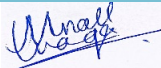
	Company Name: SU Instruments		Doc. # MDR/DOC-01/00	Issue 01
	EC Declaration of Conformity: Reusable Surgical and Dental Instruments Class I (See Annex 1 Product List)			
	Date: 31-03-2023	Page 1 of 8 (Prepared / Revised by: QA Manager)		
	Revision History		Revision Detail	
Revision Level: 00 / Latest Revision Date: 31-03-2023				-

EC DECLARATION OF CONFORMITY

SU Instruments, declares under our sole responsibility that our Class 1 reusable Surgical and Dental Instruments listed in Annex 1 (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 are presently undergoing transition to MDR 2017/745.

Device Description:	<u>Reusable Surgical and Dental Instruments Class I</u> (See Annex 1 Product List)
MDR Classification	Class: I Class: Ir (Reusable Invasive Devices) Rule: 06 according to annexure VIII of MDR 2017/745 All surgically invasive devices intended for transient use are in Class IIa unless they: <u>are reusable surgical instruments, in which case they are classified as class I</u>
Assessment Route:	Annex IX (Quality Management System and Technical Documentation)
EU Rep:	Name: Yellow's medical instruments GmbH Address: Max-Planck Str. 3, D-12489 Berlin Tel no: +493023458995 Email: sales@yellows-instruments.info
Applicable Standards	ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008, ISO 10993-1:2009, ISO 10993-4:2017, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2017, MEDDEV 2. 4/1 Rev. 9, ISO 17664:2021, EN 10088-1:2014, ISO 7153-1:2016, ASTM F899:2020, BS 5194-2:1989, ISO 7151:1988
Biocompatibility:	Stainless Steel used is biocompatible and recommended for Medical Application

Approved By:	CEO		Date: 31-03-2023
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SR.#	Codes	Description	Size
1.	SUAAN3799	MAGILL Catheter Introducing Forceps straight for infants knee bent serrated fenestrated screw lock without ratchet	150 mm (6")
2.	SUAAN3800	MAGILL Catheter Introducing Forceps straight for children knee bent serrated fenestrated screw lock without ratchet	200 mm (7 7/8")
3.	SUAAN3811	MAGILL Catheter Introducing Forceps straight for adults knee bent serrated fenestrated screw lock without ratchet	250 mm (9 3/4")
4.	SUAAN7099	COLLIN Tongue Forceps straight oval serrated fenestrated screw lock with ratchet	170 mm (6 3/4")
5.	SUAAN7100	HEYWOOD-SMITH Haemorrhoidal Forceps straight oval serrated fenestrated screw lock with ratchet	200 mm (7 7/8")
6.	SUAAN7111	HEYWOOD-SMITH (MODIF.) Haemorrhoidal Forceps straight oval serrated fenestrated box lock with ratchet	210 mm (8 1/4")
7.	SUBBF0033	BRYANT Swab Forceps curved serrated box lock without ratchet	130 mm (5 1/8")
8.	SUBBF0044	LISTER Nasal Dressing Forceps straight box lock without ratchet	135 mm (5 1/4")
9.	SUBBF0066	LISTER Nasal Dressing Forceps straight box lock without ratchet	160 mm (6 1/4")
10.	SUBBF0088	LISTER Nasal Dressing Forceps straight box lock without ratchet	185 mm (7 1/4")
11.	SUBBF0100	Dressing Forceps straight serrated screw lock without ratchet	145 mm (5 3/4")
12.	SUBBF0166	Dressing Forceps straight serrated screw lock with ratchet	145 mm (5 3/4")
13.	SUBBF0211	Dressing Forceps curved serrated screw lock with ratchet	180 mm (7")
14.	SUBBF0277	DUPLAY Dressing Forceps curved serrated screw lock with ratchet	210 mm (8 1/4")
15.	SUBBF0322	GROSS Dressing Forceps straight serrated screw lock with ratchet	180 mm (7")
16.	SUBBF0333	GROSS Dressing Forceps curved serrated screw lock with ratchet	180 mm (7")
17.	SUBBF0400	GROSS Dressing Forceps straight serrated screw lock without ratchet	200 mm (8")
18.	SUBBF0411	GROSS Dressing Forceps curved serrated screw lock without ratchet	200 mm (8")
19.	SUBBF0466	GROSS Dressing Forceps straight serrated box lock with ratchet	200 mm (7 7/8")
20.	SUBBF0466	USUSI Dressing Forceps straight serrated box lock with universal ratchet sterile disposable pack of 20 pcs single packed	200 mm (7 7/8")
21.	SUBBF0477	GROSS Dressing Forceps curved serrated box lock with ratchet	200 mm (7 7/8")
22.	SUBBF0477	USUSI Dressing Forceps curved serrated box lock with universal ratchet sterile disposable pack of 20	200 mm (7 7/8")



