



**AUSTRALIAN MADE
SURGICAL FACE MASKS
& N95 RESPIRATORS**





**WORLD CLASS QUALITY ASSURANCE TO ISO STANDARDS.
STERILE MANUFACTURING CAPABILITIES, FULL CLEAN ROOM ENVIRONMENT.**

Softmed is an Australian-owned company specialising in the manufacture and distribution of healthcare and PPE products. We operate a world-class manufacturing facility for surgical masks, N95 respirators, and other PPE products. Our facility also produces non-woven fabrics that are the base raw materials for PPE product manufacturing.

Softmed is committed to delivering the highest quality medical grade products made from non-woven materials to protect frontline medical and other workers across Australia and the world.

Softmed operates an ISO 14385 based quality management system in our manufacturing operations. These operations are supported by level 7 clean rooms, sterile manufacturing and packaging capabilities and a fully equipped testing laboratory. Our production of meltblown and spunbond non-woven fabrics enables us to create fabrics to any required specification.



- A 3500m² manufacturing facility is capable of producing over 240 million Surgical Face Masks and P2/N95 Respirators.
- Softmed's Non-Woven Fabric Plant can produce Melt-Blown & Spun-Bond fabrics for over 500 million mask per year.
- Capability to manufacture the full spectrum of PPE products (Surgical Masks, Respirators, Medical Gowns, Blankets & more).
- Softmed controls the quality across the supply chain by manufacturing the PPE Non-Woven Fabric's raw materials (Meltblown & Spunbond Polypropylene) in house.
- Accredited In-house testing lab for Total Quality Management.
- Manufacturing is under ISO 14385 (Medical Grade) Quality Management Systems and our products are certified to international standards by Tier 1 external laboratories.
- Softmed's vertical integration allows for highly competitive pricing without compromising product quality.
- Highest level of product protection for medical & civilian use.



SOFTMED MISSION

To provide Australia and the world with the highest level of excellence through innovation, vertical integration and comprehensive value added medical protection products.



SURGICAL EARLOOP



SM-M101

SURGICAL TIE ON STRAPS



SM-M102

The Softmed surgical disposable mask is made of three distinct layers. The first layer is a Polypropylene Spunbond or PPSB material in light blue (or white), the second layer is white Meltblown and the third is again white PPSB.

The back and front layers (does not matter whether white or light blue) are identical in terms of the nature of the material used. The colour of the exterior layers whether white or light blue is only for aesthetical purposes, you can wear the mask either way. The middle layer stops bacteria and viruses from entering your body. So, there is no wrong way to wear a Softmed surgical mask.

ASTM F2100-19 LEVEL 3

EN 14683:2019 TYPE IIR

ARTG NUMBER 339475

COLOURS AVAILABLE



Blue | White

SPECIFICATIONS	
Brand	SOFTMED
Product Code	SM-M101/ SM-M102
Protection Level	Level 3, Type IIR
Style	Surgical disposable medical mask
Standard Approval	AS 4381:2015 Level 3
	ASTM F2100 Level 3
	EN 14683 Type IIR
Australia Compliance Standard	AS 4381:2015 Level 3
BFE	98% and higher
Fluid Resistance	160mmHg
Differential pressure (Delta P)	Less 5 H ₂ O/cm ²
Size	17.5 x 9cm
Latex	No
ARTG	339475



AVAILABLE
10 Pack | 50 Pack



N95 RESPIRATOR
EAR LOOP



SM-RF201

N95 RESPIRATOR
ADJUSTABLE HEAD LOOP



SM-RF202

N95 RESPIRATOR WITH VALVE
EAR LOOP



SM-RF201V

N95 RESPIRATOR WITH VALVE
ADJUSTABLE HEAD LOOP



SM-RF202V

N95 CUP RESPIRATOR
HEAD LOOP



SM-RC201

TGA APPROVED (ARTG 341917)

AS NZS 1716:2012

EN149 FFP2 NR (GRANTED)

