

# 口罩座談

November 21, 2020

# Disclaimer:

1. The content of this seminar should not be taken as medical advice. Please see your doctor for medical related matter.
2. This seminar does not promote or demote any company and/or product. The presenter has no relationship with the companies mentioned in this seminar.
3. Data provided in this seminar are for information only. Users of the data in this presentation should verify the accuracy of the data.

# OBJECTIVE

1. 請問您戴的是那一種？
2. 那種口罩可防 COVID-19？
3. 在美國,那裡可以買到美國製造口罩？  
台灣製造口罩？
4. 如何辨別口罩真偽？  
如何避免買到假口罩？

# OBJECTIVE #1

請問您戴的是那一種口罩？

# 口罩種類

1. 一般口罩 (Face Mask)
2. PM2.5口罩
3. 一般醫用口罩
4. 外科(手術)口罩 (Surgical)
5. KN95, N95, N95 NIOSH, N95s

Level 2口罩, 第一等級, 第二等級, 活性炭, .....

# 美國口罩分類

<https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/face-masks-and-surgical-masks-covid-19-manufacturing-purchasing-importing-and-donating-masks-during>

<https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks#s4>

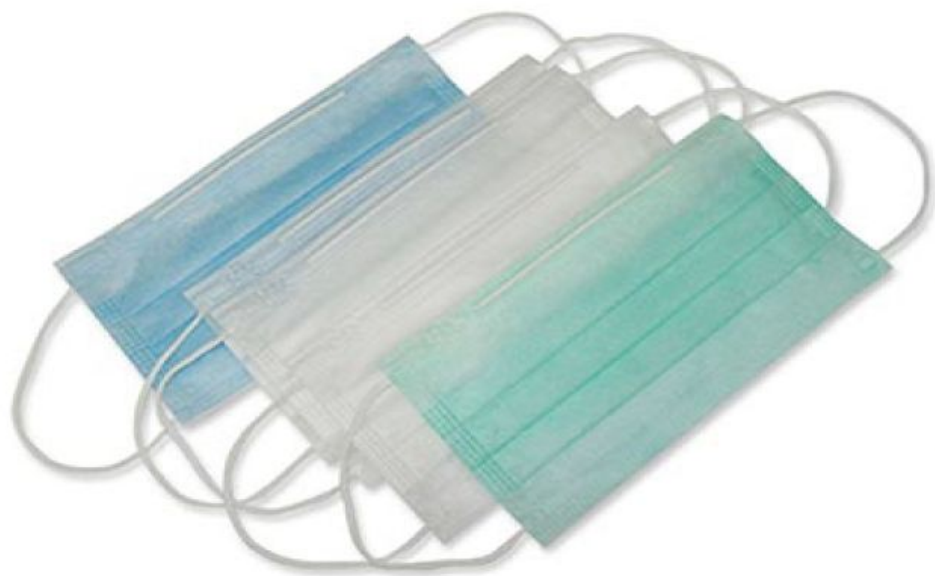
# 美國口罩分類

## 1. Face Masks

A. Non-Surgical

B. Surgical (FDA registered, cleared)

2. Respirators (NIOSH approved)



**Mask**

**vs**



**Respirator**



# MEDICAL FACE MASK MATERIAL DETAILS



# FACE MASKS MATERIALS

POLYPROPYLENE 聚丙烯

Non-woven spunbond

Non-woven melt-blown

Static Electricity, Activated carbon

# Respirator Types



**Disposable    Half Face    Full Face**

# Understanding the Difference



**Surgical Mask**



**N95 Respirator**



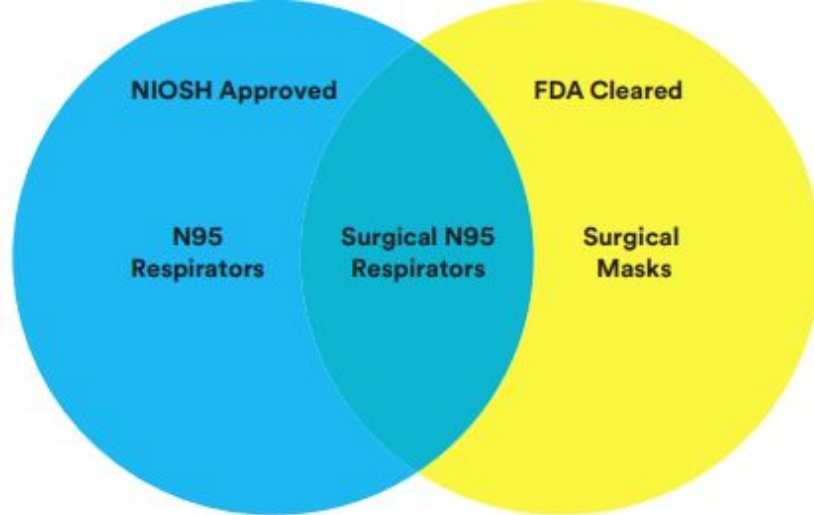
**Elastomeric Half Facepiece Respirator**