		pcs single packed	
23.	SUBBF0566	MAIER Dressing Forceps straight serrated box lock without ratchet	265 mm (10 1/2")
24.	SUBBF0577	MAIER Dressing Forceps curved serrated box lock without ratchet	265 mm (10 1/2")
25.	SUBBF0588	MAIER Dressing Forceps straight serrated box lock with ratchet	260 mm (10 1/4")
26.	SUBBF0599	MAIER Dressing Forceps curved serrated box lock with ratchet	260 mm (10 1/4")
27.	SUBBF0599	MAIER SUSI Dressing Forceps curved serrated box lock with universal ratchet sterile disposable pack of 20 pcs single packed	265 mm (10 1/2")
28.	SUBBF0600	AESULAP Sponge-/Dressing Forceps straight box lock with ratchet	220 mm (8 3/4")
29.	SUBBF0611	AESULAP Sponge-/Dressing Forceps curved box lock with ratchet	220 mm (8 3/4")
30.	SUBBF0622	ULRICH-AESULAP Sponge-/Dressing Forceps straight box lock with ratchet	265 mm (10 1/2")
31.	SUBBF0633	ULRICH-AESULAP Sponge-/Dressing Forceps curved box lock with ratchet	265 mm (10 1/2")
32.	SUBBF0655	ULRICH-AESULAP Sponge-/Dressing Forceps curved box lock with ratchet	350 mm (13 3/4")
33.	SUBBF0700	Dressing Forceps straight serrated screw lock with ratchet	240 mm (9 1/2")
34.	SUBBF0711	Dressing Forceps curved serrated screw lock with ratchet	240 mm (9 1/2")
35.	SUBBF0766	SIMS-MAIER Dressing Forceps straight serrated screw lock with ratchet	280 mm (11")
36.	SUBBF0777	SIMS-MAIER Dressing Forceps curved serrated screw lock with ratchet	280 mm (11")
37.	SUBBF0788	SIMS-MAIER Dressing Forceps straight serrated screw lock with ratchet	350 mm (13 3/4")
38.	SUBBF0911	COLLIN Dressing Forceps straight serrated box lock with ratchet	240 mm (9 1/2")
39.	SUBBF0922	CHERON Dressing Forceps straight serrated box lock handles angled to side with ratchet	240 mm (9 1/2")
40.	SUBBF0988	EMMET Dressing Forceps straight box lock with ratchet	210 mm (8 1/4")
41.	SUBBF1122	FOERSTER-BALLENGER Sponge Forceps straight serrated fenestrated box lock with ratchet	180 mm (7")
42.	SUBBF1133	FOERSTER-BALLENGER Sponge Forceps curved serrated fenestrated box lock with ratchet	180 mm (7")
43.	SUBBF1166	RAMPLEY Sponge Forceps straight serrated fenestrated box lock with ratchet	180 mm (7")
44.	SUBBF1188	RAMPLEY Sponge Forceps straight serrated fenestrated box lock with ratchet	250 mm (9 3/4")
45.	SUBBF1200	FOERSTER Sponge Forceps straight smooth fenestrated box lock with ratchet	245 mm (9 5/8")
46.	SUBBF1211	FOERSTER Sponge Forceps curved smooth	245 mm (9 5/8")



