

N95 Surgical Respirator Mask - FitClip™

The **N95 Surgical Mask** is a single-use surgical respirator for use in a healthcare environment where a person is at risk of blood or fluid splash. The mask filters out non-oil based airborne particulates and bacteria.

Featuring a lightweight flat fold design, the mask expands into a convex-shaped device with either head bands, or two bands with a FitClip™ to hold the mask in place.

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

- + Particulate Filtration Efficiency (PFE) ≥95% - 42 CFR Part 84, Subpart K
- + Blood Splash Resistance Level 3 - AS/NZS 4381:2015
- + Bacterial Filtration Efficiency (BFE) ≥98% - AS/NZS 4381:2015
- + Facial Fit (TIL) - Class P2 AS/NZS 1716:2012, Section 2.2
- + Pending inclusion on the TGA Australian Register of Therapeutic Goods (ARTG)



Testing Standards

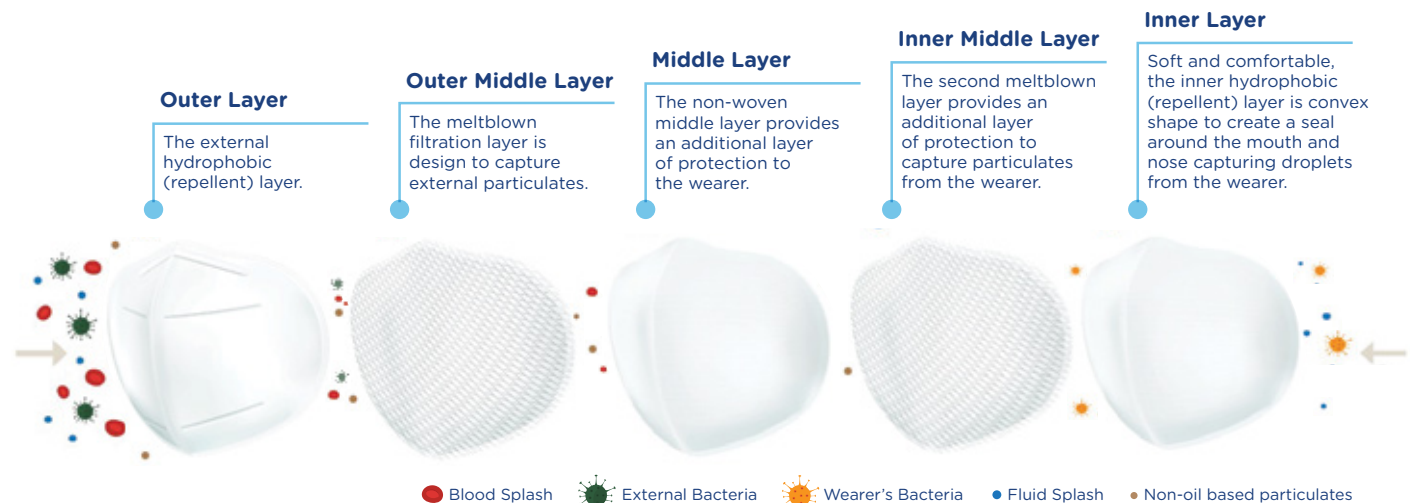
The N95 Surgical Respirator is designed and tested to meet a cross-section of global performance requirements, meeting the essential principles of an N95 Respirator specified by the **NIOSH 42 CFR Part 84**.

