

Product Technical Sheet

Level 3 Surgical Mask

Product Description

The Level 3 Surgical Mask is a single-use face mask for use in healthcare where a person is at risk of blood or fluid splash. Designed to meet Australian Standard AS/NZS 4381:2015, the mask limits the passage of blood or body fluids through the mask layers. Featuring multiple layers of lightweight material, the mask provides comfort and breathability with two ear loops to hold the mask in place.



- Designed to meet AS/NZS 4381:2015 Surgical 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 160mmHg
- Included on the TGA Australian Register of Therapeutic Goods (ARTG)
- Inner carton dimensions designed for use in vending machines
- Non-sterile & Latex Free with ear loops

Testing Standards

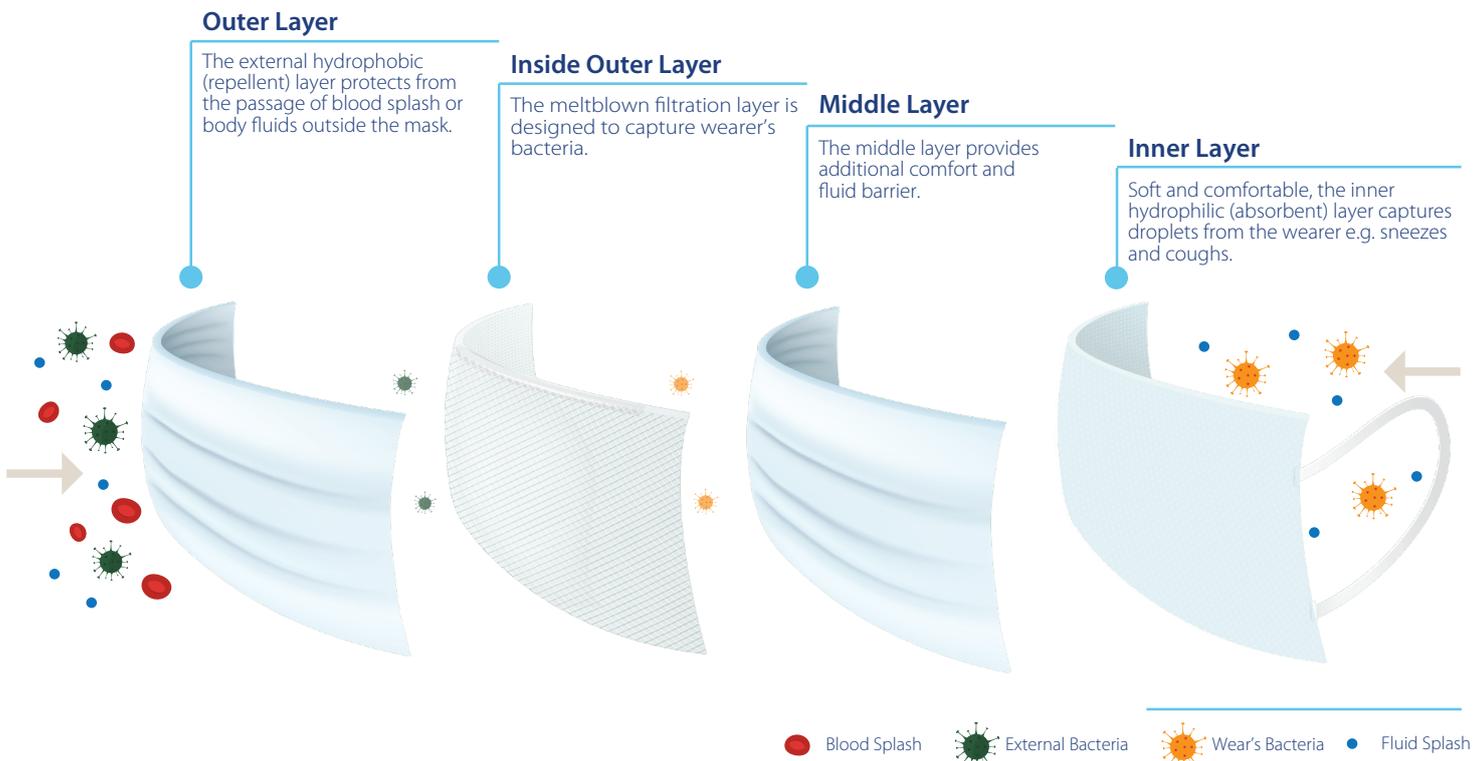
Characteristics	Test Criteria	Test Method
Bacterial Filtration Efficiency % (BFE)	$\geq 98\%$	AS/NZS 4381; ASTM F2101-14 or EN 14683:2015 Appendix B
Differential pressure, $\text{mmH}_2\text{O}/\text{cm}^2$	< 5.0	AS/NZS 4381; EN 14683:2014 Appendix C
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	160 mmHg	AS/NZS 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

