



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)



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Drapes And Custom Packs, Non-Sterile Medical Textile Products**

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standard's clauses is established and being implemented

DIN EN ISO 9001:2015

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Certification Period : 3 years (3rd year)



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

EU Quality Assurance Certificate

Medical Devices Regulation (EU) 2017/745 Annex XI Part A
(Class Is, Im and Ir Devices)



Certificate Number: M.2022.MDR.1007

Manufacturer Name : Zeyni Medikal Tekstil İnş. San. Ve Tic. Ltd. Şti.
Manufacturer Address : Yunusemre Mah. 12. Yıldırım Sk. No:17 Yıldırım BURSA / TURKEY
Single registration number-SRN : TR-MF-000017474
Authorised Representative Name : NA
(If applicable)
Authorised Representative Address : NA
Product Scope : See the product list on the following page(s).

Based on the conformity assessment for the abovementioned manufacturer's quality assurance system in accordance with (EU) 2017/745 Medical Devices Regulation Annex XI Part A, UDEM Adriatic d.o.o hereby declares that the requirements of Annex XI Part A of the Regulation (EU) 2017/745 have been met for the listed products in this certificate.

The manufacturer has established, documented and implemented a quality management system, which is subject to periodic surveillance assessments by UDEM Adriatic d.o.o. according Annex XI Part A Section 7 of the aforementioned Regulation.

For the devices covered by this certificate, the involvement of UDEM Adriatic d.o.o. in the conformity assessment procedures is limited: in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions; in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The report referenced below summarizes the result of assessments/examinations and includes reference to relevant CS, harmonized standards and test reports.

Report Number : MDR.1130
Date of Issue : 22/11/2022
Recertification Date : -
Reissue Date/No : -
Date of Expiry : 21/11/2027

UDEM Adriatic d.o.o.
General Manager

If any, Previous Certificate(s) No: NA



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Address: Radnička cesta 54/ R3 Zagreb- Croatia
E-Mail: info@udemadriatic.com **Web:** www.udemadriatic.com

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PRODUCT LIST COVERED BY THE CERTIFICATE

PRODUCT NAME	BASIC UDI-DI	RISK CLASS	EMDN CODE	MODEL	TYPE	INTENDED PURPOSE
Sterile Disposable Surgical Drapes	868 234012 101001GZ 868 234012 101002H3 868 234012 101003H5 868 234012 101004H7 868 234012 101005H9 868 234012 101006HB 868 234012 101019HL 868 234012 101020H5 868 234012 101021H7 868 234012 101022H9 868 234012 101023HB 868 234012 101024HD	Class Is	T0299	SHIRT & PANTS SHORTS	S/M/L/ XL/ XXL/ XXXL	Examination Clothes are used to wear during the surgical operations and examination purposes as sterile (Helping prevention to infection risk).
	868 234012 102001H8 868 234012 102002HA 868 234012 102003HC	Class Is	T030502	BEDDING DUVET COVER PILLOW CASE COVER SHEET	-	The bedding sets are that patients have to use before / after surgical operations in the operating room. It is completely used for patients to minimize the risk of infection.
	868 234012 101007HD 868 234012 101008HF 868 234012 101009HH 868 234012 101010H2 868 234012 101011H4 868 234012 101012H6 868 234012 101013H8 868 234012 101014HA 868 234012 101015HC 868 234012 101016HE 868 234012 101017HG 868 234012 101018HJ	Class Is	T04010103	COLONOSCOPY PANTS COLONOSCOPY SHORTS	S/M/L/ XL/ XXL/ XXXL	Examination Clothes are used to wear during the surgical operations and examination purposes as sterile. Examination Clothes are sterile products which use conditions as minimizing the risk of microbial contamination and present the protection and safety. So sterile Examination Clothes are using conditions as minimizing the risk of microbial contamination.
	868 234012 103001BCQ 868 234012 103001TDU 868 234012 103001SDS 868 234012 103002BCT 868 234012 103002TDX 868 234012 103002SDV 868 234012 103003BCW 868 234012 103003TE2 868 234012 103003SDY 868 234012 103004BCZ 868 234012 103004TE5 868 234012 103004SE3 868 234012 103005BD4 868 234012 103005TE8 868 234012 103005SE6 868 234012 103006BD7 868 234012 103006TEB 868 234012 103006SE9 868 234012 103007BDA 868 234012 103007TEE 868 234012 103007SEC	Class Is	T020199	BIFLEX PLAIN DRAPE TRIPLEX PLAIN DRAPE SMS PLAIN DRAPE BIFLEX DRAPE WITH SIDE ADHESIVE TAPE TRIPLEX DRAPE WITH SIDE ADHESIVE TAPE SMS DRAPE WITH SIDE ADHESIVE TAPE SMS FENESTRATED DRAPE BIFLEX FENESTRATED DRAPE	Width: Min:20 Max:200 Length: Min:20 Max:250 Width: Min:20 Max:200 Length: Min:20 Max:300 Width: Min:20 Max:200 Length: Min:20 Max:300	Sterile Plain drapes are used in operating rooms to cover the needed area of the patients during surgical operations, to protect the patient and the surgical team around him from situations that threaten their health and prevent any infection from spreading to the patient, surgical team and the operating environment.

