



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

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CERTIFICATE of ANALYSIS-R
(Industrial Technical Support Service)

Report no : 16563500-125.05- 64 / 3882-2
Report date : 22.06.2017
Applicant : BAYTEKS TEKSTİL SAN. VE TİC. A. Ş.
Address : ORGANİZE SAN. BÖL. 19. CADDE, NO: 9, MERKEZ/KİLİS
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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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
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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 BAYTEKS TEKSTİL SAN. VE TİC. A.Ş. dated 16/05/2017 and numbered 2669.

Table 1. The tested product.

Sample	Characteristics	Item
Surgery Set	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; 1- 2X Side Adhesive Drape (100x150cm) 2- 5X Side Adhesive Drape (150x180cm) 3- 1X Plain Drape (150x160cm) 4- 2X Op-Tape (10x30cm) 5- 1X Instruments Table Cover (200x200cm) 6- 1X Mayo Table Cover (50x150cm) 7- 4X Reinforced Gown (XL) 8- 4X Towel (40x40cm) 9- 1X Instruments Table Cover (200x200cm) 10- 1X Sterilization Wrap (110x110cm) Production date: 05/2017, STERILE EO LOT 000001, Latex Free, Single Use Only	3

Descriptions:

Signatories:

53192

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Sample	Specifications	Item
Surgery Set		3

Table 1 (contd.). The tested product.

Descriptions:

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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 cm²/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 7th day and right region of the animal in the 14th day of the test. The application plan administered on experimental animals is shown in Figure 1.

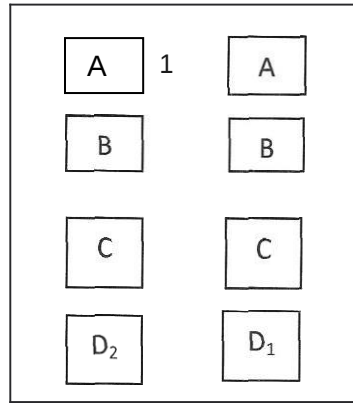


Figure 1.

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 (D₁) in the 7th day and the right topical region (D₂) in the 14th day.

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Negative Control

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

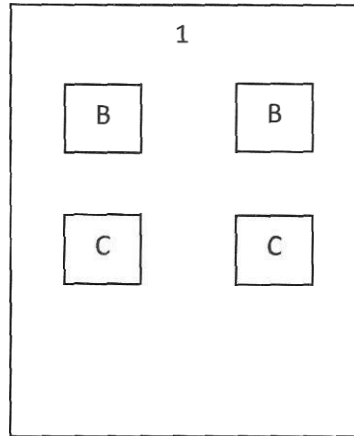


Figure 2.

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.

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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 Gown.

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 Gown	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 Gown' 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:

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ZEYNE MEDİKAL
TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.
Yunussemre Mah. 2. Yilidim Sk. No:17
Yildirim V.D. 141.000 Tic Sic No:102917
Mersis No:0908011400000001





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