CE **EC - DECLARATION OF CONFORMITY**

MANUFACTURER	PPE DESCRIPTION	APPROVED BODY
Type 5 / Type 6 Protective Coveralls	CHEMICAL PROTECTION COVERALL WITH HOOD	NVA



MİRBEY GROUP SAN.LTD.ŞTİ declares that this product complies with the following regulations:

Identification of the PPE object of the declaration: MİRMED COVER TYP 5/6

Chemical Protective Coverall

: Nonwoven chemical Protection with hood/ Single Use Designation

Colour : White

Size : S, M, L, XL, 2XL, 3XL

: Microporous laminated non-woven overall with elasticade hood. Specifications

Fastening with zip under flap. Elasticated round head, waist, cuffs and ankles. Individual pack.

EU DECLARATION OF CONFORMTY

This declaration of conformity is ussued under the sole responsibility of the manafacturer. The object of the declaration identified above is in conformity with the relevant Union harmonisation legislation: EU 2016/425 Regulation, with its requirements and with the harmonised standards:

Is in conformity with the provisions of Council Directive 89/686 EEC, and where such is the case, with the national harmonized standarts;



EN ISO 13688:2013 -Protective clothing - Requerements



EN 1073-2:2003 - Protective clothing aganist radioactive contamination



EN 13982-1:

EN ISO 13982 - 1:2004 + A1 : 2010 Type 5 -Protective clothing for use against solid particulates Type 5



:2003/AC:2004

EN 14126:2003+AC:2004 - Protective clothing aganist infective agents Types 3B,4B,5B,6B



EN 13034:

2005+A1:2009

Type 6

EN 13034:2005+A1:2009 Type 6 -Protective clothing aganist liquid chemicals



EN 1149-5:2008 - Protective clothing-Electrostatic properties-

Notified body which performed the EU Type - Examination (module B) and issued

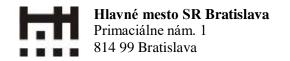
EN type - examination certificate: CE NVA

The PPE is subject to teh conformity assessment procedure to type based on internal production control plus supervised product checks at random intervals (moduleC2) under surveillance ot the notified body

OZNAČENIE:
K

POZNÁMKA: Rok výroby je uvedený na štítku balenia na každom kartóne alebo krabici.

OBLASTI POUŽITIA:
OBMEDZENIA:
VAROVANIA:
VAROVANIA.
AKO NOSIŤ OCHRANNÝ ODEV:
V
SKLADOVANIE A LIKVIDÁCIA:
EXSPIRÁCIA:



Príloha č. 2 - Návrh na plnenie kritéria na vyhodnotenie ponúk a identifikačné údaje uchádzača

Obchodné meno uchádzača: MPV Group, s.r.o.

Sídlo uchádzača: Cesta pod Hradovou 22, 040 01 Košice

IČO: 46 667 407

Meno a priezvisko štatutárneho zástupcu Mgr. Mária Puškárová

IČ DPH: SK2023519927

Názov banky: Všeobecná úverová banka a.s.

Číslo účtu (IBAN):
Telefónne číslo: +421

E-mailová adresa: obchod@zdravotnetesty.sk

Predmet zákazky: "Ochranné obleky s kapucňou"

Kritérium na vyhodnotenie ponúk: najnižšia cena za celý predmet zákazky v EUR s DPH.

Celková cena za predmet zákazky v EUR bez DPH	Výška DPH	Celková cena za predmet zákazky v EUR s DPH
Ochranné obleky s kapucňou na jednorazové použitie v celkovom množstve 10.000 ks v súlade s opisom predmetu zákazky tejto výzvy č. 14	20% = 11 600,00 €	69 600,00 €

Z toho:	Cena v EUR bez DPH	Výška DPH	Cena v EUR s DPH
Ochranné obleky s kapucňou v množstve 8 000ks (veľkosť 2XL)	46 400,00 €	9 280,00 €	55 680,00 €
Ochranné obleky s kapucňou v množstve 2 000ks (veľkosť 3XL)	11 600,00 €	2 320,00 €	13 920,00 €

Cena uvedená uchádzačom obsahuje všetky náklady, ktoré uchádzačovi vzniknú v súvislosti s plnením predmetnej zákazky.

