



变更通知书

22004292278

变更(备案)通知书

深圳市每天投资发展有限公司:

我局已于二〇二〇年四月二十一日对你企业申请的(许可经营项目)变更予以核准;对你企业的(章程修正案、许可信息、章程)予以备案,具体核准变更(备案)事项如下:

备案前章程修正案:
备案后章程修正案:
备案前许可信息: 项目:从事道路客运、货运经营 有效期:, 项目:食品流通 有效期:
备案后许可信息: 项目:第二、三类医疗器械生产 有效期:, 项目:食品流通 有效期:, 项目:建设项目环境影响审批(各区环保水务局审批) 有效期:, 项目:从事道路客运、货运经营 有效期:

章程备案

变更前许可经营项目: 酒类销售; 预包装食品销售。
目:
变更后许可经营项目: 酒类销售; 预包装食品销售。二类医疗器械、口罩、手套、护目镜、防护服、消毒液、医疗酒精、体温枪的销售, 口罩的生产

变更前一般经营项目: 普通货运, 预包装食品的零售批发。
目:
变更后一般经营项目: 预包装食品的零售批发; 二类医疗器械、口罩、手套、护目镜、消毒液、医用酒精; 口罩的生产。

税务部门重要提示: 如您在税务局使用防伪税控系统开具增值税发票, 因变更名称、住所, 需到原税务局主管税务机关办税服务厅办理防伪税控设备变更发行。

深圳市市场监督管理局
二〇二〇年四月二十一日
注册业务专用章
(电子)



KN95 mask

品牌方二类医疗+对外贸易

第二类医疗器械经营备案凭证

备案编号：粤深食药监械经营备 202024931 号

企业名称	深圳市每天投资发展有限公司
法定代表人	彭海涛
企业负责人	彭海涛
经营方式	批零兼营
住 所	深圳市龙华新区大浪办事处龙胜社区和平路 368 号龙胜商业大厦第 1 层 7-9 间
经营场所	深圳市龙华新区大浪办事处龙胜社区和平路 368 号龙胜商业大厦第 1 层 7-9 间
库房地址	深圳市龙华新区大浪办事处龙胜社区和平路 368 号龙胜商业大厦第 1 层 7-9 间
经营范围	2002 年分类目录（二类）：6801、6802、6803、6804、6805、6806、6807、6808、6809、6810、6812、6813、6815、6816、6820、6821、6822、6823、6824、6825、6826、6827、6828、6830、6831、6832、6833、6834、6840（体外诊断试剂除外），6840（诊断试剂需低温冷藏运输贮存），6840（诊断试剂不需低温冷藏运输贮存），6841、6845、6846、6854、6855、6856、6857、6858、6863、6864、6865、6866、6870、6877，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外 2017 年分类目录（二类）：01、02、03、04、05、06、07、08、09、10、11、12、13、14、15、16、17、18、19、20、21、22、6840 体外诊断试剂，6840 体外诊断试剂（不需低温冷藏运输贮存），以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外

备案部门（公章）

备案日期：2020 年 02 月 29 日



对外贸易经营者备案登记表

备案登记表编号：02084647

进出口企业代码：4403326465449

经营者中文名称	深圳每天投资发展有限公司		
经营者英文名称	Shenzhen Everyday Investment and Development Co., Ltd		
组织机构代码	326466449	经营者类型 (由备案登记机关填写)	私营有限责任公司
住 所	深圳市龙华新区大浪办事处龙胜社区和平路368号龙胜商业大厦第1层7-9间		
经营场所（中文）	深圳市龙华新区大浪办事处龙胜社区和平路368号龙胜商业大厦第1层7-9间		
经营场所（英文）	First Floor, Longsheng Commercial Building, No.368, Heping Rd, Longhua New District, Shenzhen		
联系电话	0755-27638304	联系传真	0755-82407323
邮政编码	518109	电子邮箱	service@everywine.cc
工商登记注册日期	2015-1-27	工商登记注册号	440301112144382

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	彭海涛	有效证件号	362421196032522614
注册资金	壹仟万元	(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盖章



2015 年 04 月 01 日



KN95 mask

品牌方品牌注册



口罩类目商标注册

中国商标注册号：44962636

欧盟商标注册号：18224796

WWW.CNIPA.GOV.CN WCJS.SBJ.CNIPA.GOV.CN 帮助 当前数据截至：(2020年05月20日)

