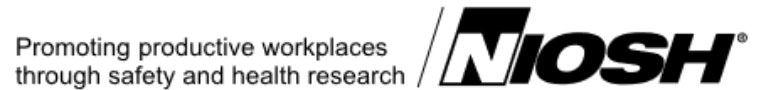




The National Personal Protective Technology Laboratory (NPPTL)



Counterfeit Respirators / Misrepresentation of NIOSH-Approval

Updated June 5, 2020

Counterfeit respirators are products that are falsely marketed and sold as being NIOSH-approved and may not be capable of providing appropriate respiratory protection to workers. When NIOSH becomes aware of counterfeit respirators or those misrepresenting NIOSH approval on the market, we will post them here to alert users, purchasers, and manufacturers.

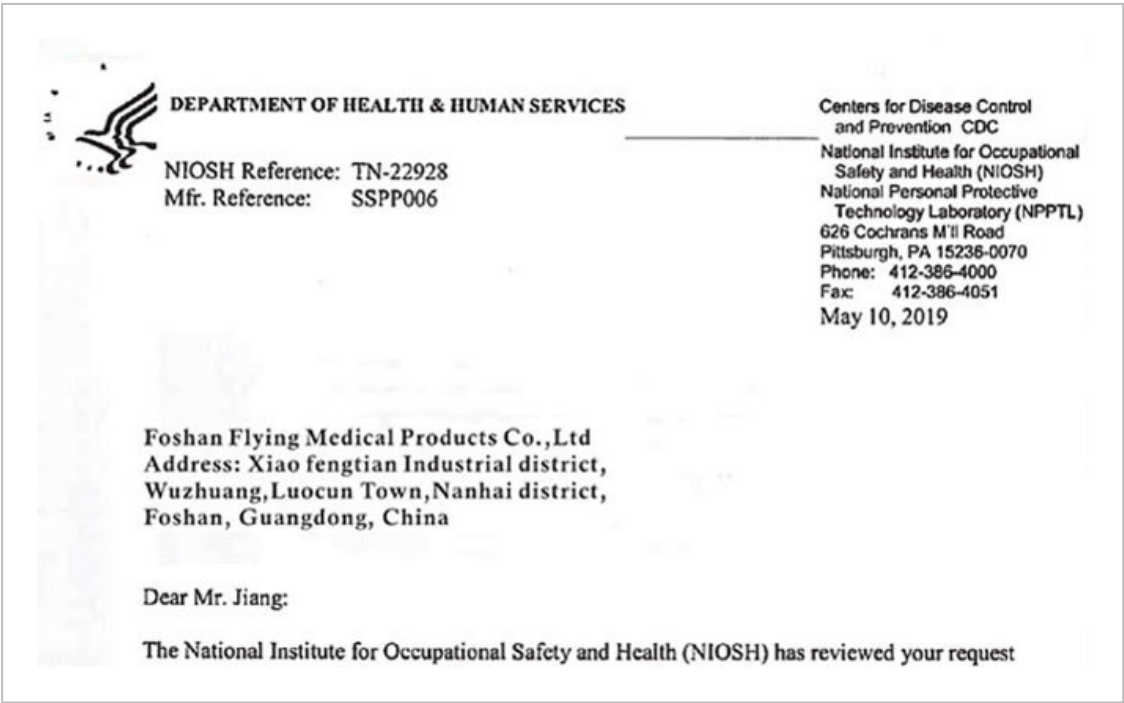
How to identify a NIOSH-approved respirator:

NIOSH-approved respirators have an approval label on or within the packaging of the respirator (i.e. on the box itself and/or within the users' instructions). Additionally, an abbreviated approval is on the FFR itself. You can verify the approval number on the [NIOSH Certified Equipment List \(CEL\)](#) or the [NIOSH Trusted-Source](#) page to determine if the respirator has been approved by NIOSH. NIOSH-approved FFRs will always have one the following designations: N95, N99, N100, R95, R99, R100, P95, P99, P100.