Som – Nie som platiteľom DPH (nehodiace sa preškrtnite)

Ak uchádzač nie je platiteľom DPH, na túto skutočnosť upozorní verejného obstarávateľa. Ak uchádzač nie je platcom DPH, ním uvedená cena bude považovaná za konečnú aj v prípade, ak by sa počas plnenia predmetu zákazky stal platiteľom DPH. V prípade, ak uchádzač je platiteľom DPH, avšak jeho sídlo je v inom členskom štáte EÚ alebo sídli mimo EÚ, uvedie v ponuke cenu, ktorá bude rozdelená na ním navrhovanú cenu bez DPH, výšku DPH a aj cenu s DPH podľa slovenských právnych predpisov (20%), aj keď samotnú DPH nebude fakturovať.

V Košiciach, dňa 5.1.2021

Mgr. Mária Puškárová





vProtect

Disposable Coverall

Photo Model General Features



Full body protection
CE Certified (EN 14126:2003+AC:2004)
Certified by European Notify Body 0493 Centexbel
Intertek Certified Superior Coverall Fabric
Aunotomic relax fit
Designed to decrease Heat Stress









vProtect



TYPE 5/6 CLASSIC COVERALL

CLOTHING CATEGORY III





Type 5
EN ISO 13982-1
Dry particle suits
for protection against

hazardous dry particle



Type 6 EN ISO 13034 Protection against liquid chemical products



Anti-static EN ISO 1149-5 Certified workwear with anti-static properties.



Anti-hazard

EN ISO 14126
Protection against biological hazards and inactive agents









(IT IS DISPOSABLE



In application of the Regulation (EU) 2016/425 of 9 March 2016 concerning the harmonization of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorized by the FPS Economy (Federal Public Services) has issued the following:

EU TYPE EXAMINATION CERTIFICATE

Nr

This EU Type examination certificate is valid until 18 Aug 2021

o: Ofer Dis Ticaret Ltd. Sti., Bursa

for: Vprotect disposable coverall -

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Regulation (EU) 2016/425.

For the argumentation, the following standards are used:

EN 14126:2003+AC:2004 Protective clothing - Performance requirements and tests methods for protective clothing

against infective agents

EN ISO 13688:2013 Protective clothing - General requirements

The personal protective equipment mentioned above satisfies the applicable essential safety requirements of the Regulation (EU) 2016/425.

The alternative test protocol that was used for testing ensures an adequate level of protection according the COMMISSION RECOMMENDATION (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat. The personal protective equipment mentioned above may only be used by healthcare personnel and only for protection against Covid-19. The EU Type examination certificate has an amended and limited validity of 1 year.

This is PPE of category III, subject to regular checks in accordance with article 19 of the European PPE Regulation. In agreement with the manufacturer's choice supervised product checks at random intervals shall be carried out to assess the quality of the final product (Module C2). The manufacturer must be able, on request, to present the test report of this quality control check. A first quality control check shall be performed at the latest on 31 Dec 2021 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical documentation (As described in 2016/425 Annex III) that is registered with number 12867.

This certificate has been drawn up in accordance with the general certification regulation of Centexbel which is available via https://www.centexbel.be

Issued by Centexbel, Notified Body 0493, in Ghent, on 18 Aug 2020

Inge Certification Manager

Certification ividiage

Attached: 1 Annex



Technologiepark 70 • BE 9052 Gent • Belgium • phone +

gent@centexbel.be • www.centexbel.be

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45 • BIC • GEBABEBB





EN 14126 Standard Overview

When choosing a garment for protection against viruses like corona virus the one that causes COVID-19, it's important to know which regulatory standard exist to help ensure proper protection.

EN 14126 is a standard for performance requirements and tests methods for protective clothing against infective agents measures the ability of a suit to protect users against bacteria, fungi and viruses.

The EN 14126 uses special test methods to measure the penetration resistance of the garment and its material to infective agents using various kinds of exposure.

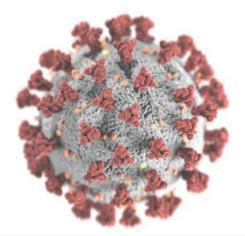
Protective clothing against infective agents has two main functions:

- to prevent infective agents from reaching the (possibly injured) skin;
- to prevent the spreading of infective agents to other people and other situations, e.g. eating or drinking, when the person has taken his protective clothing off.

