

EKOTEKS LABORATUVAR ve GÖZETİM  
HİZMETLERİ A.Ş.

20015857

06-20

## TEST RESULT

### Medical face masks - Requirements and test methods EN 14683:2019+AC:2019 (TS EN 14683+AC:2019) Original

#### BACTERIAL FILTRATION EFFICIENCY (BFE)

**Test Metodu:** EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) EK-B (\*)

A specimen of the mask material is clamped between a impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test Flow Rate	28,3 L/min
Total Test Flow Time	2 minute
Sample Sizes	20x20 cm <sup>2</sup>
Test Alanı	4.9 cm <sup>2</sup> (5 replicas)
Test Condition	(21 ± 5) °C and (85 ± 5) % relative humidity, 4 hours
Test Microorganism	<i>Staphylococcus aureus</i> ATCC 6538
Bacterial concentration (cfu/ ml )	5x10 <sup>5</sup> cfu/ ml
Incubation conditions	24 hour, 35°C ± 2°C
Washing method	Original
Positive control sample average of number of Bacteria (C)	2.9x10 <sup>3</sup> cfu/ ml
Mean particle size (MPS)	3.0 µm

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RESULTS			Requirement BFE (%)
Number of Test Sample	Test Sample (T) Number of Bacteria (cfu)	Bacterial Filtration Efficiency ( % B )	
1	12	99.6 %	≥90
2	11	99.6 %	
3	10	99.7 %	
4	10	99.7 %	
5	8	99.7 %	

cfu: Colony-forming unit

$$B = ( C - T ) / C \times 100$$

%B: Bacterial Filtration Efficiency

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

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## TEST RESULT

### Medical face masks - Requirements and test methods EN 14683:2019+AC:2019 (TS EN 14683+AC:2019) After 5 washes

#### BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metodu: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) EK-B (\*)

A specimen of the mask material is clamped between an impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test Flow Rate	28,3 L/min
Total Test Flow Time	2 minute
Sample Sizes	20x20 cm <sup>2</sup>
Test Alanı	4.9 cm <sup>2</sup> (5 replicas)
Test Condition	(21 ± 5) °C and (85 ± 5) % relative humidity, 4 hours
Test Microorganism	<i>Staphylococcus aureus</i> ATCC 6538
Bacterial concentration (cfu/ ml )	5x10 <sup>5</sup> cfu/ ml
Incubation conditions	24 hour, 35°C ± 2°C
Washing method	After 5 washes 4N@40°C, line dry according to ISO 6330:2012
Positive control sample average of number of Bacteria (C)	3.0x10 <sup>3</sup> cfu/ ml
Mean particle size (MPS)	3.0 µm

#### RESULTS

Number of Test Sample	Test Sample (T) Number of Bacteria (cfu)	Bacterial Filtration Efficiency ( % B )	Requirement BFE (%)
1	25	99.1 %	≥90
2	24	99.2 %	
3	31	98.9 %	
4	30	99.0 %	
5	35	98.8 %	

cfu: Colony-forming unit

$$B = ( C - T ) / C \times 100$$

%B: Bacterial Filtration Efficiency

C: is the mean of the total plate counts for the two positive control runs

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## TEST RESULT

### MICROBIAL CLEANLINESS (Bioburden)

**Test Metod:** EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) EK-D (\*)  
EN ISO 11737-1:2018 /TS EN ISO 11737-1 :2018 (\*)

#### Original

5 sample were taken. The sample is weighted and put in extraction liquid after shaking well (250 rpm, 5 min), inoculated on the suitable agar.

The plates are incubated for 3 days at  $30 \pm 1$  °C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively. Total microorganisms counts are calculated.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	16 cfu/g	$\leq 30$ cfu/g

\*cfu= Colony forming unit.

### MICROBIAL CLEANLINESS (Bioburden)

**Test Metod:** EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) EK-D (\*)  
EN ISO 11737-1:2018 /TS EN ISO 11737-1 :2018 (\*)

#### After 5 washes

After 5 washes. 6N@60 °C , line dry

5 sample were taken. The sample is weighted and put in extraction liquid after shaking well (250 rpm, 5 min), inoculated on the suitable agar.

The plates are incubated for 3 days at  $30 \pm 1$  °C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively. Total microorganisms counts are calculated.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	3 cfu/g	$\leq 30$ cfu/g

\*cfu= Colony forming unit.

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