



EC DECLARATION OF CONFORMITY

MANUFACTURER : TIO MEDIKAL TIBBI ÜRÜNLER TURIZM INŞAAT SAN. VE TIC. LTD. ŞTI. : MTK SITESI 5746/7 SOK. NO:8 CAMDIBI- IZMIR ADDRESS : DISPOSABLE STERILE GOWNS, COVERS, DRAPES PRODUCT

| GENERAL SURGICAL | UROLOGY | CARDBOARD ENDOSCOPY COVER |
|-----------------------|------------------------------|-----------------------------------|
| LAPAROSCOPY DRAPE | SISTOSCOPY DRAPE | MIKROSCOPY COVERS |
| | | |
| LAPARATOMY DRAPE | PERKUTAN DRAPE | CAMERA COVERS |
| GENERAL SURGICAL | TUR DRAPE | ULTRASOUND PROBE COVERS |
| DRAPE | FENESTRATED DRAPE | FLUOROSCOPY (C-ARM) COVERS |
| UNIVERSAL KIT STERILE | | FLUOROSCOPY COVER (BANDED |
| ADHESIVE DRAPE | | BAG) |
| CARDIOLOGY | SURGICAL GOWNS STANDARD, | OPHTALMICS |
| VALVE DRAPE | FULL REINFORCED SURCIGAL | EYE POUCHE |
| ANGIOGRAPHY DRAPE | GOWNS | LASER EYE DRAPE |
| CARDIOVASCULAR DRAPE | REINFORCED SURCIGAL GOWNS | E.N.T DRAPE |
| | CHEMOTHERAPY GOWNS | |
| | REUSABLE GOWNS, | |
| OPHTHALMOLOGY | PATIENT GOWNS (long sleeve) | ORTHOPEDICS |
| EYE DRAPE With 1 LCP | PATIENT GOWNS (short sleeve) | EXTREMITY DRAPE |
| EYE DRAPE With 2 LCP | VISITOR GOWNS | ARTHROSCOPY DRAPE WIth LCP |
| DRAPE FOR CATARACT | Scrub Suits | HIP DRAPE |
| SURGERY | | |
| BRAIN SURGERY | COLONOSCOPY SHORT | ABSORBABLE PATTIES, Surgical Peds |
| CRANIOTOMY DRAPE | COLONOSCOPY PANTS | |
| GYNECOLOGY | MAYO TABLE COVER | GYNECOLOGY |
| O.P.U. DRAPE | INSTRUMENT POUCH | DELIVERY DRAPE |
| E.T. DRAPE | BACK TABLE COVER | CESAREAN DRAPE |
| EPISIOTOMY KIT | | |

CLASSIFICATE LOT NUMBER

: CLASS 1s RULE I

RELATED DIRECTIVES AND ANNEX : MDD 93/42/EEC Medical Devices Directive – Annex V :YYYYMMDD

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. INCL. AMENDMENT 2007/47/EC ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

| NAME OF NOTIFIED BODY: | UDEM International Certification Auditing Training Center | |
|----------------------------|---|--|
| | Industry and Trade Co. Ltd. CE2292 | |
| NUMBER OF EC CERTIFICATE : | M.2017.106.8464 | |
| REGISTRATION DATE : | 28.05.2017 | |
| EXPIRY DATE : | 28.05.2022 | |
| | | |
| DATE: 29/05/2017 | TIO MEDIKAN TISBI ÜRÜM | |

SIGNATURE: ALI OSMAN BELKAYA GENERAL DIRECTOR

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