

CORONAVIRUS · Published May 12

American health care workers receive counterfeit N95 masks from China, AP investigation finds

By Caitlin McFall | Fox News



What's Trending: Imported N95 masks show safety issues;

Face masks for police recalled after fears they're fake – scam alert

A POLICE force is investigating if thousands of masks it purchased for officers are defective or even fake. West Yorkshire Police has recalled all of the suspect masks that had been given out to frontline officers while investigations continue.

By JON AUSTIN, SUNDAY EXPRESS CRIME EDITOR
PUBLISHED: 06:52, Mon, May 18, 2020 | UPDATED: 09:34, Mon, May 18, 2020

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Health Minister orders probe into use of counterfeit masks in hospitals

By Dana McClellan and Liam Kane
Tue 24, 2020 - 6:45m

Federal Health Minister Greg Hunt has ordered a top-level probe into concerns counterfeit face masks were used to protect doctors and nurses who may have been caring for coronavirus patients. The Therapeutic Goods Administration on Tuesday was instructed to investigate whether defective face masks had been sold to some private hospitals by companies exploiting a loophole in regulations.



COUNTERFEIT RESPIRATORS

Can you tell the difference?

HOME / NEWS / BEST STATES / CALIFORNIA NEWS

Counterfeit Masks Reaching Frontline Health Workers in US

Counterfeit face masks that provide inadequate COVID-19 protection have been distributed to frontline health care workers across the country.

By Associated Press, Wire Service Content May 13, 2020, at 11:12 a.m.

An opened box of protective masks sits on a pallet at Direct Relief's distribution center in Santa Barbara, Calif., on Wednesday, April 1, 2020. An Associated Press investigation has found millions of medical masks, gloves, gowns and other supplies being used in hospitals across the country are counterfeits, putting lives at risk. (Jonathan Epstein/FRONTLINE/ABC via AP) © THE ASSOCIATED PRESS



May 2020
Miriska Gerber

INDEX

- RESPIRATORY PROTECTION
- TYPICAL PRODUCT MARKINGS (Examples)
- THE CE MARK
- CERTIFICATES
- VERIFICATION OF CERTIFICATES
- GENUINE OR FAKE RESPIRATORS? (Examples)
- WHO CAN HELP?
- WHAT IF YOU COME ACROSS A COUNTERFEIT?
- USEFUL RESOURCES
- ACKNOWLEDGEMENTS

Disclaimer: The use of examples in this presentation does not represent an endorsement of a specific brand above another.

RESPIRATORY PROTECTION

- Respiratory protective equipment (RPE) is a type of personal protective equipment (PPE) that protects people from breathing in substances hazardous to health.
- A respirator is a protective device that covers the nose and mouth or the entire face or head.
- RPE needs to comply to a certain standard to demonstrate “protection”.
- RPE needs to be manufacture in conditions that are safe (RPE will be used on “nose, mouth, head and face)





Increase in demand/shortage in supply

- The COVID-19 pandemic has restricted export of PPE from some countries; which were the usual channels of PPE to the NZ market prior to the pandemic starting.
- The COVID-19 has increased the need of usage of N95 or equivalent type respirators (P2/FFP2/KN95) to protect workers (such as Health Care workers) from SARS-Cov-2.

This increase in demand and shortage of supply has resulted in an influx of potentially non-compliant RPE entering the NZ market.

- The non-compliant respirators pose a health risk to anyone wearing them because they will provide little, no or unknown protection against the coronavirus or any other hazardous substance it is originally intended to protect against.

DISPOSABLE RESPIRATORS: P2/N95/FFP2/KN95

- Manufacturers making a statement of compliance with AS/NZS 1716:2012 should ensure that such compliance is capable of being verified.
- Disposable respirators that meet or are compliant with AS/NZS 1716:2012 shall be clearly marked with:
 - the manufacturer's name, trade name, or mark
 - and the filter classification 'P1' or 'P2'.
- Worksafe NZ also considers other international standards for respirators to be equivalent to AS/NZS 1716:2012. These include:
 - N95 respirators that are rated compliant by the US National Institute for Occupational Safety and Health (NIOSH)
 - European 'FFP2' respirators that are compliant under EN149:2001
 - Chinese 'KN95' respirators that are compliant under GB2626:2006 (2019).
 - Some of these respirators are imported to New Zealand.

