

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 01 din 08.09.2023

Solicitantul „**MedGlobalFarm**” SRL, cu sediul **R.Moldova, mun.Chisinau,**
str.Miron Costin 17/7, of.71, tel./fax: 022-523090, e-mail
medglobalfarm@mail.ru, solicit înregistrarea în Registrul de stat al dispozitivelor
medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea
și punerea la dispoziție pe piață a:

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Câmp steril super absorbant 55x70 cm	Super absorbent sterile field 55x70 cm	Super absorbent sterile field 55x70 cm	47783
2		Set steril getabil pentru intervenții diagnostice	Disposable sterile set for diagnostic interventions	Disposable sterile set for diagnostic interventions	47783
3		Set steril getabil pentru intervenții endovasculare majore	Disposable sterile set for major endovascular interventions	Disposable sterile set for major endovascular interventions	47783
4		Set steril getabil pentru intervenții angiografice majore	Disposable sterile set for major angiographic interventions	Disposable sterile set for major angiographic interventions	47783
5		Set steril getabil pentru intervenții angiografice diagnostice	Disposable sterile set for diagnostic angiographic interventions	Disposable sterile set for diagnostic angiographic interventions	47783
6		Set steril getabil pentru angiografie	Disposable sterile set for angiography	Disposable sterile set for angiography	47783
7		Set steril getabil pentru angiografie prin abord radial	Disposable sterile set for radial approach angiography	Disposable sterile set for radial approach angiography	47783
8		Halat chirurgical steril marimea XL	STANDARD SURGICAL GOWN XL	STANDARD SURGICAL GOWN XL	47783
9		Halat chirurgical steril marimea XXL	STANDARD SURGICAL GOWN XXL	STANDARD SURGICAL GOWN XXL	47783

Se anexează următoarele acte:

declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
certificatul de conformitate CE valabil pentru dispozitivele fabricate;
actul prin care producătorul își desemnează reprezentantul/

Data 13.10.2023

Semnătura



Tablelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	



MHK MEDİKAL
TEKSTİL

EU DECLARATION OF CONFORMITY

CE
2696

Manufacturer Name : MHK MEDİKAL TEKSTİL SAN. TIC. LTD. STİ
Address : K rk n Mahallesi Hidayet Caddesi No:23/1 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 MEDİKAL
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 Assessment : 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.

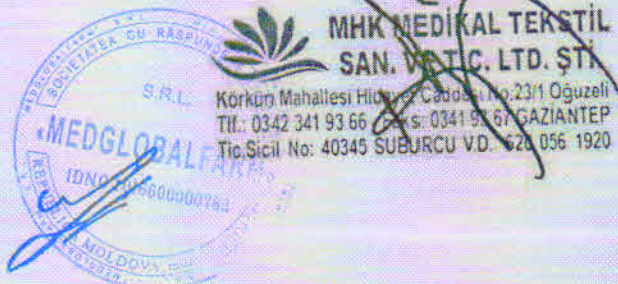
STANDARDS APPLIED :

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 / 18.07.2023
Authorized Person : MURAT KEKEÇ
Title : General Manager

Signature, Stamp



ANNEX I: LIST OF THE PRODUCTS:

Document ID: TD-09 / 10

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	
			T020499- SURGICAL GOWNS, OTHERS	TUR UROLOGY GOWN	Large	
					XLarge	
					XXLarge	
					55*70cm	
					75*75cm	
					75*90cm	
					100*150cm	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.
					85*90cm	
					160*180cm	
					100*100cm	
					120*150cm	
					150*200cm	
					150*250cm	
					75*80cm	
					65*125cm	
					-	
					50*50cm	
					75*75cm	
					75*90cm	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	
					75*100cm	
					150*240cm	
					10*30cm	
					10*50cm	
					100*100cm	
					100*120cm	
					75*80cm	
					75*80cm	

