



LABORATORISKĀ PRODUKTA SERTIFIKĀCIJA



ANALISI CHIMICO-FISICHE
MICROBIOLOGICHE
BIOCOMPATIBILITA'
CONSULENZA TECNICA
BIOTECNOLOGIE

Messrs
ManPower Consult Group Baltic Ltd.
Lapenu Street, 9
LV-1013 RIGA

Zola Predosa, 27/07/2020

Ref. Your Order P02020/07/10-1

Test Report N°20-0900-01

DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Sample description

Denomination: Face masks
Code: n.a.
Lot: n.a.
Sterilization: No
Receipt number: 17088
Receipt date: 20/07/2020
Sampling carried out by: ManPower Consult Group

Further information about the sample

Number of tested samples: 5
Size of the area of the specimens: 50 cm²
Side of the test sample facing the challenge ae

Test date

The test was started on 21-07-2020 and was c

Test method

EN 14683:2019 Annex B

Equipments and reagents

Vacuum pump "GEO Air Plus"
Modified Andersen Cascade Impactor "TE-20-6"
MMAD nebulizer 3.0 ± 0,3 µm
Culture plates containing TSA

Summary of method

A negative control is performed by passing a cascade impactor for 2 minutes.
Then the bacterial challenge of *Staphylococcus* 3,2 x 10⁸ UFC/ml, is delivered to the aerosol of A first positive control is performed, by passing flow rate of 28,3 ± 0,5 l/min for 1 minute. The additional minute, for a total test time of 2 min The control plates are removed from the casca the test on the test samples.

Mod. BFE R/00

VIA BENINI 13-40069 ZOLA PREDOSA
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The specimen is clamped in place between the first stage of the cascade impactor and the inlet cone of the nebulization collector and the procedure used for the positive control is repeated for each of the 5 specimens to be tested.

After the last specimen has been tested, a further positive control run is performed. Then all the plates are incubated at 37 ± 2°C for a length of time between 24 and 72 hours. After the incubation, for each specimen and control run, the number of colonies is counted in order to give the total number of CFU collected by the cascade impactor. The Bacterial Filtration Efficiency (BFE) is calculated for each test specimen, as a percentage, using the following formula:

$$BFE = [(C - T) / C] \times 100$$

where

C is the mean of the total plate counts for the two positive control runs.
T is the total plate count for the test specimen

Results

Determination	Collected CFU	BFE (%)	BFE (%) Type I limit	Compliance to Type I limit	BFE (%) Type II and IIR limit	Compliance to Type II and IIR limit
Negative control	0.0					
Positive control run 1	2809.0					
Positive control run 2	2876.0					
Positive control average	2842.5					
Test 1	10.0	99.6	≥ 95	Compliant	≥ 98	Compliant
Test 2	10.0	99.6	≥ 95	Compliant	≥ 98	Compliant
Test 3	14.0	99.5	≥ 95	Compliant	≥ 98	Compliant
Test 4	13.0	99.5	≥ 95	Compliant	≥ 98	Compliant
Test 5	9.0	99.7	≥ 95	Compliant	≥ 98	Compliant
Sample average	11.2	99.6	≥ 95	Compliant	≥ 98	Compliant

The present test report exclusively refers to the referenced test sample. If the sample has been sampled by the Customer, the results are referred to the sample as received.

The present test report may not be partially reproduced without the written permission of the laboratory.

(*) Data provided by the Customer. The laboratory declines responsibility.

Test verified by: Buriani Giampaolo, Ph.D.

Issue authorized by:
Head of Laboratory, Giovanni Bassini, Ch., Eng.

END OF TEST REPORT

Mod. BFE R/00

Test Report N°20-0900-01

Page 2/2

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