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 *(If applicable)*	: NA
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

If any, Previous Certificate(s) No: NA

UDEM Adriatic d.o.o.
General Manager

UDEM Adriatic d.o.o. is a Notified Body (identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

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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	Width: Min:20 Max:200 Length: Min:20 Max:250	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.
				BIFLEX DRAPE WITH SIDE ADHESIVE TAPE TRIMPLEX DRAPE WITH SIDE ADHESIVE TAPE SMS DRAPE WITH SIDE ADHESIVE TAPE	Width: Min:20 Max:200 Length: Min:20 Max:300	
				SMS FENESTRATED DRAPE BIFLEX FENESTRATED DRAPE	Width: Min:20 Max:200 Length: Min:20 Max:300	

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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 LEG COVER/ LEGGING	Width: Min:22 Max:75 Length: Min:100 Max:114 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 104044J8 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 104089JW 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					

	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					

	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)	Width: Min:35 Max:120 Length: Min:35 Max:230 Diameter: Min:Ø 60 – Max:Ø 80	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.
				CAMERA COVER	13x250	
				SCOPY COVER	Width: Min:35 Max:150 Length: Min:35 Max:150	
				MICROSCOPE COVER	2250 x 1220	
				C-ARM COVER	Ø100x 225x Ø100	
	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	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.
				LAPAROTOMI SURGICAL DRAPE	350X300	
				LAPAROSCOPY SURGICAL DRAPE	250X300	
				MINOR SURGERY DRAPE	75X75	
				DRESSING DRAPE	60X60	
				ARTHROSCOPY DRAPE WITHOUT POUCH	200X300	
				EXTREMITY DRAPE	200X300	
				HAND SURGERY DRAPE	200X300	

	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			KNEE SURGERY DRAPE	200X300	
				SHOULDER SURGERY DRAPE	200X300	
				HIP SURGERY DRAPE	200X250	
				ANGIOGRAHY SURGERY DRAPE	150X240	
				BY PASS SURGERY DRAPE	240X350	
				VALVE REPLACEMENT SURGERY DRAPE	240X350	
				EMBRIO TRANSFER (E.T.) SURGERY DRAPE	50X90	
				I.V.F SURGERY DRAPE	150X225	
				DELIVERY SURGERY DRAPE	75X150	
				CASEREAN SURGERY DRAPE WITHOUT POUCH	200X300	
				OVUM PICK UP (O.P.U) SURGERY DRAPE	130X150	
				CRANIOTOMY SURGERY DRAPE	230X300	
				SHUNT SURGERY DRAPE	150X300	
				SPINAL SURGERY DRAPE	200X300	
				PERCUTAN (PCNL) SURGERY DRAPE	150X300	
				TUR SURGERY DRAPE	200X240	
				CYSTOSCOPY SURGERY DRAPE	75X150	
				E.N.T. SURGERY DRAPE	150X200	
	868 234012 108006JU 868 234012 108019K5 868 234012 108029K8 868 234012 108030JR 868 234012 108031JT 868 234012 108032JV 868 234012 108033JX 868 234012 108034JZ 868 234012 108035K3 868 234012 108036K5 868 234012 108037K7 868 234012 108038K9 868 234012 108039KB 868 234012 108040JU 868 234012 108041JW 868 234012 108042JY 868 234012 108043K2 868 234012 108044K4 868 234012 108045K6 868 234012 108046K8 868 234012 108047KA	Class Is	T02010101	ARTHROSCOPY DRAPE WITH POUCH	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.
				CASEREAN SURGERY DRAPE WITH POUCH	200X300	
				SMS EYE SURGERY DRAPE (SINGLE POUCH)	Width: Min:100 Max:150 Length: Min:120 Max:240	
				SMS EYE SURGERY DRAPE (DOUBLE POUCH)	Width: Min:100 Max:150 Length: Min:120 Max:240	

