

EU DECLARATION OF CONFORMITY



Manufacturer Name : MHK MEDİKAL TEKSTİL SAN. TIC. LTD. ŞTİ

Adress : Körkün Mahallesi Hidayet Caddesi No 23 Oğuzeli /Gaziantep / TURKEY

Product Trade Name : Disposable Sterile Drapes, Gowns And Procedure Packs (Trays) (See Annex List of the Product)

Directive : Regulation (EU) 2017/745 on Medical Device Regulation

Brand : MHK

Basic UDI-DI : 0868082921DRPGWNFX

Classification : According To Annex VIII Of Regulation (Eu) 2017/745 (Medical Device Regulation (MDR)) Non-Invasive, Non-Active Medical Device, Class I Sterile, Rule 1

Conformity Assesment : According to Regulation (EU) 2017/745 on medical devices Annex – XI Part A PRODUCT CONFORMITY VERIFICATION

We herewith declare that:

Those above products with CE marking which are manufactured by our company all comply with REGULATION (EU) 2017/745 ON MEDICAL DEVICES, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

STANDARTS APPLIED :

EN ISO 13485	EN ISO 11135	EN ISO 13795-1
EN ISO 15223-1	EN ISO 14698-1	EN ISO 10993-1
EN ISO 14971:2019	EN ISO 14698-2	EN ISO 10993-5
EN ISO 10993-10	ISO 11737-1	

A statement that the declaration of conformity is issued under the responsibility of the manufacturer.

Place/Date : GAZİANTEP / 27.01.2023
Authorized Person : MURAT KEKEÇ
Title : General Manager

Signature, Stamp



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ANNEX I: LIST OF THE PRODUCTS:

PRODUCT NAME	BASIC UDI-DI	RISK CLASS	EMDN CODE	MODEL	TYPE	INTENDED PURPOSE
STERILE DISPOSABLE SURGICAL GOWNS	0868082921DRPGWNFX	Class Is	T020401 - SURGICAL GOWNS, STANDARD	STANDARD SURGICAL GOWN	Small	Sterile Disposable Surgical gown is intended to be protect patient from microorganisms, body fluids, and particulate material during surgical procedures.
					Medium	
					Large	
					XLarge	
					XXLarge	
					XXXLarge	
			STANDARD SURGICAL GOWN WITH WRAPPING		Small	
					Medium	
					Large	
					XLarge	
					XXLarge	
					XXXLarge	
			T020402- SURGICAL GOWNS, REINFORCED	REINFORCED SURGICAL GOWN	Small	
					Medium	
					Large	
					XLarge	
					XXLarge	
					XXXLarge	
			REINFORCED SURGICAL GOWN WITH WRAPPING		Small	
					Medium	
					Large	
STERILE DISPOSABLE SURGICAL GOWNS	0868082921DRPGWNFX	Class Is	T020402- SURGICAL GOWNS, REINFORCED	REINFORCED SURGICAL GOWN WITH WRAPPING	XLarge	Sterile Disposable Surgical gown is intended to be protect patient from microorganisms, body fluids, and particulate material during surgical procedures.
					XXLarge	
					XXXLarge	
			T020402- SURGICAL GOWNS, REINFORCED	FULL REINFORCED SURGICAL GOWN	Small	
					Medium	
					Large	
					XLarge	

					XXLarge	
					Small	
					Medium	
					Large	
					XLarge	
					XXLarge	
STERILE DISPOSABLE SURGICAL DRAPES	0868082921DRPGWNFX	Class Is	T020499- SURGIC AL GOWNS, OTHERS	TUR UROLOGY GOWN	50*50cm	Disposable Surgical Drapes consisting of them are used to protect the patient against bacterial infections during the operation by creating a sterile environment. It is used as a barrier to fluid and microbial penetration between the patient and the operating room, other surgical devices.
					75*75cm	
					75*90cm	
					100*150cm	
					85*90cm	
					160*180cm	
					100*100cm	
					120*150cm	
					150*200cm	
					150*250cm	
					75*80cm	
					65*125cm	
STERILE DISPOSABLE SURGICAL DRAPES	0868082921DRPGWNFX	Class Is	T020199- SURGIC AL DRAPES - OTHERS	SIDED DRAPE	-	Disposable Surgical Drapes consisting of them are used to protect the patient against bacterial infections during the operation by creating a sterile environment. It is used as a barrier to fluid and microbial penetration between the patient and the operating room, other surgical devices.
					50*50cm	
					75*75cm	
					75*90cm	
					100*120cm	
					75*100cm	
					150*240cm	
				OP TAPE	10*30cm	
					10*50cm	
				BABY DRAPE	100*100cm	
					100*120cm	
				ADHESIVE TAPE DRAPE	75*80cm	

