

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 Surgical Gown And Surgical Packs

NOTIFIED BODY : KİWA BELGELENDİRME HİZMETLERİ A.Ş.
ITOSB 9.CADDE NO:15 TEPEÖREN TUZLA - İSTANBUL - TÜRKİYE

ID NO : 1984

CERTIFICATION NO : M 5035.03

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 13795-1:2019, 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	Product Code	GMDN CODE
1	Disposable Surgical Pack (Abdomen Pack)	30100001988	30100001988	47783
2	Disposable Surgical Pack (Abdominal Perineal Pack No. 1)	30100002299	30100002299	47783
3	Disposable Surgical Pack (Abdominal Perineal Pack No. 2)	30100002307	30100002307	47783
4	Disposable Surgical Pack (Abdominal Perineal Pack No. 3)	30100004753	30100004753	47783
5	Disposable Surgical Pack (Caesarean Drape Pack No. 1)	30100002292	30100002292	47783
6	Disposable Surgical Pack (Caesarean Drape Pack No. 1 /Panel)	30100004407	30100004407	47783
7	Disposable Surgical Pack (Caesarean Drape Pack No. 2)	30100002293	30100002293	47783
8	Disposable Surgical Pack (Caesarean Drape Pack No.2W/Panel)	30100004549	30100004549	47783
9	Disposable Surgical Pack (Caesarean Drape Pack No. 4)	30100002306	30100002306	47783
10	Disposable Surgical Pack (Gynaecological Pack No. 1)	30100002296	30100002296	47783
11	Disposable Surgical Pack (Gynaecological Pack No. 2)	30100004053	30100004053	47783
12	Disposable Surgical Pack (Gynaecological Pack No. 2)	30100002308	30100002308	47783
13	Disposable Surgical Pack (Hip Surgery Pack)	30100003520	30100003520	47783
14	Disposable Surgical Pack (Implant Pack)	30100004521	30100004521	47783
15	Disposable Surgical Pack (Knee Arthroscopy Pack W/Pouch)	30100002006	30100002006	47783
16	Disposable Surgical Pack (Knee Arthroscopy Pack W/O Bag)	30100002005	30100002005	47783
17	Disposable Surgical Pack (Laparoscopy Drape Pack)	30100004274	30100004274	47783

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18	Disposable Surgical Pack (Laparotomy Drape Pack No. 1)	30100002298	30100002298	47783
19	Disposable Surgical Pack (Laparotomy Drape Pack No. 1)	30100004093	30100004093	47783
20	Disposable Surgical Pack (Lumbar Puncture Set)	30100004275	30100004275	47783
21	Disposable Surgical Pack (Lumbar Puncture Set)	30100002671	30100002671	47783
22	Disposable Surgical Pack (Natural Delivery Pack No. 1)	30100002668	30100002668	47783
23	Disposable Surgical Pack (Natural Delivery Pack No. 2)	30100002697	30100002697	47783
24	Disposable Surgical Pack (Natural Delivery Pack No. 3)	30100004339	30100004339	47783
25	Disposable Surgical Pack (Ophthalmic Drape Pack No. 1)	30100002301	30100002301	47783
26	Disposable Surgical Pack (Ophthalmic Drape Pack No. 2)	30100002302	30100002302	47783
27	Disposable Surgical Pack (Ophthalmic Drape Pack No. 3)	30100002315	30100002315	47783
28	Disposable Surgical Pack (Reinforced Universal Drape Pack	30100002666	30100002666	47783
29	Disposable Surgical Pack (Reinforced Universal Drape Pack W/G)	30100003027	30100003027	47783
30	Disposable Surgical Pack (Reinforced Universal drape Pack)	30100004697	30100004697	47783
31	Disposable Surgical Pack (Shoulder Arthroscopy Pack W/Pouch)	30100002004	30100002004	47783
32	Disposable Surgical Pack (Tonsil Adenoid Pack)	30100003519	30100003519	47783
33	Disposable Surgical Pack (Tonsil Adenoid Pack No. 1)	30100004694	30100004694	47783
34	Disposable Surgical Pack (TUR Pack)	30100004024	30100004024	47783
35	Disposable Surgical Pack (TUR Pack)	30100002007	30100002007	47783
36	Disposable Surgical Pack (TUR Pack W/G)	30100004025	30100004025	47783
37	Disposable Surgical Pack (Universal Drape Pack No. 1)	30100001989	30100001989	47783
38	Disposable Surgical Pack (Universal drape Pack with U-split)	30100002003	30100002003	47783
39	Disposable Surgical Pack (Universal drape Pack with U-split)	30100003518	30100003518	47783
40	Disposable Surgical Drape (Instrument Pouch30 x 40cm)	30100002312	30100002312	47783
41	Disposable Surgical Drape (Instrument Pouch40 x 50cm)	30100002313	30100002313	47783
42	Disposable Surgical Drape (Instrument Pouch40 x 70cm)	30100002314	30100002314	47783
43	Disposable Surgical Drape (Cotton gauze drape 45 x 45cm)	30100002288	30100002288	47783
44	Disposable Surgical Drape (Fenestrated Drape 75 x 90cm)	30100003031	30100003031	47783
45	Disposable Surgical Drape (Fenestrated Drape 150 x 180cm)	30100003029	30100003029	47783
46	Disposable Surgical Drape (Fenestrated Drape 150 x 240cm)	30100004696	30100004696	47783
47	Disposable Surgical Drape (Fenestrated Drape 50 x 60cm)	30100001993	30100001993	47783
48	Disposable Surgical Drape (Fenestrated Drape 90 x 120cm)	30100004022	30100004022	47783
49	Disposable Surgical Drape (Mayo Stand Cover 80 x 145cm)	30100001095	30100001095	47783
50	Disposable Surgical Drape (Mayo Stand Cover 80 x 145cm/Red)	30100002291	30100002291	47783
51	Disposable Surgical Drape (OP Tape 10 x 50cm)	30100003523	30100003523	47783
52	Disposable Surgical Drape (Plain drape 100 x 150cm)	30100001061	30100001061	47783
53	Disposable Surgical Drape (Plain drape 120 x 150cm)	30100004023	30100004023	47783
54	Disposable Surgical Drape (Plain drape 150 x 180cm)	30100001063	30100001063	47783
55	Disposable Surgical Drape (Plain drape 150 x 240cm)	30100000862	30100000862	47783
56	Disposable Surgical Drape (Plain drape 30 x 40cm)	30100003854	30100003854	47783
57	Disposable Surgical Drape (Plain drape 45 x 45cm)	30100004021	30100004021	47783
58	Disposable Surgical Drape (Plain drape 50 x 60cm)	30100001992	30100001992	47783
59	Disposable Surgical Drape (Plain drape 75 x 90cm)	30100000863	30100000863	47783
60	Disposable Surgical Drape (Plain drape 90 x 120 cm)	30100004695	30100004695	47783
61	Disposable Surgical Drape (Side adhesive drape 100 x 150cm)	30100001014	30100001014	47783
62	Disposable Surgical Drape (Side adhesive drape 150 x 180cm)	30100001031	30100001031	47783