NIOSH 42C FR84 N95 CERTIFIED

MEDICAL GRADE

SPECIFICATIONS

Brand	SOFTMED	SOFTMED	SOFTMED
PRODUCT CODE	SM-RF201, SM-RF202	SM-RF202V, SM-RF201V	SM-RC201
Protection Level	N95/P2	N95/P2	N95/P2
Style	Flat folded, comfort loop (strap), plastic nose strip	Flat folded, elastic loops, plastic nose strip, valve	Cup, comfort head loop (strap), metal nose strip
Standard Approval	AS NZS 1716:2012	AS NZS 1716:2012 P2	AS NZS 1716:2012
	42 CFR 84 N95	42 CFR 84 N95	42 CFR 84 N95
	EN149 FFP2 NR	EN149 FFP2 NR	EN149 FFP2 NR
Australia Compliance Standard	N95	N95	N95
Aerosol type	Non-Oil	Non-Oil	Non-Oil
Exhalation valve	No	Yes	No
PFE	≥95%	≥95%	≥95%
BFE	98% and higher	98% and higher	98% and higher
Fluid Resistance	160mmHg	160mmHg	160mmHg
Inhalation/Exhalation	13.8/12mmH2O	18/15.8mmH2O	13.8/12mmH2O
Flammability	Pass	Pass	Pass
Size	Half face standard	Half face standard	Half face standard
Latex	No	No	No
Protects against hazards	•	•	Yes, such as dust, mist, smoke and fumes
ARTG	341917	341917	Registered

Softmed N95 respirators are made of 6 layers of non-woven Meltblown and Spunbond material. They are accredited to Australian AS/NZS 1716:2012 P2, U.S. 42C FR84 N95 and European AN149-2001 FFP2 NR standards.

Respirators are available in flat fold and cup varieties.

Flat fold respirators are available in head loop and ear loop variants, with or without exhalation valves. Exhalation valve respirators are not suitable for use in medical settings. Softmed respirators feature PFE ≥ 95% and inhalation/exhalation 18/15.8mmH₂O.



AVAILABLE
10 Pack



LEVEL
3

HIGH PROTECTION

HIGH FLUID
RESISTANCE

160mmHg

HIGH
FILTRATION

PFE ≥ 95%





CERTIFICATES & TEST REPORTS

Australian Register of Therapeutic Goods Certificate

SOFTMED MANUFACTURING PTY LTD

SOFTMED MANUFACTURING PTY LTD - Mask, surgical, single use

ARTG Identifier: 316175

ARTG Start Date: 14/02/2020

Product Category: Medical Device Pooled Class 1

GMKN: 35377

GMKN Text: Mask, surgical, single use

Intended Purpose: A single use device intended to be placed over the nose and mouth to prevent the transmission of microorganisms through respiratory tract secretions. Mask of filtering efficiency designed to reduce the user to a minimum through the mask.

Manufacturer Details	Test Article	Test Results
SOFTMED MANUFACTURING PTY LTD	SOFTMED M100	Pass

ARTG Standard Conditions: The above Medical Device Pooled Class 1 has been entered on the Register subject to the following conditions:

Product Specific Conditions: No specific conditions have been entered against this entry.

TGA CERTIFICATE

Nelson Labs

Differential Pressure (Delta P) Final Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: The Delta P test is performed to determine the breathability of test articles by measuring the differential pressure across the test article using a manometer, at a constant flow rate. The Delta P test is performed in accordance with ASTM F2296-19.

Test Article	Delta P (mmHg)	Delta P (cmH2O)
M01	3.0	37.3
M02	3.0	37.3
M03	3.0	37.3
M04	3.0	37.3
M05	3.0	37.3

DIFFERENTIAL PRESSURE

Nelson Labs

Synthetic Blood Penetration Resistance Final Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate surgical face masks and other types of protective clothing designed to prevent splash penetration. The purpose of this procedure is to simulate an actual splash and evaluate the effectiveness of the test article in preventing the use from possible exposure to liquid and other fluids. The distance from the liquid area within the test article is 30.0 cm. A test volume of 2 mL of synthetic blood was dispensed using the testing plate method.

Test Results: Pass

SYNTHETIC BLOOD PENETRATION

Australian Register of Therapeutic Goods Certificate

SOFTMED MANUFACTURING PTY LTD

SOFTMED MANUFACTURING PTY LTD - Public respirator, single use

ARTG Identifier: 341817

ARTG Start Date: 21/02/2020

Product Category: Medical Device Pooled Class 1

GMKN: 37702

GMKN Text: Public respirator, single use

Intended Purpose: A single use public respirator designed to be placed over the nose and mouth to prevent splash penetration.

Manufacturer Details	Test Article	Test Results
SOFTMED MANUFACTURING PTY LTD	SOFTMED M100	Pass

TGA CERTIFICATE

Nelson Labs

Bacterial Filtration Efficiency (BFE) Final Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial count across a membrane filter to the bacterial count downstream. A suspension of bacteria is passed through the test article and the bacteria are captured on the membrane filter. The bacteria are then cultured on a membrane filter to determine the bacterial count downstream.

