

**1. PRODUCT**

Adhesive Drape Sheet

**2. PRODUCT CONFIRMITIES**

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009, ISO 10993-7:2008, EN 20811

**3. DESCRIPTION**

175\*175 CM - 2 pc

Nonwoven , 3 layers 55 gsm,

Antiallergenic, AirPermeable, Non-Linting

Water Proof , latex free

**4. PACKING**

The product is individually packaged. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, validity date, lot number, etc.

**5. STORAGE**

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

**6. Term of validity**

Sterile EO. 3 years from the date of production



**1. PRODUCT**

Adhesive-Absorbent Drape Sheet

**2. PRODUCT CONFIRMITIES**

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009, ISO 10993-7:2008, EN 20811

**3. DESCRIPTION**

70\*100 CM - 4 pc

Nonwoven , 3 layers 55 gsm,

Antiallergenic, AirPermeable, Non-Linting

Water Proof , latex free

**4. PACKING**

The product is individually packaged. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, validity date, lot number, etc.

**5. STORAGE**

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

**6. Term of validity**

Sterile EO. 3 years from the date of production



**1. PRODUCT**

Fenestrated Drape Sheet

**2. PRODUCT CONFIRMITIES**

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009, ISO 10993-7:2008, EN 20811

**3. DESCRIPTION**

75\*90 CM

Nonwoven , 3 layers 55 gsm,

Antiallergenic, AirPermeable, Non-Linting

Water Proof , latex free

**4. PACKING**

The product is individually packaged. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, validity date, lot number, etc.

**5. STORAGE**

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

**6. Term of validity**

Sterile EO. 3 years from the date of production



## 1. PRODUCT

## Table Cover

## 2. PRODUCT CONFIRMITIES

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009, ISO 10993-7:2008, EN 20811

### 3. DESCRIPTION

**160\*240 Cm**

Nonwoven , 2 layers 65 gsm,  
Antiallergenic, AirPermeable, Non-Linting  
Water Proof , latex free

## 4. PACKING

The product is individually packaged. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, validity date, lot number, etc.

## 5. STORAGE

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

## 6. Validity

Sterile EO. 3 years from the date of production



## 1. PRODUCT

## Super Absorbent Field

## 2. PRODUCT CONFIRMITIES

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009, ISO 10993-7:2008, EN 20811

### 3. DESCRIPTION

**55\*70 Cm**

Nonwoven ,3 layers 80 gsm,  
Antiallergenic, AirPermeable, Non-Linting  
Water Proof , latex free

## 4. PACKING

The product is individually packaged. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, validity date, lot number, etc.

## 5. STORAGE

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

## 6. Validity

Sterile EO. 3 years from the date of production

[illegible]

## FULL REINFORCED SURGICAL GOWN

1. **Intended Use:** *Protective Cloth for Surgical Operations*

2. **Sizes:**

- **XS** (length 105 cm. front 140cm, 5%, sleeve length: 50 cm  $\pm 5\%$ )
- **S** (length 110 cm.  $\pm 5\%$ , front 140 cm, sleeve length: 50 cm  $\pm 5\%$ )
- **M** (length 117,5 cm. front 145cm,  $\pm 5\%$ , sleeve length: 50 cm  $\pm 5\%$ )
- **L** (length 125 cm.  $\pm 5\%$ , front 150 cm, sleeve length: 50 cm  $\pm 5\%$ )
- **XL** (length 132,5 cm.  $\pm 5\%$ , front 150 cm, sleeve length: 55 cm  $\pm 5\%$ )
- **XXL** (length 140 cm. front 155 cm,  $\pm 5\%$ , sleeve length: 60 cm  $\pm 5\%$ )
- **XXXL** (length 150 cm.  $\pm 5\%$ , front 155 cm, sleeve length: 60 cm  $\pm 5\%$ )

3. **Material:**

- Made of Spunbond Meltblown Spunbond 35 GSM SMS Non-woven Fabric
- Glue 3 GSM
- White Protective Lamination 15 GSM
- Front Side Waterproof
- Back Side Waterabsorbent
- Elastic Sleeve Cuffs(Made of Cotton)
- Anti Bacterial
- Alcohol & Blood and Water Resistant
- Breathable
- Cartboard
- Sterile EO and Packed Individually

4. **Content:**

- Reinforced Surgical Gown ( 53 Gsm) -1 Pc.
- Towels 40x40 Cm. (Cellulose 54 Gsm)-2 Pcs.