Material Table	Outer Layer	Inside Outer Layer	Middle Layer	Inner Layer	Nose Wire
Material Description	Spunbond PP	Meltblown PP	Spunbond PP	Spunbond PP	Steel
Special Treatment	Hydrophobic	3% Electret	None	Hydrophilic	Plastic coated
Material gsm	Typically 50gsm	Typically 25gsm	Typically 25gsm	Typically 25gsm	1mm thick

Note: These performance requirements are measured on unworn masks. The mask may not meet these performance requirements during wear due to individual fit characteristics.



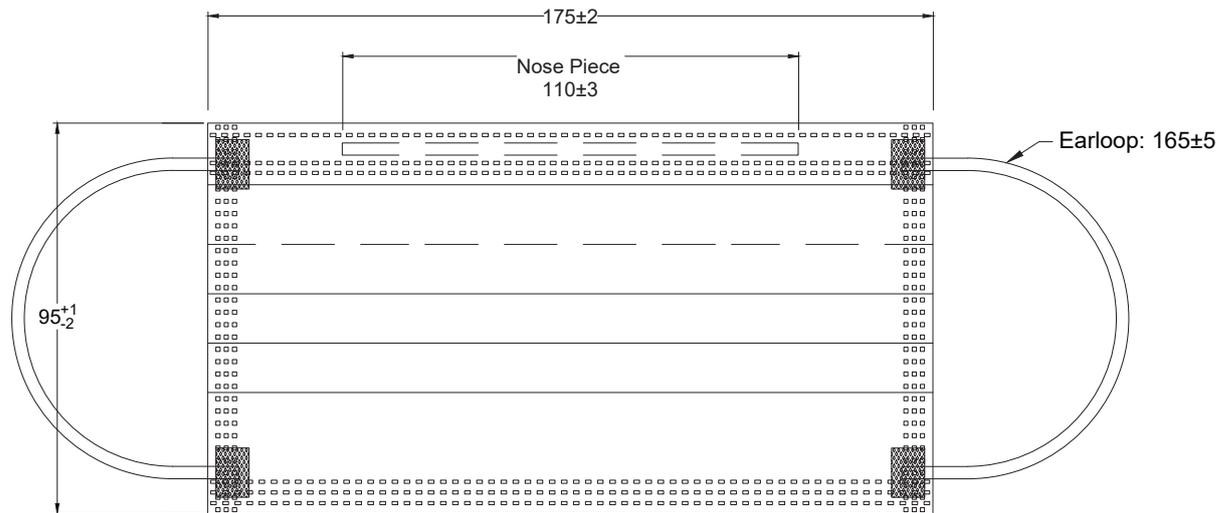
Product Specification Overview

Level 3 Surgical Mask

Product Model Details

Item Number	Item Description	Size	Width	Height	Ear Loop Length	Inner Qty	Carton Qty
W138M	Level 3 Surgical Face Mask	One Size	175mm ± 2mm	95mm ± 2mm	165mm ± 5mm	40 pieces	960 pieces

Note: Inner carton dimensions designed for use in vending machines



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.

- Hold the mask on the short edges with the ear loop connection points facing outward.
- Pinching firmly on the nose piece, place one ear loop around the back of your ear and ensure it is secure.
- Place the second ear loop up over your other ear and check the mask is evenly aligned on your face.
- Expand the pleats to ensure a secure and comfortable fit.

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.