63	Disposable Surgical Drape (Side adhesive drape 150 x 240cm)	30100000982	30100000982	47783
64	Disposable Surgical Drape (Side adhesive drape 50 x 60cm)	30100003028	30100003028	47783
65	Disposable Surgical Drape (Side adhesive drape 50 x 60cm)	30100002290	30100002290	47783
66	Disposable Surgical Drape (Side adhesive drape 75 x 75cm)	30100001579	30100001579	47783
67	Disposable Surgical Drape (Side adhesive drape 75 x 90cm)	30100001028	30100001028	47783
68	Disposable Surgical Drape (Side adhesive drape 90 x 100cm)	30100002310	30100002310	47783
69	Disposable Surgical Drape (Velcro Holder 2 x 25cm)	30100003695	30100003695	47783
70	Disposable Surgical Drape (Under Buttocks Drape 113x 90cm)	30100002289	30100002289	47783
71	Disposable Surgical Gown(Reinforced surgical gown, size L)	30100002148	30100002148	35778
72	Disposable Surgical Gown(Reinforced surgical gown, size L)	30100001981	30100001981	35778
73	Disposable Surgical Gown(Reinforced surgical gown, size M)	30100001832	30100001832	35778
74	Disposable Surgical Gown(Reinforced surgical gown, size M)	30100001980	30100001980	35778
75	Disposable Surgical Gown(Reinforced surgical gown, size XL)	30100002149	30100002149	35778
76	Disposable Surgical Gown(Reinforced surgical gown, size XL)	30100001982	30100001982	35778
77	Disposable Surgical Gown(Reinforced surgical gown, size XXL)	30100002150	30100002150	35778
77	Disposable Surgical Gown(Reinforced surgical gown, size XXL)	30100002286	30100002286	35778
79	Disposable Surgical Gown(Reinforced surgical gown, size XXL)	30100001983	30100001983	35778
80	Disposable Surgical Gown(Reinforced surgical gown, size XXXL)	30100003693	30100003693	35778
81	Disposable Surgical Gown(Standard surgical gown, size L)	30100002045	30100002045	35778
82	Disposable Surgical Gown(Standard surgical gown, size L)	30100001977	30100001977	35778
83	Disposable Surgical Gown(Standard surgical gown, size M)	30100002615	30100002615	35778
84	Disposable Surgical Gown(Standard surgical gown, size M)	30100001976	30100001976	35778
85	Disposable Surgical Gown(Standard surgical gown, size XL)	30100002056	30100002056	35778
86	Disposable Surgical Gown(Standard surgical gown, size XL)	30100001978	30100001978	35778
87	Disposable Surgical Gown(Standard surgical gown, size XXL)	30100002057	30100002057	35778
88	Disposable Surgical Gown(Standard surgical gown, size XXL)	30100001979	30100001979	35778
89	Disposable Surgical Gown(Standard surgical gown, size XXXL)	30100003694	30100003694	35778
90	Disposable Surgical Gown(Urology surgical gown, size L)	30100002316	30100002316	35778
91	Disposable Surgical Gown(Urology surgical gown, size XL)	30100000831	30100000831	35778
92	Disposable Surgical Gown(Urology surgical gown, size XXL)	30100002318	30100002318	35778
93	Disposable Surgical Gown(Urology surgical gown, size XXXL)	30100002319	30100002319	35778

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.

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