DETMOLD MEDICAL N95 SURGICAL RESPIRATOR PERFORMANCE REQUIREMENTS			
Characteristics	AS 1716:2012	42 CFR Part 84	AS 4381:2015
	P2	N95	
Quality Control	ISO 13485	NIOSH	
Particulate Filtration Efficiency (PFE)	>94% NaCl, instantaneous	>95% NaCl, 200mg	
Exhalation Resistance	<120Pa at 85L/min	<25mmH ₂ O at 85L/min	
Inhalation Resistance	<370Pa at 95L/min	<35mmH ₂ O at 85L/min	
Facial Fit (Leakage)	<8%		
Carbon Dioxide Clearance	≤1%	≤1%	
Flammability		16 CFR 1610 - Class 1	
Biocompatibility	Compatible with skin	Compatible with skin	
Bacterial Filtration Efficiency			>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

	Outer Layer	Outer Middle	Middle	Inner Middle	Inner	Nose Wire
Material Description	Spunbond PP	Meltblown PP	Carded Non-woven	Meltblown PP	Spunbond PP	Aluminum
Special Treatment	Hydrophobic	3% Electret	Lofted	3% Electret	Hydrophobic	N/A
Material gsm	Typically 70gsm	Typically 25gsm	Typically 50gsm	Typically 25gsm	Typically 50gsm	1mm thick

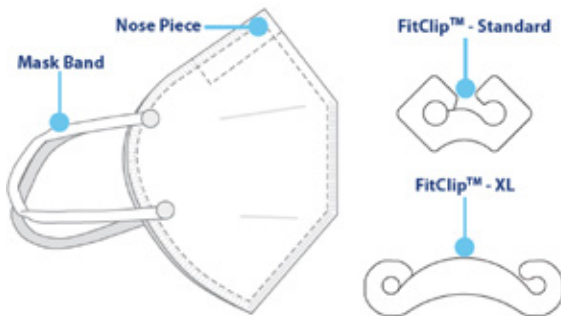


N95 Surgical Respirator Mask – FitClip™

Product Details

Item No.	Description	Size	Mask Box Stripe Colour	Width (Nominal)	Height (Nominal)	Mask Band Length (Nominal)	Masks Per Box	Masks Per Carton
W597M	N95 Surgical Respirator with FitClip™	X-Small	Salmon Pink	116mm	146mm	170mm	20	480
W314M		Small	Purple	106mm	149mm	170mm	20	480
W434M		Regular	Blue	117mm	157mm	190mm	20	480
W199M		Large	Yellow	120mm	162mm	190mm	20	480
W084M		X-Large	Green	120mm	172mm	200mm	20	480

Item No.	Description	Size	Width (Nominal)	Height (Nominal)	Inner Quantity	Carton Quantity
Supplied with all N95 P2 Sizes	FitClip™	Regular	35mm	20mm	N/A	N/A
W008S9001		Extra Large	69mm	19mm	50 pieces	N/A
W008S0001					N/A	1000 pieces



Securing the N95 Surgical Respirator with Band & FitClip™

The N95 Surgical Respirator is designed to achieve a comfortable and adequate seal by joining the mask's two bands with the FitClip™. The Detmold Medical Respirators have the Regular FitClip™ already attached, and where a longer band is required, the XL FitClip™ can be ordered separately. An inadequate seal between the Respirator and the face can result in contaminated air entering the mask. Please refer to your appropriate Respirator Fit Test Procedure to determine the required combination of mask and FitClip™.

Instructions for Use

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

There should be no gaps between the face and mask, providing an adequate seal*. Once the mask is applied it should not be touched or reapplied.



1. Move the FitClip™ to the band on your preferred side for donning*.
2. Open the mask, flattening the nose piece.



3. Lean chin into the mask and lift bands toward the crown of the head securing onto the FitClip™.
4. Adjust mask bands for a secure and comfortable fit.



5. Using both hands, firmly mould nose piece over bridge of the nose.
6. 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.



7. Look left to right, then up and down ensuring there is no movement in the mask at the nose piece.
8. Inhale and exhale deeply checking for escape of air. If air is escaping, refit the mask.



Removing the Mask

1. Without touching the mask, follow bands towards FitClip™ and gently unhook, keeping tension on the bands.
2. Lean forward maintaining control of the band tension, whilst slowly removing the mask away from the face. Ensure the mask does not flick forward or back onto the face.
3. Discard responsibly.

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 3 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

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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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