				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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	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	-	Sterile Universal Surgical drape sets are used in operating rooms to cover the needed area of the patients during General Surgery operations. Sterile General Surgical Drape sets are used in operating rooms to cover the needed area of the patients during General Surgery operations. Sterile Abdominal Surgery drape sets are used in operating rooms to cover the needed area of the patients during Abdominal Surgery operations. Sterile Laparotomy Surgical Drape sets are used in operating rooms to cover the needed area of the patients during laparotomy Surgery operations. Sterile Laparoscopy Surgical Drape sets are used in operating rooms to cover the needed area of the patients during Laparoscopy Surgery operations. Sterile Minor Surgical drape sets are used in operating rooms to cover the needed area of the patients during Minor Surgery operations. Sterile Dressing surgical drape sets are used after operations while

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(Class Is, Im and Ir Devices)

Certificate Number: M.2022.MDR.1007

	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			DRAPE SET 5. HAND SURGERY DRAPE SET 6. KNEE SURGERY DRAPE SET 7. SHOULDER SURGERY DRAPE SET 8. ARTHROPLASTY (HIP) DRAPE SET 9. VERTEBRA DRAPE SET **D. CARDIOLOGY SURGICAL DRAPE SETS:** 1. ANGIOGRAPHY DRAPE SET 2. ANGIOGRAPHY CUSTEM SET 3. BY PASS DRAPE SET 4. VALVE REPLACEMENT DRAPE SET 5. CARDIOVASCULAR DRAPE SET **E. GYNECOLOGIC SURGICAL DRAPE SETS:** 1. EMBRIO TRANSFER (E.T.) DRAPE SET 2. I.V.F DRAPE SET 3. DELIVERY DRAPE SET 4. CAESAREAN DRAPE SET 5. O.P.U. (OVUM PICK UP) DRAPE SET 6. PERINEAL SET **F. BRAIN SURGERY DRAPE SETS:** 1. CRANIATOMY DRAPE SET 2. SHUNT DRAPE SET 3. SPINAL DRAPE SET **G. OPHTHALMOLOGY SURGICAL-DRAPE SETS:** 1. EYE DRAPE SET **H. ONCOLOGHY SURGICAL DRAPE SETS:** 1. CHEMOTHERAPHY DRAPE SET **I. UROLOGICAL SURGICAL DRAPE SETS:** 1. PERCUTANEUS DRAPE SET 2. TUR DRAPE SET 3. CYSTOSCOPY DRAPE SET **J. RADIOLOGY SURGICAL DRAPE SETS:** 1. BIOPSY DRAPE SET **K. EAR- NOSE-THROAT (E.N.T.) DRAPE SETS:** 1. EAR-NOSE-THROAT (E.N.T.) DRAPE SET 2. THYROID DRAPE SET **L. ESTETIHCAL SURGERY DRAPE SETS:** 1. RHYNOPLASTY DRAPE		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. Sterile Dialysis Cover Surgical drape sets are used in operating rooms to cover the needed area of the patients during General Surgery operations. 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. Sterile Circumcision Surgical Cover drape sets are used in operating rooms to cover the needed area of the patients during General Surgery operations. 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. Sterile Arthroscopy Drape Sets With Pouch are used in operating rooms to cover the needed area of the patients during Arthroscopic Surgery operations. Sterile Lower Extremity drape sets are used in operating rooms to cover the needed area of the patients during lower Extremity Surgery operations. Sterile Upper Extremity drape sets are used in operating rooms to cover the needed area of the patients during Upper Extremity Surgery operations Sterile Hand Surgery drape sets are used in operating rooms to cover the needed area of the patients during upper extremity surgery operations Sterile Knee Surgery drape sets are used in operating rooms to cover the needed area of the patients during Knee Surgery operations Sterile Shoulder Surgery drape sets are used in operating rooms to cover the needed area of the patients during Shoulder Surgery operations. Sterile ARTHROPLASTY (HIP) drape sets are used in operating rooms