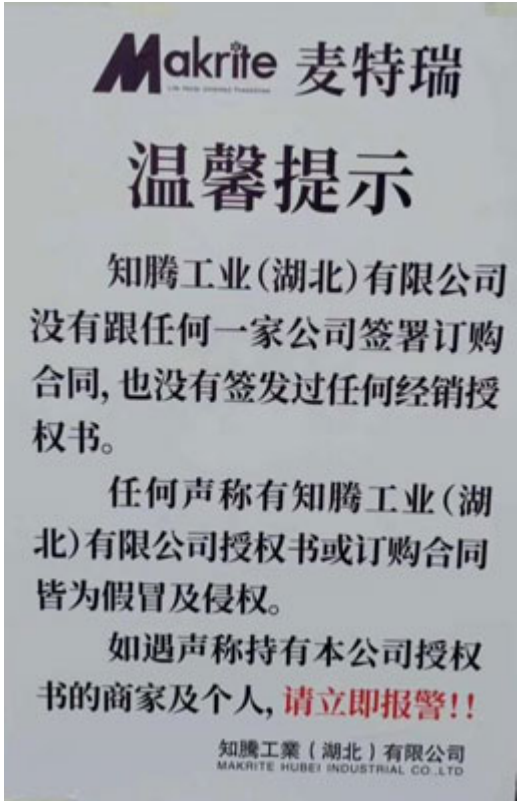
Signs that a respirator may be counterfeit:

- No markings at all on the filtering facepiece respirator
- No approval (TC) number on filtering facepiece respirator or headband
- No NIOSH markings
- NIOSH spelled incorrectly
- Presence of decorative fabric or other decorative add-ons (e.g., sequins)
- Claims for the of approval for children (NIOSH does not approve any type of respiratory protection for children)
- Filtering facepiece respirator has ear loops instead of headbands

Additional Tips for Spotting Counterfeit Respirators Before You Buy



NIOSH has not issued any letters to Foshan Flying Medical Products Co., Ltd. This letter was altered to appear that Foshan Flying Medical Products was the recipient. Any N95 filtering facepiece respirators for sale accompanied by this letter are **NOT NIOSH approved.** (6/3/2020)



Translation of letter: “Makrite Hubei Industrial Co., Ltd has not signed any purchase contracts or agreement with any company or issued any distribution authorization. Anyone claiming that they have authorization or a purchase contract with Makrite Hubei Industrial Co., Ltd is forgery and infringement. In case of any business or individual claiming to have the authorization letter or certification from Makrite Hubei Industrial Co., Ltd, please report to the police immediately.”

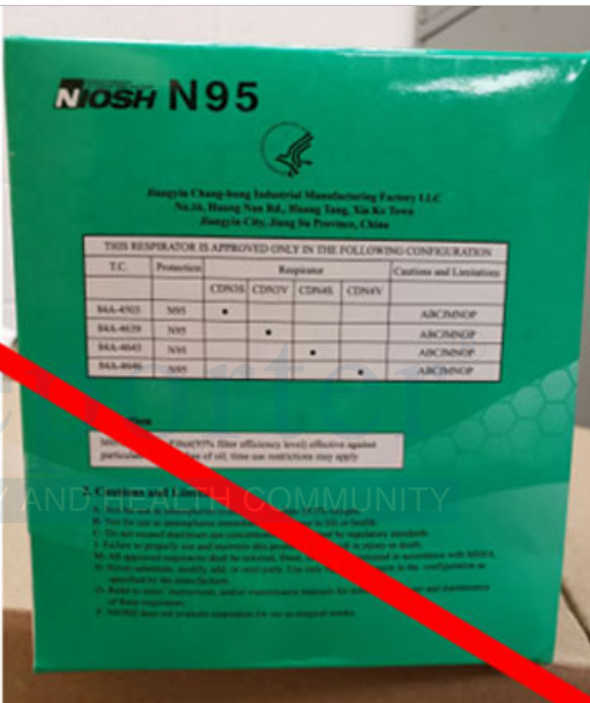
Makrite Hubei Industrial Co., Ltd, a subsidiary of NIOSH approval holder Makrite Industries Inc., issued a notice to alert customers of a product that is potentially being manufactured without the permission of Makrite and may be misrepresented as NIOSH approved. (5/15/2020)



NOT NIOSH-APPROVED



NOT NIOSH-APPROVED



This is an example of a misrepresentation of a NIOSH-approved product. Products made by Jiangyin Chang-hung Industrial or labeled GRANDE are NOT NIOSH approved. The numbers listed on the packaging, TC-84A-4503, -84A-4639, -84A-4643, and -84A-4646, are not valid NIOSH approval numbers. (5/14/2020)