According to the EU Regulations; EN 14126 certified garments must carry following pictogram.



The size viruses vary in diameter from 20 nanometres (nm; 0.0000008 inch) to 250–400 nm, due to its small size, virus can easly pass through the pinholes of ordinary protective garments. EN 14126 certified Garments, however, are proven to act as an effective barrier even against small viruses such as viruses like the one that causes Covid 19.







Technical Data Sheet []

DISPOSABLE PROTECTIVE COVERALL

Size And Description

DISPOSABLE PROTECTIVE COVERALL

Sterile

NO

Intended sterilization method

E.O

Country Of Origin

TURKEY

Transport Box Quantity

50 PCS

Pallet Quantity

800 PCS

Standard

EN 13795-1:2019 Standart Performance

EN ISO 10993-1:2009 EN ISO 10993-7:2008 EN ISO 14971:2012 EN ISO 9001:2009 EN ISO 13485:2012 EN ISO 15223-1:2012

Label of Standard

Material data

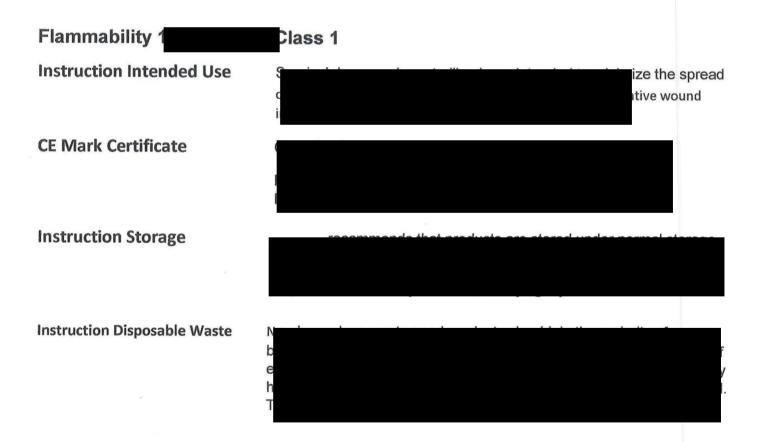
Table 1. Material Composition 2-ply laminate.

Charasteristic	Unit	Mean value	Colour
Total weight (cosist of)	g/m²		
PP SB nonwoven	g/m²		and the same of th
Hotmelt	g/m²		
Non-Breathable Cast PE Film	g/m²		

Table 2. Product Performance according to EN 13795-1:2019 (tests performed after sterilization)

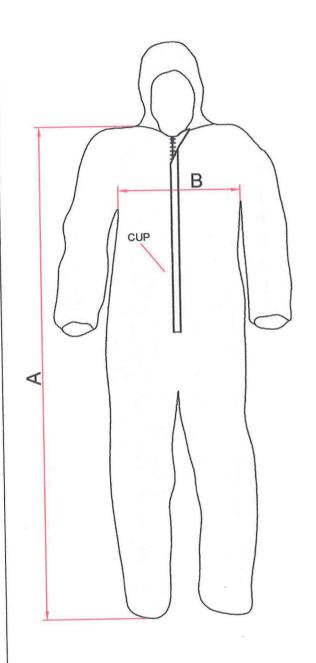
Characteristic	Characteristic Standard Unit	Unit	Requirement Proc Performance	roduct ce	
			Less Critical area	Critical area	
-				1	
				-	
				-	
-				-	
-					
				-	
			roquirou		

Product fulfill product performance requirements for critical product area.



REF NO:

DISPOSABLE PROTECTIVE COVERALL



Size	Person's Length (Cm)	Person's Chest (Cm) (B)	Coverall Length (Cm) (A)
M			
L			
XL			
	Toler	ance ± 3	



Annex - certificate

Page 1 of 3

ANNEX

EU TYPE EXAMINATION CERTIFICATE Nr. 0

1. Applicant

Ofer Dis Ticaret Ltd. Sti. Vatan Mh. 10.Deniz Sk. - No:35A Yildirim, 16270 Bursa Turkey

