

Disposable Chemo gown

Level 4



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Specifications

DISPOSABLE CHEMO GOWN LEVEL 4

Brand	V12
Application	Medical
Backstyle	Full back
Color	White
Cuff Style	Knitted Cuffs
Fastening Type	Hook and loop Neck/waist ties
Seams	Taped
Gender	Unisex
AAMI	Level 4
Material	PP+PE
Weight	60gsm
Sterility	Sterile/Non-sterile
Usage	Chemo, Hospital, Pharmacy
User	Adult
Size	M,L,XL
SKU	M- 12213702, L- 12213703, XL- 12213704
Sleeve style	Long Set-in sleeves
Origin	U.S.A.
Packaging	100pcs/case



Anti-Bacterial



Breathable



Water Resistant



Anti-Allergic



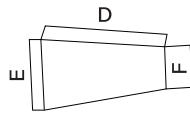
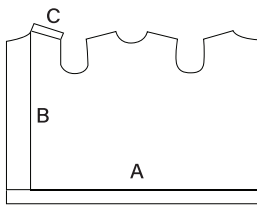
Recyclable





Dimensions

DISPOSABLE CHEMO GOWN LEVEL 4



INCH	S	M	L	XL	XXL
A	57.1	59.1	61.0	63.0	63.0
B	43.3	45.3	47.2	48.4	51.2
C	7.5	7.9	8.3	8.7	9.3
D	22.0	22.0	22.4	22.8	25.2
E	21.3	21.3	22.0	22.0	23.6
F	12.6	12.6	12.2	12.6	13.2

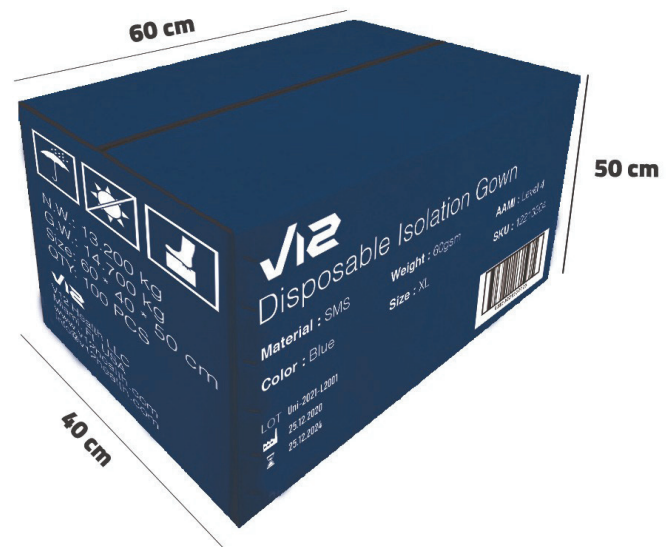
PACKAGING DIMENSIONS

N.W.: 14KG

G.W.: 15.5 KG

Size: 60x40x50cm

QTY: 100PCS



Technical Specifications



EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

TEST REPORT DENEY RAPORU

20014339-
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05-20

EKOTEKS

Customer name:	UNION SAĞLIK HİZMETLERİ TİC. LTD. ŞTİ.
Address:	CEVİZLİ MAH. ZUHAL CD. RİTİM İST. A1 BLOK NO:46-1 KAPI NO:7 İSTANBUL MALTEPE
Buyer name:	
Contact Person:	
Order No:	-
Article No:	-
Name and identity of test item:	One sample of blue fabric. (Claimed to be; BLUE/ NONWOVEN LAMINATED FABRIC)
The date of receipt of test item:	06.05.2020
Re-submitted/re-confirmation date:	-
Date of test:	06.05.2020-14.05.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	-
Number of pages of the report:	6

Seal

Date
14.05.2020

Customer Representative
Zahide TAPAN

Head of Testing Laboratory
Sevim A. RAZAK

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REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
PHYSICAL PROPERTIES TESTS		
Tensile Strength / Dry	P	
Tensile Strength / Wet	P	
Bursting Strength / Dry	P	
Bursting Strength / Wet	P	
Water Permeability	P	
P: Pass F: Fail R: Refer to retailer technologist.		
Test results were evaluated according to EN 13795-1:2019 Standard Performance Properties Critical Sample Group limit values (Table 1)		

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 : EN 13795-1:2019

SURGICAL CLOTHING AND DROPEES –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DROPEES (*);

MICROBIAL CLEANLINESS (Bioburden)

Test Method: Ref: EN ISO 11737-1:2018 (*)

The sample is put in extraciton liquid after shaking well, inoculated on the agar.
After incubation at 30 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

	<u>RESULTS</u>	<u>REQUIREMENT</u>
Microbial cleanliness (cfu/100 cm²)	190 cfu/100 cm ²	≤ 300 cfu/100 cm ²

*cfu= Colony forming unit.

