
	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 4 (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.

<b>Device Description:</b>	<b><u>Reusable Surgical and Dental Instruments Class I</u></b> (See Annex 1 Product List)
<b>MDR Classification</b>	<b>Class: I</b> 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: <b><u>are reusable surgical instruments, in which case they are classified as class I</u></b>
<b>Assessment Route:</b>	Annex IX (Quality Management System and Technical Documentation)
<b>EU Rep:</b>	<b>Name:</b> Yellow's medical instruments GmbH <b>Address:</b> Max-Planck Str. 3, D-12489 Berlin <b>Tel no:</b> +493023458995 <b>Email:</b> sales@yellows-instruments.info
<b>Applicable Standards</b>	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
<b>Biocompatibility:</b>	Stainless Steel used is biocompatible and recommended for Medical Application

<b>Approved By:</b>	CEO		<b>Date: 31-03-2023</b>
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SR.#	Codes	Description	Size
1.	SUBBD0233	Dressing Forceps (Tweezers) straight medium serrated	115 mm (4 1/2")
2.	SUBBD0255	Dressing Forceps (Tweezers) straight medium serrated	130 mm (5 1/8")
3.	SUBBD0277	Dressing Forceps (Tweezers) straight medium serrated	145 mm (5 3/4")
4.	SUBBD0299	Dressing Forceps (Tweezers) straight medium serrated	160 mm (6 1/4")
5.	SUBBD0300	Dressing Forceps (Tweezers) straight medium serrated	180 mm (7")
6.	SUBBD0311	Dressing Forceps (Tweezers) straight medium serrated	200 mm (8")
7.	SUBBD0322	Dressing Forceps (Tweezers) straight medium serrated	250 mm (10")
8.	SUBBD0333	Dressing Forceps (Tweezers) straight medium serrated	305 mm (12")
9.	SUBBD0355	Dressing Forceps (Tweezers) curved medium serrated	130 mm (5 1/8")
10.	SUBBD0377	Dressing Forceps (Tweezers) curved medium serrated	140 mm (5 1/2")
11.	SUBBD0433	Dressing Forceps (Tweezers) straight standard serrated	115 mm (4 1/2")
12.	SUBBD0455	Dressing Forceps (Tweezers) standard straight standard serrated	130 mm (5 1/8")
13.	SUBBD0477	Dressing Forceps (Tweezers) standard straight standard serrated	145 mm (5 3/4")
14.	SUBBD0477	USUSI Dressing Forceps (Tweezers) sterile disposable pack of 20 pcs single packed	145 mm (5 3/4")
15.	SUBBD0499	Dressing Forceps (Tweezers) standard straight standard serrated	160 mm (6 1/4")
16.	SUBBD0500	Dressing Forceps (Tweezers) standard straight standard serrated	180 mm (7")
17.	SUBBD0511	Dressing Forceps (Tweezers) standard straight standard serrated	200 mm (7 7/8")
18.	SUBBD0522	Dressing Forceps (Tweezers) standard straight standard serrated	250 mm (9 3/4")
19.	SUBBD0533	Dressing Forceps (Tweezers) standard straight standard serrated	300 mm (11 3/4")
20.	SUBBD0655	PATTERN SWEDEN Dressing Forceps (Tweezers) straight serrated	130 mm (5 1/8")
21.	SUBBD0677	PATTERN SWEDEN Dressing Forceps (Tweezers) straight serrated	150 mm (6")
22.	SUBBD0688	PATTERN SWEDEN Dressing Forceps (Tweezers) straight serrated	170 mm (6 3/4")
23.	SUBBD0699	PATTERN SWEDEN Dressing Forceps (Tweezers) straight serrated	200 mm (8")
24.	SUBBD0777	Dressing Forceps (Tweezers) straight extra large serrated	145 mm (5 3/4")



