



Raysafe Workwear is an Approved Contractor of PPE under LGP, MAV, WALGA and LOCAL BUY State Procurement arrangements.

TECHNICAL SHEET – FACE MASKS DISPOSABLE AND RE-USABLE (WASHABLE)

Ref 8/21

1. DISPOSABLE: Usually 3 Layer Non-Woven fabric.

A disposable non-woven mask is intended to prevent transmission of disease between persons in a non-clinical, medical or public setting it should be included in the ARTG Australian Register for Therapeutic Goods. Have a TGA Certificate.

****If these masks do not have a TGA Certificate they may be a lower grade fabric and may be ineffective in blocking Bacterial filtration up to 95%. This is currently a problem with some Imported Masks.**

A disposable non-woven mask is intended to prevent transmission of disease between persons in a non-medical, clinical, medical or surgical setting it is mandatory for inclusion in the ARTG. Have a TGA Certificate.

Levels of Fluid Resistance:

Level 1: Low risk situations 80mmHG Fluid Resistance Non-Sterile up to 95+% Bacterial Filtration Efficiency- most widely used Non-Medical, Medical and Surgical conditions.

Level 2: Medium risk 120mmHG Fluid Resistance – Non-sterile, not as widely used as Level 1 and Level 3.

Level 3: High Risk 160mmHG Fluid Resistance Non-Sterile 98+% Bacterial Filtration Efficiency.

Level 3: Operating Rooms and ICU need to use Sterile Masks Treated with Ethylene Oxide 30% approx.

The Pleated 3 or 4 Layer Mask designs allow more facial movement and have a nose adjuster.

***See TGA document “Face Masks and respirators that are regulated by the TGA”-7 pages**

Disposable: P2 (European Testing) or N95 (American Testing) Moulded Fabric Respirator Valve or Non-Valve.

Offering 94%-95% Air filter efficiency.

This design and fitting of mask does restrict facial movement and may become hotter to wear due to the tightness of fit. However, it offers a closer contoured fit.

More expensive as a disposable mask.

Valve respirators: Filter inhalation, if 2 way may not filter exhalation.

PM2.5 Filters –Activated Carbon Mask 5 ply Filters or 3 Ply Masks- usually Grey colour:

5 ply filter inserts offering 99.88% VFE Viral Filtration Efficiency.

These filters are designed to slot into masks as an insert.

They are disposable non-washable with usually 1 usage, an expensive component of a mask and are usually used in Synthetic fabric Masks which makes them heavier and hotter to wear.

Also maybe not usually necessary in everyday public use.

Standards Applicable:

AS 4381: 2015 ASTM F2101-14 Bacterial Filtration Efficiency.

ASTM F1862 Synthetic Blood Penetration.

For Disposable 3 Ply Masks to be included on the ARTG register as Non-Medical or Medical TGA approved products they must be tested in accordance and/or satisfy the requirements of the above Australian Standards.

2. **RE-USABLE WASHABLE:** 3 Layer with non-woven filtration inner layer most effective.

Cotton Outer and Inner Layers are recommended for Softness and Coolness, Less heat build-up if worn for longer periods as an option to 3 ply disposable masks.

Cotton is more environmentally friendly.

***We do not recommend using Synthetic Inner/Outer layered masks or added Chemical treatments.**

Strap tensioners or adjusters are recommended reducing different size options and more comfortable fitting. Cost effective- usually re-usable circulating 2 or 3 per person, throughout the week, allowing for washing- may last up to 3 months.

If 3 re-usable masks are issued every 3 months-averaging 1 a month- this compares to issuing 1-2 a day disposable masks per person which may be up to 5-10 a week or 20-40 a month.

Can Re-Usable Washable Fabric Masks be included in the ARTG Register or need TGA approval?

No- They are not classified as a Non-Medical or Medical device.

“Face masks for use in the community ...These types of face masks are not intended for use in a clinical setting or explicitly to prevent the transmission of disease between persons and therefore are not subject to the same regulations as surgical masks...” “This type of cloth mask ... can be manufactured and supplied without needing to be included in the ARTG”. See TGA document” Face masks and respirators that are regulated by the TGA”.

Even though they do not require listing or approval by the TGA they may offer equivalent protection from bacterial transfer as TGA approved disposable masks, as they are 3 layered.

Re-usable washable masks do not require compliance with AS 4381:2015 as they are not a non-medical or medical device and are not claiming a % Fluid Resistance or Bacterial Efficiency.

Re-usable washable masks should not be worn in a sterile environment as they are not intended for such use and are not disposable.

Raysafe Workwear under the label RAYSAFE Masks offers Local Government a Free Logo Offer.

Code 002 Fitted and Code 001 Pleated 3 Layer Cotton (Outer/Inner layer) Masks with Adjustable Straps.

Middle Filter layer- Non Woven Fabric with non-added chemicals.

We are currently testing the filter layer 80g non-woven fabric for Bacterial transmission %.

Raysafe Workwear has been instrumental in establishing Sun Protection of Textiles and Uniforms, High-Visibility Colours and Standards.

Heat Stress Management Textiles and Bamboo Uniforms such as Cell-Tec Eco Hi-Vis Shirts are the latest Safety products available.