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868 234012 103008BDD 868 234012 103008TEH 868 234012 103008SEF 868 234012 103009BDG 868 234012 103009TEL 868 234012 103009SEJ 868 234012 103010BCS 868 234012 103010TDW 868 234012 103010SDU 868 234012 103011BCV 868 234012 103011TDZ 868 234012 103011SDX 868 234012 103012BCY 868 234012 103012TE4 868 234012 103012SE2 868 234012 103013BD3 868 234012 103013TE7 868 234012 103013SE5 868 234012 103014BD6 868 234012 103014TEA 868 234012 103014SE8 868 234012 103015BD9 868 234012 103015TED 868 234012 103015SEB 868 234012 103016BDC 868 234012 103016TEG 868 234012 103016SEE 868 234012 103017BDF 868 234012 103017TEK 868 234012 103017SEH 868 234012 103018BDJ 868 234012 103018TEN 868 234012 103018SEL 868 234012 103019BDM 868 234012 103019TER 868 234012 103019SEP 868 234012 103020BCX 868 234012 103020TE3 868 234012 103020SDZ 868 234012 103020BCX 868 234012 103021TE6 868 234012 103021SE4 868 234012 103022BD5 868 234012 103022TE9 868 234012 103022SE7 868 234012 103023BD8 868 234012 103023TEC 868 234012 103023SEA 868 234012 103024BDB 868 234012 103024TEF 868 234012 103024SED 868 234012 103025BDE 868 234012 103025TEJ 868 234012 103025SEG 868 234012 103026BDH 868 234012 103026TEM 868 234012 103026SEK 868 234012 103027BDL 868 234012 103027TEQ 868 234012 103027SEN 868 234012 103028BDP 868 234012 103028TET 868 234012 103028SER			STOCKINET	Width: Min:22 Max:75 Length: Min:100 Max:114	
			LEG COVER/ LEGGING	75x110	

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868 234012 103029BDS					
868 234012 103029TEW					
868 234012 103029SEU					
868 234012 104001HN					
868 234012 104002HQ					
868 234012 104003HS					
868 234012 104004HU					
868 234012 104005HW					
868 234012 104006HY					
868 234012 104007J2					
868 234012 104008J4					
868 234012 104009J6					
868 234012 104010HP					
868 234012 104011HR					
868 234012 104012HT					
868 234012 104013HV					
868 234012 104014HX					
868 234012 104015HZ					
868 234012 104016J3					
868 234012 104017J5					
868 234012 104018J7					
868 234012 104019J9					
868 234012 104020HS					
868 234012 104021HU					
868 234012 104022HW					
868 234012 104023HY					
868 234012 104024J2					
868 234012 104025J4					
868 234012 104026J6					
868 234012 104027J8					
868 234012 104028JA					
868 234012 104029JC					
868 234012 104030HV					
868 234012 104031HX					
868 234012 104032HZ					
868 234012 104033J3					
868 234012 104034J5					
868 234012 104035J7					
868 234012 104036J9					
868 234012 104037JB					
868 234012 104038JD					
868 234012 104039JF					
868 234012 104040HY					
868 234012 104041J2					
868 234012 104042J4					
868 234012 104043J6					
868 234012 104044JB					
868 234012 104045JA					
868 234012 104046JC					
868 234012 104047JE					
868 234012 104048JG					
868 234012 104049JJ					
868 234012 104050J3					
868 234012 104051J5					
868 234012 104052J7					
868 234012 104053J9					
868 234012 104054JB					
868 234012 104055JD					
868 234012 104056JF					
868 234012 104057JH					
868 234012 104058JK					
868 234012 104059JM					
868 234012 104060J6					

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868 234012 104061J8					
868 234012 104062JA					
868 234012 104063JC					
868 234012 104064JE					
868 234012 104065JG					
868 234012 104066JJ					
868 234012 104067JL					
868 234012 104068JN					
868 234012 104069JQ					
868 234012 104070J9					
868 234012 104071JB					
868 234012 104072JD					
868 234012 104073JF					
868 234012 104074JH					
868 234012 104075JK					
868 234012 104076JM					
868 234012 104077JP					
868 234012 104078JR					
868 234012 104079JT					
868 234012 104080JC					
868 234012 104081JE					
868 234012 104082JG					
868 234012 104083JJ					
868 234012 104084JL					
868 234012 104085JN					
868 234012 104086JQ					
868 234012 104087JS					
868 234012 104088JU					
868 234012 104089JV					
868 234012 104090JF					
868 234012 105001HV					
868 234012 105002HX					
868 234012 105003HZ					
868 234012 105004J3					
868 234012 105005J5					
868 234012 105006J7					
868 234012 105007J9					
868 234012 105008JB					
868 234012 105009JD					
868 234012 105010HW					
868 234012 105011HY					
868 234012 105012J2					
868 234012 105013J4					
868 234012 105014J6					
868 234012 105015J8					
868 234012 105016JA					
868 234012 105017JC					
868 234012 105018JE					
868 234012 105019JG					
868 234012 105020HZ					
868 234012 105021J3					
868 234012 105022J5					
868 234012 105023J7					
868 234012 105024J9					
868 234012 105025JB					
868 234012 105026JD					
868 234012 105027JF					
868 234012 105028JH					
868 234012 105029JK					
868 234012 105030J4					
868 234012 105031J6					
868 234012 105032J8					
868 234012 105033JA					

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868 234012 105034JC					
868 234012 105035JE					
868 234012 105036JG					
868 234012 105037JJ					
868 234012 105038JL					
868 234012 105039JN					
868 234012 105040J7					
868 234012 105041J9					
868 234012 105042JB					
868 234012 105043JD					
868 234012 105044JF					
868 234012 105045JH					
868 234012 105046JK					
868 234012 105047JM					
868 234012 105048JP					
868 234012 105049JR					
868 234012 105050JA					
868 234012 105051JC					
868 234012 105052JE					
868 234012 105053JG					
868 234012 105054JJ					
868 234012 105055JL					
868 234012 105056JN					
868 234012 105057JQ					
868 234012 105058JS					
868 234012 105059JU					
868 234012 105060JD					
868 234012 105061JF					
868 234012 105062JH					
868 234012 105063JK					
868 234012 105064JM					
868 234012 105065JP					
868 234012 105066JR					
868 234012 105067JT					
868 234012 105068JV					
868 234012 105069JX					
868 234012 105070JG					
868 234012 105071JJ					
868 234012 105072JL					
868 234012 105073JN					
868 234012 105074JQ					
868 234012 105075JS					
868 234012 105076JU					
868 234012 105077JW					
868 234012 105078JY					
868 234012 105079K2					
868 234012 105080JK					
868 234012 105081JM					
868 234012 105082JP					
868 234012 105083JR					
868 234012 105084JT					
868 234012 105085JV					
868 234012 105086JX					
868 234012 105087JZ					
868 234012 105088K3					
868 234012 105089K5					
868 234012 105090JN					
868 234012 105091JQ					
868 234012 105092JS					
868 234012 105093JU					
868 234012 105094JW					
868 234012 105095JY					
868 234012 105096K2					

