

Linhas de Produtos Médicos – Hospitalares.

A empresa Dimatex diante do novo cenário mundial e em combate a propagação do novo vírus **COVID-19**, está lançando sua linha de produtos Médicos – Hospitalares.

Produtos:

- **Máscara cirúrgica descartável;**

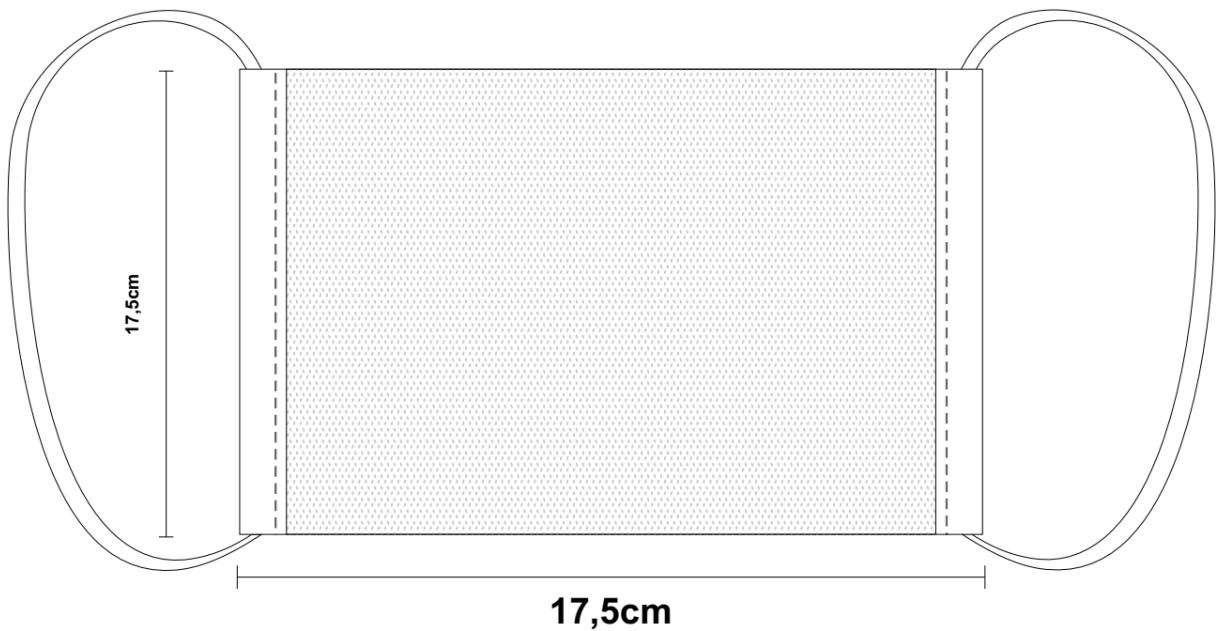
Máscara cirúrgica descartável, desenvolvida para a proteção das pessoas, contra as patologias de transmissão aérea, por gotículas e da projeção de fluídos corpóreos que possam atingir suas vias respiratórias.

Ficha Técnica:

- Não estéril;
- Atóxica;
- Não inflamável;
- Isenta de fibra de vidro;
- Fabricado tecido em não tecido ODONTO-MÉDICO-HOSPITALAR, com gramatura de 50g/m² (TNT SMMMS), **conforme Laudo técnico Nº 1272966-S01** certificado pelo laboratório técnico Nelson Labs.
- Fixação por tecido com elastano sendo livre de costura, o qual proporciona um melhor ajuste no rosto.
- Máscara abrange o rosto do queixo até o nariz;
- Camada de filtragem tripla;
- Não possui clip nasal;
- Cor branca;
- Descartável.



DESENHO TÉCNICO





Sponsor:
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BRAZIL

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

Test Article: SMMMS 50 gsm HFO
Purchase Order: 4500378558
Study Number: 1272966-S01
Study Received Date: 02 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 $1.7 - 3.0 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. 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: Engraved Side
BFE Test Area: $\sim 40 \text{ cm}^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Positive Control Average: 2.9×10^3 CFU
Negative Monitor Count: < 1 CFU
MPS: $3.0 \mu\text{m}$




Study Director _____ James W. Lusk _____

Study Completion Date _____ 11 Mar 2020 _____



1272966-S01

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pv

FRT0004-0001 Rev 22
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These results apply to the samples as received and relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms and conditions at www.nelsonlabs.com.



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Study Number 1272966-S01
Bacterial Filtration Efficiency (BFE)
and Differential Pressure (Delta P) Final Report

Results:

Test Article Number	Percent BFE (%)
1	95.9

Test Article Number	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	6.5	64.1

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request



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