1.1 银达生物介绍（Company profile)

Company profile

Zhejiang Yinda Biotechnology Co., Ltd, founded in 1999 , located in No. 1223 Hulian East Street Liushi Changsonggang Development Zone , Dongyang City , Zhejiang Province . We are a professional manufacturer which focus on R&D , Production , Sales and specialized in class I and II medical devices With 11000 square meters floor space and 24000 square meters building space.

Our main products are DISPOSABLE MEDICAL FACE MASK , SURGICAL FACK MASK , KN95 FACK MASK ,COOLING GEL PATCH ,ADHESIVE BANDAGE , NASAL STRIP , FIRST AID KIT and so on. Currently our mask production capacity is 1 million pieces per day.After decades of steady development,we have became one of the leaders in the related field of medical products and have won the following honors: Zhejiang Province Medical Association Governing Unit. Jinhua City Medical Association Vice President Unit.Dongyang City Medical Association Quality Management Standard Enterprise.

The company adheres to the principle of people-oriented, market-oriented, scientific and technological innovation, unity and efficiency, and has achieved certain achievements in the application of medical devices.The company has a high-quality staff team, college degree or above accounting for more than 30%, for the company's product quality stability and innovative development to provide a strong technical support.The company has built a 100,000-level GMP purification workshop covering 7,500 square meters and a 10,000-level laboratory covering 1,500 square meters. Meanwhile, the company has introduced advanced technologies and equipment from home and abroad and equipped with various advanced testing instruments. It is a high-tech enterprise with the right to import and export.

1.1 银达生物介绍（Company profile）

The company's purpose is "quality first, reputation first, customer first" purpose, With strong technology research and development strength, scientific and rigorous quality management system, after years of development, the company's products have passed ISO9001,2008 international quality system, the United States FDA, the European Union CE, China SFDA and other domestic and foreign certification. Make the company's product brand and quality reputation in line with international standards, thus greatly promoted the expansion of the domestic and foreign markets.Products are exported to southeast Asia, Europe, the United States, North America and other more than 30 countries and regions, good reputation and word of mouth won the majority of customers praise. And established long-term cooperation with domestic well-known enterprises "Xiuzheng Pharmaceutical Group" ,"Renhe Pharmacy Co., Ltd', "Harbin pharmaceutical group".Adhering to the concept of "excellence, development, innovation, integrity", with the development goal of striving to be a first-class enterprise, we warmly welcome new and old customers to inquire and cooperate with us. We are looking forward to providing you with high-quality all-round services, Wish to join hands with people with lofty ideals at home and abroad, common development, revitalize the cause of national medicine!Efforts to create the yinda biological gold brand!

1.2 生产车间（production workshop）

打包机
Baling press

洗手池
clean area

纸箱暂放区
cartons stored area

打码机
Code printer

鞋柜
shoe ark

环氧乙烷消毒柜
epoxy ethane disinfection cabinet

更衣柜
locker

传送门
portal

储物柜
Store content ark

1.3 生产能力（Production capacity）

KN95高速打片机

1.5 质管部门（Technical quality department)

实验室走廊

资料室

水溶恒温振荡箱器

1.5 质管部门（Technical quality department）

拉力测试仪

过滤效率测试仪

合成血液穿透测试

阻燃性能测试仪

1.6 原材料（raw materials）

熔喷布摆放区

熔喷布是口罩的重要组成部分，从验资-检测-采购-质检测-合格入库，经过5道工序，每一道都有质检人员管控。

无纺布摆放区

无纺布采用是医疗卫生的纤维无纺布防潮、透气、柔韧、质轻、不助燃、容易分解、无毒无刺激性。合格入库，整齐摆放。

分类摆放　有理有序

85级熔喷布存放区

90级熔喷布存放区

95级熔喷布存放区

99级熔喷布存放区

2.2 医疗器械出口销售证明（Free sale license）

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号： 浙金食药监械出 20200234 号
Certificate NO.： 浙金食药监械出 20200234 号

产品名称：鼻贴等产品，见附件（共 2 页）
Product(s): Nasal Strips etc.See Attachment (2 Pages)

规格型号：见附件（共 2 页）
Model: See Attachment (2 Pages)

产品注册或备案凭证号：见附件（共 2 页）
Registration certificate(s): See Attachment (2 Pages)

生产企业：浙江银达生物技术有限公司
Manufacturer: Zhejiang Yinda Biotechnology Co., Ltd

生产企业住所：浙江省东阳经济开发区长松岗功能区湖莲东街 1223 号
Address of manufacturer: No.1223, Hulian East Street, Changsonggang, Dongyang Economic Development Zone, 322104, Zhejiang Province, China

生产许可或备案凭证号：浙食药监械生产许 20140162 号 ；浙金食药监械生产备 20150029 号
Manufacturing License(s): 浙食药监械生产许 20140162 号 ；浙金食药监械生产备 20150029 号

兹证明上述产品已准许在中国生产和销售。该产品出口不受限制，出口医疗器械的企业应当保证其出口的医疗器械符合进口国（地区）的要求。
This is to certify that the above products have been registered to be manufactured and sold in China. The exportation of the product(s) is not restricted. The exporter should assure that exporting medical devices meeting requirements of the importing country(region).

