A Guide to Buying P2, or Equivalent, Respirators for use in the Australian & New Zealand Work Environment

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AIOH Australian Institute of Occupational Hygienists

AIHS Australian Institute of Health & Safety

NZOHS New Zealand Occupational Hygiene Society

IAQAA Indoor Air Quality Association Australia

Supported by ACTU australian council of trade unions

NSW Government

Government of South Australia SafeWork SA

WORKSAFE

HASANZ Health & Safety Association NZ

WORKSAFE ACT

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Contributing Organisations

Australian Institute of Occupational Hygienists

Australian Institute of Health & Safety

New Zealand Occupational Hygiene Society

Indoor Air Quality Association Australia

Supported by

Australian Council of Trade Unions

SafeWork NSW

SafeWork SA

WorkSafe WA

WorkSafe ACT

Health and Safety Association of NZ

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About this document

There has been a surge in demand for P2 respirators for use against airborne pollutants during the recent extensive bushfires and more immediately against the transmission of CoV-SARS-2. This has resulted in an increase of non-compliant respirators entering the supply chain, which has been highlighted by several bodies including SafeWork NSW and WorkSafe New Zealand.

Identifying non-compliant products presents challenges for businesses purchasing respirators for their workers, as the processes and checkpoints that provide compliance can be complex.

This guide was developed to assist those who purchase disposable P2 respirators in Australia and New Zealand for use in the workplace. Specifically, this document deals with disposable P2 respirators, commonly termed, "*Filtering Facepiece Respirators (FFP)"* or "*P2 face masks*".

Information on respirators that relate to international standards such as N95, FFP2 and KN95 are included in this document because the standards that relate to those products have been considered to be generally equivalent in times of short supply. Those products are also now more commonly found in the Australian and New Zealand marketplace.

In Australia and New Zealand, the preference is always to purchase respirators that meet the Australian and New Zealand Standard (e.g. AS/NZS1716:2012). Caution is needed when procuring respirators claiming compliance with other international standards and the purchaser should have a good understanding of the limitations involved when doing so. At the time of publication, it should be noted that the use of KN95 respirators is not recommended for use in Australian or New Zealand work environments. Preference should be given to P2 or other international equivalently designed and manufactured products, such as N95 or FFP2 respirators. Further information is provided on this topic in this guide.

This guide is based on commonly engaged practice under national and international advice. It attempts to aggregate that information to provide a simple method to what can otherwise be a very complex process of pre-purchase evaluation. This guide will be useful for those who purchase and/or use P2, or equivalent, respirators by outlining simple steps to help verify if the product complies with an appropriate standard.

Information on how to make choices on which respirator is suitable for specific purposes is not discussed in this guide *(which is covered in AS/NZS1715:2009 - Selection, use and maintenance of respiratory protective equipment),* nor is information surrounding the additional provisions needed for using respirators in health care settings. This guide does not address the complete process of respirator certification or the necessary procedures for importers and distributors.

Personal protective equipment (PPE) provides the lowest level of protection in the hierarchy of control and Work Health and Safety (WHS) legislation makes it mandatory to work through higher-order controls before using PPE such as respirators. During times of short supply of P2 respirators, users are advised to use the precautionary principle and utilise a higher level of protection than would otherwise be selected.

P2 (and equivalent) respirators – already widely used in workplaces

P2 respirators are commonly used across a range of industries including the healthcare sector, mining, construction, demolition, and hazardous materials removal. The devices are designed to protect the wearer from inhalable and respirable airborne particles, so-called "aerosols", which may pose significant health risks from exposure. Examples include bushfire smoke, respirable dust, crystalline silica, asbestos and airborne pathogens.

The importance of the right protection

It is essential that businesses purchasing respirators for their workers, or retailers buying them to on-sell, know how to identify genuine products. Failure of respirators to meet approved regulatory manufacturing standards may leave workers unprotected from harmful respiratory hazards in addition to leading wearers to a false sense of security by believing they are protected when wearing them.

Getting professional advice beyond this document. Specialists who can assist businesses in determining the type, suitability and implementation of a tailored respiratory protection program include Occupational Hygienists and Health and Safety Professionals. Associations contributing to this document maintain a list of professionals who may be available to assist with specific enquiries.

Getting Started

Understanding the complex environment of Regulation and respiratory protection

In Australia and New Zealand, respirators designed to give protection against respirable biological and non-biological particles (particulate matter) are classified and marked as P1, P2 or P3, in accordance with AS/NZS 1716:2012. An increase in the value of the P-number translates to an increase in particle removal efficiency of the respirator, and if correctly fitted, increasing levels of respiratory protection.

