

## 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

### 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 / 27.02.2023  
**Authorized Person** : MURAT KEKEÇ  
**Title** : General Manager

Signature, Stamp



### ANNEX I: LIST OF THE PRODUCTS:

<b>PRODUCT NAME</b>	<b>RISK CLASS</b>	<b>EMDN CODE</b>	<b>REF CODE</b>	<b>UDI-DI</b>
<b>SET FOR PLACING STERILE TABLETS</b>	<b>Class Is</b>	<b>T0202</b>	<b>01-051-02</b>	<b>8680829215445</b>

Document ID: TD-09 / 10