NOT NIOSH-APPROVED



NOT NIOSH-APPROVED



These are two examples of respirators being misrepresented as NIOSH approved on www.covidness.net . The SEKURA-321 is listed as NIOSH approved with approval number TC-84A-6660. Although this is a valid NIOSH approval number issued to Makrite, the website is selling a counterfeit respirator and using Makrite’s approval number without their

permission. The second example is called MIUTON. It is being misrepresented as NIOSH certified, but is NOT NIOSH approved. (5/13/2020)



This is an example of a counterfeit respirator using Shanghai Dasheng Health Products Manufacture Co. Ltd's (SDH) NIOSH approval number, TC 84A-4335, without their permission. SOUND is not a NIOSH approval holder or a private label holder. (4/28/2020)



DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-21698
Mfr. Reference: MAK-1107

Public Health Service

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051
March 11, 2020

Mr. Tailin Chen, President
Shenzhen Ende Medical Technology Co., Ltd.
C4, 9th Floor, Building D, Huilongda Industrial Park, Shuitian community,
Shilong community, Shiyao street, Bao'an, Shenzhen, Guangdong, CN 518108

Dear Mr. Chen:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted March 11, 2020. This request was for an approval of the model En-06 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference the assembly matrix MAKI 105.AML.xls.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. The approval number En-06-N95 has been assigned. This respirator is approved for protections against particulates at a N95 filter efficiency level (N95).

The CD enclosed with this letter contains the final respirator label. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

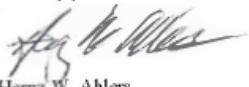
The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that the respirator has met the requirements of Title 42, Code of Federal Regulations, Part 84 (42 CFR 84).

Page 2 — — FN-17685

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely yours,



Henry W. Ahlers
Chief Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures

NIOSH did not issue this letter and test report to Shenzhen Ende Medical Technology Co., Ltd. Although they appear to be from NIOSH, these documents have been altered and the information contained has been falsified. Shenzhen Ende Medical Technology Co., Ltd. is NOT a NIOSH approval holder. Any N95 filtering

National Institute for Occupational Safety and Health

NIOSH

National Institute for Occupational Safety and Health

National Personal Protective Technology Laboratory

Technology Evaluation Branch

Certification, Evaluation and Testing Section

P.O. Box 18070

Pittsburgh, PA 15236

TEST REPORT

Task Number: TN-21698

Manufacturer: Shenzhen Ende Medical Technology Co.,Ltd.

Prepared by: Jeremy Branmen

Tests Conducted by: Jeremy Branmen

Date: March 30, 2011

Respirator Tested: EN-06

Background Information

In an application accepted March 11, 2020 Shenzhen Ende Medical Technology requested an approval of the model EN-06-N95 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference the assembly matrix MAK1105AMI.xls.

Tests Assigned

Test Description	STP Number	Reference
A. Exhalation Resistance Test	RCT-APR-STP-0003	84.180
B. Inhalation Resistance Test	TEB-APR-STP-0007	84.180
C. Sodium Chloride (NaCl) N95 Test	TEB-APR-STP-0059	84.181

Overall Results

The items tested passed laboratory testing.

Individual Test Results

See attached test data sheets.

TEB-1020 Rev. 0

Page 1 of 1

facepiece respirators from Shenzhen Ende claiming to be NIOSH-approved or accompanied by these documents are **NOT NIOSH approved.** (4/27/2020)

These are examples of counterfeit respirators using Shanghai Dasheng Health Products Manufacture Co. Ltd's (SDH) NIOSH approval numbers without their

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https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

4/11



permission. These models include, but may not be limited to, models DTC3X (marked as TC-84A-4329), DTC3W (marked as TC-84A-4335), DTC3B (marked as TC-84A-4336), DTC3Z (marked as TC-84A-8150), and Raxwell RX9501P. Note that any SDH respirators with ear loops are **NOT** NIOSH approved. (4/17/2020)



