PROTECTIVE MASK

GB2626-2006  KN95

FDA CE

EU 149:2001 +A1:2009  FFP2 NR D
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 Name: PRD Protective Masks
Main Material: Nonwoven Fabric, Meltblown Fabric, Needle-punched Cotton
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, Liusa, Puning city, Jieyan city, Guangdong, Province
Place of Production: Dongguan Guangdong

PROTECTION LEVEL

KN95  FFP2  N95

FDA  CE  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
Product Parameters

New & Good Materials, No Secondary Pollution

Multi-effect Protection & Filtration

4 Layers of Protection

- Nonwoven Fabric
- Melting Fabric
- Needle-punched Cotton
- Nonwoven Fabric
Product Parameters

Product Name: PRD Protective Masks
Model: LH-KN95(KHA)
Main Material: Nonwoven Fabric, Meltblown Fabric, Needle-punched Cotton
Protection Level: N95
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.
How to Use

1. Open the mask to make the nose clip at the top, and pull the ear straps with both your hands.
2. Hold the mask against your chin to completely cover your nose and mouth.
3. Pull the ear straps behind your ears and adjust them to make you feel comfortable.
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)
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.

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.)

<table>
<thead>
<tr>
<th>KN95</th>
<th>GB2626-2006 (Civil Grade)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFP2</td>
<td>N95</td>
</tr>
</tbody>
</table>

This dust mask is used to prevent non-oily suspended particles. Filtration Efficiency ≥95%.

Do not use if package is damaged! Please refer to the manual before use and use a mask correctly!
名称：东莞市雷火医疗器械有限公司
类型：有限责任公司（自然人独资）
法定代表人：许伟
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。）
注册资本：人民币壹佰万元
成立日期：2020年03月03日
营业期限：长期
住所：广东省东莞市企石镇宝石路561号102室
登记机关：国家市场监督管理总局
CERTIFICATE

Certificate Number UCN : 802759487332
Job : J26230
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/EE C 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 | ✓ OK |
| 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 |

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Massimiliano Bertoldi
General Manager – CELAB
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

<table>
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<th>Device Listing#</th>
<th>Code</th>
<th>Device Name</th>
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<tr>
<td>D375637</td>
<td>KHA</td>
<td>MASK, SCAVENGING</td>
<td>KN95 Mask, Disposable Mask</td>
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</tbody>
</table>

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.

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Shenzhen CCT Testing Technology Co., Ltd.
W: www.fda-test.com E: fda@fda-test.com
T: 400-8788-298 T: 86-755-36916327
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
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）
| 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 | 东莞市赛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 | 东莞市赛火医疗器械有限公司 | 商标 Brand | PRD

| 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

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**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**

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***接下页/To be continued***
## 检测结果

<table>
<thead>
<tr>
<th>序号</th>
<th>检测项目</th>
<th>单位符号</th>
<th>检测结果</th>
<th>标准要求</th>
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<tr>
<td>1</td>
<td>过滤效率</td>
<td>%</td>
<td>95.6</td>
<td>KN90（≥90.0%） KN95（≥95.0%） KN100（≥99.97%）</td>
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<tr>
<td>2</td>
<td>呼气阻力</td>
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<td>平均值0.7</td>
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<td>5</td>
<td>头带</td>
<td>/</td>
<td>合格</td>
<td>10N 10s 无破裂</td>
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<tr>
<td>6</td>
<td>可燃性</td>
<td>/</td>
<td>合格</td>
<td>预处理后燃烧不超过5s</td>
</tr>
</tbody>
</table>

***报告结束/End of report***
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