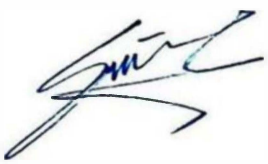
ISO 10993-10
Skin Irritation Test

FİRMA ADI : Company Name	**FELİKS PLASTİK LAMİNASYON VE AMBALAJ MALZEMELERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ**
ADRESİ : Adress	**75. YIL OSB MH. 26. CD. NO:9 ODUNPAZARI - ESKİŞEHİR / TÜRKİYE**
TESTİN ADI : Test Name	**Skin Irritation Test**
TEST STANDARDI : Test Standart	**ISO 10993-10**
LOT NUMARASI : Lot Number:	**20200907**
TİCARİ MARKA (VARSA) : Commerical Brand (If You Have)	**BODYGARD**
ÜRÜN ADI: Name of the Product	**Bodygard Surgical Gown Level 3 -KNIT CUFF**
RAPOR NUMARASI: Report Number	**2021-04/BIYO/1368FBG-001**

** Felix Plastic companies tests were made in accordance with GLP (Good Laboratory Practice) standards.

BIOCOMPATIBILITY TEST RESPONSIBLE

Vet. Hekim Simge GARLI



MEDİCERT ULUSLARARASI ÜRÜN VE SİSTEM BELGELENDİRME BAĞIMSIZ DENETİM VE EĞİTİM HİZMETLERİ LTD. ŞTİ.
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REPORT INDEX

SUMMARY:

Bodygard Surgical Gown Level 3 - Knitt Cuff sample numbered 20200907 has been subjected to a biocompatibility test according to TS EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitivity. Samples were prepared by storing 3 7ºC-72 hours in; Serum Physiological liquid under sterile conditions according to TS EN ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials standard. As a Positive Control; Sodium lauryl sulfate (SLS), previously known to have an irritant effect. As Negative Control; Serum Physiological previously known to have no irritant effect. Three rabbits were used in the study. The observation period was carried out between 05.04.2021 - 09.04.2021. The presence and absence of edema and erythema were recorded by application of the samples to the skin. The negative control was also analyzed at the same time. As a result, it was determined that the test sample **did not cause any skin irritation**.

1. INTRODUCTION

Purpose: In the report described below, the potential of a single topical application for the rabbit skin irritation assay was evaluated.

Test Guide: This study was conducted according to the requirements of the International Organization for Standardization. 10993: Biological Assessment of Medical Devices, Part 10: Tests for Irritation and Skin Sensitivity

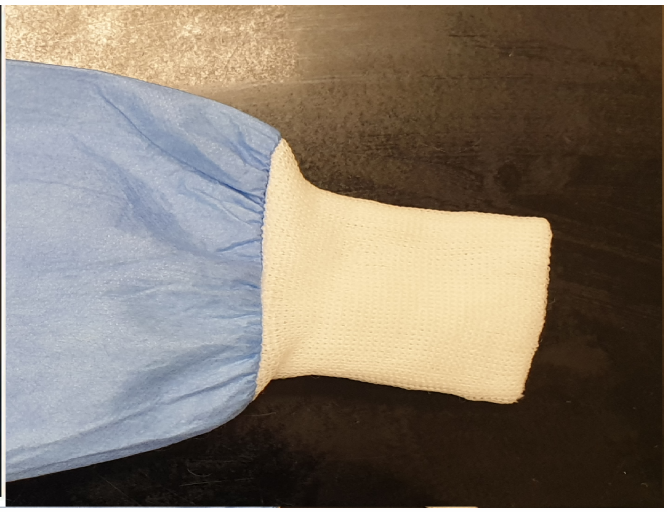
Dates

Sample Acceptance Date: **29.03.2021**
Test Date: **05.04.2021**
Observation Date: **05.04.2021 - 09.04.2021**

2. SAMPLE INFORMATION

Company Name:	Felix Plastik
Date of the Sample Acceptance:	29.03.2021 10:00
Sample Record Number:	FPBG0004/2021
Sample Lot Number:	20200907
Number of Sample:	6 Pocket
Packaging Information:	CLOSED PACKED
Delivery Method of the Sample:	CARGO
Expiration Date of the Sample:	09/2023
Production Date of the Sample:	09/2020
Description of the Sample:	Surgical Gown Knit Cuff
Characteristics of the Sample Use/Application:	Surgical Gown Level 3 - Knit Cuff sample

Sample Image:



3. TEST SYSTEM

Animal used in the test	:	RABBIT
Strain	:	NEW ZEALAND
Source	:	Burdur Mehmet Akif Ersoy University Experimental Animals Production and Research Center
Gender	:	FEMALE
Weight	:	2000-2300 KG
Age	:	6 MONTHS
Acclimation time	:	5 DAYS
Number of the animals	:	3

