



DECLARATION OF CONFORMITY



Company Name : MHK MEDİKAL TEKSTİL SAN. TIC. LTD. STİ
Address : KORKUN MAHALLESİ HİDAYET CADDESİ NO 23 OĞUZELİ /
GAZİANTEP / TURKEY
Product Name : Disposable Sterile Surgical Sets, Drapes, Gowns and Covers
Product Models : See Annex I
Brand : MHK MEDİKAL
Sterile : Yes
Classification : According to MDD 93/42/EC -Annex IX - Class I –Sterile
Conformity Assessment : According to MDD 93/42/EEC Medical Device Directive Annex V –
Production Quality Assurance
GMDN No : Disposable Surgical Drapes - 47783
Disposable Surgical Gowns – 35778
Disposable Cover -----47783

We herewith declare that:

Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directive MDD 93/42/EC, 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 11137-1	EN ISO 14698-1
EN ISO 14971:2019	EN ISO 11137-2	EN ISO 14698-2
EN ISO 11607-1	EN ISO 11607-2	EN ISO 10993-1
EN ISO 10993-5	EN ISO 10993-10	EN ISO 10993-7
EN ISO 1041	ISO 9001	

Notified Body Name : Udem International Certification Auditing Training Centre Industry and Trade. Co. Ltd.
Notified Body Number : **2292** Signature, Stamp
Registry Date : 01.10.2014
Cetification Date : 26.08.2019
Expiry Date : 27.05.2024
Place/Date : GAZİANTEP / 07.12.2020
Authorized Person : [Redacted]
Title : General Manager