

# EU Quality Assurance Certificate

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



**Certificate Number:** M.2023.MDR.1011

**Manufacturer Name** : MHK Medikal Tekstil San. Tic. Ltd. Şti.  
**Manufacturer Address** : Körkün Mah. Hidayet Cad. No:23/1 Oğuzeli 27120, Gaziantep,  
Türkiye  
**Single registration number-SRN** : TR-MF-000018593  
**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.1183  
**Date of Issue** : 24.02.2023  
**Recertification Date** : -  
**Reissue Date/No** : -  
**Date of Expiry** : 23.02.2028

**UDEM Adriatic d.o.o.**  
**General Manager**



**If any, Previous Certificate(s) No:** NA

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## PRODUCT LIST COVERED BY THE CERTIFICATE

PRODUCT NAME	RISK CLASS	EMDN CODE	MODEL/TYPE		
STERILE DISPOSABLE SURGICAL GOWNS	Class Is	T020401	STANDARD SURGICAL GOWN Small, Medium, Large, XLarge, XXLLarge, XXXLarge		
			STANDARD SURGICAL GOWN WITH WRAPPING Small, Medium, Large, XLarge, XXLLarge, XXXLarge		
		T020402	REINFORCED SURGICAL GOWN Small, Medium, Large, XLarge, XXLLarge, XXXLarge		
			REINFORCED SURGICAL GOWN WITH WRAPPING Small, Medium, Large, XLarge, XXLLarge, XXXLarge		
			FULL REINFORCED SURGICAL GOWN Small, Medium, Large, XLarge, XXLLarge		
		T020499	TUR UROLOGY GOWN Small, Medium, Large, XLarge, XXLLarge		
		STERILE DISPOSABLE SURGICAL DRAPES	Class Is	T020199	PLAIN DRAPE 50*50cm, 75*75cm, 75*90cm, 100*150cm, 85*90cm, 160*180cm, 100*100cm, 120*150cm, 150*200cm, 150*250cm, 75*80cm, 65*125cm
					SIDED DRAPE 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	TUBE HOLDER 9*18cm				
T020102	E.N.T DRAPE				
	DENTAL DRAPE				
T030199	MAYO STAND COVER 75*150cm, 78*145cm, 80*150cm				
	BACK TABLE COVER 100*120cm, 100*130cm, 100*150cm, 130*150cm, 150*150cm, 150*200cm, 200*200cm				
T020102	U SPLIT DRAPE 150*200cm, 200*260cm, 220*300cm				
	LAPOROSCOPY DRAPE 240*320cm				
	BY-PASS (CARDIOVASCULAR) DRAPE 240*300cm				
	ANGIOGRAPHY (FEMORAL) DRAPE 1				
	ANGIOGRAPHY (FEMORAL) DRAPE 2				
	ANGIOGRAPHY (FEMORAL) DRAPE 3				
	ANGIOGRAPHY (FEMORAL) DRAPE 150*330cm, 200*300cm				
CRANIOTOMY DRAPE 220*320cm					

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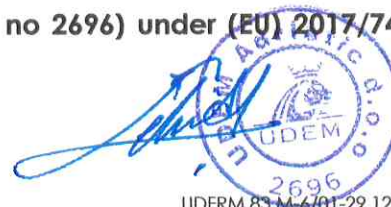
Certificate Number: M.2023.MDR.1011

		ARTHROSCOPY DRAPE 220*320cm
		UPPER EXTREMITY DRAPE 200*300cm
		LOWER EXTREMIT DRAPE 200*310cm
		T.U.R (UROLOGY) DRAPE 180*240cm
		CYSTOSCOPY DRAPE 75*150cm
		PERCUTANEOUS DRAPE 150*300cm
		CESEREAN DRAPE 200*300cm
		EYE DRAPE WITH SINGLE POUCHE 100*130cm
		EYE DRAPE WITH DOUBLE POUCHE 150*200cm
	T020199	SURGICAL DRAPE 240*340cm
		ANESTESIA DRAPE 150*180cm
		FOOT DRAPE 150*180cm
	T020102	LAPOROSCOPY DRAPE 180*240cm
		MINOR FENESTRATED DRAPE
		GENERAL OPERATION DRAPE
		HALF DRAPE
		HEAD DRAPE
		SPINAL DRAPE
		HIPPACK WITH U SPLIT
		GYNECOLOGY DRAPE
		PATIENT DRAPE
		UROLOGY DRAPE
		PEDIATRIC LAPOROTOMY DRAPE
	T030202	CAMERA COVER
	T02010102	IOBANLI INSIZYON DRAPE
	T020199	STERILE OPERATION TABLE DRAPE
	T030299	MICROSCOPE COVER
		SCOPY COVER
		FLUOROSCOPY COVER

