INTERNATIONAL FIRST CERTIFICATION

INTERNATIONAL FIRST CERTIFICATION

SERTİFİKA

Bu sertifika,

ALTINKAYA ELEKTRONİK CİHAZ KUTULARI SANAYİ TİCARET ANONİM ŞİRKETİ

HAS EMEK SANAYİ SİTESİ 1469. CADDE NO:10 İVEDİK OSB YENİMAHALLE ANKARA

kuruluşunun,

MASKE İMALAT, İTHALAT VE İHRACAT

EA 4 kapsamında,

ISO 9001:2015

Kalite Yönetim Sistemi standardının şartlarına uyan bir yönetim sistemi kurduğunu ve uyguladığını onaylamak üzere verilmiştir.

İlk Yayın Tarihi	**: 21.09.2020**
Yayın Tarihi	**: 21.09.2020**
Sertifika Geçerlilik Tarihi	**: 3 Yıl / 20.09.2023**
Sertifika Bitiş Tarihi	**: 20.09.2021**
Sertifika No	**: IFC-Q - 09 - 20 - 1592**

TÜRKAK
Kalite Yönetim Sistemi
TS EN ISO/IEC 17021-1
AB-0138-YS

TÜRKAK BDS NO
YS-8685-5E4E

Onay
01.2018/Rev.01

IFC GLOBAL SERTİFİKASYON MUAYENE VE EĞİTİM HİZMETLERİ ANONİM ŞİRKETİ
Adalet Mah. Manas Blv. No:39 / 2203 - Folkart Towers / Bayraklı İZMİR TÜRKİYE **T:** +90 850 304 35 00 **F:** +90 850 304 35 00

www.ifcglobal.com.tr **info@ifcglobal.com.tr**

INTERNATIONAL FIRST CERTIFICATION

INTERNATIONAL FIRST CERTIFICATION

SERTİFİKA

Bu sertifika,

ALTINKAYA ELEKTRONİK CİHAZ KUTULARI SANAYİ TİCARET ANONİM ŞİRKETİ

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kuruluşunun,

MASKE İMALAT, İTHALAT VE İHRACAT

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Sertifika No	**: IFC-E - 09 - 20 - 1592**

Onay

FR.220/05/2018/Rev.01

IFC GLOBAL SERTİFİKASYON MUAYENE VE EĞİTİM HİZMETLERİ ANONİM ŞİRKETİ

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INTERNATIONAL FIRST CERTIFICATION

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SERTİFİKA

Bu sertifika,

ALTINKAYA ELEKTRONİK CİHAZ KUTULARI SANAYİ TİCARET ANONİM ŞİRKETİ

HAS EMEK SANAYİ SİTESİ 1469. CADDE NO:10 İVEDİK OSB YENİMAHALLE ANKARA

kuruluşunun,

MASKE İMALAT, İTHALAT VE İHRACAT

kapsamında,

OHSAS 18001:2007

İş Sağlığı ve Güvenliği Yönetim Sistemi standardının şartlarına uyan bir yönetim sistemi kurduğunu ve uyguladığını onaylamak üzere verilmiştir.

İlk Yayın Tarihi	**: 21.09.2020**
Yayın Tarihi	**: 21.09.2020**
Sertifika Geçerlilik Tarihi	**: 3 Yıl / 20.09.2023**
Sertifika Bitiş Tarihi	**: 20.09.2021**
Sertifika No	**: IFC- O 09 - 20 - 1592**

Onay

2018/Rev.01

IFC GLOBAL SERTİFİKASYON MUAYENE VE EĞİTİM HİZMETLERİ ANONİM ŞİRKETİ
Adalet Mah. Manas Blv. No:39 / 2203 - Folkart Towers / Bayraklı İZMİR TÜRKİYE T: +90 850 304 35 00 F: +90 850 304 35 00

www.ifcglobal.com.tr info@ifcglobal.com.tr

CERTIFICATE
of Registration

This is to Certify that the

Medical Devices -- Quality Management System

of

ALTINKAYA ELEKTRONİK CİHAZ KUTULARI SANAYİ TİCARET ANONİM ŞİRKETİ

İVEDİK ORGANİZE SANAYİ BÖLGESİ HAS EMEK SANAYİ SİTESİ 1469. SOKAK NO:10 YENİMAHALLE /ANKARA / TÜRKİYE

has been independently assessed and is compliant with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

