Health & Safety Alert

Respiratory Protection not meeting Australian Standards

Background

Due to Covid-19 there is a large demand for respiratory protection equipment (RPE). Supplies of typical brands that may have been previously used are now restricted which has placed pressure across many businesses to find suitable alternatives.

Air purifying respirators such as those that provide protection against particulates are classified and marked as P1, P2 or P3 in accordance with AS/NZS 1716:2012. Around the world, RPE is subject to various other regulatory standards. It is important that when sourcing RPE that the buyer verifies that the product meets the Australian Standard or an international equivalent. Some examples of international standards that may be considered to be equivalent to AS/NZS 1716:2012 include N95 (United States – NIOSH), FFP2 (Europe EN-149-2001) and KN95 (China GB2626) for example.

We have been alerted to a number of suppliers that are selling RPE that do not meet the requirements of Australian or equivalent International Standards. These typically relate to disposable air purifying respirators labelled as “P1” or “P2” respiratory protection, or their equivalent.

Under the Work Health and Safety Regulation 2017, the PCBU who directs the carrying out of work must ensure that PPE provided is selected to minimise risk to health and safety, including by ensuring equipment is suitable for the nature of the work or hazard and a suitable size and fit for the individual who is required to use it and that it is reasonably comfortable.

Several disposable respiratory protection products are being sold in the Australian market as “P2 equivalent” including N95, KN95, and FFP2. However, it has been found that:

- the accompanying documentation has not been sourced from authorised or accredited testing facilities for the Australian or respective international standard;
- the products supplied do not match the accompanying documentation, meaning that they may be counterfeit;
- the products are not supplied with the required markings as per the relevant standard; and/or
- persons are not passing respirator fit testing in accordance with AS/NZ1715:2009 when wearing the products supplied.

The most common case of failure reported is through the supply of KN95 respiratory protection, which is often accompanied with certificates from unaccredited testing laboratories, without the required product markings, and / or are failing fit testing requirements.

Legislative Requirements

- Under WHS Legislation, Person Conducting a Business or Undertaking (PCBU) must ensure, so far as is reasonably practicable, the provision and maintenance of a work environment without risks to health & safety.
- Under WHS Legislation, the PCBU who directs the carrying out of work must ensure that personal protective equipment (PPE) provided is selected to minimise risk to health and safety, including by ensuring equipment is:
    - suitable for the nature of the work or hazard
    - a suitable size and fit for the individual who is required to use it and that it is reasonably comfortable

Actions Required

Those that purchase personal protective equipment (PPE) for use in the workplace should undertake appropriate due diligence to ascertain if the RPE to be provided for use is suitable for the nature of the work or hazard, and that it is a suitable size and fit for the individual who is required to use it. This process may include:

- Verifying if the accompanying documentation has been sourced from an authorised or accredited testing facility;
- Verifying if the product to be supplied matches the accompanying documentation;
- Verifying if the product is being supplied with the relevant required markings as per the Standard; and
- Verifying that the product to be supplied is of a suitable size and fit for the individual who is required to use it. Fit testing is required by AS/NZS1715 before a user wears a respirator in the workplace for protection.

Information on authorised organisations and testing facilities and product markings

For products being sold as meeting the requirements of AS/NZS1716:2012 (e.g., "P2" respirators), this may include verification of certification from authorised organisations such as SAI Global or BSI Group for example. Product markings required under AS/NZS 1716:2012 include items such as the manufacturer's name, trade name, or mark, the filter classification, and the Australian Standard.

For products being sold as meeting the requirements of NIOSH-42CFR84 (e.g. "N95" respirators) this may include verification of the product as an "Approved N95 Particulate Filtering Facepiece Respirator" from NIOSH for example. It may also involve checking if the product is currently listed as counterfeit. NIOSH outlines the required labelling of NIOSH-Approved N95 filtering facepiece respirators here.

Note that certificates from the Australian Government Department of Health Therapeutic Goods Administration (TGA) which may list a products as a "Public N95 respirator", are not considered acceptable evidence of certification. Buyers should be aware that the TGA has been operating under an Exemption for coronavirus medical devices since March 22nd, which negates the need for these products to undergo certain checks and balances to verify certification. Suppliers should not rely on TGA certificates alone to verify if products met the required standard, and should consult the relevant international agency for accreditation (e.g. NIOSH in the case of N95).

For products being sold as meeting the requirements of EN-149 (e.g. "FFP2" or "FFP3" respirators), this may include verification of testing in accordance with that standard by a laboratory accredited with European Accreditation. Product markings include items such as the Standard number, filter type and European conformance CE mark (not to be confused with China Export "CE" markings) for example.

For products being sold as meeting the requirements of GB2626 (e.g. "KN95" respirators), this may include verification of testing by a laboratory accredited by the China National Accreditation Service (CNAS) for Conformity Assessment. Product markings under GB2626 include items such as labelling of the standard GB2626 and the category of the filter element (e.g. "GB2626-2019 KN95").

Issued and authorised by the Deputy Executive Director Health & Safety, Sydney Metro

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Examples of Products found to not meet Australian Standards (or equivalent)

A KN95 mask supplied with Australian Standard labelling

A KN95 mask supplied with documentation from an unaccredited testing laboratory and without product markings

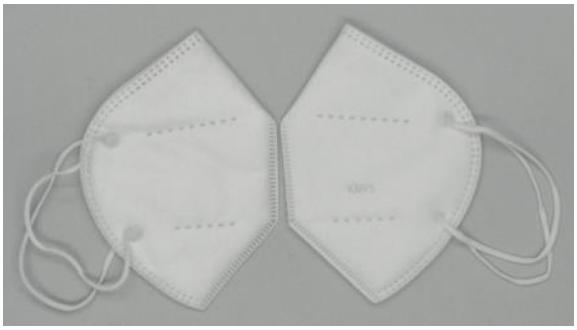
A N95 mask supplied with documentation from an unaccredited testing laboratory and without product markings

A KN95 mask supplied without testing documentation or product markings

A FFP2 mask supplied without testing certificates

A KN95 mask supplied with documentation from an unaccredited testing laboratory and without product markings

A N95 mask supplied with documentation from an unaccredited testing laboratory and without product markings



A KN95 mask supplied with documentation from an unaccredited testing laboratory and without product markings