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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

MANUFACTURER: BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş

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STERILE PRODUCTS

#	PRODUCT NAME	REF. CODE	GMDN CODE
1	DISPOSABLE SURGICAL ANGIOGRAPHY PACK	SP-05006-34	47783
2	DISPOSABLE SURGICAL RADIAL ANGIOGRAPHY PACK	SP-05006-43	47783
3	DISPOSABLE STERILE SIDE ADHESIVE DRAPE	SP-05006-23	47783

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