

Level 3 N95 Surgical Tri-Panel Respirator

The **Level 3 N95 Surgical Tri-Panel** is a single-use respirator for use in a health care environment where a person is at risk of blood or fluid splash. The respirator filters out non-oil based airborne particulates and bacteria.

Featuring a one-size-fits-most sturdy flatfold panel design, the respirator expands into a spacious, cave-in resistant device, with slip-resistant colour-coded headbands.

This respirator is suitable for use in health care and hospital settings including but not limited to operating theaters, emergency, infection control, oncology or haematology.

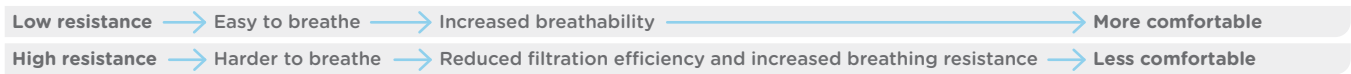


Testing Standards

We operate to Quality Management System ISO: 13845. The Level 3 N95 Surgical Tri-Panel Respirator is designed and tested to meet a cross-section of global performance requirements, meeting the essential principles of an N95 Respirator and Level 3 AS 4381:2015. Raw Materials and Finished Goods are tested routinely in Detmold Medical's validated state-of-the-art laboratory.

All Detmold Medical Respirators are designed to meet Australian conditions, comply with International specifications, and achieve high performance for filtration of sub-micron particles exceeding the 94% and 95% requirements of the AS, NIOSH, and ISO standards, whilst

maintaining a benchmark **low resistance** for breathing. Differential Pressure is the breathability and comfort indicator, which is measured whilst the respirator is worn by determining the difference of pressure across the mask under specific conditions of airflow, temperature, and humidity.

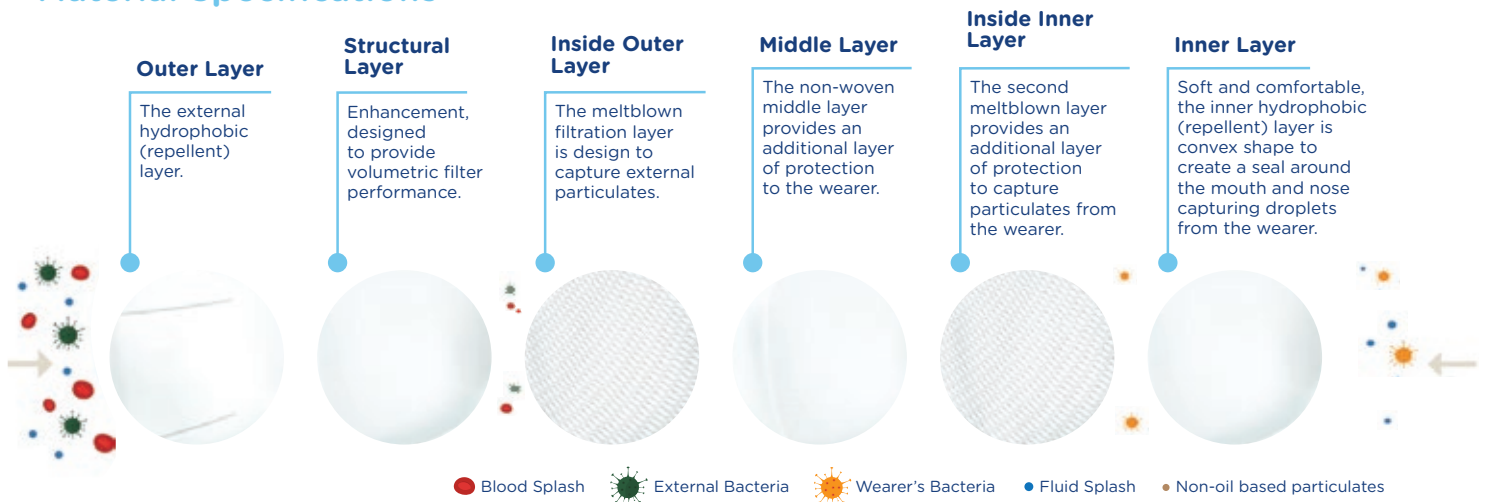


LEVEL 3 N95 SURGICAL TRI-PANEL RESPIRATOR PERFORMANCE REQUIREMENTS				
Characteristics	42 CFR Part 84	AS 4381:2015	AS/NZS 1716:2012	Quality
Medical Device Certified System				ISO 13485
ARTG*				438510
Particulate Filtration Efficiency (PFE)	N95 >95%			
Bacterial Filtration Efficiency (BFE)		>98%		
Blood Splash Resistance		Level 3 - 160mmHG		

Note: These performance requirements are measured on unworn respirators. The respirator 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 N95 Surgical Tri-Panel Respirator



Product Details

Item No.	Description	Size	Qty Per Box	Qty Per Carton	Shipper Weight	Shipper dimensions
W454M	Level 3 N95 Surgical Tri-Panel Respirator with Head Bands	One Size	20	240	5kg	374 x 704 x 238mm

Instructions for Use

Applying the Respirator | Prior to donning or doffing, ensure hand hygiene is undertaken.

There should be no gaps between the face and respirator, providing an adequate seal. Once the respirator is applied it should not be touched or reapplied. **Please discard safely after use.**



1. Holding the mask with the bands facing toward you, move the bottom flap below the bottom band and the top band behind the top nosepiece flap.
2. Using two hands, open the mask to create a cup shape and use your thumb to gently curve the nose wire, ensuring the bottom panel is unfolded and open. Cup mask in one hand, hold bottom panel tab in the other and place respirator on your face with bottom panel securely under your chin.



3. Pull top band over your head positioning it high on the crown. Then pull the bottom band over your head and position in the nape of neck below ears. Adjust bands, ensuring not twisted or obstructed between band and face.
4. Adjust mask for a comfortable fit by adjusting the top panel to sit high on the bridge of the nose and the bottom panel securely under the chin.



5. Using both hands, gently push down and inward from the centre of the mask, moulding the wire around the nose to ensure a close fit and good seal. Note: always use two hands when moulding the nose wire to avoid peaking in the wire which may result in an improper fit and effective performance.
6. Look left to right, then up and down. Ensure no movement of the mask at the nose wire.



7. Cover the front of the respirator with both hands, being careful not to move mask. Inhale and exhale deeply, checking for escape of air. Note: Any movement or escape of air indicates inadequate fit and the mask should be repositioned and refitted.
8. Repeat step 5. There should be no gaps between the face and mask, providing an adequate seal. Please follow your relevant fit check test procedure. Once the mask is applied it should not be touched or reapplied.

Removing the Mask



1. To remove the Respirator safely, lean forward as you pull mask slowly away from the face without touching the filter material. Keep tension on bands to maintain control and ensure mask does not flick back onto the face in the process.
2. Discard mask responsibly.

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 respirator 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.



DO NOT USE IF PACKAGING IS DAMAGED



KEEP DRY



DO NOT RE-USE



Caution: The respirator is designed for occupational use by healthcare professionals who are properly trained in 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 respirator 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-TPRSUR-2024-002



connect@detmoldmedical.com

1800 338 633

detmoldmedical.com