

DECLARATION OF CONFORMITY
MANUFACTURER: BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş

Organize Sanayi Bölgesi 19 Nolu Cad. No:9 MERKEZ / KİLİS
Tel: 0342 337 30 30
Fax: 0342 337 30 35

- PRODUCTS** : Sterile Gowns, Drapes and Sets
- NOTIFIED BODY** : KİWA BELGELENDİRME HİZMETLERİ A.Ş.
İTOSB 9.CADDE NO:15 TEPEÖREN TUZLA - İSTANBUL -
TÜRKİYE
- ID NO** : 1984
- CERTIFICATION NO** : M 5035.3
- CLASSIFICATION** : Class IS Rule 1 MDD 93/42/ECC Annex IX
- EXECUTED ANNEX** : MDD 93/42/ECC (For all versions).
- ANNEXV** : Conformity Assessment Route.
- APPLIED STANDARDS** : EN ISO 13485:2016, ISO 14971:2012, EN ISO 11135:2014,
EN556-1:2001/AC:2006, EN ISO 15223-1:2012, EN ISO 11737-1:2006, EN ISO 11737-2:2009,
EN ISO 14644, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-7:2008/AC:2009, EN
13795:2011+A1:2013, EN 1041:2008+A1:2013, EN ISO 11607-1:2009+A1:2014, EN ISO
11607-2:2006+A1:2014, EN ISO 19011:2011, BS EN 62366-1:2015
- APPLICATION** : The directive for our product is the Council Directive 93/42 / EECfor all
versions of medical devices.The Manufacturer of the product, Bayteks Teknik Tekstil San. And 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 PRODUCTS

| # | Product Name | Ref Code | Size | GMDN Code |
|----|--------------------------|-------------|------------|-----------|
| 1 | Plain Drape | SD-04209-01 | 150x200 cm | 35778 |
| 2 | Plain Drape | SD-04209-03 | 40x50 cm | 35778 |
| 3 | Standard Surgical Gown | SG-01201-01 | S | 35778 |
| 4 | Standard Surgical Gown | SG-01201-02 | M | 35778 |
| 5 | Standard Surgical Gown | SG-01201-03 | L | 35778 |
| 6 | Standard Surgical Gown | SG-01201-04 | XL | 35778 |
| 7 | Standard Surgical Gown | SG-01201-05 | XXL | 35778 |
| 8 | Reinforced Surgical Gown | SG-01202-01 | S | 35778 |
| 9 | Reinforced Surgical Gown | SG-01202-02 | M | 35778 |
| 10 | Reinforced Surgical Gown | SG-01202-03 | L | 35778 |

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|----------|-------------|
| DATE | 16.09.2020 |
| DOC. NO | TS-02 |
| PAGE NO | Sayfa 2 / 2 |
| REV.NO | 3 |
| REV.DATE | 10.09.2018 |

| | | | | |
|----|--------------------------|-------------|-----|-------|
| 11 | Reinforced Surgical Gown | SG-01202-04 | XL | 35778 |
| 12 | Reinforced Surgical Gown | SG-01202-05 | XXL | 35778 |
| 13 | Ceserean Pack | SP-03007-21 | STD | 47783 |
| 14 | Maternity Pack | SP-03007-34 | STD | 47783 |
| 15 | Standard Surgical Set | SP-03007-43 | STD | 47783 |
| 16 | Intervention Pack | SP-03007-89 | STD | 47783 |
| 17 | General Surgery Pack | SP-02001-34 | STD | 47783 |

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 93/42/EEC for all versions of Medical Device Directive .

the declaration of conformity is issued under the sole responsibility of the manufacturer.

Applied Directives

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

DATE OF ISSUE : 16.09.2020
REV.NO. : 3
NAME AND SURNAME : Komi Spero HEGBE
POSITION : FOREIGN TRADE SPECIALIST
SIGNATURE AND STAMP :


BAYTEKS
TEKNİK TEKSTİL SAN. VE TİC. A.Ş.
Merkez Başınar(Organize) OSB Mah. O.S.B. 2 BÖLGE
83207 Nolu Cad. No 2 Şehirkamil / ŞANLIURFA
Fabrika-Orj. San. Böl. 19 Nolu Cadde No 7 / Merkez / KİMLİS
Mersis No 0159002874000017 Tic Sic. No. 54567
Şehirkamil Vergi Dairesi Vergi No 1590028740

Declaration of Conformity to the EU Medical Device Regulation 2017/745

| | |
|--|---|
| Manufacturer Name(*) | Bayteks Teknik Tekstil San. Ve Tic. A.Ş. |
| Manufacturer Address(*) | Organize Sanayi Bölgesi, 19 Nolu Cad. No:11/2 Merkez/KİLİS |
| Manufacturer Individual Identity No. | |
| If the product is produced by someone else by the manufacturer, the Manufacturer's Name and Address(* If Any) | The product is produced by the manufacturer. |
| Product group | Sterile without function , non sterile |
| Product Name (*) | Non steril Surgical gowns and drapes |
| Descriptive Information and Explanations of the Product (*) | Presented in the attached list. |
| Conformity Assessment Procedure(*) (Attachments carried out in product assessment are marked) | <input checked="" type="checkbox"/> ANNEX-IV (ANNEX II & III) Declaration of Conformity |
| | <input type="checkbox"/> ANNEX-IX (CHAPTER I & III) Quality management system |
| | <input type="checkbox"/> ANNEX-IX (CHAPTER II) Technical Documentation Mod. |
| | <input type="checkbox"/> ANNEX-X Type Examination |
| | <input type="checkbox"/> ANNEX-XI (PART A) Production Quality Assurance |
| | <input type="checkbox"/> ANNEX-XI (PART B) Product Verification |
| Notified Body Name and Number (**) | - |
| EU Certificate Number and Description Initial/Validity date (**) | - |
| Other EU Legislation / Common Specifications / Harmonized Standards to which the product complies | - |

(*)Sections beginning with are required.

(**)The conformity assessment is mandatory for products made by the notified body.

Bayteks Teknik Tekstil San. and Tic. Inc. As a company, we declare under our sole responsibility that the devices covered by this declaration comply with the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices and that the requirements specified in the Regulation are fulfilled for these devices.

SIGNATURE DATE AND PLACE : 25.07.2022 – Merkez/KİLİS

EFFECTIVE DATE (IF ANY) : -

SIGNATORY : Ünzile KALENDEROĞLU

POSITION : MANAGER

This EU Declaration of Conformity covers ONLY products with the following catalog/reference numbers:

| | PRODUCTS NAME | REF CODE | UDI | BASIC UDI-DI | GMDN CODE |
|---|-------------------|-------------|---------------|-------------------------|-----------|
| 1 | Patient Gown S | NP-02102-01 | 8681744101509 | 86817441NS301000008083E | 35778 |
| 2 | Patient Gown M | NP-02102-02 | 8681744101493 | 86817441NS301000008073C | 35778 |
| 3 | Patient Gown L | NP-02102-03 | 8681744101486 | 86817441NS3010000193945 | 35778 |
| 4 | Patient Gown XL | NP-02102-04 | 8681744101462 | 86817441NS3010000200228 | 35778 |
| 5 | Patient Gown XXL | NP-02102-05 | 8681744101479 | 86817441NS301000026443N | 35778 |
| 6 | Patient Gown XXXL | NP-02102-06 | 8681744101721 | 86817441NS301000018313G | 35778 |