At times of short supply, respirators approved under similar international standards may be accepted. Several categories of respirators were recently recognised under national and international standards, as acceptable in Australian workplaces (Table 1). When purchasing a device advertised as being of a particular device type, it must meet the relevant national or regional standard as set out in Table 1.

Table 1: P2 Product Equivalents and their Relevant Standard

Product type	Jurisdiction	Relevant Standard	Class
P2	Australia and New Zealand	AS/NZS 1716:2012	P2
N95	USA	NIOSH-42CFR84	N95
FFP2	Europe	EN 149-2001	FFP2
KN95*	*China*	*GB 2626:2019*	*KN95*

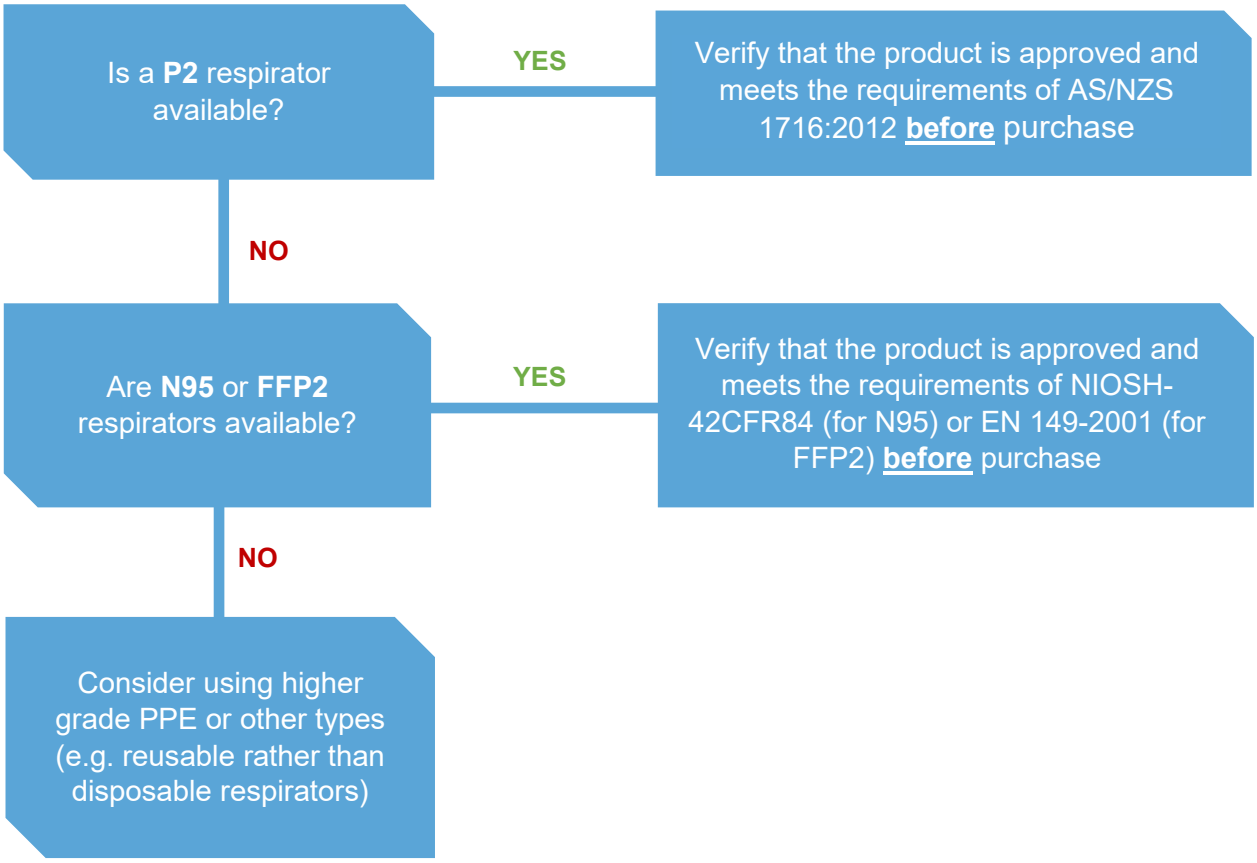
* *KN95 respirators are not recommended at the time of publication without a full understanding of compliance and equivalent quality control measures.*

*** Limited assessment of ear loop designs indicate difficulty in achieving a proper fit. Respirators with ear loops are therefore not recommended as a P2 equivalent.*

There are some subtle differences between each international standard, and a technical comparison of respirator classes may be found here. It is important to understand the type of device you are purchasing to ensure it meets the applicable Standard when making an informed purchase. This guide steps you through that process concerning the type of product being sold.

