

Masca KN95 (5 straturi)



KN95 ofera protectie impotriva particulelor solide si lichide cu diametrul mai mare de 0.3 microni, inclusiv microorganisme vii precum anumite bacterii sau virusi.

Mastile de 5 straturi de filtrare si au fost testate de laboratoare certificate din Europa. Purtarea mastii ofera un grad de protectie superior asa ca va puteti face activitatile zilnice stiind ca va protejati cat mai bine. Masca ofera confort deoarece este fabricata din cele mai bune materiale si au un elastic moale. De asemenea, banda metalica moale permite personalizarea formei in partea superioara.

Mastile dispun de elastice moi dar rezistente si au o latime ideala pentru a evita presiunea pe pielea din jurul urechilor. Elasticele sunt echilibrate astfel incat sa tina masca foarte bine pe nas si gura fara a crea disconfort.

Utilizarea corecta a mastii

Intr-o criza de sanatate precum cea actuala, orice masuri de precautie sunt binevenite, deci nu este suficient sa puneti masca si sa iesiti, deoarece gesturi precum atingerea mastii sau fata in timp ce faceti o plimbare fara sa va spalati mainile, cresc riscul si neutralizeaza activitatea preventiva a acestui instrument de protectie.

Iata ce trebuie facut inainte, in timpul si dupa utilizarea unei masti, asa cum a fost stabilit de Ministerul Sanatatii:

1. Inainte de a pune masca, spala-te pe maini
2. Aseaza masca astfel incat sa acopere gura, nasul si barbia. Este inutil sa acoperi gura daca nasul este expus.
3. Cand o porti, evita sa o atingi.
4. Cand o scoti, prinde-o de parti, fara a atinge partea din fata
5. Daca este de unica folosinta, arunc-o
6. Nu refolosi o masca decat daca se mentioneaza in mod explicit pe ambalaj ca se poate face
7. Cand dai jos masca, arunc-o intr-o punga si inchide punga
8. Spala-te pe maini imediat dupa indepartarea mastii

Masca trebuie plasata acoperind gura si nasul, deoarece utilizarea sa este inutila daca una dintre aceste doua parti este lasata expusa

Utilizarea oricarei masti „nu implica in niciun caz protectie totala impotriva contagiunii”, deoarece niciunul dintre ei nu protejeaza ochii, o alta posibila cale de intrare a virusului. De aceea, autoritatile insista ca **masca sa fie doar o masura complementara celorlalte recomandari**, cum ar fi distanta dintre persoanele de peste un metru si curatarea extrema cu apa si sapun.

A se păstra într-un loc răcoros și uscat, ferit de îngheț și lumină, în ambalajul original

Contactul cu pielea poate provoca reacții alergice persoanelor sensibile. În acest caz, părăsiți zona de risc, scoateți masa și consultați un medic



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60133273 0001

Report No.: 15085900 005

Manufacturer: Xiantao Xingrong Protective
Products Co., Ltd.
No. 46, East of Pengchang Road,
433018 Xiantao, Hubei
China

Products: Aspects of manufacture concerned with securing and
maintaining sterile conditions of Face Masks, Surgical
Gowns, Non-woven Caps, Non-woven Shoe Covers,
Plastic Shoe Covers, Coveralls

Replaces Approval, Registration No.: DD 60104282 0001

Expiry Date: 2023-12-05

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-12-06

Date: 2018-12-06

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.



DECLARATION OF CONFORMITY

PPE: KN95 Protective mask

1. Name and address of the manufacturer:

Baoding Yinhong Yuhe medical device manufacturing Co.,
Ltd .

Nanlongshan village, Dawangdian Industrial Park, Xushui
District, Baoding City, Hebei Province, China.

2. This declaration of conformity is issued under the sole
responsibility of the manufacturer.

4. Object of the declaration: Declaration that our YH/FH-1095
white KN95 mask meets the Chinese national standard.

5. The KN95 Protective mask belongs to KN95 of
GB2626-2019, which is tested and approved by NTEK, the test
report No. is S20081703001C.

6. Signed for and on behalf of: Xiaoming.Xu.

Company: Baoding Yinhong Yuhe medical device manufacturing Co.,
Ltd.

