EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

21001832
01-21

TEST REPORT
DENEY RAPORU

Customer name:	BAYTEKS TEKNİK TEKSTİL SAN. TİC. AŞ.
Address:	ORGANİZE SANAYİ BÖLGESİ 19 NO'LU CADDE NO:11 MERKEZ/KİLİS
Buyer name:	-
Contact Person:	KADİR KARAGÜN
Order No:	REF:SG-01222-05/LOT:50815
Article No:	PROTECTED SURGICAL GOWN
Name and identity of test item:	Blue non-woven gown. (Claimed to be;MEDICAL BLUE)
The date of receipt of test item:	18.01.2021
Re-submitted/re-confirmation date:	-
Date of test:	18.01.2021-25.01.2021
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:	3

Gen.f136-2/03

TESTED BY Seal EKOTEKS TESTEDİL

Date	*Customer Representative*	*Head of Testing Laboratory*
25.01.2021	Yeşim ŞAHİN	Sevim A. RAZAK 25.01.2021

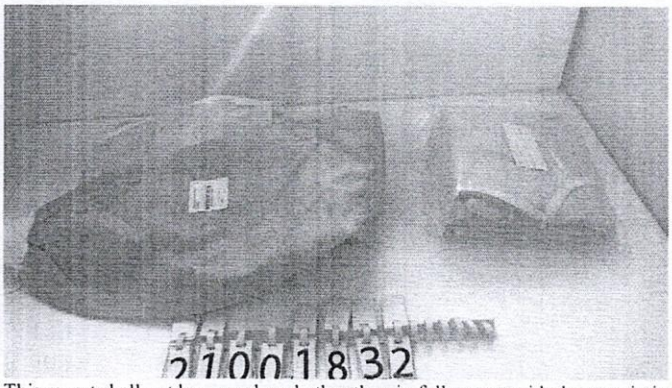
Digitally signed by Granaci Boris
Date: 2022.11.08 14:27:55 EET
Reason: MoldSign Signature
Location: Moldova

21001832
01-21

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
Lint and Other Particles Generation From Nonwoven	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 %. The declaration of conformity was given in accordance with the Simple Acceptance Decision Rule. Tests marked (*) in this report are not included in the accreditation schedule.



TEST RESULTS

LINT AND OTHER PARTICLES GENERATION FROM NONWOWEN;

Test Metod: ISO 9073-10: 2003 (*)

5 test samples that in cross direction are maintained to twisting and compression action with Gelbo Flex for inner and outer surface in a clean room condition (according to ISO 14644-1 Class 5).
Lint and particles detached from the sample are counted with counter device and classified to size range.
Min. measuring size of SOLAIR 3100 particles measuring device: 0,3 µm.
Max. measuring size of SOLAIR 3100 particles measuring device: 25 µm.
Air flow: 28,3 ± 1,4 L/min
Working mode: 30 s x 10 consecutive periods

SAMPLE, INNER SURFACE (3 µm - 25 µm)	**SAMPLE, OUTER SURFACE (3 µm - 25 µm)**
Total linting : 23 Standard deviation : 4 Coefficient of variation : 18% Coefficient of linting (CL) : 1	Total linting : 16 Standard deviation : 7 Coefficient of variation : 46% Coefficient of linting (CL) : 1
SAMPLE, MATERIAL (TOTAL)	
Total linting :39 Coefficient of linting (CL)* :2	

*According to EN ISO EN ISO 13795-1:2019, Coefficient of linting (CL) (log 10) should be ≤4 for analysis of critical product area and less critical product area of both standard performance and high performance testing.

Gen.f136-2/03

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İstanbul/ TÜRKİYE

Test
TS EN ISO/IEC 17025
AB-0583-T

EKOTEKS

TEST REPORT
DENEY RAPORU

AB-0583-T
20035727 -ing
10-20

Customer name:	BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş
Address:	-
Buyer name:	ORGANİZE SAN. MAH. 19 NOLU CAD. NO:11 MERKEZ /KİLİS
Contact Person:	KADİR KARAGÜN
Order No:	REF:SG-01222-05 LOT:50815
Article No:	PROTECTED SURGICAL APRON
Name and identity of test item:	Coated medical blue surgical gown.
The date of receipt of test item:	29.09.2020
Re-submitted/re-confirmation date:	-
Date of test:	29.09.2020-12.10.2020
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:	7

The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.

The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
	12.10.2020	Hatice ACARALP	Sevim A. RAZAK 12.10.2020

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20035727 -ing
10-20

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES		
Tensile Strength **/ Dry**	P	
Tensile Strength **/ Wet**	P	
Bursting Strength **/ Dry**	P	
Bursting Strength **/ Wet**	P	
Water Permeability	P	
MICROBIOLOGICAL TESTS		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry-Bacterial Penetration	P	
P: Pass F: Fail R: Refer to retailer technologist. (1)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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10-20

TEST RESULTS

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 ;

	RESULT	REQUIREMENT
Weft	72.5 N	≥ 20N (Dry)
Warp	162.8 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 ;

	RESULT	REQUIREMENT
Weft	75.1 N	≥ 20N (Wet)
Warp	160.1 N	≥ 20N (Wet)