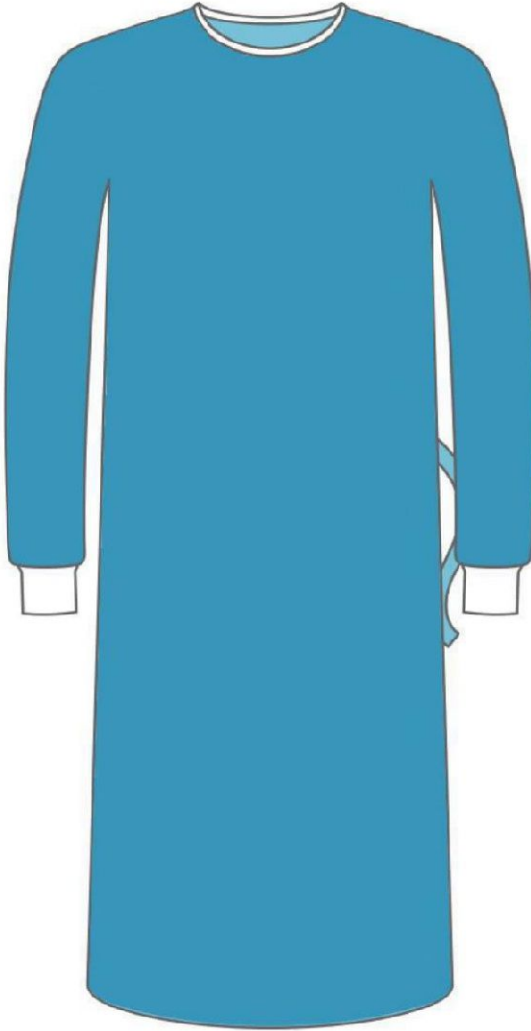
5. **Storage:** Under Normal Conditions, cool and dry places.Avoid Direct Sunlight.

### WARNING

**Do not use if package damaged or opened.**

#### 6. Packing Per Box

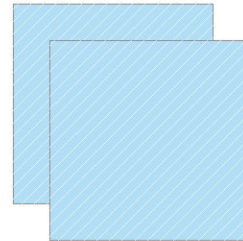
- 40Cm x 50Cm x 60 Cm Dimension of Box
- 14 Kgs Weight
- 50 Pcs



**FRONT**



**BACK**



**1. PRODUCT**

LARGE SURGICAL SET

**2. CONFORMITY ASSESSMENTS**

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009,  
ISO 10993-7:2008

**3. DESCRIPTION**

Product	Description	Quantity
Mayo Cover	80*145 cm	1
Adhesive Drape	75*90 cm	2
Towel	20*25 cm	4
Op-Tape	10*50 cm	1
Adhesive Drape	175*175 cm	1
Adhesive Drape	150*240 cm	1
Absorbent Drape	150*190 Cm	1

**4. PACKING**

The set is individually packed. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, expiration date, lot number, etc.

**5. STORAGE**

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

**6. Validity**

Sterile EO. 3 years from the date of production





## 1. PRODUCT

## Standard Surgical Set

## 2. CONFORMITY ASSESSMENTS

**ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009, ISO 10993-7:2008**

### 3. DESCRIPTION

No.	Product	Description	Quantity
1	Mayo Table Cover	80*140 cm	1
2	Adhesive Drape	150x240 cm	1
3	Adhesive Drape	175*175 cm	1
4	Adhesive Drape	75*90 cm	2
5	Towel	20*25 cm	4
6	Op-Tape	20*25 cm	1

## 4. PACKING

The set is individually packed. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, expiration date, lot number, etc.

## 5. STORAGE

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

## 6. Validity

Sterile EO. 3 years from the date of production

~~ZEYİN MEDİKAL  
TEKSTİL İNŞAAT SAN. TİC. LTD. ŞTİ.  
Yatırımcı Mh. 1400 Te. Sk. No 17  
Yıldırım BURSA  
Marmar 1400 Te. Sk. No 17  
Marmar 1400 Te. Sk. No 17~~

**1. PRODUCT**

ENT Set – 2 surgical interventions

**2. CONFORMITY ASSESSMENTS**

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009,  
ISO 10993-7:2008

**3. DESCRIPTION**

No.	Product	Description	Quantity
1	Adhesive Drape with Hole	110*190 cm	2
2	Table Cover	100*210 cm	2
3	Towel	20*20 cm	10

**4. PACKING**

The set is individually packed. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, expiration date, lot number, etc.