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868 234012 105097K4 868 234012 105098K6 868 234012 105099K8 868 234012 105100HY 868 234012 108048KC 868 234012 108049KE 868 234012 108050JX 868 234012 108051JZ 868 234012 108052K3 868 234012 108053K5 868 234012 108054K7					
868 234012 106001J4 868 234012 106002J6 868 234012 106003J8 868 234012 106004JA 868 234012 106005JC 868 234012 106006JE 868 234012 106007JG 868 234012 106008JJ 868 234012 106009JL	Class Is	T030102	TABLE COVER	Width: Min:75 Max:200 Length: Min:90 Max:230	Sterile Table Covers are used in operating rooms to cover the instrument table in order to keep safe sterile area to keep put the instruments on while surgical operation.
868 234012 107001JB 868 234012 107002JD 868 234012 107003JF 868 234012 107004JH 868 234012 107005JK 868 234012 107006JM 868 234012 107007JP 868 234012 107008JR 868 234012 107009JT 868 234012 107010JC 868 234012 107011JE 868 234012 107012JG 868 234012 107013JJ 868 234012 107014JL 868 234012 107015JN 868 234012 107016JQ 868 234012 107017JS	Class Is	T030101	INSTRUMENT COVER (FLOROSCOPY OR IMAGE INTENSIFIER COVER) CAMERA COVER SCOPY COVER MICROSCOPE COVER C-ARM COVER	Width: Min:35 Max:120 Length: Min:35 Max:230 Diameter: Min:Ø 60 – Max:Ø 80 13x250 Width: Min:35 Max:150 Length: Min:35 Max:150 2250 x 1220 Ø100x 225x Ø100	Sterile covers are used in operating rooms to cover the instruments for keeping the instruments safe and sterile during Surgery operations and create environment that is the most sterile when the patients are prone to infection while their wounds open at operation.
868 234012 108001JJ 868 234012 108002JL 868 234012 108003JN 868 234012 108004JQ 868 234012 108005JS 868 234012 108007JW 868 234012 108008JY 868 234012 108009K2 868 234012 108010JK 868 234012 108011JM 868 234012 108012JP 868 234012 108013JR 868 234012 108014JT	Class Is	T020102	ABDOMINAL SURGICAL DRAPE LAPAROTOMY SURGICAL DRAPE LAPAROSCOPY SURGICAL DRAPE MINOR SURGERY DRAPE DRESSING DRAPE ARTHROSCOPY DRAPE WITHOUT POUCH EXTREMITY DRAPE HAND SURGERY DRAPE	200x300 350X300 250X300 75X75 60X60 200X300 200X300 200X300	Sterile Plain drapes are used in operating rooms to cover the needed area of the patients during surgical operations, to protect the patient and the surgical team around him from situations that threaten their health and prevent any infection from spreading to the patient, surgical team and the operating environment.

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868 234012 108015JV 868 234012 108016JX 868 234012 108017JZ 868 234012 108018K3 868 234012 108020JN 868 234012 108021JQ 868 234012 108022JS 868 234012 108023JU 868 234012 108024JW 868 234012 108025JY 868 234012 108026K2 868 234012 108027K4 868 234012 108028K6	Class Is	T02010101	KNEE SURGERY DRAPE SHOULDER SURGERY DRAPE HIP SURGERY DRAPE ANGIOGRAHY SURGERY DRAPE BY PASS SURGERY DRAPE VALVE REPLACEMENT SURGERY DRAPE EMBRIO TRANSFER (E.T.) SURGERY DRAPE I.V.F SURGERY DRAPE DELIVERY SURGERY DRAPE CASEREAN SURGERY DRAPE WITHOUT POUCH OVUM PICK UP (O.P.U) SURGERY DRAPE CRANIOTOMY SURGERY DRAPE SHUNT SURGERY DRAPE SPINAL SURGERY DRAPE PERCUTAN (PCNL) SURGERY DRAPE TUR SURGERY DRAPE CYSTOSCOPY SURGERY DRAPE E.N.T. SURGERY DRAPE	200X300 200X300 200X250 150X240 240X350 240X350 50X90 150X225 75X150 200X300 130X150 230X300 150X300 200X300 150X300 200X240 75X150 150X200	Sterile Plain drapes are used in operating rooms to cover the needed area of the patients during surgical operations, to protect the patient and the surgical team around him from situations that threaten their health and prevent any infection from spreading to the patient, surgical team and the operating environment.
			ARTHROSCOPY DRAPE WITH POUCH CASEREAN SURGERY DRAPE WITH POUCH SMS EYE SURGERY DRAPE (SINGLE POUCH) SMS EYE SURGERY DRAPE (DOUBLE POUCH)	200X300 200X300 Width: Min:100 Max:150 Length: Min:120 Max:240 Width: Min:100 Max:150 Length: Min:120 Max:240	