证明有效日期至：2020 年 09 月 12 日
This certification valid until: 2020/09/12

备注：/
Remark: /

Zhejiang Medical Products Administration
（浙江省药品监督管理局）
2020 年 08 月 26 日
（出具单位盖章）

1

附件
ATTACHMENT
证书编号：浙金食药监械出 20200234 号 （共 2 页 第 1 页）
Certificate NO.：浙金食药监械出 20200234 号 （Page 1 of 2 Pages）

序号 SN	产品名称 Product(s)	规格型号 Model	产品注册或备案凭证号 Registration certificate(s)
1	创口贴 Adhesive Bandage	70X18mm，72X19mm，72X22mm，74X24mm，76X19mm，76X25mm，76X50mm，56X19mm，40X10mm，78X25mm，D=25mm，D=30mm，64X46mm 蝶形，50X45mm 蝶形 76X40mm 工字形	浙金械备 20150061 号
2	医用冷敷贴 Pain Relief Patch	5X3cm，6X4cm，10X7cm，10X10cm，12X8cm，12X10cm，13X8cm，14X10cm，20X10cm	浙金械备 20150043 号
3	鼻贴 Nasal Strips	55mmX18mm，44mmX14mm	浙械注准 20152660771
4	医用退热贴 Medical Cooling Gel Patch	90X40mm，110X40mm，100X45mm，110X45mm，120X45mm，100X50mm，110X50mm，120X50mm，100X60mm，110X60mm，120X60mm，100X70mm，120X70mm，150X70mm，120X80mm，200X90mm	浙金械备 20150051 号
5	医用降温贴 Medical Fever Reducing Patch	90X40mm，110X40mm，100X45mm，110X45mm，120X45mm，100X50mm，110X50mm，120X50mm，100X60mm，110X60mm，120X60mm，100X70mm，120X70mm，150X70mm，120X80mm，200X90mm	浙金械备 20150050 号

附件
ATTACHMENT
证书编号：浙金食药监械出 20200234 号 （共 2 页 第 2 页）
Certificate NO.：浙金食药监械出 20200234 号 （Page 2 of 2 Pages）

序号 SN	产品名称 Product(s)	规格型号 Model	产品注册或备案凭证号 Registration certificate(s)
6	一次性使用医用口罩 Disposable Medical Face Mask	175mmX95mm	浙械注准 20202141065
7	医用外科口罩 Surgical Face Mask	175mmX95mm	浙械注准 20202141064
8	一次性使用无菌敷贴 Disposable Wound Dressing	100mmX100mm，90mmX100mm，60mmX70mm，70mmX90mm 100mmX150mm，76mmX50mm	浙械注准 20162641110
空白 Blank	空白 Blank	空白 Blank	空白 Blank

3

2.3 FDA证书

注 册 号 ：

3008191248

Certificate Of FDA Registration

Fiscal Year 2020

This is certified that:
At The Address Stated Below Has Completed U.S. FOOD And DRUG ADMINISTRATION Medical Device Registration Through MANTONG.

ZHEJIANG YINDA BIOTECHNOLOGY CO., LTD
No. 1223, Hulian East Road, Changsonggang,Dongyang Economic Development Zone ,Dong Yang Zhejiang, CHINA 322100

Registration Number	3008191248
Owner/Operator Number	10031128
Device Listing Number	See annex

- The FDA annual establishment registration fee must be paid between Oct. 1 and Dec. 31 of every year.
- You can search the FDA registration information on this website or scan QR code: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
- Cert No.:209828MTG

Jacky M. Chuang
Executive Director
Date: 03-20-2020

MTG STANDARDS TESTING & CERTIFICATION CENTER www.fdacn.org

Certificate Of FDA Registration

Fiscal Year 2020

Annex to Cert. No.: *Cert No.:209828MTG*

Listing Number	Product Name	Product Code	Device Name
D380876	Nasal strip	LWF	DILATOR, NASAL
D243033	Cooling gel patch /Hot pack	IMD	PACK, HOT OR COLD, DISPOSABLE
D243032	Hot pack /Cold pack	IME	Pack, hot or cold, reusable
D218800	First aid kit	OHO	First aid kit without drug
D090425	Surgical dress	FYE	DRESS, SURGICAL
D090422	Gauze sponge	GDY	GAUZE/SPONGE, INTERNAL, X-RAY DETECTABLE
D090421	Eye pad	HMP	PAD, EYE
D090420	Medical scissors	JOK	SCISSORS, MEDICAL, DISPOSABLE
D090417	Ice bag /Ice pack	KYR	BAG, ICE
D090416	Medical face mask /Disposable face mask /Medical mask /3D medical protective face mask	LYU	ACCESSORY, SURGICAL APPAREL
D090406	Plastic splint /Wood splint	ILH	SPLINT, HAND, AND COMPONENTS
D090405	Wound dressing	NAD	Dressing, wound, occlusive
D090404	Hydrophilic wound dressing	NAC	Dressing, wound, hydrophilic
D090403	Adhesive bandage /Wound plasters/Adhesive tape	KGX	Tape and bandage, adhesive
END OF THE ANNEX			

