

vProtect



TYPE 5B/6B CLASSIC COVERALL







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

hazardous dry particle



Type 6B
EN ISO 13034
Protection against liquid chemical products



Anti-hazard
EN ISO 14126
Protection against biological hazards and inactive agents





AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No

: 54-20-01-R01

Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /

Certification Date / Certificate Validity Date

: 11.11.2020-05.10.2025

Belge Geçerlilik Tarihi / Document Validity Period: 5 yıl / 5 years

Firma Unvanı ve Adresi /

Company Name and Address

: OFER DIŞ TİC LTD. ŞTİ.

Vatan Mah. 10. Deniz Sok. No: 35A Yıldırım/

BURSA 16270

Ürün Adı /Modeller / Product Name / Models

Direktifi / Directive

Modülü/Kategori / Module / Category

: Vprotect Disposable Coverall- OPPE-0156

: 2016/425 REGULATION

: B MODÜLÜ/ KATEGORİ III MODULE B / CATEGORY III

: MNA M-2020-00274

Test Rapor No/ları / Test Report No Ürün Tipi / Product Type:

- EN ISO 13688 Koruyucu giyecekler - Genel özellikler / Protective clothing - General requirements

- EN 13034+ A1 Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip 6-B) / Protective Clothing Against Liquid Chemicals (Type 6-B)

- EN ISO 13982-1 Katı Parçacıklara Karşı Koruyucu Giysi (Tip 5-B)/ Protective Clothing For Use Against Solid Particulates (Type 5-B)

 EN 14126 Koruyucu Giyecekler - Patojen Organizmalara Karşı / Protective Clothing - Performance Requirements And Tests Methods For Protective Clothing Against Infective Agents

Ürünün Malzeme Bilgisi / Product Material Information: Vprotect Disposable Coverall- OPPE-0156 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir./ Vprotect Disposable Coverall- OPPE-0156 model products are manufactured using coated fabric.

Revizyon nedeni/ Reason for revision: Model adı revize edilmiştir./ The model name has been revised.

Volkan AKIN 11.11.2020 Karar Verici / Approver

Okan AKEL 11,11,2020 Şirket Müdürü / General manager









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.

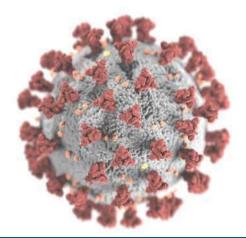
Protective clothing against infective agents has two main functions:

- 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.



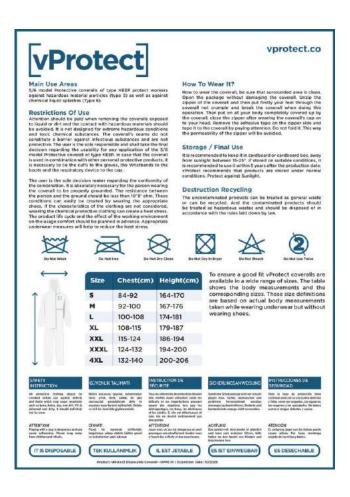
The size viruses vary in diameter from 20 nanometres (nm; 0.0000008 inch) to 250–400 nm, due to its small size, virus can easly pass through the pinholes of ordinary protective garments. EN 14126 certified Garments, however, are proven to act as an effective barrier even against small viruses such as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





Packaging Front & Back:





Labels: Chest label & Size label





DO NOT RE-USE / TEK KULLANIMLIKTIR
Manufacturer: Ofer Dis Tic Ltd Sti
tan Mh. 10 Deniz Sk No35 Yildirim Bursa Turi

Vatan Mh. 10.Deniz Sk No35 Yildirim Bursa Turkey Made in Turkey www.yprotect.co Instruction of How to Use please see packaging or website.