4. ANIMAL MANAGEMENT

Animal Care	:	The animals used in the experiments are performed in accordance with the standards of Biological Evaluation of Medical Devices - Part 2: Requirements for Animal Welfare
Food	:	The SDS brand VRF1 diet is provided as ad-libitum.
Water	:	Water is supplied as ad-libitum in suitable drinkers.
Cage System	:	Each rabbit was identified and placed in appropriate cages.
Environmental Conditions	:	12 hours night and 12 hours day environment is provided; 30-70% humidity and 16-22℃ environment is provided. Temperature and humidity are checked daily.
Personnel	:	Tests are performed by trained and appropriately qualified personnel.
Selection of the animal	:	Healthy, non-disease animals and non-pregnant animals were used under the supervision of a veterinary surgeon.
Veterinary Care	:	This study was carried out under the supervision of a veterinarian.

5. METHOD

Irritation tests were carried out in accordance with ISO 10993-10, care conditions of test animals used in the test, ISO 10993-2, preparation of samples used in the test and reference materials ISO-10993-12.

Test material to be used for irritation tests (specimen) ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation according to the sample preparation and reference materials standard, with 0.2 g / ml sterile 0.9% isotonic in accordance with ISO 10993-12 Prepared at 37 ± 1ºC for 72 ± 2 hours.

As a Positive Control; Sodium Lauryl Sulfate, previously known to have irritant effect.

As Negative Control; Serum Physiological previously known to have no irritant effect.

Irritation tests were performed on 3 healthy, adult Albino rabbits weighing less than 2 kg. Tests were performed by treating the material to be tested directly on the skin as specified in the ISO 10993-10 standard. After shaving enough to provide sufficient application area (10 cm x 15 cm) in the dorsal region of the experimental animals, the samples were applied as shown in Figure 1.

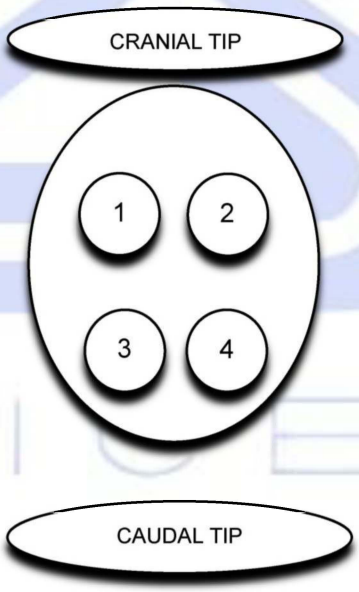


FIGURE 1: Application sides

1. Experimental Side
2. Positive Control
3. Negative Control
4. Experimental Side

6. EVALUATION

The application sites were covered with gauze and then covered with bandage for 4 hours. At the end of the contact period, the dressings were removed and the sites of application were scored for erythema and edema at the 1st hour, 24th hour, 48th hour and 72th hour according to the scoring system given in Table 1 and the irritation index, number (score) and definition in Table 2 (response category).

Table 1. Characteristics of the animals

Animal No	Age	Gender	Weight
1	6 month	Female	2,1 kg
2	6 month	Female	2,3 kg
3	6 month	Female	2,1 kg

Table 2. Scoring system for skin irritation

Reaction	Score
Erythema and eschar formation	
No erythema	0
Very mild erythema (barely visible)	1
Prominent erythema	3
Moderate erythema	2
Grading erythema with severe erythema (red as beet)	4
Edema formation	
No edema	0
Very mild edema	1
Significant edema (the edges of the area of marked edema)	2
Moderate edema (about 1 mm swollen)	3
Severe edema (swelled more than 1 mm and spread out of the exposed area)	4
Total possible score for irritation	8

Other adverse changes in skin locations should be recorded and reported.

The results of the observation following the experiment carried out in accordance with ISO 10993-10 standards are presented in Table 3 and Table 4. Figure 2-9 contains photographs of the test and sample preparation and test application.

After covering the samples with 2.5 cm x 2.5 cm sterile gauze, the whole application area was wrapped with bandage. Samples to be tested for 4 hours were applied to the region. At the end of this period, bandages were opened and samples were taken and the applied areas were marked. The remaining test materials were washed with warm water. After the procedure, the test sites were observed at 1, 24, 48 and 72 hours and samples were evaluated by taking into consideration the criteria specified in Tables 2 and 3.

