CERTIFICATE OF REGISTRATION

SERTİFİKA
CERTIFICATE OF REGISTRATION

Bu sertifika aşağıdaki kuruluşa
This certificate has been awarded to the company

OFİS570 DIŞ TİCARET İTHALAT İHRACAT SANAYİ TİCARET LTD. ŞTİ.

Merkez/ Center: Adalet Mahallesi Manas Bulvarı No:39 Kat 34 Ofis 3408 Bayraklı/ İzmir/Türkiye
Üretim /Production :Tuna 5615/1 Sokak No :20/21 Bornova / İzmir / Türkiye

Uygulanmakta olan Kalite yönetim sisteminin
To certify that the implemented Quality
management system complies with

TS EN 14126/AC:2004

Koruyucu giyecekler - Enfektif ajanlara karşı koruyucu giyecekler için performans kuralları ve deney metotları- Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

Standardına uygunluğunu belgelendirmek
amacı ile aşağıdaki kapsamda verilmiştir.
For the activities described below

KORUYUCU GİYECEKLER (TEK KULLANIMLIK)
PROTECTIVE CLOTHING (DISPOSABLE)

Sertifika No. / Certificate No.:PC-2020-1293
İlk Belgelendirme Tarihi / Initial Certification Date : 18.05.2020
Sertifika Tarihi / Date of Certificate :18.06.2020
Bitiş Tarihi / Expiry Date :18.06.2021
Belgelendirme Periyodu / Certification Period :3 Yıl / Years

System Certification Approval
Certification Manager

IFC Global Certification İnspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
info@ifcglobal.de

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

Üretici / Manufacturer OFİS570 DIŞ TİCARET İTHALAT İHRACAT SANAYİ TİCARET LTD. ŞTİ.
Adres / Address Center: Adalet Mahallesi Manas Bulvarı No:39 Kat 34 Ofis 3408 Bayraklı/ İzmir/Türkiye
Production Address: Tuna 5615/1 Sokak No :20/21 Bornova / İzmir / Türkiye
Telefon / Phone +90 232 400 0 570
Web / E-mail info@office570.com

Ürün İsmi / *Product Name*.
KORUYUCU TULUM (TEK KULLANIMLIK) / PROTECTIVE COVERALL (DISPOSABLE)

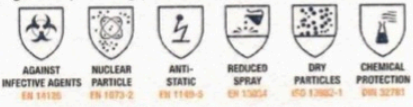
Ürün Tipi / Types of Product
TİP 4/5/6, LAMİNASYONLU ve LAMİNASYONSUZ / TYPE 4/5/6, LAMINATED and NON-LAMINATED

Beyan/Statement
Burada, AB tarafından sınıflandırılan Üretici, Dağıtıcı / Temsilci olarak kendi sorumluluğumuz altında, yukarıda ismi ve modeli geçen ürünlerin, (EU)2016/425 Kişisel Koruyucu Ekipmanlar Direktifi, 2001/95/EC (GPSD) Ürün Güvenliği Direktifi ve yönetmeliklerine uygun olarak üretildiğini beyan ederiz.
Here, under the responsibility of the EU Classified Manufacturer, Distributor / Representative, it is declared that the products mentioned above are manufactured in accordance with the (EU) 2016/425 Personal Protective Equipment Directive, 2001/95 / EC (GPSD) Product Safety Directive and Turkhish regulations.

Direktif ve Yönetmelikler / Directives and Regulations
(EU) 2016/425 Kişisel Koruyucu Ekipmanlar Direktifi / Personal Protective Equipment Directive
2001/95/EC (GPSD) Ürün Güvenliği Direktifi / Product Safety Directive