National and International P2 standards

If the Australian, New Zealand and international standards for P2 respirators are all so similar, which one should I choose?



IMPORTANT: Listing on the Australian Register of Therapeutic Goods (ARTG) is not a standard for respiratory protection. Inclusion on the ARTG does not imply that the respirator meets a particular international or Australian standard (refer Table 1). The TGA is the regulatory body for medical devices in Australia but do not set the standards that devices are manufactured to.

The TGA does not provide pre-market independent certification of respirators. Inclusion on the ARTG is intended for respirators that are medical devices. Respirators for industrial use are not required to be included on the ARTG. Further information on respirators that are regulated by the TGA can be found here.

Further, buyers should pay careful attention to "lists" compiled of suppliers of respiratory protection from various sources. Although typically assembled to provide assistance, buyers should undertake their own due diligence on each product and should not rely on verification or capability assessments performed by others.

What do I need in place before I start using P2, or equivalent, respirators?

Respiratory Protection Program	If you are intending using a P2 respirator (or equivalent) you should have a respiratory protection program in place. This program should include information on the type of respirators used and for what purposes; information on training; storage and maintenance; and information on your processes and practices for fit testing for example.
Respirator Fit Test	P2 respirators are designed to be tight-fitting. Their performance relies almost entirely on ensuring a good seal between the respirator and the wearer's face. If there is not a good seal, the device fails. Air leaks around respirator edges and the wearer will not get the level of protection needed to protect their health. The respirator must be a suitable size for the person's face and facial hair (even stubble) will compromise the seal. Workers should, therefore, undergo a respirator fit-test before they first start wearing a tight-fitting respirator. Fit-testing measures the effectiveness of the seal between the respirator and the individual wearer's face. It is required for all tight-fitting respirators, including disposable P2, N95, FFP2, and KN95 respiratory protection.
Risk Assessment	Respiratory protection is not worn in isolation, it is part of a wider planned risk management process. A risk assessment is needed to demonstrate when and where respirators are used within the workplace.

Further information can be found in AS/NZS 1715-2009 and this Guide from Work Health and Safety Queensland.

In Australia, information on respirator Fit Testing, including finding a Fit Tester or Training Provider can be obtained through the RESP-FIT national respirator fit testing, training, and accreditation program.

In New Zealand, Fit Testing trainers and competent Fit Testers can be accessed through the NZOHS Commit-2-Fit Programme.

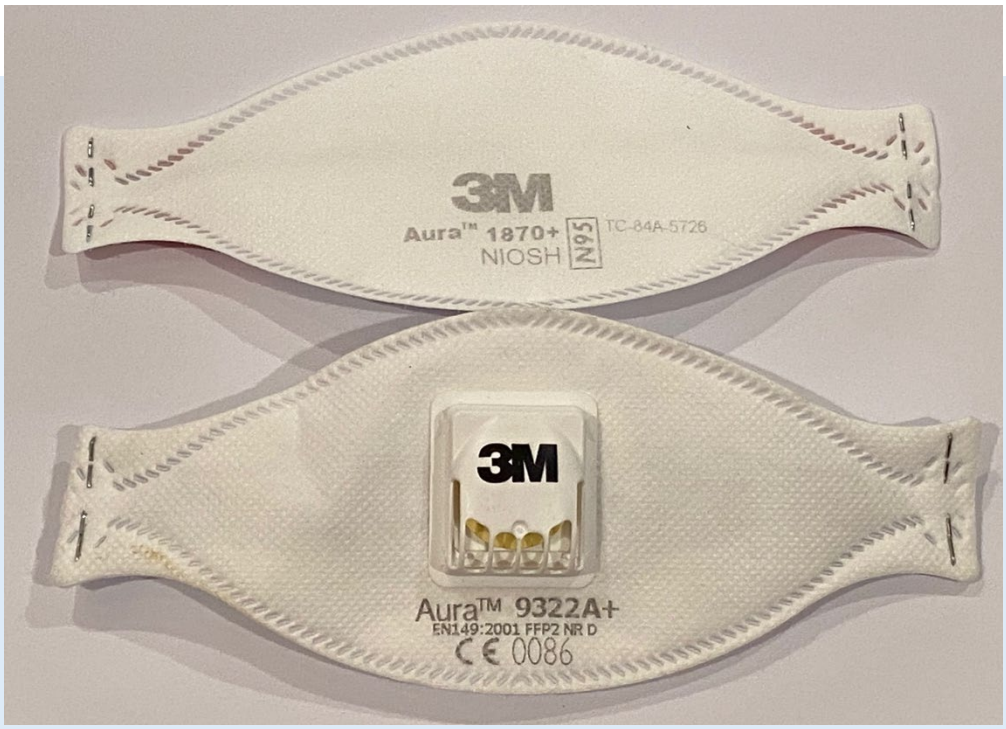
What should I look for when buying respirators?

