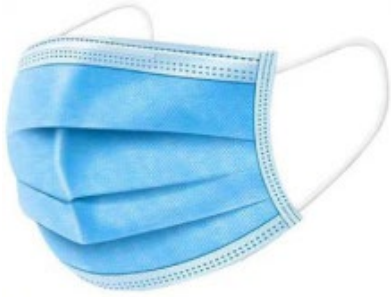
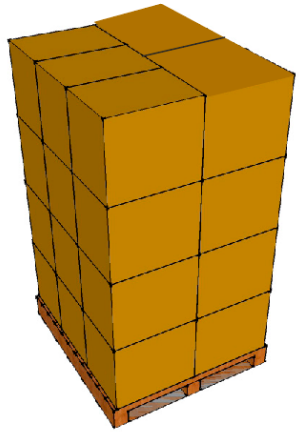
3-PLY FACE MASK



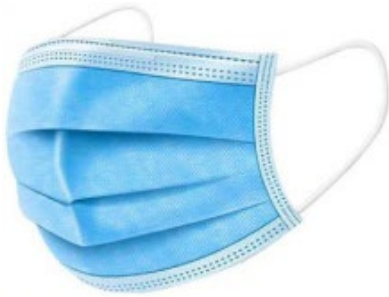
Color may vary

MASTER CASE
36 BOXES

20 CS /PALLET

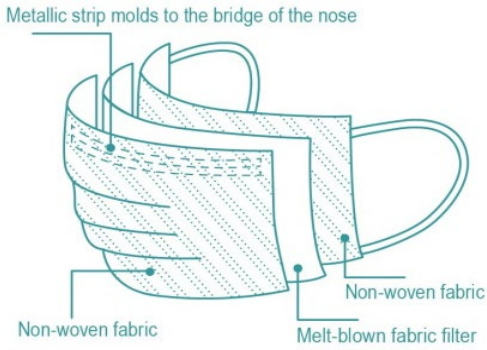


3-PLY FACE MASK



Color may vary

Content	• 50 units per Box • 36 Boxes per Master Case • Master Case has 1800 units of 3 PLY Spun Bond and Meltblown
Material	• Two outer layers of non-woven fabric • Polypropylene intermediate filter • Pleated with moldable nasal fit with bands or adjustable elastic fit around the ear
Dimensions	• Length: 6.50” – 7.08” • Width: 3.34” – 3.74” • One fold : 1.57”- 1.77” • Two fold: 0.78” – 1.18”
Characteristics	• Meets bacterial filtration efficiency (BFE) ≥ 95% • Particle filtration efficiency (PFE) a 0.1 micron ≥ 95%
Certifications	• Meets international standard norms ASTM F2100-19 • Cofepris Registration Number 1683C2012 SSA • FDA Registration Number 8030654
Sealing	• Heat sealing / ultrasound



Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

FDA

FINISHED PRODUCT SPECIFICATION		
TITTLE:		ISSUE DATE:
SURGICAL FACEMASK		EFFECTIVE DATE:
No. Doc.: **51026**	**CODE: 0890201**	REVISION No. 00
DEPARTAMENT:**QUALITY CONTROL**		**PAGE 1 of 3**

TESTING	SPECIFICATION	REFERENCES
Product Description	Surgical facemask made with three layers made with nowoven fabric:Meltblown ,White Spunbond ,Blue Spunbond an intermediate polypropylene filter;flat or pleated; with nasal fit adjustable. Fluidresistant,antiestatic,hypoallergenic. With band or elastic adjustment wound on the head or retroauricular. Disposable. Professional: with elastic to hold aroud the ear.	Degasa, S.A de C.V. Specifications
Finished	To observe under appropiate visibility conditions each of units that constitute the sample.The fabric Surface should be soft at touch.It must be not present:dirt,touch sensitive husks,wood chips, metal, glass, hair, insects or their fractions, bad odour, fungal contamination, moisture,holes,tears,stains outside the product characteristics, frayed parts, loose fibers or residuals,loose threads, lint,suspendend fines,poorly sewn or poorly sealed parts,poorly assembled parts,any waste used in the manufacturing process that adversely affects the presentation and/or the use to which it is intended the product.	Mexican Pharmacopeia Medical Devices Supplement 4a.Ed. 2017 Pag 489

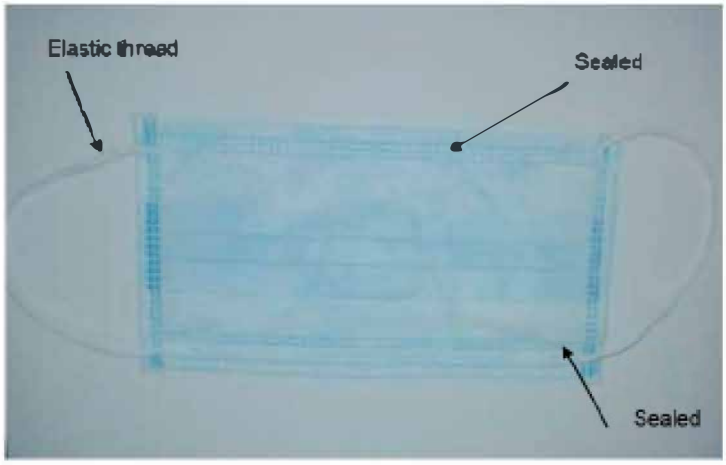
NAME	JOB POSITION	DATE	SIGNATURE
Issued by: Karina Hidalgo Martinez	Research &Development Analyst	Feb 06th 2020	
Reviewed by: Cesar Sampedro Caballero	Quality Assurance Supervisor	Feb 06 TH 2020	
Approved by Verónica Ley Fuentes	Corporate Quality Assurance and Regulatory Affairs Manager	Feb 06th 2020	