**5. STORAGE**

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

**6. Term of validity**

Sterile EO. 3 years from the date of production

ZEYNI MEDİKAL  
TEKSTİL İŞAAT SAN. VE TİC. LTD. ŞTİ.  
Yamanevler Mah. İnönü Cad. No: 17  
Yıldırım BURSA  
Tic. Sic. No: 1400 Tic. Sic. No: 102917  
Mersis: 0703001411400000001

**1. PRODUCT**

ENT Set – 5 surgical interventions

**2. CONFORMITY ASSESSMENTS**

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009, ISO 10993-7:2008

**3. DESCRIPTION**

No.	Product	Description	Quantity
1	Adhesive Drape with Hole	110*140 cm	5
2	Table Cover	100*210 cm	5
3	Towel	20*20 cm	20
4	Mayo Cover	80*140 cm	1

**4. PACKING**

The set is individually packed. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, expiration date, lot number, etc.

**5. STORAGE**

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

**6. Validity**

Sterile EO. 3 years from the date of production



**1. PRODUCT**

PROTOCOLGY Set

**2. CONFORMITY ASSESSMENTS**

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009,  
ISO 10993-7:2008

**3. DESCRIPTION**

No.	Product	Description	Quantity
1	Mayo Cover	80*145 cm	1
2	Table Cover	100*210 cm	1
3	Adhesive Drape	110*140 cm	2
4	Adhesive Drape	75*100 cm	2
5	Towel	20*25 cm	2

**4. PACKING**

The set is individually packed. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, expiration date, lot number, etc.

**5. STORAGE**

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

**6. Term of validity**

Sterile EO. 3 years from the date of production



**1. PRODUCT**

TUR Set

**2. CONFORMITY ASSESSMENTS**

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009,  
ISO 10993-7:2008

**3. DESCRIPTION**

No.	Product	Description	Quantity
1	TUR DRAPE	200*250 Cm	1
2	Table Cover	150*200 Cm	1
3	Mayo Cover	80*145 Cm	1
4	Sterile Drape	75*90 Cm	1
5	Towel	33*33 Cm	4
6	Camera Cover	15*250 Cm	1

**4. PACKING**

The set is individually packed. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, expiration date, lot number, etc.

**5. STORAGE**

The product is deposited in the original packaging. Store in a dry and clean place, away from moisture, from 0°C to + 30°C, away from direct sunlight, water droplets and solvent vapors.

**6. Validity**

Sterile EO. 3 years from the date of production







# MEDICAL QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

**Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.**

**Yunus Emre Mah. 12.Yildirim Sok. No 17 Yildirim-Bursa/Turkey**

by review of SA2-5076 numbered report for the scope

**Manufacture And Sales Of Disposable Surgical Sterile Gowns,  
Drapes And Custom Packs, Non-Sterile Medical Textile Products**

to certify that a management system in accordance with  
standard's clauses is established and being implemented

**DIN EN ISO 13485:2016**

**Certificate No :MDMS 0520 006861**

**Original Certification Date : 22.04.2020**

**Issue / Revised Date : 13.04.2022**

**Expiry Date : 21.04.2023**

**Certification Period : 3 years (3<sup>rd</sup> year)**



Universal GmbH

The authenticity of this certificate can be confirmed online or by e-mail to the Head Office via:

UNIVERSAL GmbH • Wilfried Diekmann Str., 20b, 44536 Lünen Germany • T : +49 (0) 231 9931 9960 • info@uni-cert.de • www.uni-cert.de





# QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

**Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.**

**Yunus Emre Mah. 12.Yildirim Sok. No 17 Yildirim-Bursa/Turkey**

by review of SA2-5076 numbered report for the scope

**Manufacture And Sales Of Disposable Surgical Sterile Gowns,  
Drapes And Custom Packs, Non-Sterile Medical Textile Products**

to certify that a management system in accordance with  
standard's clauses is established and being implemented

**DIN EN ISO 9001:2015**

**Certificate No : QMS 0520 006861**

**Original Certification Date : 22.04.2020**

**Issue / Revised Date : 13.04.2022**

**Expiry Date : 21.04.2023**

**Certification Period : 3 years (3<sup>rd</sup> year)**



**DAkkS**  
Deutsche  
Akkreditierungsstelle  
D-ZM-16058-01-00

Universal GmbH



The authenticity of this certificate can be confirmed online or by e-mail to the Head Office via:

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SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate has been awarded to

**ZEYİNİ MEDİKAL TEKSTİL İNŞAAT  
SANAYİ VE TİCARET LİMİTED ŞİRKETİ**

**YUNUSEMRE MAHALLESİ 12. YILDIRIM SOKAK NO:17  
YILDIRIM / BURSA / TÜRKİYE**

In recognition of the organization's Management System  
which complies with

**EN 13795-1:2019**

The scope of activities covered by this certificate is defined below

**MANUFACTURING, SALES OF DISPOSABLE, STERILE AND NON-STERILE  
SURGICAL GOWNS, INSULATED VISITOR GOWNS AND COVERS**

**TEK KULLANIMLIK, STERİL VE STERİL OLMAYAN CERRAHİ ÖNLÜK,  
İZOLASYONLU ZİYARETÇİ ÖNLÜĞÜ VE ÖRTÜLERİN İMALATI, SATIŞI**

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

Certificate Number: **SISTUREN082020161**

Date of Issue of Original Certificate: **21.08.2020**

Date of Issue of latest certificate: **23.09.2021**

Expiry Date: **20.08.2022**

Re-certification Due on: **21.07.2023**

  
*Managing Director*



**Note:** This certificate is valid only if produced with the  
continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Compliance is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid

Corporate office(SIS): Unit No. 514, 5th Floor, Vipul Business Park, Sohna Road, Sector-48, Gurgaon-122018, Haryana, India.  
International office(SIS):- URB. Santa Ana Cal. German, Schrieber 276, San Isidro, Lima, Peru 15047.  
Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91 99105 01396, + 91 96430 73391  
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Web:- http://www.siscertifications.co.in, www.siscertifications.com

Issue No.: 03

**CERTIFICATE OF COMPLIANCE**







## ZEYİNİ MEDİKAL TEKSTİL İNŞ.SAN. VE TİC. LTD. ŞTİ.

YUNUSEMRE MAH. 12 YILDIRIM SOKAK NO:17 YILDIRIM/BURSA

**Report No.** 111699085  
**Buyer** /  
**Test Item. :** Bilayered and Absorbent Drapes  
**Item No. :** /  
**Colour Name. :** /  
**Condition at delivery. :** Samples tested as received.  
**Test Scope. :** Parameters selected by customer  
**Test Specification :** Determination of hydrostatic pressure

**Applicant's Provided  
Care Instruction/Label:** -

**Sample Receiving date:** 2021-10-18 (p.m)  
**Testing Period:** 2021 10-21 to 2021-10-25  
**Test Result:** Passed

**For and on behalf of**  
**TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş**

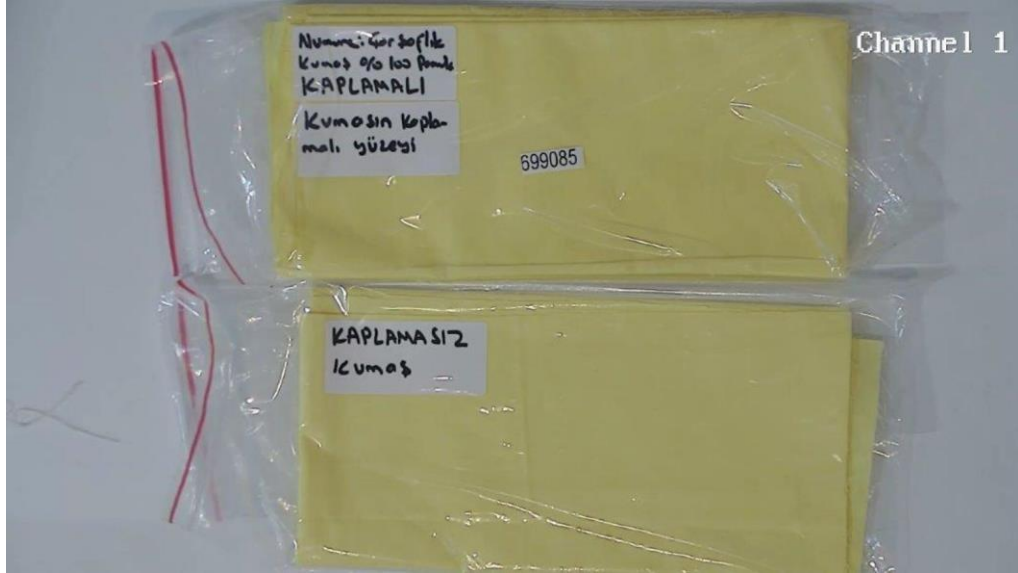
Tomris Hasańcebi / Customer  
Relations Manager

Abdullah Akil / Physical  
Laboratory Manager

## Products

Report No.: 111699085

Date: 10.25.2021



**Products**

Report No.: 111699085

Date: 10.25.2021

**Material List:**

Page 3 of 6

Material No.	Material	Color	Location
M001	Textile	-	Textile
M002	Textile + coating	-	Textile w /coating

## Products

Report No.: 111699085

Date: 10.25.2021

## Conclusion:

Page 4 of 6

### TEST PROPERTY

M001

M002

Hydrostatic Pressure Test

#

#



**TÜVRheinland®**

Precisely Right.

