



PROTECTIVE MASK

GB2626-2006 KN95



EU 149:2001 +A1:2009 • FFP2 NR D

FFP2



PROTECTIVE MASK

GB2626-2006 (Civil Grade)

KN95

APPROVED



Antiviral fiber



Skin-friendly



Particulate matter
filtration



Individual package



FDA

CE

EU 149:2001 +A1:2009 • FFP2 NR D

Product Parameters



Standard size/Earloop



**Individual Package
Clean & Hygienic**

Product Name: PRD Protective Masks

Main Material: Nonwoven Fabric, Meltblown Fabric,
Needle-punched Cotton

Execution Standard: GB2626-2006 / EU 149:2001 +A1:2009

Expiration Date: 3 Years

See the packaging indication for production batch number
and expiration date.

Manufacturer: DONGGUAN LEIHUO MEDICAL DEVICE CO.,LTD

Address: 2F, Building B & 3F, Building D, No.30 Zhonghe Industrial
Park, Liusha, Puning city, Jieyan city, Guangdong, Province

Place of Production: Dongguan Guangdong

PROTECTION LEVEL

KN95

FFP2

N95



EU 149:2001 +A1:2009 · FFP2 NR D

Product Parameters

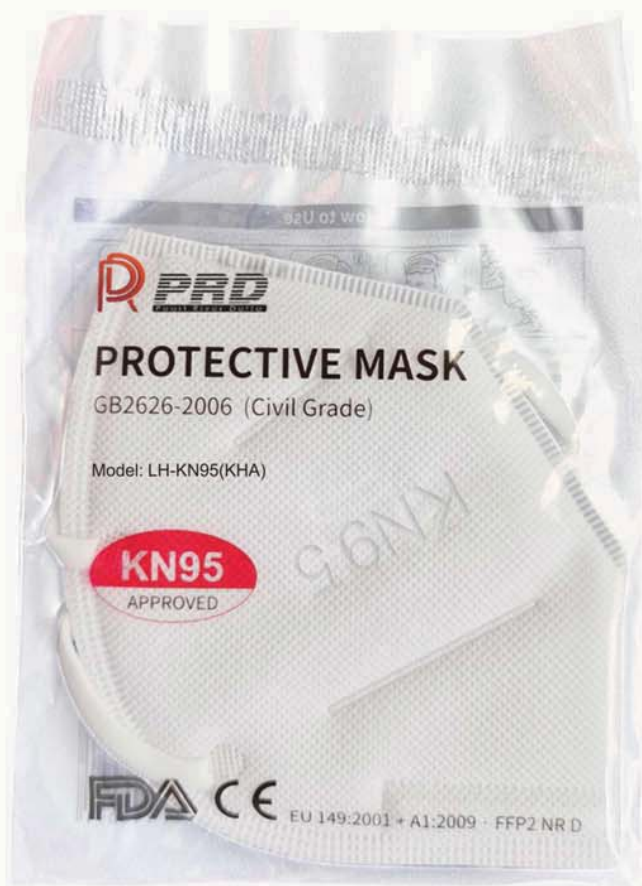


SPECIFICATIONS

MASK

(Independent Packages)

Size:10.7x16cm





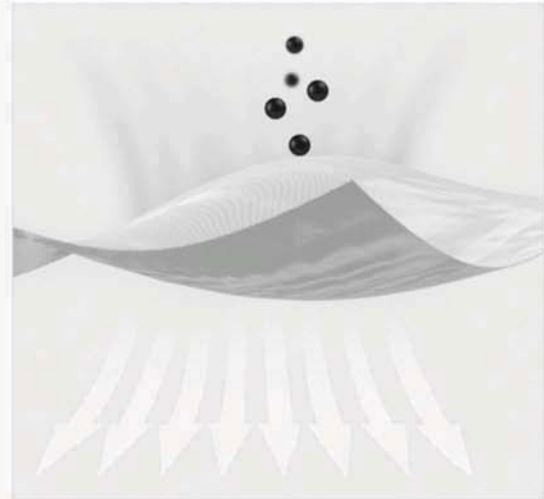
40 pcs/Box

Size:16x13x23cm

MEANS:L*W*H
 69*37*27CM
 G.W: 5.3KG
 N.W:3.2KG
 1 CASE: 10 boxes
 1 BOX: 40pcs
 1 CASE: 400pcs



New & Good Materials, No Secondary Pollution



Multi-effect Protection & Filtration



Product Parameters

Product Name: PRD Protective Masks

Model: LH-KN95(KHA)

Main Material: Nonwoven Fabric, Meltblown Fabric, Needle-punched Cotton
Protection Level: N95

Execution Standard: GB2626-2006 / EU 149: 2001 +A1: 2009

Expiration Date: 3 Years

See the packaging indication for production batch number and expiration date.

