

# 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.**

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

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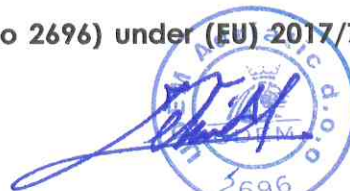
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|--|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  |  | <p>TUR DRAPE PACK<br/>VERTEBRA SURGEY DRAPE PACK<br/>ENDOSCOPY DRAPE PACK<br/>DELIVERY DRAPE PACK<br/>ARTHROSCOPY DRAPE PACK<br/>BYPASS DRAPE PACK<br/>KNEE SURGERY DRAPE PACK<br/>ET DRAPE PACK<br/>HAND SURGERY DRAPE PACK<br/>HYSTEROSCOPY DRAPE PACK<br/>HIP SURGERY DRAPE PACK WITH LATEX<br/>CRANIOTOMY DRAPE PACK<br/>ENT DRAPE PACK<br/>LUMBAR SURGERY DRAPE PACK<br/>OPHTHALMIC DRAPE PACK<br/>SURGICAL DRAPE PACK STERILE<br/>PERCUTANEOUS NEPHROLITOTOMY DRAPE PACK<br/>PERCUTANEOUS DRAPE PACK<br/>CESAREAN DRAPE PACK<br/>ARTHROPLASTY / HIP SURGERY PACK<br/>BIOPSY DRAPE PACK<br/>SURGICAL DRAPE PACK<br/>DENTAL SURGERY DRAPE PACK STERILE<br/>DELIVERY DRAPE PACK<br/>EXTREMITY DRAPE PACK<br/>GOITER / THYROID SURGERY DRAPE PACK<br/>HIP SURGERY DRAPE PACK WITHOUT LATEX<br/>CARDIOVASCULAR SURGERY DRAPE PACK<br/>ENT DRAPE PACK<br/>SHOULDER ARTHROSCOPY DRAPE PACK<br/>ARTHROSCOPY DRAPE PACK WITH POUCH<br/>SHUNT DRAPE PACK<br/>LAPAROSCOPY DRAPE PACK<br/>OB DRAPE PACK<br/>ORTHOPAEDIC DRAPE PACK<br/>ARTHROSCOPY DRAPE PACK<br/>HYSTEROSCOPY DRAPE PACK<br/>IVF DRAPE PACK<br/>PEDIATRIC ANGIOGRAPHY DRAPE PACK<br/>FEMORAL ANGIOGRAPHY DRAPE PACK<br/>RADIAL ANGIOGRAPHY DRAPE PACK<br/>TUR PACK<br/>ANGIOGRAPHY PACK<br/>SHOULDER ARTHROSCOPY PACK<br/>VERTEBRA PACK<br/>SPINAL VERTEBRA PACK<br/>CYSTOSCOPY PACK<br/>ENT PACK<br/>HEART SURGERY PACK<br/>OPU GYNAECOLOGY PACK<br/>CESAREAN PACK<br/>DELIVERY PACK<br/>UNIVERSAL PACK<br/>CRANIOTOMY PACK<br/>PEDIATRIC ANGIOGRAPHY PACK<br/>PERCUTANEOUS PACK<br/>HAND SURGERY PACK<br/>HEART VALVE SURGERY PACK<br/>ADULT ANGIOGRAPHY PACK<br/>OPHTHALMIC PACK<br/>ARTHROSCOPY DRAPE PACK<br/>HEART VALVE SURGERY PACK<br/>GENERAL SURGERY PACK</p> |  |
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|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |
|--|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  |  | DELIVERY DRAPE PACK<br>CESEREAN DRAPE PACK<br>OPU GYNAECOLOGY PACK<br>TUR PACK<br>CRANIOTOMY PACK<br>HAND SURGERY DRAPE PACK<br>OPHTHALMIC PACK<br>VERTEBRA SURGEY DRAPE PACK<br>OPHTHALMIC PACK PIP<br>OPHTHALMIC PACK PGN<br>ANGIOGRAPHY PACK CTR<br>ANGIOGRAPHY PACK 4H<br>OPHTHALMIC PACK OIK<br>OPHTHALMIC PACK OPL<br>CARDIOVASCULAR SURGERY DRAPE PACK<br>TUR PACK<br>ARTHROSCOPY DRAPE PACK<br>CRANIOTOMY PACK<br>HEART VALVE SURGERY PACK<br>HAND SURGERY DRAPE PACK<br>GENERAL SURGERY PACK<br>DELIVERY DRAPE PACK<br>CESEREAN DRAPE PACK<br>PERCUTANEOUS PACK<br>ANGIOGRAPHY PACK<br>OPU GYNAECOLOGY PACK<br>CARDIOVASCULAR SURGERY DRAPE PACK<br>ENT DRAPE PACK<br>OPHTHALMIC PACK<br>PERCUTANEOUS DRAPE PACK<br>CYSTOSCOPY DRAPE PACK<br>VERTEBRA SURGEY DRAPE PACK<br>CYSTOSCOPY DRAPE PACK<br>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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