Technical Specifications

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TEST RESULTS

Test Method: BS EN 22610:2006 (Surgical drapes, garments and fresh air clothes used as medical devices for patients, hospital staff and equipment - Test method for determining the resistance to wet bacterial permeability) (*)

A test sample is placed on the agar plate on a rotating disc. Bacteria carrier material and coating film are placed on the test sample and all parts are fixed on the disk. A finger is placed on the test sample to apply a certain force ($3N \pm 0.02$). The finger moves over the entire surface of the agar on the test specimen within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 adet 25x25cm ²
Carrier Material:	30 µm inceliğinde , 25x25cm ² Poliüretan Film
Carrier Material:	25x25cm ² HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacteria Concentration (kob / ml):	1-4x10 ⁸ kob/ml
Incubation Conditions:	(36±1)°C 48 saat

RESULTS			
Number of Populating Bacteria (cfu)		Population Rate	
X ₁	250	R _{CUM1}	0,4
X ₂	0	R _{CUM2}	0,4
X ₃	0	R _{CUM3}	0,4
X ₄	150	R _{CUM4}	0,7
X ₅	100	R _{CUM5}	0,9
Z	60		
T			560

X₁ X₅: Number of colonies grown in 5 parallel petri in the same sample

Z: number of colonies growing in sixth petri

T: X₁ + X₂ + X₃ + X₄ + X₅ + Z

R_{CUM1} = X₁/T

R_{CUM2} = (X₂ + X₁)/T

R_{CUM3} = (X₃ + X₂ + X₁)/T

R_{CUM4} = (X₄ + X₃ + X₂ + X₁)/T

R_{CUM5} = (X₅ + X₄ + X₃ + X₂ + X₁)/T

BARRIER INDEX (IB)		
	Result	Requirement(*)
I _B	3,2	≥2,8

I_B = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)

* EN 13795-1: 2019 Surgical garments and drapes - Requirements and test methods are evaluated according to Table-1.

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TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DROPEs –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DROPEs (*);

TENSILE STRENGTH; EN 29073-3:1996 (*)

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

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

Pre-load was not applied. Without wetting samples.

The average results are given for weft and warp direction of five samples

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

Dry ;

	<u>RESULT</u>	<u>REQUIREMENT</u>
Weft	31.3 N	\geq 20N (Dry)
Warp	52.3 N	\geq 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996 (*)

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

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

Pre-load was not applied. With wetting samples.

The average results are given for weft and warp direction of five samples

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

Wet ;

	<u>RESULT</u>	<u>REQUIREMENT</u>
Weft	28.9 N	\geq 20N (Wet)
Warp	50.9 N	\geq 20N (Wet)

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter

The average results are given of five samples.

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

	<u>RESULT</u>	<u>REQUIREMENT</u>
Dry ;	103.0 kPa	\geq 40 kPa (Dry)
Height at Burst*	8.5 mm	

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TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DROPEŞ –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DROPEŞ (*);

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	<u>RESULT</u>	<u>REQUIREMENT</u>
Wet ;	89 kPa	≥ 40 kPa (Wet)
Height at Burst*	9.5 mm	

WATER PERMEABILITY;; ISO 811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model
Temperature of water 20°C. Pressure increase ratio 10 mbar/min.
Performed in the conditioned room (20±2°C-65%±4)

	<u>RESULT</u>	<u>REQUIREMENT</u>
Sample 1	60.2 cmSS	≥ 20cmSS
Sample 2	65.8 cmSS	
Sample 3	67.8 cmSS	
Sample 4	58.7 cmSS	
Sample 5	69.9 cmSS	
Average	64.5 cmSS	



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Establishment:
V12 Health LLC
Business Trade Name:
V12 Health LLC

11400 NW 34 TH STREET
Doral, FL 33178
Registration Number: 3016842185
FEI Number*: 3016842185
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2021

Owner/Operator:
[V12 Health LLC](#)
11400 NW 34 TH STREET
Doral, FL US 33178
Owner/Operator Number: [10073104](#)

Official Correspondent:
Tarek Kirschen
11400 NW 34 TH STREET
Doral, FL 33178
Phone: 1-305-8909900

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set



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Federal Tax ID # 85-0688159

FDA registration # 3016842185

"Everyone Is Essential" is a trademark of V12 Health LLC

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