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

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

TEST REPORT
DENEY RAPORU

AB-0583-T
21007884-ING
03-21

Customer name:	BAYTEKS TEKSTİL SAN. VE TİC. A.Ş.
Address:	ORGANİZE SAN.BÖLG. 19 NOLU CAD. NO:9 MERKEZ/KİLİS
Buyer name:	TSE GAZİANTEP BELGELENDİRME MÜDÜRLÜĞÜ/İBRAHİM AÇAR
Contact Person:	KADİR KARAGÜL
Order No:	-
Article No:	-
Name and identity of test item:	Blue non-woven surgical gown
The date of receipt of test item:	01.03.2021
Re-submitted/re-confirmation date:	-
Date of test:	01.03.2021-11.03.2021
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:	6

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***
	11.03.2021	Zahide TAPAN	Sevim A. RAZAK 11.03.2021

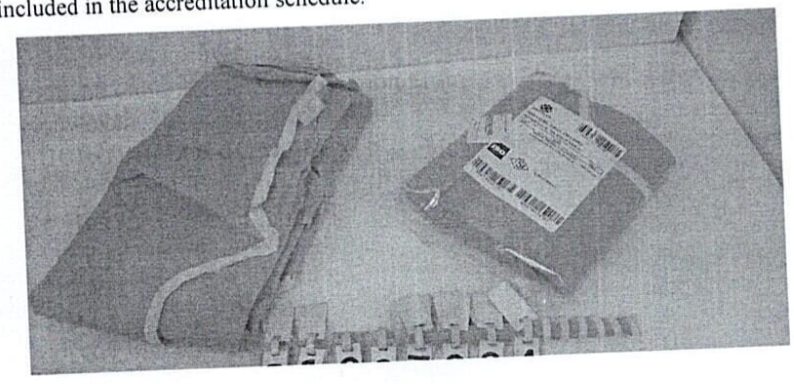
Digitally signed by Granaci Boris
Date: 2022.09.13 12:07:36 EEST
Reason: MoldSign Signature
Location: Moldova

Gen.f136-2/03

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES		
Water Permeability	P	
Lint and Other Particles Generation From Nonwoven	P	
MICROBIOLOGICAL TESTS		
Wet- Bacterial Penetration	P	
Dry-Bacterial Penetration	P	
Microbial Cleanliness (Bioburden)	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
Test results were evaluated according to EN 13795-1:2019 Standard Performance Properties limit values

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

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	54,1 cm H_2O	≥ 20 cm H_2O
Sample 2	56,2 cm H_2O	
Sample 3	53,7 cm H_2O	
Sample 4	63,7 cm H_2O	
Sample 5	60,1 cm H_2O	
Average	57,5 cm H_2O	

Gen.f136-2/03

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: Ref: EN ISO 11737-1:2018 /TS 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/ 100 cm^2)	14 cfu/100 cm^2	≤300 cfu/100 cm^2

***cfu= Colony forming unit.**

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):	$5x10^3$ kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		**Penetration Rate**	
X_1	45	R_{CUM1}	0,04
X_2	59	R_{CUM2}	0,09
X_3	93	R_{CUM3}	0,17
X_4	124	R_{CUM4}	0,28
X_5	135	R_{CUM5}	0,40
Z	659		
T	1115		

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	4,99	≥2,8

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

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TEST RESULT

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	0
2	0
3	0
4	0
5	0
6 (Control)	0
Total	0
Logarithm	-

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

RESULT	
Result (cfu/g)	**Expected Value**
0 cfu/g	≤300 cfu/g

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	:8	Total linting	:44
Standard deviation	: 5	Standard deviation	:35
Coefficient of variation	: 62%	Coefficient of variation	: 81%
Coefficient of linting (CL)	:1	Coefficient of linting (CL)	: 2

SAMPLE, MATERIAL (TOTAL)	
Total linting	51
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. both standard performance and high performance testing.

DATE	09.08.2022
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REV.DATE	

TECHNICAL DATA SHEET

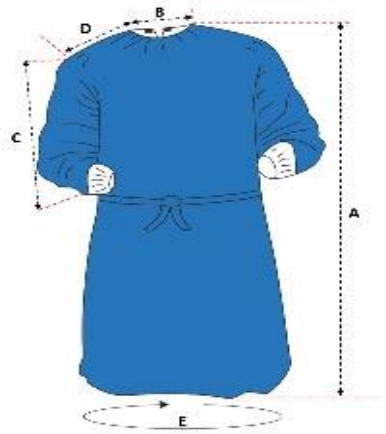
PRODUCT: **Sterile Standard Surgical Gown**

Description of Product:	Sterile Standard Surgical Gown	AllSizes	1
Raw Materials:	Sms		
Product Colour:	Medical Blue		
Reference Code:			
Weight in Grams:	40 gsm(Sms 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	AllSizes

PROPERTIES



		S	M	L	XL	XXL
Standard 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	-	-	-	-	-

PRODUCT NAME	SIZE	REF. CODE
Standard Surgical Gown	S	SG-01201-01
Standard Surgical Gown	M	SG-01201-02
Standard Surgical Gown	L	SG-01201-03
Standard Surgical Gown	XL	SG-01201-04
Standard Surgical Gown	XXL	SG-01201-05
Standard Surgical Gown	XXXL	SG-01201-06

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