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				BIFLEX EYE SURGERY DRAPE (SINGLE POUCH)	Width: Min:100 Max:150 Length: Min:130 Max:240	
				BIFLEX EYE SURGERY DRAPE (DOUBLE POUCH)	Width: 150 Length: Min:150 Max:240	
Sterile Disposable Surgical Gowns	868 234012 100001GS 868 234012 100002GU 868 234012 100003GW 868 234012 100004GY 868 234012 100005H2 868 234012 100006H4 868 234012 100007H6 868 234012 100008H8 868 234012 100009HA 868 234012 100010GT 868 234012 100011GV 868 234012 100012GX 868 234012 100013GZ 868 234012 100014H3 868 234012 100015H5 868 234012 100016H7 868 234012 100017H9 868 234012 100018HB 868 234012 100055HH 868 234012 100056HK 868 234012 100057HM 868 234012 100058HP 868 234012 100059HR 868 234012 100060HA	Class Is	T020401	STANDARD SURGICAL GOWN FULL ULTRASONIC STANDARD SURGICAL GOWN HALF ULTRASONIC STANDARD SURGICAL GOWN STANDARD CHEMOTHERAPY GOWN	S/M/L/ XL/ XXL/ XXXL	Sterile gowns are used to wear /cover during the surgical operations and examination purposes as sterile (Helping prevention to infection risk). Gowns are being barrier between sterile and non-sterile areas and helping prevention to infection risk used as sterile products. So sterile gown use conditions as minimizing the risk of microbial contamination.
	868 234012 100019HD 868 234012 100020GW 868 234012 100021GY 868 234012 100022H2 868 234012 100023H4 868 234012 100024H6 868 234012 100025H8 868 234012 100026HA 868 234012 100027HC 868 234012 100028HE 868 234012 100029HG 868 234012 100030GZ 868 234012 100031H3 868 234012 100032H5 868 234012 100033H7 868 234012 100034H9 868 234012 100035HB 868 234012 100036HD 868 234012 100037HF 868 234012 100038HH 868 234012 100039HK 868 234012 100040H4 868 234012 100041H6 868 234012 100042H8 868 234012 100043HA 868 234012 100044HC 868 234012 100045HE	Class Is	T020402	REINFORCED SURGICAL GOWN FULL ULTRASONIC REINFORCED SURGICAL GOWN HALF ULTRASONIC REINFORCED SURGICAL GOWN FULL REINFORCED SURGICAL GOWN FULL ULTRASONIC FULL REINFORCED SURGICAL GOWN HALF ULTRASONIC FULL REINFORCED SURGICAL GOWN REINFORCED CHEMOTHERAPY GOWN FULL REINFORCED CHEMOTHERAPY GOWN	S/M/L/ XL/ XXL/ XXXL	Reinforced gowns are the surgical gowns which operators and nurses has to wear in all kinds of surgical operations in operation area. Sterile gowns are used to wear/cover during the surgical operations and examination purposes as sterile (helping prevention to infection risk). They cover doctors, nurses and the patients totally in order to minimize the infection risk. Gowns are being barrier between sterile and non-sterile areas. Polyethylene is used for penetrating the water absorption.

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Certificate Number: M.2022.MDR.1007

	868 234012 100046HG 868 234012 100047HJ 868 234012 100048HL 868 234012 100049HN 868 234012 100050H7 868 234012 100051H9 868 234012 100052HB 868 234012 100053HD 868 234012 100054HF 868 234012 100061HC 868 234012 100062HE 868 234012 100063HG 868 234012 100064HJ 868 234012 100065HL 868 234012 100066HN 868 234012 100067HQ 868 234012 100068HS 868 234012 100069HU 868 234012 100070HD 868 234012 100071HF 868 234012 100072HH				
	868 234012 100073HK 868 234012 100074HM 868 234012 100075HP 868 234012 100076HR 868 234012 100077HT	Class Is	T020499	SHORT SLEEVE PATIENT EXAMINATION GOWN CUFFS PATIENT EXAMINATION GOWN LONG SLEEVE PATIENT EXAMINATION GOWN LONG SLEEVE RUBBER PATIENT EXAMINATION GOWN VISITOR GOWN	Examination Clothes are used to wear during the surgical operations and examination purposes as sterile (Helping prevention to infection risk).
Sterile Disposable Surgical Drape Sets	868 234012 200001H7 868 234012 210001HJ 868 234012 210002HL 868 234012 210003HN 868 234012 210004HQ 868 234012 210005HS 868 234012 210006HU 868 234012 210007HW 868 234012 210008HY 868 234012 210009J2 868 234012 220001HV 868 234012 220002HX 868 234012 220003HZ 868 234012 220004J3 868 234012 220005J5 868 234012 220006J7 868 234012 220007J9 868 234012 220008JB 868 234012 220009JD 868 234012 230001J8 868 234012 230002JA 868 234012 230003JC 868 234012 230004JE 868 234012 230005JG 868 234012 240001JK 868 234012 240002JM 868 234012 240003JP 868 234012 240004JR 868 234012 240005JT 868 234012 240006JV 868 234012 250001JW 868 234012 250002JY 868 234012 250003K2 868 234012 260001K9	Class Is	T020102	A. UNIVERSAL SURGICAL DRAPE SETS: 1. UNIVERSAL SURGICAL DRAPE SET B. GENERAL SURGICAL DRAPE SETS: 1. GENERAL SURGICAL DRAPE SET 2. ABDOMINAL SURGICAL DRAPE SET 3. LAPAROTOMY SURGICAL DRAPE SET 4. LAPAROSCOPY SURGICAL DRAPE SET 5. MINOR SURGICAL DRAPE SET 6. DRESSING SURGICAL DRAPE SET 7. DIALYSIS COVER SURGICAL DRAPE SET 8. ABDOMINAL PERINEAL SURGICAL DRAPE SET 9. CIRCUMCISION COVER SURGICAL DRAPE SET C. ORTHOPEDY SURGICAL DRAPE SETS: 1. ARTHROSCOPY DRAPE SET WITHOUT POUCH 2. ARTHROSCOPY DRAPE SET WITH POUCH 3. LOWER EXTREMITY DRAPE SET 4. UPPER EXTREMITY	<p>Sterile Universal Surgical drape sets are used in operating rooms to cover the needed area of the patients during General Surgery operations.</p> <p>Sterile General Surgical Drape sets are used in operating rooms to cover the needed area of the patients during General Surgery operations.</p> <p>Sterile Abdominal Surgery drape sets are used in operating rooms to cover the needed area of the patients during Abdominal Surgery operations.</p> <p>Sterile Laparotomy Surgical Drape sets are used in operating rooms to cover the needed area of the patients during laparotomy Surgery operations.</p> <p>Sterile Laparoscopy Surgical Drape sets are used in operating rooms to cover the needed area of the patients during Laparoscopy Surgery operations.</p> <p>Sterile Minor Surgical drape sets are used in operating rooms to cover the needed area of the patients during Minor Surgery operations.</p> <p>Sterile Dressing surgical drape sets are used after operations while</p>

