

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.1022

Manufacturer Name : Bayteks Teknik Tekstil San. ve Tic. A.Ş.
Manufacturer Address : Organize Sanayi Bölgesi 19 Nolu Cad. No:11/2 Merkez,
Kilis, Türkiye
Single registration number-SRN : TR-MF-000024488
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.1484
Date of Issue : 09/08/2023
Recertification Date : -
Reissue Date/No : -
Date of Expiry : 08/08/2028

UDEM Adriatic d.o.o.
General Manager



If any, Previous Certificate(s) No:

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
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PRODUCT LIST COVERED BY THE CERTIFICATE

PRODUCT NAME	RISK CLASS	MODEL/TYPE	EMDN
Steril Surgical Gown,	Is	STANDARD SURGICAL GOWN	T020401
		REINFORCED SURGICAL GOWN	T020402
		DISPOSABLE BOX GOWN STERILE	T020499
		PEDIATRIC SURGICAL GOWN ADULT SURGICAL GOWN	
Steril Surgical Drape,	Is	OPHTHALMIC DRAPE WITHOUT POUCH	T0201
		MINOR SURGERY DRAPE	
		FENESTRATED DRAPE L DISPOSABLE	
		DISPOSABLE BACK TABLE COVER	
		DISPOSABLE FENESTRATED DRAPE	
		DISPOSABLE TUR DRAPE	
		DISPOSABLE BACK TABLE COVER	
		MINOR SURGERY DRAPE	
		OPHTHALMIC DRAPE WITHOUT POUCH	
		BACK TABLE COVER	
		DISPOSABLE BACK TABLE COVER	
		DISPOSABLE BACK TABLE COVER	
		SINGLE POUCH OPHTHALMIC DRAPE	
		MINOR SURGERY DRAPE	
		DENTAL UNIT TABLE DRAPE	
		DISPOSABLE INCONTINENCE DRAPE	
		MINOR SURGERY DRAPE	
		SINGLE POUCH SPECULUM OPHTHALMIC DRAPE	
		DOUBLE POUCH OPHTHALMIC DRAPE	
		DISPOSABLE POST PARTUM SURGERY DRAPE	
		DOUBLE POUCH EXIMER LASER OPHTHALMIC DRAPE	
		SINGLE POUCH EXCIMER LASER OPHTHALMIC DRAPE	
		FENESTRATED DRAPE	
		SHUNT DRAPE	
		VERTEBRA SURGERY DRAPE DOUBLE TAPED	
		LUMBAR DISK FENESTRATED DRAPE	
		TUR DRAPE	
		IVF DRAPE	
		ANGIOGRAPHY DRAPE	
		SHOULDER ARTHROSCOPY DRAPE	
		ARTHROSCOPY DRAPE WITH POUCH	
		FENESTRATED (RECTANGULAR) DRAPE WITH TAPE	
		ANGIOGRAPHY DRAPE	
		CESAREAN DRAPE	
		MAYO TABLE COVER	
		ARTHROSCOPY DRAPE	
		VERTICAL ISOLATION DRAPE WITH POUCH	
		ARTROSCOPY MAIN DRAPE	
		HYSTEROSCOPY DRAPE	
		VERTEBRA DRAPE DOUBLE TAPED	
		BY PASS DRAPE	
		KNEE SURGERY DRAPE	
		ENDOSCOPY DRAPE FENESTRATED	
		DELIVERY LAPAROSCOPIC OVAL FENESTRATED DRAPE	
		U SPLIT DRAPE	
		OB DRAPE	
		INVITRO SURGERY DRAPE	
		TUR DRAPE WITH POUCH	

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		HIP SURGERY DRAPE TUR DRAPE EXTREMITY DRAPE THYROID DRAPE CRANIOTOMY DRAPE PERCUTANEOUS DRAPE BY PASS DRAPE PE U SPLIT DRAPE HIP SURGERY DRAPE CARDIOVASCULAR SURGERY DRAPE BOTTOM U SPLIT DRAPE LUMBAR DISC FENESTRATED DRAPE ENT U SPLIT DRAPE GYNAECOLOGY DRAPE ABDOMINAL DRAPE UNDERBUTTOCKS DRAPE HAND SURGERY UNDERPATIENT DRAPE BYPASS UNDERPATIENT DRAPE CYSTOSCOPY DRAPE DRAPE WITH POUCH OPHTHALMIC DRAPE WITH POUCH FOOT DRAPE HAND DRAPE FEMORAL RADIAL ANGIOGRAPHY DRAPE CAESAREAN DRAPE ARTHROSCOPY DRAPE WITH POUCH SIDE BANDED DRAPE CRANIOTOMY DRAPE FLAT COVER DISPOSABLE BACK TABLE COVER PERFORATED HAND DRAPE ANESTHESIA COVER PERFORATED SLEEVE DRAPE ADHESIVE DRAPE ANESTHESIA COVER BANDED DRAPE ENT DRAPE BANDED DRAPE SIDE BANDED DRAPE FLAT COVER BACK TABLE COVER FENESTRATED SPINAL DRAPE ANESTHESIA COVER TUR DRAPE WITH POUCH SPINAL VERTEBRA DRAPE DENTAL UNIT HEAD DRAPE DENTAL UNIT DRAPE	
Steril Non-Surgical Drape,	Is	STERILIZATION CREPE PAPER STERILIZATION WRAP PAPER STERILIZATION WRAP/COVER PAPER SCOPY COVER FLUOROSCOPY COVER SHOES COVER LEG COVER DISPOSABLE POUCH FOOT DRAPE STERILE	T0210
Steril Surgical Pack,	Is	ARM SURGERY DRAPE PACK ADULT ANGIOGRAPHY DRAPE PACK LAPAROSCOPY DRAPE PACK BIG BUNDLE SET IVF DRAPE PACK SPINAL DRAPE PACK URS DRAPE PACK	T0202

