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# TEST/ANALYSIS REPORT

(Industrial Services)

**Report no** : 16563500-181.06.03- 166 / **6963**

**Report date** : **04.12.2020**

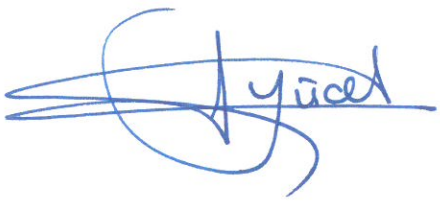
**Requested by** : VİNTEKS SAN. VE TİC. LTD.ŞTİ.

**Address** : BAĞLAR MAH. OSMANPAŞA CAD. NO:56, 34212, GÜNEŞLİ / BAĞCILAR İSTANBUL

**Subject** : IRRITATION TEST OF "PU COATED FABRIC" ACCORDING TO ISO 10993: BIOLOGICAL EVALUATION OF MEDICAL DEVICES TEST PROTOCOLS

***The results in this report are valid only for the analyzed samples.***

**Approved by**



Assoc. Prof. Fatıma YÜCEL
Head of GEBI Industrial Services

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| | |
|---|---|
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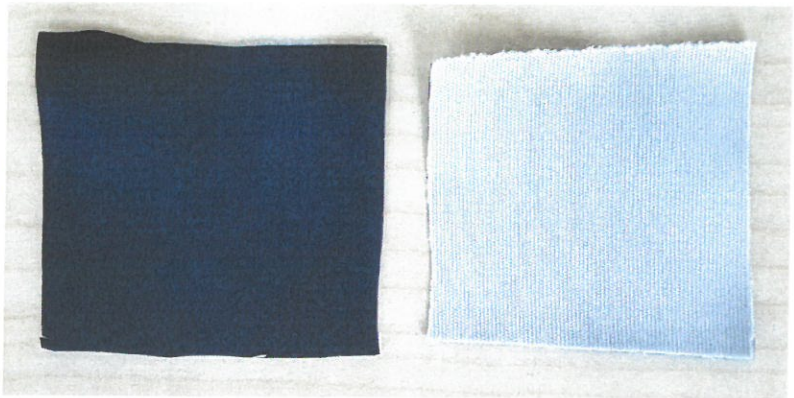
| | | | |
|---|---|---|---|
| **Sample** | : Single type sample | **Expiry date** | : -- |
| **Number of samples** | : Single piece | **Institute sample register no:** | 20/155-GMBE |
| **Sample handling** | : by Cargo | **Reception date and time** | : 11.11.2020 |
| **Condition of sample at reception:** Non-sterile samples were received in original packages. | | **Date of the analysis** | : 01.12.2020-04.12.2020 |

**Information on retention samples:**
( ) Sample returned to the customer ( x ) Retention sample available ( ) Retention sample is not taken

## 1- Sample Information

According to the application of VİNTEKS SAN. VE TİC. LTD.ŞTİ. with the reference no 5201 and dated 11/11/2020 irritation test was carried out on one type of sample which is defined as "PU Coated Fabric".

**Table 1.** Test Item

| Örnek | Özellik | Adet |
|---|---|---|
| PU Coated Fabric |  | Single Piece |

**Notes:** The information describing the test item has been declared by the company.

**Authorized Signatures:**

**53192**





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**2- Test for irritation**

The irritation test was carried out considering "ISO 10993-10: 2010 Tests for irritation and delayed-type hypersensitivity", "ISO 10993-2: 2006 Animal welfare requirements" and "ISO-10993-12: 2012 Sample preparation and reference materials" standart protocols.

Three healty young adult female New Zelland albino rabbits were used for irritation test. All three animals were heavier than 2 kg. As described in the ISO 10993-10: 2010 standart protocol, the tested product was directly applied to the application sites as shown in Figure 1.