Ürünün Ticari Markası /Trade Mark
NOİR&BLANC

Harmonize Standartlar / Harmonized Standards
TS EN 14126 Koruyucu giyecekler - Enfektif ajanlara karşı koruyucu giyecekler için performans kuralları ve deney metotları- Protective clothing – Performance requirements and tests methods for protective clothing against infective agents
TS EN ISO 13982-1 Katı parçacılara karşı kullanılan koruyucu giyecekler - Bölüm 1: hava ile yayılan katı parçacıklı kimyasal maddelere karşı vücudun tamamına koruma sağlayan kimyasal koruyucu giyecekleri için performans kuralları -Protective clothing for use against solid particulate chemicals – Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airbone solid particulate chemicals
TS EN 13034+A1 Sıvı kimyasal maddelere karşı koruyucu giyecekler - Sıvı kimyasal maddelere karşı sınırlı koruma sağlayan koruyucu giyecekler için performans kuralları (tip 6 ve tip pb [6] donanımı)- Protective clothing against liquid chemicals – Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)
TS EN 1073-2 Radyoaktif bulaşmasına karşı koruyucu giysi-Kısım 2: Radyoaktif bulaşmasının ayrılmasına karşı havalanmayan koruyucu giysi için gereklilikler ve deney metotları- Protective clothing against radioactive contamination - Part 2: Requirements and test methods for airtight protective clothing against separation of radioactive contamination
TS EN 1149-5 Koruyucu giysi - Elektrostatik özellikler - Bölüm 5: Malzeme performansı ve tasarım gereksinimleri- Protective clothing – Electrostatic properties – Part 5: Material performance and design requirements
TS EN ISO 13688 Koruyucu giyecekler-Genel özellikler- Protective clothing - General requirements
TS EN 14605+A1 Koruyucu giyecekler - Sıvı kimyasal maddelere karşı - Vücudun sadece bir kısmına koruma sağlayanlar (tip pb [3] ve tip pb [4]) dâhil, bağlantı yerleri sıvı geçirmez (tip 3) veya sprey geçirmez (tip 4) giyecekler için performans özellikleri- Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])



Sertifika No/ Certificate No: 2020.CE-2998
Sertifika Tarihi /Certificate *Date*: 11.05.2020
Sertifika Bitiş Tarihi /Certificate Expiration *Date*: 11.05.2021

Accredited System Certification Approval

European Commission

IFC Global Certification İnspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
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CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFIKÁ

eurotesting

Product Testing & Analysis and Laboratory Services

EC ATTESTATION OF CONFORMITY

(EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT DIRECTIVE

CERTIFICATE NUMBER : PC-EU-2020-1254

Holder of Certificate OFİS570 DIŞ TİCARET İTHALAT İHRACAT SANAYİ TİCARET LTD. ŞTİ.

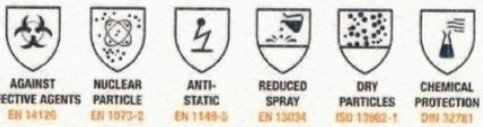
Address
Center: Adalet Mahallesi Manas Bulvarı No:39 Kat 34 Ofis 3408 Bayraklı/ İzmir/Türkiye
Production Address: Tuna 5615/1 Sokak No :20/21 Bornova / İzmir / Türkiye
0232 400 05 70 / info@office570.com

Kind of Equipment DISPOSABLE HOODED COVERALL (PROTECTIVE CLOTHING)

Trade Mark NOİR&BLANC

Type / Designation TYPE 4/5/6, LAMINATED and NON-LAMINATED

Harmonized Standards EN ISO 9001:2015,EN 13795-1, EN 14126 , EN ISO 13688, EN 14605+A1, EN 13034+A1, EN ISO 13982-1, EN 1073-2, EN 1149-5



Certificate *Date*: 24.04.2020

Certificate Expiration *Date*: 24.04.2021

CE

This certificate does not contain any explanation regarding the Personal Protective Equipment requirements governed by other laws to implement the EC directive other than the above (EU) 2016/425 council directive.

It certifies that the listed equipment complies only with the Concept protection for testing and sample and the principle protection requirements of apples and the technical documentation submitted to the Concept for testing and certification.

Seal and Date
24.04.2020

Certification Manager

MRUDULA BABAU

Eurotesting Product Testing & Analysis And Laboratory Services
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F.EU.023 / Rev.01-10.03.2019

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textile research institute

ENAC
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Nº12 / LE025
Nº12 / LE427

TEST REPORT

2020EP0639

DATE OF RECEPTION
09/03/2020

DATE TESTS
Starting: 10/03/2020
Ending: 23/04/2020

IDENTIFICATION AND DESCRIPTION OF SAMPLES

REFERENCES
JN2020 Type5/6 DISPOSABLE COVERALL

TESTS CARRIED OUT

- RESISTANCE TO FLAMING.
- RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY SYNTHETIC BLOOD.
- RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY BLOOD-BORNE PATHOGENS USING PHI-X174.
- RESISTANCE TO WET BACTERIAL PENETRATION
- FOR RESISTANCE TO DRY BACTERIAL BARRIER PENETRATION.