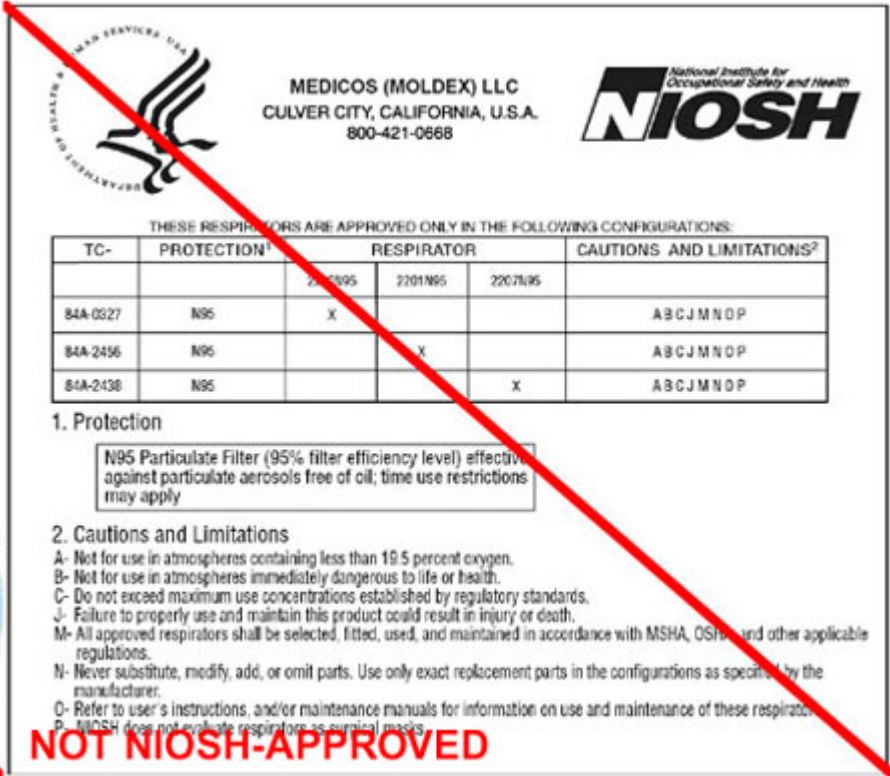
This is an example of a misrepresentation of a NIOSH-approval. G & F Products is not a NIOSH approval holder or a private label holder. (4/9/2020)



Any respirators being sold as Maskin are no longer NIOSH approved. They are counterfeit or they are no longer compliant to the NIOSH approval. (4/9/2020)



NOT NIOSH-APPROVED



NOT NIOSH-APPROVED

THESE RESPIRATORS ARE APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

TC-	PROTECTION ¹	RESPIRATOR	CAUTIONS AND LIMITATIONS ²
		220/2395	
		2201N95	
		2207N95	
84A-0327	N95	X	ABCJMNOP
84A-2456	N95		ABCJMNOP
84A-2438	N95		ABCJMNOP

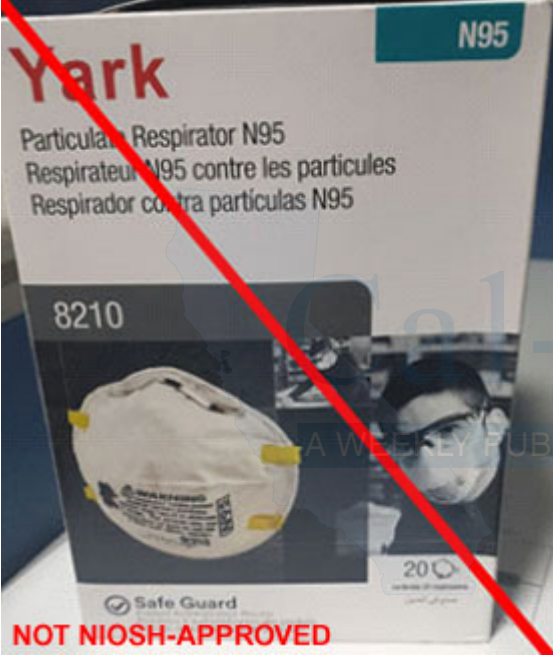
1. Protection

N95 Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply

2. Cautions and Limitations

A- Not for use in atmospheres containing less than 19.5 percent oxygen.
B- Not for use in atmospheres immediately dangerous to life or health.
C- Do not exceed maximum use concentrations established by regulatory standards.
J- Failure to properly use and maintain this product could result in injury or death.
M- All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
N- Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configurations as specified by the manufacturer.
D- Refer to user's instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
P- NIOSH does not evaluate respirators as surgical masks.