2. Description

EN 14126:2003



3. Materials and accessories

-	-	•		•
<i>r</i> 1:	uter	+-	ю	
v		10		

Seam

•

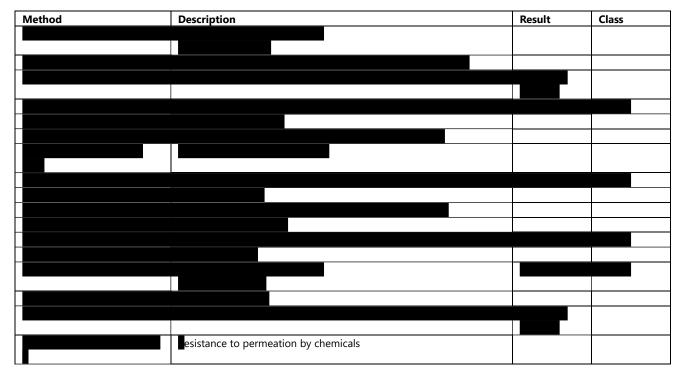


Annex - certificate Page 2 of 3

4. Technical documentation

Summary test results







Method	Description	Result	Class



Method	Description	Result	Class
E			

CENTEXBEL • TEXTILE COMPETENCE CENTRE

Technologiepark 70 • BE 9052 Gent • Belgium • phone +

gent@centexbel.be • www.centexbel.be





Ofer Dis Ticaret Ltd. Sti. Mr. Omer F Eldemir Vatan Mh. 10.Deniz Sk. - No:35A Yildirim, **16270 BURSA** Turkey

Your notice of 02-06-2020

Your reference

Date 06-08-2020

Analysis Report

Required tests:

ISO 13934-1 (2013) Determination of the breaking strength and elongation ISO 13935-2 (2014) Determination of the seam strength on existing seam - Grab

method

ISO 9073-4 (1997) **Determination of tearing resistance - method of trapezoid**

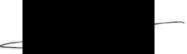
EN 863 (1995) **Determination of the puncture resistance**

ISO 3071 (2005) Determination of the pH of an aqueous extract Centexbel Whole suit requirements - visual inspection seams

ISO 16604 (2004) Resistance to penetration by blood-borne pathogens – Test

method using Phi-X174 bacteriophage

Identification Information given by the client Date of receipt number Vprotect Disposable Coverall -(with taped seams) 02-06-2020



Hilde Rubben Order responsible

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• info@vkc.be





Analysis Report 2 Date 06-08-2020 Page 2/9

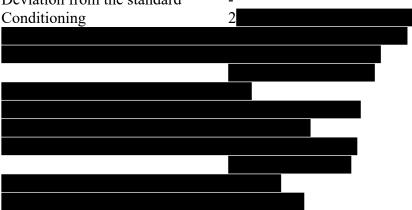
- Vprotect Disposable Coverall - (with taped seams) Reference:

Determination of the breaking strength and elongation

Date of ending the test 03-08-2020

Standard used ISO 13934-1 (2013) Product standard EN 14325 (2018)

Deviation from the standard



Conditioned

	Length	direction	Width o	lirection
Specimen	Force (N)	Elongation (%)	Force (N)	Elongation (%)







Analysis Report Date 06-08-2020 Page 3/9

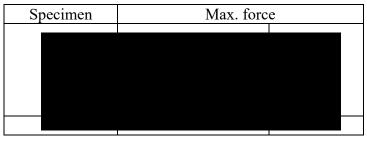
Vprotect Disposable Coverall - (with taped seams) Reference:

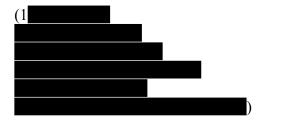
Determination of the seam strength on existing seam - Grab method

Date of ending the test 03-08-2020

Standard used ISO 13935-2 (2014) Product standard EN 14325 (2018)











Analysis Report Date 06-08-2020 Page 4/9

break.

- Vprotect Disposable Coverall - (with taped seams) Reference: Determination of tearing resistance - method of trapezoid Date of ending the test 03-08-2020 Standard used ISO 9073-4 (1997) Product standard EN 14325 (2018) Deviation from the standard Tear resistance (N) Length direction Width direction Remark





Analysis Report Date 06-08-2020 Page 5/9

- Vprotect Disposable Coverall - (with taped seams) Reference:

Determination of the puncture resistance

Date of ending the test 03-08-2020 Standard used EN 863 (1995) Product standard EN 14325 (2018)



Conditioned

Specimen	Force (Force (N)	







Analysis Report 2

Date 06-08-2020

Page 6/9

Reference: - Vprotect Disposable Coverall - (with taped seams)

Determination of the pH of an aqueous extract

Date of ending the test 03-08-2020
Standard used ISO 3071 (2005)
Product standard ISO 13688 (2013)

Extract pH





Analysis Report

Date 06-08-2020
Page 7/9

Reference:	- Vpro	otect Disposable Coverall -	(with	taped seams)
Whole suit requ	uirements - visual i	nspection seams		
Date of ending t	the test	05-08-2020		
			tbreak.	





