

SU-Instruments.

Kashmir Road,
SIALKOT-PAKISTAN

Technical Information/ Specification # SUI/CE/SDI/A	Part: First (A)	Revision level: 01	Copy # 01 01	Page # 1 of 3
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10.0. Declaration of Conformity

10.1 DECLARATION OF CONFORMITY (by the Manufacturer)

SU Instruments Pvt. Ltd, Captain Shukar Deen Street, Kotli Behram Sialkot-51310-Pakistan, declares under our sole responsibility that our Class 1 reusable Surgical and Dental Instruments listed in Annex A (product list) are manufactured in conformity with the requirements of Council Directive 93/42/EEC of June 1993, Annex VII date of issue 14.06.1993 and quality management system certified to ISO 13485:2016.

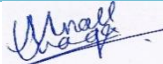
We further declare that we have **designated the following person as our Authorized Representative as required by the Medical Device Directive 93/42/EEC:**

Mr. Abaid Ullah Habib,
Yellow's medical instruments GmbH
Max-Planck Str. 3
12489 Berlin-Germany
Tel: +49-30 234 58 995
E.mail: sales@yellows-instruments.info

The Notified Body is:
SGS Belgium NV,
Noorderlaan 87 BE-2030 Antwerpen

Detail of the Products:

Non-Sterile Re-Use Surgical and Dental Instruments. See Annex A for Products

Approved By:	CEO		Date: 03-01-2021
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SU INSTRUMENTS

Captain Shukar-Din Street, Kotli Behram Stop, Kashmir Road, Sialkot – 51310 Pakistan

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Sr. No.	Product Group	Risk Class	Description	PRODUCTS CODE (SUI)	PRODUCTS CODE (CUSOMER)
1	Scissors	Class I	Surgical Scissors cvd.b/b16cm	SUBBC4155	SA-103-16
2	Scissors	Class I	Surgical Scissors cvd. b/b14cm	SUBBC4144	SA-103-14
3	Scissors	Class I	Surgical Scissors cvd. s/s16cm	SUBBC4266	SA-101-16
4	Scissors	Class I	Surgical Scissors cvd. s/s14cm	SUBBC4244	SA-101-14
5	Scissors	Class I	Surgical Scissors str. s/s 14cm	SUBBC3444	SA-100-14
6	Scissors	Class I	Surgical Scissors str. s/s 16cm	SUBBC3466	SA-100-16
7	Scissors	Class I	Surgical Scissors str. s/b 14 cm	SUBBC3244	SA-104-14
8	Scissors	Class I	Surgical Scissors str. s/b 16cm	SUBBC3266	SA-104-16
9	Scissors	Class I	Surgical Scissors str. b/b 14 cm	SUBBC3144	SA-102-14
10	Scissors	Class I	Surgical Scissors str. b/b 16cm	SUBBC3166	SA-102-16
11	Forceps	Class I	Dissecting Forceps 14.5cm	SUBBD0277	PI-524-14
12	Forceps	Class I	Dissecting Forceps 14.5cm	SUBBD1144	PI-522-14
13	Forceps	Class I	Dissecting Forceps 16cm	SUBBD0499	PI-522-16
14	Forceps	Class I	Tissue Forceps 14cm	SUBBD5577	PI-525-14
15	Forceps	Class I	Tissue Forceps 16 cm	SUBBD5599	PI-525-16
16	Forceps	Class I	Pean Forceps Str. 14cm	SUBBH4244	KA-100-14
17	Forceps	Class I	Rochester Pean Forceps 16cm	SUBBH4422	KA-100-16
18	Forceps	Class I	Hemostatic Forceps Kocher 14 cm	SUBBH6144	KA-102-14
19	Forceps	Class I	Kocher-Oschner Forceps 16cm	SUBBH6422	KA-102-16
20	Needle Holders	Class I	Needle Holder Mathieu	SUBBM3600	NA-100-14
21	Needle Holders	Class I	Needle Holder May-Hegar 14 cm	SUBBM2355	NA-101-14
22	Forceps	Class I	Cather Introducing forceps Magill 15cm	SUAAN3799	MA-402-15
23	Forceps	Class I	Cather Introducing forceps Magill 20cm	SUAAN3800	MA-402-20
24	Forceps	Class I	Cather Introducing forceps Magill 25cm	SUAAN3811	MA-402-25
25	Mallets	Class I	Reflexhammer n. Buck mit Pinsel & Nadel 19 cm	SUBBH400-RE	BH-400-19
26	Scissors	Class I	Lister Bandage Scissors 14 cm	SUBBC8611	SA-171-14
27	Scissors	Class I	Lister Bandage Scissors 16 cm	SUBBC4644	SA-171-16
28	Scissors	Class I	Lister Bandage Scissors 18 cm	SUBBC8622	SA-171-18
29	Scissors	Class I	Lister Bandage Scissors 20 cm	SUBBC8633	SA-171-20
30	Needle Holder	Class I	Mayo Hegar Needle Holder 18 cm	SUBBM2199	NA-101-18
31	Forceps	Class I	Emergency Forceps 14 cm	SUBBH1733	KA-175-14
32	Scissors	Class I	Bandage Scissors 11.5 cm	SUBBC8600	SA-171-11
34	Scissors	Class I	Umbalical Scissors Str. 14 cm	SUBBC7966	SA-137-14
35	Forceps	Class I	Pean Forceps STR 20 cm	SUBBH4466	KA-100-20
36	Hammer	Class I	Berliner Hammer	SUBBH400-RE	BH-400-21
37	Forceps	Class I	Halsted Mosquito Forceps CVD 12.5 cm	SUBBH1111	KA-118-12
38	Hammer	Class I	Babinsky Hammer 23 cm	SUHH234000	BN-400-23
39	Retractor	Class I	VOLKMANN RETRACTOR SH 21CM	SUBBT1244	AI-109-06
40	Needle Holder	Class I	Castrovejio Needle cvd tc 16 cm	SUFFD2599	KI-340-TC
43	Forceps	Class I	Feilchenfeld Forceps 11.5 cm	SUBBD9655	PI-512-11
44	Forceps	Class I	Tube Forceps n. Pean 14,5 cm	SUAAN9144	SK-104-14
45	Needle Holder	Class I	Mayo Hegar Needle Holer 16 cm	SUBBM235-16	NA-101-16
46	Needle Holder	Class I	Mathieu Needle Holder 17 cm	SUBBM1655	NA-100-17
47	Forceps	Class I	Extracting Forceps Upper Premolars Fig 7	SUDDG1077	ZA-100-07
48	Scissors	Class I	Metzenbaum Scissors CVD. 14,5 cm	SUBBC6055	SA-147-14
49	Speculum	Class I	Hartmann Nasal Speculum 25 mm	SUOOK0411	AI-142-01
50	Scissors	Class I	Dressing Scissors bl/bl CVD 18 cm	SUBBC4177	SA-103-18

