ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFICAT

MEDICAL QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.

Yunus Emre Mah. 12.Yildirim Sok. No 17 Yildirim-Bursa/Turkey

by review of SA2-5076 numbered report for the scope

Manufacture And Sales Of Disposable Surgical Sterile Gowns, Drapes And Custom Packs, Non-Sterile Medical Textile Products

to certify that a management system in accordance with standard's clauses is established and being implemented

DIN EN ISO 13485:2016

Certificate No :MDMS 0520 006861
Original Certification Date : 22.04.2020
Issue / Revised Date : 13.04.2022
Expiry Date : 21.04.2023
Certification Period : 3 years (3rd year)

Digitally signed by Dicusar Vladimir
Date: 2022.10.09 15:10:46 EEST
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFICAT

UNICERT

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.

Yunus Emre Mah. 12.Yildirim Sok. No 17 Yildirim-Bursa/Turkey

by review of SA2-5076 numbered report for the scope

Manufacture And Sales Of Disposable Surgical Sterile Gowns, Drapes And Custom Packs, Non-Sterile Medical Textile Products

to certify that a management system in accordance with standard's clauses is established and being implemented

DIN EN ISO 9001:2015

Certificate No : QMS 0520 006861

Original Certification Date : 22.04.2020

Issue / Revised Date : 13.04.2022

Expiry Date : 21.04.2023

Certification Period : 3 years (3rd year)

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-16058-01-00

Universal GmbH

The authenticity of this certificate can be confirmed online or by e-mail to the Head Office via:
UNIVERSAL GmbH • Wilfried Diekmann Str., 20b, 44536 Lünen Germany • T : +49 (0) 231 9931 9960 • info@uni-cert.de • www.uni-cert.de

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Production Quality Assurance

No. 09 0816 QS/NB

The quality system of manufacturer

Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.

Yunus Emre Mah. 12.Yıldırım Sok. No 17 Yıldırım –BURSA, Turkey

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

for the following product category(ies):

Sterile Disposable Surgical Gowns and Drapes and Drape Sets

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. The Notified Body has audited this system with limitation to those aspects of manufacture concerned with securing and maintaining sterile conditions. This part of quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance.

Valid from: 2020-06-23
Valid until: 2022-11-24
First Issued: 2009-11-26
Revision: f

Date: 2020-06-23

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Zeyni Medikal Tekstill Ins. San. Ve Tic. Ltd. Sti

Yunus Emre Mah. 12. Yildirim Sok. N° 17 Yildirim -BURSA, Turkey

Product(s):

Name: **Drape sets**

Trade name(s): -

Model(s): See table below

Class: Is

GMDN: **47783**

Drape set types	Code number
General surgery drape set	101-001-S
Laparoscopy drape set	201-001-S
Minor surgery drape set	102-001-S
Dressing surgery drape set	103-001-S
Spinal surgery drape set	301-001-S
Craniotomy surgery drape set	401-001-S
Shunt surgery drape set	401-002-S
Valve Remplacement surgery drape set	501-001-S
Cardiovascular Thoracic drape set	202-001-S
Anjyo drape set	601-001-S
By-pass drape set	602-001-S
Ophthalmic drape set 1	701-001-S
Ophthalmic drape set 2	701-002-S
Caesarean drape set	801-001-S
O.P.U surgery drape set	802-001-S
Delivery drape set	802-002-S
Dental drape set	803-001-S
Biopsie drape set	804-001-S
Cystoscopy drape set	901-001-S

GENERAL DIRECTOR:

Baki Cavar
07.06.22

STAMP & SIGNATURE

ZEYNİ MEDİKAL
TEKS.İNŞ. SAN VE TİC. LTD. ŞTİ.
Yunusemre Mh. 12. Yıldırım Sk. No:17 YILDIRIM/BURSA
Yıldırım V.D.: 998 141 1400 Ticaret Sicil No:
Mersis No: 0998141400000

Zeyni Medikal Tekstill Ins. San. Ve Tic. Ltd. Sti

Yunus Emre Mah. 12. Yildirim Sok. N° 17 Yildirim -BURSA, Turkey

Drape set types	Code number
Percutaneous drape set	901-002-S
T.U.R drape set	901-003-S
Ear-nose-throat drape set	902-001-S
Vertebra surgery drape set	903-001-S
Arthroscopy drape set	904-001-S
Extremity drape set	904-002-S
Hip surgery drape set	904-003-S
Rinoplasty set	905-001-S
Vertebra set	906-001-S
I.V.F Drape set	907-001-S
E.T set	907-002-S
Abdominal drape set	908-001-S
Hand surgery set	904-004-S
Chemotherapy drape set	909-001-S

Product(s):

Name: **GOWNS**

Trade name(s): -

Model(s): See table below

Class: Is

GMDN: **35778**

Gown Types	Code number
Standard Surgery Gowns	100-001-S
Protected Surgery Gowns	200-001-S

GENERAL DIRECTOR:

Bakr Conaar

07.06.22

STAMP & SIGNATURE

ZEYNİ MEDİKO
TEKS.İNŞ. SAN VE TİC.LTD.ŞTİ.
Yunusemre Mh. 12. Yıldırım Sk. No: 17 Yıldırım/BURSA
Yıldırım V.D. 9980471464 Ticaret No: 102917
MERS No: 0998047146400001

ZEYNI

MEDICAL

For medical devices, regulated in accordance with EC Directive 93/42/EEC

EC Declaration of Conformity

11042020-UB

Manufacturer : ZEYNİ MEDİKAL TEKSTIL INSAAT SAN. VE TIC. LTD. IST.

Address : Yunus Emre Mah. 12. Yildirim Sok. No: 17 Yildirim-Bursa / TURKEY

Trade name : Zeyni Medical

Product Name : STERILE AND DISPOSABLE SURGICAL SUPPORTS, COVERS AND COVER SETS

STERILE AND DISPOSABLE SURGICAL LINERS, DRAWER AND LID SETS

(The list of products is given in appendix-1.)

Classification : Class 1-Sterile (with sterile function)

Conformity assessment according to Annex VII and the annexes of the applied directives (Medical Device Directive 93/42/EEC; Class 1-as sterile device)

Applied harmonized standards: ISO 11135:2014, ISO 14644-3 2019, 13795 1 2019 ISO 14971 2012, 150 15223-1:2016, ISO 10993-7:2008, ISO 14937 2009

Notified body: ITC (Institute for testing and Certification, a s] Trida T Bati 299,76421 Zlin-Loky/ Czech Republic

Notified body number: CE 1023

EC certificate: 090816QS/NB

Validity of the CE certificate: 24.11.2022

GENERAL DIRECTOR:

Baki Canaer

07.06.22

STAMP & SIGNATURE

ZEYNİ MEDİKAL
TEKS.İNŞ. SAN VE TİC.LTD.ŞTİ.
Yunusemre Mh. 12. Yildirim Sk. No:17 Yildirim/BURSA
Yildirim V.D.: 998 141 1400
Mersis No: 9981414000

ZEYNI

MEDICAL

Zeyni Medikal Tekstil İnş San. and Tic. Ltd. Şti hereby declares that the above mentioned products are in compliance with all applicable provisions of Directive 93/42/EEC. The product is safe under foreseeable and reasonably foreseeable conditions of storage and use.