TYPICAL PRODUCT MARKINGS

- AS/NZ 1716:2012 Respirator Protective Devices
 - Respirators made for the Australian and New Zealand market require the following markings:



- Manufacturers Name
- AS/NZS 1716
- Classification, e.g. P1, P2, P3
- Size (if applicable)

Note that the standard may be printed on the strap instead of the body of the respirator.

TYPICAL PRODUCT MARKINGS

- NIOSH 42 CFR Part 84, Approval of Respiratory Protective Devices
 - Example of markings for respirators made for the United States market but used extensively in the Health Care sector as a standard throughout the world.

NIOSH APR-FFR standard requires a Filtering Face Piece (FFP) to have the following markings:

NIOSH
N95

Manufacturer name or logo

3M

The word 'NIOSH'

NIOSH

NIOSH Approval number

TC-84A-0006

Manufacturer model number

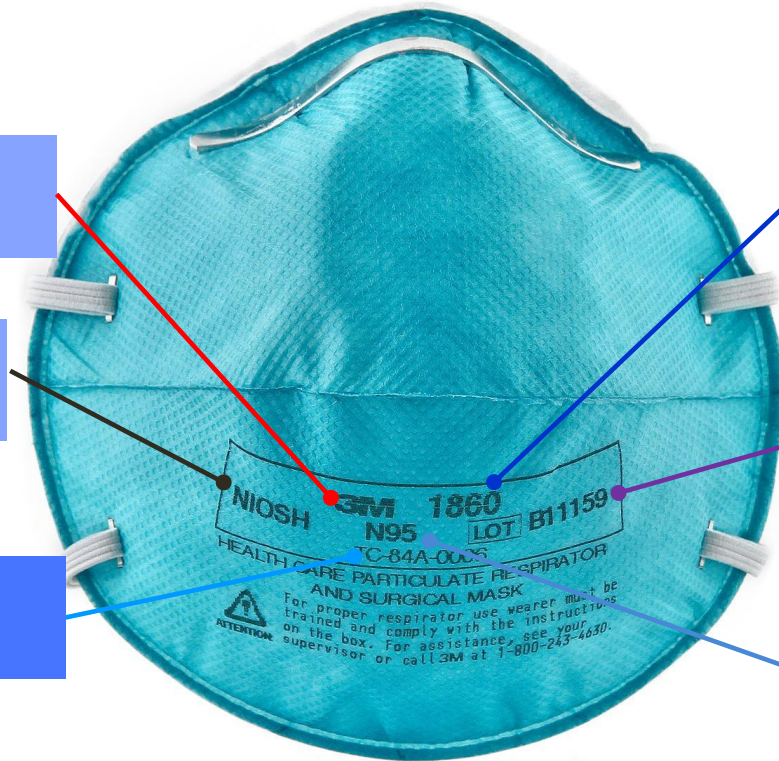
1860

Manufacturer's lot number

B11159

Filtering facepiece class

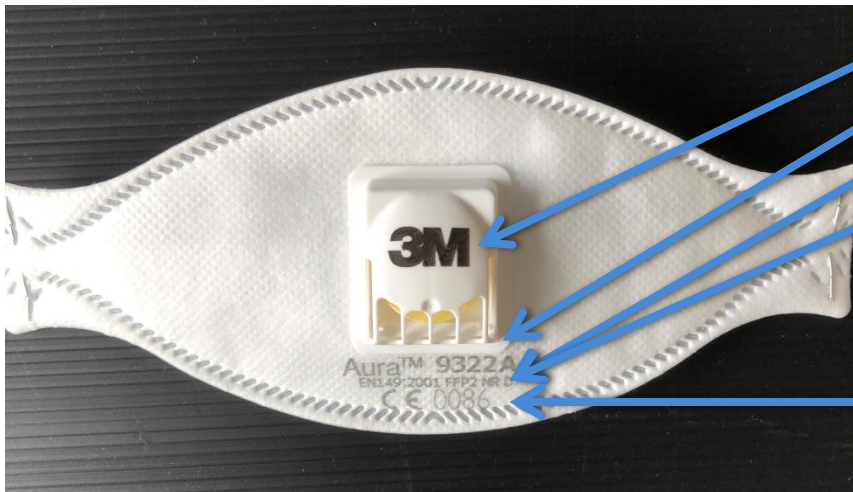
N95



Note: 'Fast-tracked' CE certified N95 may not be marked with the CE mark

TYPICAL PRODUCT MARKINGS

- EN 149:2001+A1:2009 Respiratory Protective Devices
 - Filtering facepiece (FFP) to protect against particles
 - Requirements, testing, marking
 - Respirators made for the European market require the following markings:



- Manufacturers Name
- Product Name or Model Number
- EN149:2001
- Classification, e.g. FFP1, FFP2, FFP3;
will also have 'NR' or 'R' after
NR = Single shift use
R = Re-usable
- CE mark (European certification mark) and
Approval Number

Size (if applicable)

TYPICAL PRODUCT MARKINGS

- GB 2626-2006 Respiratory protective equipment -- non-powered air-purifying particle respirator (replaced by: GB 2626-2019 Respiratory protection—Non-powered air-purifying particle respirator)
 - Respirators made for the Chinese market require the following markings:

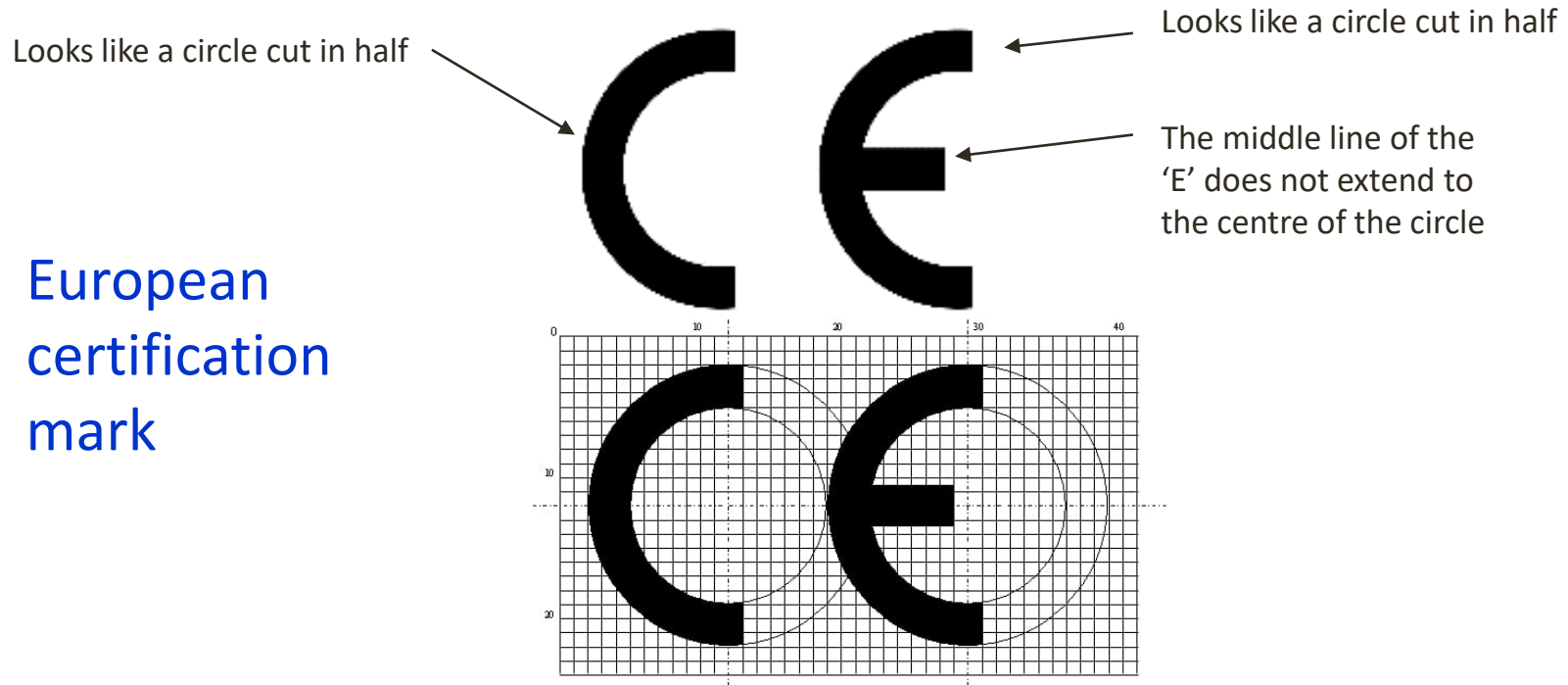


- Manufacturers Name
- Product Name or Model Number
- GB2626:2006
- Classification, e.g. KN90 / KN95 / KN100