		fenestrated box lock with ratchet	
47.	SUBBF1222	FOERSTER-BALLENGER Sponge Forceps straight oval serrated fenestrated box lock with ratchet	245 mm (9 5/8")
48.	SUBBF1233	FOERSTER-BALLENGER Sponge Forceps curved oval serrated fenestrated box lock with ratchet	245 mm (9 5/8")
49.	SUBBF1355	KELLY Sponge Forceps curved oval serrated fenestrated box lock without ratchet	320 mm (12 1/2")
50.	SUBBF1366	KELLY Sponge Forceps curved serrated fenestrated box lock with ratchet	320 mm (12 1/2")
51.	SUBBF3000	CHAPUT Tissue Grasping Forceps straight toothed (2x3) sharp screw lock with ratchet	125 mm (5")
52.	SUBBF3011	TUFFIER Tissue Grasping Forceps straight toothed (5x6) sharp screw lock with ratchet	125 mm (5")
53.	SUBBF3033	HERZ Grasping Forceps curved diam. 3 mm box lock with ratchet	155 mm (6 1/8")
54.	SUBBF3066	JACKSON Grasping Forceps straight toothed (4x5) box lock with ratchet	155 mm (6 1/8")
55.	SUBBF3077	Grasping Forceps straight toothed sharp box lock with ratchet	120 mm (4 3/4")
56.	SUBBF3099	LAHEY Tissue Grasping Forceps straight 2 x 2 prongs box lock with ratchet	155 mm (6 1/8")
57.	SUBBF3100	LAHEY Tissue Grasping Forceps straight 3 x 3 prongs box lock with ratchet width: 9 mm	155 mm (6 1/8")
58.	SUBBF3111	BRAUN Tissue Grasping Forceps straight 4 x 4 prongs box lock with ratchet width: 10 mm	155 mm (6 1/8")
59.	SUBBF3155	BRAND Grasping Forceps curved toothed (1x2)	150 mm (6")
60.	SUBBF3166	BRAND Grasping Forceps curved toothed (1x2)	185 mm (7 1/4")
61.	SUBBF3244	BRAND Grasping Forceps straight toothed (1x2)	150 mm (6")
62.	SUBBF3266	BRAND Grasping Forceps straight toothed (1x2)	185 mm (7 1/4")
63.	SUBBH0188	JOHNS-HOPKINS Applying Forceps For Bulldog C angled on flat box lock with ratchet	240 mm (9 1/2")
64.	SUBBH1000	CARREL Hemostatic Forceps straight delicate blunt screw lock	85 mm (3 1/4")
65.	SUBBH1044	MOSQUITO (HARTMANN) Hemostatic Forceps straight delicate	100 mm (4")
66.	SUBBH1055	MOSQUITO (HARTMANN) Hemostatic Forceps curved delicate	100 mm (4")
67.	SUBBH1066	JACOBSON Hemostatic Forceps straight delicate blunt	130 mm (5 1/8")
68.	SUBBH1088	MICRO-HALSTED Hemostatic Forceps straight delicate	125 mm (5")
69.	SUBBH1099	MICRO-HALSTED Hemostatic Forceps curved delicate	125 mm (5")
70.	SUAAN3799	MAGILL Catheter Introducing Forceps straight for infants knee bent serrated fenestrated screw lock without ratchet	150 mm (6")
71.	SUAAN3800	MAGILL Catheter Introducing Forceps straight for children knee bent serrated fenestrated screw lock without ratchet	200 mm (7 7/8")



72.	SUAAN3811	MAGILL Catheter Introducing Forceps straight for adults knee bent serrated fenestrated screw lock without ratchet	250 mm (9 3/4")
73.	SUBBH1100	HALSTED (MOSQUITO) Hemostatic Forceps straight delicate	125 mm (5")
74.	SUBBH1100	UHALSTED (MOSQUITO) SUSI Hemostatic Forceps straight sterile disposable pack of 20 pcs single packed	125 mm (5")
75.	SUBBH1111	HALSTED (MOSQUITO) Hemostatic Forceps curved delicate	125 mm (5")
76.	SUBBH1111	UHALSTED (MOSQUITO) SUSI Hemostatic Forceps curved sterile disposable pack of 20 pcs single packed	125 mm (5")
77.	SUBBH1144	MOSQUITO (HARTMANN) Hemostatic Forceps straight delicate toothed (1x2)	100 mm (4")
78.	SUBBH1155	MOSQUITO (HARTMANN) Hemostatic Forceps curved delicate toothed (1x2)	100 mm (4")
79.	SUBBH1188	MICRO-HALSTED Hemostatic Forceps straight delicate toothed (1x2)	125 mm (5")
80.	SUBBH1199	MICRO-HALSTED Hemostatic Forceps curved delicate toothed (1x2)	125 mm (5")
81.	SUBBH1200	HALSTED (MOSQUITO) Hemostatic Forceps straight delicate toothed (1x2)	125 mm (5")
82.	SUBBH1211	HALSTED (MOSQUITO) Hemostatic Forceps curved delicate toothed (1x2)	125 mm (5")
83.	SUBBH1233	DUNHILL Hemostatic Forceps straight delicate	125 mm (5")
84.	SUBBH1244	CAIRNS Hemostatic Forceps straight delicate blunt	150 mm (6")
85.	SUBBH1255	CAIRNS Hemostatic Forceps curved delicate blunt	150 mm (6")
86.	SUBBH1266	CAIRNS Hemostatic Forceps curved to side delicate blunt	145 mm (5 3/4")
87.	SUBBH1277	MOYNIHAN Hemostatic Forceps curved delicate blunt	150 mm (6")
88.	SUBBH1300	PROVIDENCE-HOSPITAL Hemostatic Forceps straight delicate blunt	140 mm (5 1/2")
89.	SUBBH1311	PROVIDENCE-HOSPITAL Hemostatic Forceps curved delicate blunt	140 mm (5 1/2")
90.	SUBBH1344	KELLY Hemostatic Forceps straight delicate blunt	140 mm (5 1/2")
91.	SUBBH1355	KELLY Hemostatic Forceps curved delicate blunt	140 mm (5 1/2")
92.	SUBBH1399	DANDY Hemostatic Forceps curved to side delicate blunt	140 mm (5 1/2")
93.	SUBBH1400	CRILE (BABY) Hemostatic Forceps straight delicate blunt	140 mm (5 1/2")
94.	SUBBH1411	CRILE (BABY) Hemostatic Forceps curved delicate blunt	140 mm (5 1/2")
95.	SUBBH1433	DANDY Hemostatic Forceps curved to side delicate toothed (1x2)	140 mm (5 1/2")
96.	SUBBH1444	CRILE Hemostatic Forceps straight delicate blunt	140 mm (5 1/2")
97.	SUBBH1455	CRILE Hemostatic Forceps curved delicate blunt	140 mm (5 1/2")