Jacky M. Chuang
Executive Director
Date: 03-20-2020

MTG STANDARDS TESTING & CERTIFICATION CENTER www.fdacn.org

2.4 欧代注册认证书（Euroagent certificate of registration）

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/12052020.13

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized
Zhejiang Yinda Biotechnology Co.,Ltd.
No.1223, Hulian East Street, Changsonggang, Dongyang Economic Development Zone, 322104, Zhejiang Province, China
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/775/2020**

CE

Issued on: 12/05/2020 Valid until: 11/05/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com

EC REP CERTIFICATE

ANNEX I Medical Device Products

Disposable medical face mask

Surgical face mask

Medical isolation mask

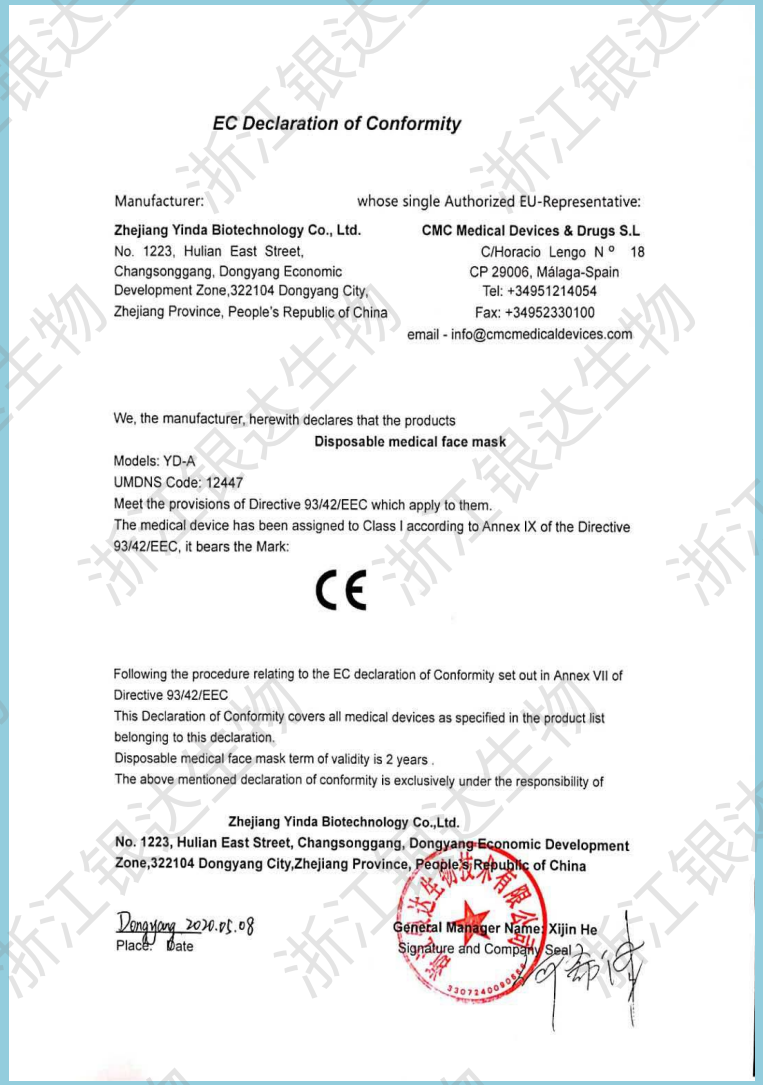
CE

www.cmcmedicaldevices.com

2.5 取得国外标准认证和注册CE声明（White list and Self declaration)

Added to White List on China Chamber of Commerce for Import and Export of Medicines and Health Products

287	曹县华鲁卫生材料有限公司 Shandong Caoxian County China Health Materials Co, Ltd	9137172172499213XW	欧盟CE
288	山东五洲医疗器械有限公司 Shandong Wuzhou Medical Equipment Co.,Ltd	913717275522399688	欧盟CE
289	烟台舒朗医疗科技有限公司 Yantai Show Long Medical Technology Co., Ltd	91370600MA3RENDW0U	欧盟CE
290	济民健康管理股份有限公司 Chimin Health Management Co.,Ltd.	91330000610008739T	欧盟CE
291	绍兴港峰医用品有限公司 Shaoxing Gangfeng Hospital Products Co.,Ltd.	9133060270447720 2W	欧盟CE
292	绍兴科誉医疗技术有限公司 Shaoxing Keyu Medical Technology Co.,Ltd.	91330602MA2D822N2M	欧盟CE
293	浙江润兰科技有限公司 Zhejiang Runlab Technology Co., Ltd.	9133100 37719 344694	欧盟CE
294	浙江银达生物技术有限公司 Zhejiang Yinda Biotechnology Co.,Ltd.	91330783717672349H	欧盟CE
295	安吉鑫沣进出口有限公司 Anji SPENQ Industrial Co., Ltd.	91330523661718730D	欧盟CE
296	仓谷医疗科技（浙江）有限公司 Canggu Medical Tech Co.,Ltd.	91330822MA2DG0N22B	欧盟CE
297	德普斯医疗器械湖州有限公司 Huzhou DEPS Medical Device Co., Ltd.	91330501MA28CGPF9Y	欧盟CE
298	江山市美绮服饰有限公司 Jiangshan Meiqi Fashion Co.,Ltd	91330881585028876G	欧盟CE
299	宁波贝格医疗器械有限公司 Ningbo Beige Medical Equipment Co.,Ltd.	91330281MA281LB78K	欧盟CE
300	宁波金格奥电器股份有限公司 Ningbo Jingeao Electronics Inc.	913302827281089110	欧盟CE



