Ofício nº 391/2020 – GP

Foz do Iguaçu, 29 de maio de 2020.

Assunto: **Resposta ao Requerimento nº 156/2020.**

Senhor Presidente,

Em atenção ao Requerimento nº 156/2020, de autoria da Nobre Vereadora Inês Weizemann, encaminhado pelo Ofício nº 330/2020-GP, de 14 de maio de 2020, dessa Casa de Leis, acerca do fornecimento de materiais nas unidades de saúde do Município, remetemos a manifestação da Diretoria de Gestão em Saúde, da Secretaria Municipal da Saúde, por meio do Memorando nº 729/2020, de 25 de maio de 2020.

Atenciosamente,

Francisco Lacerda Brasileiro
Prefeito Municipal

Ao Senhor
BENI RODRIGUES
Presidente da Câmara Municipal
FOZ DO IGUAÇU – PR

RMR / CKS

Prefeitura do Município de Foz do Iguaçu

ESTADO DO PARANÁ

.PMFI	MEMORANDO INTERNO	MI

EMITENTE: SECRETARIA DA SAÚDE/DIGS	DESTINATÁRIO: Gabinete/SMSA A/C; Inês Padilha	
ASSUNTO: Resposta Requerimento 156/2020 – Câmara de Vereadores	MEMORANDO: 729/2020	DATA: 26/05/2020

Prezado (a);

Em relação à solicitação contida no Requerimento 156/2020, informamos que :

- Em relação à fabricação e materiais utilizados, foram seguidas as orientações técnicas da RDC 356/2020 e Nota Orientativa 03/2020 da Secretaria Estadual de Saúde e o estabelecido no Termo de Referência. Igualmente, foram realizadas consultas junto ao Hospital do Trabalhador, que também estava confeccionando as máscaras. No tocante aos materiais, formam adquiridos TNT 40g 100% polipropileno e SMS com elemento filtrante. Sobre o SMS (tecido produzido com tecnologia de spunbonded + meltblown + spunbonded), atóxico, barreira bacteriana BFE (eficiência a filtração de bactérias >98,9%), com capacidade hidrorepelente, gramatura 50g/m² e na core azul, segue em anexo todas as certificações do fornecedor.
- Em relação aos aventais impermeáveis, informamos que não há falta do produto, no entanto, foram estabelecidos protocolos de uso;
- Sobre o álcool estão sendo fornecidos adequadamente, de acordo com os protocolos estabelecidos pela Diretoria de Atenção Básica para processo de desinfecção, como também são fornecidos o ácido peracético;
- Sobre o lençol impermeável não estão nos protocolos, porém é fornecido o lençol descartável na quantidade necessária;

- Informamos também que não há falta de: material para descarte de perfurocortantes, água sanitária, bloqueador solar e ataduras de crepe.

Estamos a disposição para maiores esclarecimentos.

Atenciosamente,

Rose Meri da Rosa
Diretoria de Gestão em Saúde

Nelson Labs.
A Sotera Health company

Sponsor:
Carla Ferreira Morel
Fitesa Naotecidos SA
Rua Paul Zivi, 80 - Distrito Industrial
Gravatai, RS, BR 94045-430
BRAZIL

Viral Filtration Efficiency (VFE) Final Report

Test Article:	- SSMMS 45 g/m² - LOT #500953
Purchase Order:	A02686
Study Number:	1237933-S01
Study Received Date:	04 Nov 2019
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 15
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:	Either
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:	2.9 µm

Results:

Test Article Number	Percent VFE (%)
1	93.2

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

Study Director

Janelle R. Bentz, M.S.

18 Nov 2019
Study Completion Date

1237933-S01

Nelson Labs.
A Sotera Health company

Sponsor:
Carla Ferreira Morel
Fitesa Naotecidos SA
Rua Paul Zivi, 80 - Distrito Industrial
Gravatai, RS, BR 94045-430
BRAZIL

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

Test Article:	-SSMMS 45 g/m² LOT #521483
Purchase Order:	A02774
Study Number:	1267008-S02
Study Received Date:	12 Feb 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:	Either
BFE Test Area:	~40 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
Positive Control Average:	1.8 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.3 µm

Study Director — James W. Luskin

24 FEB 2020
Study Completion Date

1267008-S02

Results:

Test Article Number	Percent BFE (%)
1	95.1

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.3	42.1

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