

# Isolation Gown

Level 2





# Specifications

## ISOLATION GOWN LEVEL 2

<b>Brand</b>	V12
<b>Application</b>	Medical
<b>Backstyle</b>	Full back
<b>Color</b>	Blue
<b>Cuff Style</b>	Knitted Cuffs
<b>Fastening Type</b>	Hook and loop Neck / waist ties
<b>Gender</b>	Unisex
<b>AAMI</b>	Level 2
<b>Material</b>	SMS
<b>Weight</b>	35-40gsm
<b>Sterility</b>	Sterile/Non-sterile
<b>Usage</b>	Hospital, Pharmacy
<b>User</b>	Adult
<b>Size</b>	M,L,XL
<b>SKU</b>	M-12213302, L-12213303, XL- 12213304
<b>Sleeve style</b>	Long Set-in sleeves
<b>Origin</b>	U.S.A. / Turkey
<b>Packaging</b>	100pcs/case



Anti-Bacterial



Breathable



Water Resistant



Anti-Allergic

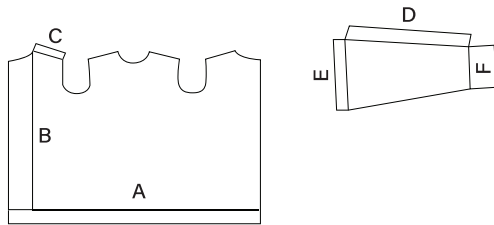


Recyclable



# Dimensions

ISOLATION GOWN LEVEL 2



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

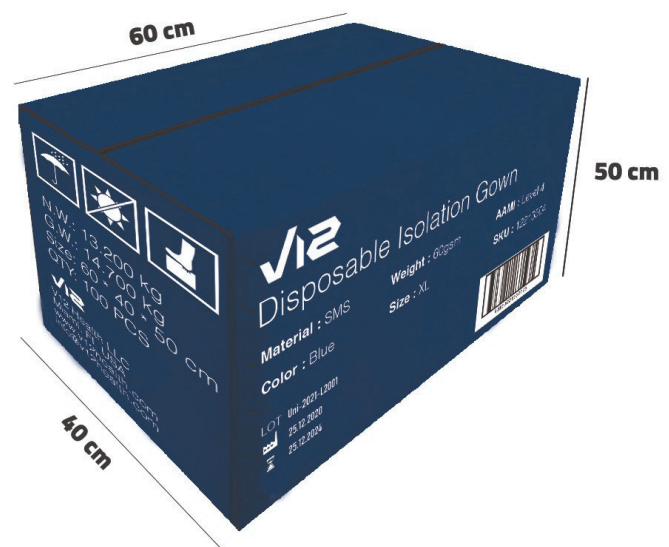
## PACKAGING DIMENSIONS

N.W.: 12KG

G.W.: 13.5 KG

Size: 60x40x50cm

QTY: 100PCS



# MASS

## MASS LABORATORY AND CONSULTANCY SERVICES

**TEST REPORT**  
DENEY RAPORU

20015011

06-20

**Customer name:** UNION SAĞLIK HİZMETLERİ TİC. LTD. ŞTİ.  
**Address:** CEVİZLİ MAH. ZUHAL CD. RİTİM İST. A1 BLOK NO:46-1 KAPI NO:7  
**Buyer name:** İSTANBUL MALTEPE -  
**Contact Person:**  
**Order No:** MB003  
**Article No:** MB003  
**Name and identity of test item:** Blue non-woven drape. (Claimed to be; Disposable drape; 35-40 g)  
**The date of receipt of test item:** 05.06.2020  
**Re-submitted/re-confirmation date:** -  
**Date of test:** 05.06.2020-20.05.2020  
**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:** 6

**Seal**



**Date**

05.06.2020

**Customer Representative**

Oğuzhan EKER

**Head of Testing  
Laboratory**

Adem SAVCI

# Technical Specifications



# MASS

LABORATORY AND CONSULTANCY SERVICES

20015011

06-20

REQUIRED TESTS	RESULT	COMMENTS
<b>MICROBIOLOGICAL TEST</b>		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
<b>PHYSICAL PROPERTIES TESTS</b>		
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 13795-1:2016 Standard Performance Properties Criticak 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.