98.	SUBBH1500	CRILE (BABY) Hemostatic Forceps straight delicate toothed (1x2)	140 mm (5 1/2")
99.	SUBBH1511	CRILE (BABY) Hemostatic Forceps curved delicate toothed (1x2)	140 mm (5 1/2")
100.	SUBBH1544	CRILE Hemostatic Forceps straight delicate toothed (1x2) long	140 mm (5 1/2")
101.	SUBBH1555	CRILE Hemostatic Forceps curved delicate toothed (1x2)	140 mm (5 1/2")
102.	SUBBH1600	LERICHE Hemostatic Forceps straight delicate blunt	150 mm (6")
103.	SUBBH1611	LERICHE Hemostatic Forceps curved delicate blunt	150 mm (6")
104.	SUBBH1644	RANKIN Hemostatic Forceps straight delicate long blunt	160 mm (6 1/4")
105.	SUBBH1655	RANKIN Hemostatic Forceps curved delicate long blunt	160 mm (6 1/4")
106.	SUBBH1666	CRILE Hemostatic Forceps straight delicate blunt	160 mm (6 1/4")
107.	SUBBH1677	CRILE Hemostatic Forceps curved delicate blunt	160 mm (6 1/4")
108.	SUBBH1688	DIXON-LOVELACE Hemostatic Forceps straight delicate blunt	160 mm (6 1/4")
109.	SUBBH1700	LERICHE Hemostatic Forceps straight delicate toothed (1x2)	150 mm (6")
110.	SUBBH1711	LERICHE Hemostatic Forceps curved delicate toothed (1x2)	150 mm (6")
111.	SUBBH1766	CRILE Hemostatic Forceps straight delicate toothed (1x2)	160 mm (6 1/4")
112.	SUBBH1777	CRILE Hemostatic Forceps curved delicate toothed (1x2)	160 mm (6 1/4")
113.	SUBBH1788	DIXON-LOVELACE Hemostatic Forceps straight delicate toothed (1x2)	160 mm (6 1/4")
114.	SUBBH1833	FRASER-KELLY (CRILE) Hemostatic Forceps curved delicate blunt	180 mm (7")
115.	SUBBH1877	JACOBSON Hemostatic Forceps curved very delicate serrated blunt	190 mm (7 1/2")
116.	SUBBH1911	DUNHILL Hemostatic Forceps curved delicate blunt	190 mm (7 1/2")
117.	SUBBH1933	GREY-TURNER Hemostatic Forceps curved delicate blunt	180 mm (7")
118.	SUBBH1966	BIRKETT Hemostatic Forceps straight delicate blunt	185 mm (7 1/4")
119.	SUBBH1966	UBIRKETT SUSI Hemostatic Forceps straight sterile disposable pack of 20 pcs single packed	185 mm (7 1/4")
120.	SUBBH1977	BIRKETT Hemostatic Forceps curved delicate blunt	185 mm (7 1/4")
121.	SUBBH1977	BIRKETT SUSI Hemostatic Forceps curved sterile disposable pack of 20 pcs single packed	185 mm (7 1/4")
122.	SUBBH1988	FUCHSIG Hemostatic Forceps curved delicate blunt	195 mm (7 3/4")
123.	SUBBH1999	NISSEN Hemostatic Forceps curved delicate blunt	185 mm (7 1/4")
124.	SUBBH2000	ADSON Hemostatic Forceps straight delicate blunt	185 mm (7 1/4")
125.	SUBBH2011	ADSON Hemostatic Forceps curved delicate blunt	185 mm (7 1/4")