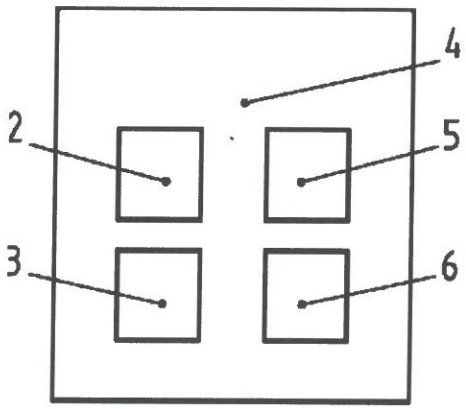


**Figure 1.** 2; test sample site, 3; negative conrol site, 6; test sample site, 5; positive control site, 4; cranial end.

**Positive Control**

90% lactic acid was used as positive control. Its appropriate or reactive response was previously shown in the test system.

**Negative Control**

Physiological saline was used as negative control. Its appropriate negative or nonreactive response was previously shown in the test system.

**Test Procedure**

The backs of the animals (a sufficient distance on both sides of the spine) were shaved to obtain enough application area. The test and control samples were applied as shown in Figure 1. As explained in ISO 10993-10: 2010 standart protocol, the application sites were covered with absorbent gauze patch and then wraped with an elastic bandage for 4 hours. At the end of contact time, the dressings were removed and the positions of the sites were marked. After that, the appearance of each application site was observed and recorded at 1h, 24h, 48h and 72h following removal of the patches. Observations were scored as described in Table 3. The results of evaluation based on the observation scores are presented in Table 4.

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**Table 2.** Scoring system for skin reaction.

| Reaction | Primary Irritation Score |
|---|---|
| **Erythema and eschar formation** | |
| No erythema | 0 |
| Very slight erythema (barely perceptible) | 1 |
| Well-defined erythema | 2 |
| Moderate erythema | 3 |
| Severe erythema (beet-redness) to eschar formation preventing grading of erythema | 4 |
| **Oedema formation** | |
| No oedema | 0 |
| Very slight oedema (barely perceptible) | 1 |
| Well-defined oedema (edges of area well-defined by definite raising) | 2 |
| Moderate oedema (raised approximately 1mm) | 3 |
| Severe oedema (raised more than 1 mm and extending beyond exposure area) | 4 |
| **Total possible score for irritation** | 8 |
| Other adverse changes at the skin shall be recorded and reported. | |

**Table 3.** Irritation response categories in rabbit.

| Mean Score | Response Category |
|---|---|
| 0 - 0,4 | Negligible |
| 0,5 - 1,9 | Slight |
| 2 - 4,9 | Moderate |
| 5 - 8 | Severe |

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**Evaluation of results**

The application sites were examined with Binocular Loupes (3X). The observation scores and mean scores for samples were represented in Table 4 and Table 5, respectively.

**Table 4.** Scores of observations.

| Animal ID | Samples | Application Sites | Observations (h) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Erythema | | | | Oedema | | | |
| | | | 1. | 24. | 48. | 72. | 1. | 24. | 48. | 72. |
| 1 | PU Coated Fabric | *Left Front Site* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | *Right Back Site* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Positive Control | *Right Front Site* | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 2 |
| | Negative Control | *Left Back Site* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | PU Coated Fabric | *Left Front Site* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | *Right Back Site* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Positive Control | *Right Front Site* | 3 | 2 | 2 | 1 | 2 | 2 | 1 | 1 |
| | Negative Control | *Left Back Site* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | PU Coated Fabric | *Left Front Site* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | *Right Back Site* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Positive Control | *Right Front Site* | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 2 |
| | Negative Control | *Left Back Site* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

**Table 5.** Scores for test and control samples.

| Samples | Primary Irritation Score | | | Primary Irritation Index (PII) |
|---|---|---|---|---|
| | Rabbit ID1 | Rabbit ID2 | Rabbit ID3 | |
| PU Coated Fabric | 0 | 0 | 0 | 0 |
| Positive Control | 4,67 | 3,00 | 4,67 | 4,11 |
| Negative Control | 0 | 0 | 0 | 0 |

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**Conclusion**

As mentioned, after the observations at the three time points for the two criterions (Table 4), *primary irritation index* were obtained by averaging the scores for the test material (Table 5). In the observations of the tested material, in any application sites and injection points erythema and oedema formations were not observed. According to data obtained from observations and the evaluation criterias defined in the ISO 10993-10: 2010, **the tested sample defined as "PU Coated Fabric" has no skin irritation effect.**

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