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)

签发日期: 2020年04月27日

批准人: 何行月

签名: 何行月

深圳市计量质量检测研究院 Shenzhen Academy of Metrology & Quality Inspection <http://www.smq.com.cn>
电子邮箱: smq@smq.com.cn 中国合格评定国家认可委员会(CMA No.): 201517007202 & 201119001402
龙华实验基地: 深圳市龙华区民治大道民康路1114号 咨询电话: 0755-27528955 传真: 0755-27528707 邮编: 518131
Longhua Experimental Base: No.115, Minshang North Road, Minshi Avenue, Longhua District, Shenzhen Tel: 0755-27528955

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、挪用或篡改本证书/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 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。含粤字编号的 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. 对农产品监督检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检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。对食品监督检查报告有异议的, 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



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
样品编号/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
抽样地点: _____
抽样人员: _____
检前样品描述: 正常, Normal.

抽样基数: _____

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 INDUSTRIAL 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
检验类别: 送样检验
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) °C (30~70) %RH
判定依据: GB 2626-2006
检测依据: GB 2626-2006

委托单号: 8249572

获样方式: 送样

检验结论:

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

主检: 谢丹菊 谢丹菊

审核: 陈开江 陈开江

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)	5.2条规定 5.2Item Requirement	1#~2#符合 Conformity	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Untreated 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°C 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

产品质检

检验报告

报告编号: WT204025604

第 4 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
3. 呼吸阻力(Pa) Resistance of inhalation and exhalation (GB 2626-2006)	总吸气阻力Total inhalation Resistance ≤350 总呼气阻力Total exhalation Resistance ≤250	(GB 2626-2006) 吸气阻力Inhalation resistance: 未预处理样品Untreated sample: 1# 2# 76.1 70.4 预处理样品Pretreated sample: 1# 2# 111.6 128.1 呼气阻力Exhalation resistance: 未预处理样品Untreated 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)	符合 Conformity
4. 死腔(%) Dead space (GB 2626-2006)	≤1	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 不应出现滑脱、断裂 No slippage, breakage	未预处理样品Untreated sample: 1#~2#: 符合Pass 预处理样品Pretreated sample: 1#~2#: 符合Pass	符合 Conformity

检验报告

报告编号: WT204025604

第 5 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
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Untreated 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) °C 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) °C for (24 ± 1) hours;
- c) (-30±3)℃环境放置(24±1)h
Place at (-30 ± 3) °C 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

报告编号: WT204025604

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3. 样品图片Photo(s) of the sample(s):



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中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report **SL52025256537201TX** Date: May 21, 2020 Page 1 of 3
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

Sara Guo (Account Executive)



Test Report **SL52025256537201TX** Date: May 21, 2020 Page 2 of 3

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 $\geq 95\%$, Type II $\geq 98\%$, Type IIR $\geq 98\%$
* 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 ΔP (Pa/cm ²)	34	34	35	36	35

Remark: Performance Requirement: Type I <40 Pa/cm², Type II <40 Pa/cm², Type IIR <60 Pa/cm²

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: $\geq 16.0\text{kPa}$
2) Distance of the medical face mask target area surface to the tip of cannula is $300 \pm 10\text{mm}$.
3) Condition and Test temperature $(21 \pm 5)^\circ\text{C}$, relative humidity $(85 \pm 10)\%$
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



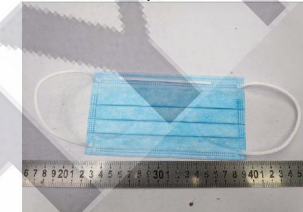
Test Report **SL52025256537201TX** Date: May 21, 2020 Page 3 of 3

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

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

检验报告

TEST REPORT



报告编号: WT204025664

第 1 页, 共 4 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 INDUSTRIAL 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 冯晶

签发日期: 2020年05月08日 签名: _____

检验报告

报告编号: WT204025664

第 2 页, 共 4 页

样品信息:

样品名称: 防护口罩Protective Face Mask
 商标: HAINUO海氏海诺
 型号/规格/等级: 无纺布平面型C001, C006
 样品编号/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
 抽样地点: _____
 抽样人员: _____
 检前样品描述: 正常, Normal.

抽样基数: _____

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 INDUSTRIAL ZONE LAIXI CITY, QINGDAO, CHINA
 委托单位电话: 17561677800
 邮政编码: _____
 受托单位: _____

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)°C (20~70)%RH
 判定依据: T/CTCA 7-2019
 检测依据: 见附录 refer to next pages

检验结论:

检验结果见附录
 Test result refer to next pages.

制: 胡月菊 审核: 陈开江 黄建飞
 主检: _____ 审核: _____

检验报告

报告编号: WT204025664

第 3 页, 共 4 页

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) I# 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) I# 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/m ³ 温度Temperature: 24.7°C 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) I#-3#符合 Conformity (定负荷:10N, 持续5s) (fixed load:10N, Lasting for 5s)	符合 Conformity

检验报告

报告编号: WT204025664

第 4 页, 共 4 页

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 (BFE) (T/CTCA 7-2019)	≥95	(YY 0469-2011) I# 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.