Step 1	**Make sure you are familiar with the Regulations and Standard requirements for the devices you are planning to purchase.** More information is provided in this guide to assist.
Step 2	**Check the markings on the product and the packaging**. When purchasing a respirator, it is vital to ensure that all markings required under each Standard match identically to those on the device. Things you are looking for on the product include the manufacturer's name (or trademark), the relevant Standard (e.g. AS/NZS 1716:2012) and the classification of the respirator (e.g. P2). More information is provided in this guide to assist.
Step 3	**Check the expiry date on the product or the packaging.** The longer respirator has been in storage, the less likely it is to perform at its full potential. Over time, components such as the strap and foam may degrade, which can affect the quality of the fit and seal. Do not use after the manufacturer's indicated expiry date.
Step 4	**Inspect the documentation**. Obtain a copy of the test certificates or approval certificates from the manufacturer that verify the product has been manufactured in accordance with the relevant Standard. Check the validity of product certificates provided by the supplier. They should display the manufacturer's name, a licence number, along with a list of the licensed models of respirators and filters. More information is provided in this guide to assist.
Step 5	**Obtain a sample of the product and check for a correct fit**. Check that the product will achieve a good facial fit by performing fit-testing on a selection of the product and the workforce before purchasing. Note that it is unlikely one P2 model type/size will fit all of the faces in your workforce and more than one model may be needed.

Valved versus non-valved respirators

Respirators with an exhalation valve provide the same level of protection to the wearer as one that does not have a valve. The presence of an exhalation valve reduces exhalation resistance and moisture build up inside the respirator.

It is important to note that respirators with exhalation valves enable unfiltered air to be released outside of the respirator. For this reason, if the respirator is being worn to protect others from droplets and particles exhaled by the wearer then respirators with exhalation valves are not recommended for this application. The selection of a suitable respirator should take this into account.



Examples of non-valved (top) and valved (bottom) respirators

About the product(s) – An overview of P2, and equivalent, respirators

Products sold as P2 respirators

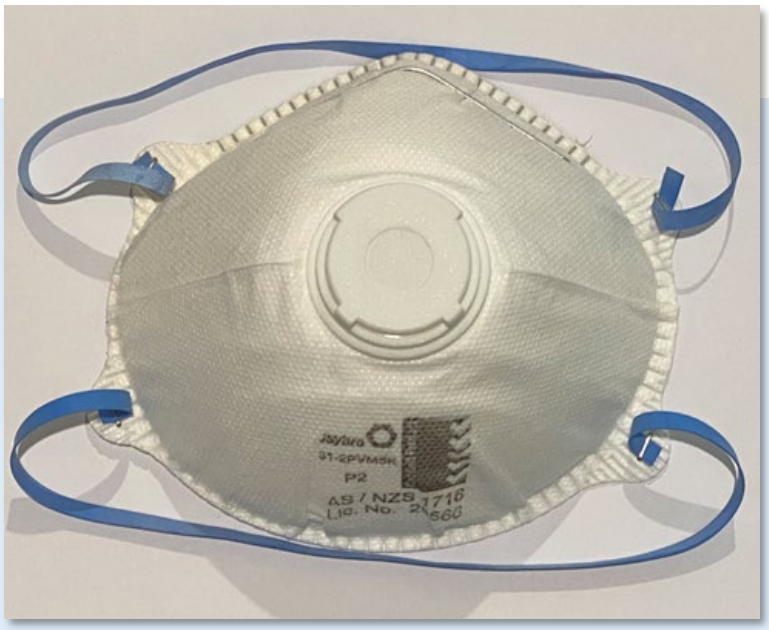
P2 respiratory protection relates to the Standard AS/NZS 1716:2012. The Standard requires the following markings on the mask or the filter. It is important to ensure that the correct respirator markings are clearly displayed before purchasing.

