

EU DECLARATION OF CONFORMITY

Manufacturer Name : MHK MEDİKAL TEKSTİL SAN. TIC. LTD. ŞTİ
Adress : Körkün Mahallesi Hidayet Caddesi No 23 Oğuzeli /Gaziantep / TURKEY
Product Trade Name : Disposable Surgical Drapes and Gowns (See Annex List of the Product)
Directive : Regulation (EU) 2017/745 on medical devices
Brand : MHK MEDİKAL TEKSTİL
Basic UDI-DI : **86808292104-103-01YG**
Classification : According to Regulation (EU) 2017/745 on medical devices-Annex VIII -
Class I – Other

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 10993-10	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

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

Place/Date : GAZİANTEP / 01.06.2021
Authorized Person : MURAT KEKEÇ
Title : General Manager

Signature, Stamp



MHK MEDİKAL TEKSTİL
SAN. TIC. LTD. ŞTİ
Körkün Mahallesi Hidayet Caddesi No:23/1 Oğuzeli
Tif.: 0342 341 93 66 Faks: 0341 93 67 GAZİANTEP
Tic.Sicil No: 40345 SUBURCU V.D: 620 056 1920

ANNEX I: LIST OF THE PRODUCTS:

PRODUCT NAME	GMDN CODE	REF (Catalogue Number)	UDI-DI Number
Standard surgical Gown	35092	04-103-01	8680829212512