

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 : 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.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

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

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	RISK CLASS	EMDN CODE	MODEL/TYPE		
STERILE DISPOSABLE SURGICAL GOWNS	Class Is	T020401	STANDARD SURGICAL GOWN Small, Medium, Large, XLarge, XXLarge, XXXLarge		
			STANDARD SURGICAL GOWN WITH WRAPPING Small, Medium, Large, XLarge, XXLarge, XXXLarge		
		T020402	REINFORCED SURGICAL GOWN Small, Medium, Large, XLarge, XXLarge, XXXLarge		
			REINFORCED SURGICAL GOWN WITH WRAPPING Small, Medium, Large, XLarge, XXLarge, XXXLarge		
			FULL REINFORCED SURGICAL GOWN Small, Medium, Large, XLarge, XXLarge		
		T020499	TUR UROLOGY GOWN Small, Medium, Large, XLarge, XXLarge		
		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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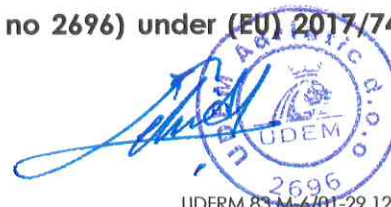
Certificate Number: M.2023.MDR.1011

			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
			LAPOROSCOPY DRAPE 180*240cm
			MINOR FENESTRATED DRAPE
			GENERAL OPERATION DRAPE
			HALF DRAPE
			HEAD DRAPE
		T020102	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
			MICROSCOPE COVER
		T030299	SCOPY COVER
			FLUOROSCOPY COVER

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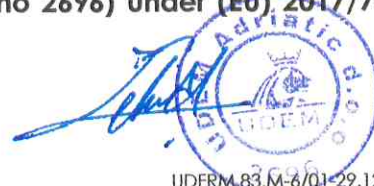
Certificate Number: M.2023.MDR.1011

		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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CERTIFICATE

MHK Medikal Tekstil
Sanayi ve Ticaret Limited Şirketi

Körkün Mah. Hidayet Cad. No:23/1 Oğuzeli GAZIANTEP / TURKEY

ISO 13485:2016

Scope: Manufacturing, sales and export of sterile and non-sterile disposable surgical gown, patient gown, patient wearings, aprons and surgical sets, purchasing, sales, export and import of sterile and non-sterile surgical glove, examination glove, pe glove, masks, bonnets, galosh, bistoury, drop set, serum sets, wooden tongue spatula

Hereby, AKSSERT Audit and Certification Ltd. Co., certifies that the above stated company gave the appropriate management system according to the requirements of the above standard. This certificate valid for 3 years since the decision date as long as the system is effectively maintained and surveillance audits are carried out. The validity of certificate can be checked through www.akssert.com, www.jas-anz.org/register. The Certificate is property of AKSSERT Audit and Certification Ltd. Co. and shall be returned if requested.

The reference standard is ISO 13485:2016

AKSSERT Audit and
Certification Ltd. Co.



Certificate Number : 85091
Registration Date : 04.09.2013
Previous Certification Cycle Expiry Date: 03.09.2022
Recertification Audit Date: 15.03.2022

Reissue Date : 22.08.2022
Revision Date/No : -
Expiry Date : 03.09.2025

Address: Mutlukent Mahallesi 1920. Cadde No:28 Çankaya/ANKARA - TÜRKİYE
Phone: +90 312 284 99 44(pbx)

E-mail: info@akssert.com Web: www.akssert.com



TÜRK STANDARDLARI ENSTİTÜSÜ

TÜRK STANDARDLARINA UYGUNLUK BELGESİ

TURKISH STANDARDS INSTITUTION

CERTIFICATE OF CONFORMITY TO TURKISH STANDARDS

Markanın Tanımı Description of the Mark



BELGE NUMARASI

REFERENCE NUMBER OF LICENCE

144138-TSE-01/02

BELGENİN İLK VERİLİŞ TARİHİ

DATE OF FIRST ISSUE OF LICENCE

26.09.2017

BELGENİN SON GEÇERLİLİK TARİHİ

LICENCE VALID UNTIL

26.09.2023

BELGE SAHİBİ KURULUŞUN ADI

NAME OF THE LICENCE HOLDER

MHK MEDİKAL TEKSTİL SANAYİ VE TİCARET LİMİTED
ŞİRKETİ

BELGE SAHİBİ KURULUŞUN ADRESİ

ADDRESS OF THE LICENCE HOLDER

KÖRKÜN MAH. HİDAYET CAD. /1 NO:23 OĞUZELİ
GAZİANTEP/TÜRKİYE

ÜRETİM YERİ ADI

NAME OF THE MANUFACTURING PLACE

MHK MEDİKAL TEKSTİL SAN. VE TİC. LTD. ŞTİ.

ÜRETİM YERİ ADRESİ

ADDRESS OF THE MANUFACTURING PLACE

KÖRKÜN MH. HİDAYET CD NO:23/1 GAZİANTEP / TÜRKİYE

İPTAL EDİLEN BELGE NUMARASI (Varsa)

INDICATION OF SUPERSEDED LICENCE (if any)

144138-TSE-01/01

TESCİLLİ TİCARİ MARKASI

REGISTERED TRADE MARK

mhk medikal

İLGİLİ TÜRK STANDARDI

RELATED TURKISH STANDARD

TS EN 13795-1 / 30.09.2019

BELGE KAPSAMI

SCOPE OF LICENCE

Cerrahi giysiler ve örtüler – Gereklilikler ve deney yöntemleri – Bölüm 1: Cerrahi örtüler ve önlükler

-CERRAHİ ÖRTÜLER-YÜKSEK PERFORMANS,KRİTİK ÜRÜN ALANI,TEK KULLANIMLIK
-CERRAHİ ÖNLÜKLER-YÜKSEK PERFORMANS,KRİTİK ÜRÜN ALANI,TEK KULLANIMLIK

Cerrahi giysiler ve örtüler – Gereklilikler ve deney yöntemleri – Bölüm 1: Cerrahi örtüler ve önlükler

-CERRAHİ ÖRTÜLER-YÜKSEK PERFORMANS,DAHA AZ KRİTİK ÜRÜN ALANI,TEK KULLANIMLIK
-CERRAHİ ÖNLÜKLER-YÜKSEK PERFORMANS,DAHA AZ KRİTİK ÜRÜN ALANI,TEK KULLANIMLIK

e-imzalı/e-signed

16.09.2022

Belgelendirme Merkezi Başkanı Adına
RIZA BUĞRA ALP GİRAY OKUMUŞ

GAZİANTEP BELGELENDİRME MÜDÜRÜ