General
Manager:  Xiaoming.Xu General Manager

Signature: Xiaoming.Xu

Place & Date: Baoding 09/09/2020



KN95新国标GB2626-2019检测报告



佛山中纺联检验技术服务有限公司
CNTAC Testing Service Co.,Ltd.(Foshan)

检测报告(Testing Report)	防伪查询网址(Security website): www.fcl-sz.org.cn 防伪码(Security code): 0127575588
报告编号(Report No): ZFLJ2629498	Page 1 of 5



Applicant Information (客户信息)

Applicant Name(委托单位) : Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd.
(保定银虹裕赫医疗器械制造有限公司)
Applicant Address(委托单位地址) : Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei Province, China.
(保定市徐水区大王店工业园区南隆善村口)
Manufacturer(生产单位) : Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd.
(保定银虹裕赫医疗器械制造有限公司)

Sample Information (样品信息)

Sample Description(样品描述) : KN95 protective mask (KN95 防护口罩)
Sample Quantity(样品数量) : 80 pieces (80 个)
Material Components(原料成分): Non-woven fabric, melt-blown fabric, hot air cotton (无纺布, 熔喷布, 热风棉)
- Sample Receiving date (收到样品的日期) : 2020-06-12
- Report date (报告日期) : 2020-06-16
- The original sample is stuck on the last paper. (送检样品原样粘贴在本报告的末页)

Test Performed (检验标准)

Judgement according to(评定依据):
GB 2626-2019 Respiratory protection— Non-powered air-purifying particle respirator
呼吸防护 自吸过滤式防颗粒物呼吸器
- Selected test(s) as requested by applicants. (本实验室根据客户要求完成以下检测内容)

Pronounce (声明)

The results shown in this report refer only to sample(s) tested unless otherwise stated. All the items are performed in the standard conditions, except the noted cases. (除非特别说明, 测试结果只对来样负责。所有测试项目均在标准规定的环境下进行, 有注明除外。)
Except for the requirement of the client, the test results and the conformity judgement of this report do not take the uncertainty of the test results into account. (除非客户要求, 本报告检测结果及符合性判定不考虑测量结果的不确定度。)

Signed for and on behalf of
CNTAC Testing Service Co.,Ltd.(Foshan)

Approved by
(批准)

张志荣





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-- Test Result (测试结果) --

Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)
1. Head harness(头带) GB 2626-2019 Section 6.11(条款 6.11) For disposable facepiece, tension 10N for 10s(随弃式面罩, 拉力 10N, 持续 10s) Before pretreatment (未经处理) No slippage or fracture (未出现滑脱和断裂) After pretreatment(经预处理) No slippage or fracture (未出现滑脱和断裂)	No slippage, fracture shall occur(不应出现滑脱或断裂)	Pass(合格)
2. Filtration Efficiency(过滤效率(盐性介质)) GB 2626-2019 Section 6.3(条款 6.3) Air flow: 85L/min, Aerosol: NaCl(气体流量 85L/min, 气溶胶颗粒: NaCl) Unit(单位): <%> Before pretreatment (未经处理) Sample 1#(样品 1) 99.6 Sample 2#(样品 2) 99.7 Sample 3#(样品 3) 99.5 Sample 4#(样品 4) 99.4 Sample 5#(样品 5) 99.5 Sample 6#(样品 6) 99.7 Sample 7#(样品 7) 99.7 Sample 8#(样品 8) 99.7 Sample 9#(样品 9) 99.5 Sample 10#(样品 10) 99.7 Sample 11#(样品 11) 99.5 Sample 12#(样品 12) 99.6 Sample 13#(样品 13) 99.7 Sample 14#(样品 14) 99.6 Sample 15#(样品 15) 99.7 After pretreatment(经预处理) Sample 1#(样品 1) 99.7 Sample 2#(样品 2) 99.6 Sample 3#(样品 3) 99.4 Sample 4#(样品 4) 99.3 Sample 5#(样品 5) 99.5	(KN95) ≥ 95.0	Pass(合格)
3. Exhalation Resistance(呼气阻力) GB 2626-2019 Section 6.6(条款 6.6) Air flow: 85L/min(通气量 85L/min) Unit(单位): <Pa> Maximum value(最大值) 116.9	≤ 210	Pass(合格)
4. Inhalation Resistance(吸气阻力) GB 2626-2019 Section 6.5(条款 6.5) Air flow: 85L/min(通气量 85L/min) Unit(单位): <Pa> Maximum value(最大值) 119.1	≤ 210	Pass(合格)