Required markings comprise:

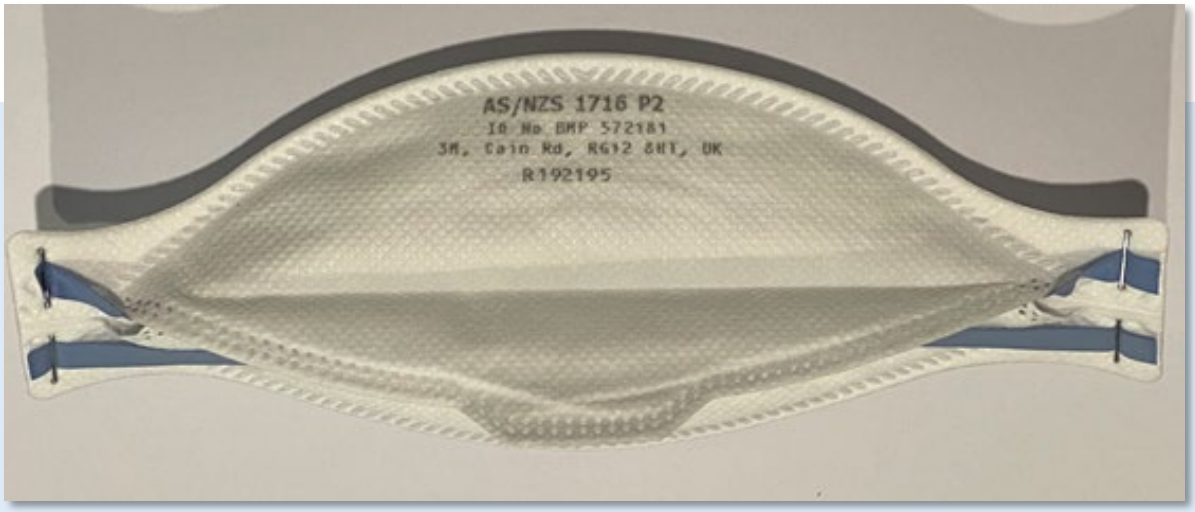
- ✓ The manufacturer's name, trade name or mark
- ✓ The filter classification (e.g. P1 or P2)
- ✓ The term “AS/NZS:1716”

Markings may be displayed on different parts of the respirator. Some examples are shown below.

An example of product markings for a P2 respirator on the head straps



An example of product markings for a P2 respirator on the face piece



An example of product markings for a P2 respirator on the face piece

For products to be approved as a P2 respirator, they need to meet the requirements of AS/NZS 1716 Section 4. A reputable supplier or manufacturer should be able to supply you with a Certificate of Compliance or similar document stating the identified product is a P2 respirator compliant with AS/NZS1716:2012.

The product may also be certified by a 3rd party body that is accredited to JAS-ANZ for AS/NZS 1716:2012. At the time of writing there were four bodies accredited which are:

- BSI Group (Australia and New Zealand) Pty Ltd
- CertMark International (CMI)
- Global-Mark Pty Ltd
- SAI Global Certification Services Pty Ltd

Certificates from these bodies can be verified through the accreditation body. See the BSI VerifEye™ Directory, the Certificate Register Search, the Global Mark Certificate Search or the SAI Global Certification Register as relevant.

Where the product is not certified, it is important to check that all of the necessary performance tests have been completed and that they meet the requirements of AS/NZS1716:2012. In order for a product to be compliant with AZ/NZS1716:2012 and be labelled a P2 respirator, the necessary markings and performance criteria have to be demonstrated to meet AS/NZS1716:2012.

Table 2 has been produced for reference for disposable P2 respirators. Note that the information and list of tests provided is not-exhaustive and AS/NZS1716:2012 should be consulted for the necessary detail.

Table 2: Performance tests and criteria required under AS/NZS1716:2012 for disposable P2 respirators