126.	SUBBH2022	HALSTED Hemostatic Forceps straight delicate blunt	185 mm (7 1/4")
127.	SUBBH2033	HALSTED Hemostatic Forceps curved delicate blunt	185 mm (7 1/4")
128.	SUBBH2055	ADSON Hemostatic Forceps curved delicate blunt	215 mm (8 1/2")
129.	SUBBH2066	HEISS Hemostatic Forceps straight delicate blunt	200 mm (7 7/8")
130.	SUBBH2077	HEISS Hemostatic Forceps curved delicate blunt	200 mm (7 7/8")
131.	SUBBH2099	HEISS Hemostatic Forceps strongly curved delicate blunt	195 mm (7 3/4")
132.	SUBBH2100	HALSTED (MOSQUITO) Hemostatic Forceps straight delicate blunt	200 mm (7 7/8")
133.	SUBBH2111	HALSTED (MOSQUITO) Hemostatic Forceps curved delicate blunt	200 mm (7 7/8")
134.	SUBBH2122	HALSTED Hemostatic Forceps straight delicate toothed (1x2)	185 mm (7 1/4")
135.	SUBBH2133	HALSTED Hemostatic Forceps curved delicate toothed (1x2)	185 mm (7 1/4")
136.	SUBBH2144	HALSTED (MOSQUITO) Hemostatic Forceps straight delicate toothed (1x2)	200 mm (7 7/8")
137.	SUBBH2155	HALSTED (MOSQUITO) Hemostatic Forceps curved delicate toothed (1x2)	200 mm (7 7/8")
138.	SUBBH2166	HEISS Hemostatic Forceps straight delicate toothed (1x2)	200 mm (7 7/8")
139.	SUBBH2177	HEISS Hemostatic Forceps curved delicate toothed (1x2)	200 mm (7 7/8")
140.	SUBBH2244	SAROT Hemostatic Forceps straight delicate blunt	240 mm (9 1/2")
141.	SUBBH2255	CRAFOORD Hemostatic Forceps curved delicate blunt	245 mm (9 5/8")
142.	SUBBH2266	SAROT Hemostatic Forceps curved serrated blunt	250 mm (9 3/4")
143.	SUBBH2277	CRAFOORD (MODIF.) Hemostatic Forceps curved delicate blunt	240 mm (9 1/2")
144.	SUBBH2288	BENGOLEA Hemostatic Forceps straight delicate blunt	245 mm (9 5/8")
145.	SUBBH2299	BENGOLEA Hemostatic Forceps curved delicate blunt	245 mm (9 5/8")
146.	SUBBH2300	BRIDGE Hemostatic Forceps straight delicate blunt	275 mm (10 3/4")
147.	SUBBH2311	BRIDGE Hemostatic Forceps curved delicate blunt	275 mm (10 3/4")
148.	SUBBH2344	SAROT Hemostatic Forceps straight delicate toothed (1x2)	240 mm (9 1/2")
149.	SUBBH2388	BENGOLEA Hemostatic Forceps straight delicate toothed (1x2)	245 mm (9 3/4")
150.	SUBBH2399	BENGOLEA Hemostatic Forceps curved delicate toothed (1x2)	245 mm (9 3/4")
151.	SUBBH3000	KROENLEIN Hemostatic Forceps straight blunt	130 mm (5 1/8")
152.	SUBBH3022	PEAN Hemostatic Forceps straight blunt	125 mm (5")
153.	SUBBH3044	PEAN Hemostatic Forceps straight blunt	140 mm (5 1/2")
154.	SUBBH3122	PEAN Hemostatic Forceps straight blunt screw lock	125 mm (5")
155.	SUBBH3166	PEAN Hemostatic Forceps straight blunt screw lock	165 mm (6 1/2")



EC Declaration of Conformity: Reusable Surgical and Dental Instruments Class I (See Annex 1 Product List)

Date: 31-03-2023

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Revision History

Revision Detail

Revision Level: 00 / Latest Revision Date: 31-03-2023

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156.	SUBBH3188	PEAN Hemostatic Forceps straight blunt screw lock	185 mm (7 1/4")
157.	SUBBH3322	SPENCER-WELLS Hemostatic Forceps straight blunt	130 mm (5 1/8")
158.	SUBBH3333	SPENCER-WELLS Hemostatic Forceps curved blunt	130 mm (5 1/8")
159.	SUBBH3344	SPENCER-WELLS Hemostatic Forceps straight blunt	150 mm (6")
160.	SUBBH3355	SPENCER-WELLS Hemostatic Forceps curved blunt	150 mm (6")