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51	Scissors	Class I	Dressing Scissors Sh/bl Str. 14 cm	SUBBC4244	SA-105-14
52	Scissors	Class I	Dressing Scissors Sh/bl Str 13 cm	SUBBC3233	SI-104-13
53	Scissors	Class I	Dressing Scissors Sh/Bl CVD 18 cm	SUBBC4277	SA-10-18
54	Scissors	Class I	Iris Scissors CVD9 cm	SUBBC1011	SA-117-09
55	Scissors	Class I	Iris Scissors Str. 11.5 cm	SUBBC1066	SA-116-11
56	Hammer	Class I	Reflexhammer n. Berliner 23 cm	BH-400-RE	BH-400-20
57	Hammer	Class I	Berliner Hammer w. Needle & Brush 21 cm	SUBBH-400-RE	BH-400-21
58	Hammer	Class I	Troemner Hammer 235g, 24 cm	SUTTS400-RE	TS-400-23
59	Laryngoscope	Class I	McIntosh Laryngoscope Blade Fig.2	SU0002	LM-400-02
60	Laryngoscope	Class I	McIntosh Laryngoscope Blade Fig.4	SU0004	LM-401-04
61	Laryngoscope	Class I	McIntosh Laryngoscope Blade Fig.5	SU0005	LM-400-06
62	Laryngoscope	Class I	Laryngoscope Handel Small	SU0006	LM-402-07
63	Speculum	Class I	Semm Speculum small 90x14 mm	SUEEL1833	VS-104-01
64	Speculum	Class I	Semm Speculum small 100x17 mm	SUEEL1844	VS-104-02
65	Speculum	Class I	Semm Speculum small 100x25 mm	SUEEL1855	VS-104-03
66	Trays	Class I	Kidney Tray W/O Lid 25 cm	SUJIG5066	AI-134-07
67	Trays	Class I	Impression Tray Upper Jaw Fig.5	SUDDR2033	AL-200-03
68	Trays	Class I	Impression Tray Upper Jaw Fig.3	SUDDR2033	AL-200-03
69	Trays	Class I	Impression Tray Upper Jaw Fig. 1	SUDDR2011	AL-200-01
70	Trays	Class I	Impression Tray Lower Jaw Fig. 3	SUDDR2044	AL-201-03
71	Trays	Class I	Impression Tray Lower jaw Fig. 4	SUDDR2311	AL-201-04
72	Trays	Class I	Impression Tray Lower Jaw Fig. 5	SUDDR2322	AL-201-05
73	Hammer	Class I	Reflex Hammer Troemer 24 cm	SUHHM8033-RE	TM-400-18
74	Forceps	Class I	Splitter Forceps n. Feilchenfeld 9 cm	SUBBD9644	PI-542-09
75	Forceps	Class I	Splitter Forceps n. Feilchenfeld 11 cm	SUBBD9655	PI-542-11
76	Speculum	Class I	Hartman-Halle Nasal Speculum Fig. 2	SUOOK0488	AI-142-02
77	Speculum	Class I	Kilian Speculum 35 mm	SUOOK0811	AI-148-01
78	Forceps	Class I	Cather Introducing forceps Magill 17cm	SUAAN1700	MA-402-17
79	Forceps	Class I	Splinter Forceps w/o Pin STR 14 cm	SUBBD0277	PI-520-14
80	Forceps	Class I	Thumb Dressing Forceps 13 cm	SUBBD0455	PI-524-13
81	Forceps	Class I	Dressing Forceps 1x2 teeth 18 cm	SUBBD5600	PI-525-18
82	Forceps	Class I	Dressing Forceps STR. 20 cm	SUBBD0511	PI-522-20
83	Needle Holder	Class I	Mayo-Hegar Needle Holder 16 cm	SUFFD2599	KI-340-TC
84	Dilator	Class I	Tracheal Dilators	SUFFA007	AI-125-10
85	CURETTE	Class I	Curette Blunt Fig.00	SUEER3211	AS-111-00
86	EXTRACTING FORCEPS	Class I	Extracting Forceps upper Premolars Fig.7	SUDDG1077	ZA-100-07
87	CURETTE	Class I	Gracey Curette Fig 7/8 17 cm	SUBBD3833	KK-300-04
88	CURETTE	Class I	Gracey Curette Fig 11/12 17 cm	SUDDDB3855	KK-300-06

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