EC Declaration of Conformity

Manufacturer:

Zhejiang Yinda Biotechnology Co., Ltd.
No. 1223, Hulian East Street,
Changsonggang, Dongyang Economic
Development Zone,322104 Dongyang City,
Zhejiang Province, People's Republic of China

whose single Authorized EU-Representative:

CMC Medical Devices & Drugs S.L
C/Horacio Lengo N º 18
CP 29006, Málaga-Spain
Tel: +34951214054
Fax: +34952330100
email - info@cmcmedicaldevices.com

We, the manufacturer, herewith declares that the products

Disposable medical face mask

Models: YD-A
UMDNS Code: 12447
Meet the provisions of Directive 93/42/EEC which apply to them.
The medical device has been assigned to Class I according to Annex IX of the Directive 93/42/EEC, it bears the Mark:

CE

Following the procedure relating to the EC declaration of Conformity set out in Annex VII of Directive 93/42/EEC
This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.
Disposable medical face mask term of validity is 2 years .
The above mentioned declaration of conformity is exclusively under the responsibility of

Zhejiang Yinda Biotechnology Co.,Ltd.
No. 1223, Hulian East Street, Changsonggang, Dongyang Economic Development Zone,322104 Dongyang City,Zhejiang Province, People's Republic of China

Dongyang 2020.05.08
Place Date

General Manager Name: Xijin He
Signature and Company Seal)

2.6 EN ISO 13485 质量管理体系

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q6 104060 0001 Rev. 00

Holder of Certificate: **Zhejiang Yinda Biotechnology Co., Ltd.**
No.1223, Hulian East Street
Changsonggang, Dongyang Economic Development Zone
322104 Dongyang City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Zhejiang Yinda Biotechnology Co., Ltd.
No.1223, Hulian East Street, Changsonggang, Dongyang Economic Development Zone, 322104 Dongyang City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Wound Plasters, Wound Dressings, Nasal Strips, Cold Dressings (Cooling Gel Patch, Ice Pack, Pain Relief Patch), Hot Dressings, First Aid Kits**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19154001

Valid from: 2020-02-19
Valid until: 2023-02-18

Date, 2020-02-19

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

2.7 SGS测试回执 And EN149 回执

SGS-SH-HL-NSA-T-73

Letter of Acknowledgement

To: Zhejiang Yinda Biotechnology Co.,Ltd.

Attn: WangWanqiu

Issue date: 26/05/2020

We hereby acknowlegde the following submission of testing request on personnel protective equipment (PPE) are received and this case is being in processing upon the request of applicant.

Details of submission:

Sample Name : FFP2 Particulate respirator

Style/Model No.: 20200410

Test request: EN149: 2001+A1:2009

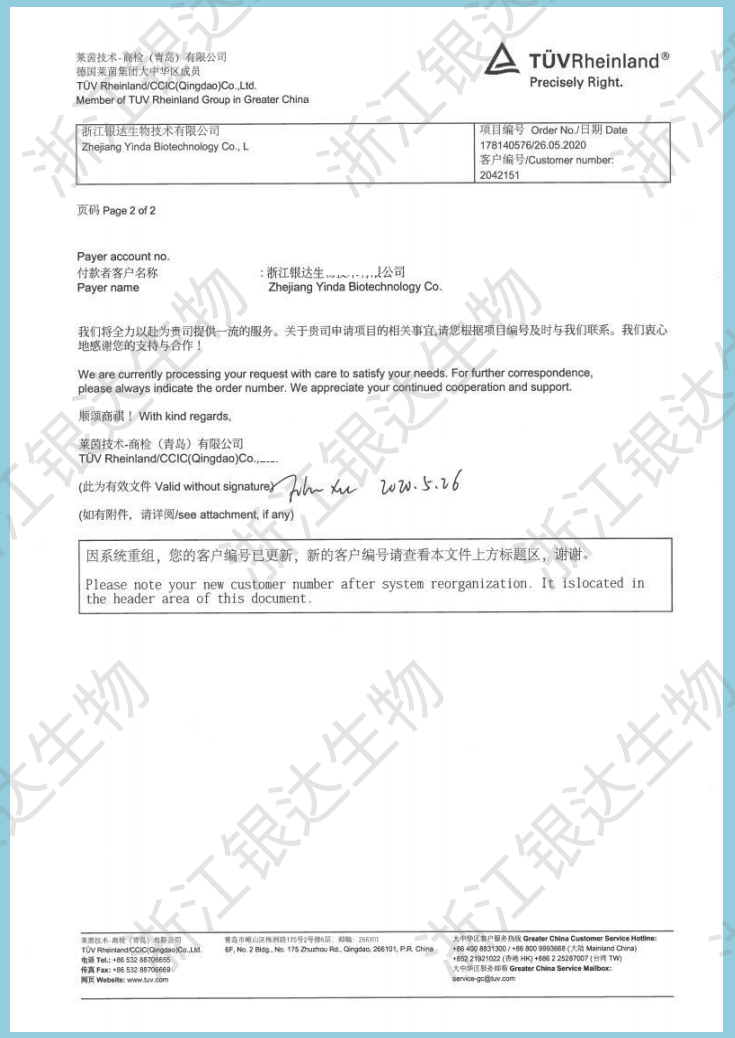
SGS report No.: SHHL2005518661MD

IMPORTANT: The formal testing report HAS NOT YET FINALIZED and that this letter is issued in the interim as per the request of client who is solely liable for complying with the testing standard

Donna Gu
CRS/Hardline SBU Certification Manager
SGS-CSTC Standards Technical Services Co., Ltd

SGS-CSTC CONSUMER AND RETAIL SGS SHANGHAI

SGS CSTC Standards Technical Services Co., Ltd. 4th Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86) 400 960 9661 www.sgsgroup.com.cn
Member of the SGS Group



莱茵技术-商检（青岛）有限公司
德国莱茵集团大中华区成员
TÜV Rheinland/CCIC(Qingdao)Co.,Ltd.
Member of TUV Rheinland Group in Greater China

TÜVRheinland®
Precisely Right.

浙江银达生物技术有限公司 Zhejiang Yinda Biotechnology Co., L	项目编号 Order No./日期 Date 178140576/26.05.2020 客户编号/Customer number: 2042151

页码 Page 2 of 2

Payer account no.
付款者客户名称 : 浙江银达生...公司
Payer name Zhejiang Yinda Biotechnology Co.

我们将全力以赴为贵司提供一流的服务。关于贵司申请项目的相关事宜,请您根据项目编号及时与我们联系。我们衷心地感谢您的支持与合作！

We are currently processing your request with care to satisfy your needs. For further correspondence, please always indicate the order number. We appreciate your continued cooperation and support.

顺颂商祺！ With kind regards,

莱茵技术-商检（青岛）有限公司
TÜV Rheinland/CCIC(Qingdao)Co.,...

(此为有效文件 Valid without signature) 2020.5.26

(如有附件，请详阅/see attachment, if any)

因系统重组，您的客户编号已更新，新的客户编号请查看本文件上方标题区，谢谢。

Please note your new customer number after system reorganization. It islocated in the header area of this document.

莱茵技术-商检（青岛）有限公司
德国莱茵集团大中华区成员
TÜV Rheinland/CCIC(Qingdao)Co.,Ltd.
Member of TUV Rheinland Group in Greater China

TÜVRheinland®
Precisely Right.

322100
浙江省 东阳
经济开发区长松岗功能区湖滨东街1223号
浙江银达生物技术有限公司

Zhejiang Yinda Biotechnology Co., Ltd.
1223, Hulian East Road, Changsonggang,
Dongyang Economic Development Zone,
322100 Zhejiang
P.R. China
贵司联系人 Your contact person
陈松定先生 Mr. Chen Songding
电话 Tel: +86 0579-86817338
传真 Fax: +86 0579-86812778

项目编号 Order No./日期 Date
178140576/26.05.2020
客户编号/Customer number:
2042151
莱茵技术-商检（青岛）有限公司
TÜV Rheinland/CCIC(Qingdao)Co.,Ltd.
我司联系人/Our contact person
周晓东 Alex Zhou
电话 ...
传真 ...
许常堂 Echo Xu
电话 Tel: ...
传真 Fax: ...
电子信箱 E-Mail: ...
电子信箱 E-Mail: ...

页码 Page 1 of 2

项目确认书 Order Confirmation

尊敬的先生/女士 Dear Sir or Madam,

感谢贵司对我方报价的确认。有关项目的确认条款如下：
Thank you very much for your order, which we registered as follows:

贵方确认函件编码 Your Ref.	: 2042151-20200526	
贵方确认函件日期 Your Date	: 26.05.2020	
报价单号码 Quotation number	: 178015862	
我方项目编码 Our order number	: 178140576	Please indicate for reference 关于贵司申请项目的相关事宜,请您根据项目编号及时与我们联系
我方项目金额 Our order Amount	: CNY	35,000.00
6% 增值税 VAT	: CNY	2,100.00
项目总额 Total	: CNY	37,100.00

我方项目内容
Order content as below

客户: 浙江银达生物技术有限公司
Client: Zhejiang Yinda Biotechnology Co., L

服务 Service: Test according to EN149:2001+ A1:2009
备注：1）仅根据EN149:2001+A1:2009标准提供测试服务，并按照此标准出具报告，不提供CE认证服务。不能承诺是否能用于清关。
2）此测试是分包至莱茵合作的ISO/IEC 17025:2017 认可的实验室进行。
Remark: 1) we only offer the test service according to standardEN149:2001+A1:2009, and issue report accordingly. CE certification service are not included. No promise for customs clearance use.
2)the test is sub-contracted to a laboratory which complies with The requirement of ISO/IEC 17025:2017.