商标详情 商标流程

 商品/服务 麻醉面罩; 人工呼吸用呼吸面罩; 医用手套; 口罩; 无菌罩布(外科用); 手术用消毒盖布; 医务人员用面罩; 外科用海绵; 医用手套; 手术衣; [查看详细信息](#)

类似群 1001,1004;

申请/注册号 44962636 申请日期 2020年03月27日 国际分类 10

申请人名称(中文) 深圳市每天投资发展有限公司

申请人名称(英文)

申请人地址(中文) 广东省深圳市龙华新区大浪办事处龙胜社区和平路368号龙胜商业大厦第1层7-9间

申请人地址(英文)

初审公告期号 注册公告期号 是否共有商标 否

初审公告日期 注册公告日期 商标类型 一般

专用权期限 商标形式

国际注册日期 后期指定日期 优先权日期

代理/办理机构  北京众达德权知识产权代理有限公司

商标流程 [点击查看](#)



FISCAL YEAR 2020 CERTIFICATION OF REGISTRATION

This certifies that:

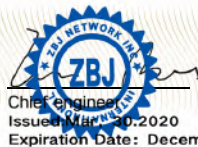
SHENZHEN EVERYDAY INVESTMENT AND DEVELOPMENT CO.,LTD
1F, LONGSHENG COMMERCIAL BUILDING, 368 HEPING ROAD, LONGSHENG
COMMUNITY, DALANG STREET LONGHUA DISTRICT, SHENZHEN,
GUANGDONG 518000 CHINA

Has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration.

See the next page for details

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

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misleading." 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, ZBJ is not affiliated with the U.S. Food and Drug Administration.



FISCAL YEAR 2020 CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10064832

Listing No.	Product Code(s)	Device Name(s)	Proprietary Name	Activities
D380420	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydratic eyewear)	protective spectacles	Foreign Exporter
D380418	OEA	Non-surgical isolation gown	Protective clothing	Foreign Exporter
D380416	MSH	Respirator, surgical	Protective masks kn95mask Particulate Respirator	Foreign Exporter
D380144	LYU	ACCESSORY, SURGICAL APPAREL	layers disposable mask	Foreign Exporter



https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

U.S. Department of Health & Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION
 Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Product Classification

This database includes:
 • a list of all medical devices with their associated classifications, product codes, FDA Premarket Review organizations, and other regulatory information.
[Learn more...](#)

Search Database: Device: Product Code: Regulation Number:

Other Databases:
 • STAP
 • De Novo
 • Medical Device Reports (MAUDE)
 • CDRH Export Certificate Validation (CECV)
 • CDRH FOIA Electronic Reading Room
 • CFR Title 21
 • CLIA
 • FDA Guidance Documents
 • Humanitarian Device Exemption
 • Medical Reports
 • Premarket Approvals (PMAs)
 • Post-Approval Studies
 • Postmarket Surveillance Studies
 • Radiation-Emitting Products
 • Radiation-Emitting Electronic Products Corrective Actions
 • Recalls
 • **Registration & Listing**
 • Standards
 • Total Product Life Cycle
 • X-Ray Assembler

U.S. Department of Health & Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION
 Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

1 result found for Owner Operator Number : 10064832

Establishment Name	Registration Number	Current Registration Yr
SHENZHEN EVERYDAY INVESTMENT AND DEVELOPMENT CO., LTD.	301889940	2020

Device: KN95mask

Other Databases:
 • Accessory, Surgical Ancillary - Layers Disposable Mask
 • Respirator, Surgical, KN95mask, Particulate Respirator, Protective Masks
 • Shield, Eye, Ophthalmic, Including Sunlens Protective Eyewear And Post-Midnight Eyewear - Protective Spectacles
 • Non-Surgical Isolation Gown - Protective Clothing

U.S. Department of Health & Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION
 Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

This database includes:
 • medical device manufacturers registered with FDA and
 • medical devices listed with FDA.
 Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.
[Learn More...](#)

Search Database: Establishment or Trade Name: Registration or FEI Number:

Other Databases:
 • STAP
 • De Novo
 • Medical Device Reports (MAUDE)
 • CDRH Export Certificate Validation (CECV)
 • CDRH FOIA Electronic Reading Room
 • CFR Title 21
 • CLIA
 • Device Classification
 • FDA Guidance Documents
 • Humanitarian Device Exemption
 • Medical Reports
 • Premarket Approvals (PMAs)
 • Post-Approval Studies
 • Postmarket Surveillance Studies
 • Radiation-Emitting Products
 • Radiation-Emitting Electronic Products Corrective Actions
 • Recalls
 • Standards
 • Total Product Life Cycle
 • X-Ray Assembler

U.S. Department of Health & Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION
 Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

Back To Search Results

Proprietary Name: Particulate Respirator, Protective masks
 Classification Name: RESPIRATOR, SURGICAL
 Product Code: MSH
 Device Class: 2
 Regulation Number: 873.4040
 Medical Specialty: General & Plastic Surgery
 Registered Establishment Name: SHENZHEN EVERYDAY INVESTMENT AND DEVELOPMENT CO., LTD.
 Registered Establishment Number: 301889940
 Owner Operator: SHENZHEN EVERYDAY INVESTMENT AND DEVELOPMENT CO., LTD.
 Owner Operator Number: 10064832
 Establishment Operations: Foreign Exporter

DayhelpTM

KN95 mask

品牌方授权生产方

**KN95
MASK**

DayhelpTM

CERTIFICATE OF ACHIEVEMENT

授权书

Hunan SanRui Biotechnology co., Ltd is a cooperative manufacturer of Shenzhen Everyday Investment and Development Co.,Ltd , Right to authorize Hunan SanRui Biotechnology co., Ltd to produce "Dayhelp" brand (KN95 mask) , This certificate of authorization shall take effect from the date of issuance.

Authorization date: May 20, 2020 to June 30, 2020.

兹 湖南三瑞生物科技有限公司 为 深圳市每天投资发展有限公司 合作的生产商，特授权湖南三瑞生物科技有限公司生产 "Dayhelp" 品牌 (KN95口罩) 的权利，本授权证书自发布之日起生效。

授权日期2020年5月20日-2020年6月30日。

DayhelpTM

Shenzhen Everyday Investment
and Development Co.,Ltd
深圳市每天投资发展有限公司

Hunan SanRui Biotechnology co., Ltd
湖南三瑞生物科技有限公司



中国国际贸易促进委员会东莞市委员会

政府信息公开

请输入搜索关键词

信息公开目录

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政府信息公开指南



法定主动公开内容

组织机构 +

政策文件 +

财政信息 +

规划计划 +

统计信息

业务工作 +

其他 -

通知公告

工作动态

重要会议

人事任免

党建工作

国际贸易预警

国际经贸调研



政府信息公开年报

法定主动公开内容 > 其他 > 国际贸易预警

索引号：134419003040939207/2020-00359

分类：

发布机构：中国国际贸易促进委员会东莞市委员会

成文日期：2020-05-21

名称：最新！取得国外标准认证或注册的医疗物资生产企业清单

文号：

发布日期：2020-05-21

主关键词：

【打印】 【字体：大 中 小】

分享到：

最新！取得国外标准认证或注册的医疗物资生产企业清单

发布日期：2020-05-21 浏览次数：258

中国医药保健品进出口商会网站显示，截至2020年5月19日，取得国外标准认证或注册的非医用口罩生产企业清单持续更新，累计73家。

截至2020年5月19日，取得国外标准认证或注册的医疗物资生产企业清单持续更新，其中，医用口罩421家；医用防护服106家；呼吸机28家；红外体温计49家；新型冠状病毒检测试剂188家。

取得国外标准认证或注册的非医用口罩生产企业清单
19日更新

取得国外标准认证或注册的非医用口罩生产企业清单

序号	生产企业	统一社会信用代码	国外注册认证情况
55	湖南三福生物科技有限公司 Hunan Sanful Biotechnology Co., Ltd	91430120668508206	欧盟CE



(The national emblem)
Business license

Business Scope: R&D of Class I Medical Devices, Class II Medical Devices, Class III Medical Devices;
Sales of Class I medical devices, Class II medical devices, Class III medical devices,
Sales and production of Class I medical devices, Class II medical devices, Class III medical devices;
Manufacture of daily and medical rubber products, sanitary materials and medical supplies. (Projects that are subject to approval according to law can only be operated after approval by relevant departments)