					65*125cm	
					175*150cm	
					125*240cm	
					150*240cm	
					160*240cm	
			T030101- COVER CAPS, INSTRUM ENTARY AND EQUIPME NTS	TUBE HOLDER	9*18cm	
					-	
			T020102- DRAPES, SPECIALI STIC SURGERY	E.N.T DRAPE	-	
				DENTAL DRAPE	-	
			T030199- COVERS, INSTRUM ENTARY AND EQUIPME NTS- OTHERS	MAYO STAND COVER	75*150cm	
					-	
					78*145cm	
					80*150cm	
STERILE DISPOSABLE SURGICAL DRAPES	0868082921DRPGWNFX	Class Is	T030199- COVERS, INSTRUM ENTARY AND EQUIPME NTS- OTHERS	BACK TABLE COVER	-	Disposable Surgical Drapes consisting of them are used to protect the patient against bacterial infections during the operation by creating a sterile environment. It is used as a barrier to fluid and microbial penetration between the patient and the operating room, other surgical devices.
					100*120cm	
					100*130cm	
					100*150cm	
					130*150cm	
					150*150cm	
					150*200cm	
					200*200cm	
			T020102- DRAPES, SPECIALI STIC SURGERY	U SPLIT DRAPE	150*200cm	
					200*260cm	
					220*300cm	
				LAPOROSCO PY DRAPE	240*320cm	
				BY-PASS (CARDIOVAS	240*300cm	

				CULAR) DRAPE		
				ANGIOGRAP HY (FEMORAL) DRAPE 1	-	
				ANGIOGRAP HY (FEMORAL) DRAPE 2	-	
				ANGIOGRAP HY (FEMORAL) DRAPE 3	-	
				ANGIOGRAP HY (FEMORAL) DRAPE	150*330cm	
				ANGIOGRAP HY (FEMORAL) DRAPE	200*300cm	
				CRANIOTOM Y DRAPE	220*320cm	
STERILE DISPOSABLE SURGICAL DRAPES	0868082921DRPGWNFX	Class Is	T020102- DRAPES, SPECIALI STIC SURGERY	ARTHROSCOP Y DRAPE	220*320cm	Disposable Surgical Drapes consisting of them are used to protect the patient against bacterial infections during the operation by creating a sterile environment. It is used as a barrier to fluid and microbial penetration between the patient and the operating room, other surgical devices.
				UPPER EXTREMITY DRAPE	200*300cm	
				LOWER EXTREMIT DRAPE	200*310cm	
				T.U.R (UROLOGY) DRAPE	180*240cm	
				CYSTOSCOPY DRAPE	75*150cm	
				PERCUTANEO US DRAPE	150*300cm	
				CESEREAN DRAPE	200*300cm	
				EYE DRAPE WITH SINGLE POUCHE	100*130cm	
				EYE DRAPE WITH DOUBLE POUCHE	150*200cm	
			T020199- SURGIC AL DRAPES- OTHERS	SURGICAL DRAPE	240*340cm	
				ANESTESIA DRAPE	150*180cm	
				FOOT DRAPE	150*180cm	
			T020102- DRAPES, SPECIALI STIC SURGERY	LAPOROSCO PY DRAPE	180*240cm	
				MINOR FENESTRATED DRAPE	-	
				GENERAL OPERATION DRAPE	-	

