

DECLARATION OF CONFORMITY

Manufacturer: *Su Biyomedikal Sistemler ve Saglik Sistemleri Ltd. Sti.*
Orhangazi Mah. 1673. Sok. No:20/2-3 Esenyurt, İstanbul, Turkey
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info@submed.com.tr www.submed.com.tr

We can confirm the following:

These medical devices are designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I of "**General requirements**" of **MDD 93/42/EEC**.

The submitted products have been tested by external laboratories according to **EN 14325:2018** and **EN 14126:2003** standards. The test results were done for checking performance features of the gowns according to **EN ISO 13043+A1:2005** standard.

The test results show that the gowns are protective clothing against liquid chemicals and provide performance requirements in **Type PB 6** class according to **EN 13043+A1:2005** standard and are in conformity with the provision of Regulation **(EU) 2016/425**.

Product Name : Surgical Gown

Product Specifications : Blue nonwoven gown

Tests carried out according to EN 14325:2018 and EN 14126:2003 standards and the test results:

EN ISO 13043:2005 TESTS				
Performed Tests	Performance	Test Result	Test Standard	Test Report No
Abrasion	Class 6	Pass	EN 14325:2018 4.4	20018421-ing
Water Permeability	Class 6	Pass	EN 14325:2018 4.4	20018421-ing
Tear Strength	Class 2	Pass	EN 14325:2018 4.7	20018421-ing
Tensile Strength	Class 1	Pass	EN 14325:2018 4.9	20018421-ing
Repellency to Liquids	Class 3	Pass	EN 14325:2018 4.12	20018421-ing
Resistance To Penetration By Liquids	Class 3	Pass	EN 14325:2018 4.13	20018421-ing
Seam Strength	Class 3	Pass	EN 14325:2018 5.5	20018421-ing
Puncture Resistance	Class 2	Pass	EN 14325:2018 4.10	20018421-ing
EN 14126:2003 TESTS				
Performed Tests	Performance	Test Result	Test Standard	Test Report No
Wet-Bacterial Penetration	Class 4	Pass	EN 22610:2016	20018421-ing
Resistance to Penetration By Blood and Body Fluids-Using Synthetic Blood	14 kPa	Pass	EN ISO 16603:2004	20020444-ing
Dry-Bacterial Penetration	Class 2	Pass	EN ISO 22612:2005	20020444-ing
Penetration by blood and other fluids-born pathogens. Phi-X174 bacteriophage method	There is no penetration	Pass	EN ISO 16604:2004	20RA07754
Penetration by biologically contaminated aerosols	Class 1	Pass	EN ISO 22611:2003	20RA07754

Please see the following pages for the test reports :



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Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

TEST REPORT
DENEY RAPORU

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Customer name: SU BİYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SAN. VE
TİC. LTD.ŞTİ.
Address: Orhangazi Mah. 1673.Sok. No:20/2-3 Esenyurt /İSTANBUL
Buyer name: -
Contact Person: BURCU YILMAZ
Order No: -
Article No: SURGICAL GOWN
Name and identity of test item: One sample of coated blue non-woven gown . (Claimed to be; Color Code:
Blue , Surgical Gown , Isolation Gown)
The date of receipt of test item: 09.06.2020
Re-submitted/re-confirmation date: -
Date of test: 09.06.2020-17.06.2020
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: 8



Date
17.06.2020

Customer Representative
Hatice ACARALP

Head of Testing Laboratory
Sevim A. RAZAK
17.06.2020

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REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
Abrasion	-	Class 6
Water Permeability	-	Class 6
Tear Strength	-	Class 2
Tensile Strength	-	Class 1
Repellency to Liquids	-	Class 3
Resistance To Penetration By Liquids	-	Class 3
Seam Strength	-	Class 3
Puncture Resistance	-	Class 2
MICROBIOLOGICAL TESTS		
Wet-Bacterial Penetration	-	Class 4
P: Pass F: Fail R: Refer to retailer technologist Tests were evaluated and classified according to BS EN 14325:2018 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 %. Tests marked (*) in this report are not included in the accreditation schedule.



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TEST RESULTS

Test Method : BS EN 14325:2018 (PROTECTIVE CLOTHING AGAINST CHEMICALS:TEST METHODS AND PERFORMANCE CLASSIFICATION OF CHEMICAL PROTECTIVE CLOTHING MATERIALS,SEAMS,JOINS AND ASSEMBLAGES (*)

ABRASION RESISTANCE AND LEAK TIGHTNESS

Clause 4.4.Abrasion Resistance (EN ISO 12947-2) ANNEX-B

Martindale Test Machine (47.5±2 rpm) with Lissajous Figure.

