ÇEVRE
ENDÜSTRİYEL ANALİZ LABORATUVARI

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0363-T

AB-0363-T
2138642E
12-21

ANALYSIS REPORT

Report No. : **2138642E** Report Date : 20/12/2021

Applicant : INTELLIGENT MEDICAL SERVICES PRODUCERS

Address : Jordan, Amman 3rd Circle, Grand Complex Building No: 14 Amman/Jordan

Sample : Face Mask Tie-on Surgical Face-masks Type IIR

Sample Package : Poly packing
Sample Amount : 100 pieces
Sampling Point : -
Sampling Method : -
Sampling Date : -
Sample Lot No. : -
Production Date : -
Packing Date : -
Expire Date : -
Producer Company : -
Product No : -
Supplier Number : -
Sample Receiving Time : 10/12/2021 11:15:00
Analysis Beginning Time : 10/12/2021 11:30:00
Analysis Completion Time : 17/12/2021

Following analysis results were obtained from the specimen which was delivered by cargo to Çevre Laboratory

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method		Information
Differential Pressure									
DP - 1	Pa/cm²	47,96	< 40	< 40	< 60	97	EN 14683 - Annex C	(*)	122, 123, 133, 144
DP - 2	Pa/cm²	47,01	< 40	< 40	< 60	97	EN 14683 - Annex C	(*)	122, 123, 133, 144
DP - 3	Pa/cm²	48,91	< 40	< 40	< 60	97	EN 14683 - Annex C	(*)	122, 123, 133, 144
DP - 4	Pa/cm²	46,46	< 40	< 40	< 60	97	EN 14683 - Annex C	(*)	122, 123, 133, 144

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Assistant Laboratory Responsible of Microbiology Laboratory

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Approved by
20/12/2021
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul

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Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method		Information
DP - 5	Pa/cm²	46,53	< 40	< 40	< 60	97	EN 14683 - Annex C	(*)	122, 123, 133, 144
Splash Resistance Pressure									
Splash Resistance Pressure	kPa	16	-	-	≥16	97	ISO 22609	(*)	122, 142, 146, 147
Number of Masks Analyzed	-	32	-	-	-	-	-	(*)	
Number of Passed Masks Analyzed	-	32	-	-	-	-	-	(*)	
Analyzed Mask Surface	-	Outside	-	-	-	-	-	(*)	
Point of Analysis	-	Midpoint	-	-	-	-	-	(*)	
Bacterial Filtration Efficiency									
BFE - 1	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	(*)	124, 129
BFE - 2	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	(*)	124, 129
BFE - 3	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	(*)	124, 129
BFE - 4	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	(*)	124, 129
BFE - 5	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	(*)	124, 129
Mean Positive Control Count	cfu	1834	-	-	-	-	EN 14683 - Annex B	(*)	
Negative Control Count	cfu	<1	-	-	-	-	EN 14683 - Annex B	(*)	
Mean Particle Size (MPS)	µm	2,9	-	-	-	-	EN 14683 - Annex B	(*)	
Microbial Limit - Bioburden									
Bioburden - 1	cfu/g	<3	≤30	≤30	≤30	97	ISO 11737-1	(*)	120, 131
Bioburden - 2	cfu/g	3	≤30	≤30	≤30	97	ISO 11737-1	(*)	120, 131
Bioburden - 3	cfu/g	<3	≤30	≤30	≤30	97	ISO 11737-1	(*)	120, 131
Bioburden - 4	cfu/g	4	≤30	≤30	≤30	97	ISO 11737-1	(*)	120, 131
Bioburden - 5	cfu/g	<3	≤30	≤30	≤30	97	ISO 11737-1	(*)	120, 131

Source of Limit Ranges : 97 Medikal Yüz Maskelerinin Test Metodları ve Performans Gereksinimleri (EN 14683)

Method
ISO : International Organization for Standardization
EN : European Standard
ISO : International Organization for Standardization

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ISO : International Organization for Standardization

Information

120 : Bioburden : Aerobic Bacteria and Mold-Yeast
Pozitive Controls : Bacillus atrophaeus
Extract Fluid : Peptone, Tween with Sodium Chloride
Extract Fluid Volume : 300 mL
Plating Method : Membrane Filtration
Agar Medium : Tryptic Soy Agar for Aerobic Bacteria Count and Sabouraud Dextrose Agar with Chloramphenicol for Mold and Yeast Count
Recovery Efficiency : Repetitive Rinse Method
Aerobic Bacteria : Plates are incubatede 3 days at 30-35°C, then enumerated.
Yeast - Mould : Plates are incubatede 5-7 days at 20-25°C, then enumerated.

122 : Conditioning Parameters : 85± 5 relative humidity and 21± 5 °C de minimum 4 hours

123 : Flow rate during testing : 8 L/dk

124 : Conditioning Parameters : 85± 5 relative humidity and 21± 5 °C de minimum 4 hours
Flow rate during testing : 28.3 L/dk
Test performed with the inside of the medical face mask in contact with the bacterial challenge.

129 : The mask analyzed according to the results of Bacterial Filtration Efficiency (BFE) provides EN 14683 Table 1. Type I,Type II and Type IIR limits.

131 : The mask analyzed according to the results of Microbial Limit - Bioburden provides EN 14683 Table 1. Type I, Type II and Type IIR limits.

133 : The mask analyzed according to the results of Differential Pressure provides EN 14683 Table 1. Type IIR limit.

142 : The Splash Resistance Pressure is determined based on the value specified in EN 14683 Table 1. Type IIR.

144 : The test was applied from the inner surface on the mask to the outher surface, as required by the standard.

146 : According to ISO 22609, when 29 or more of the 32 samples tested show "pass" results, an acceptable 4.0% quality limit is met for a single sampling plan. Acceptable 4.0% quality limit is met for normal sampling plan according to analysis results.

147 : Test Parameters : 48,0 relative humidity and 22,9 °C

Note

1. Çevre End. Analiz Lab. Hiz. Tic. A.Ş. accredited by TÜRKAK under registration number [AB-0363-T] for [TS EN ISO/IEC 17025] as test laboratory". Turkish Accreditation Agency (TURKAK) is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) and to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for the recognition of test reports.
2. When a conformity assessment is requested, legal regulations, standards or the decision rule agreed with the customer are applied by us after a risk assessment and the application method is specified in the information section of the report. The Simple Decision Rule applies where conformity assessment is requested without taking into account the measurement uncertainty.
3. Uncertainties stated in the report are expanded uncertainty (k=2, 95%). Total Uncertainty of Measurement includes the uncertainty from sampling. It is valid when the sample is taken by us.
4. The definitional information included in the analysis report and affecting the validity of the results has been declared by the customer. Our laboratory is not responsible for any losses/legal obligations that may occur due to the accuracy and use of this information.
5. Analysis report covers samples/sampling that comes to the laboratory.
6. This report and results don't not be copied and printed partially or completely without permission of Cevre Industrial Analysis Laboratory for any commercial and advertising purposes.
7. This report shall not be used for legal/administrative procedures and advertising purposes.
8. The test report without sign is not valid.
9. (*) This parameter is covered by our accreditation scope.

End of Report

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