VERIDIA

Certification Pack.

Face Mask Level 2 Reynard.

87432

This pack contains

TGA Certificate

Declaration of Conformity

Nelson Laboratory Testing Report

Date Released

July 2021

Face Mask (Reynard) 3ply Level 2 with Ear Loops **87432**

Features	- Bacteria Filtration Efficiency > 99 - 3 ply Non Woven Mask - Ear loops - Adjustable sealed nose bridge
Colour	- White
Unit	- Packet
Pack Qty	- 50
Carton Qty	- 40 x 50

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 334672 Reynard Health Supplies Pty Ltd - Mask, surgical, single use

ARTG entry for	Medical Device Included Class 1
Sponsor	Reynard Health Supplies Pty Ltd
Postal Address	Suite 403, 44 Hampden Road, Artarmon, NSW, 2064 Australia
ARTG Start Date	20/04/2020
Product category	Medical Device Class 1
Status	Active
Approval area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Reynard Health Supplies Pty Ltd	Suite 403 44 Hampden Road Artarmon, NSW, 2064 Australia

Products

1. Mask, surgical, single use

Product Type	Single Device Product	**Effective date**	20/04/2020

GMDN	35177 Mask, surgical, single use
Intended purpose	Disposable medical face mask for protection against e.g. bacteria, viruses, dust.

Specific Conditions

Public Summary

ATTACHMENT A-1

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	Reynard Health Supplies Pty Ltd
Business address:	Suite 403, 44 Hampden Road, Aartarmon, NSW, 2064, Australia
Medical device(s):	RHS 919
Classification:	Class I
GMDN code and term:	35177 Mask, surgical, single use
Scope of application:	All

For All Class I

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Standards applied: ISO 9001, AS/NZS 4381:2015, ASTM F21900-19, EN 14683:2019

Authorised signatory:

Signature

Jason Daisley, Managing Director

29/6/2020

Date

REYNARD
Health Supplies

MASKS

Nelson Laboratory Testing
July/August 2020

- L2 Fluid Penetration
- L3 Fluid Penetration
- Latex Particle Challenge
- Flammability
- Differential Pressure (Delta P)
- Microbial Cleanliness
- Viral Filtration Efficiency (VFE)
- Bacterial Filtration Efficiency (BFE)

Nelson Labs.
A Sotera Health company

Sponsor:
Robin Ferguson
Havelock North, Hawkes Bay 4157
NEW ZEALAND

Synthetic Blood Penetration Resistance Final Report

Test Article:	ARM MSK002 / ARM MSK001 / ARM MSK003 / ARM MSK004/RHS919
Study Number:	1318479-S01
Study Received Date:	09 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	31
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.5°C and 21% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-11, 13-32	None Seen
12	Yes

Robert Dieker electronically approved for
Study Director James Luskin

30 Jul 2020 15:00 (+00:00)
Study Completion Date and Time

Nelson Labs
A Sotera Health company

Sponsor:
Robin Ferguson
Havelock North, Hawkes Bay 4157
NEW ZEALAND

Synthetic Blood Penetration Resistance Final Report

Test Article:	ARM MSK002 / ARM MSK001 / ARM MSK003 / ARM MSK004/RHS919
Study Number:	1318480-S01
Study Received Date:	09 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.7°C and 21% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Brent Shelley electronically approved for
Study Director James Luskin

29 Jul 2020 18:20 (+00:00)
Study Completion Date and Time

Nelson Labs
A Sotera Health company

Sponsor:
Robin Ferguson
Havelock North, Hawkes Bay 4157
NEW ZEALAND

Latex Particle Challenge Final Report

Test Article:	ARM MSK002 / ARM MSK001 / ARM MSK003 / ARM MSK004/RHS919
Study Number:	1318482-S01
Study Received Date:	09 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 08
Deviation(s):	None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 29% relative humidity (RH) at 1821; 21°C, 29% RH at 2004
Average Filtration Efficiency:	99.84%
Standard Deviation:	0.016

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

McKenna Wild electronically approved for — 30 Jul 2020 17:15 (+00:00)
Study Director — Curtis Gerow — Study Completion Date and Time