Manufacturer: DONGGUAN LEIHUO MEDICAL DEVICE CO.,LTD

Address: Dongshan Yongshenglu No.47 Room 101, Qishi Dongguan,
Guangdong, 523500, China

Place of Production: Dongguan Guangdong

Precautions

1. If the package is damaged, it is forbidden to use the mask. It is limited to respiratory protection against non-oily particles only.

2. It is recommended to store in a dry, ventilated, non-corrosive gas environment below a humidity of 80%, Keep away from ignition sources and flammable materials.

3. This product is not applicable to special industries such as anoxic environment, underwater operation, fire control and industrial dust protection or to respiratory protection of infants.

4. Do not wear a mask if unventilated, hard in breathing or during sleep.

5. People with abnormal heart and lung functions should use masks with caution.

6. If a mask is damaged or you feel the respiratory resistance is obviously increased, replace it in time.

7. In case of any discomfort or adverse reactions during use, discontinue use immediately.

8. Do not reuse.





Nonapplicable Scenes

- Nonapplicable Scenes
- Do not use in an environment above 50°C.
- Do not use in an environment with an oxygen content of less than 20%.
- Do not use in a toxic gas environment.
- Not recommended for children, pregnant women or the elderly.



MADE IN C.C.T

How to Use

				
<p>1. Open the mask to make the nose clip at the top, and pull the ear straps with both your hands.</p> <p>2. Hold the mask against your chin to completely cover your nose and mouth.</p> <p>3. Pull the ear straps behind your ears and adjust them to make you feel comfortable.</p>			<p>4. Use both your hands to adjust the shape of the nose clip. Place your fingers in the middle of the nose clip and press it inwards while moving your fingertips along both sides of the nose clip until it is pressed to fit the bridge of your nose. (Making the nose clip get a seal with only one hand may affect the tightness of the mask).</p> <p>5. Cover the mask with your hand and exhale vigorously. If you feel the air escaping from the nose clip, it is required to tighten the nose clip; if the air escapes from the edge of the mask, readjust the headband to ensure tightness.</p>	

Inspection Method

Before use, check whether the package of the mask is damaged and the components are intact. In case of any stain or damage, discontinue use immediately. Before entering the work area, it is required to check the air tightness of the mask. If you feel a leak, please wear it again according to the instructions for how to wear a mask. You can enter the work area only after feeling no leak. (If you feel the respiratory resistance is obviously increased or the mask falls short of the standard for use, it is recommended to replace the mask immediately.)

KN95	GB2626-2006 (Civil Grade)	This dust mask is used to prevent non-oily suspended particles. Filtration Efficiency $\geq 95\%$.
FFP2 N95		



Do not use if package is damaged!
Please refer to the manual before
use and use a mask correctly!





• 4 4 0 3 8 7 0 1 3 •

统一社会信用代码
91441900MA54C7PW5L

营业执照

(副本)

(副本号: 1-1)



扫描二维码登录“
国家企业信用信息公示系统”了解更
多登记、备案、许
可、监管信息

名称 东莞市雷火医疗器械有限公司

注册资本 人民币壹佰万元

类型 有限责任公司(自然人独资)

成立日期 2020年03月03日

法定代表人 许伟

营业期限 长期

经营范围 生产: 医疗器械、日用口罩(非医用)、电
子产品; 销售: 医疗器械、日用口罩(非医
用)、日用品、电子产品; 产销: 帽子。
(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。)

住所 广东省东莞市企石镇宝石路561
号102室

登记机关



国家企业信用信息公示系统网址:

<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

CELAB®

Via Maira snc
04100 Latina
Italy
celab@celab.com



CERTIFICATE

Certificate Number **UCN** : **802759487332**
Job : J29230
Date of Issue : 2020-03-21
Certificate valid up to : 2024-03-20

Brand Name : Leihuo
Type : Protective masks
Model N : LH-KN95

Manufacturer : Dongguan Leihuo Medical Device Co., Ltd.
Address : Dongshan Yongshenglu N0.47 Room 101, Qishi, Dongguan,
Guangdong China

Standard Used : EN 14683:2005


Conclusion :

After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:

93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .

The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✓ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : HTT202003147LR	✓ OK
Presence of  symbol in the product label.	✓ OK
Presence of instruction manual	✓ OK
Use of valid Harmonized standard in the declaration of conformity	✓ OK
Presence of product description in the technical construction file	✓ OK

Copyright of this Certificate is owned by CELAB® Italy and may not be reproduced other than in full and with the prior approval of the General Manager. Use of this certificate is subjected to Celab regulation available on Celab web site.

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws- Do not use this document without full understanding of regulation.