				SET 2. LIPOSCULPTURE DRAPE SET 3. HAIR TRANSPLANT DRAPE SET **M. DENTAL SURGERY DRAPE SETS:** 1.DENTAL DRAPE SET 2.IMPLANT DRAPE SET 1 PAIR CHEMOTHERAPHY 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 BETADİNE SPONGE 1 PCS BONNET 1 PCS CAESAREAN DRAPE 1 PCS CHEMOTHERAPHY 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		to cover the needed area of the patients during Hip replacement Operations. Sterile Vertebra drape sets are used in operating rooms to cover the needed area of the patients during Vertebra Surgery operations. Sterile Angiography drape sets are used in operating rooms to cover the needed area of the patients during vascular visualization / Angiography Surgery operations. Sterile Angiography custem drape sets are used in operating rooms to cover the needed area of the patients during vascular visualization / angiography operations. 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. Sterile Valve Replacement drape sets are used in Cardiology / Valve Replacement Surgical Operations for replacing the valves in order to improve blood circulation system Sterile Cardiovascular drape sets are used during Cardiology / All kinds of Cardiovascular Surgical operations, for making new veins by-passing the blood circulation system. Sterile Embrio Transfer (E.T.) drape sets are used in operating rooms for Gynecological Operations transferring the embrio. Sterile I.V.F. drape sets are used in Gynecological I.V.F operations. Sterile Delivery drape sets are used in Gynecological Surgery operations for delivering the baby. Sterile Caesarean drape sets are used during Gynecological / Caesarean Operations as Caesarean type of delivering the baby or others. Sterile O.P.U drape sets are used in Gynecological Operations for Ovum Pick Up. Sterile Perineal drape sets are used for surgical operations and examinations in perineal area such as saucerization of perineal or ischiorectal abscress, evacuation of thrombotic piles, pile ligation, gynecological

				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 PLAİN 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 TİP 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 STOCKINITTE (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		dilation and curettage etc. Sterile Craniotomy drape sets are used in open Brain Surgery Operations. Sterile Shunt drape sets are used in open Brain Surgery / Shunt placement Surgery Operations and examinations. Sterile Spinal drape sets are used in Spine / Open Brain Surgery Operations. Sterile Eye drape sets are used in all kinds of Ophthalmology Operations. Sterile Chemotherapy drape sets are used while injecting chemotherapy drugs to the patients to cover both the patient and the nurse for protection. Sterile Percutaneous drape sets are used in Urological Operations such as Nephrology surgery and examinations. Sterile Spinal drape sets are used in Urological Operations such as T.U.R Surgery. Sterile Spinal drape sets are used in Urological Operations such as Cystoscopy operation. Sterile Biopsy drape sets are used in Biopsy Surgery Operations. Sterile E.N.T drape sets are used in E.N.T Surgery Operations. Sterile Thyroid drape sets are used in Thyroid Surgery Operations. Sterile Rhynoplasty drape sets are used in Rhinoplasty Surgery Operations. Sterile Liposculpture drape sets are used in Liposuction Surgery Operations. Sterile Hair Transplant drape sets are used in Hair transplant Surgery Operations. Sterile Dental drape sets are used in Dental Surgery Operations. Sterile Implant drape sets are used in Implant Surgery Operations.

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

				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		

Conditions for or limitations to the validity of this certificate :NA

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

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

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

ZEYNİ MEDİKAL TEKSTİL İNŞ. SANAYİ VE TİCARET LTD.ŞTİ.
Yunusemre Mh. 12. Yıldınm 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

turCare Disposable Medical Devices
Cerrahi Örtü ve Önlük

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- Crotia
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 ofCompany

ZEYNI MEDIKAL
TEKSTİL İNŞAAT SAN. ve TİC. LTD. ŞTİ.
Yunusemre Mah. 12 Yıldırım Sk. No:17
Yıldırım / BURSA
Yıldırım V.D. 999 141 1400 Tic.Sic.No:102917
Mersis No:0999141140000001

ZEYNİ 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

turCare Disposable Medical Devices
Cerrahi Örtü ve Önlük

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. : 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