This is an example of a counterfeit respirator. Medicos is selling an N95 respirator using the Moldex approval number and label without Moldex’s permission. Medicos is not a NIOSH approval holder or private label holder. (3/12/2020)

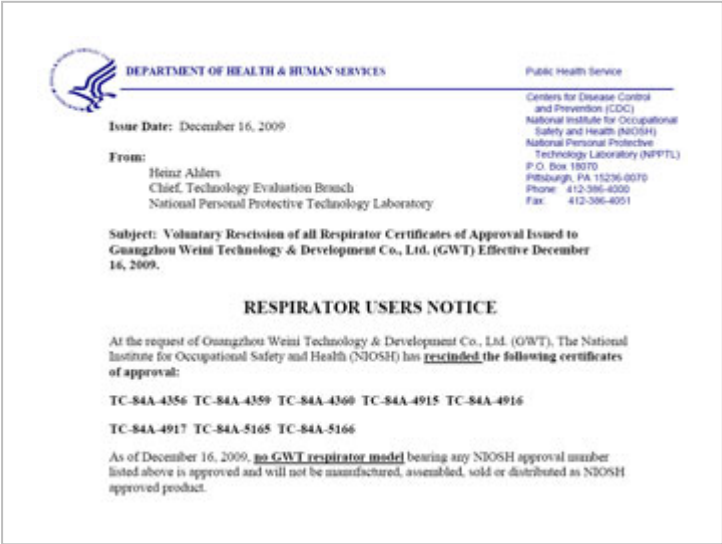


NOT NIOSH-APPROVED



NOT NIOSH-APPROVED

This is an example of a misrepresentation of the NIOSH-approval. Yark is not a NIOSH approval holder or a private label holder. Additionally, respirators from the box include the CE (European) approval mark and NIOSH N95. This is not an acceptable format for a NIOSH-approved respirator. (3/5/2020)



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15256-0070
Phone: 412-396-4000
Fax: 412-396-4001

Issue Date: December 16, 2009

From: Heinz Alders
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Subject: Voluntary Rescission of all Respirator Certificates of Approval Issued to Guangzhou Weini Technology & Development Co., Ltd. (GWT) Effective December 16, 2009.

RESPIRATOR USERS NOTICE

At the request of Guangzhou Weini Technology & Development Co., Ltd. (GWT), The National Institute for Occupational Safety and Health (NIOSH) has **rescinded** the following certificates of approval:

TC-84A-4356 TC-84A-4359 TC-84A-4369 TC-84A-4915 TC-84A-4916
TC-84A-4917 TC-84A-5165 TC-84A-5166

As of December 16, 2009, **no GWT respirator model** bearing any NIOSH approval number listed above is approved and will not be manufactured, assembled, sold or distributed as NIOSH approved product.

The Guangzhou Weini Technology & Development Co., Ltd. (GWT) respirator with model number K320 is not NIOSH-approved. GWT respirator approvals were rescinded in 2009. Please refer to our [user notice](#) for additional information. GWT respirators bearing any NIOSH approval number listed on the user notice is **NOT** NIOSH-approved. (2/10/2020)





NOT NIOSH-APPROVED

There are no markings on the face of the respirator. (11/6/2019)



NOT NIOSH-APPROVED

NIOSH does not approve any type of respiratory protection for kids. (11/6/2019)



NOT NIOSH-APPROVED

There are no markings on the face of the respirator. (11/6/2019)



NOT NIOSH-APPROVED

This product is not NIOSH-approved. Look at the markings on the front. The logo is wrong, there is no approval number (TC-84A-xxxx). (11/6/2019)



NOT NIOSH-APPROVED

This product is not NIOSH approved. No NIOSH logo or approval number on the face of the product. (11/6/2019)



NOT NIOSH-APPROVED

This product is not NIOSH approved. No NIOSH logo or approval number on the face of the product. (11/6/2019)