The company has put in place measures to ensure that all products of the type mentioned above are safe and meet the essential requirements of Directive 93/42/EEC

The company has put in place a systematic procedure to review experience gained with the devices in the post-production phase and to apply appropriate means for any necessary corrective action and keeps this systematic procedure up to date. The company undertakes to report to the competent authority any malfunction or alteration in the properties, performance or inadequacy of the product's instructions for use that could lead to the death of the patient or serious damage to the patient's health, as well as the or medical reasons that led to the systematic recall of the product by the manufacturer.

If the device is modified without the consent of the undersigned, this statement becomes invalid with respect to the modified product.

Regulated in accordance with EC Directive 93/42/EEC concerning medical devices

EC DECLARATION OF CONFORMITY

11042020-UB

GENERAL DIRECTOR:

Baki Canavar

07.06.22

STAMP & SIGNATURE

ZEYNİ MEDİKAL
TEKS.İNŞ. SAN.VE TİC.LTD.ŞTİ.
Yunusemre Mh. 12. Yıldırım Sk. No: 17 Yıldırım/BURSA
Yıldırım V.D.: 998 141 7406 Ticaret No: 102317
Mersis No: 0998141740000001

CERTIFICATE OF COMPLIANCE

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate has been awarded to

ZEYNİ MEDİKAL TEKSTİL İNŞAAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

YUNUSEMRE MAHALLESİ 12. YILDIRIM SOKAK NO:17
YILDIRIM / BURSA / TÜRKİYE

In recognition of the organization's Management System
which complies with

EN 13795-1:2019

The scope of activities covered by this certificate is defined below

MANUFACTURING, SALES OF DISPOSABLE, STERILE AND NON-STERILE SURGICAL GOWNS, INSULATED VISITOR GOWNS AND COVERS

TEK KULLANIMLIK, STERİL VE STERİL OLMAYAN CERRAHİ ÖNLÜK, İZOLASYONLU ZİYARETÇİ ÖNLÜĞÜ VE ÖRTÜLERİN İMALATI, SATIŞI

Certificate Number: **SISTUREN082020161**
Date of Issue of Original Certificate: **21.08.2020**
Date of Issue of latest certificate: **23.09.2021**
Expiry Date: **20.08.2022**
Re-certification Due on: **21.07.2023**

Managing Director

Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Compliance is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid

Corporate office(SIS): Unit No. 514, 5th Floor, Vipul Business Park, Sohna Road, Sector-48, Gurgaon-122018, Haryana, India.
International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047.
Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91 99105 01396, + 91 96430 73391
The status of this certificate can be verified on "http://www.siscertifications.com/verify/"
Web:- http://www.siscertifications.co.in, www.siscertifications.com

Issue No.: **03**

ZEYNİ MEDİKAL TEKSTİL İNŞ.SAN. VE TİC. LTD. ŞTİ.

YUNUSEMRE MAH. 12 YILDIRIM SOKAK NO:17 YILDIRIM/BURSA

Report No. 111699085

Buyer /

Test Item. :	Nonwoven fabric,3-layer, SMS
Item No. :	/
Colour Name. :	/
Condition at delivery. :	Samples tested as received.
Test Scope. :	Parameters selected by customer
Test Specification :	Determination of hydrostatic pressure

Applicant's Provided Care Instruction/Label: -

Sample Receiving date: 2021-10-18 (p.m)

Testing Period: 2021-10-21 to 2021-10-25

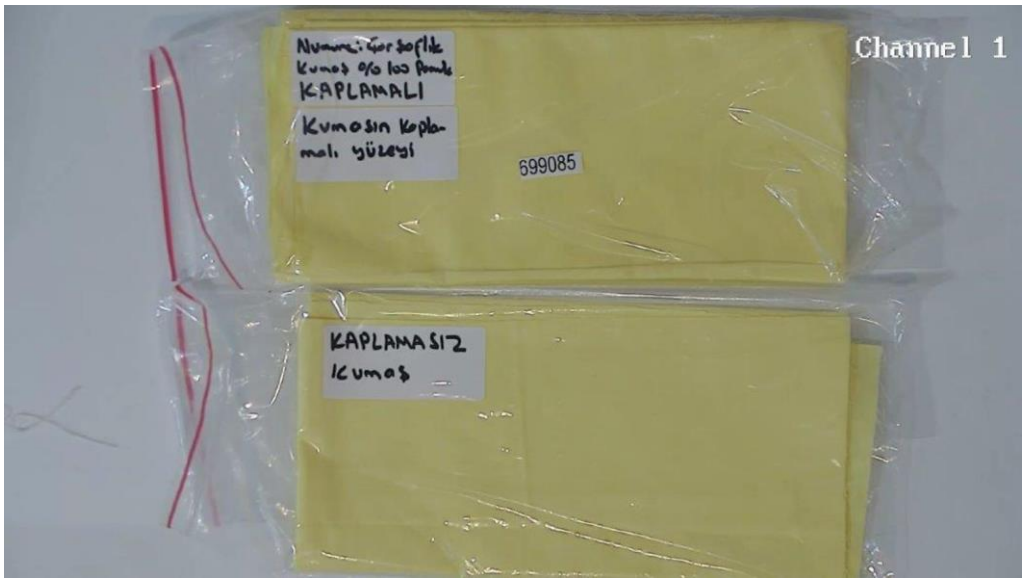
Test Result: No Comment

For and on behalf of
TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş

Tomris Hasançebi / Customer Relations Manager

Abdullah Akil / Physical Laboratory Manager

TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş.
Kozyatagi Mah. Saniye Ermutlu Sok. No:12
Colakoglu Plaza B Blok 34742 Kadikoy Istanbul,
Tel. +902166653200, Fax +902166653299, e-mail: info@tr.tuv.com



TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş.
Kozyatagi Mah. Saniye Ermutlu Sok. No:12
Colakoglu Plaza B Blok 34742 Kadikoy Istanbul,
Tel. +902166653200, Fax +902166653299, e-mail: info@tr.tuv.com

Material List:

Material No.	Material	Color	Location
M001	Textile	-	Textile
M002	Textile + coating	-	Textile w /coating

TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş.
Kozyatagi Mah. Saniye Ermutlu Sok. No:12
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Tel. +902166653200, Fax +902166653299, e-mail: info@tr.tuv.com

Conclusion:

TEST PROPERTY	M001	M002
Hydrostatic Pressure Test	#	#

TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş.
Kozyatagi Mah. Saniye Ermutlu Sok. No:12
Colakoglu Plaza B Blok 34742 Kadikoy Istanbul,
Tel. +902166653200, Fax +902166653299, e-mail: info@tr.tuv.com

1.Hydrostatic Pressure Test

Test method : EN 20811:1993

Face Side: Original
Test Conditions: 65 cm2 Test
Speed:65 cmH2O/dak

	M001	M002	Requirement
Pressure			
Average	65 cm H2O	65cm H2O	-

- END -

TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş.
Kozyatagi Mah. Saniye Ermutlu Sok. No:12
Colakoglu Plaza B Blok 34742 Kadikoy Istanbul,
Tel. +902166653200, Fax +902166653299, e-mail: info@tr.tuv.com

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Colakoglu Plaza B Blok 34742 Kadikoy Istanbul,
Tel. +902166653200, Fax +902166653299, e-mail: info@tr.tuv.com

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

P.K.21,41470 GEBZE–KOCAELI
T02626772000 F02626412309
http://www.mam.gov.tr

CERTIFICATE OF ANALYSIS

(Industrial Technical Support Service)

Report no	:16563500-125.05-89 /4654
Report date	**:23.08.2017**
Applicant	: ZEYNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.
Address	: YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA
Subject	:CYTOTOXICITY TEST CARRIED OUT for 'SURGERY DRAPE' IN THE SCOPEOF BIOCOMPATIBILITY TESTS

The results included in this report are related to only the sample analyzed.