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Medical Devices Regulation (EU) 2017/745 Annex XI Part A
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868 234012 270001KL 868 234012 280001KX 868 234012 280002KZ 868 234012 280003L3 868 234012 290001LA 868 234012 300001HL 868 234012 300002HN 868 234012 301001HT 868 234012 301002HV 868 234012 301003HX 868 234012 302001J2 868 234012 302002J4			<p>5. HAND SURGERY DRAPE SET</p> <p>6. KNEE SURGERY DRAPE SET</p> <p>7. SHOULDER SURGERY DRAPE SET</p> <p>8. ARTHROPLASTY (HIP) DRAPE SET</p> <p>9. VERTEBRA DRAPE SET</p> <p>D. CARDIOLOGY SURGICAL DRAPE SETS:</p> <p>1. ANGIOGRAPHY DRAPE SET</p> <p>2. ANGIOGRAPHY CUSTUM SET</p> <p>3. BY PASS DRAPE SET</p> <p>4. VALVE REPLACEMENT DRAPE SET</p> <p>5. CARDIOVASCULAR DRAPE SET</p> <p>E. GYNECOLOGIC SURGICAL DRAPE SETS:</p> <p>1. EMBRIO TRANSFER (E.T.) DRAPE SET</p> <p>2. I.V.F DRAPE SET</p> <p>3. DELIVERY DRAPE SET</p> <p>4. CAESAREAN DRAPE SET</p> <p>5. O.P.U. (OVUM PICK UP) DRAPE SET</p> <p>6. PERINEAL SET</p> <p>F. BRAIN SURGERY DRAPE SETS:</p> <p>1. CRANIATOMY DRAPE SET</p> <p>2. SHUNT DRAPE SET</p> <p>3. SPINAL DRAPE SET</p> <p>G. OPHTHALMOLOGY SURGICAL DRAPE SETS:</p> <p>1. EYE DRAPE SET</p> <p>H. ONCOLOGY SURGICAL DRAPE SETS:</p> <p>1. CHEMOTHERAPHY DRAPE SET</p> <p>I. UROLOGICAL SURGICAL DRAPE SETS:</p> <p>1. PERCUTANEUS DRAPE SET</p> <p>2. TUR DRAPE SET</p> <p>3. CYSTOSCOPY DRAPE SET</p> <p>J. RADIOLOGY SURGICAL DRAPE SETS:</p> <p>1. BIOPSY DRAPE SET</p> <p>K. EAR- NOSE-THROAT (E.N.T.) DRAPE SETS:</p> <p>1. EAR-NOSE-THROAT (E.N.T.) DRAPE SET</p> <p>2. THYROID DRAPE SET</p> <p>L. ESTETIHICAL SURGERY DRAPE SETS:</p> <p>1. RHYNOPLASTY DRAPE SET</p>	<p>re-dressing the operated place and named as Dressing Set. The content has included all required items in order to use while cleaning and for re-dressing the operated area.</p> <p>Sterile Dialysis Cover Surgical drape sets are used in operating rooms to cover the needed area of the patients during General Surgery operations.</p> <p>Sterile Abdominal Perineal Surgical drape sets are used in operating rooms to cover the needed area of the patients during Gynecological operations for Ovum Pick Up operations.</p> <p>Sterile Circumcision Surgical Cover drape sets are used in operating rooms to cover the needed area of the patients during General Surgery operations.</p> <p>Sterile Arthroscopy Drape Sets Without Pouch are used in operating rooms to cover the needed area of the patients during Arthroscopic Surgery operations, draping in shoulder.</p> <p>Sterile Arthroscopy Drape Sets With Pouch are used in operating rooms to cover the needed area of the patients during Arthroscopic Surgery operations.</p> <p>Sterile Lower Extremity drape sets are used in operating rooms to cover the needed area of the patients during lower Extremity Surgery operations.</p> <p>Sterile Upper Extremity drape sets are used in operating rooms to cover the needed area of the patients during Upper Extremity Surgery operations</p> <p>Sterile Hand Surgery drape sets are used in operating rooms to cover the needed area of the patients during upper extremity surgery operations</p> <p>Sterile Knee Surgery drape sets are used in operating rooms to cover the needed area of the patients during Knee Surgery operations</p> <p>Sterile Shoulder Surgery drape sets are used in operating rooms to cover the needed area of the patients during Shoulder Surgery operations.</p> <p>Sterile ARTHROPLASTY (HIP) drape sets are used in operating rooms</p>
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Certificate Number: M.2022.MDR.1007