	Surgical Mask	N95 Respirator	Elastomeric Half Facepiece Respirator
<b>Testing and Approval</b>	Cleared by the U.S. Food and Drug Administration (FDA)	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84*	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84
<b>Intended Use and Purpose</b>	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols)	Reusable device made of synthetic or rubber material
<b>Face Seal Fit</b>	Loose-fitting	Tight-fitting	Tight-fitting
<b>Fit Testing Requirement</b>	No	Yes	Yes
<b>Designed for Reuse</b>	No	No	Yes
<b>User Seal Check</b>	No	Yes. Required each time the respirator is donned (put on)	Yes. Required each time the respirator is donned (put on)
<b>Filtration</b>	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles	May be equipped with filters that block 95%, 99%, or 100% of very small particulates. Also may be equipped to protect against vapors/gases.
<b>Leakage</b>	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales
<b>Use Limitations</b>	Disposable. Discard after each patient encounter.	Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids.	Reusable and must be cleaned/disinfected and stored between each patient interaction

\*As of July 3, 2016, NIOSH evaluates NIOSH EELs intended for use in healthcare for biocompatibility, flammability, and fluid resistance to ensure conformity to relevant standards during the approval process. These tests were previously performed by the FDA.

N95 NIOSH  
Surgical  
N95s

NIOSH-approved  
FDA-cleared  
Surgical N95



<b>Function</b>	Help reduce particles inhaled by wearer	Help reduce particles both inhaled and expelled by wearer (plus fluid resistance)	Help reduce particles expelled by wearer into environment (plus fluid resistance)
<b>Application</b>	Can be used for respiratory protection when wearer might be exposed to particulate hazards	Meant to be used during surgery and other tasks during which <b>both</b> of these are true: <ul style="list-style-type: none"> <li>• Wearer requires respiratory protection <b>...and...</b></li> <li>• Expelled particulates must be contained or fluid resistance is required</li> </ul>	Can be used during surgery and other tasks to help protect patient, and/or when fluid resistance may be required

# 3M N95



8200



8210



8210Plus



8511



8577

NIOSH-APPROVED N95	N95	N95	N95	N95	
NIOSH-APPROVED P95					P95
Particulate Reduction	✓	✓	✓	✓	✓
No components made from natural rubber latex	✓	✓	✓	✓	✓
Advanced Filter Media	✓	✓	✓	✓	✓
Stretchable, Braided Headbands			✓	✓	✓
3M Cool Flow Valve				✓	✓

# 3M Surgical N95



3M™ Health Care Particulate Respirator and Surgical Mask ...



3M™ Health Care Particulate Respirator and Surgical Mask ...



3M™ VFlex™ Healthcare Particulate Respirator and ...



3M™ VFlex™ Healthcare Particulate Respirator and ...

Add to compare

Add to compare

Add to compare

Add to compare



3M™ Aura™ Health Care Particulate Respirator and ...



3M™ VFlex™ Health Care Particulate Respirator and ...



3M™ VFlex™ Health Care Particulate Respirator and ...



# KN95 vs N95

## KN95 vs N95

According to 3M ([source](#)), the Chinese KN95 standard has an equivalent specification to N95/FFP2 respirators . To quote:

*“It is reasonable to consider China KN95, AS/NZ P2, Korea 1st Class, and Japan DS FFRs as **equivalent** to US NIOSH N95 and European FFP2 respirators”*

In practice the issue is more complex, and I wouldn't take for granted that all KN95 respirators are up to the same standard.

Things to watch out for:

- Typically KN95 respirators are held in place by over-ear elastic loops, rather than behind the head elastics. This *can* result in a weaker seal. Fortunately there are methods for tightening – see [this](#) YouTube video for ideas. Products called “ear savers” can also aid with tightening, and can be found on [eBay](#) or you can [3D print them](#).
- There's no guarantee that all KN95 respirators *actually* meet the Chinese KN95 standard. However, with the current respirator shortage, unfortunately the same goes for N95/FFP also.