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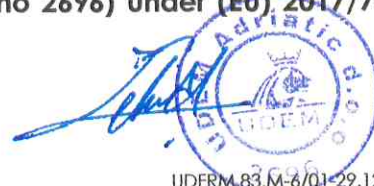
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		T030199	DISPOSABLE STERILE WASTE COLLECTION POUCHE 50*60cm		
			DISPOSABLE STERILE LIQUID COLLECTION POUCHE 40*40cm, 35*40cm		
			DISPOSABLE STERILE PORTABLE BAG PVC		
			DISPOSABLE STERILE INSTRUMENT PACK 2 COMPARTMENTS		
			DISPOSABLE STERILE INSTRUMENT PACK 3 COMPARTMENTS		
			DISPOSABLE STERILE LIQUID COLLECTION BAG WITH BARRIER		
			BARRIER-FREE DISPOSABLE STERILE LIQUID COLLECTION BAG		
		T020199	BIFLEX MEDIKAL DRAPE 40*120cm, 50*75cm		
			SLIT ORTHOPEDIC COVER		
			LEG COVER		
		STERILE DISPOSABLE SURGICAL DRAPES PACKS	Class Is	T0202	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					
STERILE DISPOSABLE SURGICAL HEART VALVE DRAPE PACK					
STERILE DISPOSABLE SURGICAL HEART VALVE DRAPE PACK 1					
STERILE DISPOSABLE SURGICAL HEART VALVE DRAPE PACK 2					
STERILE DISPOSABLE SURGICAL ANGIOGRAPHY DRAPE PACK					
STERILE DISPOSABLE SURGICAL ANGIOGRAPHY DRAPE PACK WITH PANEL					
STERILE DISPOSABLE SURGICAL CRANIOTOMY DRAPE PACK					
STERILE DISPOSABLE SURGICAL LAMINECTOMY DRAPE PACK					
STERILE DISPOSABLE SURGICAL ARTHROSCOPY DRAPE PACK					
STERILE DISPOSABLE SURGICAL ARTHROSCOPY DRAPE PACK WITH POUCHE					
STERILE DISPOSABLE SURGICAL LOWER EXTREMITY DRAPE PACK					
STERILE DISPOSABLE SURGICAL UPPER EXTREMITY DRAPE PACK					
STERILE DISPOSABLE SURGICAL HIP DRAPE PACK					
STERILE DISPOSABLE SURGICAL TUR (UROLOGY) DRAPE PACK					
STERILE DISPOSABLE SURGICAL CYSTOSCOPY DRAPE PACK					
STERILE DISPOSABLE SURGICAL PERCUTANEOUS DRAPE PACK					

