Studio di MicroBiologia ed Ecologia s.r.l.

Cap.Soc.I.V.€15.000,00
CF/P.IVA Registro Imprese Lecce 03689990756
REA 238498

Via delle Anime, 87- LECCE
Tel/fax 0832242087
www.microbiostudio.it

Test Report N° 9.358.20

These results relate only to semple tested. The report shall not be reproduced without prior written approval of Studio di Microbiologia ed Ecologia srl.

Customer Name & Adress: Stall Ardalex Srl
Calea Aviatorilor, 4
Ghiroda, Timis Romania
30720

SAMPLE PARTICULARS

SAMPLE DESCRIPTION : Medical Face Mask Cod. ST0001 Test I

SAMPLE RECEIPTED DATE :2020-12-23

REPORT RECEIPT:4.358

SAMPLED COLLECTED BY: Stall Ardalex Srl
SAMPLED POINT: Stall Ardalex Srl

TEST STARTED ON: 2020-12-23
TEST COMPLETED: 2020-12-30

RESULTS OF ANALYSIS

TEST	TEST METHOD	UNIT	RESULT
*MICROBIAL CLEANLINESS TEST (BIOBURDEN) *Test Accredieted by ACCREDIA Lab.1145*	UNI EN ISO 11737-1:2018	ufc/g	12
*BACTERIAL FILTRATION EFFICIENCY (BFE)	UNI EN 14683:2019 App. B	%	99.6
*BREATHABILITY AS DIFFERENCIAL PRESSURE	UNI EN 14683:2019 App. C	Pa/cm²	14.16
End of report			

* see attachments

Laboratory Manager

Dr.ssa Valeria D'Ostuni



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SAMPLE: Medical Face Mask Cod. ST0001 Test I

TEST: BIOBURDEN (UNI EN ISI 11737-1:2018)

Campione	N°	1	2	3	4	5	Mean
Weight	g	2.98	2.97	2.99	2.95	2.98	2.97
TSA	cfu/item	48	37	42	33	25	37
SDA	cfu/item	0	0	0	0	0	0
Bioburden totale	cfu/item	48	37	42	33	25	37
Bioburden totale	cfu/g	16	12	14	11	8	12

Following the tests carried out according to the EN 14683: 2019 standard, it was found that the product tested respects the Bioburden requirements of the standard (paragraph 5.2.2 and appendix B) for type I and II.

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SAMPLE: Medical Face Mask Cod. ST0001 Test I

Standard EN 14683:2019 – 5.2.2 Bacterial filtration efficiency (BFE)

The test methods for the in vitro evaluation of the Bacterial Filtration Effectiveness (BFE) are in accordance with the UNI EN 14683: 2019 standard "Facial masks for medical use - requirements and test methods".
The test is conducted on a sample with a diameter of approximately 50 mm.

A bacterial aerosol is generated upstream of the sample (bacteria: Staphilococcus aureus NCTC 6571). Downstream of the sample, a microbiological sampling is done to collect any bacteria that may be present. After incubation at 37°C for 24-48 hours, the microorganisms are counted.
2 positive controls are performed to evaluate the number of bacteria collected in the absence of testing sample.

BFE is calculated:
BFE (%) = (C – T)/C x 100

- C= average CFU count value in positive controls (without sample).
- T= average CFU count value in the samples downstream of the sample under examination.

Size of the test area			50.0 cm²			
Side of the sample exposed to the aerosol			Internal side			
Average value of the total plate count of the two positive controls					1.7 x 10^3 cfu	
Average value of the total plate count of the negative control					<1 cfu	
Sample	1	2	3	4	5	Mean
BFE (%)	99.9	99.9	99.9	99.9	98.2	99.6

Following the tests carried out according to the EN 14683: 2019 standard, it was found that the product tested respects the bacterial filtration efficiency requirements of the standard (paragraph 5.2.2 and appendix B) for type I and II.

YOULAB

YOULAB S.R.L. via Sele, 97 73010 Surbo (Lecce)
CF, P.IVA, n. Reg. Imprese di Lecce 04162110755

Commissioned: ***Studio di Microbiologia ed Ecologia S.r.l.***
Via delle Anime, 87 - 73100 Lecce (Le)

Attached to test report N. 9.358.20

DEVICE

Medical Face Mask Cod. ST0001 Test I

Reference legislation: UNI EN 14683:2019 App.C
Method for determing respirability (Differential pressure)
Measured quantity: Differential pressure ΔP

Calculation of the differential pressure ΔP (App.C.5)

Differential pressure: $\Delta P = (Xm1 - Xm2) / 4,9$ [Pa/cm^2]

where:

Xm_1 Pressure in Pa, measured on the low pressure side of the material;
Xm_2 Pressure in Pa, measured on the high pressure side of the material;
4,9 is the area in cm^2 of the test material;
ΔP is the differential pressure per cm^2 of test material expressed in Pa.

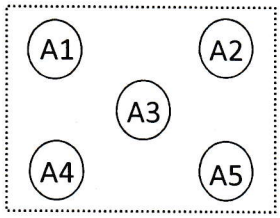
Provini/Test

Type: Complete mask
Number: 5
Number of test areas: 5, circular with a diameter of 25 mm, for each specimen (template)
Flow direction: from inside the mask to the outside of the mask
Conditioning: (21 +/- 5) °C e (85 +/- 5) % of relative humidity for at least 4 hours.

Test area layout

Test areas:

Area 1 (A1)
Area 2 (A2)
Area 3 (A3)
Area 4 (A4)
Area 5 (A5)



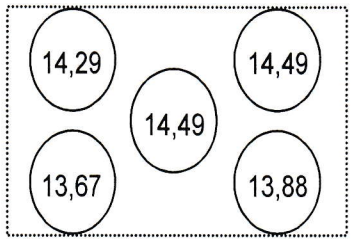
Number and locations of test areas with a

Average values of the differential

Average values by area of ΔP for the 5 specimens examined

Test result

	ΔP [Pa/cm^2]: differential pressure for each area tested by the specimen					
Provino number	Area 1 A1	Area 2 A2	Area 3 A3	Area 4 A4	Area 5 A5	ΔP [Pa/cm^2]
1	14,29	15,92	15,10	16,33	14,90	**15,31**
2	14,49	15,51	15,10	11,84	13,47	**14,08**
3	14,29	11,84	13,06	12,86	13,06	**13,02**
4	14,29	15,31	14,90	13,27	13,67	**14,29**
5	14,08	13,88	14,29	14,08	14,29	**14,12**
Means:	14,29	14,49	14,49	13,68	13,88	14,16



Air flow rate during the test : 8 [l/min]

Average differenzial pressur calculated on 5 specimens: 14,16 [Pa/cm^2]

OPERATOR:	SIMONE GEMMA (+MV)	DATE AND SIGNATURE 30/12/2020	Simone Gemma
	THE CUSTOMER FOR ACKNOWLEDGMENT	DATE AND SIGNATURE 30/12/2020	