## Products

Report No.: 111699085

Date: 10.25.2021

### 1.Hydrostatic Pressure Test

Page 5 of 6

Test method : EN 20811:1993

Face Side: Original  
Test Conditions: 65 cm2 Test  
Speed:65 cmH2O/dak

	<u>M001</u>	<u>M002</u>	<u>Requirement</u>
<u>Pressure</u>			
Average	65 cm H2O	65cm H2O	-

- END -

## Products

Report No.: 111699085

Date: 10.25.2021



SCIENTIFIC AND TECHNOLOGICAL RESEARCH COUNCIL OF TURKEY  
MARMARA RESEARCH CENTER  
GENETIC ENGINEERING and BIOTECHNOLOGY INSTITUTE

P.K.21,41470 GEBZE-KOCAELİ  
T02626772000 F02626412309  
<http://www.mam.gov.tr>

**CERTIFICATE of ANALYSIS-R**  
(Industrial Technical Support Service)

**Report no** : 16563500-125.05- 64 / 3882-2  
**Report date** : 22.06.2017  
**Applicant** : ZEYİNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.  
**Address** : YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA  
**Subject** : SENSITIZATION TEST CARRIED OUT FOR 'SURGERY SET' IN THE SCOPE OF BIOCOMPATIBILITY TESTS

*The results included in this report are related to only the sample analyzed.*

Approved by

Assoc. Prof. Dr. Fatima YÜCEL  
GMBE Industrial Services Officer

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The unsigned analysis reports are not valid.

This report is consisted of 6 pages and prepared as 2 original copies (1 original for customer and 1 original for Institute archive).

Page 1/6





**Report no** : 16563500-125.05- 64 / 3882-2  
**Applicant** : ZEYİNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.  
**Address of Applicant** : YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA

**Sample** : Standardized sample  
**Sample number** : 3  
**Delivery type of sample** : By Cargo  
**Situation in delivery time**: It was provided in closed sterilization packets under sterile conditions.

**Expiry date** : 05/2022  
**Sample registration no at Institution** : 17/35-GMBE  
**Acceptance date and hour** 16.05.2017  
**Analysis date** : 07.06.2017 – 21.06.2017

**Witness sample information** : ( ) Return to customer (x) Witness sample is available ( ) Witness sample was not taken

**1- Samples:**

The standardized 3 samples, defined as 'Surgery Set', were analyzed for sensitization tests upon the application of ZEYİNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ. dated 16/05/2017 and numbered 2669.

**Table 1. The tested product.**

Sample	Characteristics	Item
Sterile Surgical Drapes	The product is a set consisted of medical textile products in various sizes and forms used for various purposes during surgeries. 1- Drape (100x150cm)  Production date: 05/2017, STERILE EO LOT 000001, Latex Free, Single Use Only	3

**Descriptions:**

**Signatories:**

53192

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Page 2/6



Report no: 16563500-125.05- 64 / 3882-2

Sample	Specifications	Item
Surgery Set		3

**Table 1 (contd.).** The tested product.

**Descriptions:**

**Signatories:**

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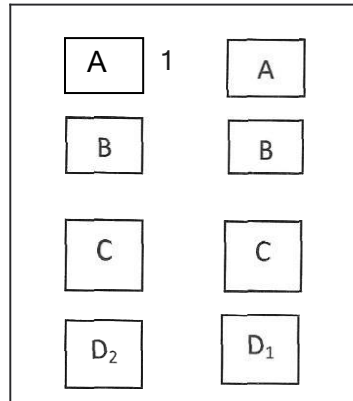
Page 3/6

Report no: 16563500-125.05- 64 / 3882-2

## 2- Skin Sensitization Test

Sensitization test was carried out in accordance with 'ISO 10993-10: 2010 tests for irritation and delayed-type hypersensitivity' standard protocol.

The extract was provided by applying 6 cm<sup>2</sup>/ml surface area/volume rate in compliance with the form and structure of the product. For this purpose, the incubation for 72 hours at 37°C was applied. The sensitization test was carried out by using adult female subjects of guinea pig (*Cavia porcellus*) family weighted between 300-500 gr. As stated in the document titled ISO 10993-10:2010, the tests were carried out with 0,1 ml subcutaneous use of material to be tested. The topical application was made to the region to which subcutaneous injection (intradermal induction phase) is not applied as left region of the animal in the 7<sup>th</sup> day and right region of the animal in the 14<sup>th</sup> day of the test. The application plan administered on experimental animals is shown in Figure 1.



**Figure 1.**

1- Head of experimental animal.

A- The test regions treated by mixing Freund's Complete Anjuvant (FCA) and serum physiological solution at the rate of 50:50.

B- The test regions treated by using only the test material.

