EU QUALITY ASSURANCE CERTIFICATE

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

(Class Is, Im and Ir Devices)

Certificate Number: MDR.2292-2025/0001

Manufacturer Name	: Medisyn Tıbbi Cihaz ve Ekipmanlar Sanayi ve Ticaret Anonim Şirketi
Manufacturer Address	: Fatih Mah. 1187 Sok. No:10 C Gaziemir İZMİR / TÜRKİYE
Single Registration Number-SRN	: TR-MF-000042967
Authorized Representative Name (If any)	: Not Applicable.
Authorized Representative Address	: Not Applicable.
Device/Device Group Name **Detailed information is in the attached device list.*	: Disposable Sterile Drapes Disposable Sterile Gowns Disposable Sterile Procedure Packs

Digitally signed by Ceaicovschi Tudor
Date: 2025.06.25 13:14:15 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

UDEM A.Ş. hereby declares that the above-mentioned manufacturer meets the requirements of Annex XI Part A of the (EU) 2017/745 Medical Device Regulation for the products listed in the annex to 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.

The conformity assessment activity carried out by UDEM A.Ş is limited to aspects relating to the establishment, assurance and maintenance of sterile conditions in the case of devices placed on the market in sterile condition; to aspects related to the conformity of the devices with metrological requirements in the case of devices with a measuring function; to aspects related to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and related instructions for use in the case of reusable surgical instruments within the scope of this certificate.

All relevant reports starting with the number UDEM.0136 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 Article 10 of Chapter 2 of Annex XII of the MDR.

Customer Number	: UDEM.0136
Issue Date	: 10.02.2025
Revision Date/No	: - / -
Validity Date	: 09.02.2030
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
Disposable Sterile Drapes	Is	T020199, T030199, T020102, T030203
Disposable Sterile Gowns	Is	T020401, T020402, T020499
Disposable Sterile Procedure Packs	Is	T0202

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

CERTIFICATE HISTORY		
Rev. No.	**Rev. Date**	**Revision Explained**
00	10.02.2025	Initial Certification

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