

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 665

**Electrostatic Protective Clothing against Infective Agents;
Type 5-B - Providing Protection to the Full Body against Airborne Solid Particulates
Type 6-B - Offering Limited Protective Performance against Liquid Chemicals**

İBİŞLER TEKSTİL SANAYİ VE DİŞ TİCARET ANONİM ŞİRKETİ

Orhangazi Mahallesi Tunç Cad. No: 5 34358 Etiler/Beşiktaş / İSTANBUL / TURKEY
are tested and evaluated according to

EN 14126:2003/AC:2004, EN ISO 13982-1:2004/A1:2010, EN 13034:2005+A1:2009, EN 149-5:2018

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: İZ MED, Model: OLI - 2021

Resistance to penetration by contaminated liquid under hydrostatic pressure: Class 3
Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids: Class 2
Resistance to penetration by contaminated liquid aerosols: Class 1
Resistance to penetration by contaminated solid particles: Class 2

The manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2)** or **Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on 08/05/2020 and will be valid for 5 years if there is no change in the relevant harmonised standard affecting the essential health and safety requirements

CE
2163



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



EU DECLARATION OF CONFORMITY

MANUFACTURER İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET ANONİM ŞİRKETİ

Orhangazi Mahallesi Tunç Caddesi No:5 34358 Esenyurt İSTANBUL / TURKEY
İSTANBUL / TURKEY

PRODUCT DESCRIPTION

A&Z MED – OLI - 2021 Model, Electrostatic Protective Clothing against infective agents;
Type 5-B - Providing Protection to the Full Body against Airborne Solid Particulates
Type 6-B - Offering Limited Protective Performance against Liquid Chemicals
with the following classification;

Resistance to penetration by contaminated liquids under hydrostatic pressure: Class 3

Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids: Class 2

Resistance to penetration by contaminated liquid aerosols: Class 1

Resistance to penetration by contaminated solid particles: Class 2

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

The Conformity is assessed with the following mechanism:

- Complies with EU 2016/425 Personal Protective Equipment Regulation establishing technical requirements for Category III products;
- Complies with Technical harmonised standards EN 14126:2003/AC:2004, EN ISO 13982-1:2004/A1:2010, EN 13034:2001/A1:2005, EN 1149-5:2018
- All required tests referred in above standards are conducted;
- Complies with other relevant harmonized legislative and community standards
- For the assessment of conformity the EU Type Examination certificate is issued, after all technical evaluations for conformity with the regulation and harmonised standards conducted, by;
UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co, as Notified Body, number 2163

MARKING, LABELLING

Marking, labelling and user information are prepared in accordance with EU 2016/425 Personal Protective Equipment Regulation and EN 14126. The information is supplied with the product considering EN ISO 15223-1:2016 and EN 1041:2008+A1:2013.

MEASURES TO ENSURE CONFORMITY

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

İlhan İBİŞ
General Manager
08/05/2020



2163



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 MAHALLESİ, TUNÇ CADDESİ, ESENYURT,
İSTANBUL, TÜRKİYE - 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	10070388
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.

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GROUP LTD.

75 Executive Drive, Aurora, Illinois, USA
www.fdahelp.us

A handwritten signature in black ink, reading "Manoj Zacharias".

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	OEZ	Non-Surgical Isolation Gown - A&Z Med Gown, A&Z Med Overall
D404263	QKR	Face mask (except N95 respirator) for general public health care personnel per IIE guidance - A&Z Med Mask

This is to Certify that



A&Z A&ZMED

İBİŞLER TEKSTİL SAN. VE DIŞ TİC. A.Ş.

ORHANGAZI 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. Cetgin



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

www.bvcsert.com

This is to Certify that



A&Z A&ZMED

İBİŞLER TEKSTİL SAN. VE DIŞ TİC. A.Ş.

ORHANGAZI 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
Certification Period : 3 Years / 16.04.2023

Expiry Date : 17.04.2023
Certified Date : 17.04.2020

Approving Officer:





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

TEST REPORT
DENEY RAPORU

20013152

04-20

EKOTEKS

Customer name: İBİŞLER TEKSTİL SAN. VE DİŞ TİC A.Ş
Address: ORHANGAZİ MAH. TUNÇ CAD. NO:5 ESENYURT/İSTANBUL
Buyer name: -
Contact Person: SALİH KAŞMER
Order No: -
Article No: -
Name and identity of test item: White protective overalls
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: -
Care Label: Not Specified
Number of pages of the report: 7



