

## EU DECLARATION OF CONFORMITY



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

**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

Report Number : MDR.1183  
Date Of Issue : 24.02.2023  
Recertification Date : -  
Reissue Date / No : -  
Date of Expiry : 23.02.2028

### 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	

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

**Place/Date** : GAZİANTEP / 18.07.2023  
**Authorized Person** : MURAT KEKEÇ  
**Title** : General Manager

Signature, Stamp



**MHK MEDİKAL TEKSTİL**  
SAN. TIC. LTD. STİ  
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:**

Document ID: TD-09 / 10

<b>PRODUCT NAME</b>	<b>RISK CLASS</b>	<b>EMDN CODE</b>	<b>REF CODE</b>	<b>UDI-DI</b>
REINFORCED UNIVERSAL PACK	Class IS	T0202	4230001	8680829215209
HEAD/NECK SURGICAL PACK	Class IS	T0202	4230002	8680829210525
MAYO STAND COVER	Class IS	T030199	4230003	8680829212222
PLAIN DRAPE	Class IS	T020199	4230004	8680829219108
SIDE ADHESIVE DRAPE	Class IS	T020199	4230005	8680829210297
FENESTRATED SURGICAL DRAPE	Class IS	T020199	4230006	8680829210846
SIDE ADHESIVE DRAPE	Class IS	T020199	4230007	8680829212024
CABLE COVER	Class IS	T030202	4230008	8680829215339
CABLE COVER	Class IS	T030202	4230009	8680829215339
STERILE LEG COVER	Class IS	T020199	4230010	8680829212321
PLAIN DRAPE	Class IS	T020199	4230011	8680829212062
MEDICAL INSTRUMENTS POUCH	Class IS	T030199	4230012	8680829211287