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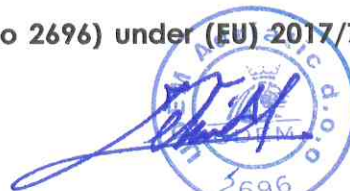
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		TUR DRAPE PACK VERTEBRA SURGEY DRAPE PACK ENDOSCOPY DRAPE PACK DELIVERY DRAPE PACK ARTHROSCOPY DRAPE PACK BYPASS DRAPE PACK KNEE SURGERY DRAPE PACK ET DRAPE PACK HAND SURGERY DRAPE PACK HYSTEROGRAPHY DRAPE PACK HIP SURGERY DRAPE PACK WITH LATEX CRANIOTOMY DRAPE PACK ENT DRAPE PACK LUMBAR SURGERY DRAPE PACK OPHTHALMIC DRAPE PACK SURGICAL DRAPE PACK STERILE PERCUTANEOUS NEPHROLITOTOMY DRAPE PACK PERCUTANEOUS DRAPE PACK CESAREAN DRAPE PACK ARTHROPLASTY / HIP SURGERY PACK BIOPSY DRAPE PACK SURGICAL DRAPE PACK DENTAL SURGERY DRAPE PACK STERILE DELIVERY DRAPE PACK EXTREMITY DRAPE PACK GOITER / THYROID SURGERY DRAPE PACK HIP SURGERY DRAPE PACK WITHOUT LATEX CARDIOVASCULAR SURGERY DRAPE PACK ENT DRAPE PACK SHOULDER ARTHROSCOPY DRAPE PACK ARTHROSCOPY DRAPE PACK WITH POUCH SHUNT DRAPE PACK LAPAROSCOPY DRAPE PACK OB DRAPE PACK ORTHOPAEDIC DRAPE PACK ARTHROSCOPY DRAPE PACK HYSTEROGRAPHY DRAPE PACK IVF DRAPE PACK PEDIATRIC ANGIOGRAPHY DRAPE PACK FEMORAL ANGIOGRAPHY DRAPE PACK RADIAL ANGIOGRAPHY DRAPE PACK TUR PACK ANGIOGRAPHY PACK SHOULDER ARTHROSCOPY PACK VERTEBRA PACK SPINAL VERTEBRA PACK CYSTOSCOPY PACK ENT PACK HEART SURGERY PACK OPU GYNAECOLOGY PACK CESAREAN PACK DELIVERY PACK UNIVERSAL PACK CRANIOTOMY PACK PEDIATRIC ANGIOGRAPHY PACK PERCUTANEOUS PACK HAND SURGERY PACK HEART VALVE SURGERY PACK ADULT ANGIOGRAPHY PACK OPHTHALMIC PACK ARTHROSCOPY DRAPE PACK HEART VALVE SURGERY PACK GENERAL SURGERY PACK	
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		DELIVERY DRAPE PACK CESEREAN DRAPE PACK OPU GYNAECOLOGY PACK TUR PACK CRANIOTOMY PACK HAND SURGERY DRAPE PACK OPHTHALMIC PACK VERTEBRA SURGEY DRAPE PACK OPHTHALMIC PACK PIP OPHTHALMIC PACK PGN ANGIOGRAPHY PACK CTR ANGIOGRAPHY PACK 4H OPHTHALMIC PACK OIK OPHTHALMIC PACK OPL CARDIOVASCULAR SURGERY DRAPE PACK TUR PACK ARTHROSCOPY DRAPE PACK CRANIOTOMY PACK HEART VALVE SURGERY PACK HAND SURGERY DRAPE PACK GENERAL SURGERY PACK DELIVERY DRAPE PACK CESEREAN DRAPE PACK PERCUTANEOUS PACK ANGIOGRAPHY PACK OPU GYNAECOLOGY PACK CARDIOVASCULAR SURGERY DRAPE PACK ENT DRAPE PACK OPHTHALMIC PACK PERCUTANEOUS DRAPE PACK CYSTOSCOPY DRAPE PACK VERTEBRA SURGEY DRAPE PACK CYSTOSCOPY DRAPE PACK MINOR SURGERY PACK	
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Conditions for or limitations to the :
validity of this certificate

CERTIFICATE HISTORY		
Rev. No.	Rev. Date	Description of Revision
00	09/08/2023	Initial Certification



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