

Level 2 Medical Mask

The **Level 2 Medical 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 risk of moderate 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 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
- + Performs to Level L3 standard – certified to L2
- + Single-use, non-sterile and Latex-free with ear loops
- + Sterile options on special request only



Medical
Device
ISO 13485

Testing Standards

We operate to Quality Management System ISO: 13845. The Level 2 Medical 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 2 MEDICAL MASK PERFORMANCE REQUIREMENTS

Characteristics	42 CFR Part 84	AS 4381:2015	AS/NZS 1716:2012	Quality
Medical Device Certified System				ISO 13485
ARTG*				373510
Particulate Filtration Efficiency (PFE)				
Bacterial Filtration Efficiency (BFE)		>98%		
Blood Splash Resistance		Level 2 – 120mmHG		

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

Outer Layer

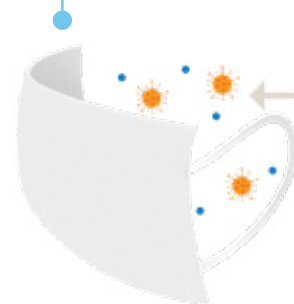
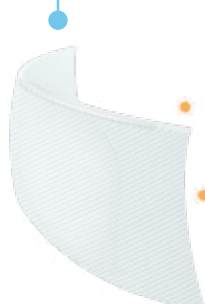
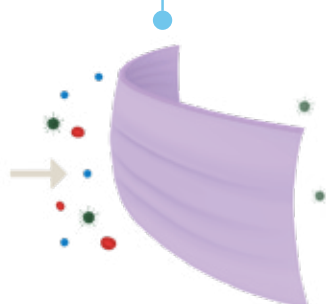
The external hydrophobic (repellent) layer protects from the passage of blood splash or body fluids outside the mask.

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.



● Blood Splash ● External Bacteria ● Wearer's Bacteria ● Fluid Splash


Level 2 Medical Mask

Product Details



Item No.	Description	Design	Qty Per Box	Qty Per Carton	Shipper Weight	Shipper dimensions
W731M	Level 2 Medical Face Mask	Standard Ear Loop	50	1200	6kg	415 x 635 x 259mm

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.**



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



2. Holding 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 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

©2024 Detmold Medical. All Rights Reserved. February 2024. #DM-MMED-2024-002



 connect@detmoldmedical.com
 1800 338 633
detmoldmedical.com