Gen. 11.36-2/03



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 Testing reports without signature and seal are not valid.

## **MASS** LABORATORY AND CONSULTANCY SERVICES

20015011
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06-20
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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  $30 \pm 1$  ° C for 72 hours, growth microorganisms are counted on the agar.

	<b><u>RESULTS</u></b>	<b><u>REQUIREMENT</u></b>
<b>Microbial cleanliness (cfu/100 cm<sup>2</sup> )</b>	250 cfu/100 cm <sup>2</sup>	≤300 cfu/100 cm <sup>2</sup>

\*cfu= Colony forming unit.

**TEST METHOD : EN 13795-1:2019**

**SURGICAL CLOTHING AND DROPEES –REQUIREMENTS AND TEST METHODS**

**ANNEX 1: SURGICAL CLOTHING AND DROPEES (\*);**

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

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 weft and warp direction of five samples  
 Performed in the conditioned room (20±2°C-65%±4).

**Dry ;**

	<b>RESULT</b>	<b>REQUIREMENT</b>
<b>Weft</b>	21.6 N	≥ 20N (Dry)
<b>Warp</b>	44.3 N	≥ 20N (Dry)

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

Instron 5969 (Load: 50 kN), Strip Method.  
 Speed: 100 mm/min±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±2°C-65%±4).

**Wet ;**

	<b>RESULT</b>	<b>REQUIREMENT</b>
<b>Weft</b>	20.0 N	≥ 20N (Wet)
<b>Warp</b>	41.9 N	≥ 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±2°C-65%±4).

	<b>RESULT</b>	<b>REQUIREMENT</b>
<b>Dry ;</b>	98.5 kPa	≥ 40 kPa (Dry)
<b>Height at Burst*</b>	11.3 mm	

### TEST RESULTS

**TEST METHOD : EN 13795-1:2019**

**SURGICAL CLOTHING AND DROPEES –REQUIREMENTS AND TEST METHODS**

**ANNEX 1: SURGICAL CLOTHING AND DROPEES (\*)**

**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>
<b>Wet ;</b>	86.2 kPa	≥ 40 kPa (Wet)
<b>Height at Burst*</b>	10.7 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>
<b>Sample 1</b>	21 cmSS	≥ 20cmSS
<b>Sample 2</b>	22 cmSS	
<b>Sample 3</b>	27.3 cmSS	
<b>Sample 4</b>	21.9 cmSS	
<b>Sample 5</b>	22,0 cmSS	
<b>Average</b>	22.84 cmSS	



### 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.

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

### RESULTS

Number of Populating Bacteria (cfu)		Population Rate	
X <sub>1</sub>	350	R <sub>CUM1</sub>	0.2
X <sub>2</sub>	300	R <sub>CUM2</sub>	0.5
X <sub>3</sub>	250	R <sub>CUM3</sub>	0.6
X <sub>4</sub>	240	R <sub>CUM4</sub>	0.8
X <sub>5</sub>	220	R <sub>CUM5</sub>	1
Z	60		
T		1420	

X<sub>1</sub> ..... X<sub>5</sub>: Number of colonies grown in 5 parallel petri in the same sample

Z : number of colonies growing in sixth petri

T: X<sub>1</sub> + X<sub>2</sub> + X<sub>3</sub> + X<sub>4</sub> + X<sub>5</sub> + Z

R<sub>CUM1</sub> = X<sub>1</sub>/T

R<sub>CUM2</sub> = (X<sub>2</sub> + X<sub>1</sub>)/T

R<sub>CUM3</sub> = (X<sub>3</sub> + X<sub>2</sub> + X<sub>1</sub>)/T

R<sub>CUM4</sub> = (X<sub>4</sub> + X<sub>3</sub> + X<sub>2</sub> + X<sub>1</sub>)/T

R<sub>CUM5</sub> = (X<sub>5</sub> + X<sub>4</sub> + X<sub>3</sub> + X<sub>2</sub> + X<sub>1</sub>)/T

### BARRIER INDEX (IB)

I <sub>B</sub>	Result	Requirement(*)
	2.9	≥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.



# Certifications

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## Establishment Registration & Device Listing

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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



**V12 Health, LLC**

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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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