医疗器械生产许可证

许可证编号：湘食药监械生产许20149018号

企业名称：湖南三瑞生物科技有限责任公司

生产地址：湖南望城经济开发区黄金创业园C4栋1楼、C4栋2楼、C3栋1楼、C3栋501-3

法定代表人：赵博

生产范围：II类：14-15 病人护理防护用品；14-14 医护人员防护用品；14-13 手术室感染控制用品；14-05 非血管内导（插）管；08-06 呼吸、麻醉用管路、面罩；02-15 手术器械-其他器械；02-13 手术器械-吻（缝）合器械及材料；02-11 手术器械-牵开器；

企业负责人：赵博

住所：湖南望城经济开发区黄金创业园C4栋2楼

发证部门：湖南省药品监督管理局

有效期至：2024年05月23日

发证日期：2020年03月12日



Medical Device Production License

Scope of production: Class II: 14-15 patient care protective equipment; 14-14 medical staff protective equipment; 14-13 operating room infection control equipment; 14-05 non-vascular guide (intubation) tube; 08-06 breathing and anesthesia Tubes and masks; 02-15 surgical instruments-other instruments 02-13 surgical instruments-kiss(sewing) closure instruments and materials; 02-11 surgical instruments-retractors;



KN95 mask

产品包装一





KN95 mask

产品外箱规格一

Dayhelp™ KN95 -20pcs/box

ITEM 产品	Protective mask 防护口罩
Quality Standards 执行标准	GB2626-2006
MODEL 型号	KN95 Mask
COLOR 颜色	White 白色
QTY 数量	1200pcs (20pcs/box; 60boxes/ctn) 1200片(20片/盒 ; 60盒/箱)
G.W. 毛重	23.626 lbs 10.717 kg
MEAS 箱规	65cm*33.5cm*51cm



Dayhelp™ KN95 -50pcs/box

ITEM 产品	Protective mask 防护口罩
Quality Standards 执行标准	GB2626-2006
MODEL 型号	KN95 Mask
COLOR 颜色	White 白色
QTY 数量	1000pcs (50pcs/box; 20boxes/ctn) 1000片(50片/盒 ; 20盒/箱)
G.W. 毛重	22.147 lbs 10.046 kg
MEAS 箱规	65cm*33.5cm*51cm





KN95 mask

产品合格证

Dayhelp™
KN95
MASK

合格证

QUALIFIED CERTIFICATE
MADE IN CHINA

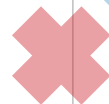
产品名称: KN95口罩(非医用)
执行标准: GB2626-2006
产品尺寸: 15x10.5(±0.5)cm
主要原料: 无纺布54%、熔喷布25%、热风棉21%
产品颜色: 白色
生产批号: M420200524
生产日期: 2020年5月24日
有效期: 3年

Name: KN95 Mask (Non medical)
Manufacture Standard: GB2626-2006
Size: 15x10.5(±0.5)cm
Material: 54% Non-woven fabric,
25% Melt-blown Nonwoven Fabric, 21% Hot-air cotton
Color: white
Lot Number: M420200524
Production Date: 24-May-20
Best Before: 3 years

生产厂商: 湖南三瑞生物科技有限公司
生产地址: 湖南省望城经济开发区黄金创业园C4栋2楼
Manufactured By: Hunan SanRui Biotechnology co., Ltd
Manufacture Address: 2F, Building C4, Golden Venture Park, Wangcheng Economic
Development Zone, Hunan Province

品牌及出品商: 深圳市每天投资发展有限公司
品牌及出品商地址: 深圳市龙华区大浪办事处龙胜社区和平路368号龙胜商业大厦1层
Brand owner by: Shenzhen Everyday Investment and development Co., Ltd
Brand owner Address: 1f, Longsheng Commercial Building, 368 Heping Road,
Longsheng Community, Dalang Street, Longhua District, Shenzhen

本产品为非医疗器械仅供应急使用
This product is non-medical equipment for emergency use only.





Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425
Certificate No.: CE-PC-200414-063-01-9A

Certificate holder: Hunan Sanrui Biotechnology Limited Liability Company
2/F, Building C 4, Golden Enterprise Park, Wangcheng District
Economic Development Zone, Hunan Province, China

Product: **Particle Filtering Half Mask**
Folding filtering half mask without valve fitted with ear loops
Classification: FFP1 NR

Model reference: SRNS-PM-III-A

Standard(s): EN 149:2001+A1:2009

Test report No.: 2020(D) - 0017

Issue date: 2020-05-01

Expiry date: 2020-07-31

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425 and meeting the needs of WHO document dcp-ncov.pdf and EU Commission Recommendation (EU) 2020/403.

Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.

CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.

If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.

This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.



Approved by Ireland
Government
as a Notified Body
for CE Marking No.2834



Approved by



Owen Bian, Director

CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15,
D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.



Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200414-063-FPC-A

Certificate holder: Hunan Sanrui Biotechnology Limited Liability Company
2/F, Building C 4, Golden Enterprise Park, Wangcheng District
Economic Development Zone, Hunan Province, China

The scope of the certification for: **Respiratory Protective Equipment**
Products covered by the certificate are described below.

Model: Particle Filtering Half Mask
SRNS-PM-III-A

Standard: EN 149:2001+A1:2009

Validity from: 2020-05-01

To: 2020-07-31

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation. The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE as identified on this certificate whilst this certificate remains valid.

This certificate is the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.



Approved by Ireland
Government
as a Notified Body
for CE Marking No.2834



Approved by



Owen Bian, Director

CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15,
D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
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National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing)
 No.55 Taoranting Street, Xicheng District, Beijing, China.
 Phone: +86 10 63519250
 Fax: +86 10 63519250

The Testing Center is accredited for compliance with ISO/IEC 17025. The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards. CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT

Particulate respirator-half facepiece

EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

Product: Particulate filtering half mask
Report No: 2020 (D) - 0017
Client: CCQS Certification Services Limited
Model (s): SRNS-PM-III-A
Date(s) of tests: 2020.03.18-2020.04.15

DESCRIPTION OF SAMPLES

General Information	Classification	Main Components
Manufacturer	FFP1 NR	Folding mask
Manufacturer Address	Hunan Sanrui Biotechnology Limited Liability Company 2/F, Building C4, Golden Enterprise Park, Wangcheng District District Economic Development Zone, Hunan, China	

Signed:

陈倬为 Chen Zhuowei
 Authorized Signatory, Lab Director

Issued: 2020.4.16

Page 1 of 10



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国家质量监督检验检疫总局 (北京)

Report No: 2020 (D) - 0017

Page 2 of 10

Conditions:

The test results presented in this report relate to the samples tested only.

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国家质量监督检验检疫总局 (北京)

Test Results

- 7.3 Visual inspection** Not tested¹
 The visual inspection shall include the marking and information supplied by the manufacturer.
 Note1: As requested by the client, marking and information supplied by the manufacturer was not inspected.
- 7.4 Package** Pass²
 Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.
 Note2: In accordance with the requirement.
- 7.5 Material** Pass³
 Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

 Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

 After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

 When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.
 Note3: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.
- 7.6 Cleaning and disinfecting** N/A⁴
 If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.
 Note4: Single shift use only.
- 7.7 Practical performance** Pass⁵
 The particle filtering half mask shall undergo practical performance tests under realistic conditions.
 Note5: No imperfections.
- 7.8 Finish of parts** Pass⁶
 Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.
 Note6: No sharp edges or burrs.
- 7.9.1 Total inward leakage** Pass⁷
 For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3

 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3
 Note7: FFP1 respirator. Test results are shown in Annex A Table 7.9.1-A&B.
- 7.9.2 Penetration of filter material** Pass⁸
 The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.
 Sodium chloride test 95 l/min Paraffin oil test 95 l/min
 FFP1 ≤20% FFP1 ≤20%
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- FFP2 ≤6% ≤6%
- FFP3 ≤1% ≤1%
- Note8: FFP1 respirator. Test results are shown in Annex A Table 7.9.2.

