ISO 10993-10
Skin Sensitization 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 Sensitization 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-003**

** 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.
Tersane Mah. Cemal Gürsel Cad. No: 11/3
Halide Hanım Apt. Karşıyaka / İZMİR
Tel: 0232 327 33 44 Fax: 0232 327 33 45
Karşıyaka V.D: 613 073 9815

REPORT INDEX

SUMMARY:

Bodygard Surgical Gown Level 3 - Knit Cuff sample numbered 20200907 has been subjected to biocompatibility testing 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 37ºC-72 hours in SF under sterile conditions according to TS EN ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials standard. The extract was intradermally injected into 10 guinea pigs. 5 experimental animals were used as control group and previously determined Serum Physiological was injected. On day 7, after the completion of the intradermal induction phase, the superficial induction phase was applied to both the test group and the control group. On the 14 th day after the induction phase, the stimulation phase was applied to the test group and the control group. The dressings and patches were removed after 24 hours. Necessary evaluations were made according to Magnusson and Kligman ratings at 24th and 48th hours. Under the terms of this study, Implantek scaff-OS Dental Implant extract showed no evidence of sensitization.

1. INTRODUCTION

Purpose: This test was performed to evaluate the sensitivity of the sample described below to cause sensitivity.

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

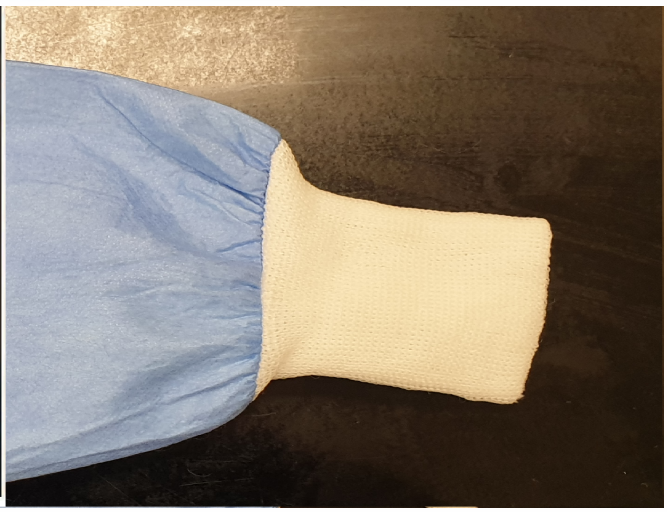
Dates

Sample Acceptance Date : 29.03.2021
Test Date : 31.03.2021
Observation Date : 31.03.2021 – 14.04.2021

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 Knit Cuff
Characteristics of the Sample Use/Application:	Surgical Gown Level 3 Knit Cuff

Numune Görseli:



3. TEST SYSTEM

Animal used in the test	:	GUINEA PIG
Strain	:	DUNKIN HARTLEY
Source	:	Burdur Mehmet Akif Ersoy University Experimental Animals Production and Research Center
Gender	:	MALE
Weight	:	400-500 gr
Age	:	10-12 Week
Acclimation time	:	5 DAYS
Number of the animals	:	15

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 animal 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°C 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

Sensitization tests; Intradermal Induction Phase was completed after superficial Induction Phase and Stimulation Phase followed by observation of animals and evaluation of results. In Induction Phase; 0.1 ml intradermal administration was carried out with the following ingredients.

TEST GROUP: Novafix Elastic Fixing Tape A3294 -10 HX10 CM and FCA (Freund's Complete Adjuvant) mixture in a volume ratio of 50:50, Test Sample in the Test Group (Undiluted Extract)

CONTROL GROUP: SERUM PHYSIOLOGICAL, 50:50 volume ratio of SERUM PHYSIOLOGICAL and FCA (Freund's Complete Adjuvant) mixture

Surface Induction Phase; On day 7 after completion of the intradermal induction phase; TEST GROUP; superficial application is made to the intrascapular region with 8 cm square absorbent gauze to close the injection sites.

CONTROL GROUP; Only SERUM PHYSIOLOGICAL is applied. The dressings and patches are removed after 48 hours.