C- The test regions treated by mixing the sample applied in region A and the test material applied in region B at the rate of 50:50.

D- The test material was made as its topical application is 0.3 ml to the intracapsular region.

One pair of 0.1 ml injection was made to the left and right regions of the animal during the applications in A, B and C regions.

In the region D, it was applied to the left region (D<sub>1</sub>) in the 7<sup>th</sup> day and the right topical region (D<sub>2</sub>) in the 14<sup>th</sup> day.

### Descriptions:

### Signatories:

53006



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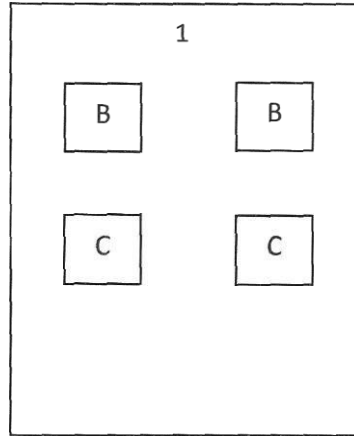
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Report no: 16563500-125.05- 64 / 3882-2

### Negative Control

Negative control was comparatively carried out in 2 different regions in 2 different applications (Figure 2).



**Figure 2.**

1- Head of experimental animal.

B- Serum Physiological 0.1 ml.

C- Freund's Complete Anjuvant (FCA) and serum physiological solution at the rate of 50:50 was mixed and applied.

D-0.3 ml serum physiological was applied to the topical regions.

The test materials were applied to experimental animals as shown in Figure 2 one day after they were shaved to provide an application field and to control animals as shown in Figure 3. All applications were made as 0.1 ml to subcutaneous. The regions were not closed in anyway after application. In the topical application, the test material for experimental animals and 0.3 ml serum physiological for control animals were applied to the skin, the application regions were bandaged with gauze bandage and all application regions were wrapped with elastic bandage after application. The gauze bandages were contacted with the regions for 48 hours. At the end of application duration, the bandages were removed and the reactions on the skin were noted. The second topical application was carried out after 7 days and the same experimental processes were followed.

**Descriptions:**

**Signatories:**

53006



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Report no: 16563500-125.05- 64 / 3882-2

### Applied test material

10 animals were test material and 5 animals for control were used in the application. Total 15 animals were used in this test since there was only one test material.

### Test Material: Surgical Drape

Reaction
No visible change
Clear or patched rash
Moderate or confluent rash
Intensive rash or pocks

Table 2. Evaluation criteria and scoring.

### Evaluation Average

Samples	Result
Surgical Drape	0,4
Negative Control Application	0,4

Table 3. Average score values.

### Result

As stated in the test carried out for test and control samples, the observations were scored by taking into account the evaluation and scoring criteria given in the Table 2. The rash was seen on the skin of animals in the group to which 'Surgical Drape' extract was applied as a result of evaluation. The sensitization score was found as 0.4 (Table 3) as a result of observations. A significant weight loss and visible negative effects in general health condition were not observed in experimental animals. According to the results obtained, it was determined that the material tested did not have any sensitive (sensitive to matter) effect according to the evaluation criteria and protocol stated in ISO 10993-10:2010 document.

### Descriptions:

#### Signatories:

53006



53192



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SCIENTIFIC AND TECHNOLOGICAL RESEARCH COUNCIL OF TURKEY  
MARMARA RESEARCH CENTER  
GENETIC ENGINEERING and BIOTECHNOLOGY INSTITUTE

P.K.21,41470 GEBZE-KOCAELI  
T02626772000 F02626412309  
<http://www.mam.gov.tr>

**CERTIFICATE OF ANALYSIS**  
(Industrial Technical Support Service)

Report no :16563500-125.05-89 /4654  
Report date :23.08.2017  
Applicant : ZEYİNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.  
Address : YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA  
Subject :CYTOTOXICITY TEST CARRIED OUT for 'SURGERY DRAPE' IN THE SCOPE OF BIOCOMPATIBILITY TESTS

*The results included in this report are related to only the sample analyzed.*

Approved by

Assoc. Prof. Dr. Fatima YÜCEL  
GMBE Industrial Services Officer

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Report no :16563500-125.05-89/4654  
Applicant :ZEYNI MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD.ŞTİ  
Address of Applicant : YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA

Sample : Standardized sample	<b>Expiry date: 05/2022</b>
<b>Sample number</b> : 3	Sample registration no at Institution:17/70-GMBE
<b>Delivery type of sample</b> : By Cargo	Acceptance date and hour:11.08.2017
Situation in delivery time: It was provided in closed sterilization packets under sterile conditions	Analysis date :14.08.2017–17.08.2017

**Witness sample information:** ( )Return to customer (x)Witness sample is available ( )Witness sample was not taken

### 1-Samples

The standardized 3 samples, defined as 'Surgery Set', were analyzed for cytotoxicity test upon the application of ZEYNI MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ. dated 14.08.2017 and numbered 3940.