- 7.10 Compatibility with skin** Pass⁹
 Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.
 Note9: No irritation or any other adverse effect to health.
- 7.11 Flammability** Pass¹⁰
 When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.
 Note10: Test results are shown in Annex A Table 7.11.
- 7.12 Carbon dioxide content of the inhalation air** Pass¹¹
 The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume)
 Note11: Test results are shown in Annex A Table 7.12.
- 7.13 Head harness** Pass¹²

 The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.
 Note12: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.
- 7.14 Field of vision** Pass¹³
 The field of vision is acceptable if determined so in practical performance tests.
 Note13: Pass the practical performance tests.
- 7.15 Exhalation valve** N/A¹⁴
 A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

 If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

 Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

 When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.
 Note14: No exhalation valve.
- 7.16 Breathing resistance** Pass¹⁵
- | Classification | Maximum permitted resistance (mbar) | | |
|----------------|-------------------------------------|----------|------------|
| | Inhalation | | Exhalation |
| | 30 l/min | 95 l/min | |
| FFP1 | 0.6 | 2.1 | 3.0 |
| FFP2 | 0.7 | 2.4 | 3.0 |
| FFP3 | 1.0 | 3.0 | 3.0 |
- Note15: FFP1 respirator. Test results are shown in Annex A Table 7.16.
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Report No: 2020 (D) - 0017

Page 5 of 10

7.17 Clogging

N/A¹⁶

7.17.2 Breathing resistance

Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow

The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material

Sodium chloride test 95 l/min

FFP1 ≤20%

FFP2 ≤6%

FFP3 ≤1%

Note 6: Single shift use only.

Paraffin oil test 95 l/min

≤20%

≤6%

≤1%

7.18 Demountable parts

Pass¹⁷

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Note 17: In accordance with the requirement.

9 Marking

Not tested

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

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Report No: 2020 (D) - 0017

Page 6 of 10

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

End of Test Results



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Annex A: Summarization of Test Data

Table 7.9.1-A Inward leakage test data

Test specification: EN 149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	5.21	6.61	6.42	6.09	5.42	6.0
Gong	2	A.R.	6.24	7.64	7.51	7.32	6.24	7.0
Yu	3	A.R.	5.32	6.89	6.71	6.39	6.11	6.3
Zhi	4	A.R.	7.24	8.31	8.42	8.09	7.98	8.0
Fang	5	A.R.	6.64	7.92	7.81	6.99	6.77	7.2
Hu	6	T.C.	8.14	9.21	9.11	8.69	8.32	8.7
Xu	7	T.C.	8.23	9.62	9.51	9.24	8.86	9.1
Deng	8	T.C.	7.24	8.11	8.09	7.74	7.32	7.7
Zhang	9	T.C.	7.04	7.92	7.69	7.54	7.23	7.5
Zhou	10	T.C.	6.81	7.62	7.51	7.32	7.11	7.3
All 50 individual exercise results were not greater than 25 %							Pass	
All 10 individual wearer arithmetic means were not greater than ≤ 22 %								

Table 7.9.1-B Facial dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Yi	120	130	109	59
Gong	122	140	115	65
Yu	119	160	139	55
Hu	112	122	119	63
Xu	110	130	118	60
Deng	115	119	110	59
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63
Fang	115	129	120	50
Chen	116	150	132	56
Zhou	110	121	110	53

Table -7.9.2 Penetration of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	4.62	Pass
		12	4.71	
		13	4.66	
	Simulated wearing treatment	14	4.92	
		15	4.88	
		16	4.82	
	Mechanical strength+ Temperature conditioned	17	4.72	
		18	4.81	
		19	4.89	
Paraffin oil test	As received	20	10.6	
		21	11.2	
		22	11.8	
	Simulated wearing treatment	23	13.3	
		24	14.2	
		25	13.8	
	Mechanical strength+ Temperature conditioned	26	12.2	
		27	13.0	
		28	12.8	
Flow conditioning: Single filter: 95.0 L/min				

Table 7.11 Flammability

Test specification: EN 149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	Burn for 1 s	Pass
	30	Burn for 1 s	
Temperature conditioned	31	Burn for 1 s	
	32	Burn for 1 s	

Table 7.12 Carbon dioxide content of the inhalation air
Test specification: EN 149-2001 Clause 8.7

Condition	Sample No.	Result	Assessment
As received	33	0.51%	Mean value 0.5% Pass
	34	0.52%	
	35	0.53%	

Table 7.16 Breathing resistance (mbar)
Test specification: EN 149-2001 Clause 8.9

