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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

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- 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 5035.2
- 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	GMDN CODE
1	BACK TABLE COVER L	SD-00200-01	47783
2	BACK TABLE COVER S	SD-00200-04	47783
3	BACK TABLE COVER M	SD-00200-09	47783
4	LAMINATED BACK TABLE COVER	SD-00200-10	47783
5	SINGLE POUCH OPHTHALMIC DRAPE L	SD-01601-01	47783
6	SINGLE POUCH OPHTHALMIC DRAPE S	SD-01601-02	47783
7	SINGLE POUCH OPHTHALMIC DRAPE M	SD-01601-03	47783
8	SINGLE POUCH EXCIMER LASER OPHTHALMIC DRAPE L	SD-01601-04	47783
9	SINGLE POUCH EXCIMER LASER OPHTHALMIC DRAPE S	SD-01601-05	47783
10	SINGLE POUCH SPECULUM OPHTHALMIC DRAPE	SD-01601-06	47783
11	SINGLE POUCH EXCIMER LASER OPHTHALMIC DRAPE M	SD-01601-06	47783
12	DOUBLE POUCH OPHTHALMIC DRAPE M	SD-01602-01	47783

13	DOUBLE POUCH OPHTHALMIC DRAPE S	SD-01602-02	47783
14	DOUBLE POUCH OPHTHALMIC DRAPE L	SD-01602-03	47783
15	DOUBLE POUCH EXIMER LASER OPHTHALMIC DRAPE L	SD-01602-04	47783
16	DOUBLE POUCH EXIMER LASER OPHTHALMIC DRAPE S	SD-01602-05	47783
17	DOUBLE POUCH EXIMER LASER OPHTHALMIC DRAPE M	SD-01602-06	47783
18	OPHTHALMIC DRAPE WITHOUT POUCH L	SD-01701-01	47783
19	OPHTHALMIC DRAPE WITHOUT POUCH S	SD-01701-02	47783
20	OPHTHALMIC DRAPE WITHOUT POUCH M	SD-01701-03	47783
21	SURGERY TABLE DRAPE -S	SD-04209-01	47783
22	SURGERY TABLE COVER - L	SD-04209-02	47783
23	SURGERY TABLE COVER-M	SD-04209-03	47783
24	SURGERY TABLE COVER-XL	SD-04209-04	47783
25	INCONTINENCE DRAPE	SD-04209-18	47783
26	MINOR SURGERY DRAPE 100(±10)X100(±10)CM	SD-04210-01	47783
27	MINOR SURGERY DRAPE 110(±10)X120(±10)CM	SD-04210-02	47783
28	MINOR SURGERY DRAPE 110(±10)X130(±10)CM	SD-04210-03	47783
29	MINOR SURGERY DRAPE 110(±10)X140(±10)CM	SD-04210-04	47783
30	MINOR SURGERY DRAPE 130(±10)X130(±10)CM	SD-04210-05	47783
31	MINOR SURGERY DRAPE 150(±10)X150(±10)CM	SD-04210-06	47783
32	MINOR SURGERY DRAPE 150(±10)X200(±10)CM	SD-04210-07	47783
33	MINOR SURGERY DRAPE 150(±10)X250(±10)CM	SD-04210-08	47783
34	MINOR SURGERY DRAPE 150(±10)X300(±10)CM	SD-04210-09	47783
35	MINOR SURGERY DRAPE 20(±10)X20(±10)CM	SD-04210-10	47783
36	MINOR SURGERY DRAPE 200(±10)X200(±10)CM	SD-04210-11	47783
37	MINOR SURGERY DRAPE 200(±10)X250(±10)CM	SD-04210-12	47783
38	MINOR SURGERY DRAPE 200(±10)X300(±10)CM	SD-04210-13	47783
39	MINOR SURGERY DRAPE 40(±10)X40(±10)CM	SD-04210-14	47783
40	MINOR SURGERY DRAPE 60(±10)X60(±10)CM	SD-04210-15	47783
41	MINOR SURGERY DRAPE 80(±10)X100(±10)CM	SD-04210-16	47783
42	MINOR SURGERY DRAPE 80(±10)X80(±10)CM	SD-04210-17	47783
43	MINOR SURGICAL DRAPE	SD-04210-18	47783
44	FENESTRATED DRAPE M	SD-04211-01	47783
45	FENESTRATED DRAPE S	SD-04211-02	47783
46	FENESTRATED DRAPE L	SD-04211-03	47783
47	ANGIOGRAPHY DRAPE PACK L	SD-04504-01	47783
48	ANGIOGRAPHY DRAPE PACK M	SD-04504-02	47783
49	ANGIOGRAPHY DRAPE PACK S	SD-04506-01	47783
50	FOOT DRAPE	SD-04700-05	47783
51	ARTHROSCOPY DRAPE PACK L	SD-04702-01	47783
52	ARTHROSCOPY DRAPE PACK S	SD-04702-02	47783
53	ARTHROSCOPY DRAPE PACK M	SD-04702-03	47783
54	ARM SURGERY DRAPE PACK	SD-04709-01	47783
55	TUR DRAPE	SD-04803-01	47783
56	DENTAL UNIT HEAD DRAPE	SD-04910-01	47783
57	DENTAL UNIT TABLE DRAPE	SD-04910-02	47783

