



Product Service

TÜV SÜD Product Service GmbH • Ridlerstraße 65 • 80339 Munich • Germany

**Choose certainty.
Add value.**

Munich, 2011-11-23

**“For Presentation at Department of Health, Executive Yuan, R.O.C.(Taiwan)”
Confirmation concerning certificate G2S 10 12 47015 005**

We confirm that the following enclosed certificate:

G2S 10 12 47015 005 (valid until 2016-02-20)

issued to the following auditee

**Suzhou Addison Non-woven Product Co., Ltd.
No. 168, Litai Road, Yuanhe Town
215133 Suzhou
PEOPLE'S REPUBLIC OF CHINA**

covers the Directive 93/42/EEC on Medical Devices with the following products:

List of Surgical Gown

No.	Product(s)	Model
1	Standard Gown, M	67-1110-S
2	Standard Gown, L	67-1120-S
3	Standard Gown, XL	67-1130-S
4	Standard Gown, XXL	67-1140-S
5	Fabric High Performance Gown, M	67-2110-S
6	Fabric High Performance Gown, L	67-2120-S
7	Fabric High Performance Gown, XL	67-2130-S
8	Fabric High Performance Gown, XXL	67-2140-S
9	Poly Reinforced Gown, M	67-3110-S
10	Poly Reinforced Gown, L	67-3120-S
11	Poly Reinforced Gown, XL	67-3130-S
12	Poly Reinforced Gown, XXL	67-3140-S
13	Impervious Gown (Breathable), M	67-4110-S
14	Impervious Gown (Breathable), L	67-4120-S
15	Impervious Gown (Breathable), XL	67-4130-S
16	Impervious Gown (Breathable), XXL	67-4140-S

List of Surgical Drapes

No.	Product(s)	Model
1	Universal set Reinforced (Paediatric)	70-1000-S
2	Universal set Reinforced I	70-1001-S
3	Universal slit sheet set	70-1002-S
4	Universal slit sheet set I	70-1003-S
5	Minor surgery set up set	70-1010-S
6	Minor surgery set	70-1011-S
7	Minor surgery set I	70-1012-S
8	Craniotomy Drape	70-1020-S
9	Laparotomy/Chest set	70-1030-S
10	Laparotomy/Chest set I	70-1031-S
11	Laparotomy Transverse set II	70-1032-S
12	Laparoscopy set	70-1033-S
13	Abdominal/Perineal set MIC	70-1034-S
14	Chest slit set	70-1035-S
15	Rectum set	70-1040-S
16	Aneasthesia pack	70-1050-S
17	Angiography set	70-2000-S
18	Angiography set I	70-2001-S



No.	Product(s)	Model
19	Brachial Angiography set	70-2002-S
20	Cardiovascular set	70-2010-S
21	Varicose vein set	70-2020-S
22	Gynaecology set	70-3000-S
23	Gynaecology set I	70-3001-S
24	Gynaecology set with collection bag II	70-3002-S
25	Gyn/Urology/Cystoscopy	70-3010-S
26	Gynaecology/abdominal set	70-3020-S
27	Caesarean section set	70-3030-S
28	OB pack	70-3040-S
29	Urology set	70-4000-S
30	Universal Hand/Foot set	70-5000-S
31	Hand set large reinforced	70-5001-S
32	Universal Upper Extremity set	70-5010-S
33	Universal Lower Extremity set	70-5011-S
34	Bilateral Knees Replacement Drape	70-5012-S
35	Hip set reinforced	70-5020-S
36	Hip slit set reinforced	70-5021-S
37	Hip slit set reinforced with approach drape I	70-5022-S
38	Vertical isolation set	70-5030-S
39	Shoulder arthroscopy set reinforced	70-6000-S
40	Shoulder arthroscopy slit set reinforced	70-6001-S
41	Arthroscopy	70-6010-S
42	ENT set	70-7000-S
43	ENT slit set reinforced	70-7010-S
44	Eye drape	70-8000-S
45	Eye drape I	70-8001-S
46	Full body Eye drape	70-8010-S
47	Mayo stand cover	71-1000-S
48	Back table cover	71-2000-S
49	Back table cover	71-2001-S
50	Back table cover	71-2002-S
51	Drape	71-3010-S
52	Drape	71-3011-S
53	Drape	71-3012-S
54	Transparent drape self adhesive	71-3020-S
55	Drape self adhesive	71-3021-S
56	Head drape self adhesive	71-3022-S
57	Head drape self adhesive	71-3023-S
58	Head drape self adhesive	71-3024-S
59	Head drape self adhesive	71-3025-S
60	Foot drape self adhesive	71-3026-S
61	Self adhesive drape	71-3027-S
62	Self adhesive drape	71-3028-S



