A&Z MED

Personal Protective Equipment

OLI-2022 MASK

Non-woven, triple layer, disposable mask.

Fabric surface blocks liquids within a special technology.

Our products prevent perspiration by their breathability characteristic, and provide a healthy and comfortable use.

Prevent the expansion and growth of bacterias.

STANDARDS: EN 14683:2019+AC:2019

ISO-9001:2015 ISO-13485:2016

A&ZMED
Personal Protective Equipment

OLI-2022 MASK

LAYER -1

PRODUCT	%100 Polypropylene Spunbond
COLOR	BLUE / WHITE
WEIGHT	20

MADE TEST	AVARAGE VALUE +/- %10	METHOD
TENSILE STRENGTH N / 5 cm (MD)	39,44	NWSP 110.1 R0(15)
TENSILE STRENGTH N / 5 cm (CD)	27,10	NWSP 110.1 R0(15)
ELONGATION % (MD)	72,00	NWSP 110.1 R0(15)
ELONGATION % (CD)	81,00	NWSP 110.1 R0(15)
WEIGHT (gr/m2)	20,0	NWSP 130.1 R0(15)
STRIKE THROUGH TIME (s)	0,00	NWSP 070.7 R0(15)
REWET (g)	0,00	NWSP 070.9 R1(15)

LAYER -2

PRODUCT	%100 Polypropylene Meltblown
COLOR	WHITE
WEIGHT	25

MADE TEST	AVARAGE VALUE +/- %10	METHOD
TENSILE STRENGTH N / 5 cm (MD)	13,80	NWSP 110.1 R0(15)
TENSILE STRENGTH N / 5 cm (CD)	12,40	NWSP 110.1 R0(15)
ELONGATION % (MD)	42,00	NWSP 110.1 R0(15)
ELONGATION % (CD)	53,60	NWSP 110.1 R0(15)
WEIGHT (gr/m2)	25,0	NWSP 130.1 R0(15)
HYDROSTATIC HEAD (mmH_2O)	412,00	NWSP 080.6 R0(15)
BACTERIAL FILTRATION EFFICIENCY, BFE (%)	≥ 95	EN 14683:2019

LAYER -3

PRODUCT	%100 Polypropylene Spunbond
COLOR	BLUE / WHITE
WEIGHT	30

MADE TEST	AVARAGE VALUE +/- %10	METHOD
TENSILE STRENGTH N / 5 cm (MD)	66,30	NWSP 110.1 R0(15)
TENSILE STRENGTH N / 5 cm (CD)	41,20	NWSP 110.1 R0(15)
ELONGATION % (MD)	81,20	NWSP 110.1 R0(15)
ELONGATION % (CD)	88,50	NWSP 110.1 R0(15)
WEIGHT (gr/m2)	30,0	NWSP 130.1 R0(15)
STRIKE THROUGH TIME (s)	0,00	NWSP 070.7 R0(15)
REWET (g)	0,00	NWSP 070.9 R1(15)

İBİŞLER TEKSTİL A.Ş.
Orhangazi Mah. Tunç Cad. No:5 34538 Esenyurt / İstanbul - TURKEY
+90 212 602 04 05 www.ibisler.com info@ibisler.com

A&ZMED
Personal Protective Equipment

OLI-2022 MASK

(Instructions)
1) Open the package, take out the mask, hold the two ends of the mask with the bridge of the nose facing upwards;
2) The mask covers the mouth, nose, and jaw, and the earband is placed behind the ear;
3) Press the bridge strip to fit the bridge of the nose;
4) Adjust the position of the mask appropriately to make it comfortable to wear;
5) Wear correctly according to the front and back sides. Do not touch the inside of the mask with your hands.

(Precautions)
1) Please read the instructions carefully to avoid touching the inner layer of the mask with your hands;
2) Non-sterile masks should not be used in areas with strict microbiological index control;
3) Please check the packing before use, if the packing is damaged, it is forbidden to use;
4) This product isd disposable and cannot be used repeatedly;
5) If liquid splashing, mask damage, dampness, or significant increase in breathing resistance occur during wearing, please replace it in time;
6) After using the product, it should be disposed of in accordance with the requirements of the hospital or environmental protection department.

