### **O-BRUSH**

### **KN95** Respirator Mask

# TECHNICAL DATA SHEET



#### Description

KN95 - GB2626-2006

5 layers of protection
Filtration of 95% against non-oily particles
Flow rate - 85 L/min
Total Inward Leakage ≤ 8% leakage
Inhalation resistance ≤ 350 Pa
Exhalation resistance ≤ 250 Pa

Manufactured in China

#### **Directions**

- Clean your hands with soap and water or hand sanitizer before touching the mask.
- Place respirator against your face, with the bottom under chin and metal nosepiece across bridge of nose.
- Place each ear loop around your ears.
- Use both hands to bend the metal nosepiece to fit snugly against your nose and face. The respirator may not fit as well if you pinch the
  metal nosepiece using one hand. Use two hands. Slide fingers down both sides of metal nosepiece to seal it against your nose and face

#### **Packaging**

Shipping carton of 1500 masks.

Box Dimensions/Weight

68x40x65cm/ approximately 11kg per carton

#### **Regulatory Information**

GB2626-2006 Standard (China)

EN 149:2001 + A1:2009 Standard (European Union)

#### **Storage Information**

Respirators should be stored indoors, in their original packaging, in a structured storage space away from direct sunlight where they can't become crushed or distorted.

#### **Shelf Life**

2 years

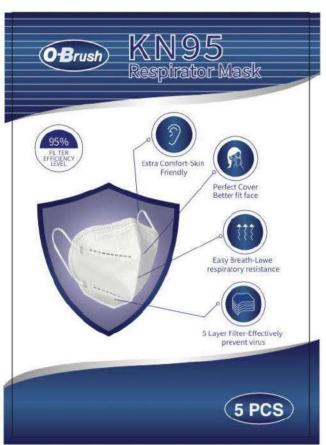
#### Caution

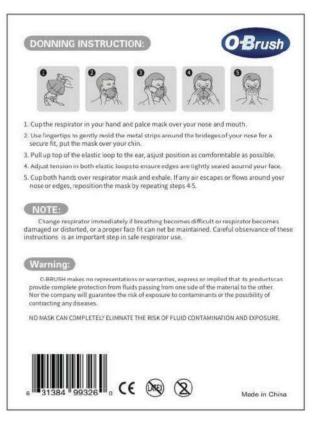
Respirators are designed to help reduce the wearer's exposure to airborne particles. Respirators must be properly selected and carefully donned (put on) and doffed (taken off) in a clean area, and worn the entire time in the contaminated area to have a significant effect on reducing exposure. Having the respirator off even 10% of the time in a contaminated area significantly reduces the protective effect of the respirator.

The dimensions and properties listed above can vary within pre-established specifications. This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.

#### **Images**







# Certificate of Compliance

ECM

No. 0P200322E.GNM0011

Technical Construction File no. TPPEMJ2003133594-AG01

Certificate's Holder:



Certification ECM
Mark:



Product: Model(s): KN95(Not Sterile)

KN95

Verification to:

Standard:

EN 149:2001+A1:2009

related to CE Directive(s):

R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Valuntary Mark for the certification of products. RG01\_ECM rev.3 available at: www.entecerma.it

Issuance date: 22 March 2020 Expiry date: 21 March 2025

> Reviewer Technical expert Amanda Payne

Approver ECM Service Director Luca Bedonni





#### CERTIFICATION OF FDA REGISTRATION

This certifies that:



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

#### Owner/Operator Number:

FDA

Device Listing#:

Listing No	Code	Device Name	Proprietary Name		
D376778 KHA		MASK, SCAVENGING	Disposable respirator KN95		

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.

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Expiration Date: 12/31/2020

Chief engine

Issued: 03/20/2020



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

# 检测报告

# TEST REPORT

 报告编号
 KN95 口罩

 委托单位





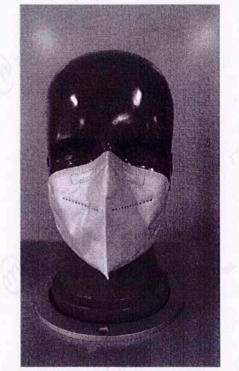
检测编号: Test No.

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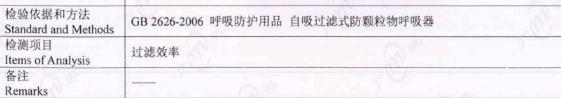
# 检测报告 TEST REPORT

收样日期: 2020 年 02 月 14 日 Date Received 检测日期: 2020 年 02 月 17 日 Date Analyzed

样品名称 Name of Sample KN95 口罩		检测类型 Test Type	委托检测	
委托单位 Applicant		样品来源 Sample Source	委托方送检	
生产单位 Manufacturer		商标 Brand		
生产日期 Date of Production	2020年02月14日	生产批号 Batch Number		
型号规格 Type and Specification	-	样品数量 Quantity of Sample	16 个	
样品状态 State of Sample	片状	样品包装 Packing of Sample	袋装	



样品图片 Sample Picture



\*\*\*接下页/To be continued\*\*\*







检测编号: Test No.

# 广州市微生物研究所

# 检测报告 TEST REPORT

收样日期: 2020年02月14日 Date Received

检测日期: 2020年02月17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
	0	0.4		KN90 (≥90.0%)
1 76	过滤效率	%	99.6	KN95 (≥95.0%)
				KN100 (≥99.97%)

\*\*\*报告结束/End of report\*\*\*











# 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。
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- 七、 因报告中所用语言产生的歧义,以中文为准。

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