As received	Flow rate	36					37					38					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
As received	Inhalation	30 l/min	0.4	0.4	0.5	0.3	0.3	0.3	0.4	0.5	0.4	0.5	0.4	0.5	0.5	0.5	0.5
		95 l/min	1.6	1.7	1.7	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.6	1.6	1.5	1.6	1.7
	Exhalation	160 l/min	1.8	1.7	1.8	1.8	1.7	1.8	1.8	1.9	1.9	1.8	1.9	1.8	1.8	1.7	1.8
Simulated wearing treatment	Inhalation	30 l/min	0.5	0.5	0.4	0.4	0.4	0.5	0.5	0.4	0.5	0.5	0.4	0.5	0.4	0.5	0.5
		95 l/min	1.7	1.7	1.6	1.6	1.6	1.8	1.7	1.8	1.6	1.6	1.7	1.8	1.6	1.6	1.6
	Exhalation	160 l/min	1.9	1.9	1.8	1.8	1.7	1.9	1.9	1.9	1.8	1.9	1.9	1.9	1.8	1.8	1.9
Temperature conditioned	Inhalation	30 l/min	0.4	0.4	0.4	0.4	0.4	0.5	0.4	0.5	0.5	0.5	0.4	0.5	0.4	0.5	0.4
		95 l/min	1.6	1.7	1.7	1.7	1.6	1.7	1.7	1.6	1.6	1.7	1.6	1.7	1.6	1.6	1.7
	Exhalation	160 l/min	1.7	1.8	1.8	1.9	1.8	1.9	1.8	1.9	1.9	1.9	1.9	1.9	1.8	1.9	1.9
Flow conditioned	Inhalation	30 l/min	0.4	0.4	0.4	0.4	0.3	0.4	0.5	0.5	0.5	0.5	0.4	0.5	0.5	0.4	
		95 l/min	1.6	1.6	1.7	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.6	1.6	1.7	1.6	
	Exhalation	160 l/min	1.7	1.8	1.7	1.7	1.7	1.7	1.7	1.8	1.7	1.7	1.7	1.7	1.7	1.8	
Assessment		Pass															

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

End of Annex A

ANNEX B PHOTOS OF SAMPLES



End of Annex B

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No: 200130169 共3页 第1页

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客户认定信息	个人防护口罩 100个 商标: 斯三瑞 批号: 20200501 纤维成分: SRSN-PM-III-A		
检验性质	委托检测	样品受理/测试开始日期	2020-05-16
判定依据	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》		
综合检验结论	—		
检验检测结果	检验检测项目	判定依据	判定
	视野	GB 2626-2006	符合
	NaCl颗粒物过滤效率	GB 2626-2006	符合
	吸气阻力	GB 2626-2006	符合
	呼气阻力	GB 2626-2006	符合
	可燃性	GB 2626-2006	符合
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检验检测项目 (计量单位) [样品识别]	测试方法	标准值及允差	检验检测结果	判定	备注
●视野(°)	GB 2626-2009 6.8	≥60	65	符合	
●NaCl颗粒物过滤效率 (%)	GB 2626-2006 6.3 空气流量: 83L/min 气流速度: 15m/s 温度: 22.5℃ 湿度: 35.0%	过滤效率: ≥95.0 (KN95)	过滤效率: 1# 99.965 2# 99.998 3# 99.963 4# 99.978 5# 99.824 6# 99.815 7# 99.798 8# 99.960 9# 99.475 10# 99.180 温湿度预处理后样品 1# 99.884 2# 99.780 3# 99.815 4# 99.837 5# 99.962	符合	
●吸气阻力 (Pa)	GB 2626-2006 6.5 头模: 中号	≤350	未处理样品: 1# 105.3 2# 103.6 预处理样品: 1# 105.2 2# 106.7	符合	
●呼气阻力 (Pa)	GB 2626-2006 6.6 头模: 中号	≤250	未处理样品: 1# 74.2 2# 75.5 预处理样品: 1# 88.3 2# 90.2	符合	
●可燃性 (s)	GB 2626-2006 6.15	持续时间 ≤5	持续时间 未处理样品: 1# 0.0 2# 0.0 温湿度预处理后样品: 3# 0.0 4# 0.0	符合	
●头带	GB 2626-2006 6.11	面罩的每条头带、带扣及其他调节部件在承受10N的拉力, 持续10s, 不应出现滑脱或断裂。	未处理样品: 1# 符合要求 温湿度预处理后样品: 1# 符合要求	符合	
●外观检查[2个]	GB 2626-2006 6.1	按标准5.2条要求	符合要求		

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