Approved by

Assoc. Prof. Dr. FatimaYÜCEL
GMBE Industrial Services Officer

TÜBİTAK MAM

Report no	:16563500-125.05-89/4654
Applicant	:ZEYNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD.ŞTİ
Address of Applicant	: YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA

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:17/70-GMBE Acceptance date and hour:11.08.2017 Analysis date :14.08.2017–17.08.2017

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 cytotoxicity test upon the application of ZEYNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ. dated 14.08.2017 and numbered 3940.

Sample	Characteristics	Item
Sterile Surgical Drapes	The product is a set consisted of medical textile products in various sizes and forms used for various purposes during surgeries. 1- Drape (100x150cm) Production Date: 05/2017, STERILE EO LOT 000001, Latex Free, Single Use Only	3

Table 1.Product tested.

Descriptions:

Signatories:

53192 (signature)

P.K.21,41470 GEBZE–KOCAELİ

262677 2000 F 02626412309
http://www.mam.gov.tr

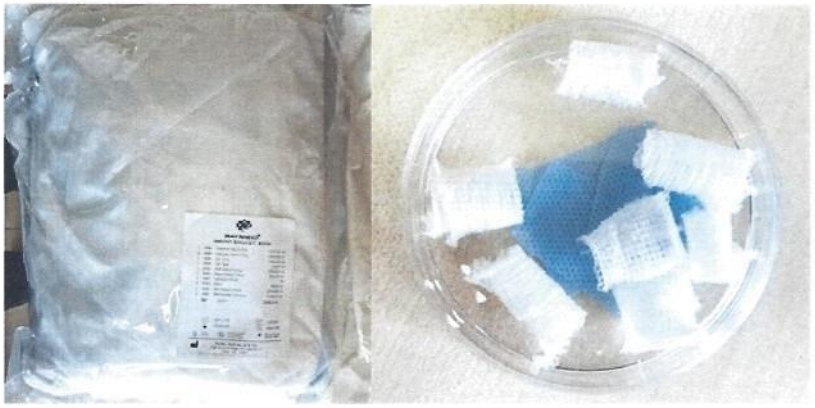
Sample	Specifications	Item
Surgery Set		3

Table1 (contd.).Product tested.

Descriptions:

Signatories:

53192

P.K.21,41470GEBZE–KOCAELİ

262677 2000 F 02626412309
http://www.mam.gov.tr

Report no:16563500-125.05-89/4654

Cytotoxicity Test

The cytotoxicity tests were carried out in accordance with 'Biological evaluation of medical products: ISO 10993-5: 2009 Tests for in vitro cytotoxicity' standards.

Beginning date of test:

Expiry date of test:

Sample description: The sample characteristics are as explained in the Part 1. The samples were provided by '**ZEYNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.**' firm. The tests werecarried out by taking parts from surgery set selected as representing the product.

Explanation of cell strain used and its reasons: L929 rat cell strain was used. It was selected since it is one of the cell strains recommended by ISO 10993-5 and appropriate for representation of mammals system.

Explanation of cell strain used and its reasons: L929 rat cell strain was used. It was selected since it is one of the cell strains recommended by ISO 10993-5 and appropriate for representation of mammals system.

Name and batch number of the firm provided the feed used and the serum and antibiotics added: DMEM/F12 (Sigma cat # D0547-10X-1, lot #SLBH4393) + 10% Fetal bovine serum (Gibco Life Sciences Cat # 10270-106, lot #41G2943K)+ penicilinle streptomycin (Gibco Life Sciences, Cat # 15140-122, lot # 1688254) were used as feed lot.

Test method: Direct contact method.

Rational: The analyses of toxic effect of solid matters, dissolved in liquid, as a result of contact with cell.

Direct contact protocol: The 'Surgical Drape' was provided as sterile and not subjected to a sterilization process once again. The 'Surgical Drape' was cut to the extent of 1/10 of total surface area of cells and put into middle of pits over the cells.

Test protocol: L929 cells were counted and implanted in &' pits as 4 X 10^5 cell/pit and incubated for 24 hours at 37^{O}C and 5% CO_2. The samples prepared as explained above and the controls were immediately added on cells and incubated for 24 hours at 37^{O}C and 5% CO_2. The samples were contacted with cells for 24 hours and then observed microscopically. Following this process, WST-1 agent at 1:50 rate was added onto the cells and the color formation was waited for 2 hours. 100 µ liquid from each pit was taken and poured into 3 pits in 96 sizes so that the absorbance measure was realized at microplate reader, at 450 nm and 650 nm reference wave length for viability test.

Cytotoxicity Measure method: WST-1 cell viability analyses (Colorimetric)

Rational: The consistent and sensitive measurement of cell viability.

Descriptions:

Signatories: 52966 53077

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http://www.mam.gov.tr

Negative, positive and other controls:
Controls:
Control 1- The plates on which any material was not put but only the cells were implanted
Control 2- The sterile and dry whatmann paper cut in 1 cm X 1 cm sizes.
Negative Control: Whatmann paper saturated with PBS (25µl) and cut in 1cm X 1cm sizes.
Positive Control: Whatmann paper saturated with EMS (Ethyl methanesulfonate, Merck Millipore, 820774) (25µl) and cut in 1cm X 1cm sizes.

RESULT:

Cell response and other observations:

Quantitative Evaluation

It was observed that there was no cell direct under the sample. However, the same result was observed in PBS saturated whatmann paper samples. A zonal toxic effect was not observed around the sample. This observation was reflected in qualitative evaluation.

	Degree		Degree
Sample		Control 1, Empty	0
Surgery Drape	**0**	Control 2, dry Whatmann paper	0
		Negative Control, PBS saturated Whatmann paper	0
		Positive Control, EMS saturated Whatmann paper	4

Table 2. Quantitative Evaluation.

Degree	Reactivity	Situation
0	None	Clear intracytoplasmic granuls, no any cell lysis, no impact on cell growth.
1	Less	The rate of cells, which are become rounded, representing poor adhesion and/or having no intracytoplasmic granules, showing morphological changes and partly lysis, is below 20%.
2	Slight	The rate of cells, which are become rounded and having no intracytoplasmic garnuls, is below 50%, there is no extensive cell lysis; growth inhibition is below 50%.
3	Moderate	Less than 70% of cells are rounded or showing lysis and growth inhibition is not more than 50%.
4	Serious	All or almost all of the cells are showing lysis.