Stimulation Phase; On the 14th day following the completion of the superficial induction phase; superficial application to untreated areas of experimental animals is covered with absorbent gauze.

In the Intracutaneous Induction Phase

CONTROL GROUP; Only SERUM PHYSIOLOGICAL is applied. The dressings and patches are removed after 24 hours.

24 hours and 48 hours after completion of the stimulation phase, the sites of stimulation in the skin of the animals in the test and control groups are observed. Observations are performed under full spectrum illumination. Skin reactions for erythema and edema are completed and graded according to the Magnusson and Kligman ratings indicated in Table 1 for each stimulation site at each time interval.

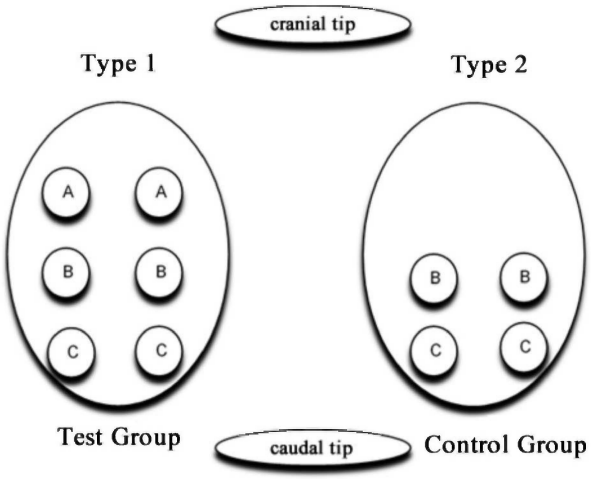


Table 1. Magnusson and Kligman rating scale

Patch Test Reaction	Rating Scale
No visible changes	0
Discrete or patchy erythema	1
Moderate or adjacent erythema	2
Evident	3
Severe erythema or swelling	4

6. EVALUATION

Table 2. Results of the test and control groups at 24 and 48 hours depending on the Magnusson and Kligman rating scale

GROUP	GUINEA PIG NO	AREA	MAGNUSSON AND KLIMMAN RATING ERYTHEM / PAYMENT	
			EVALUATION TIME POINT	
			24th h	48. SAAT
Bodygard Surgical Gown	1	A	2	1
		B	0	0
		C	1	0
	2	A	2	1
		B	0	0
		C	1	1
	3	A	2	1
		B	0	0
		C	1	1
	4	A	2	2
		B	0	0
		C	1	1
	5	A	2	2
		B	0	0
		C	1	1
	6	A	2	1
		B	0	0
		C	1	1
	7	A	2	2
		B	0	0
		C	2	1
	8	A	1	1
		B	0	0
		C	1	0
	9	A	2	1
		B	0	0
		C	1	1
	10	A	2	1
		B	0	0
		C	1	1

Table 3. Mean Scorring of the values of Table 2

GROUP	GUINEA PIG NO	AREA	MAGNUSSON AND KLIMMAN RATING ERYTHEM / PAYMENT	
			EVALUATION TIME POINT	
			24th h	24th h
CONTROL GROUP	1	A	-	-
		B	0	0
		C	1	1
	2	A	-	-
		B	0	0
		C	1	1
	3	A	-	-
		B	0	0
		C	1	1
	4	A	-	-
		B	0	0
		C	1	1
	5	A	-	-
		B	0	0
		C	1	1

GROUPS	Mean Results
Test Group	0.82
Control Group	0.48

Table 4. End of test weight table of the test animals

TEST GROUP Guinea pig no	1	2	3	4	5	6	7	8	9	10
Weights at the end of the test	425	432	437	466	451	431	459	434	499	467
CONTROL GROUP Guinea pig no	1		2		3		4		5	
Weights at the end of the test	460		448		435		449		450	

7. RESULT

Following the tests, observations were made in two different time periods as stated. The mean score was obtained by averaging the values obtained. The sensitization score was 0.87 for the sample samples tested. It was determined that the health conditions of the animals were not good and there was no significant weight loss. According to the obtained results, **it was determined that the tested sample does not have sensitizing properties** based on the protocol and evaluation criteria specified in ISO 10993-10.

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