Sample	Characteristics	Item
Sterile Surgical Drapes	The product is a set consisted of medical textile products in various sizes and forms used for various purposes during surgeries. 1- Drape (100x150cm)  Production Date: 05/2017, STERILE EO LOT 000001, Latex Free, Single Use Only	3

Table 1.Product tested.

### Descriptions:

### Signatories:

53192 (signature)

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P.K.21,41470 GEBZE-KOCAELİ

Report no:16563500-125.05-89/4654

Sample	Specifications	Item
Surgery Set		3

Table1 (contd.).Product tested.

Descriptions:

Signatories:

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Report no:16563500-125.05-89/4654

### Cytotoxicity Test

The cytotoxicity tests were carried out in accordance with 'Biological evaluation of medical products: ISO 10993-5: 2009 Tests for in vitro cytotoxicity' standards.

**Beginning date of test:**

**Expiry date of test:**

**Sample description:** The sample characteristics are as explained in the Part 1. The samples were provided by 'ZEYİN MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.' firm. The tests were carried out by taking parts from surgery set selected as representing the product.

**Explanation of cell strain used and its reasons:** L929 rat cell strain was used. It was selected since it is one of the cell strains recommended by ISO 10993-5 and appropriate for representation of mammals system.

**Explanation of cell strain used and its reasons:** L929 rat cell strain was used. It was selected since it is one of the cell strains recommended by ISO 10993-5 and appropriate for representation of mammals system.

**Name and batch number of the firm provided the feed used and the serum and antibiotics added:** DMEM/F12 (Sigma cat # D0547-10X-1, lot #SLBH4393) + 10% Fetal bovine serum (Gibco Life Sciences Cat # 10270-106, lot #41G2943K)+ penicillinle streptomycin (Gibco Life Sciences, Cat # 15140-122, lot # 1688254) were used as feed lot.

**Test method:** Direct contact method.

**Rational:** The analyses of toxic effect of solid matters, dissolved in liquid, as a result of contact with cell.

**Direct contact protocol:** The 'Surgical Drape' was provided as sterile and not subjected to a sterilization process once again. The 'Surgical Drape' was cut to the extent of 1/10 of total surface area of cells and put into middle of pits over the cells.

**Test protocol:** L929 cells were counted and implanted in 8 pits as  $4 \times 10^5$  cell/pit and incubated for 24 hours at 37°C and 5% CO<sub>2</sub>. The samples prepared as explained above and the controls were immediately added on cells and incubated for 24 hours at 37°C and 5% CO<sub>2</sub>. The samples were contacted with cells for 24 hours and then observed microscopically. Following this process, WST-1 agent at 1:50 rate was added onto the cells and the color formation was waited for 2 hours. 100 µ liquid from each pit was taken and poured into 3 pits in 96 sizes so that the absorbance measure was realized at microplate reader, at 450 nm and 650 nm reference wave length for viability test.

**Cytotoxicity Measure method:** WST-1 cell viability analyses (Colorimetric)

**Rational:** The consistent and sensitive measurement of cell viability.

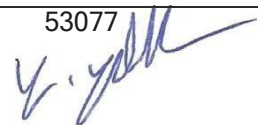
Descriptions:

**Signatories:**

52966



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**Negative, positive and other controls:**

**Controls:**

**Control 1-** The plates on which any material was not put but only the cells were implanted

**Control 2-** The sterile and dry whatmann paper cut in 1 cm X 1 cm sizes.

**Negative Control:** Whatmann paper saturated with PBS (25µl) and cut in 1cm X 1cm sizes.

**Positive Control:** Whatmann paper saturated with EMS (Ethyl methanesulfonate, Merck Millipore, 820774) (25µl) and cut in 1cm X 1cm sizes.

**RESULT:**

**Cell response and other observations:**

**Quantitative Evaluation**

It was observed that there was no cell direct under the sample. However, the same result was observed in PBS saturated whatmann paper samples. A zonal toxic effect was not observed around the sample. This observation was reflected in qualitative evaluation.