# 台灣口罩分類

<https://www.fda.gov.tw/TC/siteContent.aspx?sid=11139&fbclid=IwAR23uqQb-mA6YScO9IzlvU2kBLoMTm8TfCvZIJMugWzAhEwdXO4hsZEmpBY>

# 我國醫用口罩管理制度 簡介



行政院衛生署食品藥物管理局  
醫療器材及化粧品組

# 台灣口罩分類

1. 非醫用口罩
2. 醫用(療)口罩 (T FDA)
  - 2.1 一般醫用口罩
  - 2.2 外科(手術)口罩
  - 2.3 醫用N95口罩,  
N95外科口罩(外科手術D2防塵面罩)

- **醫療器材**的定義—藥事法第13條：

本法所稱醫療器材，係包括診斷、治療、減輕或直接預防人類疾病，或足以影響人類身體結構及機能之儀器、器械、用具及其附件、配件、零件。

- 標示或宣稱作為醫療用途之口罩屬於醫療器材 → 直接預防疾病

- 非醫療用途之防塵口罩（僅標示一般性規格、過濾材質種類及其效率，或是宣稱減少、降低工作人員吸入工作環境之化學物質與危險物者，如N95），不以醫療器材列管。

## ● 一般醫用面罩：

- 醫療人員於執行醫療程序（不包括外科手術）時配戴之面罩，主要用途為防止病人與醫護人員之間微生物、體液及粒狀物質之傳遞與感染，屬**第1等級**醫療器材。
- 許可證字號：衛署醫器製（輸）壹字第000000號
- 檢測效能要求包括：
  - ☑ 細菌過濾效率95%以上
  - ☑ 壓差（呼吸阻抗）5 mm H<sub>2</sub>O/cm<sup>2</sup>以下



## • 外科口罩：

- 醫療人員為執行手術程序（Surgical procedure）而穿戴的面罩，屬**第2等級**醫療器材。
- 許可證字號：衛署醫器製（輸）字第000000號
- 檢測效能要求包括：
  - ☑ 細菌過濾效率95%以上
  - ☑ 壓差（呼吸阻抗）5 mm H<sub>2</sub>O/cm<sup>2</sup>以下
  - ☑ 合成血液穿透性最小通過壓力80 mmHg
  - ☑ 次微米粒子（NaCl微粒0.075 μm）防護效率80%以上
  - ☑ 可燃性1級（3.5秒以上的阻燃性或不著火）

- 前述醫療用口罩如另標示/宣稱具N95（或等同）效果，則稱之為

醫用N95口罩或

N95外科口罩（相當於CNS 14774中的外科手術D2防塵面罩）

- 除原有檢測效能要求外，其防護效率及呼吸氣阻抗（壓差）改依CNS14755（Z2125）「拋棄式防塵口罩」D2等級（等同或以上者）之性能規格要求：

- 次微米粒子（NaCl微粒 $0.075\ \mu\text{m}$ ）防護效率95%以上
- 吸氣阻抗350 Pa（35 mmH<sub>2</sub>O）以下
- 呼氣阻抗250 Pa（25 H<sub>2</sub>O）以下



# PM 2.5 Filter Masks

## 防霾PM 2.5 口罩

Filter fine particulate matter up to 2.5  $\mu\text{m}$

Replaceable activated carbon filter

台灣規範 CNS 15980

ABCD 四個等級



# REVIEW

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# OBJECTIVE #2

那種口罩可防 COVID-19?

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Level 1口罩, 第一等級, 第二等級, .....

Particles  
filtered  
by masks

Coronavirus



0.1μm

Bacillus  
Bacteria



0.5μm

PM2.5



2.5μm

Red blood cell



7μm

PM10



10μm

#seetheair

# 美國 Surgical Mask & N95

規範

		ASTM F2100-19		
		Level 1	Level 2	Level 3
Barrier Testing	BFE % ASTM F2101, EN 14683	≥95	≥98	
	PFE % ASTM F2299	≥95	≥98	
	Synthetic Blood ASTM F1862, ISO22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg
Physical Testing	Differential Pressure EN 14683	<5.0 mmH <sub>2</sub> O/cm <sup>2</sup>	<6.0 mmH <sub>2</sub> O/cm <sup>2</sup>	
Safety Testing	Flammability 16 CFR Part 1610	Class 1 (≥ 3.5 seconds)		
	Microbial Cleanliness ISO 11737-1	Not required		
	Biocompatibility ISO 10993	510 K Guidance recommends testing to ISO 10993		
Sampling ANSI/ASQC Z1.4 ISO 2859-1		<ul style="list-style-type: none"> <li>• AQL 4% for BFE, PFE, Delta P</li> <li>• 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing)</li> <li>• 14 masks for Flammability</li> </ul>		



# N95 Respirator

1. 42 CFR part 84
2. Filters at least 95% of 0.3  $\mu\text{m}$  particles.
3. Tested and Approved by  
National Institute for Occupational Safety and Health  
(NIOSH)

