EU Quality Assurance Certificate

Medical Devices Regulation (EU) 2017/745 Annex XI Part A (Class Is, Im and Ir Devices)

Certificate Number: M.2022.MDR.1009

Manufacturer Name	: Tio Medikal Tıbbi Ürün. Turz. İnş. San. Tic. Ltd. Şti.
Manufacturer Address	: Buca Osb Mah. 2/20 Sk. Sepe Blok No:53 Buca, İzmir, Türkiye
Single registration number-SRN	: TR-MF-000019233
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.1435
Date of Issue	: 19.12.2022
Recertification Date	: -
Reissue Date/No	: 17.01.2024/01
Date of Expiry	: 18.12.2027

If any, Previous Certificate(s) No: -

UDEM Adriatic d.o.o.
General Manager

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	EMDN CODE	MODEL/TYPE
STERILE SINGLE USE SURGICAL DRAPE SETS	Class Is	T020199	General Surgical Drape Set
			Laparoscopy Drape Set
			Laparotomy Drape Set
			Biopsy Drape Set
			By-Pass (Cardiovascular) Drape Set
			Valve Replacement Drape Set
			Angiography Drape Set
			Craniotomy Drape Set
			Spinal Vertebra Drape Set
			Ophthalmic Drape Set 1
			Ophthalmic Drape Set 2
			Cataract Drape Set
			E.N.T. Drape Set
			O.P.U Drape Set
			Maternity Drape Set
			Caesarean Drape Set
			Embryo Transfer Drape Set
			Gynecology Drape Set
			Tese Drape Set
			Hysteroscopy Drape Set
			Percutaneous Drape Set
			Cystoscopy Drape Set
			T.U.R. Drape Set
			Extremity Drape Set
			Arthroscopy Drape Set
			Hip Drape Set
STERILE SINGLE USE SURGICAL DRAPES	Class Is	T020199	Plain Drape
			Side Tape Drape
			Tool Table Drape
			Minor Hole Drape
			Hip Drape (U Slit drape)
			Mayo Stand Drape

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			Ophthalmic Drape with Pouch
			Laser (Lasic) Eye Drape
			Angiography Drape (Femoral)
			Angiography Drape (Radial)
			Gynecology Drape
			Extremity Drape
			Craniotomy Drape
			Arthroscopy Drape
			By-Pass (Cardiovascular) Drape
			Embryo Transfer Drape
			T.U.R. Drape
			Percutaneous Drape
			Cesarean Drape
			Laparoscopy Drape
			Laparotomy Drape
STERILE SINGLE USE SURGICAL GOWNS	Class Is	T020401	Standard Surgical Gown
		T020402	Reinforced Surgical Gown
			Full Reinforced Surgical Gown
STERILE SINGLE USE EQUIPMENT AND CAMERA DRAPES	Class Is	T030202	Camera Cover
		T030102	Fluoroscopy Cover
			Probe Cover
			TEE/TEO Probe Cover
			Round Tube Covers
			Tube Covers
			C-Arm Scopy Cover
			Scopy Cover
			Light Handle Cover
STERILE SINGLE USE MICROSCOPE COVER	Class Is	T030102	Microscope Sheath (Zeiss – Leica)

Conditions for or limitations to the validity of this certificate : none

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CERTIFICATE HISTORY		
Rev. No.	**Rev. Date**	**Description of Revision**
00	19/12/2022	Initial Certification
01	17/01/2024	Product Dimension Information was Removed, New Models were Added

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