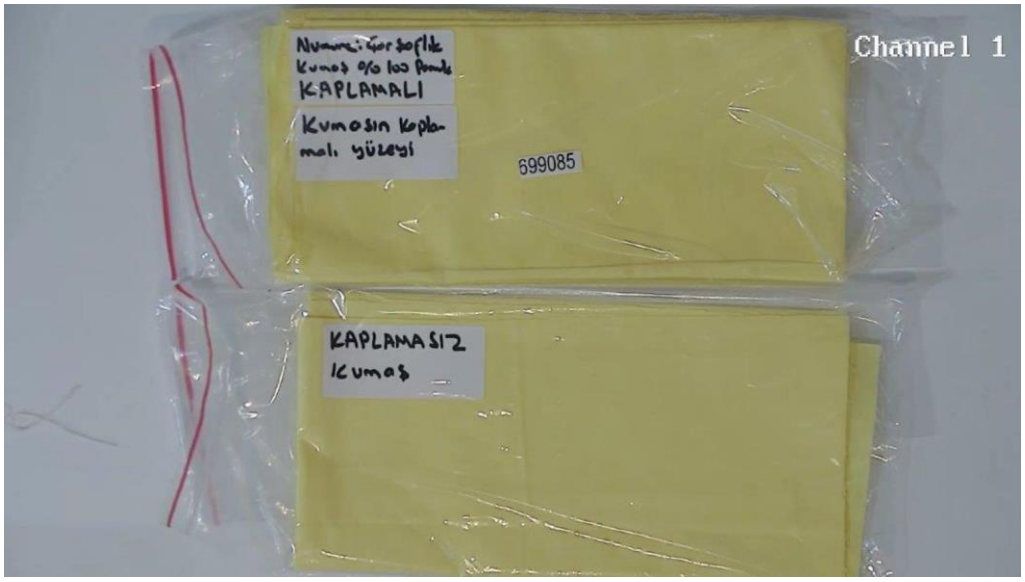
Test Result: Passed

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

Tomris 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 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
Colakoglu Plaza B Blok 34742 Kadikoy Istanbul,
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
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TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş.
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EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

EKOTEKS

TEST REPORT
DENEY RAPORU

20018576 – ing-Add
12-05

Customer name:	ZEYNİ MEDİKAL TEKTSİL İNŞ. SANAYİ VE TİC. LTD. ŞTİ.
Address:	Yunusemre Mah. 12. Yıldırım Sk. No:17 Yıldırım - BURSA
Buyer name:	-
Contact Person:	Davut Daşdan
Order No:	-
Article No:	-
Name and identity of test item:	Surgical Gowns-SMS
The date of receipt of test item:	12.05.2021
Re-submitted/re-confirmation date:	-
Date of test:	12.05.2021-12.05.2021
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	Not specified.
Number of pages of the report:	14

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
	12.05.2021	Servin YURTSEVEN	Sevim A. RAZAK 12.05.2021

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

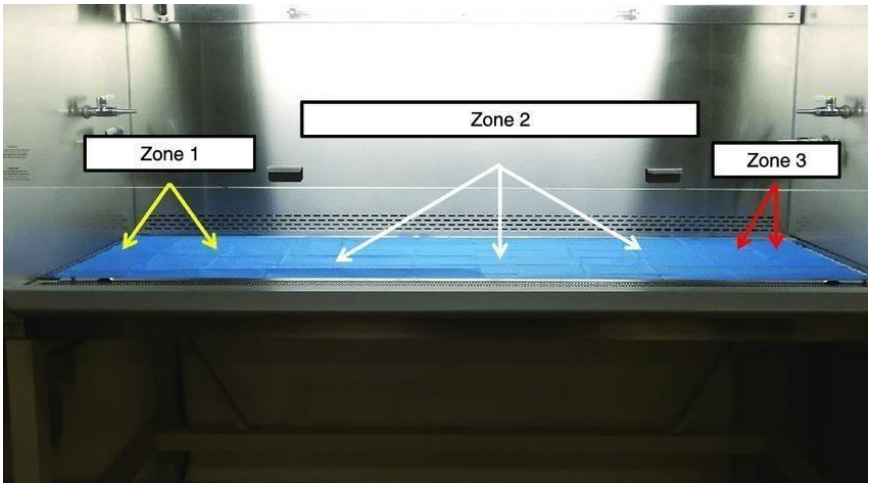
20018576 – ing-Add
05-26

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden) (1)	P	
Wet-Bacterial Penetration(1)	P	
PHYSICAL PROPERTIES TESTS		
Tensile Stregth **/ Dry**	P	
Tensile Stregth **/ Wet**	P	
Bursting Strength **/ Dry**	P	
Bursting Strength **/ Wet**	P	

P: Pass
F: Fail
R: Refer to retailer technologist.

