

DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

REPORT N. 06196-21 Rev.00

Customer: **SC EURO IMPACT Srl**
Strada Principale, Ruscova, NO. 698 - Judetul Maramures

TEST METHOD UNI EN 14683:2019 Annex C

TIME SCHEDULE

Acceptance N.:	21-05554
Reception date:	09/09/2021
Start test date:	15/09/2021
End test date:	15/09/2021
Operator:	Dr. F. Bergonzini

TEST SAMPLE IDENTIFICATION

Name:	DISPOSABLE MEDICAL MASK ELIMEDICAL
Sample Typology:	MEDICAL MASK
Composition:	Polypropylene nonwoven, Non-woven filter fabric Meltblown, 25g m2, elastic 3mm, nosewire 3mm
Quantity tested:	5
Code (REF):	not provided
LOT:	A1-98-01.09.2021
Manufacturing date:	01.09.2021
Expiry date:	36 MONTHS FROM THE DATE OF PRODUCTION
Sterilization Method:	Not sterile
Sterilization Batch:	n.a.
Sterilization Date:	n.a.
Sterilization Unit:	n.a.

The information concerning the test sample were provided by the Customer. All data related to the test sample are under the responsibility of the Customer and have not been verified by the test laboratory.

Issue Date	Rev.	Change Description	Prepared by Dr. F. Bergonzini (Laboratory Technician)	Verified and Approved by Dr. Renzo Giovanni Coronati (Managing Director Laboratory)
16/09/2021	00	First Issue		

This test report is digitally signed by Dr. Renzo Giovanni Coronati.
The digital signature has legal value according to Italian D. Lgs. 82/2005 and subsequent amendments.

*The sampling is performed by the Customer. The test results relate only to the test sample as received.
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PROCEDURES

All procedures used during this study are recorded in the Laboratory Coronati Consulting s.r.l.

PURPOSE

The purpose of this procedure is to evaluate the suitability of the mask in meeting the breathability requirement as specified in the reference standard document. Determining the differential pressure between the two sides of the sample crossed by a constant and controlled air flow, this procedure allows you to evaluate whether this device has sufficient air permeability.

OPERATING METHODS (according to UNI EN 14683:2019 Annex C, par. C.4)

After a conditioning period of minimum 4 hours at $85 \pm 5\%$ of relative humidity (RH) and $21 \pm 5^\circ\text{C}$, each sample is placed in the holder and subjected to an 8 l/min air flow generated by a vacuum pump. The differential pressure on the tested area is read directly using a differential manometer. Tested areas number and location on mask are reported in the following figure 1.

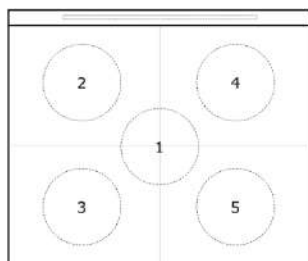


Figure 1

ACCEPTANCE CRITERIA (according to UNI EN 14683:2019 par. 5.2.7, table 1)

	Type I (a)	Type II	Type IIR
Differential Pressure	< 40 Pa/cm ²	< 40 Pa/cm ²	< 60 Pa/cm ²
(a) Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by health care professionals in an operating room or in other medical settings with similar requirements.			

RESULTS

N° test area	Differential Pressure (ΔP)				
	Flow rate: 8 L/min				
	Sample 1 (Pa/cm ²)	Sample 2 (Pa/cm ²)	Sample 3 (Pa/cm ²)	Sample 4 (Pa/cm ²)	Sample 5 (Pa/cm ²)
1	46,6	46,7	49,2	46,6	46,6
2	44,9	48,0	47,6	44,5	39,2
3	44,6	49,3	45,2	46,0	43,8
4	40,9	41,9	41,4	46,9	46,0
5	42,0	41,1	45,6	41,0	45,2
ΔP Average	43,8	45,4	45,8	45,0	44,1
Expanded Uncertainty (k=2)	2,9	3,0	3,0	3,0	2,9

CONFORMITY EVALUATION

MASK TYPE	DIFFERENTIAL PRESSURE (ΔP) IDONEITY				
I e II	FAIL	FAIL	FAIL	FAIL	FAIL
IIR	PASS	PASS	PASS	PASS	PASS
The evaluation of medical face mask type is carried out without taking into account the uncertainty					

-----End of Report-----