Table 3. Irritation categories in rabbits

Mean Score	Irritation category
0 – 0.4	Negligible
0.5 – 1.9	Light
2 – 4.9	Middle
5 - 8	Serious

TEST RESULTS

Table 4. Evaluation scores for the sample.

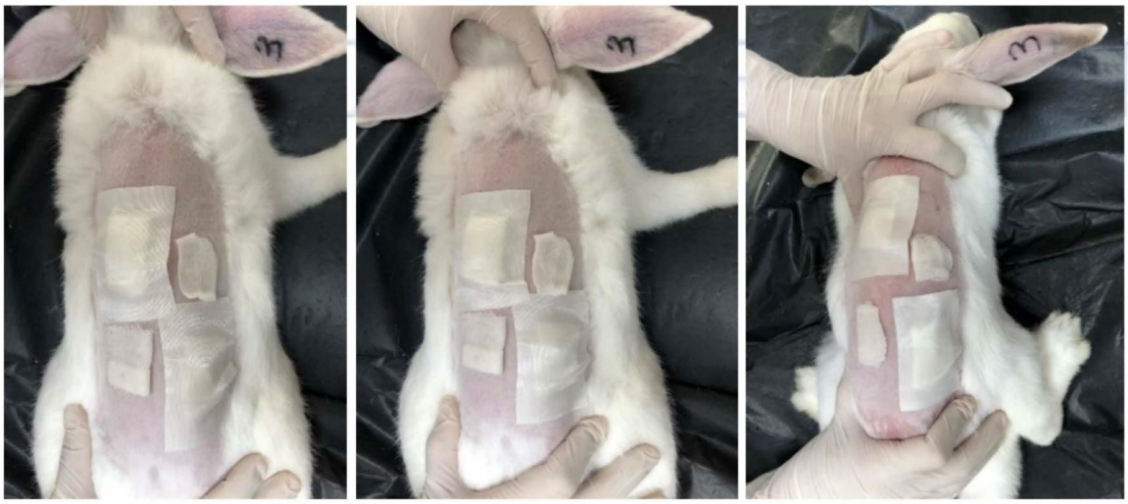
Animal No	Groups	Application Side	Observation (h)							
			Erythema				Erythema			
			1	24	48	72	1	24	48	72
1. Rabbit	Sample	1	0	0	0	0	0	0	0	0
		4	0	0	0	0	0	0	0	0
	Positive Control	2	3	2	1	1	1	2	2	1
	Negative Control	3	0	0	0	0	0	0	0	0
2. Rabbit	Sample	1	0	0	0	0	0	0	0	0
		4	0	0	0	0	0	0	0	0
	Positive Control	2	3	2	1	1	1	2	2	1
	Negative Control	3	0	0	0	0	0	0	0	0
3. Rabbit	Sample	1	0	0	0	0	0	0	0	0
		4	0	0	0	0	0	0	0	0
	Positive Control	2	3	2	2	1	2	2	2	1
	Negative Control	3	0	0	0	0	0	0	0	0

Table 5. Mean score and irritation categories

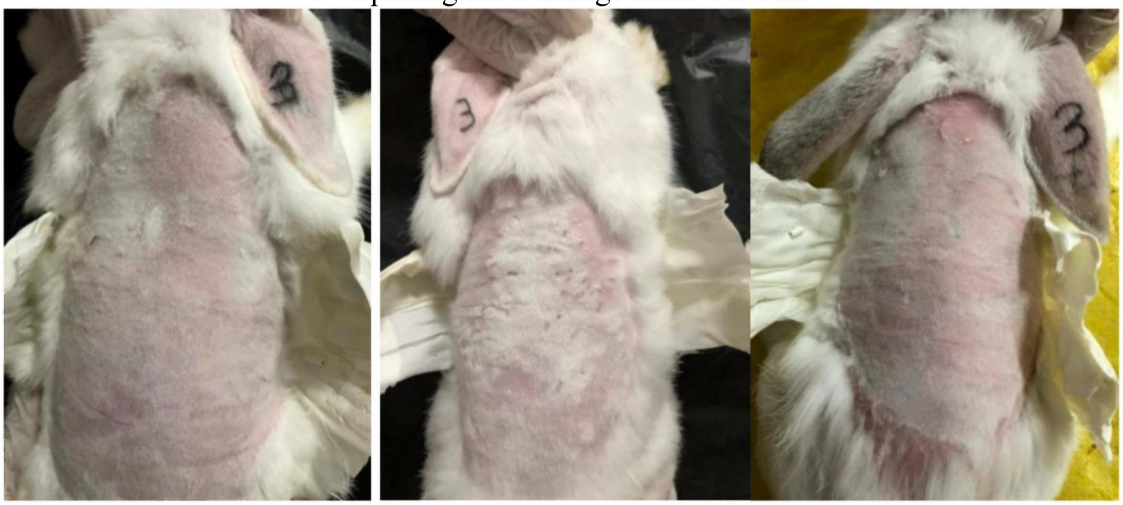
Groups	Application side	Erythema	Edema	Total	Irritation Category
Sample	2	0	0	0	Negligible
	6	0	0	0	Negligible
Negative Control	3	0	0	0	Negligible
	5	0	0	0	Negligible