产品/型号 Product/Model: Mask

付款者客户编号 : 2042151

4.2 FFP2 CE证书

UNIVERSAL

UNIVERSAL
CERTIFICATION
NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PE-736

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Zhejiang Yinda Biotechnology Co., Ltd.
No.1223, Hulian East Street, Changsonggang, Dongyang Economic Development Zone, 322104, Zhejiang Province, China

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: FIRSTDOC **Model:** YD-N2
Filtering half mask
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **11/06/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE 2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
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CERTIFICATION
NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-736/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Zhejiang Yinda Biotechnology Co., Ltd.
No.1223, Hulian East Street, Changsonggang, Dongyang Economic Development Zone, 322104, Zhejiang Province, China

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial Nr.	Date	Issuing NB Nr.
FIRSTDOC / YD-N2	FFP2 NR	2163-PPE-736	11.06.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **11/06/2020** and will be valid for one year, until **10/06/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE 2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

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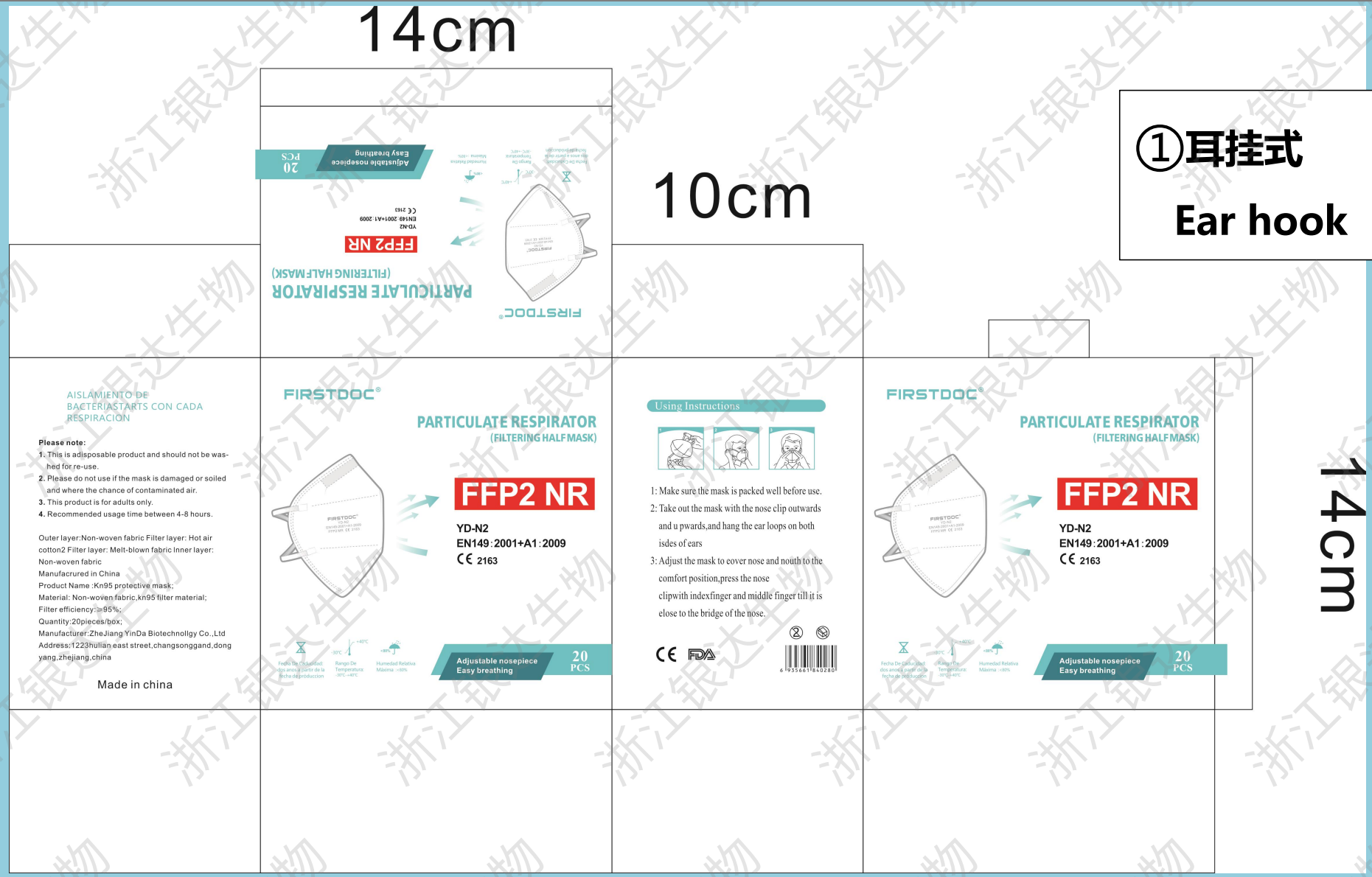
4.21 FFP2 Product display 样品展示 And bag design 小袋设计