# 台灣醫用(療)口罩

## 規範

表三、我國醫用面(口)罩之性能試驗項目及規格要求

性能	試驗方法	一般醫用面(口)罩	外科手術面(口)罩			外科手術 D2 防塵面(口罩)
			一級防護	二級防護	三級防護	
抗合成血液穿透性，最小通過壓力 (mmHg)	依 CNS 14776 醫用面(口)罩對抗合成血液穿透阻力的試驗法	-	80	120	160	80
細菌過濾效率 (%)	依 CNS 14775 醫用面(口)罩細菌過濾效率的試驗法	≥95	≥95	≥98	≥98	-
次微米粒子防護效率 <sup>1</sup> (%)	A 法(乳膠球法)：依 ASTM F2299-03	-	≥95	≥98	≥98	-
	B 法(鹽霧法)：依 CNS 14755 之 8.2	-	≥80	-	-	≥95
壓差 (mmH <sub>2</sub> O/cm <sup>2</sup> )	依 CNS 14777 醫用面(口)罩空氣交換壓力之試驗法(壓差試驗)	≤5	≤4	≤5	≤5	≤5
防焰性/可燃性	依 CNS 10285 纖維製品防焰性試驗法(可燃性試驗)之 C 法(燃燒速度試驗)	-	1 級 (≥3.5 秒或不著火)	1 級 (≥3.5 秒或不著火)	1 級 (≥3.5 秒或不著火)	1 級 (≥3.5 秒或不著火)
呼吸氣阻抗 (Pa)	依 CNS 14755 之 8.1 口罩定流量吸氣阻抗及定流量呼氣阻抗試驗	-	-	-	-	吸氣：≤350 呼氣：≤250

# REVIEW

## 那種口罩可防 COVID-19?

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Level 2口罩, 第一等級, 第二等級, 活性炭, .....

# OBJECTIVE #3

在美國,那裡可以買到  
美國製造可靠口罩?  
台灣製造可靠口罩?

\*\*\*The data in this file are for information only. The users should verify the accuracy themselves.\*\*\*

## Face Masks

Made in	Supplier Name/Website/Manufacturer			
USA	Armburst USA	Surgical Mask ASTM Level 3	\$29.90/box old labels	50 pcs/box
	<a href="https://www.armbrustusa.com/">https://www.armbrustusa.com/</a>	FDA Registered	\$39.90/box new colors	50 pcs/box
	<b>Armburst USA</b>			
Taiwan	MOCACARE	台灣一般醫用口罩 >98% BFE, >95% PFE	\$22.99/box	50 pcs/box
	<a href="https://store.mocacare.com/pages/mask-tw">https://store.mocacare.com/pages/mask-tw</a>	Procedure Mask ASTM Level 1	\$25.99/box	50 pcs/box
	台灣口罩, 選自台灣國家隊廠商 格安德、恆大、康那香	Procedure Mask ASTM Level 2	\$33.99/box	50 pcs/box
Taiwan	Taiwan Masks	Surgical Mask ASTM Level 3	\$50/box	50 pcs/box
	<a href="https://taiwan-masks.com/collections/csd">https://taiwan-masks.com/collections/csd</a>	Non-Surgical Mask >95% PFE/BFE	\$40/box multiple colors	50 pcs/box
	台灣中衛口罩 CSD			
Taiwan	Taiwan Masks	Non-Surgical Mask >99% PFE/BFE	\$25-\$32/box multi colors	50 pcs/box
	<a href="https://taiwan-masks.com/collections/taiwan-comfort-champ">https://taiwan-masks.com/collections/taiwan-comfort-champ</a>			
	台灣康匠口罩 Taiwan Confort Champ			
Taiwan	MaskFromTaiwan	台灣一般醫用口罩 >99% BFE	\$25/box	50 pcs/box
	<a href="https://en.maskfromtaiwan.com/">https://en.maskfromtaiwan.com/</a>			
	台灣善存口罩Storewell Mask			
Taiwan	台灣口罩專賣店 Shield Zone	台灣一般醫用口罩, ASTM Level 1	\$25/box	50 pcs/box
	<a href="https://www.shieldzones.com/">https://www.shieldzones.com/</a>			

下面 7-8 是美國製造但品質不詳

7	USA	Get PPE Here USA <a href="https://getppehereusa.com/">https://getppehereusa.com/</a> 美國 Get PPE Here USA	No FDA Registration, Non-Surgical	\$34.95/box	50 pcs/box
8	USA	Luosh USA <a href="https://www.luoshusa.com/">https://www.luoshusa.com/</a> 美國 Luosh USA	No FDA Registration, Non-Surgical >95% BFE	\$33.95/box	50 pcs/box

