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 : 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

Digitally signed by Chirtoacă Iurie
Date: 2022.01.14 18:34:16 EET
Reason: MoldSign Signature
Location: Moldova

Report no : 16563500-125.05- 64 / 3882-2
Applicant : BAYTEKS TEKSTİL SAN. VE TİC. A.Ş.
Address of Applicant : ORGANİZE SAN. BÖL. 19. CADDE, NO: 9, MERKEZ/KİLİS

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 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

P.K.21, 41470 GEBZE — KOCAELİ
262 677 20 00 F 0 262 641 23 09
http://www.mam.gov.tr

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

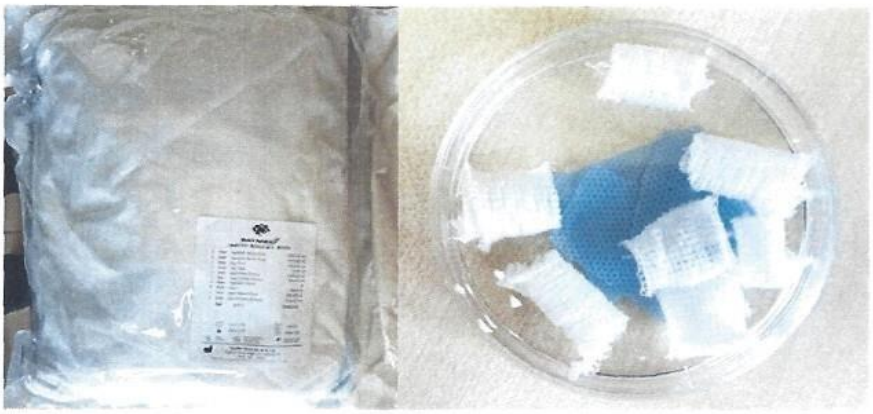
Sample	Specifications	Item
Surgery Set		3

Table 1 (contd.). The tested product.

Descriptions:

Signatories:

53192

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

P.K.21, 41470 GEBZE — KOCAELİ
262 677 20 00 F 0 262 641 23 09
http://www.mam.gov.tr

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^2/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^{O}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 rigt region of the animal in the 14th day of the test. The application plan administered on experimental animals is shown in Figure 1.

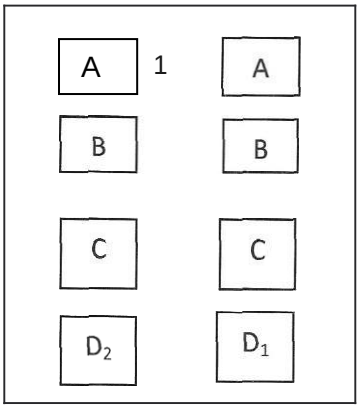


Figure 1.

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 (D_1) in the 7th day and the right topical region (D_2) in the 14th day.

Descriptions:

Signatories:

53006

53192

262 677 20 00 F 0 262 641 23 09
http://www.mam.gov.tr

Negative Control

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

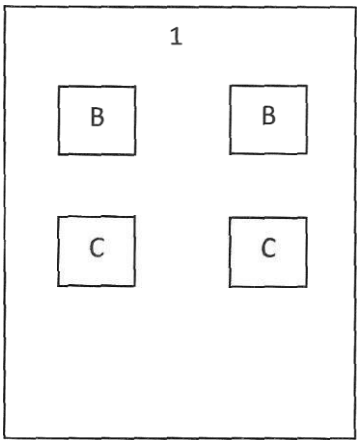


Figure 2.

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 **53192**

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:

53006 53192