> Certifiying Notify Body No: 2841 MNA Labaratuarlari

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TYPE 5B/6B CLASSIC COVERALL



CATEGORY III



2841



Type 5B EN 150 13982-1 Ory particle suits for protection against hazardous dry particle



Type 6B EN ISO 13034 Protection against liquid chemical products



Anti-hazard
EN 150 14126
Protection agains
biological hazard
and inactive age-s



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: 1-607-753-6711 Facsimile: 1-607-756-9891 www.intertek.com

TEST STANDARD

ANSI/AAMI PB70:2012 American National Standard on Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities using ASTM F1671 / F1671M - 13: Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

AUTHORIZATION

Quote Number: Qu-01085425-2

PRODUCT DESCRIPTION

Sample Type: Gown Material

ID Number:

55gsm Breathable Laminate for Protective Clothing / Coverall Suit - S064

SAMPLE INFORMATION

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

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SECTION 1

CONCLUSION

This test report completes the testing covered by quote number Qu-01085425-2.

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.

Project Project Kristine Perrotti Kimberly Lea Reviewer: Owner: Engineer, Chem/Bio/Clothing Team Title: Engineer, PPE Bio Lab Title: Signature: **Signature** Date 08-07-2020 Date: 08-07-2020

SECTION 2

ASTM F1671 / F1671M - 13 TEST DATA SHEETS

PRODUCT DESCRIPTION: 55gsm Breathable Laminate for Protective Clothing / Coverall Suit - S064

CONDITIONING: At a temperature of 21 ± 5 °C and a relative humidity of 30-80% until equilibrium is reached or for at least 24 hours, whichever is shorter.

TESTING PROCEDURE USED: Procedure A: 0 psig for 5 minutes, 2 psig for 1 minute, 0 psig for 54 minutes. No, stainless steel retaining screen used.

TEST RESULTS:

Quality Control Samples	PFU/ml	Results	
Negative Control	0	Acceptable (valid test)	
Pre-test Bacteriophage Titer	3.0x10 ⁸	Acceptable (valid test)	
Post Test Bacteriophage Titer 3.0x108		Acceptable (valid test)	
Settle Plate(s)	0	Acceptable (valid test)	

Sample Number	Sample Thickness (mils)	Sample Weight (g)	Assay Volume (mls)	Number Plate 1	of Plaques Plate 2	Assay Titer (PFU/ml)	Test Terminated Due to Liquid Penetration	Pass/Fail
1	10	0.3259	5	0	0	0	No	Pass
2	10	0.3273	5	0	0	0	No	Pass
3	9	0.3135	5	0	0	0	No	Pass
Averages	10	0.3222		*10	<u> </u>	\$3.	3 14	

SECTION 3

ANSI/AAMI PB70:2012 CLASSIFICATION of BARRIER PERFORMANCE of SURGICAL GOWNS, ISOLATION GOWNS, OTHER PROTECTIVE APPAREL, SURGICAL DRAPES, and DRAPE ACCESSORIES

Level	Test	Result	AQL requirement (Alpha = .05)	RQL requirement (Beta = 0.10)
1	AATCC 42	≤4.5 g	4%	20%
2	AATCC 42 AATCC 127	≤1.0 g ≥20 cm	4%	20%
3	AATCC 42 AATCC 127	≤1.0 g ≥50 cm	4%	20%
4	ASTM F1671 (surgical gowns, isolation gowns and other protective apparel) ASTM F1670 (surgical	Pass	4%	20%
	drapes and drape accessories)	Pass	4%	20%



ÜRÜN SPEKT FORMU (MATERIAL SPECIFICATION FORM)