下面 9 是可靠的美國公司網站, 中國產品

下面 10-13 是可靠的美國公司網站, 中國產品, 品質不詳

9	China	Claire Med <a href="https://www.claire-med.com/">https://www.claire-med.com/</a> 中國 Foshan Niceday Sanitary Products	Face Mask ASTM Level 1	\$22.90/Box	50 pcs/box
10	China	Amazon <a href="https://www.amazon.com/">https://www.amazon.com/</a>	No FDA Registration, Non-Surgical	\$12.99 to \$27.98/box	50 pcs/box
11	China	Walmart <a href="https://www.walmart.com/">https://www.walmart.com/</a>	No FDA Registration, Non-Surgical	\$20.95 to ...../box	50 pcs/box
12	China	Wlagreen <a href="https://www.walgreens.com/">https://www.walgreens.com/</a>	No FDA Registration, Non-Surgical	\$10.99 to ...../box	25 pcs/box
13	China	Costco <a href="https://www.costco.com/">https://www.costco.com/</a>	No FDA Registration, Non-Surgical	\$11.99 to ...../box	50 pcs/box



# N95 NIOSH Approved Respirators

[https://www.cdc.gov/niosh/npptl/topics/respirators/disp\\_part/N95list1-g.html](https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1-g.html)

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

1	USA	Clinical Supplies	N95 NIOSH N95 NIOSH N95 NIOSH	3M Model 9205+ 3M Model 8511 3M Model 8210V 3M Model 8210	\$149.95/Box \$79.95/Box \$76.95/Box \$159.95/Box	20 pcs/box 10 pcs/box 10 pcs/box 20 pcs/box
			<a href="https://clinicalsuppliesusa.com/collections/3m-masks">https://clinicalsuppliesusa.com/collections/3m-masks</a>			
2	USA	Armbrust	N95 NIOSH	in NIOSH for approval, 預售, 預計12月出貨	\$39.00/Box	10 pcs/box
			<a href="https://www.armbrustusa.com/">https://www.armbrustusa.com/</a>			
3	USA	eBay	N95 NIOSH	3M Model 8511 3M Model 1860 Surgical 3M Model 8200 3M Model 9205+	\$42.99/Box \$39.95/Box \$89.99/Box \$69.49/Box	10 pcs/box 3 pcs/box 20 pcs/box 10 pcs/box
			<a href="https://ebay.com">https://ebay.com</a>			
4	USA	Amazon	N95 NIOSH	None		
5	Taiwan	CoveCare	N95 NIOSH, CDC NIOSH Approval # 84A-3713	San Huei United 三暉綜合 Model SH9550A	\$17.99/Bag	3 pcs/Bag
			<a href="https://www.cov.care/n95-facemasks">https://www.cov.care/n95-facemasks</a>			
6	China	Zunch Labs	N95 NIOSH, CDC NIOSH Approval # 84A-6973	Model Harley L188	\$7.25/ea	
			<a href="https://ppe.zunchlabs.com/product/masks/n95-niosh-and-cdc-certified-mask/">https://ppe.zunchlabs.com/product/masks/n95-niosh-and-cdc-certified-mask/</a>			
7	China	Bona Fide Masks	N95 NIOSH, CDC NIOSH Approval # 84A-6973 N95 NIOSH, CDC NIOSH Approval # 84A-7228	Model Harley L188 Model Harley L288	\$79.60/box \$114.00/box	20 pcs/box 20 pcs/box
			<a href="https://bonafidemasks.com/face-masks/N95-Respirators/">https://bonafidemasks.com/face-masks/N95-Respirators/</a>			



# OBJECTIVE #4

如何辨別口罩真偽？

如何避免買到假口罩？

## 小心中國偽標「MIT」口罩！海關21天內已攔下72.6萬片

2020/08/31 18:29



財政部關務署統計至30日止，短短21天海關就已攔下72.6萬片偽MIT口罩。（記者巫其倫攝）

## 國家隊以中製非醫療口罩混充台灣醫療口罩

1. 口罩國家隊**加利**公司 8 月進口 337 萬片中國製口罩充當台灣貨，流入實名制通路
2. 口罩國家隊**豪品**公司 8 月進口 718 萬片中國製口罩充當台灣貨，400 多萬片流入市面

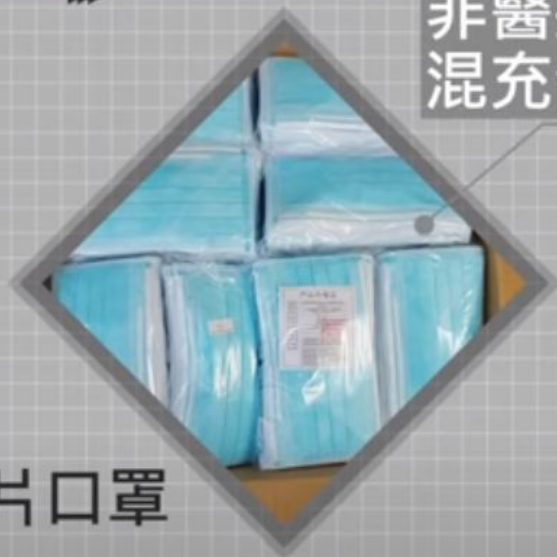
## 假冒國家隊公司包裝盒，賣出仿冒口罩

1. **漢寶**公司地下口罩工廠，假冒國家隊「台灣優紙」公司包裝盒，賣出仿冒口罩 75 萬片
2. **崇光**公司從中國進口一般口罩，假冒國家隊「日昇」口罩販賣，已對外銷售 120 萬片
3. **富達實業**向當地不知名工廠採買 61 萬片一般口罩，冒用國家隊「宏璋」包裝盒，以醫用口罩名義販售