Table 3. **Evaluation criteria and scoring for cytotoxicity test.**

Descriptions:

Signatories: 52966 53077

P.K.21,41470GEBZE–KOCAELİ
2626772000 F02626412309
http://www.mam.gov.tr

According to the evaluation criteria given in the Table 3, L929 cell culture was exposed to 'Surgical Drape' for 24 hours in order to examine its potential for causing to cell death according to the control and the cell viability was found as %98.11 ±1.31 according to the control as a result of ISO 10993-5 cytotoxicity test carried out in the scope of biocompatibility.

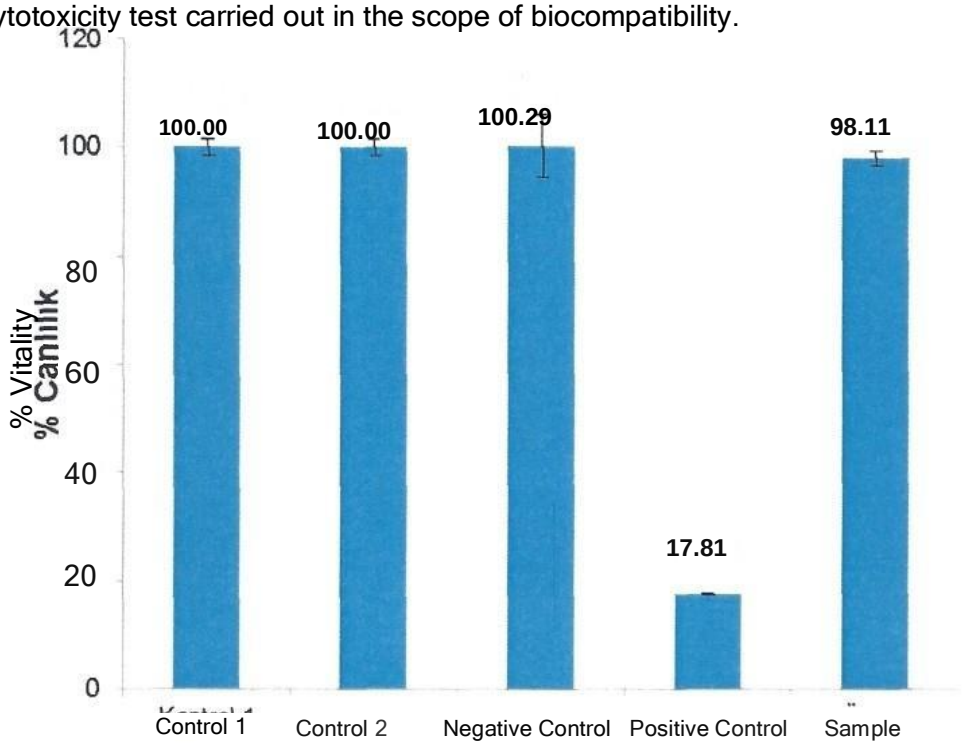


Figure 1. The viability analyses, carried out by using extracts from samples called 'Surgical Drape', are shown in the Figure.

Cytotoxicity of 'Surgical Drape' sample; The absorbance values of samples were normalized by
using Negative Control 2 absorbance values in parallel with the samples for 100% viability.

The data, obtained for each sample, was provided as a result of triplicated process in tests of 3 extracts from 3 randomly selected samples.
EVALUATION:
No cytotoxic effect according to the viability test carried out by using 'Surgical Drape' extraction method.

Descriptions:

Signatories: **52966** **53077**

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 : ZEYNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.

Address : YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA

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

TÜBİTAK
MAM

Report no : 16563500-125.05- 64 / 3882-2
Applicant : ZEYNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.
Address of Applicant : YUNUSEMRE MAH. 12. YILDIRIM SK. NO:17 YILDIRIM BURSA

Sample : Standardized sample	**Expiry date** : 05/2022
Sample number 3	**Sample registration no at Institution** : 17/35-GMBE
Delivery type of sample : By Cargo	
Situation in delivery time: It was provided in closed sterilization packets under sterile conditions.	**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 ZEYNİ MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ. dated 16/05/2017 and numbered 2669.

Table 1. The tested product.

Sample	Characteristics	Item
Sterile Surgical Drapes	The product is a set consisted of medical textile products in various sizes and forms used for various purposes during surgeries. 1- Drape (100x150cm) 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

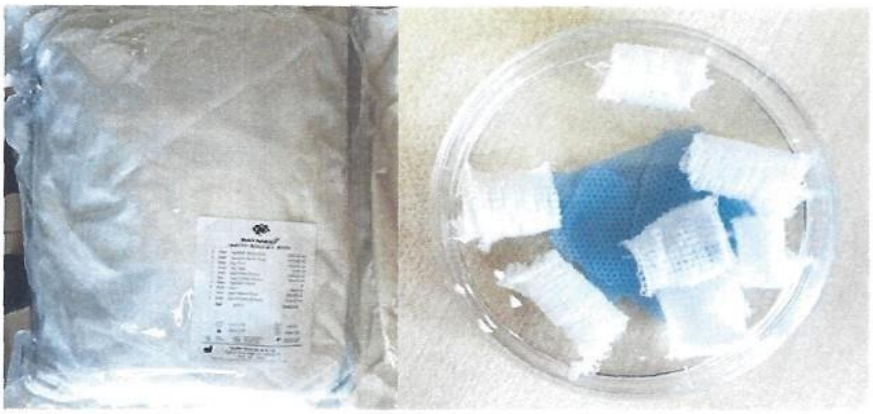
Sample	Specifications	Item
Surgery Set		3

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.

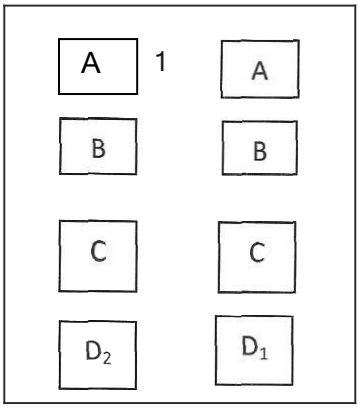


Figure 1.

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:

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Negative Control

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

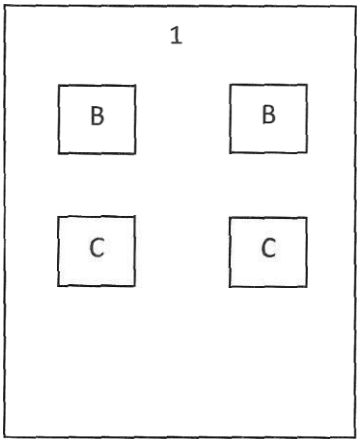

Figure 2.

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.

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 Drape

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 Drape	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 Drape' 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

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KOCAELİ ÜNİVERSİTESİ
Deneysel Tıp Araştırma ve Uygulama Birimi
(DETAB)

TEST REPORT

Report Number : 2021-087

Report Date (d/m/y) : 27/08/2021

Test Material (Description) : Standard Surgical Gown

Demand Owner Company : Zeyni Medikal Tekstil İnşaat San. ve Tic. LTD ŞTİ.

