

## DECLARATION OF CONFORMITY

**MANUFACTURER** : **BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş**  
Organize Sanayi Bölgesi 19 Nolu Cad. No:9 MERKEZ/KİLİS-TÜRKİYE  
**Tel:** 0342 337 30 30  
**Fax:** 0342 337 30 35

**PRODPUCT** : **Non Sterile Gowns, Drapes, Accessories and Packs**

**NOTIFIED BODY** : **KIWA BELGELENDİRME HİZMETLERİ A.Ş.**  
ITOSB 9.Cadde No:15 Tepeören Tuzla - İstanbul - Türkiye

**CLASSIFICATION** : **CLASS 1 NON-STERILE PRODUCTS**

**SCOPE** : **NON-STERILE PRODUCTS**

**EXECUTED ANNEX** : **V**  
**APPLIED STANDARDS** : **EN ISO 13485:2016**

**APPLICATION** : Our product sare in compliance with the non-sterile version of the Medical Device Directive MDD 93/42/EEC (incl. 2007/47/EC) ANNEX V ALL VERSIONS. The Manufacturer of the products, 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, blood derivatives orphthalates.

### NON STERILE PRODUCTS

PRODUCTS	REF CODE
Medical Gown S	NP-02102-01
Medical Gown M	NP-02102-02
Medical Gown L	NP-02102-03
Medical Gown XL	NP-02102-04
Medical Gown XXL	NP-02102-05
Medical Gown XXXL	NP-02102-06

The products listed in the list above and their contents are classified Class 1 non-sterile products. These products, their contents, and their accessories do not take part in any other class.

### Applied Directives

Medical Device Directive MDD 93/42/EEC (incl. 2007/47/EC) ANNEX V ALL VERSIONS.

**REV. DATE** : 16.09.2020  
**REV. NO.** : 03 – M.5035.03

**NAME AND SURNAME** : **Komi Spero HEGBE**  
**POSITION** : **Export Sales Specialist**  
**SIGNATURE AND STAMP** :  
**DATE** : **22.02.2021**

  
**BAYTEKS**  
TEKNİK TEKSTİL SAN. VE TİC. A.Ş.  
Merkez Başınar(Organize) OSB Mah. 0.5.B. 2.BÖLGE  
83207 Nolu Cad. No 2 Şehirkamil / KİLİS  
Fabrika:Org San/Böl 19 Nolu Cadde No:9 Merkez / KİLİS  
Mersis No 015900387400017 Tic Sic No 54557  
Şehirkamil Vergi Dairesi Vergi No 1590038749