STERILE DISPOSABLE SURGICAL DRAPES	0868082921DRPGWNFX	Class Is	T020102- DRAPES, SPECIALI STIC SURGERY	HALF DRAPE	-	Disposable Surgical Drapes consisting of them are used to protect the patient against bacterial infections during the operation by creating a sterile environment. It is used as a barrier to fluid and microbial penetration between the patient and the operating room, other surgical devices.
				HEAD DRAPE	-	
				SPINAL DRAPE	-	
				HIPPACK WITH U SPLIT	-	
				GYNECOLOG Y DRAPE	-	
				PATIENT DRAPE	-	
				UROLOGY DRAPE	-	
				PEDIATRIC LAPOROTOM Y DRAPE	-	
			T030202- COVERS, CAMERA	CAMERA COVER	-	
			T020101 02- SURGIC AL DRAPES, INCISIO N WITH ANTIBAC TERIAL	IOBANLI INSIZYON DRAPE	-	
			T020199- SURGIC AL DRAPES- OTHERS	STERILE OPERATION TABLE DRAPE	-	
			T030299- COVERS, ROBOTIC SURGERY - OTHERS	MICROSCOPE COVER	-	
				SCOPY COVER	-	
				FLUOROSCOPI Y COVER	-	
			T030199- COVERS, INSTRUM ENTARY AND EQUIPME NTS- OTHERS	DISPOSABLE STERILE WASTE COLLECTION POCHE	50*60cm	
STERILE DISPOSABLE SURGICAL DRAPES	0868082921DRPGWNFX	Class Is	T030199- COVERS, INSTRUM ENTARY AND EQUIPME NTS- OTHERS	DISPOSABLE STERILE LIQUID COLLECTION POCHE	40*40cm	Disposable Surgical Drapes consisting of them are used to protect the patient against bacterial infections during the operation by creating a sterile environment. It is used as a barrier to fluid and microbial penetration between the patient and the operating room, other surgical devices.
				DISPOSABLE STERILE LIQUID COLLECTION POCHE	35*40cm	
				DISPOSABLE STERILE PORTABLE BAG PVC	-	
				DISPOSABLE STERILE INSTRUMENT	-	

				PACK 2 COMPARTMENTS		
				DISPOSABLE STERILE INSTRUMENT PACK 3 COMPARTMENTS	-	
				DISPOSABLE STERILE LIQUID COLLECTION BAG WITH BARRIER	-	
				BARRIER-FREE DISPOSABLE STERILE LIQUID COLLECTION BAG	-	
				BIFLEX MEDIKAL DRAPE	-	
				BIFLEX MEDIKAL DRAPE	40*120cm	
STERILE DISPOSABLE SURGICAL DRAPES	0868082921DRPGWNFX	Class Is	T020199- SURGICAL DRAPES- OTHERS	BIFLEX MEDIKAL DRAPE	50*75cm	
				SLIT ORTHOPEDIC COVER	-	
				LEG COVER	-	
STERILE DISPOSABLE SURGICAL DRAPE PACKS	0868082921DRPGWNFX	Class Is	T0202 - SURGICAL KITS (only with EC certificate)	STERILE DISPOSABLE SURGICAL GENERAL OPERATION DRAPE PACK	-	Disposable Surgical Drape Packs consisting of them are used to protect the patient against bacterial infections during the operation by creating a sterile environment. It is used as a barrier to fluid and microbial penetration between the patient and the operating room, other surgical devices and operating room personnel. The same intended usage that is valid for the specific set types are as follows:
				STERILE DISPOSABLE SURGICAL GENERAL OPERATION DRAPE PACK	-	
				STERILE DISPOSABLE SURGICAL GENERAL SURGEY DRAPE PROCEDURE PACK	-	
				STERILE DISPOSABLE SURGICAL GENERAL OPERATION DRAPE PACK 2	-	
				STERILE DISPOSABLE SURGICAL GENERAL OPERATION DRAPE PACK 3	-	

				STERILE DISPOSABLE SURGICAL BY-PASS DRAPE PACK	-	This pack is produced for by-pass operations to be performed in certain parts of the patient. There is no pouch on the cover, there is an extra absorbent area.
STERILE DISPOSABLE SURGICAL DRAPE PACKS	0868082921DRPGWNFX	Class Is	T0202 - SURGICAL KITS (only with EC certificate)	STERILE DISPOSABLE SURGICAL HEART VALVE DRAPE PACK	-	This pack is designed for use in open heart surgeries. The patient is covered by paying attention to the markings on the cover. All areas of the hospital fully benefit from pop-up windows. There are various small side covers in the pack. There are pouches for various wastes.
				STERILE DISPOSABLE SURGICAL HEART VALVE DRAPE PACK 1	-	
				STERILE DISPOSABLE SURGICAL HEART VALVE DRAPE PACK 2	-	
				STERILE DISPOSABLE SURGICAL ANGIOGRAPHY DRAPE PACK	-	This pack is used in angiography operations. There are two holes at a distance of 70 cm from the head. Holes with a center of 24 cm were drilled with a diameter of 10 cm to fit the groin. It is covered with an incision. There is a sponge with a handle for the antiseptic solution used in the operation area, and a tube cap (fluoroscopy sheath) to prevent contamination of the existing device during the operation.
				STERILE DISPOSABLE SURGICAL ANGIOGRAPHY DRAPE PACK WITH PANEL	-	
				STERILE DISPOSABLE SURGICAL CRANIOTOMY DRAPE PACK	-	The operation area is covered with incision. There is a filtered pouch (fluid collection bag) under the incision area. The flat cover is placed under the patient, and the side band covers are placed on the patient's sides.
				STERILE DISPOSABLE SURGICAL LAMINECTOMY DRAPE PACK	-	This pack is designed to be used in herniated disc and spine surgeries. There are side covers in the packs, allowing the patient to be covered in one go.
				STERILE DISPOSABLE SURGICAL ARTHROSCOPY DRAPE PACK	-	It is the pack used for operations in the knee area. After the leg cover is placed on the