Address of Demand Owner : Yunus Emre Mahallesi 12 Yıldırım Sokak No: 17 Yıldırım/ Bursa/TÜRKİYE

Applied Test Standard : TS EN ISO 10993-10:2014

(ISO 10993-10:2013- Clause 6.3)

Applied Test : Animal Irritation Test

Approved by
Prof. Dr. Tijen UTKAN
Director of DETAB

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Summary

The extract of the test material entitled Standard Surgical Gown and manufactured by Zeyni Medikal Tekstil İnşaat San. ve Tic. LTD ŞTİ. was tested using the Animal Irritation Test technique for evaluating its skin irritation potential in accordance with the standards and requirements outlined in TR EN ISO10993-10:2014. The extract was prepared at 72 °C over a 24-hour period. Sesame oil was used as solvents. Gauze patches (25 mm x 25 mm) were soaked with extract and placed/bandaged on the shaved skin of the rabbits for 4 hours. The skin reactions in the form of erythema and swelling were evaluated 1, 24, 48 and 72 hours after the end of the application period. The primary irritation index (PII) scores were calculated for the application of the test material and positive control. Severe skin reactions were observed in the positive control (SDS) group while no erythema or swelling was observed in the test sites where the extract was applied (PII=0.0) and negative control sites. Data of each group met the criteria for the validity of the test results. The extract of the test material did not generate a potential skin irritation in rabbits under the conditions outlined above. The reserve sample is archived at the Experimental Medical Research and Application Unit (DETAB), Kocaeli University.

Dates

Test Start Date (d/m/y)	: 03/08/2021
Test End Data (d/m/y)	: 06/08/2021

Signatures of Researchers

Prof. Dr. Tijen UTKAN :

Prof. Dr. Yusufhan YAZIR :

Doç. Dr. Ayşe KARSON :

DVM. Cüneyt ÖZER :

1. Introduction

1.1. Aim and Scope

The aim of this study is to investigate the skin irritation potential of the tested material/its extract. To this end, we used the rabbit skin irritation test as an in vivo test technique. In this test, the extract gathered from the test material is applied on the shaved skin sites of rabbits for a duration of 4 hours and erythema and swelling responses were evaluated 1, 24, 48, and 72 hours after the application period. The scoring system utilized to quantify the observations categorizes the irritation properties of the test material/its extract in four different classes (negligible, slight, moderate, severe).

1.2. Guidelines (standards) and principles

The standards that outlined the guidelines followed during the design, application and evaluation phases of the current study are listed below under corresponding categories:

Design Phase: TS EN ISO 10993-1. 2011-03 (EN ISO 10993-1:2009) (ref.1).

Skin irritation test application, recording, and evaluation phases: TS EN ISO 10993-10:2014: Clause 6.3- animal irritation test (ref.2).

Preparation of the test materials (extracts): TS EN ISO-10993-12:2013: Clause 10.1 (ref.3).

Husbandry, care, application and monitoring of animals: TS EN ISO 10993-2:2006 (ref.4).

This study was approved by the Institutional Animal Care and Use Committee, Kocaeli University. The health of the subjects and their husbandry were monitored by and the study was designed and implemented under the supervision of an experienced veterinarian with specialization in lab animals and applications. All the procedures were conducted in accordance with the good laboratory practice regulations (21 CFR part 58).* Kocaeli University Experimental Medicine Research and Application Unit (DETAB) has a working authorization certificate within the framework of the regulation on the welfare and protection of animals of the Ministry of Agriculture and Forestry for experimental and other scientific purposes (24.07.2018-006).
* DETAB is not GLP certified.

1.3. References

1. TS EN ISO 10993-1. 2011-03 (EN ISO 10993-1:2009) Tıbbi cihazların biyolojik değerlendirilmesi- Bölüm 1: Bir risk yönetim sürecinde değerlendirme ve deney.

2. TS EN ISO 10993-10:2013-04 (EN ISO 10993-10:2012) Tıbbî cihazların biyolojik değerlendirilmesi- Bölüm 10: Tahriş ve cilt duyarlılığı için deneyler

3. TS EN ISO 10993-2:2006-10 (EN ISO 10993-2:2006) Tıbbî cihazların biyolojik değerlendirilmesi- Bölüm 2: Hayvan refahı için gerekli şartlar.

4. TS EN ISO 10993-12:2013-4 Tıbbi cihazların biyolojik değerlendirilmesi- Bölüm 12: Numune hazırlanması ve referans malzemeler (EN ISO 10993-12:2012) Direktif:90/385/EEC,93/42/EEC EN ISO 10993-12:2012 / 10.04.2013

2. Description of test and control material

2.1. Test Material

Name	: Standard Surgical Gown
Lot/Reference Number	: 4A-0121
Production and Expiration Date	: -
Shipment	: Cargo
Quantity (Number, Volume, Weight)	: N=2
Description at Time of Receipt	: In sealed package
Sterilization Method	: EO
Storage	: At the room temperature
Description and Function of the Test Material/Product	: Disposable surgical gown
Physical and Chemical Properties of the Test Material*	: Non-woven blue surgical gown.
Reserve Sample	: Returned to Owner ☐
	Archived ☒
	Reserve Sample was not received ☐

Figure 1: Photograph(s) of the product

* Information regarding the physical and chemical properties of the test material were provided by the company/institution requesting the test.

3. Description of the test system

Species: Rabbit (New Zealand)
Sample Size: 3
Age: 4-6 months
Sex: Male
Identification: Ear marking
General Health Status: Healthy, naive, adult rabbit were used.

4. Animal husbandry and care

Housing: Conventional
Room Temperature: 20-24 ^{0}C
Room Humidity: %40-60
Room Dark/Light Cycle: 12 hours light/12 hours dark
Water Consumed (Daily): Ad lib, 100-600 ml
Feed Consumed (Daily): Ad lib, 100-300 g
Feed: MBD brand rabbit feed

5. Materials and Methods

5.1. Preparation of test samples and materials

The selection of the samples and the preparation of the extracts were carried out according to the standards described in TS EN ISO 10993-12:2013 (ref.4). The extract gathered from the test material was used since the test material was not suitable to maintain direct contact with the skin (ref.4-Clause 7). The preparation of the extracts from sample material gathered under aseptic conditions (ref.4-Clause 8) was carried out under ratio, temperature, and duration parameters as described in Table 1 (ref.4-Clause 3 and 10). Each part of the test product was included (at ratios that reflect the material constitution of the product) in the extraction process (ref.4-Clause 9). A 10% sodium lauryl sulfate (SLS) solution, which carries the characteristics of reference material and is widely utilized in the irritation test was used in the positive control test. Sesame oil was used for the negative control. All solutions were prepared under the same conditions.

