

## 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** 

**Title** 