How to Wear a Mask

How to Remove Masks

Made in Turkey

İBİŞLER TEKSTİL A.Ş.
Orhangazi Mah. Tunç Cad. No:5 34538 Esenyurt / İstanbul - TURKEY
+90 212 602 04 05 www.ibisler.com info@ibisler.com

8682742370706

UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD - 098

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993,

the products manufactured by

İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET ANONİM ŞİRKETİ

at the following address

Orhangazi Mahallesi Tunç Caddesi No:5 34358 Esenyurt / İSTANBUL

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name: A&Z MED
Model: ALI - 2022
Type: II

are tested according the following initial type tests by the manufacturer

Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

For the assessment of conformity, the following documents were also applied
Results of laboratory tests Ekoteks Testing Laboratory - BFE
Results of laboratory tests Ekoteks Testing Laboratory - Differential Pressure
Results of laboratory tests Ekoteks Testing Laboratory - Microbial Cleanliness

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the medical face masks manufactured and designed for use during the medical operations or similar medical situations with same requirements which require restriction of infectious materials to be spread to patients. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) Annex I, §23 of the Medical Device Regulation (EU) 2017/745. This information includes; reference to EN 14683 standard, type of mask (as indicated in Table 1) and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as described below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 04/05/2020 and valid until 03/05/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

İSTANBUL –04/05/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Genel Müdür

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be concuted annually following the surveillance audits, updating the publicationdate without changing the certificate number.

EU DECLARATION OF CONFORMITY

PRODUCER

İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET ANONİM ŞİRKETİ
Orhangazi Mahallesi Tunç Caddesi No:5 34358 Esenyurt / İSTANBUL

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 fr[illegible] the environment (Type I and/or Type II)

The Producer / the Manufacturer declare[illegible] his se[illegible] res[illegible]onsibility that the product above is, under conditions of normal use and conditio[illegible] define[illegible] by the P[illegible]ducer / the Manufacturer, safe and meets all the necessary legal conditions and re[illegible]iremen[illegible]s. The pro[illegible]uct, a medical device that is intended for single use and sol[illegible]y in ac[illegible]rdan[illegible] wi[illegible] the Produce[illegible] / the Manufacturer's instructions.

The Conformity is ass[illegible]ed espe[illegible]ally with the [illegible]ollo[illegible]ng provisions:

- Governmen[illegible] Regulation [illegible]o. 93/42/EE[illegible] Medical devices establishing technical re[illegible]irements for medical de[illegible]ces, in effect[illegible] wordin[illegible]
- Technical [illegible]ndard EN 14683[illegible]9+AC:2019 Medical face masks [illegible]Requ[illegible]ements a[illegible] test metho[illegible]
- Other releva[illegible]harmoniz[illegible]d legislation
- Other relevant [illegible], national and community standards
- For the assessment of conformity, the followin[illegible]ocume[illegible]s were also applied[illegible]
- Tests for irritation and delayed-type hyp[illegible]se[illegible]itivity
- Results of laboratory tests Ekoteks [illegible]sting La[illegible]orat[illegible]y BFE[illegible]
- Results of laboratory tests Ek[illegible]eks [illegible]ting Lab[illegible]atory Differential Pressure
- Results of laboratory t[illegible] Ekoteks Te[illegible]ing Labo[illegible]tory Mi[illegible]robial Cleanliness

MARKİNG, LABEL[illegible]İNG

Annex I, §13[illegible] the [illegible]dic[illegible] Devices Di[illegible]tive (93[illegible]42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/74[illegible] specifi[illegible] the [illegible]formation [illegible]at should be specified on the packaging in which the medical face m[illegible]k is [illegible]oplie[illegible] Th[illegible]llowi[illegible]n[illegible]for[illegible]tion shall be supplied:
[illegible]pe of m[illegible]k (a[illegible]ndicate[illegible] in Table 1). EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be co[illegible]idere[illegible]

ME[illegible]SURES TO ENSURE CONFORMITY

The Pr[illegible]ucer / 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.

