

# 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 DRAPE	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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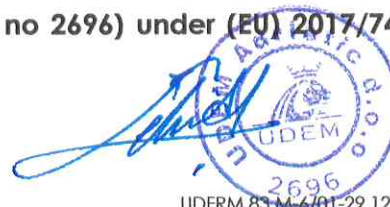
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			ARTHROSCOPY DRAPE 220*320cm
			UPPER EXTREMITY DRAPE 200*300cm
			LOWER EXTREMIT DRAPE 200*310cm
			T.U.R (UROLOGY) DRAPE 180*240cm
			CYSTOSCOPY DRAPE 75*150cm
			PERCUTANEOUS DRAPE 150*300cm
			CESEREAN DRAPE 200*300cm
			EYE DRAPE WITH SINGLE 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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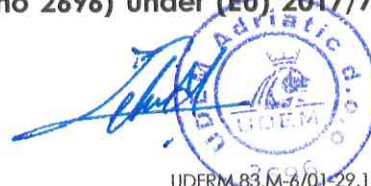
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		T030199	DISPOSABLE STERILE WASTE COLLECTION POUCHE 50*60cm
			DISPOSABLE STERILE LIQUID COLLECTION POUCHE 40*40cm, 35*40cm
			DISPOSABLE STERILE PORTABLE BAG PVC
			DISPOSABLE STERILE INSTRUMENT PACK 2 COMPARTMENTS
			DISPOSABLE STERILE INSTRUMENT 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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