

Level 3 N95 Surgical Respirator - Head band and FitClip™

The **Level 3 N95 Surgical Respirator** is a single-use surgical respirator for use in a healthcare 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 lightweight flat fold design, the respirator expands into a convex-shaped device with either head bands, or two bands with a FitClip™ to hold the respirator in place. The knitted head bands are skin-friendly and well tolerated.

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.

Sterile options on special request only.

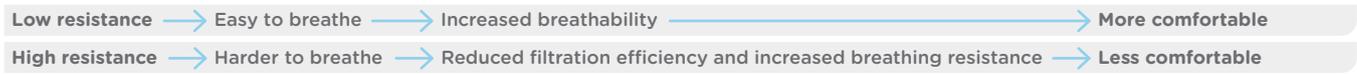


Testing Standards

We operate to Quality Management System ISO: 13845. The Level 3 N95 Surgical 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.

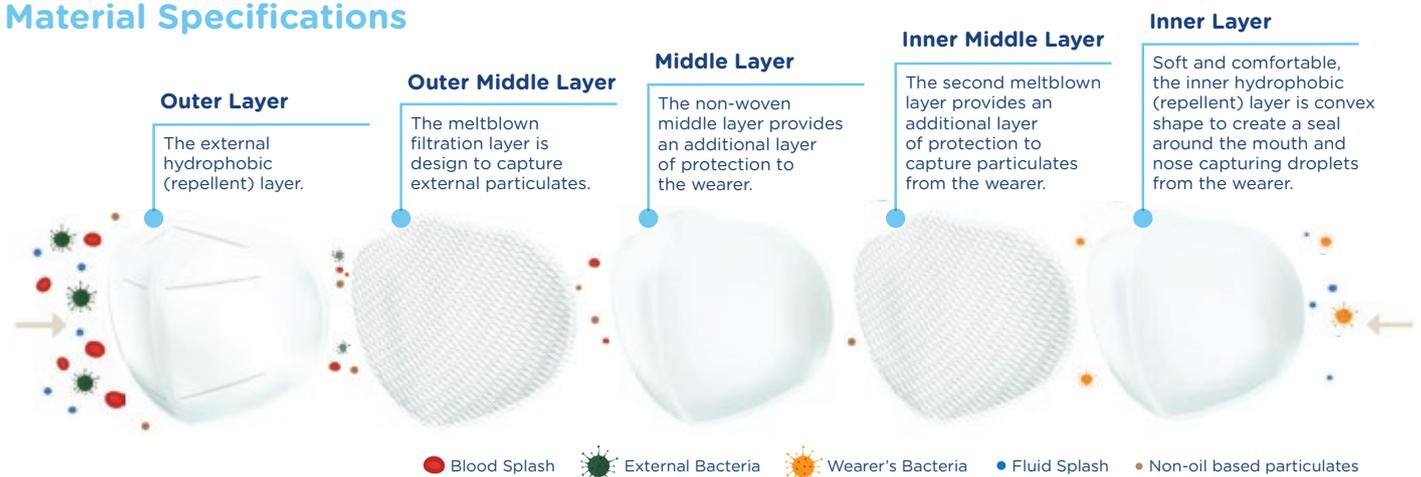


LEVEL 3 N95 MEDICAL SURGICAL RESPIRATOR PERFORMANCE REQUIREMENTS				
Characteristics	42 CFR Part 84	AS 4381:2015	AS/NZS 1716:2012	Quality
Medical Device Certified System				ISO 13485
ARTG				382970
Particulate Filtration Efficiency (PFE)	N95 >95%			
Bacterial Filtration Efficiency (BFE)		>98%		
Blood 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 Respirator



Product Details

Item No.	Description	Size	Qty Per Box	Qty Per Carton	Shipper Weight	Shipper dimensions
W125M	Level 3 N95 Surgical Respirator with Head Band	X-Small	20	480	5.5kg	324 x 505 x 333mm
W350M		Small				
W247M		Regular				
W029M		Large				
W158M		X-Large				

Item No.	Description	Size	Inner Quantity	Carton Quantity	Shipper Weight	Shipper dimensions
W597M	Level 3 N95 Surgical Respirator includes regular size FitClip™ 	X-Small	20	480	5.5kg	324 x 505 x 333mm
W314M		Small				
W424M		Regular				
W199M		Large				
W084M		X-Large				

The Level 3 N95 Surgical Respirator achieves a comfortable and adequate seal by joining the respirator's two bands with the regular sized FitClip™ (included). When a larger/longer band is required, the XL FitClip™ can be ordered separately.

W008S9001	FitClip™ Supplied with all sizes	Regular (35 x 20mm)	N/A	N/A	N/A	N/A
W008S0001	X-Large FitClip™ to be ordered separately 	X-Large (69 x 19mm)	50 pieces	N/A	57g	75 x 85 x 22mm
			N/A	1000 pieces	1.2kg	125 x 176 x 150mm

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.**

Follow these steps for the Head Band version



- Place head bands toward the front of the mask. Open the mask, creating a gentle curve in the nose wire.
- Place hand at the base of the mask (gripping the front seal making sure the bands sit above your hand).
- Lean chin into the mask and pull over the bottom band to rest around your neck below the ears. Pull over the top band and position at the crown of the head.
- Position the mask nose piece above the nasal flares. The mask should sit on the soft area of the nose rather than on the bone of the nose.
- Adjust mask bands for a secure and comfortable fit.
- Continue with step 5 below.

Follow these steps for the FitClip™ version



- Move the FitClip™ to the band on your preferred side for donning*.
- Open the mask, flattening the nose piece.
- Lean chin into the mask and lift bands toward the crown of the head securing onto the FitClip™.
- Adjust the mask bands for a secure, comfortable fit.
- Using both hands, firmly mould nose piece over bridge of the nose.
- Pinch the nose piece (angled over the nostril) and drop the jaw gently, allowing the mask to fit to the natural shape of your face.
- Look left to right, then up and down ensuring there is no movement in the mask at the nose piece.
- Inhale and exhale deeply checking for escape of air. If air is escaping, refit the mask.

Removing the Mask



- Without touching the mask, lean forward.
- Head Band** follow the bottom band and safely lift it over your head. Follow the top band and safely remove the bands and mask. **FitClip™** follow bands towards FitClip™ and gently unhook, keeping tension on both bands. Safely remove the bands and mask.
- Ensure the mask does not flick forward or back onto the face.
- Discard responsibly.

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.



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

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*FitClip™ design may vary. Contact Detmold Medical if an alternate FitClip™ size is required. *Follow your relevant fit check test procedure.



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