Table 1: Parameters used for extract preparation

	Sterilization	Amount	Volume	Concentration	Water Temperature	Duration
Test material	Sterile (EO)	30 cm^2	5 ml	6 cm^2/ml	37^0 C	72 hours
Negative Control	Sterile	-	-	-		

There was no difference in the appearance of the solvents (color, clarity, particle etc.) at the end of the extraction procedure. Extracts were stored in the room temperature and used on the day of preparation without subjecting them to further processing (pH calibration, centrifuge, filtration, etc. - ref.4-Clause 10).

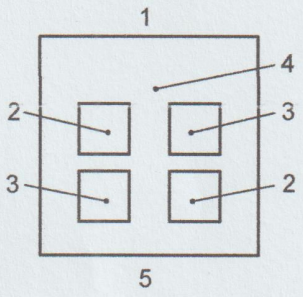
5.2. Experimental Procedures

5.2.1. Preparation

6-24 hours prior to the start of the experimental procedures, rabbits were weighted and fur in the test areas were shortened and shaved. Observations regarding the state of the skin at the test sites were recorded and reported.

5.2.2. Application

Folded gauze patches (2.5 cm x 2.5 cm) were soaked in 0.5 ml test extract or negative control solution and applied on diagonally located sites on the back of the animal (Figure 2). These patches were secured with bandages and kept in place for 4 hours. At the end of the 4-hour contact duration, the bandage and patches were removed and the application site locations were marked with permanent ink by marking the corners. The remaining experimental material was cleaned with warm water and the corresponding areas were dried.



1. Cranial end (head)
2. Experimental Sites (Test Material)
3. Control Sites (Solvent)
4. Shaved Test Site
5. Caudal end (tail)

Figure 2: Application plan

5.3. Observations and recordings

Skin reactions of erythema and swellings at the marked skin area were monitored and recorded according to the criteria outlined in Table 2 1 (±0.1), 24 (±2), 48 (±2), and 72 (±2). hours following the removal of the patches (ref.2-Clause 6.6.5). Observations were carried out with naked eye and microsurgery microscope with powerful illumination (Leica IC90 E). The dimensions of the swelling responses were measured with a digital caliper. The overall health of the rabbits was also monitored throughout testing and unexpected skin responses outside the marked test areas were examined. All evaluations were made in a fashion that was blind to the animal IDs and groups.

Table 2: *Skin Irritation Scoring*

Reaction	
Erythema and Eschar Formation	
No Erythema	0
Very Slight Erythema (barely perceivable)	1
Well-defined Erythema	2
Moderate Erythema	3
Severe Erythema (beet-redness) and eschar formation	4

Edema Formation	
No Edema	0
Very Slight Edema (barely perceivable)	1
Well-defined Edema (Edges of area well-defined by definite raising)	2
Moderate Edema (raised approximately 1 mm/0.1 cm)	3
Severe Edema (raised more than 1 mm/0.1cm extending beyond exposure area)	4

5.4. Evaluation and analysis

Observations recorded at the 24th (±2), 48th (±2) and 72nd (±2) hours were included in the calculations (Appendix 1). In order to categorize the skin irritation response, primary irritation index (PII) was determined (Table 3). PII refers to the mean PII of three different subjects. PII is calculated separately for the test and control samples. In order to calculate the PII, the erythema and swelling scores of each animal is summed between 2 sites and 3 observation times (24., 48., and 72. hours) and then divided by 6 in order to find the average score. The PII gathered for the negative control is subtracted from the PII gathered from the test sample in the corresponding rabbit (Table 3).

Table 3: *Irritation Index Categorization*

Primary Irritation Index	Irritation Category
0 – 0.4 range	Negligible
0.5 – 1.9 range	Slight
2 – 4.9 range	Moderate
5 – 8 range	Severe

6. Test Results

All animals were clinically normal throughout the study. The skin reaction (erythema and swelling) scores of the test sites were not different from the scores noted for the negative control sites. The PPI score for the test sample was 0.0 (Table 4). No unexpected or suspect skin reactions were observed on the skin outside the marked skin test area. Individual skin reaction scores are presented in Appendix 1.

Table 4. *Primary irritation scores and index*

Animal ID	ATS	-	ACS	I-IS	T-IS	PII	Response Category
1	0.0	-	0.0	0.0	0.0	0.0	Negligible
2	0.0	-	0.0	0.0			
3	0.0	-	0.0	0.0			

ATS: Average Test Score; ACS: Average Control Score; I-IS-Individual Primary Irritation Score; TIS: Total Irritation Score, PII: Primary Irritation Index of Test Sample

7. Conclusion

The test sample of "Standard Surgical Gown" (Manufacturer: Zeyni Medikal Tekstil İnşaat San. ve Tic. LTD ŞTİ.) was tested and evaluated according to the Rabbit Skin Irritation Test (TS ISO 10993-10:2014- Clause 6.3). In conclusion, it was found that the test sample **did not cause any erythema or swelling** that are considered as indicators of irritation. **The skin reactions caused by the test material was categorized as in the negligible category**.

Appendix-1 (Skin Irritation Observations)

ID	Groups	Area	Observation							
			1. Hour		24. Hour		48. Hour		72. Hour	
			Erthm	Swell	Erthm	Swell	Erthm	Swell	Erthm	Swell
1	*Test Sample*	R(2)	0	0	0	0	0	0	0	0
		L(2)	0	0	0	0	0	0	0	0
	Negative Control	R(3)	0	0	0	0	0	0	0	0
		L(3)	0	0	0	0	0	0	0	0
2	*Test Sample*	R(2)	0	0	0	0	0	0	0	0
		L(2)	0	0	0	0	0	0	0	0
	Negative Control	R(3)	0	0	0	0	0	0	0	0
		L(3)	0	0	0	0	0	0	0	0
3	*Test Sample*	R(2)	0	0	0	0	0	0	0	0
		L(2)	0	0	0	0	0	0	0	0
	Negative Control	R(3)	0	0	0	0	0	0	0	0
		L(3)	0	0	0	0	0	0	0	0

ID	Groups	Area	Observation							
			1. Hour		24. Hour		48. Hour		72. Hour	
			Erthm	Swell	Erthm	Swell	Erthm	Swell	Erthm	Swell
1	*Positive Control*	R(2)	0	0	2	4	2	2	3	3
		L(2)	0	0	2	4	2	2	3	3
	Negative Control	R(3)	0	0	0	0	0	0	0	0
		L(3)	0	0	0	0	0	0	0	0
2	*Positive Control*	R(2)	1	0	2	4	2	2	3	3
		L(2)	0	0	2	3	2	3	3	2
	Negative Control	R(3)	0	0	0	0	0	0	0	0
		L(3)	0	0	0	0	0	0	0	0
3	*Positive Control*	R(2)	1	0	3	2	3	3	3	3
		L(2)	1	0	3	2	3	3	3	3
	Negative Control	R(3)	0	0	0	0	0	0	0	0
		L(3)	0	0	0	0	0	0	0	0

Erhm: Erythema, *Swell:* Swelling, *R:* Right, *L:* Left
Note: Under ideal circumstances, positive control study is repeated every 6 months

KOCAELİ ÜNİVERSİTESİ
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TEST REPORT