İlhan İBİŞ
General Manager
ISTANBUL 04/05/2020

CE

Certificate of Registration
2020

This is to certify that the registration of

IBISLER TEKSTIL SANAYI VE DIS TICARET ANONIM SIRKETI

B BLOK, NO: 5 ORHAN GAZI MAHALLESI TUNC CADDESI, ESENYURT,

ISTANBUL, TURKEY - 34522

with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd with the information provided by Ibisler Tekstil Sanayi Ve Dis Ticaret Anonim Sirketi

Owner/Operator Number	**10071588**
Date of Registration	**May 22, 2020**
Date of Expiration	**December 31, 2020**
US Agent	**Liberty Management Group Ltd.**
Device Listing Numbers	**See Annex**
Certificate Number	**3005220120**

This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Liberty Management Group Ltd. is not affiliated with the U.S. Food and Drug Administration.

LMG LIBERTY MANAGEMENT GROUP LTD.

75 Executive Drive, Aurora, Illinois, USA

www.fdahelp.us

Manoj Zacharias

President

Liberty Management Group LTD.

Dated: June 11, 2020

Certificate of Registration
2020

Annex - Device Listings

Listing Number	Code	Device Name - Proprietary Names
D404264	OEA	Non Surgical Isolation Gown - A&Z Med Gown, A&Z Med Coverall
D404263	QKR	Face mask (except N95 respirator) for general public healthcare personnel per IIE guidance - A&Z Med Mask

This is to Certify that

BVCS
BRITISH VERITAS CERTIFICATION SERVICES

A&Z A&ZMED

İBİŞLER TEKSTİL SAN. VE DIŞ TİC. A.Ş.

ORHANGAZİ MAH. TUNÇ CAD. NO:5/B ESENYURT / İSTANBUL,TURKEY

Conforms to the Requirements of

ISO 9001:2015

Quality Management System

Tulum ve Medikal Maske Dikimi ve Satışı.

Jumpsuit and Medical Mask Sewing and Sale .

Certificate Number : Q.020.080.TR
Certification Period : 3 Years / 16.04.2023

Expiry Date : 17.04.2023
Certified Date : 17.04.2020

Approving Officer:

A. Ozgun

BRITISH VERITAS CERTIFICATION SERVICES
BVCS
CERTIVICATION
www.bvcscert.com

HMI Certification Training Ltd.
492 Bearwood Rd, Smethwick B66 4HB, Birmingham / West Midland - England
This certificate remains the property of HMI it is valitidy is subject to arrangement between the certificated client and HMI. For further detalis go to
www.bvcscert.com

This is to Certify that

BVCS
BRITISH VERITAS CERTIFICATION SERVICES

A&Z A&ZMED

İBİŞLER TEKSTİL SAN. VE DIŞ TİC. A.Ş.

ORHANGAZİ MAH. TUNÇ CAD. NO:5/B ESENYURT / İSTANBUL,TURKEY

Conforms to the Requirements of

ISO 13485:2016

Medical Device Quality Management System

Tulum , Medikal Önlük ve Medikal Maske Dikimi ve Satışı.

Jumpsuit,Medical Gowns and Medical Mask Sewing and Sale .

Certificate Number	: M.020.080.TR	**Expiry Date**	: 17.04.2023
Certification Period	: 3 Years / 16.04.2023	**Certified Date**	: 17.04.2020

Approving Officer:

BRITISH VERITAS CERTIFICATION SERVICES
BVCS
CERTIVICATION
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EKOTEKS LABORATUVAR ve GÖZETİM
HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

TEST REPORT
DENEY RAPORU

20013151-ing
04-20

Customer name:	
Address:	İBİŞLER TEKSTİL SAN. VE DIŞ TİC A.Ş ORHANGAZİ MAH. TUNÇ CAD. NO:5 HADIMKÖY ESENYURT/İSTANBUL
Buyer name:	-
Contact Person:	SALİH KAŞMER
Order No:	-
Article No:	-
Name and identity of test item:	Blue mask
The date of receipt of test item:	16.04.2020
Re-submitted/re-confirmation date:	-
Date of test:	16.04.2020-27.04.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	Men's &Women's&Kid's Wear / Mask
Care Label:	Not Specified
Number of pages of the report:	5