(1) This report was reissued to add this test result.
(2) Test results were evaluated according to EN 13795-1:2019 Standard Performance Properties Critical Sample Group limit values (Table 1)

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified.If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. Tests marked (*) in this report are not included in the accreditation schedule.



EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20018576 – ing-Add
12-05

TEST RESULTS

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: Ref: EN ISO 11737-1:2018 (*)

The sample is put in extraciton liquid after shaking well, inoculated on the agar.
After incubation at 30 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

	RESULTS	**REQUIREMENT**
Microbial cleanliness (cfu/g)	206 cfu/100 cm^2	≤300 cfu/100 cm^2
1	208	
2	211	
3	206	
4	204	
5	198	
6	202	
7	203	
8	202	
9	201	
10	200	

***cfu= Colony forming unit.**

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20018576–ing-Add
12-05

TEST RESULTS

Test Method: BS EN 22610: 2006 (Surgical gowns, garments and fresh air clothes used as medical devices for patients, hospital staff and equipment - Test method for determination of resistance to wet bacterial permeability) (*)

A test sample is placed on the agar plate on a rotating disc. Bacteria carrier material and coating film are placed on the test sample and all parts are fixed on the disk. A finger is placed on the test sample to apply a certain force (3N ± 0.02). The finger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
Coating Material:	25x25cm2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	1-4x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
X1	55	RCUM1	0,01
X2	72	RCUM2	0,15
X3	154	RCUM3	0,34
X4	178	RCUM4	0,56
X5	156	RCUM5	0,74
Z	212		
T	827		

X1 …… X5: Number of colonies growing in 5 parallel petri in the same sample
Z: number of colonies growing in the sixth petri dish
T: X1 + X2 + X3 + X4 + X5 + Z

RCUM1 = X1/T
RCUM2 = (X2 + X1)/T
RCUM3 = (X3 + X2 + X1)/T
RCUM4 = (X4 + X3 + X2 + X1)/T
RCUM5 = (X5 + X4 + X3 + X2 + X1)/T

BARRIER INDEX (IB)		
	Result	Expected value (*)
IB	4,14	≥2,8

IB = 6 – (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)

* EN 13795-1:2019 Surgical gowns - Requirements and test methods are evaluated according toTable-1.

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20018576 – ing-Add
12-05

TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL GOWN –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL GOWNS(*);

TENSILE STRENGTH; EN 29073-3:1996 (*)

Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. Without wetting samples.
The average results are given for weft and warp direction of five samples
Performed in the conditioned room (20±2°C-65%±4).

Dry ;

	RESULT	REQUIREMENT
Weft	52.2 N	≥ 20N (Dry)
Warp	93.6 N	≥ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996 (*)

Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. With wetting samples.
The average results are given for weft and warp direction of five samples
Performed in the conditioned room (20±2°C-65%±4).

Wet ;

	RESULT	REQUIREMENT
Weft	55.0 N	≥ 20N (Wet)
Warp	101.9 N	≥ 20N (Wet)

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 29 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Dry ;	141.2 kPa	≥ 40 kPa (Dry)
Height at Burst*	12.9 mm	

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20018576 – ing-Add
12-05

TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL GOWN –REQUIREMENTS AND TESTMETHODSANNEX 1: SURGICAL GOWN (*);

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 45.2 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	**REQUIREMENT**
Wet ;	139.4 kPa	≥ 40 kPa (Wet)
Height at Burst*	14.3 mm	

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20018576 – ing-Add
12-05

The resistance to dry microbial penetration

[Material]Test Method: EN ISO 22612:2005

Test principle:

The test is carried out on test pieces each fixed in a container. In every container except one a portion of talc contaminated with Bacillus subtilis is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at the base of each container at a short distance below the test piece. The apparatus supporting the containers is then vibrated by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate, the sedimentation plates are removed and incubated. The numbers of colonies produced are counted.

Test equipment:

Resistance to dry microbial penetration test
Incubator
Electronic balance
Autoclave

The environmental conditions of the laboratory and test condition:

Test environment temperature: 24.5℃, Relative humidity: 56.0%

Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

Culture medium: TGE agar medium; Other materials: talc and ethyl alcohol.

