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
22010571-ing
04-22

Customer name:	NURTEKS TEKSTİL VE MEDİKAL SAN. DŞ. TİC. A.Ş.
Address:	Veliköy OSB Mah. 9. Cad. No:35/1 ÇERKEZKÖY-TEKİRDAĞ
Buyer name:	-
Contact Person:	DİLEK SARICA
LOT No:	2204110765B18
Article No:	-
Name and identity of test item:	Blue non-woven gown.
The date of receipt of test item:	14.04.2022
Re-submitted/re-confirmation date:	-
Date of test:	14.04.2022-29.04.2022
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:	8

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*
TESTED BY EKOTEKS TEST EDİLMİŞTİR	29.04.2022	Tuğba AKTAŞ	Sevim A. RAZAK 29.04.2022

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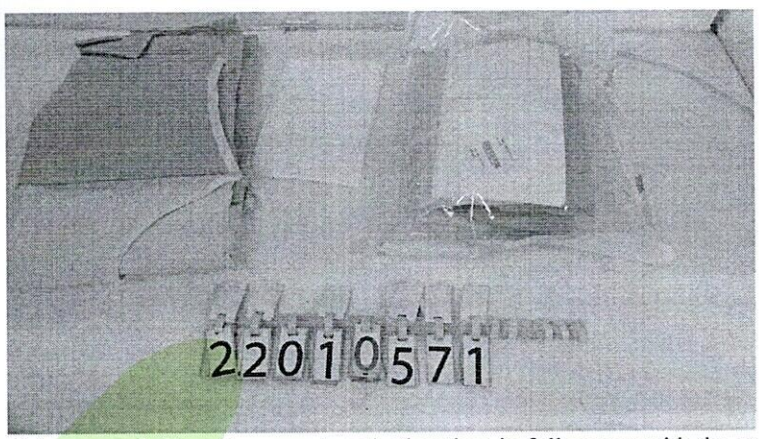
REQUIRED TESTS	EVALUATION	COMMENTS
PHYSICAL PROPERTIES		
Tensile Strength / **Dry**	P	
Tensile Strength / **Wet**	P	
Bursting Strength / **Dry**	P	
Bursting Strength / **Wet**	P	
Water Permeability	P	
Lint and Other Particles Generation From Nonwoven	P	
MICROBIOLOGICAL TESTS		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	-	See results.

P: Pass
F: Fail
R: Refer to retailer technologist.
Test results were evaluated according to EN 13795-1:2019(*) High 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

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	57,2 N	≥ 20N (Dry)
Warp	134,3 N	≥ 20N (Dry)

Total Uncertainty (%) : ± 4,9 %

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	53,3 N	≥ 20N (Wet)
Warp	137,8 N	≥ 20N (Wet)

Total Uncertainty (%) : ± 4,9 %

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 ;	159,0 kPa	≥ 40 kPa (Dry)
Height at Burst*	13,0 mm	

Total Uncertainty (%) : ± 3,4%

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TEST RESULTS

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 ;	180,0 kPa	≥ 40 kPa (Wet)
Height at Burst*	12,6 mm	
Total Uncertainty (%) :	± 3,4%	

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	152,0 cmH_2O	≥ 100 cmH_2O
Sample 2	170,3 cmH_2O	
Sample 3	165,2 cmH_2O	
Sample 4	162,2 cmH_2O	
Sample 5	163,2 cmH_2O	
Average	162,6 cmH_2O	
Total Uncertainty (%) :	± 7,7%	

TEST RESULT

LINT AND OTHER PARTICLES GENERATION FROM NONWOWEN; 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: 10 µm,
Air flow: 28,3 ± 1,4 L/min
Working mode: 30 s x 10 consecutive periods

PARTICLE SIZE (µM)	0.3	0.3 – 0.5	0.5 – 1.0	1.0 – 3.0	3.0 – 5.0	5.0 – 10.0
INNER SURFACE (Mean of 5 counts)	1920	308	194	10	4	**2**
INNER SURFACE (Standard deviation)	1289	224	126	7	3	**2**
INNER SURFACE (Coefficient of variation(%)	67	73	65	72	70	**99**
OUTER SURFACE (Mean of 5 counts)	2809	337	192	8	2	1
OUTER SURFACE (Standard deviation)	1750	184	85	2	1	1
OUTER SURFACE (Coefficient of variation(%)	62	55	44	26	35	70

SAMPLE, INNER SURFACE (3 µm – 10 µm)		SAMPLE, OUTER SURFACE (3 µm – 10 µm)	
Total linting	:12	Total linting	: 6
Standard deviation	: 8	Standard deviation	: 3
Coefficient of variation	: %64	Coefficient of variation	: %42
Coefficient of linting (CL)	: 1	Coefficient of linting (CL)	: 1

SAMPLE, MATERIAL (TOTAL) (3 µm – 10 µm)

Total linting	:18
Coefficient of linting (CL)*	:1

*According to EN ISO EN ISO 13795-1:2019, Coefficient of linting (CL) for $\Sigma > 3.0$ µm should be $\log_{10} \leq 4$ for analysis of critical product area and less critical product area of both standard performance and high performance testing.