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58	DENTAL UNIT DRAPE	SD-04911-01	47783
59	STANDARD SURGICAL GOWN-S	SG-01201-01	35778
60	STANDARD SURGICAL GOWN-M	SG-01201-02	35778
61	STANDARD SURGICAL GOWN -L	SG-01201-03	35778
62	STANDARD SURGICAL GOWN-XL	SG-01201-04	35778
63	STANDARD SURGICAL GOWN-XXL	SG-01201-05	35778
64	STANDARD SURGICAL GOWN - XXXL	SG-01201-06	35778
65	BOX GOWN	SG-01201-07	35778
66	ADULT SURGICAL GOWN -L	SG-01201-08	35778
67	ADULT SURGICAL GOWN -S	SG-01201-09	35778
68	PEDIATRIC SURGICAL GOWN	SG-01201-10	35778
69	REINFORCED SURGICAL GOWN-S	SG-01202-01	35778
70	REINFORCED SURGICAL GOWN-M	SG-01202-02	35778
71	REINFORCED SURGICAL GOWN-L	SG-01202-03	35778
72	REINFORCED SURGICAL GOWN-XL	SG-01202-04	35778
73	REINFORCED SURGICAL GOWN - XXL	SG-01202-05	35778
74	REINFORCED SURGICAL GOWN-XXXL	SG-01202-06	35778
75	REINFORCED SURGICAL GOWN	SG-01202-07	35778
76	FULLY REINFORCED SURGICAL GOWN-S	SG-01203-01	35778
77	FULLY REINFORCED SURGICAL GOWN-M	SG-01203-02	35778
78	FULLY REINFORCED SURGICAL GOWN-L	SG-01203-03	35778
79	FULLY REINFORCED SURGICAL GOWN-XL	SG-01203-04	35778
80	FULLY REINFORCED SURGICAL GOWN-XXL	SG-01203-05	35778
81	FULLY REINFORCED SURGICAL GOWN-XXXL	SG-01203-06	35778
82	VERTEBRA DRAPE PACK L	SP-01004-01	47783
83	VERTEBRA DRAPE PACK S	SP-01004-03	47783
84	VERTEBRA DRAPE PACK M	SP-01004-04	47783
85	SPINAL DRAPE PACK	SP-01004-05	47783
86	LUMBAR SURGERY DRAPE PACK	SP-01004-06	47783
87	CRANIOTOMY DRAPE PACK	SP-01005-01	47783
88	SHUNT DRAPE PACK	SP-01006-01	47783
89	SURGICAL DRAPE PACK S	SP-02001-01	47783
90	SURGICAL DRAPE PACK L	SP-02002-01	47783
91	GENERAL SURGERY PACK L	SP-02003-01	47783
92	GENERAL SURGERY PACK M	SP-02004-01	47783
93	LAPAROSCOPY DRAPE PACK L	SP-02006-01	47783
94	LAPAROSCOPY DRAPE PACK M	SP-02006-02	47783
95	ENDOSCOPY DRAPE PACK	SP-02007-01	47783
96	DELIVERY DRAPE PACK L	SP-02008-01	47783
97	DELIVERY DRAPE PACK M	SP-02008-01	47783
98	ET DRAPE PACK	SP-03002-01	47783
99	IVF DRAPE PACK L	SP-03003-01	47783
100	IVF DRAPE PACK M	SP-03004-01	47783
101	DELIVERY DRAPE PACK S	SP-03005-01	47783
102	CAESEREAN DRAPE PACK L	SP-03007-01	47783

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103	CAESEREAN DRAPE PACK M	SP-03007-02	47783
104	HYSTEROSCOPY DRAPE PACK	SP-03008-01	47783
105	ENT DRAPE PACK L	SP-04001-01	47783
106	ENT DRAPE PACK S	SP-04002-01	47783
107	ENT DRAPE PACK M	SP-04003-01	47783
108	GOITER / THYROID SURGERY DRAPE PACK	SP-04004-01	47783
109	POST PARTUM SURGERY DRAPE PACK	SP-04306-01	47783
110	BYPASS DRAPE PACK	SP-05001-01	47783
111	HEART SURGERY DRAPE PACK	SP-05002-01	47783
112	BIOPSY DRAPE PACK	SP-05007-01	47783
113	OPHTHALMIC DRAPE PACK	SP-06001-01	47783
114	KNEE SURGERY DRAPE PACK	SP-07001-01	47783
115	ARTHROSCOPY DRAPE PACK WITH POUCH	SP-07002-01	47783
116	HIP SURGERY DRAPE PACK WITHOUT LATEX	SP-07003-01	47783
117	ORTHOPAEDIC DRAPE PACK	SP-07003-01	47783
118	ARTHROPLASTY / HIP SURGERY PACK	SP-07004-01	47783
119	HIP SURGERY DRAPE PACK WITH LATEX	SP-07005-01	47783
120	SHOULDER ARTHROSCOPY DRAPE PACK	SP-07006-01	47783
121	EXTREMITY DRAPE PACK	SP-07007-01	47783
122	HAND SURGERY DRAPE PACK	SP-07009-01	47783
123	PERCUTANEOUS NEPHROLITOTOMY DRAPE PACK	SP-08001-01	47783
124	PERCUTANEOUS SURGERY DRAPE PACK	SP-08001-02	47783
125	CYSTOSCOPY DRAPE PACK	SP-08002-01	47783
126	TUR DRAPE PACK	SP-08003-01	47783
127	URS DRAPE PACK	SP-08003-02	47783
128	DENTAL SURGERY DRAPE PACK	SP-09004-01	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 .

Applied Directives

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

DATE OF ISSUE : 02.08.2019

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BAYTEKS
TEKNİK TEKSTİL SAN. VE TİC. A.Ş.
Merkez : Başpınar (Organize) OSB Adı: O.S.B. 2.BÖLGE
83207 Nolu Cad. No:2 Şişli/Şişli/İSTANBUL
Fabrika: Org. San. Böl. 2. Organize Alanı No:9 Merkez : Kims
Mersis No: 0159003874900017 Tic. Sic. No: 54557
Şehitkamil Vergi Dairesi Vergi No: 1590038749