

# Level 2 Medical Procedure Mask

## Product Technical Sheet



The **Level 2 Medical Procedure Mask** is designed to meet Australian Standard AS 4381:2015 and is suitable for use in environments such as hospitals, day surgeries, dental clinics, aged care facilities and veterinary clinics where there is moderate risk of fluid or blood splash.

Providing protection where there is a risk of bacterial exposure, these masks are also suitable for use in workplace settings such as customer service, pharmacy, retail, food service, and beauty clinics.

Featuring multiple layers of lightweight material and a distinctive purple fluid-resistant outer layer, the Level 2 Medical Procedure Mask is designed to be easily identified for the protection requirements of your specific setting.

This mask is suitable for use by both clinicians and patients.



- + Included on the TGA Australian Register of Therapeutic Goods (ARTG)
- + Single-use, non-sterile and Latex-free with ear loops
- + Designed to meet AS 4381:2015 Medical Face Masks
- + Bacterial Filtration Efficiency (BFE)  $\geq 98\%$
- + Differential pressure,  $\text{mmH}_2\text{O}/\text{cm}^2 < 5.0$
- + Resistance to penetration by synthetic blood to 120mmHg



## Testing Standards

Characteristics	Test Criteria	Test Method
Bacterial Filtration Efficiency % (BFE)	$\geq 98\%$	AS 4381; ASTM F2101-14 or EN 14683:2014 Appendix B
Differential pressure, $\text{mmH}_2\text{O}/\text{cm}^2$	$< 5.0$	AS 4381; EN 14683:2014 Appendix C
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	120mmHg	AS 4381; ISO 22609 or ASTM F1862/F1862M-13

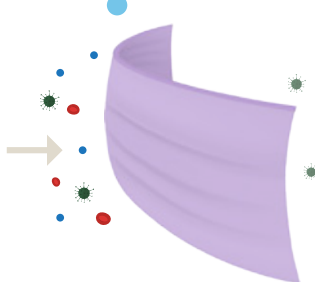
Note: These performance requirements are measured on unworn masks. The mask may not meet these performance requirements during wear due to individual fit characteristics. For situations requiring respiratory protection, respirators designed for use in healthcare settings should be considered.

## Material Specifications

	Outer Layer	Middle Layer	Inner Layer	Nose Wire
<b>Material Description</b>	Spunbond PP	Meltblown PP	Spunbond PP	Steel
<b>Special Treatment</b>	Hydrophobic	Electret	Hydrophobic	Plastic coated
<b>Material gsm</b>	Typically 50gsm	Typically 25gsm	Typically 50gsm	1mm thick

### Outer Layer

The external hydrophobic (repellent) layer protects the wearer from moderate blood splash or body fluids outside the mask.



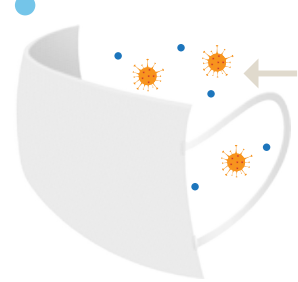
### Middle Layer

The meltblown filtration layer is designed to capture the wearer's bacteria.



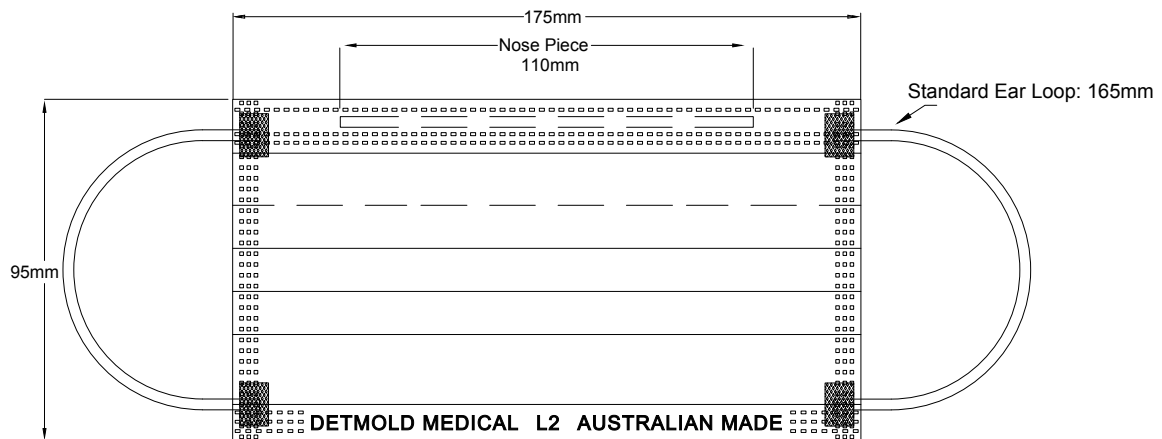
### Inner Layer

Soft and comfortable, the inner hydrophobic (repellent) layer captures droplets from the wearer e.g. sneezes and coughs.



# Level 2 Medical Procedure Mask

## Product Specification Overview



### Product Details

Item No.	Description	Size	Width (Nominal)	Height (Nominal)	Ear Loop Length (Nominal)	Masks Per Box	Masks Per Carton
W731M	Level 2 Medical Procedure Face Mask	Standard Ear Loop	175mm	95mm	165mm	50	1200

### Instructions for Use

Always check mask fit to ensure it is secured at the bridge of the nose and mouth. There should be minimal gaps between the mask and face. Appropriate hand hygiene should always be used when touching the mask. Masks should not be reapplied and should be discarded safely after use.



1. Hold the mask on the short edges with the ear loop connection points facing outwards.



2. Pinching firmly on the nose piece, place one ear loop around the back of your ear and ensure it is secure.



3. Place the second ear loop up over your other ear and check the mask is evenly aligned on your face.  
4. Expand the pleats to ensure a secure and comfortable fit.



5. Check mask fit to ensure it is secured at the bridge of the nose and mouth. There should be minimal gaps between the mask and face.

### Inclusion on the TGA Australian Register of Therapeutic Goods (ARTG)

Medical device products are regulated by the TGA under the Therapeutic Goods Act 1989. Before supply in Australia, these goods need to be included on the ARTG. To meet the requirements for inclusion on the Register, Detmold Medical must demonstrate product quality, safety and performance in accordance to Australian or international standard requirements. This pre-market data is provided for assessment, and market authorisation is then granted to allow entry of the therapeutic goods to the ARTG.

### Storage Recommendations

Store mask in the original packaging, away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals. When stored in accordance with recommendations, the product is designed for use within 2 years from date of manufacture.



**Caution:** The mask is designed for occupational use by healthcare professionals who are properly trained in mask use and limitations. Misuse may result in sickness or death. DO NOT use in any manner not indicated in the Instructions for Use. Always read the label. Discard the mask if it becomes damp, soiled, damaged, or difficult to breathe through. Do not use if the packaging is damaged.

## Contact Detmold Medical to place an order today

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