Massimiliano Bertoldi
General Manager – CELAB
www.celab.com

www.celab.com



Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

DONGGUAN LEIHUO MEDICAL DEVICE CO., LTD.
Dongshan Yongshenglu No.47 Room 101, Qishi
Dongguan, Guangdong, 523500, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10063202



Device Listing#:

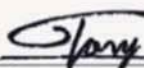
Listing No	Code	Device Name	Proprietary Name
D375637	KHA	MASK, SCAVENGING	KN95 Mask, Disposable Mask

CCT 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. CCT 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. CCT 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 misbranding." 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, CCT is not affiliated with the U.S. Food and Drug Administration.

Shenzhen CCT Testing Technology Co., Ltd.
W: www.fda-test.com E: fda@fda-test.com
T: 400-8788-298 T: 86-755-36916737

Web: <http://www.fda.gov> Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: webmail@oc.fda.gov


Chief engineer

Issued: 03/18/2020

Expiration Date: 12/31/2020





160010260248



(2016)国认监认字(099)号



中国认可
国际互认
检测
TESTING
CNAS L1499

检 验 报 告

检验报告编号: No. 2020(尘) - 603

样品名称: P-Mask 防尘口罩 (颗粒物防护呼吸器)

委托单位: 东莞市雷火医疗器械有限公司

检验类别: 委 托

国家劳动保护用品质量监督检验中心(北京)





中国认可
国际互认
检测
TESTING
CNAS L0823



检测编号: KJ20200309
Test No.

广州市微生物研究所
GUANG ZHOU INSTITUTE OF MICROBIOLOGY

检测报告
TEST REPORT

收样日期: 2020 年 02 月 15 日
Date Received

检测日期: 2020 年 02 月 25 日
Date Analyzed

样品名称 Name of Sample	PRD 防护口罩	检测类型 Test Type	委托检测
委托单位 Applicant	东莞市雷火医疗器械有限公司	样品来源 Sample Source	委托方送检
生产单位 Manufacturer	东莞市雷火医疗器械有限公司	商标 Brand	
生产日期 Date of Production	2020.02.14	生产批号 Batch Number	20200213A
型号规格 Type and Specification	KN95	样品数量 Quantity of Sample	1 份 (55 片)
样品状态 State of Sample	片状	样品包装 Packing of Sample	袋装
样品图片 Sample Picture			
检验依据和方法 Standard and Methods	GB 2626-2006 呼吸防护用品 自吸过滤式防颗粒物呼吸器		
检测项目 Items of Analysis	1. 过滤效率 2. 呼气阻力 3. 吸气阻力 4. 死腔 5. 头带 6. 阻燃性		
备注 Remarks	---		

接下页/To be continued



中国认可
国际互认
检测
TESTING
CNAS L0823



检测编号: KJ20200309
Test No.

广州市微生物研究所
GUANG ZHOU INSTITUTE OF MICROBIOLOGY

检测报告
TEST REPORT

收样日期: 2020年02月15日
Date Received

检测日期: 2020年02月25日
Date Analyzed

检测结果
Test Results

序号	检测项目	单位符号	检测结果	标准要求
1	过滤效率	%	95.6	KN90 (≥90.0%) KN95 (≥95.0%) KN100 (≥99.97%)
2	呼气阻力	Pa	31.5	≤250
3	吸气阻力	Pa	41.7	≤350
4	死腔	[%]	平均值0.7	≤1.0
5	头带	/	合格	10N 10s 无断裂
6	可燃性	/	合格	预处理后燃烧不超过5s

报告结束/End of report

编制:
Editor

徐国洋

审核:
Checker

郭明

签发:
Issuer

李华

签发日期 (公历)
Date Reported





中国认可
国际互认
检测
TESTING
CNAS L0823



声 明

- 一、 本检测报告涂改增删无效，未加盖检测单位“检验检测专用章”无效，无相关责任人签名无效，复印件无效。
- 二、 对送检样品，报告中的样品信息由委托方声称，本单位不对其真实性负责；本检测报告仅对送检样品负责。
- 三、 对报告的异议应于报告签发之日起 15 个工作日内向本单位提出，逾期视为承认本报告。微生物检测不复检。
- 四、 本检测报告及我单位名称不得用于产品标签、广告、评优及商品宣传等。
- 五、 报告中标“*”项目为还未通过广东省资质认定和中国合格评定国家认可委员会认可的项目；标“#”为只通过中国合格评定国家认可委员会认可的项目；标“+”为只通过广东省资质认定的项目。
- 六、 报告中未取得广东省资质认定的项目，检测数据和结果仅作为科研、教学或内部质量控制之用。
- 七、 因报告中所用语言产生的歧义，以中文为准。



联系地址：广州市黄埔区科学城尖塔山路 1 号

检验地址：（与联系地址不同时填写此项）

邮政编码：510663

联系电话：（8620）61302671

网址：<http://www.ggtest.com.cn>