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
21035303-İNG
11-21

Customer name:	
Address:	UAB ARİBOLT DIDLAUKIO STREET 80-96 VILNIUS-LITHUANIA
Buyer name:	-
Contact Person:	-
Order No:	-
Article No:	ARIMASK-ARI-02
Name and identity of test item:	Non-woven mask.(Claimed to be;50 Sample)
The date of receipt of test item:	22.11.2021
Re-submitted/re-confirmation date:	-
Date of test:	22.11.2021-29.11.2021
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

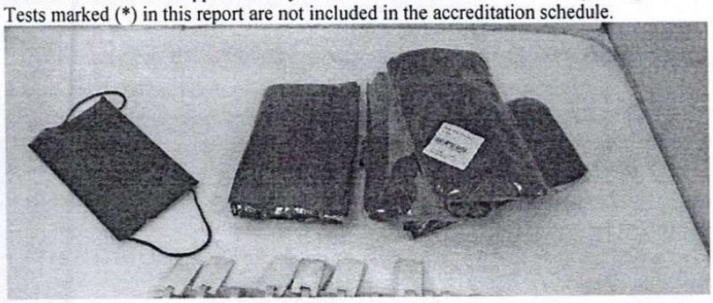
The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.Deney laboratuvarı olarak faaliyet gösteren EKOTEKS LABORATUVAR 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*
TEST EDİLMİŞTİR TESTED EKOTEKS	29.11.20211	Ayşe KASTAMONU	Sevim A. RAZAK 29.11.2021

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.



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	36.5 Pa/cm²	< 60 Pa/cm²
2	36.9 Pa/cm²	
3	36.5 Pa/cm²	
4	35.6 Pa/cm²	
5	34.9 Pa/cm²	
Average Result	36.8 Pa/cm²	

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	33	**%98.9**	**Type I ≥95**
2	35	**%98.8**	**Type II ≥98**
3	36	**%98.8**	
4	38	**%98.7**	
5	37	**%98.8**	

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

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	3 cfu/g	≤30 cfu/g
2	3 cfu/g	
3	3 cfu/g	
4	3 cfu/g	
5	3 cfu/g	
Average Result	3 cfu/g	

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	≥16 kPa Type IIR
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	
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	

EU DECLARATION OF CONFORMITY

MANUFACTURER
UAB ARIBOLT
Didlaukio g. 80/96 LT-08326 Vilnius/Lithuania

PRODUCT DESCRIPTION

Layered and molded medical device classified in the Class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Brand Name: ARIMASK **Model**: ARI-02
Type IIR
Device UDI-DI Number: 4779036ARI02X7
Product Risk Class: Class I / Product Performance Class: Class I

Medical masks, as a medical device, manufactured from spunbond and meltblown fabrics, with ear loops and nose bridge. The mask is available 2 size (kids and standard) and have white, blue, black, pink colour variants.

The Producer / the Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Producer's / the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- Government Regulation no. 2017/745/EU Medical devices establishing technical requirements for medical devices, in effective wording
- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
- Other relevant harmonized legislation
- Other relevant local, national and community standards
- For the assessment of conformity, the following documents were also applied to:
- Tests for irritation and delayed-type hypersensitivity
- Results of laboratory tests Ekoteks Testing Laboratory Bavterial filtration efficiency (Annex I)
- Results of laboratory tests Ekoteks Testing Laboratory Microbial Cleanliness (Annex I)
- Results of laboratory tests Ekoteks Testing Laboratory Differential Pressure (Annex I)
- Results of laboratory tests Ekoteks Testing Laboratory Splash Resistance Pressure (Annex I)

MARKING, LABELLING

Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied:
Type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN ISO 20417:2021 should be considered

MEASURES TO ENSURE CONFORMITY

The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

CE

Arif KAZDAL
General Manager
2021 / VILNIUS

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