9 kPa pressure,

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

RESULT

No abrasion @ 2000 revs

CLASS

6

Classified according to the
Table-1

Determination of the highest number of abrasion rubs which does not cause damage to the material and which shall be used for the performance classification.

The abrasion resistance of sample shall be Classified according to the levels of performance given in Table-1

Table-1 Classification of Abrasion Resistance

Class	Number of rubs
6	>2000
5	>1000
4	>400
3	>100
2	>40
1	>10

Clause 4.4.2.3 Hydrostatic head end –point determination (EN 20811)

If the average hydrostatic head exceeds 200mm,then the hydrostatic head method is applicable and the leak tightness shall be determined.

WATER PERMEABILITY ; EN ISO 811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model

Temperature of water 10.°C. Pressure increase ratio 10 mbar/dk.

Performed in the conditioned room (20±2°C-65%±4)

RESULT

1876.8 mm SS

1632.0 mm SS

1662.6 mm SS

1530.0 mm SS

1668.7 mm SS

REQUIREMENT

>200 mmSS

Sample 1

Sample 2

Sample 3

Sample 4

Average

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TEST RESULT

TRAPEZOIDAL TEAR STRENGTH

Clause: 4.7. Trapezoidal Tear Resistance TS EN ISO 9073-4:2002(*)

Instron 5969 Speed:100±10 mm/min, Gauge length:5cm

The average results are given for width and length direction of five samples.

2 pre-tension applied

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

Width **RESULT**
30.0 N

Length 45.8 N

CLASS
1

Classified according to
the Table-4

Table-4 Classification of Trapezoidal Tear Resistance

Class	Tear Strength
6	>150 N
5	>100 N
4	>60 N
3	>40 N
2	>20 N
1	>10 N

TENSILE STRENGTH

Clause 4.9. Tensile Strength EN ISO 13934-1:2013

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 width and length direction of five samples.

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

Width **RESULT**
51.8N

Length 85.3 N

CLASS
1

Classified according to
the Table-5

Table-4 Classification of Tensile Strength

Class	Tensile Strength
6	>1000 N
5	>500 N
4	>250 N
3	>100 N
2	>60 N
1	>30N

TEST RESULT

REPELLENCY TO LIQUIDS

Clause 4.12 Repellency to Liquids (EN ISO 6530:2005)

When tested in accordance with EN ISO 6530 for repellency to the liquid chemicals given in Table -9, the material shall be classified According to the levels performance in given Table-10 for each chemical tested.

Use those liquids against which protection is required, water is also convenient and safe liquid for general screening purposes.

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

For each test liquid ,cut six test specimens of (360±2)mm by (235±5)mm from the sample.

Chemicals shall be of analytical purity grade.

Discharged the test liquid (10cm 3) within (10±1)s

Table-9 List of reference chemicals for absorption ,penetration and repellency testing

Chemical	Concentration weight %	Temperature of chemical (±2°C)
Sulfuric Acid (H ₂ SO ₄)	30	20
Sodium Hydroxide (NaOH)	10	20
o-Xylene	Undiluted	20

Table 10- Classification of Repellency to liquids

Class	Repellency Index (<i>I_R</i>)
3	> 90 %
2	>80 %
1	>70 %

Clause 4.13 Resistance to penetration by liquids (EN ISO 6530)

Table 11- Classification of Resistance to penetration by liquids

Class	Penetration Index (<i>I_p</i>)
3	< 1 %
2	< 5 %
1	<10 %

RESULT

Chemical	Concentration weight %	<i>I_p</i>	Class	<i>I_R</i>	Class
Sulfuric Acid (H ₂ SO ₄)	30	< 1%	3	> 90%	3
Sodium Hydroxide (NaOH)	10	< 1 %	3	> 90%	3
o-Xylene	Undiluted	< 1%	1	> 80%	2

I_p:index of penetration

I_R: index of repellency

I_A: index of absorbtion

* Classification could not be made because the values in the table in the standard are not appropriate.

TEST RESULT

SEAM STRENGTH-GRAB METHOD

Clause 5.5 Seam Strength ISO 13935-2: 2014

Jaw Speed: 50±5 mm/min, Gauge Length: 100 mm±1 mm.

