Consultancy and Laboratory Services for Biomedical Quality

DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

REPORT N. 8172-20 Rev.00

Customer: IDEANTIS SRL
VIALE MONTE NERO 80 - 20135 - MILANO

TIME SCHEDULE

Acceptance N.:	20-7995
Samples receiving date:	26/11/2020
Start test date:	01/12/2020
End test date:	01/12/2020
Coronati Consulting Operator:	Dr. F. Bergonzini

TEST LABORATORY
Coronati Consulting srl Via L. Gavioli, 3 I-41037 Mirandola (MO) Certified ISO 9001/ ISO 13485

REFERENCE DOCUMENTS
UNI EN 14683:2019 "Medical face masks - Requirements and test methods" - Annex C

TEST SAMPLE IDENTIFICATION

Name (1÷5):	Maskèdra
Sample Typology:	Mascherina chirurgica
Composition:	poliuretano+poliammide12+Spunbond+Melt blown+natural rubber+poliestere
Quantity tested:	5
Code (REF):	N/A
Batch:	001
Manufacturing date:	ottobre 2020
Expiry date:	Non applicabile
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)	Verifed and Approved by: Dr. Renzo Giovanni Coronati (Managing Director Laboratory)
01/12/2020	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.

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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 sample 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)
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 sample are reported in the following figure 1.

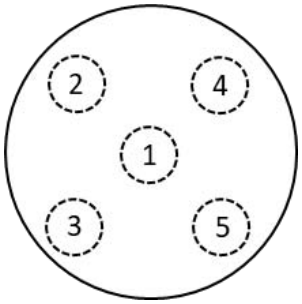

Figure 1

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

	Differential Pressure (ΔP)				
	Flow rate: 8 L/min				
N° test area	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	34,47	34,22	35,47	37,65	36,49
2	34,35	42,02	33,98	34,27	29,12
3	32,29	34,06	37,29	34,47	40,47
4	40,69	36,37	37,37	35,14	35,37
5	35,49	38,53	36,45	37,88	35,71
ΔP Average	35,46	37,04	36,11	35,88	35,43

MASK TYPE	**DIFFERENTIAL PRESSURE (ΔP) IDONEITY**				
I e II	PASS	PASS	PASS	PASS	PASS
IIR	PASS	PASS	PASS	PASS	PASS

ANNEXES
Annex 01: Sample Composition