LAMİNELİ ÜRÜN SPER	KTİ / LAMINATED P	RODUCT SPECIFICATION	NC							
-			LAMİNELİ ÜRÜN SPEKTİ / LAMINATED PRODUCT SPECIFICATION							
55 gsm Reinforced Breathable Laminated Fabric for Surgical Gown and Protective Overall Suit										
BEYAZ / WHITE										
28 gsm SSMMS Nonwoven + 25 gsm Triple-layered Breathable Medical PE Film + 2 gsm Hotmelt										
-										
29/06/2020		VERSIYON NO (VERSION NO)	1							
TEST METODU (TEST METHOD)	BIRIM (UNITS)	HEDEF (TARGET)	MINIMUM (MINIMUM)	MAKSİMUM (MAXIMUM)						
WSP 130.1	g/m²	55.00	53.00	57.00						
WSP 110.4	N/ 25mm	44	40.0	-						
WSP 110.4	%	50	35	80						
WSP 110.4	N/ 25mm	20.0	17.0	-						
WSP 110.4	%	65	50	80						
WSP 401.0	N/ 25mm	1.00	0.70	-						
WSP 70.5	gr/m²/gün	3000	2000	12000						
WSP 80.6	mmSS	2000	1800	-						
ASTM D2457	Gloss unit	9.0	8.0	10.0						
GÜLSAN	%	80.0	75.0	85.0						
GÜLSAN	mm	0.210	0.180	0.240						
GÜLSAN	mm	Talep Edilen Requested	-3	3						
emanlari of the Material) Triple-Layered PE Film										
	•	Hotmelt								
• SSMMS Spunbond										
	BEYAZ / WHITE 28 gsm SSMMS Nonword - 29/06/2020 TEST METODU (TEST METHOD) WSP 130.1 WSP 110.4 WSP 110.4 WSP 110.4 WSP 110.4 WSP 201.0 WSP 70.5 WSP 80.6 ASTM D2457 GÜLSAN GÜLSAN	BEYAZ / WHITE 28 gsm SSMMS Nonwoven + 25 gsm Triple - 29/06/2020 TEST METODU (TEST METHOD) WSP 130.1 WSP 110.4 WSP 110.4 WSP 110.4 WSP 110.4 WSP 110.4 WSP 110.4 WSP 110.4 WSP 30.6 MSP 80.6 ASTM D2457 Gloss unit GÜLSAN MM GÜLSAN MM GÜLSAN MM MM MM MM MM MM MM MM MM	BEYAZ / WHITE 28 gsm SSMMS Nonwoven + 25 gsm Triple-layered Breathable Med - 29/06/2020 TEST METODU (TEST METHOD) (UNITS) HEDEF (TARGET) WSP 130.1 g/m² 55.00 WSP 110.4 N/ 25mm 44 WSP 110.4 % 50 WSP 110.4 % 65 WSP 110.4 % 65 WSP 401.0 N/ 25mm 1.00 WSP 70.5 gr/m²/gün 3000 WSP 80.6 mmSS 2000 ASTM D2457 Gloss unit 9.0 GÜLSAN 90.0 GÜLSAN mm 0.210 Triple-Layered Triple-Layered Triple-Layered	BEYAZ / WHITE 28 gsm SSMMS Nonwoven + 25 gsm Triple-layered Breathable Medical PE Film + 2 gsm						

<u>KALİTE KONTROL MÜDÜRÜ</u> (QUALİTY CONTROL MANAGER) Erkan ÇELİK ARGE UZMANI (R&D SPECIALIST) İbrahim ERKOL FABRİKA MÜDÜRÜ (PLANT MANAGER) Kadir TAMER

Dok. No: KY-F11-P16 Rev. No: 2

OF REGISTRATION ERTIFICATE





Management Systems Certification Body

MSCB - 131





This Certificate has been awarded to

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Date of Issue of Latest Certificate: 27.06.2020

Expiry Date: 26.06.2021



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

ISO 13485: 2016

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Sertifika Yayın Tarihi / Certificate Issue Date

Sertifika Geçerlilik Tarihi / Certificate Validity Date

Sertifika Periyodu / Certificate Period

: 20082402

: OFER DIS TICARE

: 26.08.2020

: 26.08.2021

: 1 Yıl / 1 Year

Certification Manager Belgelendirme Müdürü

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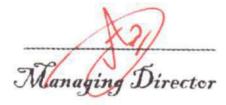
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COTTON WEAVING, OVERALLS, APRON AND MASK

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