



MATERIĀLU ATBILSTĪBAS APLIECINĀJUMI

质量证书

certificate of quality  
证书编号(Certificate No): 2020WZK0016  
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规格型号 175mm

产品名称	熔喷
Product Name	
商标	—
Trademark	
颜色	白
Color	
检验检测类别	委
Test Type	
委托单位名称	
Name	
单位地址	
Address	
生产单位	
Manufacturer	
送样日期	
Sampling Date	
检验检测依据	
Test Basis	
检验检测结论	
Conclusion	



Study Number 1274100-S01  
Bacterial Filtration Efficiency (BFE)  
and Differential Pressure (Delta P) Final Report

Results:

Percent BFE (%)

97.6

96.2

96.1



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

Test Article: 30 gsm - ID #030220-8  
Study Number: 1274100-S01  
Study Received Date: 09 Mar 2020  
Testing Facility: Nelson Laboratories, LLC  
9260 S. Redwood Rd  
San Leandro City, CA 94123 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<sup>7</sup> colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.5 µm. The aerosols were drawn through a six-stage viable particle Andersen sampler for collection. The 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 620.

Test Side: Either  
BFE Test Area: ~40 cm<sup>2</sup>  
BFE Flow Rate: 28.3 Liters per minute (L/min)  
Delta P Flow Rate: 8 Liters per minute (L/min)  
Positive Control Parameters: 68 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours  
Negative Control Average: 2.2 ± 10<sup>4</sup> CFU  
MPS: <1 CFU  
MPS: 2.9 µm

Study Director

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James W. Luskin



ANAB  
13 Mar 2020  
Study Completion Date