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 29 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Dry ;	201.4 kPa	≥ 40 kPa (Dry)
Height at Burst*	14.9 mm	

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20035727 -ing
10-20

TEST RESULTS

TEST METHOD: EN 13795-1: 2019

SURGICAL CLOTHING AND DRAPES –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DRAPES ;

BURSTING STRENGTH; ISO 13938-1:1999
SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 45.2 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Wet ;	190.2 kPa	≥ 40 kPa (Wet)
Height at Burst*	13.8 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)

	RESULT	REQUIREMENT
Sample 1	147.0 cmSS	≥ 100cmSS
Sample 2	150.0 cmSS	
Sample 3	157.2 cmSS	
Sample 4	163.3 cmSS	
Sample 5	160.1 cmSS	
Average	158.6 cmSS	

TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DRAPES –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DRAPES (*);

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: 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.

	RESULTS	**REQUIREMENT**
Microbial cleanliness (cfu/g)	32 cfu/g	≤300 cfu/g Type I and Type II mask

TEST RESULT

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 determination of 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 ± 0.02). The finger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
Coating Material:	25x25cm2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	2x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		**Penetration Rate**	
X_1	**0**	**R_{CUM1}**	0
X_2	**0**	**R_{CUM2}**	0
X_3	**0**	**R_{CUM3}**	0
X_4	**0**	**R_{CUM4}**	0
X_5	**0**	**R_{CUM5}**	0
Z	**459**		
T	459		

X1 …… X5: Number of colonies growing in 5 parallel petri in the same sample
Z: number of colonies growing in the sixth petri dish
T: $X_1 + X_2 + X_3 + X_4 + X_5 + Z$

$R_{CUM1} = X1/T$
$R_{CUM2} = (X2 + X1)/T$
$R_{CUM3} = (X3 + X2 + X1)/T$
$R_{CUM4} = (X4 + X3 + X2 + X1)/T$
$R_{CUM5} = (X5 + X4 + X3 + X2 + X1)/T$

BARRIER INDEX (I_B)		
	Result	**Expected value (*)**
I_B	6	≥2,8

$I_B = 6 – (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$

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

Test Method: ISO 22612: 2005 (Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration)
Samples and containers are sterilized. Agar plates are placed in each container. Samples are placed aseptically in the apparatus. The covers are closed. After making a pot in the sample with the piston, the pistons are removed and 0.5 g ± 0.1 g are added to five samples from the powder contaminated with bacteria and the six to the non-contaminated powder. Then all openings are closed with a plastic bag. The device is operated to give 20,800 vibrations per minute. The test time is 30 minutes. After the test is over, all agar plates are incubated at 35 ° C for 24 hours.

Sample amount:	6 pieces 20x20 cm^2	
Mikroorganism:	*Bacillus subtilis ATCC 9372*	
Bacterial concentration (cfu/ml):	$1x10^8$	
Incubation conditions:	35°C / 24 hours	
RESULTS		
Number of Populationg Bacteria (cfu)		
1	1	
2	2	
3	1	
4	3	
5	2	
6 (Control)	0	
Total	9	
Logarithm	0.95	
** EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.*		
RESULT		
Result (cfu/g)		**Expected Value**
9 kob/gr		≤300kob/gr

DATE	09.08.2022
DOC.NO	MF69
PAGE NO	1
REV.NO	
REV.DATE	

TECHNICAL DATA SHEET

PRODUCT: **Sterile Reinforced Surgical Gown**

Description of Product:	Sterile Reinforced Surgical Gown , 35 gsm Sms+Reinforced	AllSizes	1
Raw Materials:	Sms+Reinforced		
Product Colour:	Medical Blue		
Reference Code:			
Weight in Grams:	35 gsm(Sms For Gown)+(Reinforced For Gown)		
Package:	Individually Pouch		

Product: MDD Manufactured in accordance with 93/42 / EEC Annex / IX requirements. Products and materials used do not contain metal.

Product Materials		
Unit / Size		
1	Sms + Reinforced	AllSizes

PROPERTIES

		S	M	L	XL	XXL
Reinforced Surgical Gown	A	117,0	125,0	132,0	140,0	150,0
	B	33,0	34,0	36,0	36,0	37,0
	C	57,0	58,0	59,0	60,0	63,0
	D	17,5	18,0	19,5	21,0	22,5
	E	142,0	146,0	155,0	160,0	167,0
	F	53,0	53,0	53,0	53,0	53,0

PRODUCT NAME	SIZE	REF. CODE
Reinforced Surgical Gown	S	SG-01202-01
Reinforced Surgical Gown	M	SG-01202-02
Reinforced Surgical Gown	L	SG-01202-03
Reinforced Surgical Gown	XL	SG-01202-04
Reinforced Surgical Gown	XXL	SG-01202-05
Reinforced Surgical Gown	XXXL	SG-01202-06

Tolerances: **+/- 2% cm**

Measurement: **cm**

Package Information

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into Baymed's standard sized carton; dimensions are as follows:
Height = 44 cm; Length = 40 cm ve Width = 60 cm.

Preparation Date

QUALİTY CONTROL APPROVAL