STERILE
DISPOSABLE
SURGICAL
DRAPES

0868082921DRPGWNFX

Class
Is

T020199-
SURGICAL
DRAPES -
OTHERS

PLAIN DRAPE

STERILE
DISPOSABLE
SURGICAL
DRAPES

0868082921DRPGWNFX

Class
Is

T020199-
SURGICAL
DRAPES -
OTHERS

SIDED DRAPE

OP TAPE

BABY DRAPE

ADHESIVE
TAPE DRAPE



PRODUCT NAME	RISK CLASS	EMDN CODE	REF CODE	UDI-DI
Disposable sterile set for diagnostic interventions	Class Is	T0202	01-051-02	8680829215445
Disposable sterile set for major endovascular interventions	Class Is	T0202	01-051-02	8680829215445
Disposable sterile set for major angiographic interventions	Class Is	T0202	03-052-01	8680829215438
Disposable sterile set for diagnostic angiographic interventions	Class Is	T0202	03-052-01	8680829215438
Disposable sterile set for angiography	Class Is	T0202	03-052-01	8680829215438
Disposable sterile set for radial approach angiography	Class Is	T0202	03-052-01	8680829215438
Sterile surgical hood (gown) size XL	Class Is	T020401	16-041-04	8680829211041
Sterile surgical hood (gown) size XXL	Class Is	T020401	16-041-05	8680829211058



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, 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 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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Medical Devices Regulation (EU) 2017/745 Annex XI Part A
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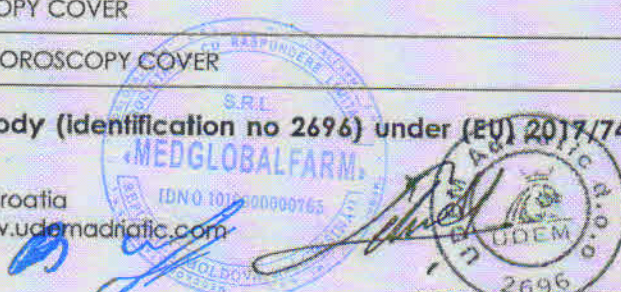
Certificate Number: M.2023.MDR.1011

		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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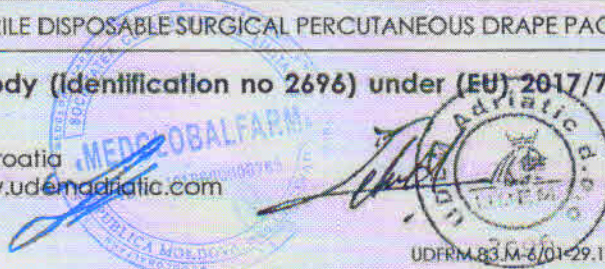


Certificate Number: M.2023.MDR.1011

		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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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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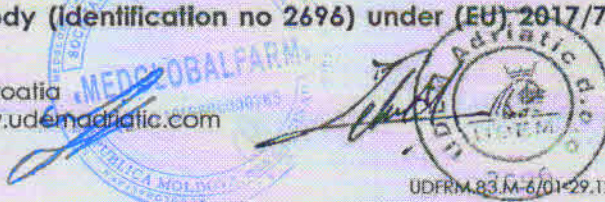


Certificate Number: M.2023.MDR.1011

		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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EU Quality Assurance Certificate

Medical Devices Regulation (EU) 2017/745 Annex XI Part A
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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.

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EU Quality Assurance Certificate

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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



AUTHORIZATION LETTER

We, **MHK MEDİKAL TEKSTİL SAN. VE TİC. LTD. ŞTİ.** manufacturer of the Disposable Sterile Surgical Gowns, Drapes and Packs, having our factory at Korkun Mah. Hidayet Cad. No:23, Oğuzeli, Gaziantep, Turkey hereby authorize,

MED GLOBALFARM SRL
Str. Miron Costin 17/7, of.71
Chişinău, 2068
Moldova

to register, promote and distribute our products, participate tenders for all **MHK MEDİKAL TEKSTİL SAN. VE TİC. LTD. ŞTİ.** products in Moldova.

This letter is valid until 31.12.2025.

Sincerely yours,

11.10.2023
Gaziantep, Turkey

Signature:



Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: Medglobalfarm SRL, cu sediul mun. Chișinău, str. Miron Costin
17/7, of. 71,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al
Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate
pentru notificarea dispozitivului medical:

Câmp steril super absorbant 55x70 cm

Set steril getabil pentru intervenții diagnostice

Set steril getabil pentru intervenții endovasculare majore

Set steril getabil pentru intervenții angiografice majore

Set steril getabil pentru intervenții angiografice diagnostice

Set steril getabil pentru angiografie

Set steril getabil pentru angiografie prin abord radial

Halat chirurgical steril marimea XL

Halat chirurgical steril marimea XXL

Sunt autentice și corespund realității.

Director general Granaci Boris



Semnătura

Data 13.10.2023