Tests marked with * are not included within the scope of the ENAC accreditation

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RESULTS

RESISTANCE TO FLAMING

Standard

EN 13274-4:2001 (Method 3). Moving burner test

Apparatus

PROTERMIC-TX 13043II2

Verification of the apparatus

Application flame. The thermometer submitted to test is mounted so that it she could go on across a flame to a temperature (800 ± 50) ºC to a speed of (60±5) mm/s

Test date

16/03/2020

Conditioned

24h. in indoor ambient conditions at (20 ± 2) ºC and (65 ± 5) % RH

Ambient conditions test

21,7ºC y 45,8% RH

Gas used

Propane

Observation or deviation from the standard

Face exposed to the flame

Outer surface

Uncertainty of test

± 0.06 s

>>>

RESULTS

Reference JN2020 Type5/6 DISPOSABLE COVERALL

Pre-Treatment Original

Specimen	1	2	3
After flame time (s)	No	No	No
Swollen drops	No	No	No

PERFORMANCE LEVEL ACCORDING EN 14325:2004	PASS

According to point 4.14 of the Norm EN 14325:2004 from the resistance to the inflammation, the material of the clothes must not form drops, must prove to be self extinguishing and must not continue burning during more than 5 seconds after withdrawing the flame

RESULTS

RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY SYNTHETIC BLOOD

Standard: ISO 16603:2004 Procedure: C

Principle:

A specimen is subjected to a body fluid stimulant (synthetic blood) for a specified time and pressure sequence. A visual observation is made to determine when, or if, penetration occurs. Any evidence of synthetic blood penetration constitutes failure. Results are reported as PASS / FAIL.
In the method, the specimen is inserted in the penetration cell with the normal outside surface of the textile towards the cell reservoir which is further filled with synthetic blood. The other face is in contact with retaining screen (which ensures a good bearing of the textile during the pressure application).

The pressure application procedure is the following:

- 0 KPa for 5 min
- 1,75 KPa for 5 min
- 3,5 KPa for 5 min
- 7 KPa for 5 min
- 14 KPa for 5 min
- 20 KPa for 5 min

Test date: 04/04/2020

Environmental condition: 21 ºC and 30 % H.R

Tested side: External side

Pretreatment: ---

RESULTS

RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY SYNTHETIC BLOOD

Results:

Reference of the sample	JN2020 Type5/6 DISPOSABLE COVERALL		
Results	**Replicate 1**	**Replicate 2**	**Replicate 3**
0 KPa for 5 min	PASS	PASS	PASS
1,75 KPa for 5 min	PASS	PASS	PASS
3,5 KPa for 5 min	PASS	PASS	PASS
7 KPa for 5 min	PASS	PASS	PASS
14 KPa for 5 min	PASS	PASS	PASS
20 KPa for 5 min	PASS	PASS	PASS
Retaining screen specifications	Not used		

RESULTS

RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY BLOOD-BORNE PATHOGENS USING Phi-X174

Standard: ISO 16604:2004.

Procedure: C.

Principle:

In the method, the material is placed in the test cell. The good side of the test material is directly in contact with a suspension of bacteriophage (phi-X174) After assembly, the cell is placed in the apparatus as defined in the standard and the corresponding pressure is applied:

- 5 minutes in contact without pressure application.
- 5 minutes at 20 kPa.

End of test, the sample surface that has not been in contact with the bacteriophage suspension is clarified. The rinsing liquid is then placed on an agar plate which has previously been inoculated with *Escherichia coli* (used as host bacteria of bacteriophage).The plates are incubated for 24 hours at 37 ° C, the presence of colonies on the agar surface means that the bacteriophage has passed through the sample.

Results are expressed in the form: PASS or FAIL test. The detection of only one plaque constitutes a failure of the textile.

Date test: 06/04/2020 – 08/04/2020

Sample reference: JN2020 Type5/6 DISPOSABLE COVERALL

Dimension of the test specimens: 7,5 cm x 7,5 cm.

Bacteriophage: Bacteriophage Phi-X174 (ATCC 13706-B1).

Host bacteria of the used of bacteriophage: *Escherichia Coli* (ATCC 13706).

Retaining screen: not use.

Bacteriophage concentration:

- Starting: $2.87 \cdot 10^8$ (PFU/ml).
- Ending: $2.21 \cdot 10^8$ (PFU/ml).

Compatibility ratio: 1,06

RESULTS

RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY BLOOD-BORNE PATHOGENS USING Phi-X174

Results:

Reference	Test 1	Test 2	Test 3
JN2020 Type5/6 DISPOSABLE COVERALL	PASS (-)	PASS (-)	PASS (-)
Negative Control	(-)	(-)	(-)
Positive Control	(+)	(+)	(+)

Remarks:

- Symbols used in the table of results meaning the following:

  (+) = Penetration of bacteriophages.