25.	SUBBD0788	BONNEY Dressing Forceps (Tweezers) straight serrated	175 mm (7")
26.	SUBBD0811	Dressing Forceps (Tweezers) straight delicate serrated	200 mm (8")
27.	SUBBD0833	RAMSEY Dressing Forceps (Tweezers) straight serrated	180 mm (7")
28.	SUBBD1300	OCHSNER Suture Forceps straight serrated	145 mm (5 3/4")
29.	SUBBD1511	ADSON DUROGRIP TC Atraumatic Forceps straight	120 mm (4 3/4")
30.	SUBBD1544	DUROGRIP TC Atraumatic Forceps straight delicate	145 mm (5 3/4")
31.	SUBBD1566	DUROGRIP TC Atraumatic Forceps straight delicate	180 mm (7")
32.	SUBBD1577	DUROGRIP TC Atraumatic Forceps straight delicate	200 mm (7 7/8")
33.	SUBBD1588	DUROGRIP TC Atraumatic Forceps straight delicate	230 mm (9")
34.	SUBBD1599	DUROGRIP TC Atraumatic Forceps straight delicate	250 mm (9 3/4")
35.	SUBBD1600	CUSHING DUROGRIP TC Atraumatic Forceps straight	180 mm (7")
36.	SUBBD1644	DUROGRIP TC Atraumatic Forceps straight	145 mm (5 3/4")
37.	SUBBD1655	DUROGRIP TC Atraumatic Forceps straight	200 mm (7 7/8")
38.	SUBBD1666	DUROGRIP TC Atraumatic Forceps straight	250 mm (9 3/4")
39.	SUBBD1688	GRUENWALD DUROGRIP TC Atraumatic Forceps straight bayonet-shaped	185 mm (7 1/4")
40.	SUBBD1711	WANGENSTEEN DUROGRIP TC Atraumatic Forceps straight	150 mm (6")
41.	SUBBD1733	WANGENSTEEN DUROGRIP TC Atraumatic Forceps straight	230 mm (9")
42.	SUBBD1800	DUROGRIP TC Ligature Forceps	200 mm (8")
43.	SUBBD1811	FERRIS-SMITH DUROGRIP TC Ligature Forceps straight	175 mm (7")
44.	SUBBD1900	GERALD Micro Forceps straight serrated (cross) flat handle width: 1 mm	180 mm (7")
45.	SUBBD1911	GERALD Micro Forceps straight toothing DE BAKEY flat handle width: 1 mm	180 mm (7")
46.	SUBBD1922	GERALD DIADUST Micro Forceps straight diam. 1 mm ring tip flat handle diamond dust coated	180 mm (7")
47.	SUBBD1933	GERALD DIADUST Micro Forceps curved diam. 1 mm ring tip flat handle diamond dust coated	180 mm (7")
48.	SUBBD1944	GERALD DIADUST Micro Forceps straight flat handle width: 1 mm diamond dust coated	180 mm (7")
49.	SUBBD1955	GERALD Micro Forceps straight toothing DE BAKEY flat handle width: 1 mm	200 mm (7 7/8")
50.	SUBBD1966	GERALD DIADUST Micro Forceps straight flat handle width: 1 mm diamond dust coated	200 mm (7 7/8")
51.	SUBBD1977	GERALD Micro Forceps straight serrated (cross) flat handle width: 1 mm	250 mm (9 3/4")
52.	SUBBD1988	CUSHING DUROGRIP TC Forceps straight delicate	250 mm (9 3/4")
53.	SUBBD2000	DIADUST Forceps straight diam. 1 mm flat handle	180 mm (7")



54.	SUBBD2011	DIADUST Forceps straight diam. 1 mm flat handle	210 mm (8 1/4")
55.	SUBBD2100	Dressing Forceps (Tweezers) straight delicate serrated	115 mm (4 1/2")
56.	SUBBD2133	GILLIES Dressing Forceps (Tweezers) straight delicate serrated	155 mm (6 1/8")
57.	SUBBD2155	SEMKEN Dressing Forceps (Tweezers) straight delicate serrated	125 mm (5")
58.	SUBBD2166	SEMKEN Dressing Forceps (Tweezers) straight delicate serrated	150 mm (6")
59.	SUBBD2177	SEMKEN Dressing Forceps (Tweezers) straight delicate serrated	155 mm (6")
60.	SUBBD2200	ADSON (MICRO) Dressing Forceps (Tweezers) straight delicate serrated platform tip	120 mm (4 3/4")
61.	SUBBD2211	MICRO-ADSON Dressing Forceps (Tweezers) straight delicate serrated width: 1 mm titanium	120 mm (4 3/4")
62.	SUBBD2222	ADSON Dressing Forceps (Tweezers) straight delicate serrated	120 mm (4 3/4")
63.	SUBBD2222	UADSON SUSI Dressing Forceps (Tweezers) delicate pattern sterile disposable pack of 20 pcs single packed	120 mm (4 3/4")
64.	SUBBD2233	ADSON (MICRO) Dressing Forceps (Tweezers) straight delicate serrated	150 mm (6")
65.	SUBBD2244	ADSON Dressing Forceps (Tweezers) straight delicate serrated	180 mm (7")
66.	SUBBD2255	HUDSON Dressing Forceps (Tweezers) straight delicate serrated	125 mm (5")
67.	SUBBD0233	Dressing Forceps (Tweezers) straight medium serrated	115 mm (4 1/2")
68.	SUBBD0255	Dressing Forceps (Tweezers) straight medium serrated	130 mm (5 1/8")
69.	SUBBD0277	Dressing Forceps (Tweezers) straight medium serrated	145 mm (5 3/4")