Clause	Test and reference to the Appendix in AS/NZS1716	Performance Criteria
2.2.1, 2.2.2	Total inward leakage (TIL) (Appendix B and Appendix D)	No individual exercise result to exceed 8% total inward leakage Mean result of test subjects not to exceed 8% total inward leakage
3.1.1	General design requirements	Be designed to fit a wide range of facial contours and head sizes of the workplace population; the device to remain in place during normal work practices.
3.1.2	Exhalation valve assembly (applicable only to respirators with exhalation valves)	Self-closing and not remain open after outward airflow have ceased
3.2.4	Exhalation valve leakage (Appendix F)	Leakage not to exceed 30 mL/min
3.2.5	Exhalation resistance (Appendix G)	The exhalation resistance of the entire assembly, measured relative to the static pressure in the facepiece to be less than or equal to 120 Pa
3.2.6	Security of attachments	Each strap and its attachment to a half facepiece shall withstand an axial tensile force of 10N applied for 10 seconds in the direction of pulling when the facepiece is fitted
4.3.1	General	Performance requirements apply to the whole filter and inlet valve assembly including all parts through which the inhaled air passes
4.3.2	Simulated rough usage (Appendix H)	No visible deterioration
4.3.3	Simulated wear treatment (Appendix E)	Exhaled air humidity pre-conditioning which is performed prior to the following listed tests
4.3.4	Inhalation resistance (Appendix G)	Not to exceed the following values for the filter assembly: • 70 Pa at 30 +/-1 L/min • 240 Pa at 95 +/-2 L/min Not to exceed the following values for the assembled respirator: • 120 Pa at 30 +/-1 L/min • 370 Pa at 95 +/-2 L/min
4.3.5	Test of filtering efficiency (Appendix I)	Not more than 6% penetration

Products sold as N95 respirators

N95 respirators in the USA are regulated by the National Personal Protective Technology Laboratory (NPPTL) part of the National Institute for Occupational Safety and Health (NIOSH), is a division of the Centers for Disease Control and Prevention (CDC).

Specific product markings are required under the NIOSH Standard NIOSH-42CFR84 for an N95 respirator. Further details are available through the CDC website here.

Required markings comprise:

- ✓ Manufacturer's name or trademark – in this case, 3M
- ✓ The NIOSH name in block letters or the NIOSH logo
- ✓ Filter type - N95
- ✓ Model number – in this case Aura 1870+
- ✓ NIOSH approval number – starting with TC-

An example of product markings for an N95 respirator on the face piece

A guide to common indicators of non-compliance can be found here.

Once the markings have been deemed compliant, check to ensure the product is approved as an N95 respirator by NIOSH. This may be done by searching for the product under their list of Approved N95 Particulate Filtering Facepiece Respirators or Approved Surgical N95 respirators. The information in the listing should be carefully cross-checked with the product to ensure every detail is the same.

Limitations of Federal Drug Administration (FDA) registration

Surgical N95 respirators are also rated as a surgical mask with a fluid resistance rating administered by the USA Food and Drug Administration (FDA). The FDA states that it does not issue any kind of certification to confirm compliance with the criteria set out under that registration process. Having the product listed by the FDA does not mean that the product meets a certain respiratory protection standard.

Buyers should be aware that the FDA logo is for the official use of the U.S. Food and Drug Administration (FDA) and not for use on private sector materials such as respiratory protection. Any claim that a face mask is *"FDA approved*" is false.

FDA certificates should not be used by manufacturers, distributors, suppliers, or importers to make claims about their products meeting certain respiratory protection standards. Buyers should refer to the applicable Standard for the product being purchased.

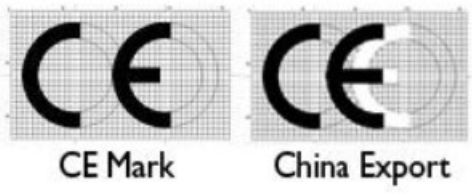
Products sold as FFP2 respirators

FFP2 supply in the European Union (EU) is regulated by Regulation (EU) 2016/425 *Personal Protective Equipment*.

Respiratory protection sold in the EU must have a declaration of conformity. Under this declaration, manufacturers are obliged to carry out a formal assessment of conformity, create a technical file, issue a declaration of conformity and place a CE mark on the product.

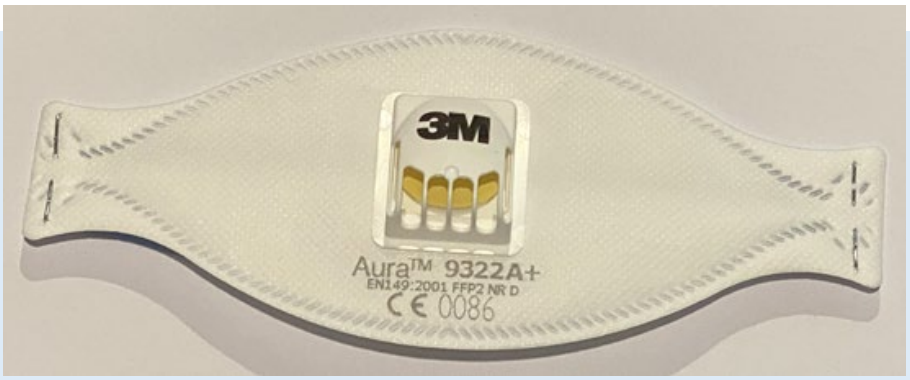
WARNING: the European CE mark should not be confused with the 'China Export' mark.

