UNIVERSAL
CERTIFICATION

EU TYPE EXAMINATION CERTIFICATE

Certificate No:

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

EN 14126:2003/AC:2004, EN ISO 13982-1:2004/A1:2010, EN 13034:2005+A1:2009, EN 1149-5:2018

Based on the type examination connected with the evaluation of test reports and 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: Model:

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

PRODUCT DESCRIPTION

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 Personel Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Technical harmonised standards EN ISO 13982-1:2004/A1:2010, EN 13034:2005+A1:2009, 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 to 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

CE
2163

Certificate of Registration
2020

This is to certify that the registration of

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	
Date of Registration	May 22, 2020
Date of Expiration	December 31, 2020
US Agent	
Device Listing Numbers	**See Annex**
Certificate Number	

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
	OEA	
	QKR	

BVCS
BRITISH VERITAS CERTIFICATION SERVICES

This is to Certify that

A&Z A&ZMED

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 :

Certification Period : 3 Years / 16.04.2023

Expiry Date : 17.04.2023

Certified Date : 17.04.2020

Approving Officer:

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.

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	:	**Expiry Date**	: 17.04.2023
Certification Period	: 3 Years / 16.04.2023	**Certified Date**	: 17.04.2020

Approving Officer:

A. Otgu

BRITISH VERITAS CERTIFICATION SERVICES
BVCS
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EKOTEKS

TEST REPORT
DENEY RAPORU

04-20

Gen.f136-2/03

Customer name:	
Address:	
Buyer name:	-
Contact Person:	
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

TESTED BY EKOTEKS TEST EDİLMİŞTİR

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
	27.04.2020	Hatice AGARALP	Sevim A. RAZAK
			27.04.2020

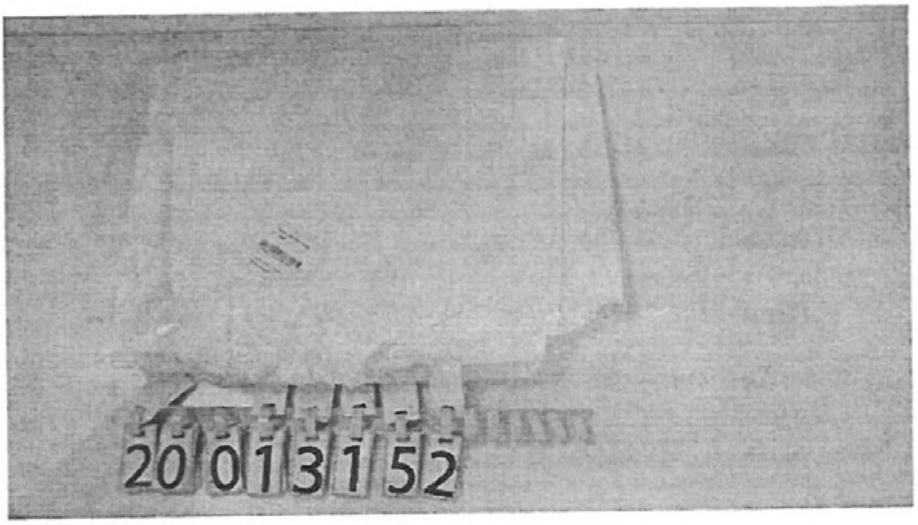
04-20

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

Gen.f136-2/03

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.



04-20

TEST RESULTS

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

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).

Gen.f136-2/03

RESULT	CLASS
No abrasion @ 450 revs	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 water10.°C. Pressure increase ratio 10 mbar/dk.
Performed in the conditioned room (20±2°C-65%±4)

	RESULT	REQUIREMENT
Sample 1	576.3 mm SS	>200 mmSS
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

04-20

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)

	RESULT	CLASS
Width	35.7 N	1 Classified according to the Table-4
Length	68.2 N	

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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 Strenght 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).

	RESULT	CLASS
Width	41.4 N	1 Classified according to the Table-5
Length	83.9 N	

Table-4 Classification of Tensile Strenght

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

04-20

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 cenvenient 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

Gen.f136-2/03

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 (Ip)*
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

04-20

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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	Seam Strength (N)	Fail	CLASS
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

CLASS	*Seam strength*
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)

	RESULT	Requirement
Pull Strength	181.2 N	-

* No change in the sample was observed.

04-20

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.

Gen.f136-2/03