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NOT NIOSH-APPROVED



NOT NIOSH-APPROVED



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NOT NIOSH-APPROVED

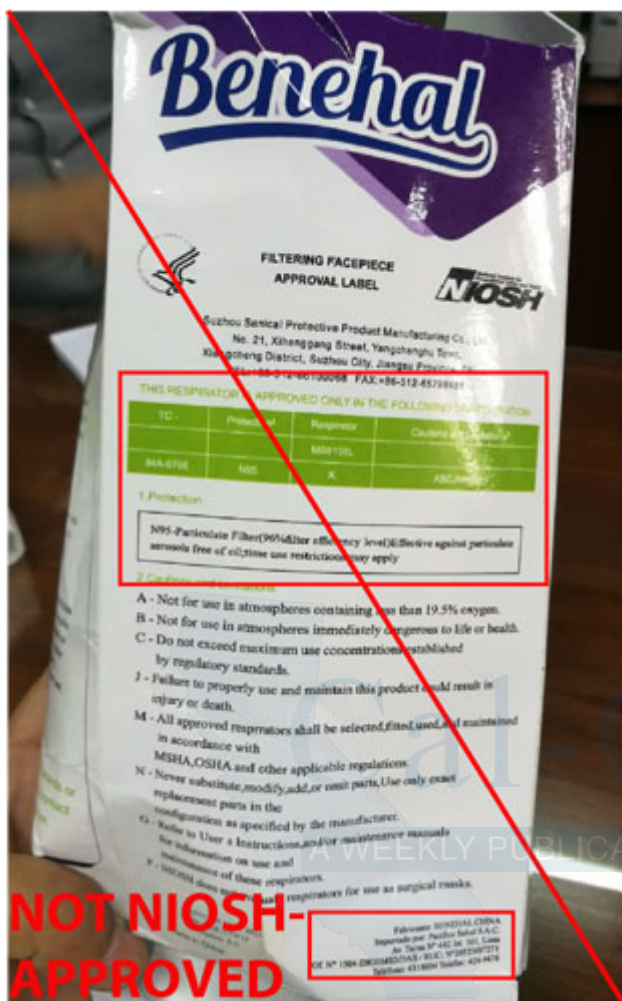


Images here are examples of counterfeit respirators. These respirators are being sold as if they are NIOSH-approved even though the manufacturer, Anhui Tongcheng YaGe Health Materials, Co., Ltd, is not listed as a NIOSH approval holder or a private label holder. (10/23/2019)

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These are examples of misrepresentation of the NIOSH-approval. PitBull Safety Products is not a NIOSH approval holder. (10/07/2019)



This is an **example of a counterfeit respirator**. Pacifico Salud SAC is selling units using the Suzhou Sanical Protection (SSP) approval number (TC-84A-6766) and label without SSP's permission. Additionally, there are two errors on the respirator package. The first error is that they claim the N95 respirator is 96% efficient. The second error is located in the bottom right corner of the package where it states the respirator is manufactured by Benehal China, who is not a NIOSH approval holder. (1/4/2019)

This counterfeit respirator, NT-V2 Nano Bi-Directional respirator, is being advertised as a NIOSH-approved, using a NIOSH approval number. The TC number (TC 84A-0427) belongs to a 3M full facepiece respirator with cartridges and was used without 3M's permission. Additionally, this counterfeit respirator was *not* manufactured by Pasture Pharma.



This respirator is being sold as if it is NIOSH-approved, even though the manufacturer, FitSeal, is not listed as a NIOSH approval holder or a private label holder. (2/19/2019)

This is an **example of misrepresentation of the NIOSH-approval**. All approvals for Wein Products (WPI) were rescinded in 2011. However, the manufacturer's website continues to state the ViraMask N99ESC is certified by NIOSH. [View the user notice announcing the rescission.](#)