4.22 FFP2 BOX Design 彩盒设计



4.22 FFP2 Test Report 检测报告

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L7901

检验检测报告

TEST REPORT

STFWT202012434

Product Name: Particulate respirator (Filtering half mask)

Trust Unit: Zhejiang Yinda Biotechnology Co., Ltd.

Manufacturer: ————

Test Category: Entrusted Inspection

SPC 江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

Test Report

STFWT202012434 page 1 of 10

Product Name	Particulate respirator (Filtering half mask)	Specification Type	YD-N2
		Trademark	——
Trust Unit	Zhejiang Yinda Biotechnology Co., Ltd.	Tel	——
Manufacturer	——	Sample Grade	FFP2
Sample Quantity	70 pcs	Sample Receiving Date	2020-05-05
Test Category	Entrusted inspection	Serial Number	——
Samples Conditions	Meet the testing requirements		
Document and Decide Accordance	EN 149：2001+A1：2009《*Respiratory protective devices -Filtering half masks to protect against particles-Requirements，testing，marking*》		
Test Conclusion	The samples were tested, the items tested meet the requirements of EN 149:2001+A1:2009 standard for FFP2 level. Signature Date：2020-05-26		
Remarks	The head harness of the mask provided by the applicant is ear hanging. Compatibility with skin is not recognized by the center. The test data are only for reference. The sample is not marked for reuse and does not require testing for blocking performance. The test conclusion of this report is only for the items inspected and does not mean that the uninspected items or functions meet the requirements. The results apply to the sample as received.		

Approver 钱琴 Examiner 杨森 Major tester 丁依

SPC JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.

7.5 Material **Pass**[1]

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.

Note1: Refer to Annex A for test data.

7.6 Cleaning and disinfecting **N/A**[2]

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.

Note2: Non-reusable respirator.

7.7 Practical performance **Pass**[3]

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note3: Refer to Annex A for test data.

7.8 Finish of parts **Pass**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

7.9.1 Total inward leakage **Pass**[4]

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:

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

Note4: Refer to Annex A for test data.

7.9.2 Penetration of filter material **Pass**[5]

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note5: Refer to Annex A for test data.

7.10 Compatibility with skin **Pass**[6]

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.

Note6: Refer to Annex A for test data.

7.11 Flammability **Pass**[7]

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.

Note7: Refer to Annex A for test data.

7.12 Carbon dioxide content of the inhalation air **Pass**[8]

The carbon dioxide content of the inhalation air (dead space) shall not exceed an

Note8: Refer to Annex A for test data.

7.13 Head harness **Pass[9]**

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

Note9: Refer to Annex A for test data.

7.14 Field of vision **Pass[10]**

The field of vision is acceptable if determined so in practical performance tests.

Note10: Refer to Annex A for test data.

7.15 Exhalation valve **N/A[11]**

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.

Note11: Valve-less respirator.

7.16 Breathing resistance **Pass[12]**

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note12: Refer to Annex A for test data.

7.17 Clogging **N/A[13]**

7.17.2 Breathing resistance **N/A[13]**

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	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

N/A[13]

Note13: Non-reusable respirator.

7.18 Demountable parts **N/A[14]**

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

Note14: No demountable parts.

Annex A: Summarization of Test Data

Clause		Result			Assessment
7.5	Material	Simulated wearing treatment	1#	No mechanical failure	Pass
			2#	No mechanical failure	
			3#	No mechanical failure	
		Temperature conditioned	4#	No mechanical failure	
			5#	No mechanical failure	
			6#	No mechanical failure	
7.9	Practical performance	As received	7#	No mechanical failure	Pass
			8#	No mechanical failure	
7.9.1	Total inward leakage	Individual exercise result			Pass
		As received	9#	47 out of the 50 individual exercise results ≤ 11%	
			10#	47 out of the 50 individual exercise results ≤11%	
			11#	47 out of the 50 individual exercise results ≤ 11%	
			12#	47 out of the 50 individual exercise results ≤11%	
			13#	47 out of the 50 individual exercise results ≤ 11%	
		Temperature conditioned	14#	47 out of the 50 individual exercise results ≤11%	
			15#	47 out of the 50 individual exercise results ≤ 11%	
			16#	47 out of the 50 individual exercise results ≤11%	
			17#	47 out of the 50 individual exercise results ≤ 11%	
			18#	47 out of the 50 individual exercise results ≤11%	
		Individual wearer arithmetic means			
		As received	9#	9 individual wearer arithmetic means≤ 8%	
			10#	9 individual wearer arithmetic means≤ 8%	
			11#	9 individual wearer arithmetic means≤ 8%	
			12#	9 individual wearer arithmetic means≤ 8%	
			13#	9 individual wearer arithmetic means≤ 8%	
		Temperature conditioned	14#	9 individual wearer arithmetic means≤ 8%	
			15#	9 individual wearer arithmetic means≤ 8%	
			16#	9 individual wearer arithmetic means≤ 8%	
			17#	9 individual wearer arithmetic means≤ 8%	
			18#	9 individual wearer arithmetic means≤ 8%	

