

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

PRODUCT NAME	RISK CLASS	EMDN CODE	REF CODE	UDI-DI
Reinforced Surgical Gown – XL	Class IS	T020402	4227104	8680829219665
Knee Arthroscopy Pack With Fluid Bag	Class IS	T0202	4227112	8680829215544
TUR Pack	Class IS	T0202	4227121	8680829215117
Reinforced Universal Drape Pack	Class IS	T0202	4218101	8680829215209
Reinforced Universal Drape Pack	Class IS	T0202	4218103	8680829215209
Reinforced Universal Drape Pack With Gowns	Class IS	T0202	4227122	8680829215209
Tur Pack No. 2	Class IS	T0202	4230508	8680829215117
Reinforced Universal Drape Pack Nr 3	Class IS	T0202	4231401	8680829215209
Mayo Stand Cover	Class IS	T030199	4230003	8680829212222
Hand/Foot Surgical Drape Pack	Class IS	T0202	4230511	8680829210525
Arthroscopy Drape Pack With Liquid Pouch No.2	Class IS	T0202	4230512	8680829215155
Pediatric Universal Drape Pack	Class IS	T0202	4230513	8680829215568
Hip Pack U Split	Class IS	T0202	4230514	8680829215148