						patient's leg, it is fixed with an elastic bandage.
STERILE DISPOSABLE SURGICAL DRAPE PACKS	0868082921DRPGWNFX	Class Is	T0202 - SURGICAL KITS (only with EC certificate)	STERILE DISPOSABLE SURGICAL ARTHROSCOPY DRAPE PACK WITH POUCHES	-	Pouch arthroscopy is used to cover the patient in liquid-washed knee surgeries. There are 2 elastic parts on the cover. Because of this part, the knee pouch is taken, 20 liters of liquid can be kept in the fluid pouch due to the operation and the pouch. Cleaning the pillow from the suction cover, excess water system.
				STERILE DISPOSABLE SURGICAL LOWER EXTREMITY DRAPE PACK	-	It is the pack that used for operations in the lower extremity area.
				STERILE DISPOSABLE SURGICAL UPPER EXTREMITY DRAPE PACK	-	It is the pack that used for operations in the upper extremity area. The U-slit drape is fixed to the neck of the patient. Anesthesia drape and side tape drapes are used to cover the patient's sides.
				STERILE DISPOSABLE SURGICAL HIP DRAPE PACK	-	This pack, which is used in hip surgery, has 1 main cover with a u-slit. The cover with the U-split is inserted between the legs so that the patient's hip is exposed and is adhered to the skin with tape and the patient is covered. Then, the cover with the side tape is covered and the patient is prepared for the operation.
				STERILE DISPOSABLE SURGICAL TUR (UROLOGY) DRAPE PACK	-	The urological TUR drape is designed to cover the legs in one piece and cover the whole patient. The patient is covered while the patient lies in the lithotomy position. There is an incision area on the drape for abdominal intervention. In the perineum, there is a rectal touch control finger and a fluid collection pouch. There is a particle filtering part and aspiration plug on

						the liquid collection pouch.
STERILE DISPOSABLE SURGICAL DRAPE PACKS	0868082921DRPGWNFX	Class Is	T0202 - SURGIC AL KITS (only with EC certificat e)	STERILE DISPOSABLE SURGICAL CYSTOSCOPY DRAPE PACK	-	Cystoscopy drape packs is a cover drape packs used for gynecological intervention to a female patient. The legs of the patient are covered with the help of sheaths. The flat cover is opened under the patient. The cystoscopy drape is adhered to the perineal region of the patient and prepared for the operation.
				STERILE DISPOSABLE SURGICAL PERCUTANEO US DRAPE PACK	-	This pack is produced for use in kidney surgeries. There is a 25x25cm incision opening in the middle of the drape. There is a strainer pouch under the incision opening. There is a camera cover in the pack to keep the camera sterile.
				STERILE DISPOSABLE SURGICAL DELIVERY DRAPE PACK WITH POCHE	-	Pouched Bottom Drape is the cover that opens under the patient when the patient is in the lithotomy position and has a pouch to collect the fluids that come out during delivery. There is an aspiration plug on the pouch. The banded abdominal drape is the cover that opens on the patient. There are 2 leg drape and they are worn on the legs separately. The baby drape is used to wrap and dry the baby after birth. The protective gown is the gown worn by the midwife.
				STERILE DISPOSABLE SURGICAL DELIVERY DRAPE PACK WITHOUT POUCHE	-	The lower drape is the cover that opens under the patient when the patient is in the lithotomy position. The banded abdominal cover is the cover that opens over the patient. The leg drapes are 2 pieces and are worn on the legs separately. The baby cover is used to wrap and dry the baby after birth. The protective gown is the gown worn by the midwife.
				STERILE DISPOSABLE SURGICAL CESAREAN DRAPE PACK	-	This pack is produced for cesarean section surgeries. There is a pouch with a 20x25 incision opening in the