The differences are explained in more detail here. The only visible differences are the location of the letter "E" and a slightly smaller horizontal line in the "E" in the CE mark, so great care is required when making this assessment.



Example of the CE Mark and the China Export Mark

Specific product markings for FFP2 are required for respirators certified under the EN-149-2001 Standard.



An example of product markings for an FFP2 respirator on the facepiece

A guide to common indicators of non-compliance can be found here.

Required markings comprise:

- ✓ The manufacturer's name or logo – in this case, 3M
- ✓ European Standard Number – EN149:2001
- ✓ Manufacturer model number – in this case, Aura 9322A+
- ✓ Filtering facepiece class – FFP2 "NR" (non-reusable)
- ✓ European certification mark CE
- ✓ The notified body responsible for the certification – in this case, 0086

If the product contains the necessary markings under EN-149, check that the notified body is authorised for *"Equipment providing respiratory protection"* under Regulation (EU) 2016-425. This can be verified through the Nando website. Note that several non-compliant products have been identified to contain product markings that on face value appear to meet the EN-149 Standard. Buyers must verify CE certificates as some respiratory protection has been found to have a "CE" mark that is not from a notified body competent for equipment providing respiratory protection.

The product should have also been tested by a laboratory that was accredited to perform testing to the EN-149 standard.

Products sold as KN95 respirators

As reported by the Health and Safety Executive in the UK, a substantial number of face masks, claiming to be of KN95 standards provide inadequate respiratory protection and have been shown to potentially be inferior quality products. Further, KN95 labelled devices have in some cases been accompanied by fake or fraudulent paperwork.

KN95 is a performance rating under the Chinese standard GB2626, the requirements of which are broadly the same as the European standard EN149:2001+A1:2009 for FFP2 respiratory protection. However, there is no independent certification or assurance of their quality, and products manufactured to KN95 rating are declared as compliant by the manufacturer. Compliance with GB2626:2006 is achieved by passing the required performance and marking tests on supplied product samples. There is no assessment of the existing or ongoing quality management system of the manufacturer as part of this process. There can, therefore, be discrepancies in quality between batches if the manufacturer does not have an established quality system. China does not maintain a list of products that are certified to KN95.

Buyers should be aware that unlike P2, N95 or FFP2 respirators, most KN95 respirators are manufactured with ear loops rather than headband straps. NIOSH state caution should be used when purchasing a respirator with ear loops as the head harness, as preliminary assessments have indicated that it is difficult to achieve an adequate fit when wearing respirators with earloop designs. NIOSH has strongly recommended against purchasing a respirator with ear loops without conducting a fit test with multiple people (with varied facial structures). This is a critical issue, because even if all the product testing and documentation are found to be genuine, respirators that do not effectively fit, do not effectively protect the wearer. NIOSH has also performed testing on a range of KN95 respirators from many sources with respect to filtration efficiency and found significant failures for many models.

Feedback from industry has also highlighted that the vertical fold down the front of this style of mask can also create a gap at the bottom of the chin of the wearer. These design elements have been

shown to affect the stability and face fit performance of the product resulting in difficulty in the wearer to pass a respirator fit test. If the wearer cannot pass a fit test, the product will not offer the protection that it is designed to achieve.

In summary, the critical issues associated with KN95 respirators include their actual filtration efficiency, inconsistent quality, and poor effective face fit performance across a range of individuals. The ability to assess these is a difficult problem for the prospective purchaser.

At this stage, the use of KN95 respirators is not recommended for use in Australian or New Zealand work environments.

Buyers should beware of products being sold as KN95 respirators that claim to meet the standards of other countries. Buyers should check that the product meets those standards through following some of the simple steps outlined in the previous sections.

In times of reduced supply when absolutely no other options are available

When P2, N95, or FFP2 respirators, or other options for controlling the hazard are not available and buyers have the resources to take the due diligence required to ensure that a certification or quality assurance process is in place, then KN95 respirators may be considered suitable for use by the purchaser. Note that numerous regulatory authorities both locally and internationally have banned their use in the workplace, so purchasers should verify whether they are legally allowed to be used in their location and occupational setting.

Buyers will need to routinely check that the product being sold is subject to the same level of quality control and assurance as would be expected from an Australian product.