Analysis Report

Date 06-08-2020
Page 8/9

Reference: - Vprotect Disposable Coverall - (with taped seams)

Resistance to penetration by blood-borne pathogens – Test method using Ph bacteriophage

Date of ending the test 16-07-2020

Standard used ISO 16604 (2004)

Product standard EN 14126 (2003) + AC (2004)







Analysis Report 2 Date 06-08-2020 Page 9/9

Results

Compatibility test

Test specimen	Compatibility ratio		
T			
<u>Test</u>			
Test pressure			
Bacteriophage concer	ntration		
Bacteriophage concer	atration		

Test validity

Controls	Number of PFU/ml of assay fluid	Pass/Fail results

Sample results

Test	Sampling	Number of PFU/ml of	Pass/Fail results
specimen	area	assay fluid	

Pass = no penetration of bacteriophages through the specimen Fail = penetration of bacteriophages through the specimen

Classification according to EN 14126

Pressure at which the sample passes the test	Classification	



TEST REPORT

SCOPE OF WORK

Performance Testing of Surgical Gowns to ANSI/AAMI PB70:2012 American National Standard for Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities

ISSUE DATE

July 8, 2020

PAGES

5

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3933 US Route 11 Cortland, New York 13045

Telephone: Facsimile: 100: 150 5051 www.intertek.com

TEST STANDARD

AUTHORIZATION

Quote Number: Q

PRODUCT DESCRIPTION

Sample Type: Gown Material

ID Number:

SAMPLE INFORMATION

Dates Samples Received: June 22, 2020
Condition of Samples: Production Run
Date of Testing: July 7, 2020





3933 US Route 11 Cortland, New York 13045

Telephone: 1-Facsimile: 1www.intertek.com

SECTION 1

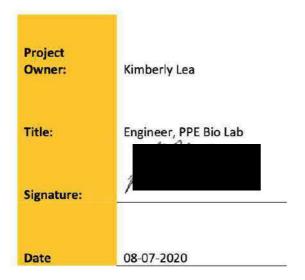
CONCLUSION

This test report completes the testing covered by quote number Qu

The observations and test results in this report are relevant only to the sample tested. Intertek makes no representations or warranties, express or implied, regarding units that were not tested including, but not limited to, units that may be part of the same lot.

If there are any questions regarding the results contained in this report, or any other services offered by Intertek, please do not hesitate to contact the undersigned.

Please note this Test Report does not represent authorization for the use of any Intertek certification marks.





SECTION 2 PRODUCT DESCRIPTION: **TEST RESULTS:** PFU/ml **Quality Control Samples** Results Sample Assay **Number of Plaques Test Terminated** Sample Sample **Assay Titer** Thickness Volume Due to Liquid Pass/Fail Number Weight (g) (PFU/ml) Plate 1 Plate 2 Penetration (mils) (mls)

SECTION 3



Level	Test	Result	AQL requirement (Alpha = .05)	RQL requirement (Beta = 0.10)
1	AATCC 42	24 5 4	40/	200/
4				



Dok. No: Rev. No: 2

OF REGISTRATION ERTIFICATE





Management Systems Certification Body

MSCB - 131





This Certificate has been awarded to

OFER DIŞ TİCARET LİMİTED ŞİRKETİ

VATAN MAH. 10. DENİZ SOK. NO: 35/Z1 YILDIRIM / BURSA / TÜRKİYE

In recognition of the organization's Managements System which complies with

ISO 9001:2015

The scope of activities covered by this certificate is defined below

MANUFACTURING, SALES AND EXPORT OF TOWEL, LOINCLOTH,
COTTON WEAVING, OVERALLS, APRON AND MASK

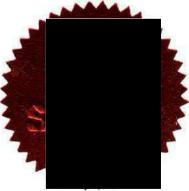
HAVLU, PEŞTAMAL, PAMUKLU DOKUMA, TULUM, ÖNLÜK VE MASKE İMALAT, SATIŞ VE İHRACATI