Test Article	BFE (%)
M01	99.9

BFE

Nelson Labs

Synthetic Blood Penetration Resistance Final Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate surgical face masks and other types of protective clothing designed to prevent splash penetration. The purpose of this procedure is to simulate an actual splash and evaluate the effectiveness of the test article in preventing the use from possible exposure to liquid and other fluids. The distance from the liquid area within the test article is 30.0 cm. A test volume of 2 mL of synthetic blood was dispensed using the testing plate method.

Test Results: Pass

BLOOD PENETRATION RESISTANCE

Nelson Labs

Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the differential pressure of non-powered air-purifying respirators in accordance with 42 CFR Part 84.100. The air exchange differential or breathing resistance is measured by comparing the pressure across the test article during inhalation and exhalation.

Test Article	Inhalation Resistance (cmH2O)	Exhalation Resistance (cmH2O)
M01	15.0	15.0

INHALATION/EXHALATION RESISTANCE

TEST REPORT

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the differential pressure of non-powered air-purifying respirators in accordance with 42 CFR Part 84.100. The air exchange differential or breathing resistance is measured by comparing the pressure across the test article during inhalation and exhalation.

Test Article	Inhalation Resistance (cmH2O)	Exhalation Resistance (cmH2O)
M01	15.0	15.0

INHALATION/EXHALATION



Nelson Labs

Bacterial Filtration Efficiency (BFE) Final Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial count across a membrane filter to the bacterial count downstream. A suspension of bacteria is passed through the test article and the bacteria are captured on the membrane filter. The bacteria are then cultured on a membrane filter to determine the bacterial count downstream.

Test Article	BFE (%)
M01	99.9

BFE

Intertek

Test Report

Report Ref: INT201200001

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the breathability of test articles by measuring the differential pressure across the test article using a manometer, at a constant flow rate. The Delta P test is performed in accordance with ASTM F2296-19.

Test Article	Delta P (mmHg)	Delta P (cmH2O)
M01	3.0	37.3

INTERTEK

SGS

Test Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the breathability of test articles by measuring the differential pressure across the test article using a manometer, at a constant flow rate. The Delta P test is performed in accordance with ASTM F2296-19.

Test Article	Delta P (mmHg)	Delta P (cmH2O)
M01	3.0	37.3

SGS REPORT

Nelson Labs

Flammability of Clothing Textiles Final Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the flammability of plain surface clothing fabrics by measuring the time of ignition, the length of flame spread, the propagation of flame, and the amount of char residue remaining. The test is performed in accordance with ASTM D2875-19.

Test Article	Flammability
M01	Pass

FLAMMABILITY

Intertek

Test Report

Report Ref: INT201200001

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the breathability of test articles by measuring the differential pressure across the test article using a manometer, at a constant flow rate. The Delta P test is performed in accordance with ASTM F2296-19.

Test Article	Delta P (mmHg)	Delta P (cmH2O)
M01	3.0	37.3

INTERTEK

Intertek

Test Report

Report Ref: INT201200001

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the breathability of test articles by measuring the differential pressure across the test article using a manometer, at a constant flow rate. The Delta P test is performed in accordance with ASTM F2296-19.

Test Article	Delta P (mmHg)	Delta P (cmH2O)
M01	3.0	37.3

INTERTEK

Nelson Labs

Sodium Chloride (NaCl) Aerosol Test Final Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the penetration of sodium chloride aerosol through the test article. The test is performed in accordance with ASTM F2296-19.

Test Article	Penetration (%)
M01	0

PFE

SURGICAL FACE MASK

SGS

Test Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the breathability of test articles by measuring the differential pressure across the test article using a manometer, at a constant flow rate. The Delta P test is performed in accordance with ASTM F2296-19.

Test Article	Delta P (mmHg)	Delta P (cmH2O)
M01	3.0	37.3

SGS HEAD LOOP REPORT

SGS

Test Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the breathability of test articles by measuring the differential pressure across the test article using a manometer, at a constant flow rate. The Delta P test is performed in accordance with ASTM F2296-19.

Test Article	Delta P (mmHg)	Delta P (cmH2O)
M01	3.0	37.3

SGS EAR LOOP REPORT

SGS

Test Report

Test Article: M01

Study Number: 120000001

Test Facility: Nelson Laboratories, LLC

Test Period: 12 Aug 2020

Test Results: Pass

Summary: This procedure is performed to evaluate the breathability of test articles by measuring the differential pressure across the test article using a manometer, at a constant flow rate. The Delta P test is performed in accordance with ASTM F2296-19.

Test Article	Delta P (mmHg)	Delta P (cmH2O)
M01	3.0	37.3

SGS VALVE REPORT

N95 RESPIRATOR





Softmed

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