以下空白 END OF REPORT

产品质检



LABORATORIO ANALISI
Errata Corrigé 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

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

Sample Identification: XIAN5001 - 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 Representative - 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

Document digitally signed in accordance with current legislation by Dott.ssa Sonia Giannone - Ordine Naz. Dei Biologi Albo Professionale N° 050063
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



LABORATORIO ANALISI
Errata Corrigé 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), (%)	94,6	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



LABORATORIO ANALISI
Errata Corrigé 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 cm²
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 1h
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 number 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

产品质检



LABORATORIO ANALISI
Errata Corrigé 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 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 <i>UNI EN 14683:2019 (Annex B)</i>	%	99,5
Bacterial filtration efficiency BFE, Sample 2 <i>UNI EN 14683:2019 (Annex B)</i>	%	99,7
Bacterial filtration efficiency BFE, Sample 3 <i>UNI EN 14683:2019 (Annex B)</i>	%	99,5
Bacterial filtration efficiency BFE, Sample 4 <i>UNI EN 14683:2019 (Annex B)</i>	%	99,6
Bacterial filtration efficiency BFE, Sample 5 <i>UNI EN 14683:2019 (Annex B)</i>	%	99,8
Bacterial filtration efficiency BFE, Mean <i>UNI EN 14683:2019 (Annex B)</i>	%	99,6

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



LABORATORIO ANALISI
Errata Corrigé 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

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 cm²
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 cm² 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.



LABORATORIO ANALISI
Errata Corrigé 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 4 summarizes results obtained with the differential pressure test.

Table 4

Parameter Test Method	U.M.	Results
Differential pressure, Sample 1 <i>UNI EN 14683:2019 (Annex C)</i>	Pa/cm ²	34,2
Differential pressure, Sample 2 <i>UNI EN 14683:2019 (Annex C)</i>	Pa/cm ²	31,3
Differential pressure, Sample 3 <i>UNI EN 14683:2019 (Annex C)</i>	Pa/cm ²	30,6
Differential pressure, Sample 4 <i>UNI EN 14683:2019 (Annex C)</i>	Pa/cm ²	32,8
Differential pressure, Sample 5 <i>UNI EN 14683:2019 (Annex C)</i>	Pa/cm ²	32,6
Differential pressure, Mean <i>UNI EN 14683:2019 (Annex C)</i>	Pa/cm ²	33

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产品质检



Errata Corrigé 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

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 Polysorbete 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.

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Errata Corrigé 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.

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Errata Corrigé 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 Corrigé/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 ISO 7218: 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 / 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 / Amd1: 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.

The results included in this Test Report refer only to the sample tested. In case the sampling is not performed by our staff, the laboratory is not responsible for the sample information reported in this test report and the results refer only to the sample received. This Test Report may not be partially reproduced, unless Tecnal's written approval.

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产品质检



检验报告

TEST REPORT



(替代WT204025656报告)

报告编号: WT204032177

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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 INDUSTRIAL 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



检验报告

报告编号: WT204032177

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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 Appearance (YY/T 0969-2013)	4.1 条 4.1 Requirement	(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)	1. 结构 Structure 4.2 条 4.2 Requirement	(YY/T 0969-2013) 1#~3# 符合 Conformity	符合 Conformity
2. 尺寸 Size 4.2 条 4.2 Requirement	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. 鼻梁 Nose clip (YY/T 0969-2013)	4.3.1 条 4.3.1 Requirement 4.3.2 条 4.3.2 Requirement	(YY/T 0969-2013) 1#~3# 符合 Conformity 长度 length (cm): 1# 2# 3# 10.2 10.3 10.2	符合 Conformity
4. 口罩带 Mask string (YY/T 0969-2013)	4.4.1 条 4.4.1 Requirement 4.4.2 条 4.4.2 Requirement	(YY/T 0969-2013) 符合 Conformity 1#~3# 符合 Conformity (定负荷 Fixed load: 10N, 持续 continuous: 5s)	符合 Conformity



检验报告

报告编号: WT204032177

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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)	(YY 0469-2011) 1# 2# 3# 100 100 100 ≥95	(YY 0469-2011) 1# 2# 3# 100 100 100	符合 Conformity
6. 通气阻力 (Pa/cm ²) Ventilation resistance (YY/T 0969-2013)	(YY/T 0969-2013) 1# 2# 3# 39.3 42.7 39.1 (气体流量 Gas flow: 8L/min)	(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) ≤100 <4	(GB 15979-2002) ≤100 <4	符合 Conformity
细菌菌落总数 (CFU/g) Total amount of bacterial colony	不得检出 No detected	未检出 Not detected	
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	

产品质检



检验报告

TEST REPORT



(替代WT204029174报告)

报告编号: WT204032179

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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30日

签名: 何行月



检验报告

报告编号: WT204032179

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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	随弃式面罩 Disposable facepiece: 1.56 (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) °C 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) °C for (24 ± 1) hours;

c) (-30±3)℃环境放置(24±1)h

Place at (-30 ± 3) °C 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 INDUSTRIAL ZONE LAIXI CITY, QINGDAO, CHINA.

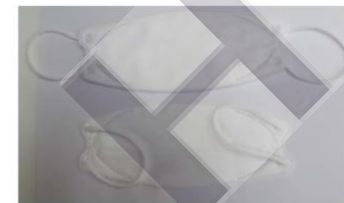


检验报告

报告编号: WT204032179

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4. 样品图片 Photo(s) of the sample(s):



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