FINISHED PRODUCT SPECIFICATION

TITLE		ISSUE DATE:
SURGICAL FACEMASK		EFFECTIVE DATE:
No. Doc.: **51026**	**CODE: 0890201**	REV. 00
DEPARTAMENT: **QUALITY CONTROL**		**PÁG.** 2 OF 3

TESTING	**SPECIFICATION**	**REFERENCES**
DIMENSIONS (cm)	Length(A) 16.5 – 18.0 Width (B) 8.5 - 9.5 One Fold (C) 4.0 – 4.5 Two Fold (D) 2.0 – 3.0 Ref. Professional facemask	Degasa, S.A de C.V. Specifications
COLOR	The colors of the fabric must be in White or blue	Degasa, S.A de C.V. Specifications
CUT STABILITY	When the fabric is cut, in any of its directions, it should not have fiber detachments.	Mexican Pharmacopeia Medical Devices Supplement 4a.Ed. 2017 Pag 490
WEIGHT	Meltblown fabric 20.0 to 22.0 g/m² White Spunbond fabric 25.0 to 27.0 g/m² Blue Spunbond fabric 25.0 to 27.0 g/m²	Mexican Pharmacopeia Medical Devices Supplement 4a.Ed. 2017 Pag 490 NMX-A-301/1-INNTEX-2009.pag 489, (The raw material is analyzed according to standard ,due to dimension of the specimen mentioned in the standard)
LEVEL1 BARRIER		ASTM F2100-11
FLUID RESISTANCE	80 mm Hg	ASTM F1862 at 80 mm Hg
BACTERIAL FILTRATION EFFICIENCY IN EXCESS (BFE)	98%	ASTM F2100-11
BACTERIAL FILTRATION EFFICIENCY (BFE)	≥98 %Type II	EN14863
Delta-P	Less than or equal to 2.5	ASTM F2100-11
FLAMMABILITY	CLASS 1	ASTM F2100-11

Design	Observe Layer	Inner Layer	Reverse Layer	Mask Size	Nose piece
			Width	Length	
Ear loop	20g/m SPP	20g/m SPP	175 mm + 2 mm	95 mm 2 mm	PVC Coated Wire



Color may vary

Historical Changes	Revision
New document	00

Nelson Labs.
A Sotera Health company

Sponsor:
Veronica Ley Fuentes
Degasa S.A. de C.V.
Av. Centenario 15, Civac
Jiutepec, Morelos, 62578
MEXICO

Synthetic Blood Penetration Resistance Final Report

Test Article:	Sample Lot #5A0119145
Study Number:	1279084-S01
Study Received Date:	20 Mar 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:	23.6°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: 80 mmHg (10.7 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Study Director: Hang Hung for James W. Luskin

31 Mar 2020
Study Completion Date

1279084-S01

Nelson Labs.
A Sotera Health company

Sponsor:
Veronica Ley Fuentes
Degasa S.A. de C.V.
Av. Centenario 15, Civac
Jiutepec, Morelos, 62578
MEXICO

Latex Particle Challenge Final Report

Test Article:	Sample Lot #5A0119145
Study Number:	1279078-S01
Study Received Date:	20 Mar 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 07
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.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the average number of particles penetrating the test article compared to the average of the control values.

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:	22°C, 23% relative humidity (RH) at 10:07 a.m.; 24°C, 22% RH at 2:19 p.m.
Average Filtration Efficiency:	96.7%
Standard Deviation:	0.48

Curtis Gerow
Study Director — Curtis Gerow, B.S.

01 Apr 2020
Study Completion Date

1279078-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	415	11,562	96.4
2	384	12,036	96.8
3	319	11,285	97.2
4	333	11,070	97.0
5	441	10,940	96.0

Nelson Labs.
A Sotera Health company

Sponsor:
Veronica Ley Fuentes
Degasa S.A. de C.V.
Av. Centenario 15, Civac
Jiutepec, Morelos, 62578
MEXICO

Flammability of Clothing Textiles Final Report

Test Article:	Sample Lot #5A0119145
Study Number:	1281762-S01
Study Received Date:	26 Mar 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.

Curtis Gerow
Study Director — Curtis Gerow, B.S.

03 Apr 2020
Study Completion Date

1281762-S01

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:
Veronica Ley Fuentes
Degasa S.A. de C.V.
Av. Centenario 15, Civac
Jiutepec, Morelos, 62578
MEXICO

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	Sample Lot #5A0119145
Study Number:	1279077-S01
Study Received Date:	20 Mar 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.

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
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~172 mm x ~156 mm
Positive Control Average:	2.7 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Liang Huang for James W. Luskin
Study Director

06 APR 2020
Study Completion Date

1279077-S01

Results:

Test Article Number	Percent BFE (%)
1	96.1
2	93.7
3	90
4	95.7
5	94.2

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	2.3	23.0
2	3.7	36.6
3	2.4	24.0
4	2.9	28.8
5	4.1	40.7

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