Dimensions of the test specimens: 200mm×200mm

Sample: 12 pieces

Vibration frequency: 20800 times/min; Vibration time: 30 min.

Test bacteria: The fourth generation of spores of bacillus subtilis ATCC 9372

Concentration of bacterium: 1.8×10^{8} CFU/g

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Results:

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	19	≤300 (Surgical Gown performance less critical productarea) EN 13795-1:2019	**Pass**
2	17		
3	31		
4	15		
5	10		
6	25		
7	16		
8	28		
9	17		
10	8		

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The resistance to wet bacterial penetration[Material]Test Method: EN ISO 22610:2006

Test principle:

A test specimen is placed on an agar plate. A sheet of donor material, of corresponding size and carrying the bacteria, is placed on the test specimen with the contaminated side face down and covered by a sheet of approximately 10 μm high density polyethylene (HDPE) film. Two tithing conical steel rings hold the three sheets together, applying a tensile force. An abrasion-resistant finger is placed on top of the materials with a specified force to bring the test specimen in contact with the agar. The finger is moved over the entire surface of the plate in less than 15 min by means of a pivoted lever moved by an exocentric cam. The assemblage of materials, stretched by the weight of the steel rings, ensures that only a small area of the test specimen is brought into contact with the agar surface at any one time. Due to the combined effect of rubbing and liquid migration, bacteria may pass from the donor material through the test specimen down to the agar surface. After being tested for 15 min, the agar plate is replaced by a fresh one, and the test is repeated with the same donor and test specimen. Allowing 15 min for each test, five tests are performed with the same pair of donor and test specimen. In this way, the test allows for an estimation of the penetration over time. Finally, the bacterial contamination on the top side of the test specimen is estimated using the same technique. The agar plates are incubated in order to observe the bacterial colonies, which are then enumerated.

Test equipment:

The resistance to wet bacterial penetration test
Incubator
Electronic balance
Autoclave

The environmental conditions of the laboratory and test condition:

Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
Culture medium: Tryptone Soya Agar, Tryptic Soy Broth, peptone water and nutrient agar medium.
Dimensions of the test specimens: 25cm×25cm
The carrier material: solvent-cast polyurethane (PU) film of 30 μm thickness
Nutrient agar to from the brim: 3 mm
Test bacteria: The fifth generation of staphylococcus aureus ATCC 29213
Concentration of bacterium: 2.3×10^4 CFU/ml

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Results:

Sample	Barrier index	Requirement Barrier index	Conclusion
1	6.7	≥6 (Surgical Gown: performance critical product area) EN 13795-1:2019	**Pass**
2	6.6		
3	6.6		
4	6.6		
5	6.6		

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Lint and other particles generation in the dry state[Material]

Test Method: EN ISO 9073-10:2004

Test principle:

This procedure describes a modified Flex method in which the sample is subjected to a combined twisting and compression action in a test chamber. During the flexing, air is withdrawn from chamber and particulates in the air stream are counted and classified in a particle counter. Depending on the choice of counter, the size ranges can fall within the limits of 0.3 μm or 0.5 μm to 25 μm.

Test equipment:

Flex tester with particle counter

The environmental conditions of the laboratory:

Test environment temperature: 20.2℃, Relative humidity: 64.7%

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Results:

Size of particles counted (µm)	**Sample**		**Measured value Coefficient of linting log_{10}**	**Requirement Coefficient of linting log_{10}**	**Conclusion**
3～25	A: Face	1	2.1	≤4.0 (Surgical Gown: performance critical product area) EN 13795-1:2019	**Pass**
		2	2.1		
		3	2.1		
		4	2.1		
		5	2.2		
	B: Face	1	2.0		
		2	2.1		
		3	2.0		
		4	2.2		
		5	2.1		

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Static hydrostatic resistance[Material]Test
Method: EN ISO 811:2018

Test principle:

The hydrostatic head supported by a fabric is a measure of the opposition to the passage of water through the fabric. A specimen is subjected to a steadily increasing pressure of water on one side of the fabric, under standard conditions, until penetration occurs in three places. The pressure at which the water penetrates the fabric at the third place is noted.

Test equipment:

Hydrostatic tester

Water, grade 3 water in accordance with ISO 3696.