Seam Type : 301. 100 % Polyester core-spun sewing-thread was used.

5kN. load was applied.

The average results are given for width and length direction of five samples.

Performed in the conditioned room(20±2°C-65%±4)

	<u>Seam Strength (N)</u>	<u>Failure</u>	<u>Requirement</u>
Width	109.8	FTJ	3 Classified according to the Table-13
Length	76.2	FTJ	

FTJ : Fabric Tear At The Jaw

Table 13- Classification of Seam Strength

CLASS	Seam strength
6	>500 N
5	>300 N
4	>125 N
3	>75 N
2	>50 N
1	>30 N

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TEST RESULT

PUNCTURE RESISTANCE

Clause 4.10.Puncture Resistance EN 863 (*)

Performed in the conditioned room(20±2°C-65%±4)

The average results are given four samples.

<u>SAMPLE</u>	<u>PUNCTURE RESISTANCE RESULT (N)</u>	<u>REQUIREMENT</u>
1	24.9	2 Classified according to the Table- 6
2	26.0	
3	29.3	
4	23.9	
Average Result	26.0	

RESULT

26.0 N

CLASS

Table-4 Classification of Puncture Resistance
(Tablo-6)

<i>Class</i>	<i>Puncture Resistance</i>
6	>250 N
5	>150 N
4	>100 N
3	>50 N
2	>10 N
1	>5N

Gen.fl136-2/03

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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 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 ($3N \pm 0.02$). 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):	1-4x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS

Breakthrough time, t min	Number of Populating Bacteria (cfu)		Penetration Rate	
15	X ₁	0	R _{CUM1}	0
30	X ₂	0	R _{CUM2}	0
45	X ₃	0	R _{CUM3}	0
60	X ₄	35	R _{CUM4}	0.06
75	X ₅	49	R _{CUM5}	0.15
	Z	457		
	T			541

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: 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

EVALUATION

Result	Class (*)
45 < t ≤ 60	4

(*) BS EN 14126:2003 Protective Clothing —Performance requirements and tests methods for protective clothing against infective agents

Class	Breakthrough time, t min
6	t > 75
5	60 < t ≤ 75
4	45 < t ≤ 60
3	30 < t ≤ 45
2	15 < t ≤ 30
1	≤ 15 min

Gen.fl136-2/03

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TEST RESULTS

DETERMINATION OF THE RESISTANCE TO PENETRATION BY BLOOD AND BODY FLUIDS-USING SYNTHETIC BLOOD; ISO 16603:2004 (*)

Textest, FX 3000-IV model + External Blood Cell

Test samples were conditioned at $60 \pm 10\%$ relative humidity and $21 \pm 5^\circ \text{C}$ for at least 24 hours before testing.

Test Procedure Applied:		A procedure			
Pressure (kPa)	Time (Min.)	Test Result			Overall Result
		Test 1	Test 2	Test 3	
0	5	Pass	Pass	Pass	PASS
14	1	Pass	Pass	Pass	
0	4	Pass	Pass	Pass	
Thickness of material tested (mm):		0,4	0,4	0,4	
Weight of material tested (g/m ²) :		53	53	53	

DETERMINATION OF THE RESISTANCE TO PENETRATION BY BLOOD AND BODY FLUIDS-USING SYNTHETIC BLOOD; ISO 16603:2004 (*)

Textest, FX 3000-IV model + External Blood Cell

Test samples were conditioned at $60 \pm 10\%$ relative humidity and $21 \pm 5^\circ \text{C}$ for at least 24 hours before testing.

Test Procedure Applied:		C procedure			
Pressure (kPa)	Time (Min.)	Test Result			Overall Result
		Test 1	Test 2	Test 3	
0	5	Pass	Pass	Pass	Shall be determined by the customer
1,75	5	Pass	Pass	Pass	
3,5	5	Pass	Pass	Pass	
7	5	Pass	Pass	Pass	
14	5	Pass	Pass	Pass	
20	5	Fail	Fail	Fail	
Thickness of material tested (mm):		0,4	0,4	0,4	
Weight of material tested (g/m ²) :		53	53	53	

Gen.fl136-2/03

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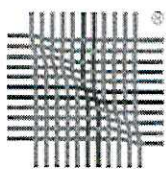
TEST RESULTS