Seal TESTED BY EKOTEKS TEST EDİLMİŞTİR

Date
27.04.2020

Customer Representative
Hatice ACARALP

Head of Testing Laboratory
Sevim A. RAZAK
27.04.2020

Gen.f136-1/03

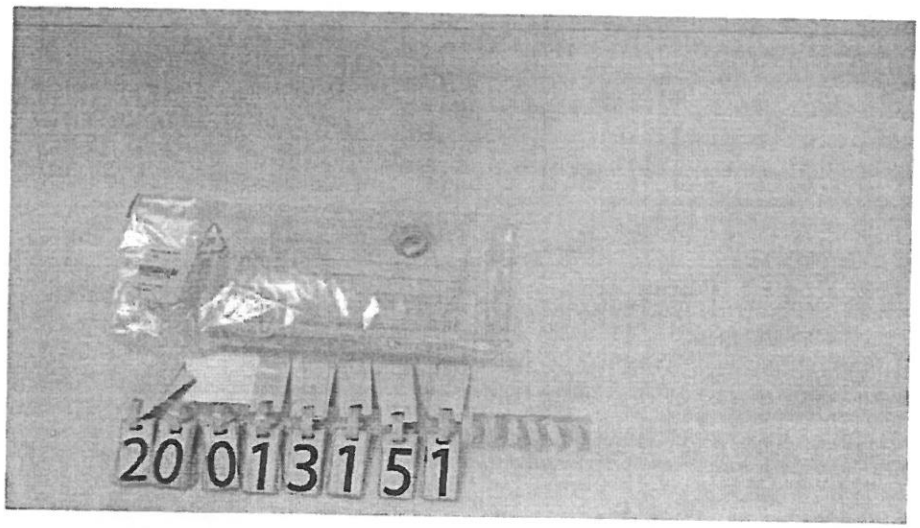
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20013151-ing
04-20

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
Breathability (Differential Pressure) [3]	P	
MICROBIOLOGICAL TEST		
Bacterial Filration Efficiency (BFE) [1]	P	**Type 2**
Microbial Cleanliness (Bioburden) [2]	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
[1]Test results were evaluated according to EN 14683:2019+AC:2019 Annex-B/Table- 1)limit values
[2]Test results were evaluated according to EN ISO 11737-1:2018 limit values
[3]Test results were evaluated according to EN 14683:2019+AC:2019 Annex -C/Table- 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.



Gen.f136-2/03

TEST RESULTS

BREATHABILITY (Differential Pressure)

Test Method : EKOTEKS 70 - Ref: EN 14683:2019+AC:2019 Annex-C (*)

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 .

	RESULT	REQUIREMENT
Differential Pressure) (Pa/cm^2)	24.6 Pa/cm^2	< 40 Pa/cm^2 Type I and Type II mask

TEST RESULTS

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metod: EKOTEKS 70 (In-House Method-Bacterial Filtration Efficiency Testing –BFE /Ref: EN 14683:2019+AC:2019 Annex B 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/dk
Test Flow Time	2 dakika
Sample Sizes	20x20 cm^2
Microorganism	*Staphylococcus aureus* ATCC 6538
Bacterial concentration (cfu/ ml)	$5x10^5$ kob/ ml
incubation conditions	24 saat, 35˚C ± 2˚C
Positive control sample average of number of Bacteria (C)	$1.96x10^3$ kob/ ml

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu/ml)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	25	**98.7 %**	**Type I ≥95** **Type II ≥98**
2	24	**98.8 %**	
3	24	**98.8 %**	
4	23	**98.8 %**	
5	23	**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 RESULTS

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: Ref: 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)	24 cfu/g	≤30 cfu/g Type I and Type II mask

***cfu= Colony forming unit.**