12/25 後**醫療**口罩有雙鋼印才准賣，全台料掀  
假貨潮出清存貨

# 陸製口罩混充MIT

非醫療級別  
混充台灣製



加利科技公司老闆  
**林明進**

109  
8

中國進口  
**337**萬片口罩

新北市

紐幣

▼ 0.0307

19.6578

11:59:52

## 實名制口罩中國製 加利科技公司勒令停業

換貨人潮 "口罩之亂"再現? 民眾湧藥局退中國製口罩

# 在台灣如何避免買到仿冒台灣製口罩？

1. 選擇有外盒的口罩，外盒上應標誌 醫用口罩，衛生福利部的醫療器材許可證核准字號，廠商資訊，批號，生產日期，有效日期，CNS 14774 等，無簡體字，但也有外盒仿冒得與原廠一模一樣。
2. 規定上，一般通路是只能銷售一般口罩，不能銷售專業口罩，只有醫療通路才能合法銷售專業口罩。選擇合法及合格通路，確認貨品有合法來源。
3. 從9/24/2020起，台灣製造醫用口罩應有雙鋼印 “Made in Taiwan” “MD”  
從12/25/2020起，醫用口罩只準賣有雙鋼印的。



# 選購醫用口罩的要點：辨識核准字號

衛生福利部的醫療器材許可證核准字號。

**一般醫用口罩**的許可證字號為以下三種之一：

- 一、衛部(署)醫器**製壹**字第XXXXXX號(**國產**第一等級醫療器材)
- 二、衛部(署)醫器**輸壹**字第XXXXXX號(**輸入**第一等級醫療器材)
- 三、衛部(署)醫器**陸輸壹**字第XXXXXX號(**中國大陸輸入**第一等級醫療器材)

**手術口罩**的醫療器材許可證字號為以下三種之一：

- 一、衛部(署)醫器**製**字第XXXXXX號(**國產**第二、第三等級醫療器材)
- 二、衛部(署)醫器**輸**字第XXXXXX號(**輸入**第二、第三等級醫療器材)
- 三、衛部(署)醫器**陸輸**字第XXXXXX號(**中國大陸輸入**第二、第三等級醫療器材)



**CenYu**

Medical Mask

濤宇 醫療口罩

成人適用 (未滅菌)



50入

粉藕紫

BEE > 99%

安全防護

三層立體

親膚透氣

本產品符合CNS14774國家測試標準 Made in Taiwan



# 涔宇醫療口罩

竹市藥販 字第 6212053413 號

竹市藥製 字第 6112051097 號

衛部醫器製 壹字第 008403 號

符合口罩潔淨室生產

尺寸：17.5 x 9.5cm

藥廠/製造商：涔宇科技有限公司

服務電話：03-5303652

地址：新竹市香山區中華路四段402號2樓



# 湊字醫療口罩

## 主要材料

表面層：潑水性不織布，

防治霧氣、水氣、液體滲入

過濾層：M.B 靜電過濾不織布，

有效阻隔細菌效率BFE值>99%以上

親膚層：複合纖維、親膚性佳，不易引起過敏

批號：同製造日期

有效期限：五年



4 719880 410033

通過CNS14774、CNS14775國家測試標準

岑宇

醫療口罩

CenYu Medical Mask

成人適用

**CenYu50**  
Made in Taiwan PCS/枚

安全防護 ●  
三層結構 ●  
親膚透氣 ●

普羅旺斯  
Lavender



MY HEALTH NEW LIFE  
Made in Taiwan



CY-2020/08/28

國家標準 GB 7714  
圖書編目

AT HEALTH CARE  
100% PURE  
100% PURE  
100% PURE

**BLUEEAGLE**<sup>®</sup>

- Guard your health -



f 分享

## 【藍鷹牌】N95醫療口罩 成人立體型活性炭醫用口罩 50入/盒(束帶式/灰色)

CNS認證 高規N95 包覆更完美  
衛部醫器製壹字第006639號

高市衛醫器廣字第10710002號  
台灣原料 台灣製造 品質有保障

立體形狀 具空氣室呼吸更方便  
有效隔離灰塵 粉塵等髒空氣

可阻隔95%大小在0.3微米以上的微粒

3期0利率 [31家](#) 12期分期 [4家](#)