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	19	12,132	99.84
2	16	11,623	99.86
3	17	11,552	99.85
4	19	11,835	99.84
5	22	12,153	99.82

Nelson Labs
A Sotera Health company

Sponsor:
Robin Ferguson
Havelock North, Hawkes Bay 4157
NEW ZEALAND

Flammability of Clothing Textiles Final Report

Test Article:	ARM MSK002 / ARM MSK001 / ARM MSK003 / ARM MSK004/RHS919
Study Number:	1318477-S01
Study Received Date:	09 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0073 Rev 06
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Article Side Tested: Outside Surface
Orientation: Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Brent Shelley electronically approved for — 31 Jul 2020 20:55 (+00:00)
Study Director Curtis Gerow — Study Completion Date and Time

Results:

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

IBE = Test Article ignited, but extinguished

Nelson Labs.
A Sotera Health company

Sponsor:
Robin Ferguson
Havelock North, Hawkes Bay 4157
NEW ZEALAND

Differential Pressure (Delta P) Final Report

Test Article:	ARM MSK002 / ARM MSK001 / ARM MSK003 / ARM MSK004/RHS919
Study Number:	1318476-S01
Study Received Date:	09 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Delta P Flow Rate:	8 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~175 mm x ~156 mm

Results:

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.5	34.0
2	3.7	35.9
3	3.7	36.1
4	3.7	36.6
5	3.7	36.7

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Sean Shepherd electronically approved for James Luskin
Study Director

05 Aug 2020 20:09 (+00:00)
Study Completion Date and Time

Nelson Labs
A Sotera Health company

Sponsor:
Robin Ferguson
Havelock North, Hawkes Bay 4157
NEW ZEALAND

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	ARM MSK002 / ARM MSK001 / ARM MSK003 / ARM MSK004/RHS919
Study Number:	1318478-S01
Study Received Date:	09 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 202003948 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	2.9	<3	<3	<6.0	<2.1
2	3.0	<3	<3	<5.9	<2.0
3	3.9	<3	<3	<5.9	<1.5
4	3.9	11	<3	<13.6	<3.5
5	3.9	20	<3	<23.2	<5.9
Recovery Efficiency	45.7%				

< = No Organisms Detected
Note: The results are reported as colony forming units (CFU) per mask.

Gabrielle Waldron electronically approved for
Study Director Robert Putnam

05 Aug 2020 16:33 (+00:00)
Study Completion Date and Time

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	84%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Tryptic Soy Agar Potato Dextrose Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3-7 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 5-7 days at 20-25°C, then enumerated.

Nelson Labs
A Sotera Health company

Sponsor:
Robin Ferguson
Havelock North, Hawkes Bay 4157
NEW ZEALAND

Viral Filtration Efficiency (VFE) Final Report

Test Article:	ARM MSK002 / ARM MSK001 / ARM MSK003 / ARM MSK004/RHS919
Study Number:	1318481-S01
Study Received Date:	09 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0007 Rev 16
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Test Area:	~40 cm^2
VFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	1.5 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.7 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

McKenna Wild electronically approved for — 10 Aug 2020 16:37 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent VFE (%)
1	99.9
2	99.7
3	99.9
4	99.8
5	99.4

The filtration efficiency percentages were calculated using the following equation:

$$\% VFE = \frac{C - T}{C} x\ 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Nelson Labs.
A Sotera Health company

Sponsor:
Robin Ferguson
Havelock North, Hawke's Bay, 4157
NEW ZEALAND

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	ARM MSK002 / ARM MSK001 / ARM MSK003 / ARM MSK004/RHS919
Study Number:	1318475-S01
Study Received Date:	09 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~175 mm x 152 mm
Positive Control Average:	2.4 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

Trang Truong electronically approved for — 18 Aug 2020 00:49 (+00:00)
Study Director — James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.3
2	99.5
3	99.5
4	99.5
5	99.5

The filtration efficiency percentages were calculated using the following equation:

$$\% \, BFE = \frac{C - T}{C} \, x \, 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request