



CE
2292

EU DECLARATION OF CONFORMITY

Manufacturer Name : MEDISYN TIBBİ CİHAZ VE EKİPMANLAR SANAYİ VE TİCARET ANONİM ŞİRKETİ
Single Registration Number (SRN): TR-MF-000042967
Address : Fatih Mah. (Bucağı/Köyü) 1187 Cad. Bina No:10 C Gazimir İZMİR TÜRKİYE
Product Trade Name : Disposable Sterile Drapes, Gowns And Procedure Packs (See Annex-I List of the Product) TIBBİ CİHAZ VE EKİPMANLAR SANAYİ VE TİCARET ANONİM ŞİRKETİ
Directive : Regulation (EU) 2017/745 on Medical Device Regulation
Brand : SYNTEX
Classification : According To Annex VIII Of Regulation (Eu) 2017/745 (Medical Device Regulation (MDR)), Class I Sterile
Conformity Assesment : According to Regulation (EU) 2017/745 on medical devices Annex – XI Part A PRODUCT CONFORMITY VERIFICATION

We herewith declare that:

Those above products with CE marking which are manufactured by our company all comply with REGULATION (EU) 2017/745 ON MEDICAL DEVICES, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

STANDARTS APPLIED :

EN ISO 13485	EN ISO 11135	EN ISO 13795-1
EN ISO 15223-1	EN ISO 14698-1	EN ISO 10993-1
EN ISO 14971:2019	EN ISO 14698-2	EN ISO 10993-5
EN ISO 10993-10	ISO 11737-1	

A statement that the declaration of conformity is issued under the responsibility of the manufacturer.

Notified Body :

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. Body Number : 2292

Address : Mutlukent Mahallesi 2073 Sokak No:10 Umitkoy-CANKAYA Ankara /Türkiye

Email : udem@udem.com.tr **Website** : www.udem.com.tr

CE Certificate Issues Date :10.02.2025
CE Certificate Validity Date :09.02.2030
CE Certificate Number :MDR.2292-2025/0001

Place/Date : GAZİANTEP / 11.02.2025
Authorized Person : AHMET YAPICIOĞLU
Title : Quality Management Representative
Signature :