

# Level 3 Surgical Mask

The **Level 3 Surgical Mask** is a single-use face mask for use in healthcare where a person is at high risk of blood or fluid splash.

Designed to meet Australian Standard AS 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.

Available in head tie and ear loop attachment options.

- + Non-sterile and Latex Free
- + Sterile options on special request only
- + Anti-fog visor option offering extra eye and face splash protection
- + Visor comes with 2-sided screen protection to ensure clear vision.



## Testing Standards

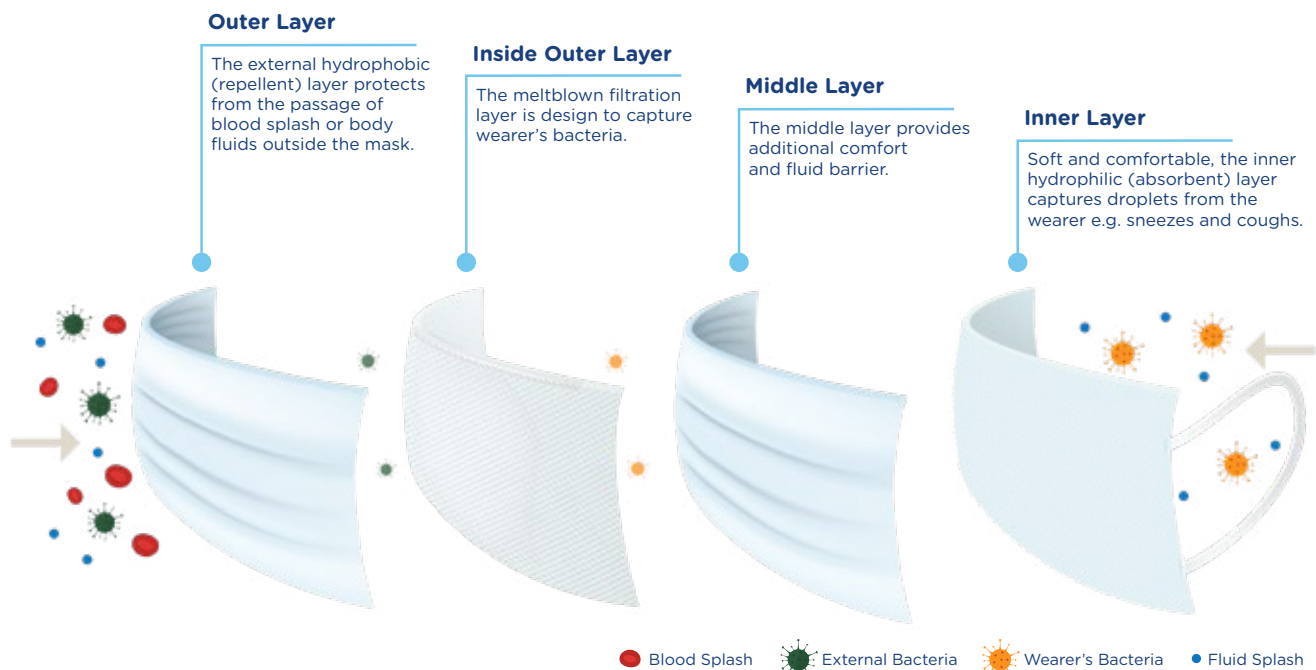
We operate to Quality Management System ISO: 13845. The Level 3 Surgical Mask is designed and tested to meet the essential principles of AS 4381:2015. Raw Materials and Finished Goods are tested routinely in Detmold Medical's validated state-of-the-art laboratory.

### LEVEL 3 SURGICAL MASK PERFORMANCE REQUIREMENTS

Characteristics	42 CFR Part 84	AS 4381:2015	AS/NZS 1716:2012	Quality
Medical Device Certified System				ISO 13485
ARTG*				337503
Particulate Filtration Efficiency (PFE)				
Bacterial Filtration Efficiency (BFE)		>98%		
Blood Splash Resistance		Level 3 - 160mmHG		

**Note:** These performance requirements are measured on unworn masks. The mask may not meet these performance requirements during wear due to individual fit characteristics. Please consult your fit testing procedure. This product is designed for use in a healthcare setting.

## Material Specifications



Level 3 Surgical Mask

Product Details



Item No.	Description	Design	Qty Per Box	Qty Per Carton	Shipper Weight	Shipper dimensions
W874M	Level 3 Surgical Face Mask	Shortened Ear Loop	40	960	6kg	415 x 635 x 259mm
W138M		Standard Ear Loop	40	960	6kg	415 x 635 x 259mm
W515M		Head Ties	25	600	5kg	370 x 601 x 240mm
W541M	Level 3 Surgical Face Mask with Visor	Visor and Head Ties	25	300	5.8kg	394 x 749 x 258mm

Instructions for Use

**Applying the Mask** | Prior to donning or doffing, ensure hand hygiene is undertaken. Once the mask is applied it should not be touched or reapplied. Please discard safely after use.

Ear Loop



1. Hold the mask on the short edges with the ear loop connection points facing outward.
2. Holding firmly on to 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.

Visor and Head Ties

Head Ties



1. Before fitting, peel-off visor protectors from both sides of the visor.
2. Continue with Step 1 of fitting the head ties mask.
1. Position mask over the nose with the blue side facing outward and the wire nose piece at the top. Pinch firmly on nose piece to shape over the nose.
2. Holding the nose piece, expand the pleats to fit over the chin. Pull the upper two ties to the crown of the head and tie a bow.
3. Tie the lower ties at the nape of the neck Expand pleats to ensure they are covering the nose and chin.
4. Check nose piece to ensure a comfortable and secure fit. Reshape if required.

Inclusion on the Australian Register of Therapeutic Goods (ARTG)

Medical device products are regulated by the 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. Storage temperature -20°C to +30°C at <80% relative humidity. When stored in accordance with recommendations, the product is designed for use within 5 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



connect@detmoldmedical.com  
1800 338 633  
detmoldmedical.com