Size (if applicable)

THE MARK

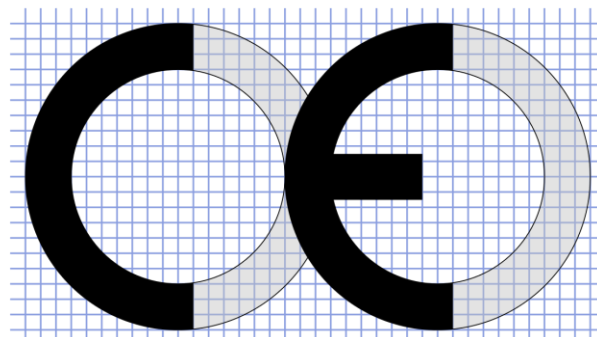
The CE mark is a specific design and should appear as shown below:



- Every legitimate CE-marked product is considered to be with better quality and proven safety than any other bearing a look-alike, not official, CE mark.

THE 'CHINESE EXPORT' MARK

- The CE “Chinese export” mark can be seen on some, not all, products produced in and exported from China.
- The mark is with a similar design. As a result, you can think that your product is CE marked and safe to use. The “Chinese export” mark is not an official European mark and is considered as fake.
- Such products haven’t had any risk assessment, safety evaluation, or testing.
- They haven’t been certified against the relevant CE standards, and their placing on the EU market is seen as an illegal act.



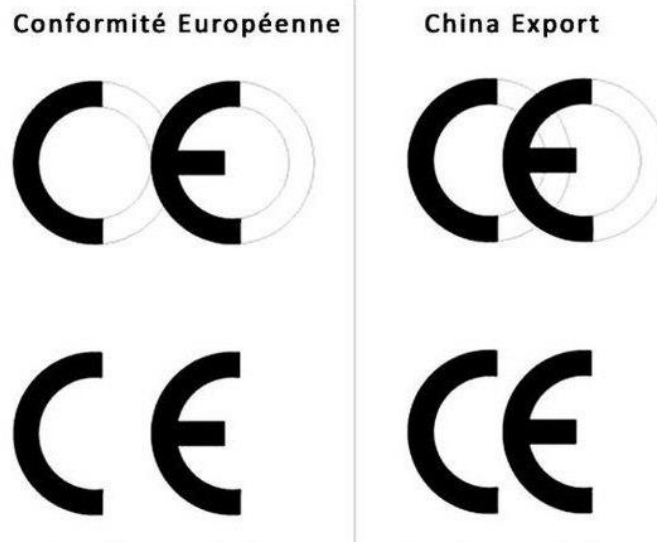
"Conformité Européenne"



"China Export"

THE 'CHINESE EXPORT' MARK

- Even though that the “Chinese export” mark resembles the official European CE Mark, it doesn't respect its dimensions or proportions.
- The difference between the two marks.
 - The letters are formed identically, but the spacing between them is different.
 - A correct CE mark has the E started on the circular profile drawn out by the C character.



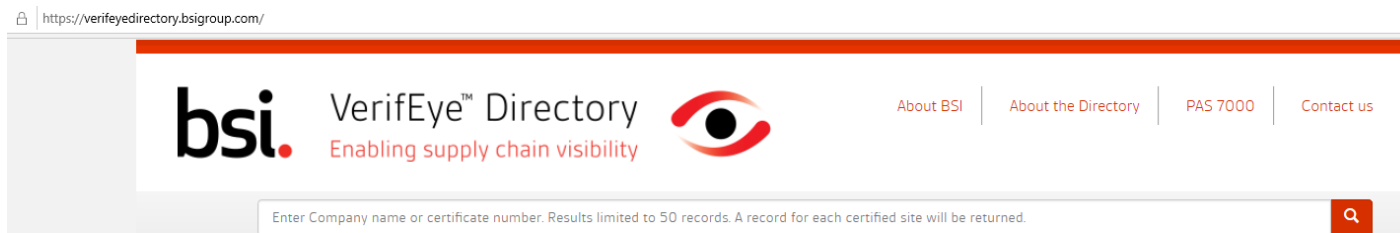
CERTIFICATES

- Counterfeit manufacturers are quickly becoming aware of the markings that need to be on these respirators;
 - Don't just assume because it has all the markings it must be an original.
- Prior to procurement, request the compliance certificates or verification documentation/letter to prove that the respirator meets the standard it claims;
- Verify the compliance certificates;
 - Inspect content on the certificate;
 - Search via the certifiers online tool; or
 - Contact the certifier.
- Communicate;
- Don't just assume your distributor verified it;
- Be alert and don't let the shortage of stock influence your judgement!

