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. ITOSB 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

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 :

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)**	■	ANNEX-IV (ANNEX II & III)	Declaration of Conformity
	☐	ANNEX-IX (CHAPTER I & III)	Quality management system
	☐	ANNEX-IX (CHAPTER II)	Technical Documentation Mod.
	☐	ANNEX-X	Type Examination
	☐	ANNEX-XI (PART A)	Production Quality Assurance
	☐	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	BASİC 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