1- Package Opening

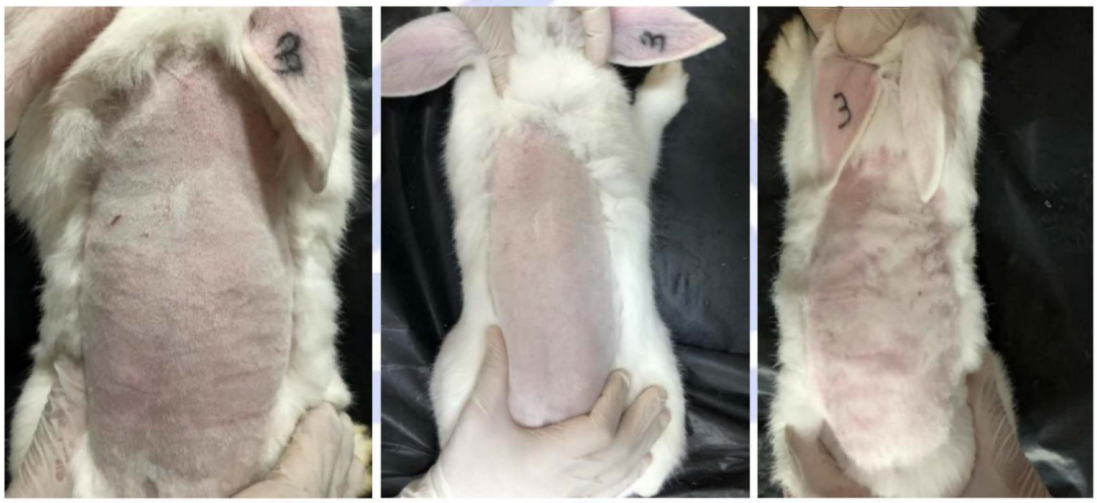
2- Application



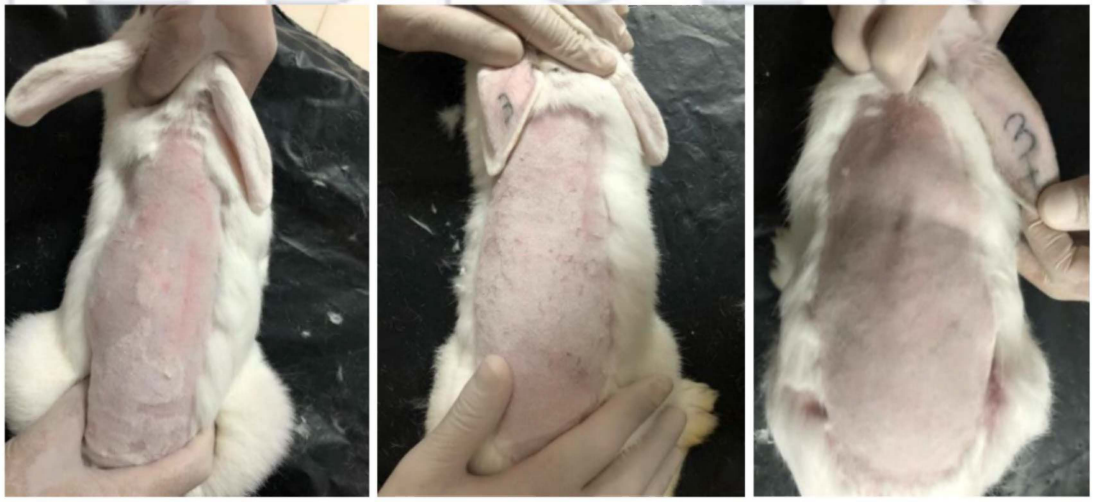
3- Opening the Bandage After 4 Hours



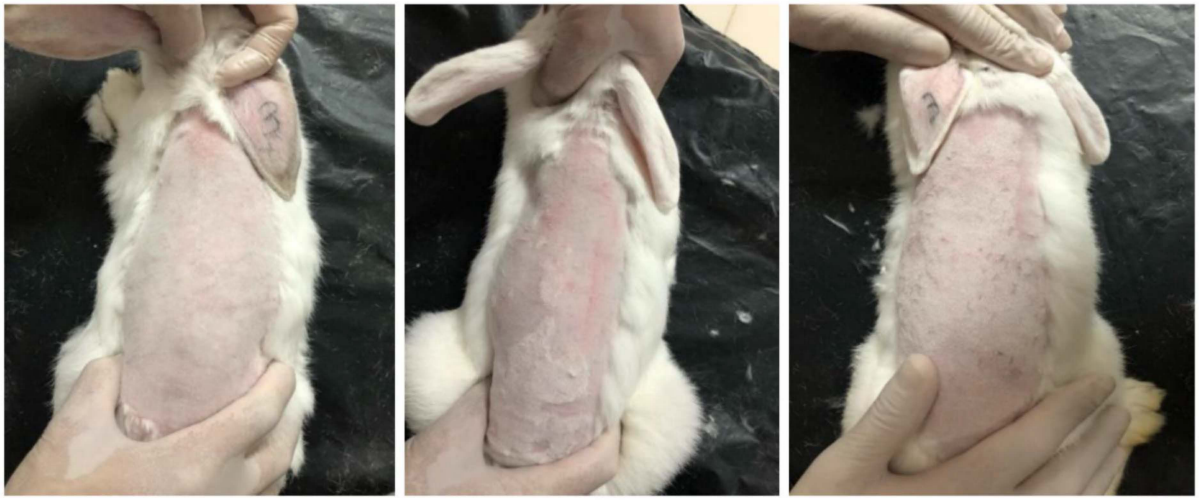
4- Observation After 1 Hour



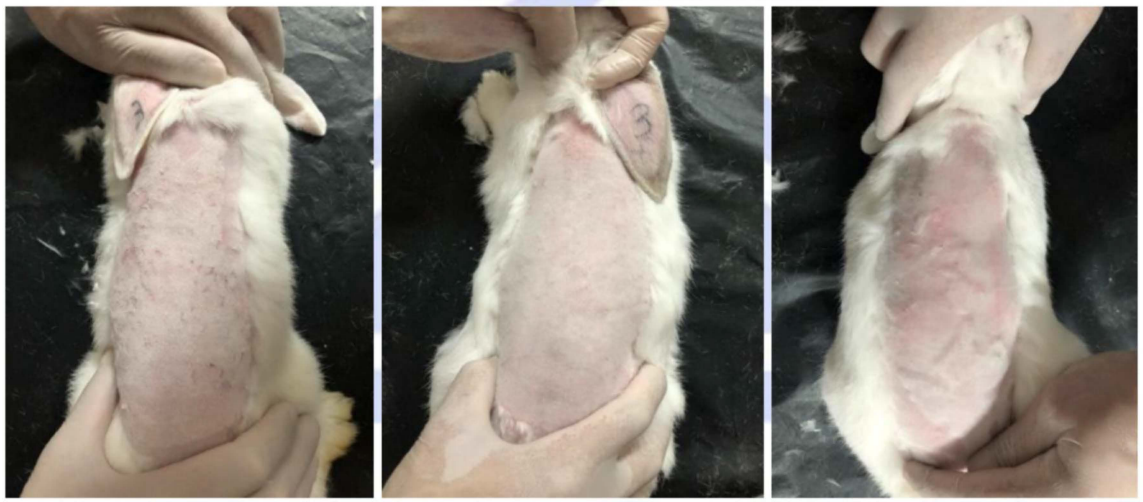
5- Observation 24 Hours Later



6- Observation 48 Hours Later



7- Observation 72 Hours Later



7. RESULT

As mentioned above, after the observations at the three time points for the two criterions (Table 3)., overall mean scores were obtained by averaging the scores for the test material (Table 4). In the observations of the tested material, in any application sites and injection points, erythema and edema formations were not observed. According to the data obtained from observations and the evaluation criteria defined in the ISO 10993:10-2010, **the tested sample defined as the sample has no irritation effect**.

8. RECORD

All raw data and a copy of the final report are stored in the Medicert archive files.

9. REFERENCES

- Guide For The Care And Use Of Laboratory Animals Eighth Edition National Research Council of The National Academies
- TS EN ISO 10993-1 Biological evaluation of Medical Devices - Chapter 1: Evaluation and experiment in a risk management process
- TS EN ISO 10993-2 Biological evaluation of Medical Devices – Chapter 2: Conditions for animal welfare
- TS EN ISO 10993-10 Biological evaluation of Medical Devices – Chapter 10: Experiments for irritation and skin sensitivity
- TS EN ISO 10993-12 Biological evaluation of Medical Devices – Chapter 12: Sample preparation and reference materials