  (-) = No penetration of bacteriophages.

- In accordance with the standard point 4.1.4.1, the product should be classify as **CLASS 6** according with the following table:

Table of classification of resistance to penetration of contaminated liquids under hydrostatic pressure.

Class	Hydrostatic pressure at which the material passes the test
6	20 kPa
5	14 kPa
4	7 kPa
3	3,5 kPa
2	1,75 kPa
1	0 kPa[a]

[a] Means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell.

RESULTS

RESISTANCE TO WET BACTERIAL PENETRATION

Standard

EN 14126:2003; EN ISO 22610:2006

Test date

22/04/2020 - 23/04/2020

Verifications of equipment operation performed

-Adjustment of the force of the finger to 3 ± 0,02 N according to point 8.3.
-Verification with carbon paper according to point 10.2.
-Verification with reference material according to point 10.3.

Environmental conditions

- Temperature (ºC): 21
- Relative humidity (%): 38

Distance from the agar surface to the edge of the Petri dish (mm):

3

Size specimens:

25 cm x 25 cm

Carrier material

Material de PU (Schuett-biotec GmbH)

Staphylococcus aureus suspension ATCC 29213 (CECT 794) (cfu/mL)

49,000

Nº tested specimens

5

Pre-treatment

>>>

RESULTS

Sample reference

JN2020 Type5/6 DISPOSABLE COVERALL

Batch n°

Results

Replica	1	2	3	4	5
Test time	**ufc**	**ufc**	**ufc**	**ufc**	**ufc**
15 min	14	21	6	51	0
30 min	1	15	12	1	1
45 min	3	0	3	3	0
1 h	3	1	0	5	0
1h 15min	2	0	0	5	0
Test specimen upside down	244	458	158	314	90
cfu/plate maximum	14	21	12	51	1

Calculated barrier index I_B

Replica	1	2	3	4	5	Average[(2)]
I_B	5,7	5,7	5,5	5,3	6,0	**5,6** ± 0,2

Remarks

- [(2)]Average value (n = 5) ± U (extended uncertainty) for a probability of coverage of 95%

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RESULTS

Remarks
In accordance with the standard point 4.1.4.4, the product should be classify as **CLASS 1** according with the following table:

Table.Classification of resistance to penetration of biological agents by mechanical contact with substances containing contaminated liquids.

Class	Penetration time (t min)
6	t > 75
5	60 < t ≤ 75
4	45 < t ≤ 60
3	30 < t ≤ 45
2	15 < t ≤ 30
1	≤ 15 min

- [(1)]Data provided by the Customer.

_____///

RESULTS

Sample reference

JN2020 Type5/6 DISPOSABLE COVERALL

Batch number[(1)]

Results

Test pieces	ufc
1	9
2	28
3	8
4	7
5	31
6	61
7	-
8	1
9	7
10	3
Average	17,22

Remarks:

In accordance with the standard normareqselected_val, the results must be in the values of the following table, taking care of the application of the product:

Table of Performance requirements for surgical gowns and drapes.

Characteristic	Unit	Requirement
Resistance to microbial penetration- Dry	**CFU**	**≤ 300[a]**

Test conditions: challenge concentration 10^8 cfu/g talc and 30 minutes vibration time.

///

RESULTS

TEST METHOD FOR RESISTANCE TO DRY BACTERIAL BARRIER PENETRATION

Standard
EN ISO 22612:2005

Test date
06/04/2020 - 07/04/2020

Principle

The test is carried out on test pieces fixed each in a container. In each container except one a portion of talc contaminated with Bacillus subtilis is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at base of each container at a short distance below the test piece.

The apparatus supporting the containers is then brought into vibration by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate. The sedimentation plates are removed and incubated; the numbers of colonies produced are counted.

Equipment

- 9 cm diameter Petri dishes containing TGE agar.
- 50 g of talc (95% < 15µ).
- Purified spores of Bacillus subtilis in a concentration of $8,5 \cdot 10^8$ ufc/g talc.
- 12 test pieces 20x20 cm, of reference barrier material.

Pre-treatment

>>>

EU type certificate

CERTIFICATE No. 20/2482/00/0161

PPE TYPE COVERALL
REF: JN2020 Type5/6 DISPOSABLE COVERALL

AITEX, Notified Body No. 0161 for the application of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016, in which the essential health and safety requirements that Personal Protective Equipment (PPE) must comply with.