Date
27.04.2020

Customer Representative
Hatice ACARALP

Head of Testing Laboratory
Sevim A. RAZAK

27.04.2020

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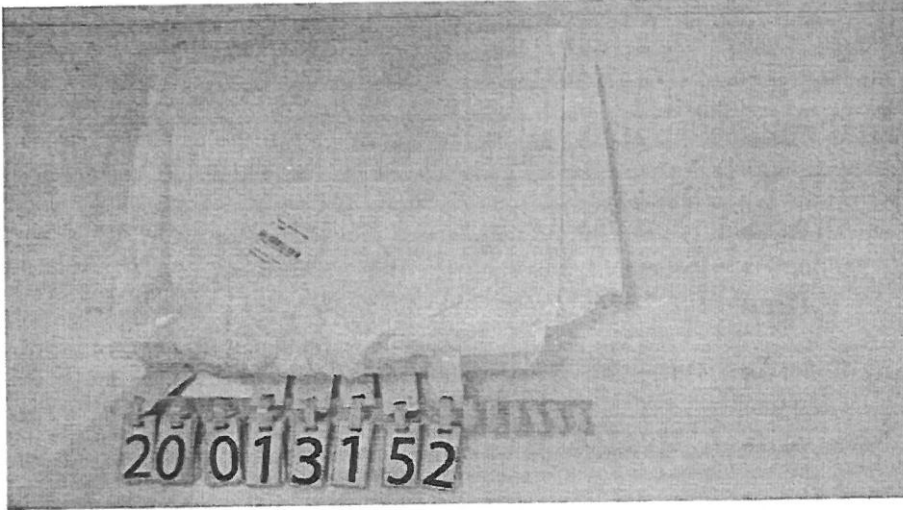
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20013152

04-20

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
Abrasion	-	Class 6
Water Permeability	P	See result
Tear Strength	-	Class 2
Tensile Strength	-	Class 1
Repellency to Liquids	-	See result
Resistance To Penetration By Liquids	-	See result
Seam Strength	-	Class 2
Accessory Strength	-	See result
Flammability ⁽¹⁾	F	See result
P: Pass F: Fail R: Refer to retailer technologist Tests were evaluated and classified according to BS EN 14325:2018 limit values. (1) Tests were evaluated EN 13274-4:2001-Method 2 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.



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TEST RESULTS

Test Method : BS EN 14325:2018 (PROTECTIVE CLOTHING AGAINST CHEMICALS:TEST METHODS AND PERFORMANCE CLASSIFICATION OF CHEMICAL PROTECTIVE CLOTHING MATERIALS,SEAMS,JOINS AND ASSEMBLAGES (*)

ABRASION RESISTANCE AND LEAK TIGHTNESS

Clause 4.4.Abrasion Resistance (EN ISO 12947-2) ANNEX-B

Martindale Test Machine (47.5±2 rpm) with Lissajous Figure.

9 kPa pressure,

Performed in the conditioned room (20±2°C-65%±4).

RESULT

No abrasion @ 450 revs

CLASS

4

Classified according to the
Table-1

Determination of the highest number of abrasion rubs which does not cause damage to the material and which shall be used for the performance classification.

The abrasion resistance of sample shall be Classified according to the levels of performance given in Table-1

Table-1 Classification of Abrasion Resistance

Class	Number of rubs
6	>2000
5	>1000
4	>400
3	>100
2	>40
1	>10

Clause 4.4.2.3 Hydrostatic head end –point determination (EN 20811)

If the average hydrostatic head exceeds 200mm,then the hydrostatic head method is applicable and the leak tightness shall be determined.

WATER PERMEABILITY ; EN ISO 811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model

Temperature of water 10.°C. Pressure increase ratio 10 mbar/dk.

Performed in the conditioned room (20±2°C-65%±4)

RESULT

Sample 1 576.3 mm SS
Sample 2 1683.0 mm SS
Sample 3 1305.6 mm SS
Sample 4 1683.0 mm SS
Sample 5 L.S.
Average 1312.0mm SS
L.S.: Lack of Sample

REQUIREMENT

>200 mmSS

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TEST RESULT

TRAPEZOIDAL TEAR STRENGTH

Clause: 4.7.Trapezoidal Tear Resistance TS EN ISO 9073-4:2002(*)

Instron 5969 Speed:100±10 mm/min, Gauge length:5cm

The average results are given for width and length direction of five samples.

