EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0583-T

# TEST REPORT
*DENEY RAPORU*

| |
|---|
| AB-0583-T |
| 21027124 -İNG |
| 09-21 |

| | |
|---|---|
| ***Customer name:*** | IPOS MEDİKAL DIŞ TİC. A.Ş. |
| ***Address:*** | EYÜP SULTAN MAH. YADGAR SOK. NO:141/1 SANCAKTEPE/İSTANBUL |
| ***Buyer name:*** | - |
| ***Contact Person:*** | - |
| ***Order No:*** | - |
| ***Article No:*** | IPOS-TYPIIR-BLAU |
| ***Name and identity of test item:*** | Blue non-woven mask.(Claimed to be; Colour Code: Blue ) |
| ***The date of receipt of test item:*** | 08.09.2021 |
| ***Re-submitted/re-confirmation date:*** | - |
| ***Date of test:*** | 08.09.2021-13.09.2021 |
| ***Remarks:*** | - |
| ***Sampling:*** | The results given in this report belong to the received sample by vendor. |
| ***End-Use:*** | - |
| ***Care Label:*** | Not Specified |
| ***Number of pages of the report:*** | 6 |

***The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.Deney laboratuvarı olarak faaliyet gösteren EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. TÜRKAK'tan AB-0583-T akreditasyon dosya numarası ile ISO 17025:2017 standardına göre akredite edilmiştir.***
***The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.***

| *Seal* | *Date* | *Customer Representative* | *Head of Testing Laboratory* |
|---|---|---|---|
| TESTED BY EKOTEKS TEST EDİLMİŞTİR | 13.09.2021 | Ayşe KASTAMONU | Sevim A. RAZAK 13.09.2021 |

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| REQUIRED TESTS | EVALUATION | COMMENTS |
|---|---|---|
| **PHYSICAL PROPERTIES TESTS** | | |
| Breathability (Differential Pressure) | P | |
| Blood Splash Resistance[1] | P | |
| **MICROBIOLOGICAL TEST** | | |
| Bacterial Filtration Efficiency (BFE) | P | Type IIR |
| Microbial Cleanliness (Bioburden) | P | |

P: Pass
F: Fail
R: Refer to retailer technologist.

Test results were evaluated according to EN 14683:2019+AC:2019 limit values

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified. If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %.The declaration of conformity was given in accordance with the Simple Acceptance Decision Rule. Tests marked (*) in this report are not included in the accreditation schedule.



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# TEST RESULT

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

### 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 $cm^2$ |
| **Test Condition** | (21 ± 5) °C and (85 ± 5) % relative humidity, 4 hours |
| **Test Microorganism** | *Staphylococcus aureus* ATCC 6538 |
| **Bacterial concentration (cfu/ ml )** | $5x10^5$ cfu/ ml |
| **incubation conditions** | 24 hour, 35°C ± 2°C |
| **Positive control sample average of number of Bacteria (C)** | $3.0x10^3$ 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** | 45 | **%98.5** | **Type I ≥95** |
| **2** | 42 | **%98.6** | **Type II ≥98** |
| **3** | 46 | **%98.5** | |
| **4** | 48 | **%98.4** | |
| **5** | 47 | **%98.4** | |

*cfu: Colony-forming unit*

B= ( C-T ) / C x 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

# TEST RESULT

## BREATHABILITY (Differential Pressure)

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

Test Condition (21 ± 5) °C ve (85 ± 5) % relative humidity, 4 hrs
Test area is 25 mm in diameter , 5 different sample was taken
Adjusted airflow is 8 l/min.The differential pressure is read directly using a differential pressure manometer .

| SAMPLE | DIFFERENTIAL PRESSURE RESULT | REQUIREMENT |
| --- | --- | --- |
| 1 | 26.3 Pa/cm$^2$ | < 60 Pa/cm$^2$ |
| 2 | 25.7Pa/cm$^2$ | |
| 3 | 28.7 Pa/cm$^2$ | |
| 4 | 22.3 Pa/cm$^2$ | |
| 5 | 23.5 Pa/cm$^2$ | |
| Average Result | 25.3 Pa/cm$^2$ | |

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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

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 ± 1 ° C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively.Total microoragnisms counts are calculated.

| SAMPLE | RESULTS | REQUIREMENT |
| --- | --- | --- |
| 1 | 2 kob/g | ≤30 cfu/g |
| 2 | 2 kob/g | |
| 3 | 2 kob/g | |
| 4 | 2 kob/g | |
| 5 | 2 kob/g | |
| Average Result | 2 kob/g | |

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# TEST RESULT

## SPLASH RESİSTANCE

**Test Metod:** EN 14683:2019+AC :2019 (Clause 5.2.4) the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1
ISO 22609 :2004 Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
Test Condition (21 ± 5) °C ve (85 ± 5) % relative humidity, 4 hrs32 different samples were taken

| | SPLASH RESISTANCE PRESSURE (kPa) | RESULTS | REQUIREMENT |
|---|---|---|---|
| 1 | >21.3 kPa | PASS | |
| 2 | >21.3 kPa | PASS | |
| 3 | >21.3 kPa | PASS | |
| 4 | >21.3 kPa | PASS | |
| 5 | >21.3 kPa | PASS | |
| 6 | >21.3 kPa | PASS | |
| 7 | >21.3 kPa | PASS | |
| 8 | >21.3 kPa | PASS | |
| 9 | >21.3 kPa | PASS | |
| 10 | >21.3 kPa | PASS | |
| 11 | >21.3 kPa | PASS | |
| 12 | >21.3 kPa | PASS | |
| 13 | >21.3 kPa | PASS | |
| 14 | >21.3 kPa | PASS | |
| 15 | >21.3 kPa | PASS | |
| 16 | >21.3 kPa | PASS | ≥16 kPa Type IIR |
| 17 | >21.3 kPa | PASS | |
| 18 | >21.3 kPa | PASS | |
| 19 | >21.3 kPa | PASS | |
| 20 | >21.3 kPa | PASS | |
| 21 | >21.3 kPa | PASS | |
| 22 | >21.3 kPa | PASS | |
| 23 | >21.3 kPa | PASS | |
| 24 | >21.3 kPa | PASS | |
| 25 | >21.3 kPa | PASS | |
| 26 | >21.3 kPa | PASS | |
| 27 | >21.3 kPa | PASS | |
| 28 | >21.3 kPa | PASS | |
| 29 | >21.3 kPa | PASS | |
| 30 | >21.3 kPa | PASS | |
| 31 | >21.3 kPa | PASS | |
| 32 | >21.3 kPa | PASS | |