			<p>SET 2. LIPOSCULPTURE DRAPE SET 3. HAIR TRANSPLANT DRAPE SET</p> <p>M. DENTAL SURGERY DRAPE SETS: 1.DENTAL DRAPE SET 2.IMPLANT DRAPE SET</p> <p>1 PAIR CHEMOTHERAPY GLOVES 1 PAIR SURGERY GLOVES LARGE 1 PCS ABDOMINAL DRAPE 2 PCS ALCOHOLIC SWAB 3 PCS ANESTHESIA DRAPE 1 PCS ANESTHESIA DRAPE WITH ADHESIVE TAPE 1 PCS ANGIOGRAPHY DRAPE 1 PCS ARTHROSCOPY DRAPE WITH POUCH 1 PCS ARTHROSCOPY DRAPE WITHOUT POUCH 1 PCS BABY DRAPE 1 PCS BETADINE SPONGE 1 PCS BONNET 1 PCS CAESAREAN DRAPE 1 PCS CHEMOTHERAPY DRAPE 1 PCS CRANIOTOMY DRAPE 1 PCS CYSTOSCOPY DRAPE 2 PCS DRAPE 2 PCS DRAPE WITH ADHESIVE 2 PCS DRAPE WITH ADHESIVE TAPE 4 PCS DRAPE WITH SIDE ADHESIVE TAPE 1 PCS ELASTIC BANDAGE 1 PCS EXTREMITY DRAPE 1 PCS EYE DRAPE WITH POUCH 1 PCS FACE MASK 1 PCS FLUOROSCOPY COVER 2 PCS HAND TOWEL 1 PCS HIP U DRAPE 1 PCS HOLE DRAPE WITH ADHESIVE TAPE 1 PCS I.V.F. DRAPE 2 PCS TOOLS TABLE DRAPE 1 PCS K.V.C. DRAPE 1 PCS LAPAROSCOPY DRAPE 2 PCS LEG COVER 1 PCS LEG DRAPE 1 PCS LEG DRAPE WITH</p>	<p>to cover the needed area of the patients during Hip replacement Operations.</p> <p>Sterile Vertebra drape sets are used in operating rooms to cover the needed area of the patients during Vertebra Surgery operations.</p> <p>Sterile Angiography drape sets are used in operating rooms to cover the needed area of the patients during vascular visualization / Angiography Surgery operations.</p> <p>Sterile Angiography custom drape sets are used in operating rooms to cover the needed area of the patients during vascular visualization / angiography operations.</p> <p>Sterile By-pass drape sets are used in Cardiology / By-pass Surgical Operations for making new veins by-passing the blood circulation system and examination.</p> <p>Sterile Valve Replacement drape sets are used in Cardiology / Valve Replacement Surgical Operations for replacing the valves in order to improve blood circulation system</p> <p>Sterile Cardiovascular drape sets are used during Cardiology / All kinds of Cardiovascular Surgical operations, for making new veins by-passing the blood circulation system.</p> <p>Sterile Embryo Transfer (E.T.) drape sets are used in operating rooms for Gynecological Operations transferring the embryo.</p> <p>Sterile I.V.F. drape sets are used in Gynecological I.V.F operations.</p> <p>Sterile Delivery drape sets are used in Gynecological Surgery operations for delivering the baby.</p> <p>Sterile Caesarean drape sets are used during Gynecological / Caesarean Operations as Caesarean type of delivering the baby or others.</p> <p>Sterile O.P.U drape sets are used in Gynecological Operations for Ovum Pick Up.</p> <p>Sterile Perineal drape sets are used for surgical operations and examinations in perineal area such as saucerization of perineal or ischiorectal abscess, evacuation of thrombotic piles, pile ligation, gynecological</p>
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				<p>ADHESIVE TAPE 2 PCS LEGGINGS STANDARD 1 PCS MARKER & RULER 1 PCS MAYO TABLE DRAPE 1 PCS MINOR HOLE DRAPE 1 PCS LAPAROTOMY DRAPE 1 PCS LAPAROSCOPIC ABDOMINAL PERINEAL DRAPE 1 PCS NITRILE GLOVES 1 PCS NONWOVEN OP- TAPE 1 PCS O.P.U. DRAPE 1 PCS OPAQUE SET 8 PCS OP-TAPE 2 PCS PACK OF STERILIZATION 1 PCS PATIENT DRAPE 1 PCS PATIENTS MOUTH HOLE DRAPE 1 PCS PERCUTANEOUS DRAPE 1 PCS PERINE U DRAPE 1 PCS PLAIN DRAPE 1 PCS PROTECTIVE GLASSES 2 PCS REFLECTOR DRAPE 3 PCS REINFORCED SURGERY GOWN LARGE 3 PCS REINFORCED SURGICAL GOWN 1 PCS RHINOPLASTY DRAPE 1 PCS SCALPEL TIP NO:11 1 PCS SCOPY COVER 1 PCS SHOULDER DRAPE 1 PCS SHUNT DRAPE 1 PCS SIDA DRAPE 4 PCS SIDE DRAPE WITH ADHESIVE TAPE 1 PCS SIDE TAPED DRAPE 1 PCS SOLUTION CUP 250CC 1 PCS SOLUTION CUP 500CC 10 PCS SPANCH 1 PCS SPINAL DRAPE 1 PCS SPLIT E.N.T. DRAPE 1 PCS SPONGE 2 PCS STANDARD SURGERY GOWN LARGE 1 PCS STANDART SURGERY GOWN 1 PCS STERILIZATION WRAPE 1 PCS STOCKINITE (FOR HAND) 1 PCS T.U.R. DRAPE 1 PCS TABLE COVER 1 PCS TABLE COVER DRAPE 1 PCS THYROID DRAPE 4 PCS TOWEL 2 PCS TRANSPARENT DRAPE 3 PCS TRANSPARENT</p>	<p>dilation and curettage etc.</p> <p>Sterile Craniotomy drape sets are used in open Brain Surgery Operations.</p> <p>Sterile Shunt drape sets are used in open Brain Surgery / Shunt placement Surgery Operations and examinations.</p> <p>Sterile Spinal drape sets are used in Spine / Open Brain Surgery Operations.</p> <p>Sterile Eye drape sets are used in all kinds of Ophthalmology Operations.</p> <p>Sterile Chemotherapy drape sets are used while injecting chemotherapy drugs to the patients to cover both the patient and the nurse for protection.</p> <p>Sterile Percutaneous drape sets are used in Urological Operations such as Nephrology surgery and examinations.</p> <p>Sterile Spinal drape sets are used in Urological Operations such as T.U.R Surgery.</p> <p>Sterile Spinal drape sets are used in Urological Operations such as Cystoscopy operation.</p> <p>Sterile Biopsy drape sets are used in Biopsy Surgery Operations.</p> <p>Sterile E.N.T drape sets are used in E.N.T Surgery Operations.</p> <p>Sterile Thyroid drape sets are used in Thyroid Surgery Operations.</p> <p>Sterile Rhynoplasty drape sets are used in Rhynoplasty Surgery Operations.</p> <p>Sterile Liposculpture drape sets are used in Liposuction Surgery Operations.</p> <p>Sterile Hair Transplant drape sets are used in Hair transplant Surgery Operations.</p> <p>Sterile Dental drape sets are used in Dental Surgery Operations.</p> <p>Sterile Implant drape sets are used in Implant Surgery Operations.</p>
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Certificate Number: M.2022.MDR.1007