VISA ATM 貨到付款 ibon [說明](#)

信用卡紅利折抵刷卡金 [多家銀行](#)

PChome儲值

取貨付款

LINE Pay 拍錢包

台灣Pay

建議售價 \$500

網路價 **\$439**

適用折價券

## 西藥、醫療器材、化粧品許可證查詢

[詳細處方成分](#) | [藥物外觀](#) | [仿單/外盒資料](#) | [授權使用](#) | [健保藥價查詢](#) | [離開](#)

### 許可證詳細內容

\* \* \* 衛部醫器製壹字第006639號 \* \* \*

註銷狀態		註銷日期	
註銷理由		製造許可登錄編號	
有效日期	111/03/17	發證日期	106/03/17
許可證種類	醫 器		
舊證字號		醫療器材級數	第一等級
通關簽審文件編號			
中文品名	藍鷹牌 N95立體型活性碳醫用口罩 (未滅菌)		
英文品名	"Blue Eagle" N95 Medical Activated Carbon Face Mask (Non-Sterile)		
效能	限醫療器材管理辦法「醫療用衣物(I.4040)」第一等級鑑別範圍。		
醫器規格	空白		
劑型		包裝	
標籤、仿單及包裝加註			
醫器主類別一	I一般及整型外科手術裝置	醫器次類別一	I4040醫療用衣物
醫器主類別二		醫器次類別二	



## 3M 9010V 粒狀物呼吸防護N 95口罩(20入/盒)

- ◆特有高效靜電濾材，對於空氣中粒狀污染物及液體不含油性之氣膠過濾效率可達95%以上。
- ◆3M Cool flow™ 冷流呼氣閥設計，減少配戴時的悶熱感，呼吸更順暢。
- ◆鼻樑墊設計，可緊密貼合臉部，眼鏡不易起霧。
- ◆柔軟內層，和臉部輕柔接觸，佩戴舒適。
- ◆單包裝折疊式方便攜帶，提供隨身防護。
- ◆美國 NIOSH 認證 N 95 口罩

3期0利率 31家 12期分期 4家

建議售價 \$900

VISA 貨到付款 ibon 說明

網路價 **\$790**

信用卡紅利折抵刷卡金 多家銀行

PChome儲值

取貨付款

LINE Pay 拍錢包

街口支付 街口支付

台灣Pay

f 分享

完售，請參考其他商品



# Counterfeit Respirators / Misrepresentation of NIOSH-Approval

Updated August 25, 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

# Required Labeling of NIOSH-Approved N95 Filtering Facepiece Respirators

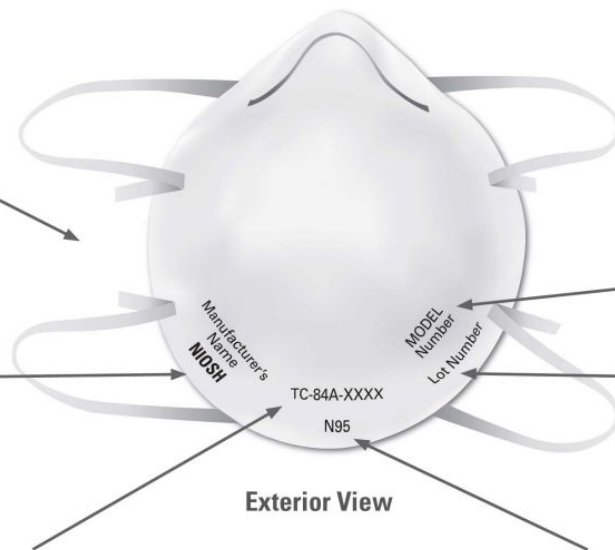
For more information about NIOSH-Approved respirators, go to: <http://knowits.NIOSH.gov>

**Example of Exterior Markings**— Approval holder business name, a registered trademark or an easily understood abbreviation.

If privately labeled, the private label name or logo will appear instead of the approval holder business name.

**NIOSH**— NIOSH name in block letters or NIOSH logo.

**TC-Approval Number (TC-84A-XXXX)**— For products manufactured after September 2008, the TC-Approval number is required to appear on the product.



**Model # XXXX**— Model Number or Part Number

**Lot # XXXX**— Lot Number and Date of Manufacture (recommended, but not required)

**Filter Designation**— NIOSH filter series. Alpha-numerical rating followed by filter efficiency level (example, N95, N99, N100, R95, P95, P99, P100)





3M is the world's largest maker of N95 respirator masks.



