



Health Alert: Imported KN95 Masks

Purpose

IDPH recommends discontinuing the use of any imported KN95 respirators for procedures that require the use of an N95 or similar respirator unless their authenticity and performance (through fit testing) can be verified.

- KN95 masks from China may not meet performance standards
- Counterfeit KN95 masks are reportedly flooding the marketplace
- Illinois has distributed KN95 masks throughout the state

Background

An increasing number of imported respirators from China have received an emergency use authorization from the U.S. Food and Drug Administration (FDA). The Illinois Department of Public Health is aware of at least two instances of vendors offering for sale counterfeit versions of such respirators.

Monday afternoon, the State of Missouri announced that it is recalling approximately 48,000 KN95 respirators that had been distributed to first responders during the first week of April. According to the announcement shared with Missouri's emergency response partners (see attached), testing by the Missouri Department of Health and Senior Services demonstrated that some of these respirators did not meet standards. They included respirators labeled "Huabai" and "Sanqi" as well as unmarked respirators that did not bear a brand name (see attached images); however, the State of Missouri is recalling **all** previously distributed KN95 respirators.

Recommendation

IDPH recommends the following to partner agencies who have received personal protective equipment from the State of Illinois:

1. Discontinue using any KN95 respirators for procedures that require the use of an N95 or similar respirator unless their authenticity and performance (through fit testing) can be verified.
2. Stop distributing any KN95s that have not been added to Appendix A of FDA's emergency use authorization.
3. Remove from service any KN95s that have already been received.
4. Do not use KN95s whose performance cannot be verified through successful fit testing.

The authenticity of a respirator can be gauged by checking Appendix A (<https://www.fda.gov/media/136663/download>) to FDA's emergency use authorization

(<https://www.fda.gov/media/136664/download>). Only respirators that meet FDA's eligibility criteria will be added to Appendix A as an authorized respirator.

End users may also want to check NIOSH's website (<https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html>), as well as the manufacturer's website for additional information.

The use of respiratory protection in workplaces is governed by the U.S. Occupational Safety and Health Administration Respiratory Protection Standard (29 CFR 1910.134). This standard includes a requirement to perform an initial fit test to ensure employees are provided with a respirator that properly fits their face. Employees must be fit tested using the exact size, make and model respirator they will actually wear so first responders, health care providers, and others who receive newly purchased or donated respirators that differ from the respirators employees normally wear should be conducting fit testing for each new make or model respirator to confirm a proper fit. Employees should only utilize respirators that fit properly in conjunction with a written respiratory protection program. Moreover, employees should be trained to perform a user seal check every time they put on the respirator using procedures recommended by the manufacturer.

Michael L. Parson
Governor

Sandra K. Karsten
Director of Public Safety



STATE OF MISSOURI

James Remillard
Acting Director

STATE EMERGENCY MANAGEMENT AGENCY

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April 13, 2020

Dear Emergency Response Partner:

The **Missouri State Emergency Management Agency** is recalling approximately 48,000 KN95 masks that do not meet standards. These masks were distributed to local law enforcement and fire service agencies in all regions of the state on April 2 and April 8.

The recalled masks **may** bear the names "Huabai," "SANQUI," or be unmarked, with Chinese characters on the cellophane packaging, **or other names**. See the images below for the three types of masks we have identified to date.

If your agency received KN95 masks from SEMA, we request that they be taken out of circulation and placed in a secure location until arrangements can be made for SEMA to collect the masks.

Please do not utilize these masks during responses that require an N95 respirator mask.

SEMA will NOT distribute any additional KN95 masks.

While the **Centers for Disease Control and Prevention** has included KN95 masks as an alternative to other certified masks for emergency COVID-19 response when supplies are short, further inspection by SEMA and the **Missouri Department of Health and Senior Services** determined some of the masks in the April 2 and 8 shipments did not meet standards.

For more information on the CDC's guidelines for N95 masks and alternatives during the COVID-19 emergency, [click](#) here and go to the section titled "When N95 Supplies are Running Low."

Included below are images of the three KN95 masks SEMA has identified for recall. As stated above we are recalling ALL KN95 masks distributed by SEMA.

We appreciate our local partners around the state who are selflessly responding to the challenges of COVID-19 and regret distribution of these masks that did not meet DHSS standards.

We continue our efforts to obtain PPE for our law enforcement and fire service agency partners.

Sincerely,

A handwritten signature in black ink, appearing to read "J. W. Remillard".

Jim Remillard
Acting SEMA Director



A Nationally
Accredited
Agency





SAN QI 三奇

9505

自吸过滤式防颗粒物呼吸器
GB2626-2006 KN95

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www.sanqicn.com

商标: 那时花开®

品名: KN95防护口罩

材质: 纺粘无纺布、热风布、KN95熔喷过滤布

尺寸: 对折测量约为10.8x16cm

执行标准: GB2626-2006 KN95

生产日期:

保质期: 3年 (储存条件: 温度-25℃至50℃, 相对湿度75%以下)

生产商: 山东云豪卫生用品股份有限公司

地址: 山东省临朐县城关街道工业园西路607号

电话: 400-999-7266

传真: 0536-3497766

合格