The environmental conditions of the laboratory and test condition:

Pretreatment: Condition the test specimens at 20.1℃ air at 65.2% RH for 24 h

Face side tested

Temperature of the water: 20.0℃

Rate of increasing water pressure: 10cmH_2 O/min

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Results:

Sample	Measured value (cmH_2O)	Requirement (cmH_2O)	Conclusion
1	125 18	≥100 ≥10 (Surgical Gown performance critical product area) EN 13795-1:2019	**Pass**

1. PRODUCT

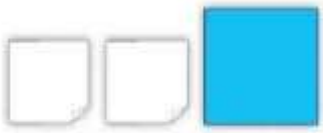
Standart Surgical Gown

2. 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

3. DESCRIPTION:

Products	Surgical gown,Full Protection, assure air permeability Adjustable, with velcro closure at the neck, it is provided with 4 ties. Ultrasonic seems, Raglan type. Including two towels 40*40 and CSR Wrapping 60*60 cm Validity 5 years from the date of production
Fabric	**SMS**
Weight	**42 gr/m2.**
Color	**Blue – 150 +-10 Cm**



4. PACKING

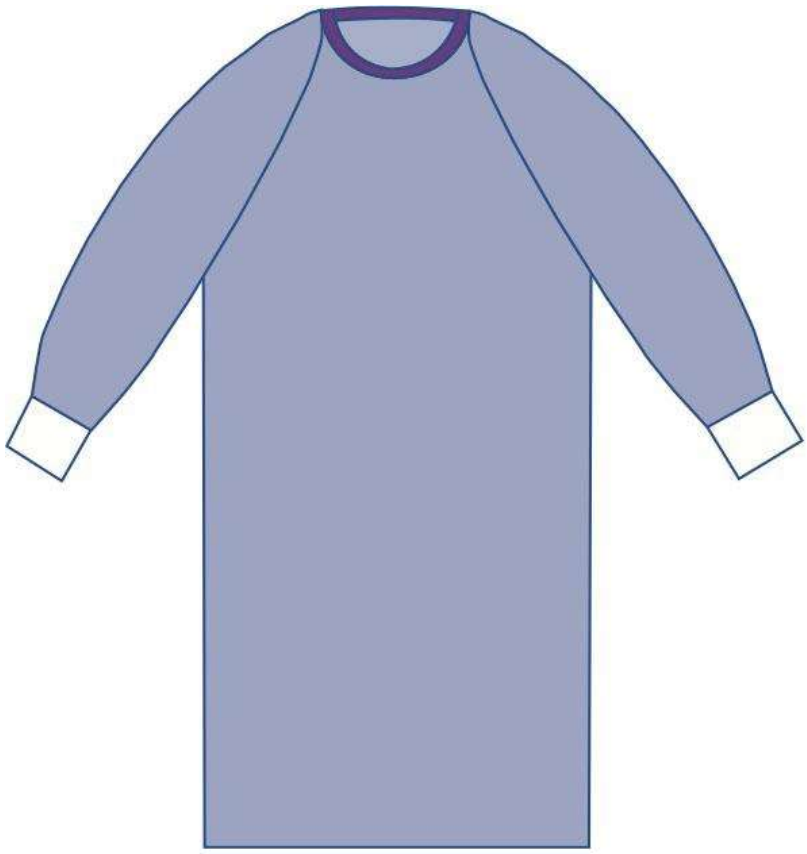
The product is individually packaged. On the packaging is the inscription with the name and address of the manufacturer, the product model, description, dimensions, date of manufacture, validity date, lot number, etc.

5. STORAGE

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

6. Term of validity

5 years from the date of production



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QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

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

by review of RA1-5076 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

Revised Date : 13.04.2022

Expiry Date : 21.04.2024

Certification Period : 3 years (1st year)

Deutsche Akkreditierungsstelle D-ZM-16058-01-00

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MEDICAL QUALITY MANAGEMENT SYSTEM CERTIFICATE

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DIN EN ISO 13485:2016

Certificate No :MDMS 0423 009795

Original Certification Date : 22.04.2020

Revised Date : 13.04.2022

Expiry Date : 21.04.2024

Certification Period : 3 years (1st year)

Universal GmbH