PRODUCTION OF STERILE AND NON STERILE DISPOSABLE SURGERY MASK

STERİL VE NON STERİL TEK KULLANIMLIK CERRAHİ MASKE ÜRETİMİ

Certificate No.: TR52672H

Date of initial registration	**17 June 2020**
Date of this Certificate	**17 June 2020**
Surveillance audit on or before	**16 June 2021**
Recertification Due / Certificate expiry	**16 June 2023**

This Certificate is property of Staunchly Management & System Services Ltd. and remains valid subject to satisfactory surveillance audits.

Director

STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.
Suite 48, 88-90 Hatton Garden, London, EC1N 8PN.

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

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

TEST REPORT
DENEY RAPORU

AB-0583-T
20033391-ing
09-20

Customer name:	ALTINKAYA ELEKTRONİK CİHAZ KUTULARI SAN. TİC.
Address:	Has Emek Sanayi Sitesi 1469. Cadde No: 10 İvedik OSB Yenimahalle/ ANKARA
Buyer name:	-
Contact Person:	FÜSUN ANLADI CEYLAN
Order No:	-
Article No:	MARKA: ALVENT MODEL: MA-250
Name and identity of test item:	Blue non-woven medical mask.
The date of receipt of test item:	11.09.2020
Re-submitted/re-confirmation date:	-
Date of test:	11.09.2020-21.09.2020
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:	5

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.

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.

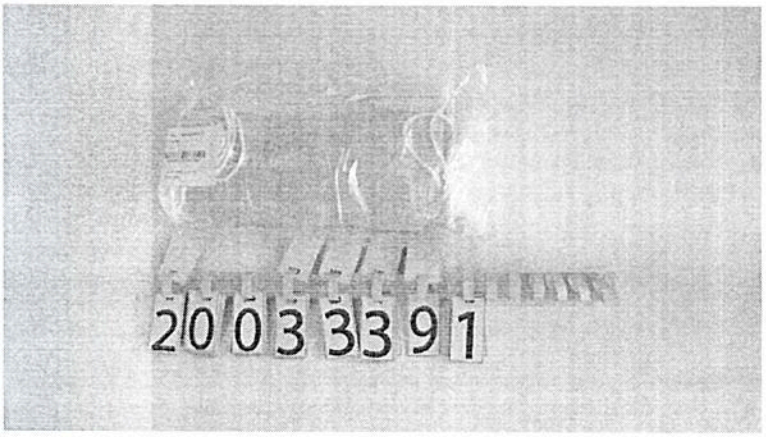
The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
	21.09.2020	Tuğba AKTAŞ	Sevim A. RAZAK 21.09.2020

AB-0583-T
20033391-ing
09-20

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency-BFE	P	Type IIR
Microbial Cleanliness(Bioburden)	P	
PHYSICAL PROPERTIES		
Breathability(Differential Pressure)	P	
Splash Resistance	P	
P: Pass F: Fail R: Refer to retailer technologist. Tests results were evaluated according to EN 14683:2019+AC :2019 Tablo 1 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 %. Tests marked (*) in this report are not included in the accreditation schedule.



AB-0583-T
20033391-ing
09-20

TEST RESULTS

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metod: (Bacterial Filtration Efficiency Testing –BFE /Ref: EN 14683:2019+AC:2019 Medical Face Masks,Requirements and Test Methods

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
Test Flow Time	2 minute
Sample Sizes	5 pieces mask
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)	**$2.5x10^3$ cfu/ ml**

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu/ml)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	45	**%98.2**	**Type I ≥95** **Type II ≥98**
2	36	**%98.6**	
3	40	**%98.4**	
4	50	**%98.0**	
5	33	**%98.7**	

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

AB-0583-T
20033391-ing
09-20

TEST RESULTS

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN ISO 11737-1:2018
The sample is put in extraciton liquid after shaking well, inoculated on the agar.
After incubation at 30 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	16 cfu/g	≤30 cfu/g Type I and Type II mask

*cfu= Colony forming unit.