This is an example of a misrepresentation of a NIOSH-approved product. Products labeled as DermaCare or Espomega, with model numbers HY8710, HY8812, and HY8816, are NOT NIOSH approved. (8/7/2020)



This is an example of a misrepresentation of a NIOSH approval. Intech Safety Pvt. Ltd. is not a NIOSH approval holder or a private label holder. (8/7/2020)

**Discounted N95 Mask Available to Readers While Supplies Lasts**

R AND D Healthcare, Inc is offering Readers substantial discounts on N95 Masks while supplies last.

The company has decided to ship masks directly to consumers to comply with social distancing guidelines and mitigate person-to-person contact.

- NIOSH approved N95- TC-849-6973
- Meets CDC guidelines for Mycobacterium tuberculosis exposure control
- FDA cleared for use as a surgical mask
- 99% BFE (Bacterial Filtration Efficiency) according to ASTM F2101
- Fluid resistant according to ASTM F1862
- Respirator contains no components made from natural rubber latex

A misleading advertisement has appeared in newspapers. The product, advertised as NIOSH approved, is listed under an invalid NIOSH approval number. Additionally NIOSH has been notified by Guangzhou Harley Commodity Co., Ltd. that their



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)



These are two examples of respirators being misrepresented as NIOSH approved on [www.covidness.net](http://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)





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

# 在美國如何避免買到仿冒台灣製口罩？

因為仿冒得太厲害，想要光從外觀判別口罩真偽並不容易

Made in Taiwan 鋼印也被仿製的很像

有些台灣製的口罩也沒有打上 Made in Taiwan 的鋼印

1. 台灣政府對於**合規申請出口**的台灣製口罩，提供產品抽樣檢驗，生產履歷的確認，合格通過者才會發給**出口證明**，表示是合法出口，多一份來自官方的保障。無論是網購，團購等，合法出口者應該都要有出口證明，才能確認口罩的來源。

2. 另外無論是在美國或台灣，規定上，一般通路是只能銷售一般口罩，是不能銷售專業口罩的，**只有醫療通路才能合法銷售專業口罩**。因此選擇合法及合格通路，**確認貨品有合法來源**，應該可以有效降低買到來路不明仿冒產品的風險。

3. **散裝的風險比較高**，選擇有外盒的口罩，外盒上的資訊可以提供參考，如廠商資訊，批號，生產日期等，但也有外盒仿冒的與原廠一模一樣。

# BARCODE



Barcodes identify the country of origin of **the manufacturing company**.

They **do not** indicate **where the product is made**.

For the country where the product is made, look for label **“Made in XXX”**, or **“Product of XXX”**.

0 USA/Canada

1 USA

471 Taiwan

690-699 China

# 在下列場所您戴什麼口罩？

1. 超市買菜
2. 購物 (Walmart, Costco, CVS, Lowes 之類)
3. 看醫生
4. 看牙醫
5. 散步
6. 餐館
7. 坐飛機
8. 探望病人

種類	功能	適用時機及注意事項
棉布口罩	過濾較大之顆粒、灰塵，避免吸入灰塵或將飛沫噴出。	<ol style="list-style-type: none"> <li data-bbox="788 121 1740 153">1. 進入人潮擁擠或空氣不流通之公共場所、平時清潔工作時使用。</li> <li data-bbox="788 192 1707 224">2. 每日清洗或替換；有髒污、潮濕、破損時應立即清洗或更換。</li> </ol>
醫用口罩	避免醫護人員飛沫影響病人，或吸入病人咳出的飛沫微粒。	<ol style="list-style-type: none"> <li data-bbox="788 265 1846 347">1. 有感冒、發燒、咳嗽等呼吸道症狀時使用；實驗室及禽畜養殖場工作人員、醫護人員照顧病人或民眾探病時使用。</li> <li data-bbox="788 385 1518 418">2. 每日替換；有髒污、潮濕、破損時應立即更換。</li> <li data-bbox="788 456 1074 489">3. 不得重複使用。</li> </ol>
活性炭口罩	可以吸附有機氣體、惡臭分子及毒性粉塵。	<ol style="list-style-type: none"> <li data-bbox="788 532 1360 565">1. 騎乘機車、噴漆、噴灑農藥時使用。</li> <li data-bbox="788 603 1740 636">2. 每日替換；無法吸附異味時、髒污、潮濕、破損時應立即更換。</li> </ol>
醫用活性炭口罩	兼具醫用口罩與活性炭口罩功能	請參考前項。
N95口罩	呼吸阻抗大，執行會產生飛沫微粒等特殊處置時使用。	<ol style="list-style-type: none"> <li data-bbox="788 803 1485 836">1. 不適合一般民眾日常生活使用及長時間配戴。</li> <li data-bbox="788 874 1074 907">2. 避免重複使用。</li> </ol>
醫用N95口罩	兼具醫用口罩與N95口罩性能。	請參考前項。