						operation area and to collect fluids on all four sides of the opening. There are also 2 aspiration plugs on it.
STERILE DISPOSABLE SURGICAL DRAPE PACKS	0868082921DRPGWNFX	Class Is	T0202 - SURGICAL KITS (only with EC certificate)	STERILE DISPOSABLE SURGICAL EYE DRAPE PACK WITH SINGLE POCHE	-	This pack is produced for ophthalmic operations. The eye cover is single-pocketed. It is applied to whichever eye it is desired, thanks to the sign showing which side the pouch is on. After the patient's eye cover is covered, a flat cover is available to cover the remaining part.
				STERILE DISPOSABLE SURGICAL EYE DRAPE PACK WITH DOUBLE POCHE	-	This pack is produced for ophthalmic operations. The eye cover is double pouched. After the patient's eye cover is covered, there is a plain drape to cover the remaining part.
				STERILE DISPOSABLE SURGICAL GYNECOLOGICAL OPU DRAPE PACK	-	It is a gynecological intervention pack that used in IVF. In the lithotomy position, the patient's legs are covered by separate sheaths. There is an OPU drape with a taped hole in the form of a pot. The operation is performed by sticking the taped hole to the perineal region.
				STERILE DISPOSABLE SURGICAL E.N.T. DRAPE PACK	-	It is a drape pack produced for ear nose and throat surgeries. It includes covers suitable for covering these areas. As with all our drapes, the patient is easily covered with the direction signs on the drape and is prepared for the operation.
				STERILE DISPOSABLE SURGICAL MINOR SURGICAL DRAPE PACK	-	Small operations are also produced for use. It is used for biopsy, small abscess or minor injuries. Minor surgical drape is perforated and taped. It is fixed to the operation area by means of adhesive tape.
				STERILE DISPOSABLE SURGICAL IMPLANT DRAPE PACK	-	The implant drape pack is produced for dental implant operations. There is a U-shaped slit in the neck area of the patient cover. Includes various hose covers and table cover.
				STERILE DISPOSABLE SURGICAL DENTAL DRAPE PACK	-	This dental drape pack is produced for dental operations.
STERILE DISPOSABLE	0868082921DRPGWNFX	Class Is	T0202 - SURGICAL	STERILE DISPOSABLE SURGICAL	-	This laparotomy drape pack is produced for

SURGICAL DRAPE PACKS			AL KITS (only with EC certificat e)	LAPOROTOMY DRAPE PACK		laporotomic operations.
				STERILE DISPOSABLE SURGICAL CHEMOTHERA PY DRAPE PACK	-	This drape pack is produced for chemoteraphy operations.
				STERILE DISPOSABLE SURGICAL CHEMOTHERA PY DELETION DRAPE PACK	-	This drape pack is produced for chemoteraphy deletion operations.
				STERILE DISPOSABLE SURGICAL CIRCUMCISIO N DRAPE PACK	-	This drape pack is produced for circumcision operation.
				STERILE DISPOSABLE SURGICAL LITOTOMY DRAPE PACK	-	This drape pack is produced for litotomy operation.
				STERILE DISPOSABLE SURGICAL HAND SURGICAL DRAPE PACK	-	This drape pack is produced for hand surgical operation.
				STERILE DISPOSABLE SURGICAL BARIATRIC DRAPE PACK	-	This drape pack is produced for bariatric operation.
				STERILE DISPOSABLE SURGICAL SHOULDER ARTHROSCOP Y DRAPE PACK	-	This drape pack is produced for shoulder arthroscopy operation.
				STERILE DISPOSABLE SURGICAL SHOULDER ARTHROSCOP Y DRAPE PACK WITH POUCHE	-	This drape pack is produced for shoulder arthroscopy operation.
STERILE DISPOSABLE SURGICAL DRAPE PACKS	0868082921DRPGWNFX	Class Is	T0202 - SURGIC AL KITS (only with EC certificat e)	STERILE DISPOSABLE SURGICAL EPIDURAL DRAPE PACK	-	This drape pack is produced for epidural operation.
				STERILE DISPOSABLE SURGICAL ABORTION DRAPE PACK	-	This drape pack is produced for abortion operation.
				STERILE DISPOSABLE SURGICAL ORTHOPEDIC S DRAPE PACK	-	This drape pack is produced for orthopedic operation.
				STERILE DISPOSABLE SURGICAL U	-	This drape pack is produced for general operation.

				SLIT DRAPE PACK		
				STERILE DISPOSABLE SURGICAL ANESTHESIA DRAPE PACK	-	This drape pack is produced for general operation if it needs anesthesia.