EXAMINATION CERTIFICATE (BSI)

- Prior to purchasing any form of safety equipment supported by a certificate appearing to be issued by BSI, **verify** to ensure that such certificate is genuine.
- There are 2 ways for you to verify that the certificate is genuine:
- Link in pdf certificate:

Do you have the original, digital copy (in pdf) of the certificate? Find the link at the bottom of this certificate. If you click on this link you can see if the certificate is valid.
- Through the BSI VerifEye Directory:
 - You can look up the corresponding certificate through the BSI VerifEye Directory: Enter the name of the organization or the certificate number in this directory. You can find the VerifEye Directory via the following link: <https://verifeyedirectory.bsigroup.com/>.



- Should you not be able to verify the validity of the certificate in this way, you can send the digital version of the certificate to the e-mail address product.certification@bsigroup.com . This should be the official certificate.

EXAMINATION CERTIFICATE (SAI GLOBAL)

https://register.saiglobal.com/



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Welcome to SAI Global Certification Register

The SAI Global register allows you to search and verify products and organizations that have achieved certification with SAI Global.

Since there are many different types of standards that companies can be certified against, it is useful to check what was covered, and that the company continues to be certified.

The search result displays the company name, site and standard. To view the scope of certification, click on the License Number.

If you are an SAI Global registered company, and you'd like to display your certification credentials on your website, simply copy the URL link from the Licence page.

Certificate Search

Select one
Licence No.
Company Name

Search

[Advanced Search](#)

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NIOSH-APPROVED RESPIRATORS

National Institute for Occupational Safety and Health (NIOSH)

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



Certified Equipment List

The NIOSH Certified Equipment List has a new look.

The National Institute for Occupational Safety and Health (NIOSH), under authorization of the Occupational Safety and Health Act of 1970, provides a testing, approval, and certification program assuring respirators used in the workplace meet the standards of 42 CFR Part 84. Since 1994, NIOSH has maintained a searchable, online version of the Certified Equipment List.

[Certified Equipment List](#)

[2016 Reformatted Certified Equipment List](#)

GENUINE OR FAKE PRODUCT?



- No Standard number
- No manufacturer name, logo or model number
- No markings on packaging
- (No EU CE mark and Notified Body number)



- Unusual design
- No EU Notified Body Number
- No manufacturer name, logo or model number
- No 'N' or 'NR' marking



- No EU Notified Body Number
- No 'N' or 'NR' marking
- ISO:9001 is not relevant to RPE certification

OTHER EXAMPLES CURRENTLY ON THE MARKET



Q: I would like to purchase masks for COVID-19. How do I know if they are counterfeit or fraudulent?

A: The FDA does not issue any kind of certification to demonstrate a manufacturer is in compliance with the FDA's requirements.

The FDA does not have an exhaustive list of all counterfeit or fraudulent products. To report fraudulent COVID-19 products to the FDA, please email FDA-COVID-19-Fraudulent-Products@fda.hhs.gov.

<https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/face-masks-and-surgical-masks-covid-19-manufacturing-purchasing-importing-and-donating-masks-during>

- Sold on a NZ website
- Claims to hold FDA approval
- No Standard number
- No manufacturer name, logo or model number
- No markings on packaging
- Company name and address not shared on the certificate
- No traceability between Product name and unique model number on certificate
- The FDA does not issue any kind of certification to demonstrate a manufacturer is in compliance with the FDA's requirements.

