

# 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

**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

# 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

## 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					

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



# EU Quality Assurance Certificate

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



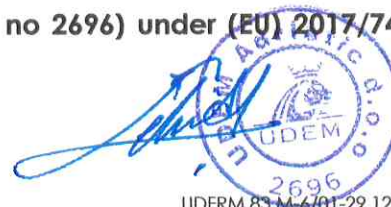
Certificate Number: M.2023.MDR.1011

		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

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



# EU Quality Assurance Certificate

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



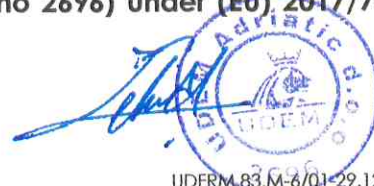
Certificate Number: M.2023.MDR.1011

		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					

**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



# 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

			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



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

# 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

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



**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

akssert

# 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](http://www.akssert.com), [www.jas-anz.org/register](http://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](mailto:info@akssert.com) Web: [www.akssert.com](http://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



<b>BELGE NUMARASI</b> REFERENCE NUMBER OF LICENCE	144138-TSE-01/02
<b>BELGENİN İLK VERİLİŞ TARİHİ</b> DATE OF FIRST ISSUE OF LICENCE	26.09.2017
<b>BELGENİN SON GEÇERLİLİK TARİHİ</b> LICENCE VALID UNTIL	26.09.2023
<b>BELGE SAHİBİ KURULUŞUN ADI</b> NAME OF THE LICENCE HOLDER	MHK MEDİKAL TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
<b>BELGE SAHİBİ KURULUŞUN ADRESİ</b> ADDRESS OF THE LICENCE HOLDER	KÖRKÜN MAH. HİDAYET CAD. /1 NO:23 OĞUZELİ GAZİANTEP/TÜRKİYE
<b>ÜRETİM YERİ ADI</b> NAME OF THE MANUFACTURING PLACE	MHK MEDİKAL TEKSTİL SAN. VE TİC. LTD. ŞTİ.
<b>ÜRETİM YERİ ADRESİ</b> ADDRESS OF THE MANUFACTURING PLACE	KÖRKÜN MH. HİDAYET CD NO:23/1 GAZİANTEP / TÜRKİYE
<b>İPTAL EDİLEN BELGE NUMARASI (Varsa)</b> INDICATION OF SUPERSEDED LICENCE (if any)	144138-TSE-01/01
<b>TESCİLLİ TİCARİ MARKASI</b> REGISTERED TRADE MARK	mhk medikal
<b>İLGİLİ TÜRK STANDARDI</b> RELATED TURKISH STANDARD	TS EN 13795-1 / 30.09.2019
<b>BELGE KAPSAMI</b> 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