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MARMARA RESEARCH CENTER  
GENETIC ENGINEERING and BIOTECHNOLOGY INSTITUTE

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

Report no :16563500-125.05-89 /4654  
Report date :23.08.2017  
Applicant :BAYTEKS TEKSTİL SAN.VE TİC. A.Ş.  
Address :ORGANİZE SAN. BÖL.19.CADDE, NO:9,MERKEZ/KİLİS  
Subject :CYTOTOXICITY 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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Page 1/6





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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:17/70-GMBE  
Acceptance date and hour:11.08.2017  
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 BAYTEKS TEKSTİL SAN. VE TİC. A.Ş. dated 14.08.2017 and numbered 3940.

| Sample      | Characteristics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Item |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| Surgery Set | <p>The product is a set consisted of medical textile products in various sizes and forms used for various purposes during surgeries. The 'reinforced gown' product having a direct contact with human was selected as the reference since the products included in the set have the same qualifications in terms of raw materials and production process and the tests were carried out with this product. The products were provided as set and sterile. The components formed the surgery set are listed below;</p> <ul style="list-style-type: none"><li>1- 2X Side Adhesive Drape (100x150cm)</li><li>2- 5X Side Adhesive Drape (150x180cm)</li><li>3- 1X Plain Drape (150x160cm)</li><li>4- 2X Op-Tape (10x30cm)</li><li>5- 1X Instruments Table Cover (200x200cm)</li><li>6- 1X Mayo Table Cover (50x150cm)</li><li>7- 4X Reinforced Gown (XL)</li><li>8- 4X Towel (40x40cm)</li><li>9- 1X Instruments Table Cover (200x200cm)</li><li>10-1X Sterilization Wrap (110x110cm)</li></ul> <p>Production Date: 05/2017, STERILE EO<br/>LOT 000001, Latex Free, Single Use Only</p> | 3    |

Table 1.Product tested.

### Descriptions:

### Signatories:

53192 (signature)

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Page 2/6

Report no:16563500-125.05-89/4654

| Sample      | Specifications                                                                     | Item |
|-------------|------------------------------------------------------------------------------------|------|
| Surgery Set |  | 3    |

Table1 (contd.).Product tested.

Descriptions:

Signatories:

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Page 3/6

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 'BAYTEKS TEKSTİL SAN. VE TİC. A.Ş.' 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.

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**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)+ penicillin 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 Gown' was provided as sterile and not subjected to a sterilization process once again. The 'Surgical Gown' 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:

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Page 4/6

Report no:16563500-125.05-89/4654

**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 Gown  | 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 granules, 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 granules, 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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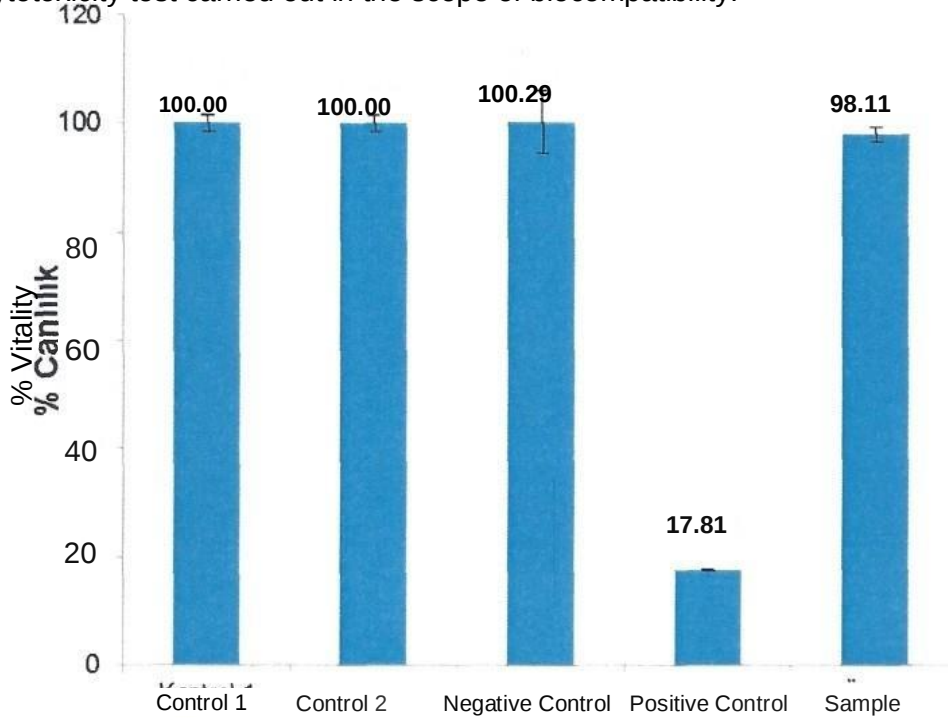
Page 5/6



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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 Gown' 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 Gown', are shown in the Figure.

**Cytotoxicity of 'Surgical Gown' 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 Gown' extraction method.

**Descriptions:**

**Signatories:** 52966 53077



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