ASOCIACIÓN DE INVESTIGACIÓN DE LA INDUSTRIA TEXTIL (AITEX)
Plaza Emilio Sala, 1 · Alcoy (Alicante) 965542200 · info@aitex.es
www.aitex.es

CERTIFICATE No. 20/2482/00/0161

Has obtained EU TYPE EXAMINATION in compliance with what is stated in Regulation (EU) 2016/425 and in agreement with the applicable test procedures and technical specifications

Intended for the protection of the entire body of the user, with the exception of the head, hands and feet, according to the following standard/s:

- EN 340:2003 y EN ISO 13688:2013 General requirements
- EN 1149-5:2018 against the risk of accumulation of electrostatic loads according the standard EN 1149-3:2004.
- EN 13034: 2005 + A1: 2009 for protection against chemical risks as a complete suit (**type [6]**) against chemical liquids sodium hydroxide (10%), sulfuric acid (30%) and 1-Butanol
- EN ISO 13982-1: 2004 / A1: 2010 for the protection against risks of penetration of solid particles suspended in the air as a complete path (**type 5**) according to EN ISO 13982-2: 2004.

Having achieved the performance requirements specified in Technical Test Report No. **2020EP0205UE** and the PPE's Technical Documentation.

Description of the PPE:

Coverall made in white non-woven fabric with an exterior white laminated.

The materials that form the PPE, are described in the technical report nº 2020EP0205UE.

It shall be the manufacturer's responsibility to provide specific information of this certificate and the tested levels of protection.

The CAT. III PPE shall only be used in conjunction with one of the conformity assessment procedures according to module C2 or module D described in article 19 letter c) of the Regulation (EU) 2016/425.

Digitally Signed by: Silvia Devesa
Date: 23/03/2020 16:31:15
Location: Alcoy

Silvia Devesa Valencia
Laboratory Subdirector and Innovation

Date of issue of the Certificate: 23rd of March 2020
Date of expiry: 23rd of March 2025

Lucia Martinez
Head of PPE and Ballistics department

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1.- AITEX is liable only for the results of the methods of analysis used, as expressed in the report and referring exclusively to the materials or samples indicated in the same which are in its possession, the professional and legal liability of the Centre being limited to these. Unless otherwise stated, the samples were freely chosen and sent by the applicant.
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3.- The Offer and / or Order to which the applicant gives approval through signature and seal, constitutes the Legally Executable Agreement in which AITEX is responsible for safeguarding and guaranteeing the absolute confidentiality of the management of all the information obtained or created during the performance of the contracted activities.
4.- In the eventuality of discrepancies between reports, a check to settle the same will be carried out in the head offices of AITEX. Also, the applicants undertake to notify AITEX of any complaint received by them as a result of the report, exempting this Centre from all liability if such is not done, the periods of conservation of the samples being taken into account.
5.- AITEX is not responsible for the information provided by customers, which is reflected in the Report, and may affect the validity of the results.
6.- AITEX will provide at the request of the person concerned, the treatment of complaints procedure.
7.- AITEX is not responsible for an inadequate state of the sample received that could compromise the validity of the results, expressing such circumstance, in the test reports.
8.- AITEX may include in its reports, analyses, results, etc., any other evaluation which it considers necessary, even when it has not been specifically requested.
9.- When a Declaration of Conformity is requested, if not indicated otherwise, the decision rule will be applied according to ILAC-G8 & ISO 10576-1, in case of ambiguity, or indeterminacy
10.- The uncertainties of tests, which are made explicit in the Results Report, have been estimated for a k = 2 (95% probability of coverage). If not informed, they are available to the client in AITEX.
11. - The original materials and rests of samples, not subject to test, will be retained in AITEX during the twelve months following the issuance of the report, so that any check or claim which, in his case, wanted to make the applicant, should be exercised within the period indicated.
12.- This report may only be sent or delivered by hand to the applicant or to a person duly authorised by the same.
13.- The results of the tests and the statement of compliance with the specification in this report refer only to the test sample as it has been analyzed / tested and not the sample / item which has taken the test sample.
14.- The client must attend at all times, to the dates of the realization of the tests.
15.- According to Resolution EA (33) 31, the test reports must include the unique identification of the sample, and any brand or label of the manufacturer may be added. It is not allowed to re-issue test reports of untested sample names (references), they can only be re-issued for error correction or inclusion of omitted data that were already available at the time of the test. The laboratory can not assume responsibility for declaring that the product with the new trade name / trademark is strictly identical to the one originally tested; This responsibility belongs to the client.