



EC DECLARATION OF CONFORMITY

MANUFACTURER : TIO MEDİKAL TIBBİ ÜRÜNLER TURİZM İNŞAAT SAN. VE TIC. LTD. ŞTİ.

ADDRESS: 2/20 STR. No: 53 Buca OSB 35400 BUCA/ İZMİR/ TURKEY

PRODUCTS: disposable **sterile SINGLE DRAPES AND COVERS**

GENERAL SURGICAL LAPAROSCOPY DRAPE LAPARATOMY DRAPE GENERAL SURGICAL DRAPE UNIVERSAL KIT STERILE ADHESIVE DRAPE	UROLOGY SISTOSCOPY DRAPE PERKUTAN DRAPE TUR DRAPE FENESTRATED DRAPE	CARDBOARD ENDOSCOPY COVER MIKROSCOPY COVERS CAMERA COVERS ULTRASOUND PROBE COVERS FLUOROSCOPY (C-ARM) COVERS FLUOROSCOPY COVER (BANDED BAG)
CARDIOLOGY VALVE DRAPE ANGIOGRAPHY DRAPE CARDIOVASCULAR DRAPE	GYNECOLOGY O.P.U. DRAPE E.T. DRAPE EPISIOTOMY DRAPE	BRAIN SURGERY CRANIOTOMY DRAPE
OPHTHALMOLOGY EYE DRAPE With 1 LCP EYE DRAPE With 2 LCP DRAPE FOR CATARACT SURGERY EYE POUCHES LASER EYE DRAPE E.N.T DRAPE OPHTALMIC DRAPE	GYNECOLOGY DELIVERY DRAPE CESAREAN DRAPE UNDERBUTTOCK DRAPE MAYO TABLE COVER INSTRUMENT POUCH BACK TABLE COVER	ORTHOPEDICS EXTREMITY DRAPE ARTHROSCOPY DRAPE With LCP HIP DRAPE ABSORBABLE PATTIES , Surgical Peds

RISK CLASS: CLASS 1s RULE I

RELATED DIRECTIVES AND ANNEX: MDR (EU) 2017/745 Medical Devices Regulation Annex XI Part A

LOT NUMBER FORMAT: YYMMDDNO

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF (EU) 2017/745 Medical Devices Regulation Annex XI Part A. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

NAME OF NOTIFIED BODY: UDEM Adriatic d.o.o

NUMBER OF EC CERTIFICATE : M.2022.MDR.1009

REGISTRATION DATE : 19.12.2022

EXPIRY DATE : 18.12.2027

ALI OSMAN BELKAYA
GENERAL DIRECTOR

DATE: 19/12/2022

SIGNATURE:

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