Certificate Number:

Date of Issue of Orginal Certificate: 27.06.2020
Date of Issue of Latest Certificate: 27.06.2020

Expiry Date: 26.06.2021





Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been rewiewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the revelant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid. This is an accredited certificate isseud by SIS Certifications Pvt. Ltd. sanctioned for issue by International Accreditation Services, 3060 Saturn Street Suite 100 Brea, California 92821-1732, USA.

Email us: support@siscertifications.com, info@siscertifications.co.in Call: - Www.siscertifications.com www.siscertifications.com
The status of this certificate can be verified on "http://www.siscertifications.co.in".

FIADO



SERTIFIKA / CERTIFICATE

OFER DIŞ TİCARET LİMİTED ŞİRKETİ

VATAN MAH. 10. DENİZ SOK. NO: 35 İÇ KAPI NO: Z1 YILDIRIM / BURSA / TURKEY

Kuruluşunun 66 TULUM, ÖNLÜK VE MASKE İMALAT, SATIŞ VE İHRACATI 99 Kapsamı için

For scope "MANUFACTURING, SALES AND EXPORT, OVERRALLS, APRON AND MASK"

ISO 13485: 2016

TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ Medical Devices Quality Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / Certificate Number

Sertifika Kodu / Certificate Code

Sertifika Yayın Tarihi / Certificate Issue Date

Sertifika Geçerlilik Tarihi / Certificate Validity Date

Sertifika Periyodu / Certificate Period

: OFER DIŞ TİCARET : 26.08.2020

: 26.08.2021 : 1 Yıl / 1 Year



System effectively and timely surveillance audits this document is valid as long as the 1-years. NVA control the conduct of standards. Although due care and competence, including gross negligence will not accept responsibility. This document or proprietary rights owned by NVA and must be returned upon request.

Sistem etkin bir şekilde sürdürüldükçe ve gözetim tetkikleri zamanında yapıldığı müddetçe bu belge 1 yıl geçerlidir. NVA denetim yürütülmesinde gerekli itina ve yetkinlik göstermesine rağmen büyük ihtimallerde dahil sorumluluk kabul etmeyecektir. Bu belgenin mülkiyet hakkı NVA aittir ve istenildiğinde iade edilmelidir.

www.nvakalite.com info@nvakalite.com



SERTIFICATE OF REGISTRATION





ACCREDITED

Management Systems
Certification Body

MSCB - 131





This Certificate has been awarded to

OFER DIŞ TİCARET LİMİTED ŞİRKETİ

VATAN MAH. 10. DENİZ SOK. NO: 35/Z1 YILDIRIM / BURSA / TÜRKİYE

In recognition of the organization's Managements System which complies with

ISO 14001:2015

The scope of activities covered by this certificate is defined below

MANUFACTURING, SALES AND EXPORT OF TOWEL, LOINCLOTH, COTTON WEAVING, OVERALLS, APRON AND MASK

HAVLU, PEŞTAMAL, PAMUKLU DOKUMA, TULUM, ÖNLÜK VE MASKE İMALAT, SATIŞ VE İHRACATI

Certificate Number: S

Date of Issue of Orginal Certificate: 27.06.2020
Date of Issue of Latest Certificate: 27.06.2020

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The status of this certificate can be verified on "http://www.siscertifications.co.in".

OF REGISTRATION ERTIFICATE





MSCB - 131



This Certificate has been awarded to

OFER DIŞ TİCARET LİMİTED ŞİRKETİ

VATAN MAH. 10. DENİZ SOK. NO: 35/Z1 YILDIRIM / BURSA / TÜRKİYE

In recognition of the organization's Managements System which complies with

ISO 45001:2018

The scope of activities covered by this certificate is defined below

MANUFACTURING, SALES AND EXPORT OF TOWEL, LOINCLOTH,
COTTON WEAVING, OVERALLS, APRON AND MASK

HAVLU, PEŞTAMAL, PAMUKLU DOKUMA, TULUM, ÖNLÜK VE MASKE İMALAT, SATIŞ VE İHRACATI

Certificate Number:

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