No.	Product(s)	Model
63	Self adhesive drape	71-3029-S
64	Hand drape reinforced	71-3030-S
65	Drape self adhesive reinforced	71-3031-S
66	Head drape self adhesive reinforced	71-3032-S
67	Head drape self adhesive reinforced	71-3033-S
68	Head drape self adhesive reinforced	71-3034-S
69	Head drape self adhesive reinforced	71-3035-S
70	Foot drape self adhesive reinforced	71-3036-S
71	Lateral drape self adhesive reinforced	71-3037-S
72	Lateral drape self adhesive reinforced	71-3038-S
73	Slit sheet drape self adhesive	71-3039-S
74	Slit sheet drape self adhesive	71-3040-S
75	Slit sheet drape self adhesive	71-3041-S
76	Slit sheet drape self adhesive	71-3042-S
77	Chest U-drape self adhesive	71-3043-S
78	Slit sheet self adhesive reinforced	71-3044-S
79	Slit sheet drape self adhesive reinforced	71-3045-S
80	Slit sheet self adhesive reinforced	71-3046-S
81	Slit sheet self adhesive reinforced with perineal cover	71-3047-S
82	Slit sheet self adhesive reinforced	71-3048-S
83	Slit sheet self adhesive reinforced	71-3049-S
84	Fenestrated drape	71-3050-S
85	Fenestrated drape	71-3051-S
86	Fenestrated drape	71-3052-S
87	Minor procedure fenestrated drape	71-3053-S
88	Epidural drape self adhesive	71-3054-S
89	Functional drape	71-3055-S
90	Functional drape	71-3056-S
91	Laparotomy drape	71-3057-S
92	Laparoscopy function drape	71-3058-S
93	Under buttocks drape with fluid collection pouch	71-3059-S
94	Abdominal drape	71-3060-S
95	Laparotomy drape with armboard cover	71-3061-S
96	Transverse laparotomy drape	71-3062-S
97	Gyn. Mic. drape	71-3063-S
98	Gynaecology drape reinforced	71-3064-S
99	Gynaecology drape with bag functional	71-3065-S
100	Gyn - cyst drape	71-3066-S
101	Gynae - abdominal drape reinforced	71-3067-S
102	Caesarean section drape with intergrated fluid collection pouch	71-3068-S
103	Baby drape	71-3069-S
104	Bar drape	71-3070-S
105	Rectum drape reinforced	71-3071-S



No.	Product(s)	Model
106	Angiography drape	71-3072-S
107	Angiography drape	71-3073-S
108	Angiography drape	71-3074-S
109	Extremity drape self adhesive	71-3075-S
110	Extremity drape self adhesive	71-3076-S
111	Extremity drape reinforced	71-3077-S
112	Extremity drape reinforced	71-3078-S
113	Universal hand/food drape reinforced	71-3079-S
114	Urology drape	71-3080-S
115	Hip drape with pocket	71-3081-S
116	Vertical drape with collection pouch	71-3082-S
117	Shoulder arthroscopy drape	71-3083-S
118	Arthroscopy drape with fluid collection pouch	71-3084-S
119	Basic ophthalmic drape	71-3085-S
120	Basic ophthalmic drape	71-3086-S
121	Full body ophthalmic drape	71-3087-S
122	OR tape	71-4000-S
123	Velcro	71-4001-S
124	Stockinet	71-5000-S
125	Stockinet	71-5001-S
126	Foot cover	71-6000-S
127	Set up cover	71-6001-S
128	PE Cover	71-6002-S
129	Perineal cover	71-6003-S
130	Leggings	71-7000-S
131	Towels cellulose	71-7001-S
132	Suture bag	71-7002-S
133	Cotton buds	71-7003-S
134	Gauze	71-7004-S
135	CSR Wrap	71-7005-S

With this letter, TÜV SÜD Product Service GmbH confirms that the above products are certified and permitted to be labeled with the CE Mark and may be marketed in the European Union.


 i.A. Norbert Stuibler
 TÜV SÜD PRODUCT SERVICE GMBH
 Medical Health Services
 Foreign Affairs

