

# Certification of Translation Accuracy

Translation of **Report** from **Italian** to **English**

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A copy of the translation is attached to this certification.



Mike Bortscheller  
Authorized Representative  
Order Date: December 31, 2020

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SME srl

Studio di MicroBiologia ed Ecologia srl  
LECCE - Via delle ANIME,87 tel-fax 0832242087

**TEST REPORT NO. 1.315\_20**

Customer: FNT Meltblown Srl  
Corso Stati Uniti, 15 35127 Padova - PD

Industry:	MEDICAL DEVICES	
Product Category:	Medical devices	
Product declared by the customer:	Meltblown material for face masks	
Sampling point	company	
Sampling procedure:	by the customer	
Packaging/container type:	Plastic bag	Temperature on arrival: Room temperature
Sampling operator:	Customer	Sample date: 10/11/2020
Sampling report:	MD RRO MPA dm 1.315 sample delivered at 9.00	Date received: 10/11/2020
Quantity delivered:	30 pcs	Start Date: 10/11/2020
Agreement/Contract:	.	End Date: 12/11/2020

This test report only concerns the declared and analyzed sample. If the sampling has not been carried out by the laboratory, the customer is responsible for the sample data and the results are referred to the sample received. The test report may not be partially reproduced without written approval by the issuing laboratory.

SAMPLES DESCRIPTION	VALUES	UNIT OF MEASUREMENT	UNCERTAINTY <sup>oo</sup>
<b>Average bacterial filtration efficiency</b>	<b>99.6</b>		%.
Method: UNI EN 14683:2019 App B.			
<b>Average differential pressure</b>	<b>11.55</b>	<b>Pa/cm2</b>	
Method: UNI EN 14683:2019 App C.			
<b>Notes:</b>			
See attachments			

Issue date 18 November 2020

Laboratory Manager  
Dr.ssa VALERIA D'OSTUNI  
[SIGNATURE]

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<sup>oo</sup> Extended uncertainty calculated by applying a coverage factor of 2 corresponding to a confidence level of approximately 95%

End of test report No. 1.315\_20

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Microbiological, Biomolecular and Agrochemical  
Analyses for company self-monitoring  
Puglia Regional List N°30P (Reg. Regional 1/06)

Attached to test report number 1.315\_20

Sample: Meltblown material for face masks

Standard EN 14683:2019 - 5.2.2 Bacterial Filtration Efficiency (BFE)

The test methods used for the in vitro analysis of Bacterial Filtration Efficiency (BFE) derive from UNI EN 14683:2019 "Medical face masks- requirements and test methods".

The test has been carried out on a sample of approximately 50 mm diameter.

A bacterial aerosol has been generated upstream of the sample (bacteria: Staphiloccus aureus NCTC 6571).

A microbiological sampling has been carried out downstream of the sample to collect any bacteria present.

After incubation at 37°C for 24 - 48 hours, the micro-organisms have been counted.

Two positive controls have been carried out to assess the number of bacteria collected in absence of the tested sample.

The BFE has been calculated as follows:

BFE (%) =  $(C - T)/C \times 100$  where:

- C = average CFU count value in controls positive (without sample)
- T = average CFU count value in downstream samplings of the tested sample.

Tested area dimension	50.0 cm <sup>2</sup>					
Side of the sample exposed to the inner aerosol	internal					
Average value of the total count of the dishes for the two positive controls						3.0 x 10 <sup>3</sup> cfu
Average value of the total count of the dishes for the two negative controls						<1 cfu
Sample	1	2	3	4	5	Average
BFE (%)	99.4	99.8	99.7	99.4	99.5	99.6

The tests carried out according to the EN 14683:2019 standard showed that the tested product is COMPLIANT with the standard bacterial filtration efficiency requirements (paragraph 5.2.2 and Appendix B) for types I and II.

Where a declaration of conformity is made, the estimated extended uncertainty and/or confidence interval shall not be taken into account for acceptability purposes of the analytical data with respect to the limit value.

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Customer: Studio di MicroBiologia ed Ecologia S.r.l.  
Via delle ANIME, 87 - 73100 Lecce (Le)

## TEST REPORT N.184\_20

### DEVICE

**FNT Meltblown SRL: Meltblown material for face masks n. 1.315**

Referenced regulation: UNI EN 14683:2019 App C.  
Method used to determine the breathability (differential pressure)  
Measured size:  $\Delta P$  Differential pressure

### $\Delta P$ Differential pressure calculation (App.C.5)

Differential pressure:  $AP = (Xm1 - Xm2) / 4.9$  [Pa/cm<sup>2</sup>]

where:

Xm1 Pressure in Pa, measured on the low-pressure side of the material;  
XM2 Pressure in Pa, measured on the high-pressure side of the material;  
4.9 is the area in cm<sup>2</sup> of the test material;  
 $\Delta P$  is the differential pressure for cm<sup>2</sup> of the tested material expressed in Pa

### Specimens

Type: Filter  
Number: 5  
Number of tested areas: 5, rounds with a diameter of 25 mm, for each specimen (mask)  
Flow direction: from the inside of the mask toward the outside of the mask  
Conditioning: (21 +/- 5) °C and (85 +/- 5) % of relative humidity for at least 4 hours.

### Tested areas layout:

Tested areas:  
Area 1 (A1) Tested areas number and position  
Area 2 (A2) Differential pressure average values  
Area 3 (A3) Differential pressure for each tested area  
Area 4 (A4)  
Area 5 (A5)

### Test results

AP [Pa/cm<sup>2</sup>]: Differential pressure for each tested area

Specimen number	Area 1 A1	Area 2 A2	Area 3 A3	Area 4 A4	Area 5 A5	$\Delta P$ [Pa/cm <sup>2</sup> ]
1	12.24	11.63	12.65	11.84	10.82	11.84
2	10.61	10.41	12.24	10.61	11.43	11.06
3	10.61	11.22	12.65	12.65	11.84	11.80
4	11.02	11.63	12.24	11.22	12.24	11.67
5	11.63	10.20	12.45	11.84	10.82	11.39
Averages	11.22	11.02	12.45	11.63	11.43	11.55

Air flow during test: 8 [l/min]

Average differential pressure calculated on the 5 specimens: 11.55 [Pa/cm<sup>2</sup>]

OPERATOR: FRANCESCO MUCI (+MV) DATE and SIGNATURE 12/11/2020 [SIGNATURE]  
CUSTOMER'S ACKNOWLEDGMENT DATE and SIGNATURE 12/11/2020