SPLASH RESİSTANCE (ONLY FOR TYPE IIR)

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 hrs

6 different samples were taken

	SPLASH RESISTANCE PRESSURE (kPa)	RESULTS	REQUIREMENT
1	>21.3 kPa	**PASS**	≥16 kPa
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**	
Average Result	>21.3 kPa	**PASS**	

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09-20

TEST SONUÇLARI

BREATHABILITY (Differential Pressure)

Test Method: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) Annex-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	25.1 Pa/cm^2	< 60 Pa/cm^2
2	29.8 Pa/cm2	
3	28.9 Pa/cm2	
4	29.2 Pa/cm2	
5	27.1 Pa/cm2	
Average Result	28.0 Pa/cm2	

ALVENT®

EU declaration of conformity

According to *93/42/EEC*

CE

Declaration of conformity no - Revision : ***DoC002-00***
Technical File No - Rev: ***ALF202013-00***

Legal Manufacturer	**Altınkaya Elektronik Cihaz Kutuları San. Tic. A.S.** 1469. cadde No:10 İvedik OSB 06378 Yenimahalle / ANKARA Turkey Tel: +90 312 963 1613 mask@alvent.com.tr
Product Brand	**ALVENT**
Product Name	TYPE IIR Earloop Surgical Mask with meltblown layer
Product Range	Disposable Surgical Face Mask
Product Code	MA-250
Medical Device Classification	Class 1 non-sterile rule 1
GMDN class	35177 surgical face mask, single use
UNSPSC Code	42131713 Surgical Mask

We herewith *declare under our sole responsibility that the above mentioned product bear the CE Marking, and meet the provisions of the following Council Directive(s) as transposed into national laws.*

General Applicable Directives	*Council Directive 93/42/EEC of 14 June 1993 (MDD 93/42/EEC) as amended*
Annex 93/42/EEC	*VII*
Notified Body	*N/A*
Harmonised Standards	EN 14683:2019+AC-EQV
Applicable standards	EN ISO 11737-1 :2018 EN ISO 10993-1 :2009 EN ISO 9073-4 EN ISO 29073-3

All supporting documentation is retained at the manufacturer's premises

Authorized Signature

Ahmet Altınışık
Managing Director

Ankara
Place

24.09.2020
Date

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

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

AB-0583-T
20033390-ing
09-20

TEST REPORT
DENEY RAPORU

Customer name:	ALTINKAYA ELEKTRONİK CİHAZ KUTULARI SAN. TİC.
Address:	Has Emek Sanayi Sitesi 1469. Cadde No: 10 İvedik OSB Yenimahalle/ ANKARA
Buyer name:	-
Contact Person:	FÜSUN ANLADI CEYLAN
Order No:	-
Article No:	MARKA: ALVENT MODEL: MA-356
Name and identity of test item:	Blue non-woven medical mask.
The date of receipt of test item:	11.09.2020
Re-submitted/re-confirmation date:	-
Date of test:	11.09.2020-21.09.2020
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:	5

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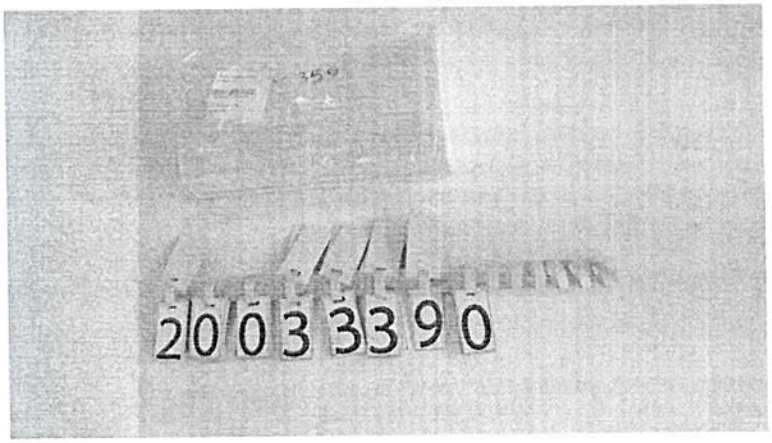
	21.09.2020	Tuğba AKTAŞ	Sevim A. RAZAK 21.09.2020