				HOSE COVER 1 PCS TUBE HOLDER (VELCRO) 1 PCS UNDER ARM DRAPE 2 PCS UNIVERSAL BAG 1 PCS UPPER EXTREMITE DRAPE 1 PCS VIDEO CAMERA COVER 1 PCS VINYL GLOVES 1 PCS WASTE BAG 2 PCS WOUND PAD 1 PCS TRAY		
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Conditions for or limitations to the validity of this certificate :NA

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EU Quality Assurance Certificate

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Certificate Number: M.2022.MDR.1007

CERTIFICATE HISTORY		
Rev. No.	Rev. Date	Description of Revision
00	22/11/2022	Initial Certification

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EC Declaration of Conformity

issued in accordance with EC directive (EU) 2017/745 relating to Medical
Devices Regulation

Manufacturer: Zeyni Medical Tekstil Ins. San. Ve Tic. Ltd. Sti.
Adress: Yunus Emre Mah. 12. Yildirim Sk. No:17 Yildirim
Bursa/ TURKEY
Commercial Name: Zeyni
Product Name: Sterile Disposable Surgical Gowns

- Standard Surgical Gowns
- Full Ultrasonic Standard Surgical Gowns
- Half Ultrasonic Standard Surgical Gowns
- Standard Chemotherapy Gowns
- Reinforced Surgical Gown
- Full Ultrasonic Reinforced Surgical Gown
- Half Ultrasonic Reinforced Surgical Gown
- Full Reinforced Surgical Gown
- Full Ultrasonic Full Reinforced Surgical Gown
- Half Ultrasonic Full Reinforced Surgical Gown
- Reinforced Chemotherapy Gown
- Full Reinforced Chemotherapy Gown

ZEYNI MEDİKAL TEKSTİL İNŞ. SANAYİ VE TİCARET LTD.ŞTİ.

Yunusemre Mh: 12. Yildirim Sk. No: 17 Yildirim - BURSA / TÜRKİYE
Tel.: 0224. 369 32 32 Faks: 0224. 369 32 36 Mobil: +90533 143 53 56
e-mail : info@zeynimedical.com.tr • www.zeynimedical.com.tr





Classified as: Class I Sterile Medical Devices according to the Directive (EU) 2017/745 Medical Devices Regulation

Applied directives: The Directive (EU) 2017/745 on medical devices, conformity assesment according to Annex VII

Applied Harmonized Standards: EN ISO 13485:2016, EN ISO 15223-1:2016, EN 1041:2008+A1:2013
EN ISO 14155:2011 EN ISO 10993-1:2018, EN ISO 10993-5:2009 EN ISO 10993-10:2014, EN 13795-1:2019

Notified Body : UDEM Adriatic d.o.o. Radnicki cesta 54/R3 Zagreb- Croatia

Notified Body Number: CE 2696

EC Certificate : M.2022.MDR.1007

EC Certificate Validity: 21.11.2027

The Company Zeyni Medical Tekstil Ins. San. Ve Tic. Ltd. Sti. Herewith declares that the above mentioned product meets all aplicable provisions of the Directive (EU) 2017/745. The product is safe under prescribed and reasonably foreseeable conditions of storage and use.

The company has implemented measures assuring that all the products of the mentioned type are safe and fulfil essential requirements of the (EU) 2017/745 Directive. If the device is modified without the agreement of the undersign, this declaration become invalid in relation to the modified product.

Date of issue: 22.11.2022

Baki Polat Canavar, CEO

On behalf of Company

ZEYNI MEDİKAL
TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.
Yunusemre Mah. 12 Yıldırım Sk. No:17
Yıldırım / BURSA
Yıldırım V.D. 88 141 1400 Tic.Sic.No:102917
Mersis No:0998141140000001

ZEYNI MEDİKAL TEKSTİL İNŞ. SANAYİ VE TİCARET LTD.ŞTİ.

Yunusemre Mh. 12. Yıldırım Sk. No: 17 Yıldırım - BURSA / TÜRKİYE
Tel.: 0224. 369 32 32 Faks: 0224. 369 32 36 Mobil: +90533 143 53 56
e-mail : info@zeynimedical.com.tr • www.zeynimedical.com.tr





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate has been awarded to

**ZEYİNİ 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**

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

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, Schrieber 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

CERTIFICATE OF COMPLIANCE





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

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

Report No. 111699085
Buyer /
Test Item. : Bilayered and Absorbent Drapes
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: Passed

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

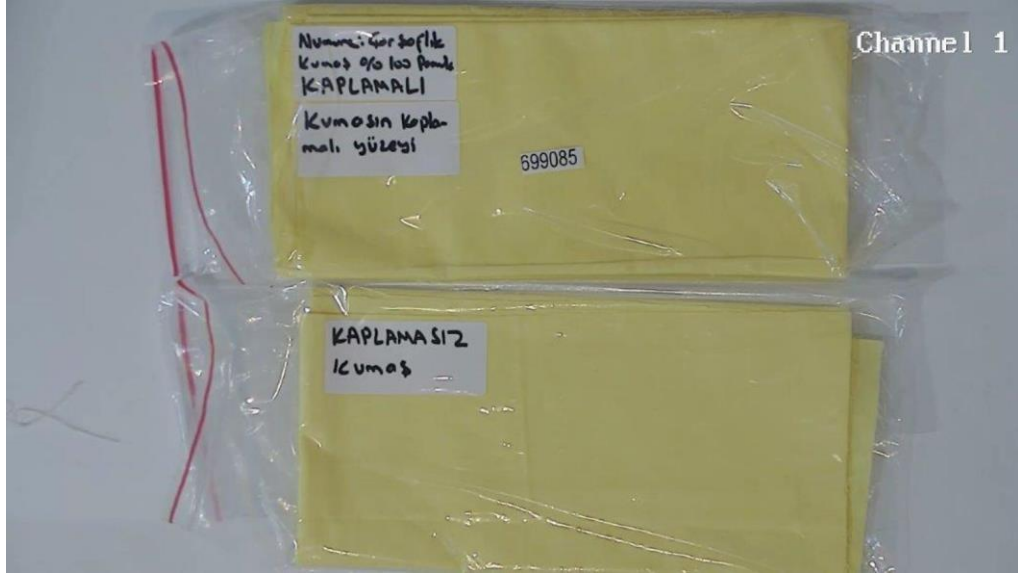
Tomris Hasańcebi / Customer
Relations Manager

Abdullah Akil / Physical
Laboratory Manager

Products

Report No.: 111699085

Date: 10.25.2021



Products

Report No.: 111699085

Date: 10.25.2021

Material List:

Page 3 of 6

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

Products

Report No.: 111699085

Date: 10.25.2021

Conclusion:

Page 4 of 6

TEST PROPERTY

M001

M002

Hydrostatic Pressure Test

#

#



TÜVRheinland®

Precisely Right.