Report Number	: 2021-088
Report Date (d/m/y)	: 27/08/2021
Test Material (Description)	: Standard Surgical Gown
Demand Owner Company	: Zeyni Medikal Tekstil İnşaat San. ve Tic. LTD ŞTİ.
Address of Demand Owner	: Yunus Emre Mahallesi 12 Yıldırım Sokak No: 17 Yıldırım/ BURSA
Applied Test Standard	: TS EN ISO 10993-10:2014 (ISO 10993-10:2013- Clause 7.5)
Applied Test	: Guinea Pig Maximization Test Technique

Approved by
Prof. Dr. Tijen UTKAN
Director of DETAB

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Summary

The extract of the test material, Standard Surgical Gown that is manufactured by Zeyni Medikal Tekstil İnşaat San. ve Tic. LTD ŞTİ. was tested using the Guinea Pig Maximization Test technique for evaluating its skin sensitization potential in accordance with the standards and requirements outlined in TR EN ISO10993-10:2014. The extract was prepared at 37 °C over a 72-hour period. 0.9% sesame oil was used as solvent. Two weeks after the intradermal and topical induction applications, the extract of test material was applied directly on the skin of the subjects for 24 hours through patches secured by bandage. The skin reaction was evaluated 24 and 48 hours after the removal of the patches. The extract of the test material prepared in sesame oil did not generate skin sensitization in guinea pigs under the conditions outlined above. The reserve sample is archived at the Experimental Medical Research and Application Unit (DETAB), Kocaeli University.

Dates

Test Start Date (d/m/y)	: 29/07/2021
Test End Data (d/m/y)	: 24/08/2021

Signatures of Researchers

Prof. Dr. Tijen UTKAN :

Prof. Dr. Yusufhan YAZIR :

Doç. Dr. Ayşe KARSON :

DVM. Cüneyt ÖZER :

1. Introduction

1.1. Aim and Scope

The aim of this study is to investigate the delayed type skin sensitization potential of the tested material/its extract. To this end, we used Guinea pig maximization test procedure, which is considered as a sensitive test in sensitization studies. In this test, the extract gathered from the test material is administered intradermally and topically in combination with an adjuvant that increases sensitization. Two weeks after the two-stage induction applications, the extract is put in direct contact with the skin for a 24-hour period (challenge phase). 24 and 48 hours after the challenge phase, the skin inflammation indicators (e.g., erythema and swelling responses) were characterized and quantified between 0 and 4 according to Magnusson and Kligman scoring scale. The results of the test are evaluated in terms of the rate of the positive sensitization response. The challenge phase is repeated in case of suspect results.

1.2. Guidelines (standards) and principles

The standards that outlined the guidelines followed during the design, application and evaluation phases of the current study are listed below under corresponding categories:

Design Phase: TS EN ISO 10993-1. 2011-03 (EN ISO 10993-1:2009) (ref.1).

Guinea pig skin sensitization test application, recording, and evaluation phases: TS EN ISO 10993-10:2014: Clause 7.5- Guinea pig maximization test (ref.2).

Preparation of the test materials (extracts): TS EN ISO-10993-12:2013: Clause 10.1 (ref.3).

Husbandry, care, application and monitoring of animals: TS EN ISO 10993-2:2006 (ref.4).

This study was approved by the Institutional Animal Care and Use Committee, Kocaeli University. The health of the subjects and their husbandry were monitored by and the study was designed and implemented under the supervision of an experienced veterinarian with specialization in lab animals and applications. All the procedures were conducted in accordance with the good laboratory practice regulations (21 CFR part 58)*. Kocaeli University Experimental Medicine Research and Application Unit (DETAB) has a working authorization certificate within the framework of the regulation on the welfare and protection of animals of the Ministry of Agriculture and Forestry for experimental and other scientific purposes (24.07.2018-006).
* DETAB is not GLP certified.

1.3. References

1. TS EN ISO 10993-1. 2011-03 (EN ISO 10993-1:2009) tıbbi Cihazların biyolojik değerlendirilmesi- Bölüm 1: Bir risk yönetim sürecinde değerlendirme ve deney.

2. TS EN ISO 10993-10:2013-04 (EN ISO 10993-10:2012) Tıbbî cihazların biyolojik değerlendirilmesi- Bölüm 10: Tahriş ve cilt duyarlılığı için deneyler

3. TS EN ISO 10993-2:2006-10 (EN ISO 10993-2:2006) Tıbbî cihazların biyolojik değerlendirilmesi- Bölüm 2: Hayvan refahı için gerekli şartlar.

4. TS EN ISO 10993-12:2013-4 Tıbbi cihazların biyolojik değerlendirilmesi- Bölüm 12: Numune hazırlanması ve referans malzemeler (EN ISO 10993-12:2012) Direktif:90/385/EEC,93/42/EEC EN ISO 10993-12:2012 / 10.04.2013

2. Description of test and control material

2.1. Test Material

Name	: Standard Surgical Gown
Lot/Reference Number	: 4A-0121
Production Date	: -
Shipment	: Cargo
Quantity (Number)	: N=2
Description at Time of Receipt	: In sealed package
Sterilization Method	: EO
Storage	: At the room temperature
Description and Function of the Test Material/Product	: Disposable sterile surgical gown
Physical and Chemical Properties of the Test Material*	: Non-woven blue surgical gown.
Reserve Sample	: Returned to Owner ☐
	Archived ☒
	Reserve Sample was not received ☐

Figure 1: Photograph(s) of the test product

* Information regarding the physical and chemical properties of the test material were provided by the company/institution requesting the test.

3. Description of the test system

Species: Guinea Pig
Strain: Cavia Porcellus
Sample Size: Test:10, negative control: 5, positive control: 5
Age: 4-6 months
Sex: Male
Identification: Ear marking
General Health Status: Healthy, naive, adult Guinea pigs were used.

4. Animal husbandry and care

Housing: Conventional
Room Temperature: 20-24 ^{0}C
Room Humidity: %40-60
Room Dark/Light Cycle: 12 hours light/12 hours dark
Water Consumed (Daily): Ad lib, 10 ml water/100 g body weight
Feed Consumed (Daily): Ad lib, 6 g feed/100 g body weight
Feed: MBD brand Guinea pig feed

5. Materials and Methods

5.1. Preparation of test samples and materials

The extract gathered from the test material was used in the test. The selection of the samples and the preparation of the extract was carried out according to the standards described in TS EN ISO 10993-12:2013 (ref.4). The preparation of the extracts from the sample material gathered under aseptic conditions (ref.4-Clause 8) was carried out using the shaking method under ratio, temperature, and duration parameters as described in Table 1 (ref.4-Clauses 3 and 10). Each part of the test product was included (at ratios that reflect the material constitution of the product) in the extraction process (ref.4-Clause 9). As solvent, we used apolar sesame oil (SO). The solvent was used instead of extracts in the negative control group. The control solvents were prepared under the same conditions as the extract preparation.

Table 1: Parameters used for extract preparation

	Sterilization	Amount	Volume	Concentration	Water Temperature	Duration
Test material	Sterile (EO)	30 cm^2	5 ml	6 cm^2/ml	37^0 C	72 hours
Negative control (SL)	Sterile	-	-	-		

There was no difference in the appearance of the solvents (color, clarity, particle etc.) at the end of the extraction procedure. Extracts were stored in the room temperature and used on the day of preparation without subjecting them to further processing (pH calibration, centrifuge, filtration, etc.; ref.4-Clause 10).