	Degree		Degree
<b>Sample</b>		Control 1, Empty	0
Surgery Drape	0	Control 2, dry Whatmann paper	0
		Negative Control, PBS saturated Whatmann paper	0
		Positive Control, EMS saturated Whatmann paper	4

**Table 2.** Quantitative Evaluation.

Degree	Reactivity	Situation
0	None	Clear intracytoplasmic granuls, no any cell lysis, no impact on cell growth.
1	Less	The rate of cells, which are become rounded, representing poor adhesion and/or having no intracytoplasmic granules, showing morphological changes and partly lysis, is below 20%.
2	Slight	The rate of cells, which are become rounded and having no intracytoplasmic garnuls, is below 50%, there is no extensive cell lysis; growth inhibition is below 50%.
3	Moderate	Less than 70% of cells are rounded or showing lysis and growth inhibition is not more than 50%.
4	Serious	All or almost all of the cells are showing lysis.

**Table 3.** Evaluation criteria and scoring for cytotoxicity test.

**Descriptions:**

**Signatories:**

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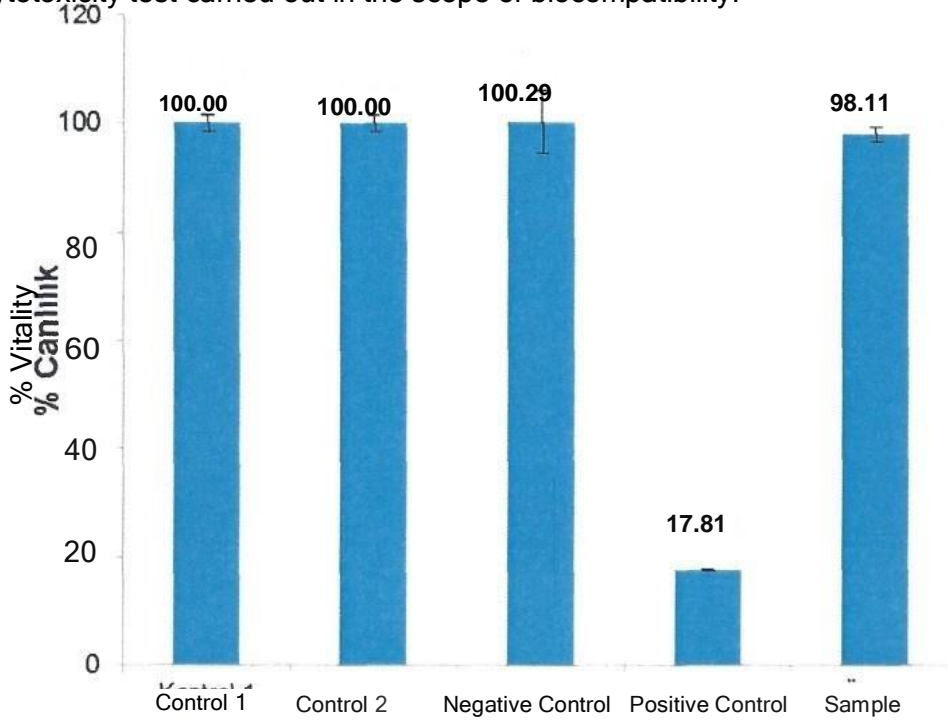
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Report no: 16563500-125.05-89/4654

According to the evaluation criteria given in the Table 3, L929 cell culture was exposed to 'Surgical Drape' for 24 hours in order to examine its potential for causing to cell death according to the control and the cell viability was found as  $98.11 \pm 1.31$  according to the control as a result of ISO 10993-5 cytotoxicity test carried out in the scope of biocompatibility.



**Figure 1.** The viability analyses, carried out by using extracts from samples called 'Surgical Drape', are shown in the Figure.

**Cytotoxicity of 'Surgical Drape' sample;** The absorbance values of samples were normalized by using Negative Control 2 absorbance values in parallel with the samples for 100% viability.

The data, obtained for each sample, was provided as a result of triplicated process in tests of 3 extracts from 3 randomly selected samples.

**EVALUATION:**

No cytotoxic effect according to the viability test carried out by using 'Surgical Drape' extraction method.

**Descriptions:**

**Signatories:**

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Application Date 03.06.2021  
Report Number 21017969

## CUSTOMER INFORMATION FORM

COMPANY  
Tel  
Adres

ZEYNI MEDİKAL LTD. STİ.  
0224 369 32 32  
YunusEmre Mah. 12 .Yildirim SK. No:17 YILDIRIM-BURSA

Sample  
Information

SuperAbsorbent Fabric 75 GSM

Sample	Model	Category	Material Group	Expiry Date
3-Layer Fabric	Super Absorbent 75 Gsm	Medical Fabrics	Non-Woven	

Sample	Department	Test	Standart	Service	Planned Deadline
3-Layer Fabric Super Absorbent 75Gsm	Microbiology	Linting and Particles Testing	ISO 9073-10:2003- MEDICAL	2.4	11.06.2023

ZEYNI MEDİKAL  
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