FILTER TECHNOLOGY

SEGRE N31000

FULLY ADJUSTABLE N99 RESPIRATOR

THE SEGRE N31000 IS A COMFORTABLE AND DURABLE N99 MASK, WITH ADJUSTABLE NOSE CLIP AND STRAPS FOR A SUPERIOR FIT.

ORDERING INFORMATION:

PART NUMBER: N31000

PACKAGING: INDIVIDUALLY WRAPPED
15 PER BOX, 10 BOXES PER CASE

PROTECTS

FILTRATION FOR PARTICULATES > 99%

BACTERIAL FILTRATION EFFICIENCY (BFE) > 99.9%

FLUID RESISTANT

GVS Filtration Inc.
2150 Industrial Drive, Findlay, OH. 45840 - USA
Tel. +1.419.423.9040 | E-mail: respirators@gvs.com

WWW.GVS.COM

National Institute for Occupational Safety and Health NIOSH

FILTER TECHNOLOGY

SEGRE N31000

FULLY ADJUSTABLE N99 RESPIRATOR

GVS N99 NIOSH CERTIFIED TC-84A-9111

CONFORMS TO US FDA GMP regulations 21 CFR Parts 210, 211 and 820.

WHAT DOES THIS MEAN?

THERE ARE TWO MAIN CLASSES OF FILTERING FACEPIECES – N95 & N99.
THE SEGRE N31000 SITS IN ONE OF THE HIGHEST CLASSIFICATION FOR A MASK – N99.
IN ORDER TO ACHIEVE THIS CLASSIFICATION, TESTS ARE PERFORMED ON THE MASK TO MEASURE IT'S FILTERING EFFICIENCY AND THE MAXIMUM LEVEL OF INWARD LEAKAGE. THE MASK IS ALSO SUBJECTED TO BREATHING RESISTANCE AND SKIN COMPATIBILITY TESTS. ALL SEGRE MASKS ARE NIOSH APPROVED.

FEATURES AND BENEFITS OF N31000

- FILTER EFFICIENCY EXCEEDS 99% & BFE 99.9%
- FOLD FLAT DESIGN - SLEAK AND COMFORTABLE
- ADJUSTABLE STRAP - UNRIVALLED ADJUSTABILITY
- PADDED NOSE SUPPORT FOR INCREASED COMFORT
- ALUMINUM NOSE PIECE (MRI SAFE)
- UNVALVED - PROTECTS YOU AND THOSE AROUND YOU
- INDIVIDUALLY WRAPPED TO AVOID CROSS CONTAMINATION
- FLUID RESISTANT
- LATEX FREE
- MECHANICAL PTFE MEMBRANE FILTER
- ELECTROSTATIC PRE-FILTER

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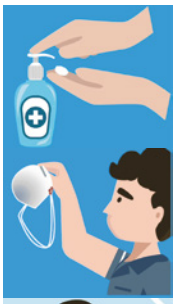
FULLY ADJUSTABLE N99 RESPIRATOR

IMPORTANT INFORMATION

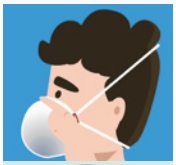


Sanitise your hands before handling a mask

Always check the mask for defects before donning

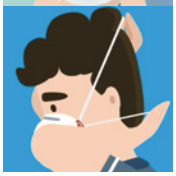
Ensure you are clean shaven when wearing a mask

Adjust the straps evenly by twisting the elastic around the clips on both sides



Press the metal clip smoothly across the bridge of the nose to achieve a good fit, and to remove possible leaks

Pressure check the seal by pressing the mask to your face, and exhaling – air should not escape anywhere around the mask



When doffing the mask, only use the straps and don't touch the body of the mask

VISIT WWW.GVS.COM/MAG/ENG FOR MORE INFORMATION

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WWW.GVS.COM

National Institute for Occupational Safety and Health NIOSH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control
and Prevention (CDC)

National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

NIOSH Reference: TN-23823
Mfr. Reference: NFC038

May 1, 2020

Mr. Graham Baines
GVS Filter Technology UK Ltd.
NFC House, Vickers Industrial Estate
Mellishaw Lane, Morecambe
Lancashire, LA3 3EN
ENGLAND

Dear Mr. Baines:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted on April 20, 2020. This request was for approval of the model Segre (part number N31000) air-purifying filtering facepiece respirator for protections against particulates at a N99 filter efficiency level. The complete configuration is detailed on assembly matrix, file name: *GVS-Segre-Assembly-Matrix-AMb.xlsx*, revision B, dated April 8, 2020.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired to be produced in languages other than English. Approval number TC-84A-9111 has been assigned.

The final respirator label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to these approvals are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, Code of Federal Regulations, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely,

Jeffrey A. Peterson -S
Digitally signed by Jeffrey A. Peterson -S
Date: 2020.05.01 09:31:37 -04'00'

Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosure

Nelson Labs
A Sotera Health company

Sponsor:
Pierre Dizier
GVS Filter Technology UK
Vickers Industrial Estate Mellishaw Lane
Morecambe, Lancashire, LA3 3EN
UNITED KINGDOM

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

Test Article:	F31000/N31000 Lot #OL 20/00551
Purchase Order:	FO-2020/01722/21
Study Number:	1299170-S01
Study Received Date:	13 May 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:	~9.1 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
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:	~230 mm x ~155 mm
Positive Control Average:	1.7 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.2 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

David Brown electronically approved for — 05 Jun 2020 05:03 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	>99.9[a]
2	>99.9[a]
3	>99.9
4	>99.9[a]
5	>99.9[a]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	12.6	123.3
2	11.7	114.9
3	10.3	101.2
4	12.9	126.1
5	11.8	115.8

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

Nelson Labs
A Sotera Health company

Sponsor:
Rob Davis
GVS Filter Technology UK
nfc house, vickers ind estate, mellishaw
morecambe, lancashire, LA3 3EN
UNITED KINGDOM

Synthetic Blood Penetration Resistance Final Report

Test Article:	F30000/N31000 Facemasks
Purchase Order:	FO-2020/02277/21
Study Number:	1311153-S01
Study Received Date:	17 Jun 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:	23.5°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: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Adam Brigham electronically approved for
Study Director James Luskin

22 Jul 2020 15:24 (+00:00)
Study Completion Date and Time