2 pre-tension applied

Performed in the conditioned room. (20±2°C - 65% ±4)

Width **RESULT**
35.7 N

Length 68.2 N

CLASS

1

Classified according to
the Table-4

Table-4 Classification of Trapezoidal Tear Resistance

Class	Tear Strength
6	>150 N
5	>100 N
4	>60 N
3	>40 N
2	>20 N
1	>10 N

TENSILE STRENGTH

Clause 4.9.Tensile Strength EN ISO 13934-1:2013

Instron 5969 (Load: 50 kN), Strip Method.

Speed: 100 mm/min±10, Gauge length 200 mm.

Pre-load was not applied. Without wetting samples.

The average results are given for width and length direction of five samples.

Performed in the conditioned room (20±2°C-65%±4).

Width **RESULT**
41.4 N

Length 83.9 N

CLASS

1

Classified according to
the Table-5

Table-4 Classification of Tensile Strength

Class	Tensile Strength
6	>1000 N
5	>500 N
4	>250 N
3	>100 N
2	>60 N
1	>30N

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**TEST RESULT
REPELLENCY TO LIQUIDS**

Clause 4.12 Repellency to Liquids (EN ISO 6530:2005)

When tested in accordance with EN ISO 6530 for repellency to the liquid chemicals given in Table -9, the material shall be classified According to the levels performance in given Table-10 for each chemical tested.
Use those liquids against which protection is required, water is also convenient and safe liquid for general screening purposes.
Performed in the conditioned room (20±2°C-65%±4).

For each test liquid ,cut six test specimens of (360±2)mm by (235±5)mm from the sample.
Chemicals shall be of analytical purity grade.
Discharged the test liquid (10cm 3) within (10±1)s

Table-9 List of reference chemicals for absorption ,penetration and repellency testing

Chemical	Concentration weight %	Temperature of chemical (±2°C)
Sulfuric Acid (H2SO4)	30	20
Sodium Hydroxide (NaOH)	10	20
o-Xylene	Undiluted	20

Table 10- Classification of Repellency to liquids

Class	Repellency Index (I _R)
3	> 90 %
2	>80 %
1	>70 %

Clause 4.13 Resistance to penetration by liquids (EN ISO 6530)

Table 11- Classification of Resistance to penetration by liquids

Class	Penetration Index (I _p)
3	< 1 %
2	< 5 %
1	<10 %

RESULT

Chemical	Concentration weight %	I _p	Class	I _R	Class
Sulfuric Acid (H2SO4)	30	0 %	3	95.7 %	3
Sodium Hydroxide (NaOH)	10	0 %	3	95.9 %	3
o-Xylene	Undiluted	4.5 %	2	80.6 %	2

I_p: index of penetration
I_R: index of repellency
I_A: index of absorbtion

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TEST RESULT

SEAM STRENGTH-GRAB METHOD

Clause 5.5 Seam Strength ISO 13935-2: 2014

Jaw Speed: 50±5 mm/min, Gauge Length: 100 mm±1 mm.

Seam Type : 301. 100 % Polyester core-spun sewing-thread was used.

5kN. load was applied.

The average results are given for width and length direction of five samples.

Performed in the conditioned room(20±2°C-65%±4)

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	<u>Seam Strength (N)</u>	<u>Fail</u>	<u>CLASS</u>
Sleeve	75.2 N	FTJ	1 Classified according to the Table-13
Crotch	54.2 N	FTJ	
Inner side seam	82.9 N	FTS	
Front center seam	68.2 N	FTS	
Back center seam	71.8 N	FTS	
Waist	77.3 N	FTJ	
Hat	63.3 N	FTS	

FTS : Fabric Tear At The Seam

FTJ : Fabric Tear At The Jaw

Table 13- Classification of Seam Strength

<u>CLASS</u>	<u>Seam strength</u>
6	>500 N
5	>300 N
4	>125 N
3	>75 N
2	>50 N
1	>30 N

ACCESSORY STRENGTH; ISO 13935-2: 2014

INSTRON 4411

Performed in the conditioned room(20±2°C-65%±4)

	<u>RESULT</u>	<u>Requirement</u>
Pull Strength	181.2 N	-

* No change in the sample was observed.

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TEST RESULT

FLAMMABILITY ;

Clause 4.14. Flammability Resistance EN 13274-4:2001(*)- Method 2

Conditioning	65±5 % RH, 20±2°C/24 hours
Test atmosphere	16-32° (±1°C)
Flame height	40± 4 mm
Gas type	Propane
Flame temperature	800±50°C
Flame application time	12 sec
RESULT	FAIL; Complete burning of sample during 12 sec. duration of flame application.

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