BAYMED

CE

DECLARATION OF CONFORMITY
(UYGUNLUK BEYANI)

MANUFACTURER: BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş
Organize Sanayi Bölgesi 19 Nolu Cad. No:11/2 MERKEZ/KİLİS
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This declaration of conformity has been prepared in MDR 2017/745 Part II, Article 19, Annex IV; The document is arranged in the home page program for all users.

UDI -DI : See the Sterile Products table.
PRODUCT : Sterile Disposable Surgical Gowns, Sterile Disposable Surgical Drapes, Sterile Disposable Surgical Packs.

NOTIFIED BODY : **UDEM Adriatic d.o.o**
R3 Radnička cesta 54/ R3, Green Gold Centar, IV. kat, 10000, Zagreb, Hırvatistan

ID NO 2696

CND(EMDN) CODE : **See the Sterile Products table.**

SRN NUMBER : TR-MF-000024488

CERTIFICATE NUMBER : M.2023.MDR.1022

CERTIFICATE VALID UNTIL : 08.08.2028

CLASSIFICATION : Class I Sterile (MDR 2017/745 – Annex VIII / Chapter III – Article 4 – Rule 1)

SCOPE : Sterile Disposable Surgical Gowns, Sterile Disposable Surgical Drapes, Sterile Disposable Surgical Packs.

ADDITIONAL : EK XI A
APPLIED STANDARDS : TS EN ISO 13485:2016, ISO 14971:2020, EN ISO 11135:2014, TS EN ISO 15223-1:2021, TS EN ISO 11737-1:2018, EN ISO 11737-2:2020, TS EN ISO 14644-1:2021, TS EN ISO 14644-2:2021, TS EN ISO 10993-1:2021, TS EN ISO 11607-1:2020, TS EN ISO 11607-2:2020, TS EN ISO 11138-1:2017, TS EN ISO 11140-1:2015

The directive for our product is the Council Directive MDR 2017/745 ECC for all versions of medical devices. The Manufacturer of the product, Bayteks Teknik Tekstil San. ve Tic. A.Ş, is responsible for the requirements of this council directive. Our products are not medical devices that contains human blood derivatives, animal products, animal skin, tissues, or blood derivatives or phthalates.

STERILE PRODUCT			
PRODUCT NAME	**BASIC UDI**	**MODEL NO**	**EMDN**
REINFORCED SURGICAL GOWN-L	86817441ST30100001593B9	SG-02202-03	T020402
REINFORCED SURGICAL GOWN-XL	86817441ST30100004029AU	SG-02202-04	T020402
CAMERA COVER 15X250 CM	86817441ST30100001445AR	SU-40011-03	T030199
GENERAL SURGERY PACK	86817441ST30100001776BK	SP-02004-188	T0202

The products listed in the list above and their contents are classified Class 1 Sterile products. These products, their content, and their accessories do not take part in any other class.We herewith declare that the above mentioned products conforms general requirements of the Council Directive MDR 2017/745 ECC for all versions of Medical Device Directive .

Applied Directives

Medical Device Directive MDR 2017/745 ECC ANNEX XI A ALL VERSIONS.

DATE OF ISSUE : 25.08.2
024 REV. NO. : 1

Name and Surname : Yaşar ÇALIŞKAN
Position : Sales Chief
Date of signature : 20.01.2025
Place of Signature : Kilis - Türkiye