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Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)
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5. General Requirement(基本要求) GB 2626-2019 Section 5.1(条款 5.1)

The materials shall meet the following requirements
(材料应符合以下要求):

N/A
(No supporting materials provided
无提供证明材料)

Materials in direct contact with the face shall be harmless to the skin(直接与面部接触的材料对皮肤应无害)

N/A
(No supporting materials provided
无提供证明材料)

The filter material shall be harmless to human body(滤材对人体应无害)

Accordance (符合)

The materials used shall have sufficient strength and shall not be damaged and deformed in normal use(所用材料应具有足够的强度,在正常使用中不应出现破损和影响使用效果的变形)

Accordance (符合)

Wear should not produce obvious tenderness or tingling
(佩戴时不应产生明显的压痛或刺痛感)

The structural design shall meet the following requirements(结构设计应符合以下要求):

Accordance (符合)

Structural damage shall not occur and the components shall be designed, assembled and installed without any risk to the user(应不易产生结构性破损,部件的设计、组成和安装不应使用者构成任何危险)

Accordance (符合)

The design of head harness shall be elastic material or adjustable, easy to wear and remove, and it shall be able to firmly fix the facepiece on the face, without obvious compression or tenderness(头带的设计应为弹性材料或可调,便于佩戴和摘除,应能将面罩牢固地固定在脸上,且佩戴时不应出现明显的压迫或压痛现象)

Accordance (符合)

Should not significantly affect vision
(不应明显影响视野)

Accordance (符合)

The structure of the disposable facepiece shall be able to ensure the fit with the face, and should not appear deformation in normal use(随弃式面罩的结构应能保证与面部的密合,且应在正常使用中不出现变形。)



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Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)
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6. Appearance Inspection(外观检查) GB 2626-2019 Section 6.1 and 6.2(条款 6.1 和 6.2)

Accordance(符合)

The surface should not be damaged, deformation and other obvious defects. (样品表面不应破损、变形和有明显的其他缺陷。)

Pass(合格)

Accordance(符合)

Component materials and structures shall be able to withstand normal operating conditions and possible temperature, humidity and mechanical shocks. (部件材料和结构应能耐受正常使用条件及可能遇到的温度、湿度和机械冲击。)

Accordance(符合)

After temperature and humidity pretreatment, components should not fall off, damage and deformation. (经温度湿度预处理处理后, 部件不应脱落、损坏和变形。)

7. Flammability(可燃性) GB 2626-2019 Section 6.15(条款 6.15)

Unit(单位): <s>

After flame time(续燃时间)

Before pretreatment(未经处理)

sample 1#(样品 1) 0

sample 2#(样品 2) 0

After pretreatment(经预处理)

sample 1#(样品 1) 0

sample 2#(样品 2) 0

After flame time(续燃时间) ≤ 5

Pass(合格)

8. Visual field(视野) GB 2890-2009 section 6.8(条款 6.8)

Below visual field(下方视野) 74.0°

Below visual field(Half-mask)

(下方视野(半面罩)) ≥ 35°

Pass(合格)

Binocular visual field(双目视野) 93.6%

Binocular visual field(Half mask)

(双目视野(半面罩)) ≥ 65%

9. Dead Space(死腔) GB 2626-2019 Section 6.9(条款 6.9)

Unit(单位): <%>

Volume fraction of carbon dioxide

(二氧化碳的体积分数)

0.2

The volume fraction of carbon dioxide(二氧化碳的体积分数) ≤ 1

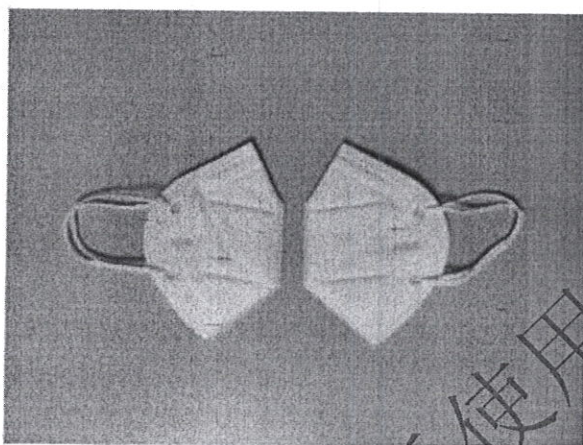
Pass(合格)



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