EU QUALITY ASSURANCE CERTIFICATE

(EU) 2017/745 Medical Device Regulation Annex XI Part A

Certificate Number: MDR.2292-2025/0008

Manufacturer Name	: Mediteks Sağlık Hizmetleri Tıbbi Malz. Teks. Ürün. San. ve Dış Tic. A.Ş.
Manufacturer Address	: Head Office Address: Maslak Polaris Plaza Maslak Mah. Ahi Evran Cad. No:21, Kat 6, Office No:33, 34398 Sarıyer İSTANBUL / TÜRKİYE Manufacturing Address: Organize San. Bölgesi 4. Cad. No:5 Süloğlu EDİRNE / TÜRKİYE
Single Registration Number-SRN	: TR-MF-000022021
Authorized Representative Name (If any)	: Not Applicable.
Authorized Representative Address	: Not Applicable.
Device/Device Group Name **Detailed information is in the attached device list.*	: - Sterile or Non-Sterile, With or Without X-Ray Composite Abdominal Compress - Sterile or Non-Sterile, With or Without X-Ray Gas Compress - Sterile or Non-Sterile, With or Without X-Ray Abdominal Compress - Sterile or Non-Sterile, With or Without X-Ray Cotton Pad - Sterile or Non-Sterile, With or Without X-Ray Gauze - Sterile Gauze Bandage

Based on the conformity assessment of the quality management system of the above-mentioned manufacturer according to Annex XI Part A of (EU) 2017/745 Medical Device Regulation, UDEM A.Ş. declares that the relevant requirements are met for the products listed in this certificate.

The manufacturer has established, documented and implemented a quality management system that is subject to periodic surveillance. assessments by UDEM A.Ş. in accordance with Annex XI Part A Section 7 of the related regulation

All relevant reports starting with the number UDEM.0026 of the customer organization referred to below summarize the outcome of the assessments/reviews and refer to the relevant common specifications, if any, harmonized standards and test reports. Upon request, these reports are available in UDEM A.Ş. records in accordance with Section 10 of Chapter II of Annex XII of the MDR. For Class III and Class IIb devices covered by this certificate, an EU Type Examination Certificate is required before being placed on the market in accordance with Annex X of (EU) 2017/745 Medical Device Regulation.

Customer Number	: UDEM.0026
Issue Date	: 21.04.2025
Revision Date/No	: - / -
Validity Date	: 20.04.2030
Previous Certificate(s) No., if any	: Not Applicable.

General Manager
Stamp - Signature

UDEM A.Ş. is a Notified Body under the (EU) 2017/745 Medical Device Regulation. Notified Body No: 2292

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ANNEX: DEVICE LIST WITHIN THE SCOPE OF THE CERTIFICATE

DEVICE PRODUCT/DEVICE GROUP	RISK CLASS	EMDN CODE	INTENDED USE *Should be specified only for class IIb and class III devices.*
Sterile or Non-Sterile, With or Without X-Ray Composite Abdominal Compress	IIa	M020202	-
Sterile or Non-Sterile, With or Without X-Ray Gas Compress	IIa	M020102	-
Sterile or Non-Sterile, With or Without X-Ray Abdominal Compress	IIa	M020103	-
Sterile or Non-Sterile, With or Without X-Ray Cotton Pad	IIa	M020105	-
Sterile or Non-Sterile, With or Without X-Ray Gauze	IIa	M020199	-
Sterile Gauze Bandage	Is	M020107	-

**Limitations on the conditions of the certificate: Not Applicable.*

CERTIFICATE HISTORY		
Rev. No.	**Rev. Date**	**Revision Explained**
00	21.04.2025	Initial Certification

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