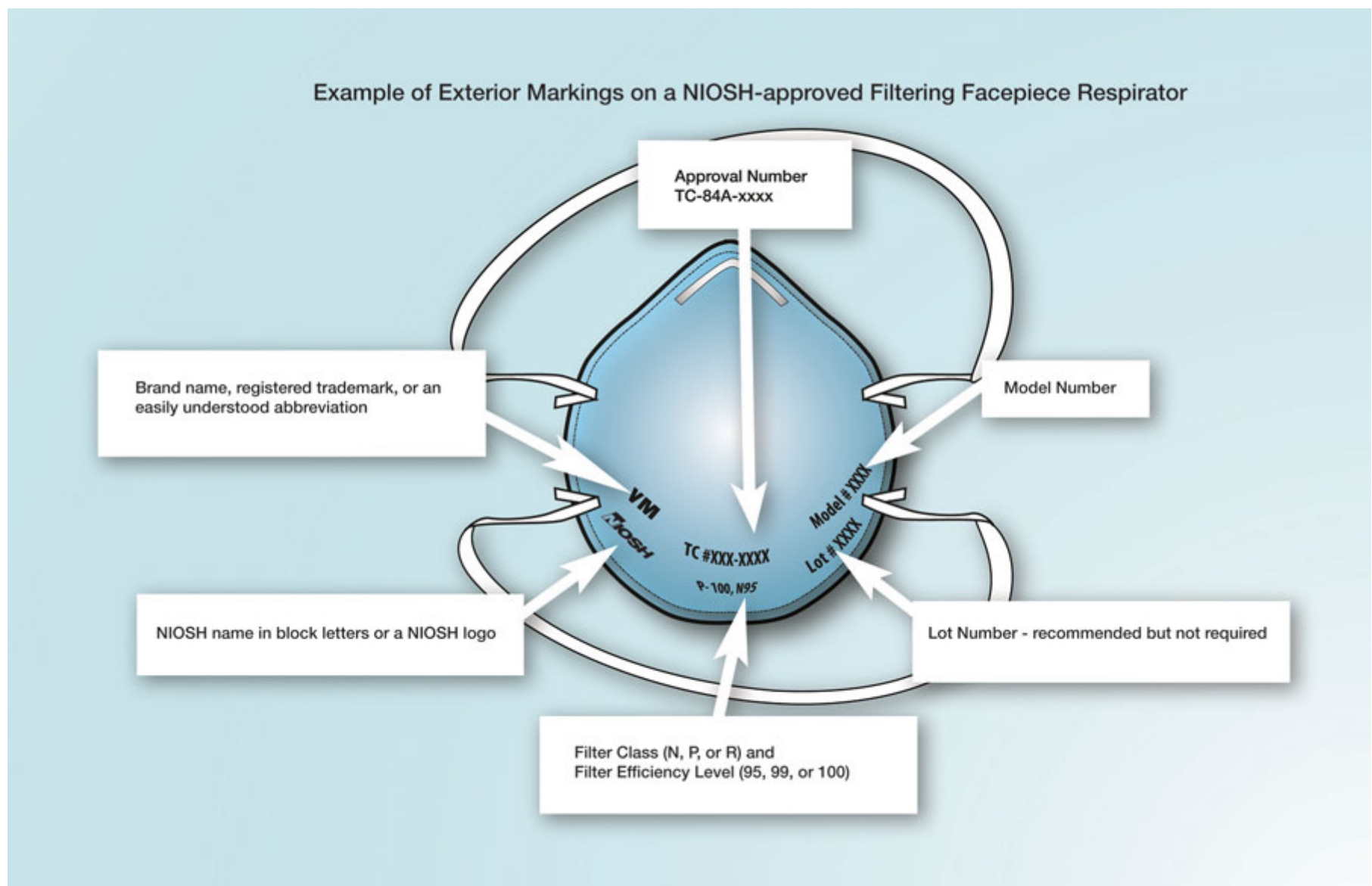
This is an **example of a counterfeit N95 Respirator** that was brought to NIOSH's attention. While the TC number and private label holder are valid, this unapproved unit can be identified by the misspelling of NIOSH on the front of the respirator.



These are **examples of counterfeit respirators**. These respirators are being sold as if they are NIOSH-approved even though the manufacturer, Zubi-Ola, is not listed as a NIOSH approval holder or a private label holder.

Check the respirator approval markings (graphic below) or the [Certified Equipment List](#) to verify your respirator is NIOSH-approved. Additional information is available on the NIOSH [Trusted Source page](#).

Example of the Correct Exterior Markings on a NIOSH-Approved Filtering Facepiece Respirator



Page last reviewed: June 5, 2020