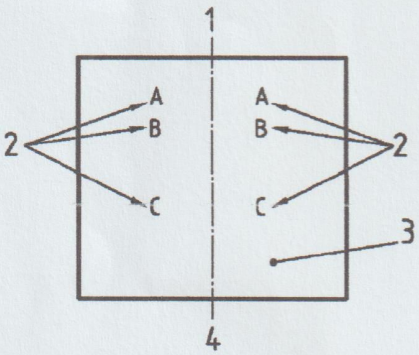
Other materials:
For the positive control, a solution of 0.08% paraformaldehyde (PFA) diluted in phosphate buffered serum was used (ref.2-Clause 7).

Freund's Complete Adjuvant (FCA): FCA is used in order to increase sensitivity. FCA was mixed with solvent and extract at different concentrations (FAC/Solvent: 1/1; FCA/Solvent: 1/3; FCA/Solvent/Extract: 1/1/2) and injected intradermally during the first induction phase.

5.1.1. Intradermal Induction Phase

24 hours prior to the intradermal injection, fur of the test areas on the animals' back were shortened and then shaved. Each adjuvant, solvent and extract solution described below was administered to each animal via bilateral intradermal injections (0.1 ml) at sites in the dorsal scapular region (A, B, and C of Figure 2).

Site A: FCA was mixed with solvent (SO) at 50:50 volume ratio to prepare stable solution and then injected.
Site B: Undiluted extract was injected to the animals in the experimental group and only the solvent (SO) was injected to the animals in the control group.
Site C: Undiluted extract concentration (used in Site B) was mixed with FCA's stable solution (used in Site A) at 50:50 volume ratio and injected to animals in the experimental group. Animals in the control groups were injected with SO or PFA solutions using the same concentration of adjuvant and solvent.



1. Cranial End
2. Intradermal Injection Site
3. Shaved Intrascapular Site
4. Caudal End

Figure 2: Sensitization application plan

5.2.2. Topical Induction Phase

Topical induction phase was applied 7 days following the intradermal induction phase. One day prior to the application, the skin was shaved. 24 hours later 8 cm^2 gauze patches soaked in test samples (extract) were placed such that they covered intradermal injection sites (Figure 2) at the back of the animals. Patches were secured with medical elastic tape. Bandages and patches were removed after a 48 hour-long period.

5.2.3. Challenge Phase

The challenge phase was conducted 14 days after the completion of the topical induction phase. Application sites were shaved one day before the application. Patch soaked with the extract was topically applied on the previously untreated healthy skin on the sides of the animal. These patches were secured with an elastic medical tape and bandaged. The same procedure was applied on the animals in the control groups.

5.3. Observations and recordings

Skin reactions were monitored and recorded 24 (±2) and 48 (±2) hours following the removal of the patches at the end of the topical induction and challenge applications. Erythema and swelling responses on the induction and challenge sites of experimental and control animals were described

and evaluated according to Magnusson and Kligman sensitization scale (Table 2). Observations were carried out under full-spectrum lighting with naked and microsurgery microscope (Leica IC90 E). All evaluations were made in a fashion that was blind to the animal IDs and groups.

Table 2: Magnusson and Kligman Scoring Scale

Patch (Filter Paper) Reaction Test	**Rating Score**
No visible changes	0
Discrete and patchy erythema	1
Moderate and adjacent erythema	2
Clear erythema	3
Severe erythema and swelling	4

The health of the animals was monitored daily throughout the test period. The body weights were recorded prior to the applications (Appendix 1).

5.4. Evaluation and analysis

The patch reactions were scored by a score between 0 and 4 based on evaluations in accordance with the Magnusson and Kligman rating scale. The skin reactions in the test and control groups were compared 24 and 48 hours after the challenge phase. The primary approach adopted during evaluation of the observations is outlined below:

Conditions that are considered as sensitization responses:

- Detection of high values in the experimental group provided that all the values in the control group are lower than 1.
- If values of 1 and higher are observed in the control group, detecting scores that are higher than the highest score observed in the control group.

When suspect results are gathered, it is recommended that the challenge phase is repeated (re-challenge) 1 to 2 weeks after the first challenge phase.

6. Test Results

All animals were clinically normal throughout the study. The sensitization response rates were 0 at the test and negative control regions. Individual scores reflecting skin reaction evaluations and the images of skin reactions at the sites where the test, positive and negative samples were applied are presented in Appendix 1 (Table 4).

7. Conclusion

The test sample of "Standard Surgical Gown" (Manufacturer: Zeyni Medikal Tekstil İnşaat San. ve Tic. LTD ŞTİ.) was tested and evaluated according to the Guinea Pig Maximization Test. In conclusion, it was found that the test sample **did not cause any erythema or swelling** that are considered as indicators of sensitization/sensitivity.

Appendix-1

Table 1: Animal Weights

ID	Test Group	Negative Control Group	Positive Control Group
1	415	586	345
2	420	650	391
3	395	678	317
4	399	683	310
5	405	645	387
6	387		
7	370		
8	365		
9	370		
10	375		

Table 2. (Skin Sensitization Individual Results)

Results gathered after the topical induction phase

24. hour	1	2	3	4	5	6	7	8	9	10
Test (extract)	0	0	0	0	0	0	0	0	0	0
Control (solvent)	0	0	0	0	0	-	-	-	-	-
Positive control (PFA)	2	2	3	1	2					

48. hour	1	2	3	4	5	6	7	8	9	10
Test (extract)	0	0	0	0	0	0	0	0	0	0
Control (solvent)	0	0	0	0	0	-	-	-	-	-
Positive control (PFA)	2	3	2	2	2					

Results gathered after the challenge phase

24. hour	1	2	3	4	5	6	7	8	9	10
Test (extract)										
Control (solvent)	0	0	0	0	0	0	0	0	0	0
Positive control (PFA)	3	2	2	2	2	-	-	-	-	-

48. hour	1	2	3	4	5	6	7	8	9	10
Test (extract)	0	0	0	0	0	0	0	0	0	0
Control (solvent)	0	0	0	0	0	-	-	-	-	-
Positive control (PFA)	3	2	2	3	3					

Note: Under ideal circumstances, positive control study is repeated every 6 months

1. PRODUCT

STANDARD SURGICAL GOWN

2. CODE

Model 100-001-S.

3. PRODUCT CONFIRMITIES

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014, ISO 14644-3:2019, ISO 14791:2012, ISO 14937: 2009, ISO 10993-7:2008, EN 20811

4. DESCRIPTION

Nonwoven , disposable gown, SMS, 3-Layers 40 GSM, Velcro at the Neck, four ties , Elastic Cuff, laser sleeves , length 60 cm, gown length – 155 cm, cellulose napkins – 2 pc.

Sizes: XL, 2XL

5. PACKING

The product is individual packaged. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, validity date, lot number, etc.

6. STORAGE

0°C - + 30°C, Avoid Sunlight, Avoid Humidity

7. Validity

Sterile EO. 3 years from the date of production