Products

Report No.: 111699085

Date: 10.25.2021

1.Hydrostatic Pressure Test

Page 5 of 6

Test method : EN 20811:1993

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

	<u>M001</u>	<u>M002</u>	<u>Requirement</u>
<u>Pressure</u>			
Average	65 cm H2O	65cm H2O	-

- END -

Products

Report No.: 111699085

Date: 10.25.2021



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 : ZEYİNİ 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 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

This report and its results may not be partly or wholly replicated or published for commercial or advertisement purposes. Also, any firm, except Public Enterprises, may not use this report in any legal transactions.
The analysis with (*) mark in the report were accredited.
The unsigned analysis reports are not valid.

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

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Report no:16563500-125.05-89/4654

Sample	Specifications	Item
Surgery Set		3

Table1 (contd.).Product tested.

Descriptions:

Signatories:

53192



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The analysis with (*) mark in the report were accredited.

The unsigned analysis reports are not valid.

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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 'ZEYİN MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.' firm. The tests were carried 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)+ penicillinle 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 8 pits as 4×10^5 cell/pit and incubated for 24 hours at 37°C and 5% CO₂. The samples prepared as explained above and the controls were immediately added on cells and incubated for 24 hours at 37°C and 5% CO₂. 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.

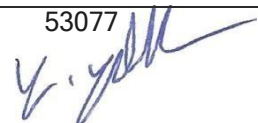
Descriptions:

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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.

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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.

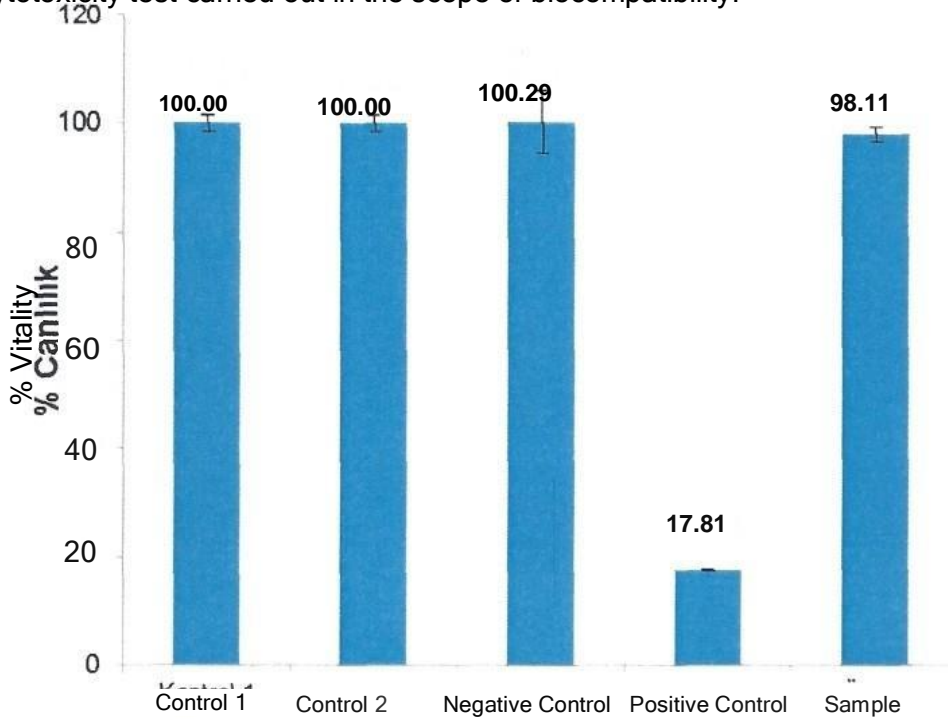


Figure 1. The viability analyses, carried out by using extracts from samples called 'Surgical Drape', are shown in the Figure.

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.

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<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 : ZEYİNİ 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

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Applicant : ZEYİNİ 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 : 17/35-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 ZEYİNİ 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

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Sample	Specifications	Item
Surgery Set		3

Table 1 (contd.). The tested product.

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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 cm²/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°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 right region of the animal in the 14th day of the test. The application plan administered on experimental animals is shown in Figure 1.

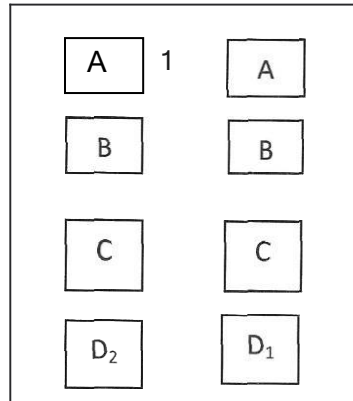


Figure 1.

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 (D₁) in the 7th day and the right topical region (D₂) in the 14th day.

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Negative Control

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

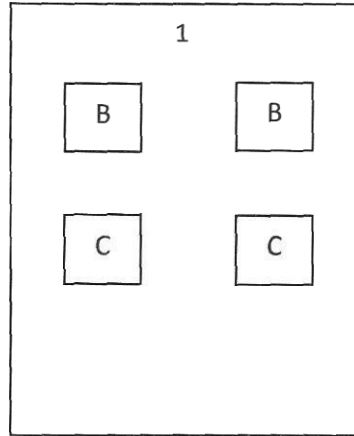


Figure 2.

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.

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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.

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