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			STERILE DISPOSABLE SURGICAL DELIVERY DRAPE PACK WITH POUCHE
			STERILE DISPOSABLE SURGICAL DELIVERY DRAPE PACK WITHOUT POUCHE
			STERILE DISPOSABLE SURGICAL CESAREAN DRAPE PACK
			STERILE DISPOSABLE SURGICAL EYE DRAPE PACK WITH SINGLE POUCHE
			STERILE DISPOSABLE SURGICAL EYE DRAPE PACK WITH DOUBLE POUCHE
			STERILE DISPOSABLE SURGICAL GYNECOLOGICAL OPU DRAPE PACK
			STERILE DISPOSABLE SURGICAL E.N.T. DRAPE PACK
			STERILE DISPOSABLE SURGICAL MINOR SURGICAL DRAPE PACK
			STERILE DISPOSABLE SURGICAL IMPLANT DRAPE PACK
			STERILE DISPOSABLE SURGICAL DENTAL DRAPE PACK
			STERILE DISPOSABLE SURGICAL LAPOROTOMY DRAPE PACK
			STERILE DISPOSABLE SURGICAL CHEMOTHERAPY DRAPE PACK
			STERILE DISPOSABLE SURGICAL CHEMOTHERAPY DELETION DRAPE PACK
			STERILE DISPOSABLE SURGICAL CIRCUMCISION DRAPE PACK
			STERILE DISPOSABLE SURGICAL LITOTOMY DRAPE PACK
			STERILE DISPOSABLE SURGICAL HAND SURGICAL DRAPE PACK
			STERILE DISPOSABLE SURGICAL BARIATRIC DRAPE PACK
			STERILE DISPOSABLE SURGICAL SHOULDER ARTHROSCOPY DRAPE PACK
			STERILE DISPOSABLE SURGICAL SHOULDER ARTHROSCOPY DRAPE PACK WITH POUCHE
			STERILE DISPOSABLE SURGICAL EPIDURAL DRAPE PACK
			STERILE DISPOSABLE SURGICAL ABORTION DRAPE PACK
			STERILE DISPOSABLE SURGICAL ORTHOPEDICS DRAPE PACK
			STERILE DISPOSABLE SURGICAL U SLIT DRAPE PACK
			STERILE DISPOSABLE SURGICAL ANESTHESIA DRAPE PACK

Conditions for or limitations to the validity of this certificate : None



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## CERTIFICATE HISTORY

Rev. No.	Rev. Date	Description of Revision
00	24.02.2023	Initial Certification



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# DECLARATION OF CONFORMITY



**Company Name** : MHK MEDİKAL TEKSTİL SAN. TIC. LTD. STİ  
**Address** : KORKUN MAHALLESİ HIDAYET CADDESİ NO 23 OGUZELİ /  
GAZİANTEP / TURKEY  
**Product Name** : Disposable Sterile Surgical Sets, Drapes, Gowns, Suit  
**Brand** : MHK MEDİKAL TEKSTİL  
**Sterile** : Yes  
**Classification** : **According to Annex VIII of Regulation (Eu) 2017/745 (Medical  
Device Regulation (MDR) Non-Invasive, Non-Active Medical  
Device, Class I Sterile, Rule I**  
**Conformity Assessment** : According to Regulation (EU) 2017/745 on medical devices Annex -  
XI Part A PRODUCT COMFORMITY VERYFICATION

**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.

**STANDARDS APPLIED :**

EN ISO 13485	EN ISO 11135	EN ISO 14698-1
EN ISO 15223-1	EN ISO 11137-1	EN ISO 14698-2
EN ISO 13795-1-3	EN ISO 13938-1	EN ISO 9001
EN ISO 11607-1	EN ISO 11607-2	EN ISO 9073-6

PRODUCT NAME	EMDN CODE	CUSTOMER REF
<b>STERILE DISPOSABLE PRODUCTS SET</b>		
Universal large set	T0202	Marco2023-950
Set for maxillofacial surgery	T0202	Marco2023-951
Universal small set	T0202	Marco2023-952
Set for varicose veins of the lower limbs	T0202	Marco2023-953
Caesarean section kit	T0202	Marco2023-954
Partition kit	T0202	Marco2023-955
Laparoscopy kit	T0202	Marco2023-956

**Notified Body Number** : 2696  
**Certification Date** : 24.02.2023  
**Expiry Date** : 23.02.2028

**Place/Date** : GAZİANTEP / 12.12.2023  
**Authorized Person** : MURAT KEKEÇ

Signature, Stamp  
**MHK MEDİKAL TEKSTİL  
SAN. VE TİC. LTD. ŞTİ.**  
Körkün Mahallesi Hıdırel Çaddesi No:2311 Oğuzeli  
Tlf.: 0342 341 93 66 Faks: 0341 93 67 GAZİANTEP  
Tic.Sicil No: 40345 SUBURCU V.D: 620 056 1920