

## DECLARATION OF CONFORMITY

Manufacturer: *Su Biyomedikal Sistemler ve Saglik Sistemleri Ltd. Sti.*  
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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**.

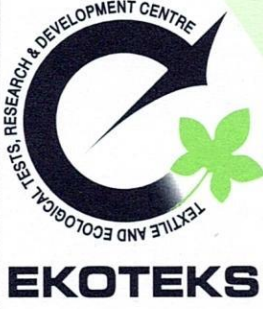
**Product Name :** Surgical Gown

**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 |
|--------------------------------------------------------------------------------------------------------------------------------------------|--------|----------|
| <b>PHYSICAL PROPERTIES TESTS</b>                                                                                                           |        |          |
| 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  |
| <b>MICROBIOLOGICAL TESTS</b>                                                                                                               |        |          |
| Wet-Bacterial Penetration                                                                                                                  | -      | Class 4  |
| P: Pass<br>F: Fail<br>R: Refer to retailer technologist<br>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 <sub>2</sub> SO <sub>4</sub> ) | 30                     | 20                              |
| Sodium Hydroxide (NaOH)                         | 10                     | 20                              |
| o-Xylene                                        | Undiluted              | 20                              |

**Table 10- Classification of Repellency to liquids**

| Class | Repellency Index ( <i>I<sub>R</sub></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<sub>p</sub></i> ) |
|-------|--------------------------------------------|
| 3     | < 1 %                                      |
| 2     | < 5 %                                      |
| 1     | <10 %                                      |

## RESULT

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

*I<sub>p</sub>*:index of penetration

*I<sub>R</sub>*: index of repellency

*I<sub>A</sub>*: index of absorbtion

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

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## 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<br>Classified according to the<br>Table-13 |
| Length | 76.2                     | FTJ            |                                              |

FTJ : Fabric Tear At The Jaw

Table 13- Classification of Seam Strength

| <b>CLASS</b> | <b>Seam strength</b> |
|--------------|----------------------|
| 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<br/>RESULT (N)</u> | <u>REQUIREMENT</u>                           |
|----------------|-------------------------------------------|----------------------------------------------|
| 1              | 24.9                                      | 2<br>Classified according to the Table-<br>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                        |

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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.

|                                            |                                        |
|--------------------------------------------|----------------------------------------|
| <b>Sample amount:</b>                      | 5 pieces 25x25cm2                      |
| <b>Carrier Material:</b>                   | 30 µm thin, 25x25cm2 Polyurethane Film |
| <b>Coating Material:</b>                   | 25x25cm2 HDPE Film                     |
| <b>Microorganism:</b>                      | Staphylococcus aureus ATCC 29213       |
| <b>Bacterial Concentration (kob / ml):</b> | 1-4x104 kob / ml                       |
| <b>Incubation Conditions:</b>              | (36 ± 1) ° C 48 hours                  |

## RESULTS

| Breakthrough time, t<br>min | Number of Populating Bacteria<br>(cfu) |     | Penetration Rate  |      |
|-----------------------------|----------------------------------------|-----|-------------------|------|
| 15                          | X <sub>1</sub>                         | 0   | R <sub>CUM1</sub> | 0    |
| 30                          | X <sub>2</sub>                         | 0   | R <sub>CUM2</sub> | 0    |
| 45                          | X <sub>3</sub>                         | 0   | R <sub>CUM3</sub> | 0    |
| 60                          | X <sub>4</sub>                         | 35  | R <sub>CUM4</sub> | 0.06 |
| 75                          | X <sub>5</sub>                         | 49  | R <sub>CUM5</sub> | 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: 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

## 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<br>min |
|-------|-----------------------------|
| 6     | t > 75                      |
| 5     | 60 < t ≤ 75                 |
| 4     | 45 < t ≤ 60                 |
| 3     | 30 < t ≤ 45                 |
| 2     | 15 < t ≤ 30                 |
| 1     | ≤ 15 min                    |

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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 <sup>2</sup> ) : |             | 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 <sup>2</sup> ) : |             | 53          | 53     | 53     |                                     |

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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.

|                                                                                                                                                                            |                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| <b>Sample amount:</b>                                                                                                                                                      | 6 pieces 20x20 cm <sup>2</sup>     |
| <b>Mikroorganism:</b>                                                                                                                                                      | <i>Bacillus subtilis</i> ATCC 9372 |
| <b>Bacterial concentration (cfu/ml):</b>                                                                                                                                   | 1x10 <sup>8</sup>                  |
| <b>Incubation conditions:</b>                                                                                                                                              | 35°C / 24 hours                    |
| <b>RESULTS</b>                                                                                                                                                             |                                    |
| <b>Number of Population Bacteria (cfu)</b>                                                                                                                                 |                                    |
| 1                                                                                                                                                                          | 1                                  |
| 2                                                                                                                                                                          | 2                                  |
| 3                                                                                                                                                                          | 7                                  |
| 4                                                                                                                                                                          | 8                                  |
| 5                                                                                                                                                                          | 12                                 |
| 6 (Control)                                                                                                                                                                | 0                                  |
| Total                                                                                                                                                                      | 30                                 |
| Logarithm                                                                                                                                                                  | 1.47                               |
| <b>EVALUATION</b>                                                                                                                                                          |                                    |
| <b>Result</b>                                                                                                                                                              | <b>Class (*)</b>                   |
| 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> |                                    |
| <b>Sınıf</b>                                                                                                                                                               | <b>Penetrasyon (log kob)</b>       |
| 3                                                                                                                                                                          | $\leq 1$                           |
| 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>                                                     |                                    |
| <b>RESULT</b>                                                                                                                                                              |                                    |
| <b>Result (cfu/g)</b>                                                                                                                                                      | <b>Expected Value</b>              |
| 30                                                                                                                                                                         | $\leq 300$ cfu/g                   |

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C.F. e P.IVA 01724710122

## Test Report 20RA07754

of 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.

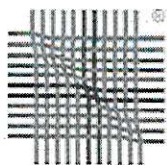
The sample pass the test when the viral particles don't penetrate them through the sample to one determined pressure and doesn't come found plaques due to cell lysis.

All acceptance criteria was met.

Results contained in this report refer only to tested manufactures.

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**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**