

TEST REPORT X.200820.01 Rev.0

Date of issue: 28/05/2020

Page 1 of 2

Customer: **RAMINA SRL - Grantorto (PD)**

Sample No. 200820

Sample type: Meltblown roll for face masks

Description: Art. Test 1 - 20 g/m²

Arrival date: 22/05/2020

Testing date(s): 22/05/2020 until 27/05/2020

Testing site: External qualified laboratory

This Test Report is issued within the Quality Management System of Next Technology Tecnotessile Soc.Naz. di Ricerca rl and of its CEQ Laboratory, documented by the Quality Manual and related Procedures. The Quality Management System assures the traceability of the measurements to the national and international standards of the International System (SI) measurement units, through a metrology chain originating from first line samples provided with calibration certificates proving the traceability to the SI system standards, as required in ISO 9001: 2015 (par.7.1.5.1).

The results reported were obtained by applying the standards and / or technical procedures indicated on the following pages, and refer only to the tested samples, in the state in which they were at the time of the test itself.

Any measurement uncertainty declared in this Test Report is expressed as expanded uncertainty obtained by multiplying the standard uncertainty for a coverage factor $k = 2$, corresponding - in the case of normal distribution - to a confidence level of approximately 95%.

SIGMA MEDICAL
Dedicated to Health

Operator: M. Malpaganti

Head of Laboratory: G. Gori

This Report has been issued after internal electronic approval and authorization

The reproduction of this document is allowed only in full copy conforming to the original. Partial compliant reproduction is permitted only after written authorization of the CEQ, to be quoted in the reproduction itself.

Company with quality system certified ISO 9001: 2015 by TÜV Italia (Cert. No. 50 100 14364) for:

- Design and provision of applied research and development services and technology transfer services
- Design and provision of training services
- Design and provision of consultancy services on management systems
- Chemical, physical, mechanical, electrical and non-destructive laboratory tests
- Calibration of measuring and testing equipment

Mod.CEQ-3101-A16 Rev.2

TEST REPORT X.200820.01 Rev.0

Date of issue: 28/05/2020

Page 2 of 2

FACE MASKS (FOR EITHER MEDICAL OR NON-PROFESSIONAL USE)	
Description:	Maschere facciali ad uso medico - Requisiti e metodi di prova - Metodo per la determinazione in vitro dell'efficienza di filtrazione batterica (BFE) e della pulizia microbica
Ref. Standards:	UNI EN 14683:2019 Annex B - Annex D
Test procedure:	PT-LAB-3101-A16

SAMPLING - CONDITIONING
Sampling: Carried out by the customer
Conditioning before testing: (21±2) °C and (85±5)% RH for 4hrs

SPECIMENS CHARACTERISTICS		
Device name and ID code:	#	Art. Test 1 - 20 g/m2
Device dimensions:		Fabric
No. of layers:	#	1
Materials adopted:	#	Meltblown
Fiber composition:	#	Not declared

Datum is customer-provided

DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY - Operating parameters and controls							
Specim. dimensions: 100x100 mm				Test area dimensions (dm ²):			
Test-aerosol impacted side: Internal				Flow during test: 28.3 L/min			
Aver. Plate count in positive controls: 1929 UFC/g				Aver. Plate count in negative controls: 0 UFC/g			
BFE RESULTS							
Parameters	Specimen					Average	Requirements
	1	2	3	4	5		
Bacterial Filtration Efficiency (BFE %)	98.7	99.3	99.1	99.0	99.1	99.0	Type I: ≥95 Type II: ≥98 Type IIR: ≥98

Possible non-conforming results are labelled with '#'

DETERMINATION OF MICROBIAL CLEANLINESS			
The results is expressed by addition of the TSA and SDA counts (see UNI EN 14683:2019 Annex D) and refers to the average of 5 samples extracted from the package: the upper and lower ones, and 3 random masks else.			
Parameter	Result	Requirements	Notes
Microbial Cleanliness [UFC/g]			

Test not carried out (upon customer's request)

The results have been assessed according to the requirements of UNI EN 14683:2019

Operator: M. Malpaganti

Head of Laboratory: G. Gori

This Report has been issued after internal electronic approval and authorization