

## EU DECLARATION OF CONFORMITY



**Manufacturer Name** : MHK MEDİKAL TEKSTİL SAN. TIC. LTD. ŞTİ

**Address** : Körkün Mahallesi Hidayet Caddesi No:23/1 Oğuzeli /Gaziantep / TURKEY

**Product Trade Name** : Disposable Sterile Drapes, Gowns And Procedure Packs (Trays) (See Annex List of the Product)

**Directive** : Regulation (EU) 2017/745 on Medical Device Regulation

**Brand** : MHK MEDİKAL

**Basic UDI-DI** : 0868082921DRPGWNFX

**Classification** : According To Annex VIII Of Regulation (EU) 2017/745 (Medical Device Regulation (MDR) ) Non-Invasive, Non-Active Medical Device, Class I Sterile, Rule 1

**Conformity Assessment** : 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.

### STANDARDS 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    |                |

The present declaration of conformity is issued under the responsibility of the manufacturer.

**Certificate Number** : M.2023.MDR.1011  
**Notified Body Name/ID:** UDEM Adriatic d.o.o / 2696  
**Date of Expiry** : 23.08.2028  
**Place/Date** : GAZİANTEP / 18.07.2023  
**Authorized Person** : MURAT KEKEÇ  
**Title** : General Manager

Signature, Stamp

  
Körkün Mahallesi Hidayet Caddesi No:23/1 Oğuzeli  
Tlf.: 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                 | RISK CLASS | EMDN CODE | REF CODE  | CUSTOMER CODE | UDI-DI        |
|------------------------------|------------|-----------|-----------|---------------|---------------|
| REINFORCED SURGICAL GOWN XXL | Class Is   | T020402   | 16-042-05 | 240541        | 8680829211102 |