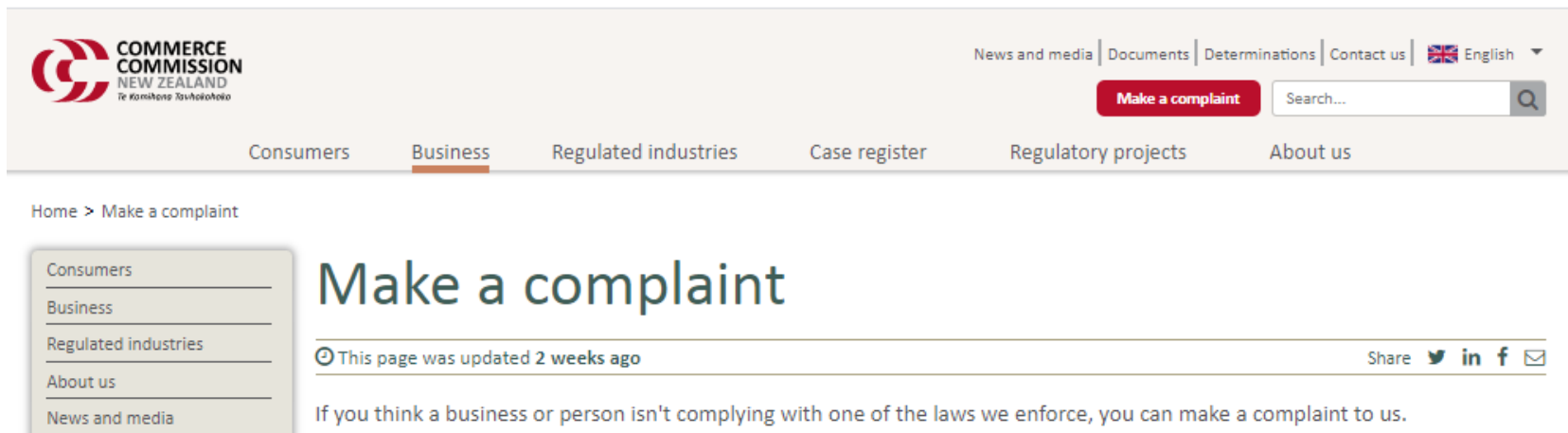
WHO CAN HELP?

If in doubt,

- seek advice from an occupational hygienist by visiting the NZOHS website <https://nzohs.org.nz>
- reach out via the COVID-19 Helpline Covid-19@nzohs.org.nz or
- visit the HASANZ register <https://register.hasanz.org.nz/>

WHAT IF YOU COME ACROSS A COUNTERFEIT?

- We strongly encourage people to report these to:
 - Worksafe: Report non-compliant PPE to <https://worksafe.govt.nz/notifications/health-or-safety-concern/raise-a-concern-form/>
 - Commerce Commission



The screenshot shows the Commerce Commission New Zealand website. The header includes the logo, navigation links (News and media, Documents, Determinations, Contact us), a language selector (English), and a search bar. The main navigation bar has links for Consumers, Business (highlighted), Regulated industries, Case register, Regulatory projects, and About us. A red 'Make a complaint' button is visible. Below the navigation bar, the breadcrumb 'Home > Make a complaint' is shown. On the left, a sidebar menu lists: Consumers, Business, Regulated industries, About us, and News and media. The main content area is titled 'Make a complaint' and includes a timestamp 'This page was updated 2 weeks ago', social sharing icons, and the text: 'If you think a business or person isn't complying with one of the laws we enforce, you can make a complaint to us.'

USEFUL RESOURCES

National Links (Worksafe):

Advise for businesses regarding Respiratory Protective Equipment

- <https://worksafe.govt.nz/topic-and-industry/personal-protective-equipment-ppe/respiratory-protective-equipment/advice-for-businesses/>

Managing supply issues for PPE

- <https://worksafe.govt.nz/managing-health-and-safety/novel-coronavirus-covid/managing-supply-issues-for-ppe/>

Safety Alert: Non-compliant respiratory protective equipment on the market

<https://worksafe.govt.nz/about-us/news-and-media/non-compliant-respiratory-protective-equipment-on-the-market/>

International Links:

British Safety Industry Federation (BSIF): Fake PPE Certificates

- <https://www.bsif.co.uk/campaigns-projects/fake-certificate/>
- <https://www.bsif.co.uk/are-you-concerned-about-ppe-certificates/>

European Safety Federation: COVID-19 Suspicious certificates for PPE

- <https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe>

HSE: Report a defective product

- <https://www.hse.gov.uk/work-equipment-machinery/report-defective-product.htm>

EU Notified Bodies

- https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=155501

Centers for Disease Control and Prevention (CDC):

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

ACKNOWLEDGEMENT

Thank you to the
British Occupational Hygiene Society (BOHS)
and
Worksafe NZ

for the collaborative approach in generating awareness which
will help protect our workers from being issued with a
counterfeit respirator.

