# ANALYSIS REPORT

Report No. **: 2018742E** Report Date : 20/08/2020

Applicant : UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.

Address : Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye/İstanbul/Turkey

Sample : Medical Face Mask

Sample Package : Poly packing

Sample Amount : 100 pieces

Sampling Point : -

Sampling Date : 11/08/2020

Sample Lot No. : -

Sample Carrying Conditions / Preservation Technique : -

Production Date : -

Packing Date : -

Expire Date : -

Producer Company : Narkonteks Tekstil İhr. İth. San. ve Tic. A.Ş.

Sample Receiving Time : 11/08/2020 17:15:00

Analysis Beginning Time : 12/08/2020 09:00:00

Analysis Completion Time : 20/08/2020

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

| Parameters | Unit | Finding | Tip I | Tip II | Tip IIR | LR Source | Method | Information |
|---|---|---|---|---|---|---|---|---|
| Differential Pressure | | | | | | | | |
| DP - 1 | Pa/cm² | 24,6 | < 40 | < 40 | < 60 | 97 | EN 14683 - Annex C | 122, 123, 126, 144 |
| DP - 2 | Pa/cm² | 29,5 | < 40 | < 40 | < 60 | 97 | EN 14683 - Annex C | 122, 123, 126, 144 |
| DP - 3 | Pa/cm² | 23,5 | < 40 | < 40 | < 60 | 97 | EN 14683 - Annex C | 122, 123, 126, 144 |
| DP - 4 | Pa/cm² | 25,2 | < 40 | < 40 | < 60 | 97 | EN 14683 - Annex C | 122, 123, 126, 144 |
| DP - 5 | Pa/cm² | 25,3 | < 40 | < 40 | < 60 | 97 | EN 14683 - Annex C | 122, 123, 126, 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 | - | 31 | - | - | - | - | - | |

**Kübra HANCI AKAN**
**Microbiology Laboratory Responsible**

**Approved by**
**20/08/2020**
**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 |
|---|---|---|---|---|---|---|---|---|
| Analyzed Mask Surface | - | Outside | - | - | - | - | - | |
| Point of Analysis | - | Midpoint | - | - | - | - | - | |
| Bacterial Filtration Efficiency | | | | | | | | |
| BFE - 1 | % | >99,9 | ≥95 | ≥98 | ≥98 | 97 | EN 14683 - Annex B | 122, 124, 129 |
| BFE - 2 | % | >99,9 | ≥95 | ≥98 | ≥98 | 97 | EN 14683 - Annex B | 122, 124, 129 |
| BFE - 3 | % | >99,9 | ≥95 | ≥98 | ≥98 | 97 | EN 14683 - Annex B | 122, 124, 129 |
| BFE - 4 | % | >99,9 | ≥95 | ≥98 | ≥98 | 97 | EN 14683 - Annex B | 122, 124, 129 |
| BFE - 5 | % | >99,9 | ≥95 | ≥98 | ≥98 | 97 | EN 14683 - Annex B | 122, 124, 129 |
| Mean Positive Control Count | cfu | 1835 | - | - | - | - | EN 14683 - Annex B | |
| Negative Control Count | cfu | <1 | - | - | - | - | EN 14683 - Annex B | |
| Mean Particle Size (MPS) | µm | 3,2 | - | - | - | - | EN 14683 - Annex B | |
| Microbial Limit - Bioburden | | | | | | | | |
| Bioburden - 1 | cfu/g | 21 | ≤30 | ≤30 | ≤30 | 97 | ISO 11737-1 | 120, 131 |
| Bioburden - 2 | cfu/g | 12 | ≤30 | ≤30 | ≤30 | 97 | ISO 11737-1 | 120, 131 |
| Bioburden - 3 | cfu/g | 18 | ≤30 | ≤30 | ≤30 | 97 | ISO 11737-1 | 120, 131 |
| Bioburden - 4 | cfu/g | 16 | ≤30 | ≤30 | ≤30 | 97 | ISO 11737-1 | 120, 131 |
| Bioburden - 5 | cfu/g | 11 | ≤30 | ≤30 | ≤30 | 97 | ISO 11737-1 | 120, 131 |

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

A: Acceptable NA: Not Acceptable

MU: Measurement Uncertainty

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

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123 : Flow rate during testing : 8 L/dk
124 : Flow rate during testing : 28.3 L/dk
Test performed with the inside of the medical face mask in contact with the bacterial challenge.
126 : The mask analyzed according to the results of Differential Pressure provides EN 14683 Table 1. Type I, Type II and Type IIR limits.
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.
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 : 51,6 relative humidity and 26,1 °C

**Note**

1. When request, the conformit assessment is carried out in accordance with the legal regulations and standards or the decision rules which are agreed with the customer.
2. Descriptive information about the samples / sampling in the analysis report has been declared by the customer. Our laboratory is not responsible for the legal losses.
3. Analysis report covers samples/sampling that comes to the laboratory.
4. 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.
5. This report shall not be used official purposes related to Enviromental Regulations.
6. The test report without sign is not valid.

End of Report

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