Several product markings for KN95 respirators are required under GB 2626-2019 *Respiratory protection—Non-powered air-purifying particle respirator* (and formerly under GB2626-2006).

Required markings include:

- ✓ The manufacturers' name or trademark
- ✓ Reference to the standard GB 2626 (e.g. “GB2626-2019”)
- ✓ The category of the filter (e.g. “KN95”)

An example of product markings for a KN95 respirator

A guide containing common indicators of non-compliance can be found here.

If the product contains the necessary markings, it is important to check to ensure that the product was tested by a laboratory accredited by the China National Accreditation Service (CNAS) for Conformity.

There are several test houses in China capable of doing these tests, which are a mixture of government and commercial types. Any manufacturer can claim compliance to GB2626 if they have a compliant test report from an accredited laboratory (Note: GB2626:2019 has been released but required compliance with this latest version has been delayed to 2021).

Most CNAS test reports are accompanied by a “QR” code on the front page of the report, which links back to an online version of the test report. The QR code should be used to check that the online version of the test report and the copy provided by the supplier matches exactly.

The product on the test certificate also needs to be checked to verify if it is the same as the product in question. This includes checking the manufacturer's name, the model number, and the photograph of the product (including the markings) on the test certificate with the product being sold for an exact match.

There is an optional certification path in China known as LA certification. This is an added validation process that includes attention to the manufacturer’s quality control system and processes, including a factory inspection every three years. This process is reasonably widespread - by entering the certification number (as found on the LA mark), the product status can be checked online.

Any certificate provided should be crossed checked with the issuing authority. There have been many examples of false documentation, both of test reports and certificates. Note that even if listed, this is not a guarantee of the performance and authenticity of the product that would be received.

The Chinese State Administration for Market Regulation maintains a list of suppliers whose batches of non-medical masks did not pass quality supervision and random inspection. Note this list does not provide specific product lines of concern.

The Ministry of Commerce in the People’s Republic of China has put in place measures to enhance quality oversight and step up export regulation for epidemic prevention and control supplies. From April 26th, 2020, China implemented conditions whereby non-medical use face masks were required to conform to Chinese standards or the relevant requirements for a particular device in the receiving country. The Ministry of Commerce maintains a list of validated Medical and Non-Medical Use Face Masks manufactured by companies with Certification/Authorisation from other Countries.

Identifying non-compliant products

A significant number of products have been found in both the Australian and New Zealand supply chain, that do not meet the referenced International Standards.

In addition to checking that the product meets the referenced standards through following the steps outlined in the previous sections; the following resources help identify non-approved products across both Australia and New Zealand.

New Zealand

The New Zealand Occupational Hygiene Society provides useful resources, including a checklist and a webinar on counterfeit respirators.

USA

The US was facing shortages of respiratory protection for healthcare and associated workers due to COVID-19, prompting a call to increase the availability of acceptable devices. NIOSH undertook assessments of the filter efficiency for some respirators that were reportedly certified by a different international certification authority. This list can be checked to verify if the product's results are available and then further checked to see if a minimum filtration efficiency of 95% was achieved.

If listed, the product should be checked against the photograph of the product listed in the respective Test Report. As stated by NIOSH, the results listed do not mean that the product is approved, and are not to be used by manufacturers, distributors, suppliers, and importers to make claims about their products and/or to influence purchasers. However, if the product is listed and the minimum filtration efficiency of 95% was not achieved, buyers are recommended to not purchase the product.

Buyers can also check if the product being sold is listed by NIOSH as Counterfeit or a Misrepresentation of NIOSH-Approval and review some examples of non-compliant devices.

The CDC has published Factors to Consider when Planning to Purchase Respirators from Another Country which is also a helpful resource.

United Kingdom

The British Occupational Hygiene Society provides useful information on identifying counterfeit devices, the link may be found here.

Europe

The European Safety Federation provides information on suspicious certificates for PPE, which is regularly updated. This is a good resource to check if the certificate provided is from an institute that is not a notified body competent for PPE or if the documents are fake.

In addition, it is possible to lookup whether the product is listed in a Safety Alert by the European Commission also (by entering "Protective equipment" into "Category" and searching).

Canada

Health Canada provides important safety information for certain respirator masks including medical device recalls.

Version Control

Version 2.0	Explanative text added under table 1 re use of KN95's ** TGA paragraph p3 updated Additional explanation p6 regarding use of valved RPE to protect wearers Added CertMark International as a JAS-ANZ accredited body Table 2 provided for clarity Minor edits and typo correction for better readability	October 2020
Version 1.0	First release	June 2020