AB-0583-T
20033390-ing
09-20

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency-BFE	P	Type IIR
Microbial Cleanliness(Bioburden)	P	
PHYSICAL PROPERTIES		
Breathability(Differential Pressure)	P	
Splash Resistance	P	
P: Pass F: Fail R: Refer to retailer technologist. Tests results were evaluated according to EN 14683:2019+AC :2019 Tablo 1 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 %. Tests marked (*) in this report are not included in the accreditation schedule.



AB-0583-T
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TEST RESULTS

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metod: (Bacterial Filtration Efficiency Testing –BFE /Ref: EN 14683:2019+AC:2019 Medical Face Masks,Requirements and Test Methods

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
Test Flow Time	2 minute
Sample Sizes	5 pieces mask
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)	**$2.74x10^3$ cfu/ ml**

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu/ml)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	48	**%98.2**	**Type I ≥95** **Type II ≥98**
2	35	**%98.7**	
3	51	**%98.1**	
4	43	**%98.4**	
5	40	**%98.5**	

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

AB-0583-T
20033390-ing
09-20

TEST RESULTS

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN ISO 11737-1:2018
The sample is put in extraciton liquid after shaking well, inoculated on the agar.
After incubation at 30 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	12 cfu/g	≤30 cfu/g Type I and Type II mask

*cfu= Colony forming unit.

SPLASH RESİSTANCE (ONLY FOR TYPE IIR)

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

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Test Condition (21 ± 5) °C ve (85 ± 5) % relative humidity, 4 hrs

6 different samples were taken

	SPLASH RESISTANCE PRESSURE (kPa)	RESULTS	REQUIREMENT
1	>21.3 kPa	**PASS**	≥16 kPa
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**	
Average Result	>21.3 kPa	**PASS**	

AB-0583-T
20033390-ing
09-20

TEST SONUÇLARI

BREATHABILITY (Differential Pressure)

Test Method: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) Annex-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	19.8 Pa/cm^2	< 60 Pa/cm^2
2	21.5 Pa/cm2	
3	24.0 Pa/cm2	
4	21.5 Pa/cm2	
5	22.6 Pa/cm2	
Average Result	21.8 Pa/cm2	

ALVENT®

EU declaration of conformity

According to *93/42/EEC*

Declaration of conformity no - Revision : ***DoC003-00***
Technical File No - Rev: ***ALF202014-00***

Legal Manufacturer	**Altınkaya Elektronik Cihaz Kutuları San. Tic. A.S.** 1469. cadde No:10 İvedik OSB 06378 Yenimahalle / ANKARA Turkey Tel: +90 312 963 1613 mask@alvent.com.tr
Product Brand	**ALVENT**
Product Name	Surgical Face Mask Type IIR Softloop
Product Range	Disposable Surgical Face Mask
Product Code	MA-356
Medical Device Classification	Class 1 non-sterile rule 1
GMDN class	35177 surgical face mask, single use
UNSPSC Code	42131713 Surgical Mask

We herewith *declare under our sole responsibility that the above mentioned product bear the CE Marking, and meet the provisions of the following Council Directive(s) as transposed into national laws.*

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Notified Body	*N/A*
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Applicable standards	EN ISO 11737-1 :2018 EN ISO 10993-1 :2009 EN ISO 9073-4 EN ISO 29073-3

All supporting documentation is retained at the manufacturer's premises

Authorized Signature

Ahmet Altınışık
Managing Director

Ankara
Place

24.09.2020
Date