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Messrs
HELLENIC MEDICAL SUPPLIES GP
6 th km Xanthi - Lefkopetra
67100 XANTHI GREECE

Zola Predosa, 25/01/2021

Ref. Your Order /

Test Report N°21-0013-01

DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Sample description

Denomination: SURGICAL FACE MASKS
Code: 005001
Lot: 30112020
Sterilization: No
Receipt number: 19632
Receipt date: 15/01/2021
Sampling carried out by: HELLENIC MEDICAL SUPPLIES GP

Further information about the sample

Number of tested samples: 5
Size of the area of the specimens: 50 cm^2
Side of the test sample facing the challenge aerosol: internal side

Test date

The test was started on 20-01-2021 and was completed on 21-01-2021

Test method

EN 14683:2019 Annex B

Equipments and reagents

Vacuum pump "GEO Air Plus"
Modified Andersen Cascade Impactor "TE-20-830"
MMAD nebulizer 3,0 ± 0,3 µm
Colture plates containing TSA

Summary of method

A negative control is performed by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 minutes.
Then the bacterial challenge of Staphylococcus Aureus ATCC 6538, with a concentration of 1,7 x 10^3 to 3,2 x 10^3 UFC/ml, is delivered to the aerosol chamber.
A first positive control is performed, by passing the bacterial challenge through the cascade impactor at a flow rate of 28,3 ± 0,5 l/min for 1 minute. The airflow is maintained through the cascade impactor for 1 additional minute, for a total test time of 2 minutes.
The control plates are removed from the cascade impactor and fresh plates are placed in order to perform the test on the test samples.

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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℃ for a lenght 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	2535.0					
Positive control run 2	2290.0					
Positive control average	2412.5					
Test 1	13.0	99.5	≥ 95	Compliant	≥ 98	Compliant
Test 2	6.0	99.8	≥ 95	Compliant	≥ 98	Compliant
Test 3	3.0	99.9	≥ 95	Compliant	≥ 98	Compliant
Test 4	4.0	99.8	≥ 95	Compliant	≥ 98	Compliant
Test 5	20.0	99.2	≥ 95	Compliant	≥ 98	Compliant

(#) Data provided by the Customer. The laboratory declines responsibility for such data.

Test verified by: Buriani Giampaolo, PhD.

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

END OF TEST REPORT

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