Total Uncertainty (%) : Inner surface: ± 9,4 % Outer Surface: ± 12,1 %

TEST DETAILS AND RESULTS

Test: Microbial Cleanliness (Bioburden)

Test Method: EN ISO 11737-1:2018/Amd 1:2021 / TS EN ISO 11737-1 :2018/Amd 1:2021-05 Sterilization of health care products-Microbiological Methods-Part 1 : Determination of population of microorganisms on products Amendment 1

Test Principle: This method is applied to check the absence of live microorganism populations on the medical material. Samples to be used for the test should be supplied as presented to the end user in their original packaging. When selecting 5 samples, the top and bottom 3 samples are randomly selected. If the mask contains a visor or similar accessories, it should be tested in this way..

Test Details	
Number of Tested Sample	Min.5 samples / randomly selected
Shaker	5 min at 250rpm
Test Conditions	Temperature: 20±2 °C,relative humidity: 50±4%
Total viable aerobic microbial count	Temperature : 30±1°C Time: 72 hrs , PCA medium (Lot No: 807251)
Total fungi count	Sıcaklık: 20-25 °C Süre: 7 gün , SDA medium (Lot No: UK303787/061)
Used Test Solution	Sodium chloride peptone buffer

RESULT						REQUIREMENT
Number of Sample	**Weight (g)**	**Aerobic cfu/100 ml**	**Fungal cfu/100 ml**	**Total Bioburden (cfu/sample)**	**Total Bioburden (cfu/100 cm²)**	**Total Bioburden (cfu/100 cm²)**
1	2	4	1	15	7,5	≤300 cfu /100 cm²
2	2,3	4	1	15	6,5	
3	1,8	2	2	12	6,7	
4	1,7	5	1	18	10,5	
5	4,6	8	1	27	16,9	

**CFU: Colony forming unit*

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TEST DETAILS AND RESULTS

Test: Determine resistance to wet bacterial penetration

Test Method: ISO 22610:2018 Surgical drapes, gowns and fresh air suits used as medical devices for patients, clinical staff and equipment - test method to determine resistance to wet bacterial penetration

Test Principle: A test specimen is placed on an agar plate. A sheet of donor material, of corresponding size and carrying the bacteria, is placed on the test specimen with the contaminated side face down and covered by a polymer film. Two tithing conical steel rings hold the three sheets together, applying a tensile force. An abrasion-resistant finger is placed on top of the materials with a specified force to bring the test specimen in contact with the agar. The finger is moved over the entire surface of the plate in less than 15 min by means of a pivoted lever moved by an exocentric cam. The assemblage of materials, stretched by the weight of the steel rings, ensures that only a small area of the test specimen is brought into contact with the agar surface at any one time. Due to the combined effect of rubbing and liquid migration, bacteria may pass from the donor material through the test specimen down to the agar surface. After being tested for 15 min, the agar plate is replaced by a fresh one, and the test is repeated with the same donor and test specimen. Allowing 15 min for each test, five repetitions are performed with the same pair of donor and test specimen. In this way, the test allows for an estimation of the penetration over time. The agar plates are incubated in order to observe the bacterial colonies, which are then enumerated.

Details of test specimen assembly

Type of material tested	Nonwoven surgical gown fabric
Dimensions of test specimens (cm)	25 x 25
Number of samples tested	
Donor material and its thickness	Polyurethane film on siliconized carrier paper, 25 µm -30 µm
Cover film and its thickness	High density polyethylene, 30 µm
Description of the tested sample, Lot number	Non-woven fabric. LOT: 2204110765B18
Sterilization (please specify)	-

Conditions of test equipment

Test time	15 minutes
Agar plate rotation speed (r/min)	60 ± 1
Force exerted by the steel finger(N)	3.00 ± 0.05
Distance to brim (mm)	3.0 ± 0.5

Test environment and environmental controls

Temperature (°C) of the test environment	**20±5°C**
Relative humidity (%) of the test environment	**50±5%**
Number of colonies for the donor drying incubator	$1x10^4$
Number of colonies for the duration of test	$1x10^4$

Microorganism

Species and strain number	*Bacillus atrophaeus* ATCC 9372
Concentration of inoculum (spores/mL)	$9,5 \times 10^4$
Volume of test inoculum (mL)	1.0

Results of viable counts and percentage penetration values (*P*)						
	Colony counts on petri plates					
Specimen	**1th**	**2th**	**3rd**	**4th**	**5th**	**Total colony count (*S*)**
X1	1	0	0	0	0	0,2
X2	0	1	0	0	0	0,2
X3	0	0	1	1	0	0,4
X4	1	0	0	0	2	0,6
X5	0	2	1	1	0	0,8
S	2	3	2	2	3	2,4
I	10.000	10.000	10.000	10.000	10.000	10.000
Pn(%)	0,02	0,03	0,02	0,02	0,03	0,024

For each test specimens the percentage penetration values (*P*, %) was calculated using the following formula:

$P(\%) = (S \times 100) / I$

where, *I* is the bacterial challenge of spores on donor