Clause		Result			Assessment
7.9.2	Penetration of filter material/%	Sodium chloride test(95L/min)			Pass
		As received	19#	2.05	
			20#	2.09	
			21#	2.14	
		Simulated wearing treatment	22#	2.21	
			23#	2.29	
			24#	2.37	
		M.S.+T.C.	25#	2.53	
			26#	2.61	
			27#	2.48	
		Paraffin oil test(95L/min)			
		As received	28#	5.48	
			29#	5.41	
			30#	5.52	
		Simulated wearing treatment	31#	5.53	
			32#	5.61	
			33#	5.59	
		M.S.+T.C.	34#	5.82	
			35#	5.74	
			36#	5.69	
7.10	Compatibility with skin	As received	9#	No irritation or any other adverse effect to health	Pass
			10#	No irritation or any other adverse effect to health	
			11#	No irritation or any other adverse effect to health	
			12#	No irritation or any other adverse effect to health	
			13#	No irritation or any other adverse effect to health	
		Temperature conditioned	14#	No irritation or any other adverse effect to health	
			15#	No irritation or any other adverse effect to health	
			16#	No irritation or any other adverse effect to health	
			17#	No irritation or any other adverse effect to health	
			18#	No irritation or any other adverse effect to health	
7.11	Flammability	As received	37#	Didn't burn	Pass
			38#	Didn't burn	
		Temperature conditioned	39#	Didn't burn	
			40#	Didn't burn	

Clause		Result				Assessment
7.12	Carbon dioxide content of the inhalation air/%	As received				Pass
		41#	42#	43#	Mean value	
		0.53	0.54	0.52	0.53	
7.13	Head hardness	As received				Pass
		9#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		10#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		11#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		12#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		13#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		Temperature conditioned				
		14#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		15#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		16#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		17#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		18#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
7.14	Field of vision	As received	7#	Passed the practical performance tests		Pass
			8#	Passed the practical performance tests		

Clause		Result				Assessment
			Inhalation		Exhalation	
			30 l/min	95 l/min	160 l/min	
7.16	Breathing resistance (mbar)	As received				Pass
		41# A	0.4	1.6	2.3	
		41# B	0.4	1.7	2.4	
		41# C	0.4	1.6	2.3	
		41# D	0.4	1.6	2.3	
		41# E	0.4	1.6	2.3	
		42# A	0.4	1.6	2.3	
		42# B	0.4	1.6	2.3	
		42# C	0.4	1.6	2.3	
		42# D	0.4	1.7	2.4	
		42# E	0.4	1.6	2.3	
		43# A	0.4	1.6	2.3	
		43# B	0.4	1.6	2.4	
		43# C	0.4	1.6	2.3	
		43# D	0.4	1.7	2.3	
		43# E	0.4	1.6	2.3	
		Simulated wearing treatment				
		44# A	0.4	1.6	2.3	
		44# B	0.4	1.6	2.4	
		44# C	0.4	1.6	2.3	
		44# D	0.4	1.7	2.3	
		44# E	0.4	1.6	2.3	
		45# A	0.4	1.6	2.3	
		45# B	0.4	1.7	2.3	
		45# C	0.4	1.6	2.3	
		45# D	0.4	1.6	2.4	
		45# E	0.4	1.6	2.3	
		46# A	0.4	1.7	2.3	
		46# B	0.4	1.6	2.4	
		46# C	0.4	1.6	2.3	
		46# D	0.4	1.6	2.3	
		46# E	0.4	1.6	2.3	

Clause		Result					Assessment
				Inhalation		Exhalation	
				30 l/min	95 l/min	160 l/min	
		Temperature conditioned					
7.16	Breathing resistance	47#	A	0.4	1.6	2.3	Pass
			B	0.4	1.6	2.3	
			C	0.4	1.6	2.4	
			D	0.4	1.7	2.3	
			E	0.4	1.6	2.3	
		48#	A	0.4	1.6	2.3	
			B	0.4	1.6	2.4	
			C	0.4	1.7	2.3	
			D	0.4	1.6	2.3	
			E	0.4	1.6	2.3	
		49#	A	0.4	1.7	2.3	
			B	0.4	1.6	2.3	
			C	0.4	1.6	2.4	
			D	0.4	1.6	2.3	
			E	0.4	1.6	2.3	
7.16	Breathing resistance	A: facing directly ahead B: facing vertically upwards C: facing vertically downwards D: lying on the left side E: lying on the right side					
Remarks : M.S.: Mechanical strength; T.C.: Temperature conditioning; N/A: Not applicable							

Original Sample

======= End of Report =======

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