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 \pm 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
Mikroorganizm:	<i>Bacillus subtilis</i> 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	7
4	8
5	12
6 (Control)	0
Total	30
Logarithm	1.47
EVALUATION	
Result	Class (*)
1 < log kob \leq 2	2
<i>* EN 14126: 2003 Protective Clothing - Performance Properties and Test Methods of Protective Clothing Against Infectious Agents are evaluated according to Table-4.</i>	
Sınıf	Penetrasyon (log kob)
3	≤ 1
2	1 < log kob \leq 2
1	2 < log kob \leq 3
<i>* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.</i>	
RESULT	
Result (cfu/g)	Expected Value
30	≤ 300 cfu/g

Gen.fl36-2/03



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Innovation experience

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Test Report 20RA07754

21/07/2020

Messrs

**SU BIYOMEDİKAL SİSTEMLER VE SAĞLIK
HİZMETLERİ SAN VE TİC.LTD STİ.**

Orhangazi Mah. Sok.1673 No.20 kat 2-3 Esenyurt 20
İstanbul - TR

Samples and identifications

Sample 20LA12647

Receipt date: 08/07/2020

Sample receiving date: 08/07/2020

Description

Description: Coated blue non-woven gown Art. SURGICAL GOWN

Sampling carried out by: Customer

This Test Report consists of the following results

0112 Protective clothing. Penetration by blood and other body fluids-born pathogens. Phi-X174 bacteriophage method

0134 Protective clothing. Penetration by biologically contaminated aerosols

Protective clothing. Penetration by blood and other body fluids-born pathogens. Phi-X174 bacteriophage method

Product standard	UNI EN 14126:2004
Test method	ISO 16604:2004 + UNI EN 14126:2004 Par. 4.1.4.1
Test equipment	Penetration test cell
Name of test microorganism	Bacteriophage Phi-X 174 (ATCC 13706-B1 LOT: CNCM 14812)
Specimens dimensions	(75x75) mm
Penetration survey method	Plaque-forming units (PFU)
Number of specimens	3
Procedure	Procedure B (0 kPa for 5 min, 14 kPa for 1 min and 0 kPa for 0 min.)
Pretreatment	No
Test began on:	14/07/2020
Test ended on:	17/07/2020

Results for sample 20LA12647

	UM	result
Pre-test bacteriophage titer	PFU/ml	6.8E+007
Post-test bacteriophage titer	PFU/ml	6.7E+007
Test pressure	kPa	14
1st specimen		Pass
2nd specimen		Pass
3rd specimen		Pass
Negative control (polyethylene 10 µm)		Pass
Positive control		Fail

Pass. The specimen resist to penetration and micro-organism used for test doesn't pass through the fabric.

Fail. The specimen doesn't resist to penetration and micro-organism used for test pass through the fabric.

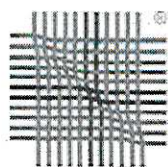
The sample pass the test when the viral particles don't penetrate them through the sample to one determined pressure and doesn't come found plaques due to cell lysis.

All acceptance criteria was met.

Results contained in this report refer only to tested manufactures.

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Institute member of National Registry Office of Research code E0190Y27 and of the Highly Qualified Laboratories Association according to law 46 (02/17th/1982) and authorized to carry out applied research programmes by the Ministry of University and Scientific Research and Technology.



Protective clothing. Penetration by biologically contaminated aerosols

Product standard	UNI EN 14126:2004
Test method	ISO/DIS 22611:2003 + UNI EN 14126:2004 Par. 4.1.4.3
Culture medium	Nutrient agar (Oxoid LOT: 2438261)
Name of test microorganism	Staphylococcus aureus (ATCC 6538 LOT: DSM 799-0415)
Test equipment	Perspex box with Collison atomizer
Specimens dimensions	Diameter 25 mm
Number of specimens	4
Pretreatment	No
Test began on:	14/07/2020
Test ended on:	16/07/2020

Results for sample	20LA12647	UM	result
Micro-organisms extract to membrane REFERENCE (Value A)			
1st specimen		CFU	6.7E+002
2nd specimen		CFU	8.2E+002
3rd specimen		CFU	7.7E+002
4th specimen		CFU	7.1E+002
Average (A)		CFU	7.4E+002
Micro-organisms extract to membrane specimen (Value B)			
1st specimen		CFU	0
2nd specimen		CFU	0
3rd specimen		CFU	0
4th specimen		CFU	0
Average (B)		CFU	0.0
Penetration ratio (A/B)		Log10 CFU	<1

Issue date
21/07/2020

Microbiological Laboratory Manager
dott. Giovanni Tanchis

End of Test Report 20RA07754